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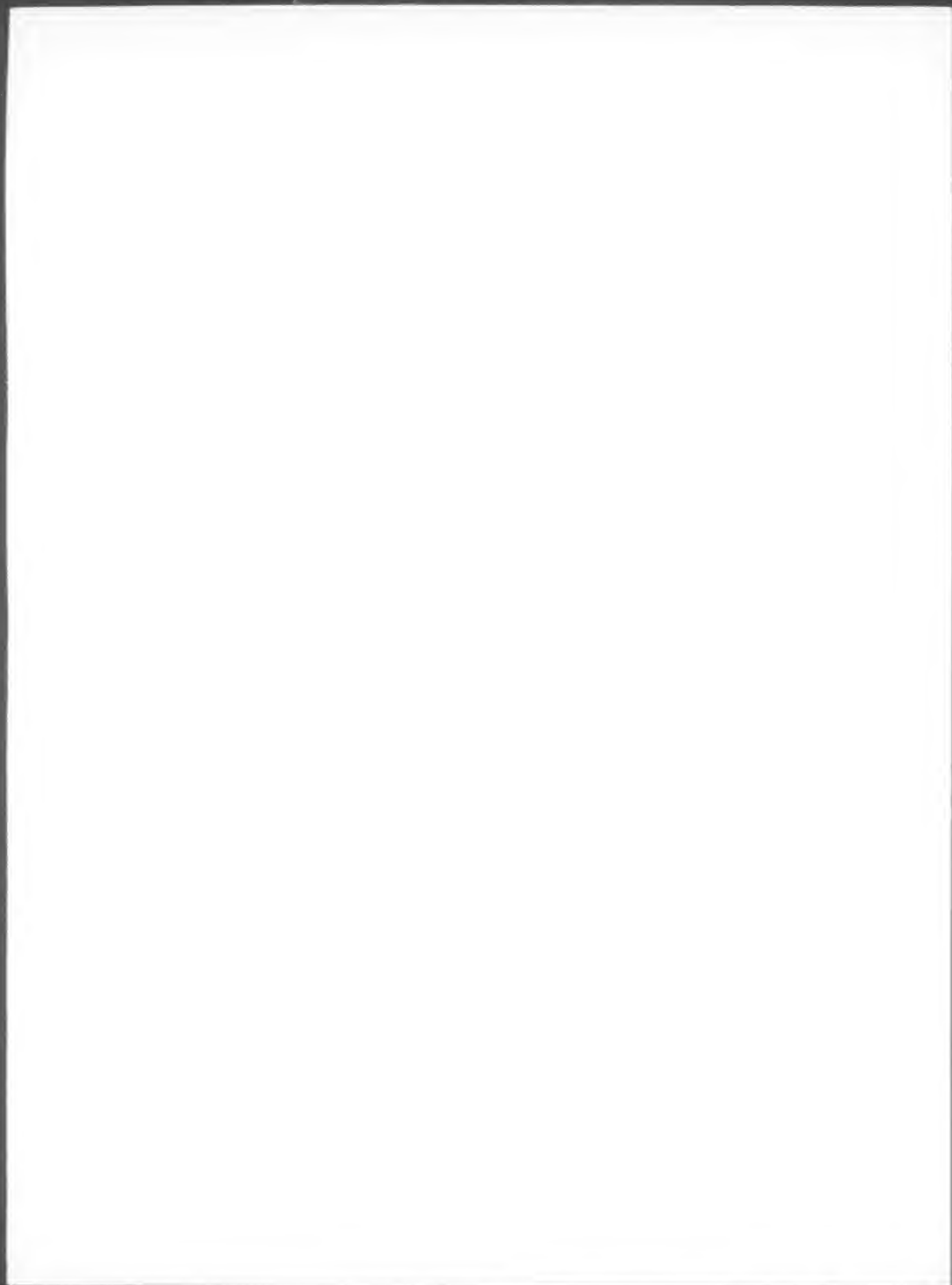
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## DEPARTMENT OF HOMELAND SECURITY

### Office of the Secretary

#### 6 CFR Part 5

[Docket No. DHS-2008-0135]

### Privacy Act of 1974: Implementation of Exemptions; Department of Homeland Security General Training Records

**AGENCY:** Privacy Office, DHS.

**ACTION:** Final rule.

**SUMMARY:** At this time, the Department of Homeland Security is issuing a final rule pursuant to the Privacy Act of 1974 for the Department of Homeland Security General Training Records system of records.

**DATES:** This final rule is effective November 25, 2008.

**ADDRESSES:** You may submit comments, identified by docket number DHS-2008-0135, by one of the following methods:

- *Federal e-Rulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *Fax:* 1-866-466-5370.

- *Mail:* Hugo Teufel III, Chief Privacy Officer, Department of Homeland Security, Washington, DC 20528.

*Instructions:* All submissions received must include the agency name and docket number for this notice. All comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided.

*Docket:* For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** For general questions and privacy issues, please contact: Hugo Teufel III (703-235-0780), Chief Privacy Officer,

Privacy Office, Department of Homeland Security, Washington, DC 20528.

#### SUPPLEMENTARY INFORMATION:

**Background:** On May 8, 2006, the Department of Homeland Security (DHS) published a notice of proposed rulemaking (71 FR 26706) to exempt the General Training Records Privacy Act system of records from the following provision of the Privacy Act, 5 U.S.C. 552a(d). Elsewhere in today's **Federal Register**, the Department is issuing an updated system of records notice that does not impact the need for this final rule.

*No comments were received.*

Accordingly, DHS is implementing the rule as proposed.

Pursuant to the requirements of the Regulatory Flexibility Act, 5 U.S.C. 601-612, DHS certifies that these regulations will not significantly affect a substantial number of small entities. The final rule imposes no duties or obligations on small entities. Further, in accordance with the provisions of the Paperwork Reduction Act of 1995, 44 U.S.C. 3501, DHS has determined that this final rule would not impose new recordkeeping, application, reporting, or other types of information collection requirements.

A notice of system of records for General Training Records is also published in this issue of the **Federal Register**.

#### List of Subjects in 6 CFR Part 5

Freedom of information; Privacy.

■ For the reasons stated in the preamble, DHS proposes to amend Chapter I of Title 6, Code of Federal Regulations, as follows:

#### PART 5—DISCLOSURE OF RECORDS AND INFORMATION

■ 1. The authority citation for Part 5 continues to read as follows:

**Authority:** Public Law 107-296, 116 Stat. 2135, 6 U.S.C. 101 *et seq.*; 5 U.S.C. 301. Subpart A also issued under 5 U.S.C. 552. Subpart B also issued under 5 U.S.C. 552a.

■ 2. Add at the end of Appendix C to Part 5, Exemption of Record Systems under the Privacy Act, the following new paragraph 13:

#### Appendix C to Part 5—DHS Systems of Records Exempt From the Privacy Act

\* \* \* \* \*

13. The Department of Homeland Security General Training Records system of records consists of electronic and paper records and

will be used by DHS and its components. The Department of Homeland Security General Training Records system of records consists of electronic and paper records and will be used by DHS and its components and offices to maintain records about individual training, including enrollment and participation information, information pertaining to class schedules, programs, and instructors, training trends and needs, testing and examination materials, and assessments of training efficacy. The data will be collected by employee name or other unique identifier. The collection and maintenance of this information will assist DHS in meeting its obligation to train its personnel and contractors in order to ensure that the agency mission can be successfully accomplished. Pursuant to exemptions 5 U.S.C. 552a(k)(6) of the Privacy Act, portions of this system are exempt from 5 U.S.C. 552a(d) to the extent that records in this system relate to testing or examination materials used solely to determine individual qualifications for appointment in the Federal service. Access to or amendment of this information by the data subject would compromise the objectivity and fairness of the testing and examination process.

Dated: November 18, 2008.

**Hugo Teufel, III,**

*Chief Privacy Officer, Department of Homeland Security.*

[FR Doc. E8-28039 Filed 11-24-08; 8:45 am]

**BILLING CODE 4410-10-P**

## DEPARTMENT OF AGRICULTURE

### Natural Resources Conservation Service

#### 7 CFR Part 610

RIN 0578-AA51

### State Technical Committees

**AGENCY:** Natural Resources Conservation Service, United States Department of Agriculture.

**ACTION:** Interim final rule with request for comment.

**SUMMARY:** Section 1261 of the Food Security Act of 1985, as amended (the 1985 Act), requires the Secretary of Agriculture (Secretary) to establish a technical committee in each State to assist the Secretary in the considerations relating to implementation and technical aspects of the conservation programs authorized under the 1985 Act. Section 1262 of the 1985 Act describes the responsibilities of the State Technical Committees to

work with the United States Department of Agriculture (USDA) in an advisory capacity. Part 610, Subpart C of title 7 of the Code of Federal Regulations contains the current regulations for State Technical Committees.

Section 2711 of the Food, Conservation, and Energy Act of 2008 (2008 Act) amended Sections 1261 and 1262 of the 1985 Act to expand agricultural and forestry involvement on the committees, expand the committees' authority related to reviewing Local Working Groups' efforts to address State program priorities, and require the Secretary to standardize committee operations. Section 246(f)(3) of the Department of Agriculture Reorganization Act of 1994 exempted State Technical Committees from the Federal Advisory Committee Act. The 2008 Act clarifies that the Local Working Groups shall be considered a subcommittee of the applicable State Technical Committee for the purposes of this exemption. This interim final rule adopts these changes.

**DATES:** *Effective Date:* This rule is effective November 25, 2008.

*Comment date:* Submit comments on or before January 26, 2009.

**ADDRESSES:** You may send comments (identified by Docket Number NRCS-IFR-08010) using any of the following methods:

- *Government-wide rulemaking Web site:* Go to <http://regulations.gov> and follow the instructions for sending comments electronically.

- *Mail:* Conservation Technical Assistance Programs Division, U.S. Department of Agriculture, Natural Resources Conservation Service, 1400 Independence Avenue, SW., Room 6015-S, Washington, DC 20250-2890.

- *Fax:* (202) 720-2998

- *Hand Delivery Room:* Room 6015-S of the USDA South Office Building, 1400 Independence Avenue, SW., Washington, DC 20250, between 9 a.m. and 4 p.m., Monday through Friday, except Federal Holidays. Please ask the guard at the entrance to the South Office Building to call 202-720-4527 in order to be escorted into the building.

- This interim final rule may be accessed via Internet. Users can access the NRCS homepage at <http://www.nrcs.usda.gov/>; select the *Farm Bill* link from the menu; select the *Interim final* link from beneath the *Final and Interim Final Rules Index* title. Persons with disabilities who require alternative means for communication (Braille, large print, audio tape, etc.) should contact the USDA TARGET Center at: (202) 720-2600 (voice and TDD).

**FOR FURTHER INFORMATION CONTACT:** Lillian Woods, Acting Director, Conservation Planning and Technical Assistance Programs Division, U.S. Department of Agriculture (USDA), Natural Resources Conservation Service (NRCS), P.O. 2890, Room 6015-S, Washington, DC 20013-2890; *phone:* (202) 720-1510; *fax:* (202) 720-2998; or *e-mail:* [STC2008@wdc.usda.gov](mailto:STC2008@wdc.usda.gov), *Attn:* State Technical Committees.

**SUPPLEMENTARY INFORMATION:**

**Comments Invited**

NRCS invites interested persons to participate in this rulemaking by submitting written comments or views about the changes made by this interim final rule. The most helpful comments reference a specific portion of the regulation, explain the reason for any recommended changes, and include supporting data and references to statutory language. Please send two copies of written comments. All comments received on or before the closing date for comments will be considered. This regulation may be changed because of the comments received. All comments received, as well as a report summarizing each substantive public comment received concerning this interim final rule will be filed in the docket. The docket, including any personal information provided, will be made available for public inspection.

**Regulatory Certifications**

*Executive Order 12866*

The Office of Management and Budget (OMB) has determined that this interim final rule is not significant and will not be reviewed by OMB under Executive Order 12866.

*Regulatory Flexibility Act*

The interim final rule will not have a significant environmental impact on small entities. NRCS has determined that the Regulatory Flexibility Act does not apply.

*Environmental Analysis*

The proposed rule involves the establishment of State Technical Committees. As provided for under 7 CFR Part 1b.3—Categorical Exclusions, the proposed rule involves administrative functions that are categorically excluded from further environmental review under the National Environmental Policy Act (NEPA). Specifically, 7 CFR Part 1b.3 states: (a) The following are categories of activities which have been determined not to have a significant individual or cumulative effect on the human

environment and are excluded from the preparation of environmental assessment (EAs) or environmental impact statement (EISs), unless individual agency procedures prescribed otherwise.

(1) Policy development, planning and implementation which relate to routine activities, such as personnel, organizational changes, or similar administrative functions;

(2) Activities which deal solely with the funding of programs, such as program budget proposals, disbursements, and transfer or reprogramming of funds;

(3) Inventories, research activities, and studies, such as resource inventories and routine data collection when such actions are clearly limited in context and intensity;

(4) Educational and informational programs and activities;

(5) Civil and criminal law enforcement and investigative activities;

(6) Activities which are advisory and consultative to other agencies and public and private entities, such as legal counseling and representation; and

(7) Activities related to trade representation and market development activities abroad.

The State Technical Committee rule meets the criteria for being a categorical exclusion under Section 1b.3 (1) Policy development, planning and implementation which relate to routine activities, such as personnel, organizational changes, or similar administrative functions; and (6) Activities which are advisory and consultative to other agencies and public and private entities, such as legal counseling and representation.

*Paperwork Reduction Act*

Section 2904 of the 2008 Act provides that the promulgation and administration of Title II of the Act shall be made without regard to Chapter 35 of Title 44 of the United States Codes, also known as the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Therefore, NRCS is not reporting recordkeeping or estimated paperwork burden associated with this interim final rule.

*Executive Order 12988*

This interim final rule has been reviewed in accordance with Executive Order 12988, Civil Justice Reform. The provisions of this interim final rule are not retroactive. The provisions of this interim final rule preempt State and local laws to the extent that such laws are inconsistent with this interim final rule. Before an action may be brought in a Federal court of competent

jurisdiction, the administrative appeal rights afforded persons at parts 11, 614, and 780 of this title must be exhausted.

#### *Unfunded Mandates Reform Act of 1995*

NRCS assessed the effects of this rulemaking action on State, local, and tribal governments, and the public. This action does not compel the expenditure of \$100 million or more by any State, local, or tribal governments, or anyone in the private sector; therefore, a statement under section 202 of the Unfunded Mandates Reform Act of 1995 is not required.

#### **Discussion of State Technical Committees**

##### *Background and Purpose*

The 2008 Act amended requirements regarding the composition and responsibilities of State Technical Committees. Section 1261 of the 1985 Act, as amended, establishes the membership and responsibilities for State Technical Committees (committee(s)). When first enacted, this section required that committees be composed of "professional resource managers that represent a variety of disciplines in the soil, water, wetland, and wildlife sciences." However, the 1985 Act only required representation from Federal and State agencies. The 1985 Act directed the Secretary to include representation from the Soil Conservation Service, the Agriculture Stabilization and Conservation Service, U.S. Forest Service, Extension Service, the Farmers Home Administration, the U.S. Fish and Wildlife Service, and State Departments and agencies the Secretary deemed appropriate, including: State Fish and Wildlife agencies, State foresters or equivalent State officials, State water resources agencies, State departments of agriculture, and State associations of soil and water conservation districts. The Secretary had discretionary authority to include other agency personnel with expertise in soil, water, wetland and wildlife management. The 1996 Act (Pub. L. 104-127) expanded eligibility for State Technical Committee membership to include representatives from the private sector. In addition to the members identified under the 1985 Act, the State Technical Committee was expanded to include agricultural producers and non-profit organizations with demonstrable conservation expertise, persons knowledgeable about conservation techniques, and agribusiness. The Chief, NRCS, added the following agencies and groups based on their proven expertise with conservation programs and natural

resource issues: The Environmental Protection Agency, Bureau of Indian Affairs, U.S. Geological Survey, U.S. Army Corps of Engineers, Farm Service Agency State Committee, and Federally-recognized American Indian Tribal Governments and Alaskan Native Corporations encompassing 100,000 acres or more in the State. This full representation was incorporated in a final rule that was published on August 3, 1999.

The 2008 Act amendments add "agricultural producers and other professionals that represent a variety of disciplines in the soil, water, wetland, and wildlife sciences" and "owners of nonindustrial private forest land" as members of the committee. The U.S. Fish and Wildlife Service is no longer identified in the statute as a member of the committee, and agriculture producer members are no longer required to have conservation expertise. Agriculture producer members are now required to represent a variety of crops and livestock or poultry raised within the State. These changes are reflected in § 610.22 of this regulation.

The State Technical Committee is required under section 1261(c) to include members from a wide variety of natural resource and agricultural interests. The State Conservationist should ensure that all interests are adequately represented and heard on the committee and that recommendations, when adopted, address natural resource concerns. The committee membership in § 610.22 has been modified, as described under the summary of provisions below.

To ensure that recommendations of the State Technical Committees take into account the needs of the diverse groups served by USDA, in § 610.22, committee membership shall continue to include, to the extent practicable, individuals with demonstrated ability and skills concerning natural resource conservation subjects specific to historically underserved groups and individuals; *i.e.* minorities, women, persons with disabilities and socially and economically disadvantaged groups.

The State Conservationist determines the membership on the State Technical Committee. Individuals or groups wanting to participate as members on a State Technical Committee may submit to the State Conservationist a request that explains their interest and outlines their relevant credentials for becoming a member of the State Technical Committee. Decisions of the State Conservationist concerning membership on the committee are final and are not subject to appeal.

Section 1261 of the 1985 Act provides that each committee is advisory and has no implementation or enforcement authority. The 2008 Act amendments continue this provision in Section 1262(c)(1). In paragraph 1262(c)(2), the committees' role is expanded to provide advice on whether Local Working Groups are addressing State priorities adopted by the State Conservationist. Section 610.24, Responsibilities of State Technical Committees, paragraph (c) has been revised to incorporate this change.

The 2008 Act amendments to Section 1261(b)(1) require the Secretary to establish standard operating procedures for committees. Standard operating procedures will be incorporated in NRCS directives made available to the public through a **Federal Register** notice, NRCS offices and the NRCS Web site. The standard operating procedures will outline items such as: The best practice approach to establishing, organizing, and effectively utilizing State Technical Committees and Local Working Groups; direction on publication of meeting notices, agendas, and State Technical Committee meeting summaries; how to provide feedback on State Conservationist decisions regarding State Technical Committee recommendations; and other items as determined by the Chief.

Section 1262(d) exempts State Technical Committees from the provisions of the Federal Advisory Committee Act. The 2008 Act clarifies that any Local Working Group shall be considered to be a subcommittee of the applicable State Technical Committee. Sections 610.21, Purpose and scope, and 610.25, Specialized subcommittees, are changed to incorporate this statutory provision.

#### **Summary of Provisions**

##### *Section 610.21 Purpose and Scope*

Section 610.21 is amended to indicate that Local Working Groups, as well as State Technical Committees, are exempt from the provisions of the Federal Advisory Committee Act. Prior to the 2008 Act amendments, the statute expressly exempted only the State Technical Committees from the Federal Advisory Committee Act, although the Local Working Groups were, due to their composition of representative of elected officials, exempt from the Act.

##### *Section 610.22 State Technical Committee Membership*

Paragraph (a) of this section is revised to align the membership of the State Technical Committees with the composition required in Section 2711 of

the 2008 Act. Statutorily required members continue to include NRCS; the Farm Service Agency; the U.S. Forest Service; the National Institute of Food and Agriculture (formerly the Cooperative State Research Education and Extension Service); the state fish and wildlife agency; the state forester; the state water resources agency; the state department of agriculture; the state association of soil and water conservation districts; agribusiness; and nonprofits with demonstrable conservation expertise, though they now must have experience in working with agricultural producers in the State. In addition, owners of nonindustrial private forest land, as well as agricultural producers representing the variety of crops and livestock or poultry raised in the State, are now explicitly identified as being members of the State Technical Committee. However, agricultural producers are no longer required to have conservation expertise.

In addition to the statutorily required members, the regulations also continue to explicitly provide for membership for the state Farm Service Agency Committee and each federally recognized American Indian Tribal Government and Alaskan Native Corporation encompassing 100,000 acres or more in the State.

In § 610.22, the Fish and Wildlife Service has been removed from membership as required by statute. In addition, NRCS has removed several agencies from required membership because the 2008 Act eliminated Section 1261(c)(8) from the statute, which had included "other agency personnel with expertise in soil, water, wetland, and wildlife management" as members. These agencies include: USDA Rural Development; the U.S. Environmental Protection Agency; the Bureau of Land Management; the Bureau of Indian Affairs; the U.S. Geological Survey; the Bureau of Reclamation; the Army Corps of Engineers; and the state coastal zone management agency. However, the State Conservationist will invite representatives from these and other relevant Federal and State agencies, as well as the private sector, to participate as needed.

The regulations do not change paragraph (b) regarding membership of historically underserved groups and individuals or paragraph (c) regarding the process by which individuals or groups may request membership on a State Technical Committee.

#### *Section 610.23 State Technical Committee Meetings*

Paragraph (b) is a new provision that addresses the statutory requirement for

NRCS to develop standard operating procedures governing the operation of State Technical Committees. Specific topics that will be addressed in the standard operating procedures are identified in the regulations. The list is not exhaustive and comments are invited on the content of the standard operating procedures. The standard operating procedures will be made available to the public in a **Federal Register Notice**. The remaining language of § 610.23 has been reorganized, but has not changed.

#### *Section 610.24 Responsibilities of State Technical Committees*

Paragraph (a) is amended in the regulations to clarify that State Technical Committee members may provide information, analysis and recommendations not only to NRCS, but to other USDA agencies responsible for natural resource conservation activities and programs under Title XII of the 1985 Act. This change is consistent with the provisions of the 2008 Act.

Paragraph (b) of the regulations is consistent with the language in Section 1262 (d) of the 2008 Act. The 2008 Act deleted much of the specific guidance regarding State Technical Committee responsibilities for making technical recommendations. This change does not limit the scope of State Technical Committee responsibilities, but recognizes that State Technical Committee responsibilities should not be limited to certain specified technical areas.

Paragraph (c) was added to address the language in the 2008 Act about State Technical Committee authority to review whether Local Working Groups are addressing State priorities.

#### *Section 610.25 Subcommittees and Local Working Groups*

In the current regulations, § 610.25 addresses only specialized subcommittees of the State Technical Committee. Paragraph (a) of these interim final regulations retains the language of the current regulations, but explains that members of Local Working Groups, as well as members of State Technical Committees, can serve on specialized subcommittees. The regulations differentiate between recommendations resulting from Local Working Group meetings and from specialized subcommittee recommendations in that decisions resulting from Local Working Group sessions need not be reported in a general session of the State Technical Committee. NRCS has determined that Local Working Group recommendations need not be reported in a general

session of the State Technical Committee because, given the number of Local Working Groups in a state, it will be more efficient for the State Technical Committees to receive a summary report of the Local Working Groups' recommendations from the State Conservationist. This reporting requirement will be included in the standard operating procedures. Local Working Groups will follow the standard operating procedures and the public notice requirements.

The intent of paragraph (b) is to ensure the membership of Local Working Groups is as diverse as that of the State Technical Committees, but is focused on agricultural interests and natural resource issues existing in the local community. Paragraph (b) outlines the role of Local Working Groups and clarifies that they are to provide recommendations on local natural resource priorities and criteria for conservation activities and programs.

NRCS invites comments regarding the interaction of Local Working Groups with State Technical Committees and with NRCS at both the local and State levels. The NRCS also invites comments regarding the State Technical Committee review of whether Local Working Groups are addressing the priorities established by the State Technical Committee.

#### **List of Subjects in 7 CFR Part 610**

Soil conservation, State Technical Committee, Technical assistance, Water resources.

■ For the reasons stated in the preamble, the Natural Resources Conservation Service amends Part 610 of Title 7 of the Code of Federal Regulations as follows:

#### **PART 610—TECHNICAL ASSISTANCE**

■ 1. The authority citation for part 610 continues to read as follows:

**Authority:** 16 U.S.C. 590a–f, 590q, 2005b, 3861, 3862.

■ 2. Subpart C is revised to read as follows:

#### **Subpart C—State Technical Committees**

Sec.

610.21 Purpose and scope.

610.22 State Technical Committee membership.

610.23 State Technical Committee meetings.

610.24 Responsibilities of State Technical Committees.

610.25 Subcommittees and Local Working Groups.

**Subpart C—State Technical Committees****§ 610.21 Purpose and scope.**

This subpart sets forth the procedures for establishing and using the advice of State Technical Committees. NRCS shall establish in each State a technical committee to assist in making recommendations relating to the implementation and technical aspects of natural resource conservation activities and programs. USDA will use State Technical Committees in an advisory capacity in the administration of certain conservation programs and initiatives. Pursuant to 16 U.S.C. 3862(d), these State Technical Committees and Local Working Groups are exempt from the provisions of the Federal Advisory Committee Act (5 U.S.C. App. 2).

**§ 610.22 State Technical Committee membership.**

(a) State Technical Committees shall include agricultural producers, nonindustrial private forest land owners, and other professionals who represent a variety of disciplines in soil, water, wetlands, plant, and wildlife sciences. The State Conservationist in each State will serve as chairperson. The State Technical Committee for each State shall include representatives from among the following:

- (1) NRCS, USDA;
- (2) Farm Service Agency, USDA;
- (3) State Farm Service Agency Committee, USDA;
- (4) Forest Service, USDA;
- (5) National Institute of Food and Agriculture, USDA;
- (6) Each of the Federally recognized American Indian Tribal Governments and Alaskan Native Corporations encompassing 100,000 acres or more in the State;
- (7) State departments and agencies within the State, including the:
  - (i) Fish and wildlife agency;
  - (ii) Forestry agency;
  - (iii) Water resources agency;
  - (iv) Department of agriculture;
  - (v) Association of soil and water conservation districts; and
  - (vi) Soil and water conservation agency;
- (8) Agricultural producers representing the variety of crops and livestock or poultry raised within the State;
- (9) Owners of nonindustrial private forest land;
- (10) Nonprofit organizations, within the meaning of section 501(c)(3) of the Internal Revenue Code of 1986, with demonstrable conservation expertise and experience working with agriculture producers in the State; and

(11) Agribusiness.

(b) The State Conservationist will invite other relevant Federal agencies, and persons knowledgeable about economic and environmental impacts of conservation techniques and programs to participate as needed.

(c) To ensure that recommendations of the State Technical Committees take into account the needs of the diverse groups served by the USDA, membership shall include, to the extent practicable, individuals with demonstrated ability to represent the conservation and related technical concerns of particular historically underserved groups and individuals; *i.e.*, minorities, women, persons with disabilities and socially and economically disadvantaged groups.

(d) In accordance with the guidelines in paragraphs (a), (b) and (c) of this section, the State Conservationist establishes membership on the State Technical Committee. Individuals or groups wanting to participate on a State Technical Committee within a specific State may submit to the State Conservationist of that particular State a request that explains their interest and outlines their credentials which they believe are relevant to becoming a member of the State Technical Committee. Decisions of the State Conservationist concerning membership on the committee are final and not appealable to any other individual or group within USDA.

**§ 610.23 State Technical Committee meetings.**

(a) The State Conservationist, as Chairperson, schedules and conducts the meetings, although a meeting may be requested by any USDA agency as needed.

(b) NRCS shall establish and publish in a **Federal Register** notice national standard operating procedures governing the operation of State Technical Committees and Local Working Groups. The standard operating procedures will outline items such as: The best practice approach to establishing, organizing, and effectively utilizing State Technical Committees and Local Working Groups; direction on publication of State Technical Committee and Local Working Group meeting notices and agendas; State Technical Committee meeting summaries; how to provide feedback on State Conservationist decisions regarding State Technical Committee recommendations; and other items as determined by the Chief of NRCS.

(c) In addition to the standard operating procedures established under paragraph (b) of this section, the State

Conservationist shall provide public notice of and allow public attendance at State Technical Committee and Local Working Group meetings. The State Conservationist shall publish a meeting notice no later than 14 calendar days prior to the meeting. Notification may exceed this 14-day minimum where State open meeting laws exist and provide for a longer notification period. This minimum 14-day notice requirement may be waived in the case of exceptional conditions, as determined by the State Conservationist. The State Conservationist shall publish this notice in at least one or more newspaper(s), including recommended Tribal publications, to attain statewide circulation.

**§ 610.24 Responsibilities of State Technical Committees.**

(a) Each State Technical Committee established under this subpart shall meet on a regular basis, as determined by the State Conservationist, to provide information, analysis, and recommendations to appropriate officials of the Department of Agriculture who are charged with implementing and establishing priorities and criteria for natural resources conservation activities and programs under Title XII of the Food Security Act of 1985, including: the Conservation Reserve Program, Wetlands Reserve Program, Conservation Security Program, Conservation Stewardship Program, Farm and Ranch Lands Protection Program, Grassland Reserve Program, Environmental Quality Incentives Program, Conservation Innovation Grants, Agricultural Water Enhancement Program, Conservation of Private Grazing Land, Wildlife Habitat Incentive Program, Grassroots Source Water Protection Program, Great Lakes Basin Program, Chesapeake Bay Watershed Program, and the Voluntary Public Access and Habitat Incentive Program. Such recommendations may include but are not limited to recommendations about:

- (1) The criteria to be used in prioritizing program applications;
- (2) The state-specific application criteria; and
- (3) Priority natural resource concerns in the state.

(b) The role of the State Technical Committee is advisory in nature and the committee shall have no implementation or enforcement authority. The implementing agency reserves the authority to accept or reject the Committee's recommendations. However, the implementing USDA agency shall give strong consideration to

the State Technical Committee's recommendations.

(c) State Technical Committees shall review whether Local Working Groups are addressing State priorities.

#### § 610.25 Subcommittees and Local Working Groups.

(a) *Subcommittees.* In some situations, specialized subcommittees, made up of State Technical Committee members, may be needed to analyze and examine specific issues. The State Conservationist may assemble certain members, including members of Local Working Groups, to discuss, examine, and focus on a particular technical or programmatic topic. The subcommittee may seek public participation, but it is not required to do so. Nevertheless, recommendations resulting from these subcommittee sessions, other than sessions of Local Working Groups, shall be made only in a general session of the State Technical Committee where the public is notified and invited to attend. Decisions resulting from recommendations of Local Working Groups will be communicated to NRCS in accordance with the standard operating procedures described in § 610.23(b).

(b) *Local Working Groups.* (1) A Local Working Group shall be composed of conservation district officials, agricultural producers representing the variety of crops and livestock or poultry raised within the local area, nonindustrial private forest land owners, and other professionals representing relevant agricultural and conservation interests and a variety of disciplines in the soil, water, plant, wetland, and wildlife sciences who are familiar with private land agricultural and natural resource issues in the local community;

(2) Local Working Groups provide recommendations on local natural resource priorities and criteria for conservation activities and programs.

(3) The Local Working Groups will follow the standard operating procedures described in § 610.23(b) and the public notice requirements set forth in § 610.23(c).

**Arlen L. Lancaster,**

Chief, Natural Resources Conservation Service.

[FR Doc. E8-27657 Filed 11-24-08; 8:45 am]

BILLING CODE 3410-16-P

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 39

[Docket No. FAA-2008-0834; Directorate Identifier 2007-SW-78-AD; Amendment 39-15746; AD 2008-24-06]

RIN 2120-AA64

#### Airworthiness Directives; Agusta S.p.A. Model A109A and A109A II Helicopters

**AGENCY:** Federal Aviation Administration (FAA), Department of Transportation (DOT).

**ACTION:** Final rule.

**SUMMARY:** This amendment supersedes an existing airworthiness directive (AD) for the specified Agusta S.p.A. (Agusta) model helicopters. This AD results from a revised mandatory continuing airworthiness information (MCAI) issued by an aviation authority to identify and correct an unsafe condition on an aviation product. The aviation authority of Italy, with which we have a bilateral agreement, reports that the previous MCAI should not apply to newly redesigned and improved tail rotor blades. This AD requires the same inspections as the current AD but limits the applicability to only three part-numbered tail rotor blades. This AD requires actions that are intended to prevent fatigue failure of a tail rotor blade (blade), loss of a tail rotor, and subsequent loss of control of the helicopter.

**DATES:** This AD becomes effective on December 30, 2008.

The incorporation by reference of certain publications is approved by the Director of the Federal Register as of December 30, 2008.

**ADDRESSES:** You may examine the AD docket on the Internet at <http://regulations.gov> or in person at the Docket Operations office, U.S. Department of Transportation, 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.

You may get the service information identified in this AD from Agusta, Via Giovanni Agusta, 520 21017 Cascina Costa di Samarate (VA), Italy, telephone 39 0331-229111, fax 39 0331-229605/222595, or at [http://customersupport.agusta.com/technical\\_advice.php](http://customersupport.agusta.com/technical_advice.php).

*Examining the AD Docket:* The AD docket contains the notice of proposed rulemaking (NPRM), the economic

evaluation, any comments received, and other information. The street address and operating hours for the Docket Operations office (telephone (800) 647-5527) are in the **ADDRESSES** section of this AD. Comments will be available in the AD docket shortly after they are received.

#### FOR FURTHER INFORMATION CONTACT:

Sharon Miles, Aviation Safety Engineer, FAA, Rotorcraft Directorate, Regulations and Guidance Group, Fort Worth, Texas 76193-0111, telephone (817) 222-5122, fax (817) 222-5961.

#### SUPPLEMENTARY INFORMATION:

##### Discussion

We issued an NPRM on July 27, 2008 to amend 14 CFR part 39 to include a superseding AD that would apply to the specified Agusta model helicopters. That NPRM was published in the **Federal Register** on August 6, 2008 (73 FR 45644) and proposed the same inspection requirements as the current AD. It also proposed to limit the applicability to only three part-numbered tail rotor blades.

You may obtain further information by examining the MCAI and any related service information in the AD docket.

##### Comments

By publishing the NPRM, we gave the public an opportunity to participate in developing this AD. However, we received no comment on the NPRM or on our determination of the cost to the public. Therefore, based on our review and evaluation of the available data, we have determined that air safety and the public interest require adopting the AD as proposed.

##### Relevant Service Information

Agusta has issued Bollettino Tecnico No. 109-110, Revision A, dated December 12, 2005 (BT). The actions described in the MCAI are intended to correct the same unsafe condition as that identified in the service information.

##### Differences Between This AD and the MCAI

The MCAI states to comply with the manufacturer's BT. This AD differs from the incorporated portions of the BT as follows:

(1) We refer to the compliance time as hours time-in-service rather than flight hours.

(2) We do not require you to contact the manufacturer.

##### Costs of Compliance

We estimate that this AD will affect about 40 helicopters of U.S. registry. We also estimate that it will take about 2.5



work-hours to inspect the affected blades of each helicopter at an average labor rate of \$80 per work-hour. The cost of performing the daily magnifying glass visual inspection is negligible. Based on these figures, we estimate the cost of this AD on U.S. operators to be \$48,000, assuming 6 dye-penetrant inspections a year, negligible costs for the magnifying glass inspection, and no cracked blades are found.

#### 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 product(s) identified in this rulemaking action.

#### Regulatory Findings

We determined that this AD will not have federalism implications under Executive Order 13132. This AD will 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.

Therefore, I certify this AD:

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); and
3. 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.

We prepared an economic evaluation of the estimated costs to comply with this AD and placed it in the AD docket.

#### List of Subjects in 14 CFR Part 39

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

#### Adoption of the Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the FAA amends 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:

**2008-24-06 Agusta S.p.A. Amendment 39-15746; Docket No. FAA-2008-0834; Directorate Identifier 2008-SW-78-AD.**

#### Effective Date

(a) This airworthiness directive (AD) becomes effective on December 30, 2008.

#### Other Affected ADs

(b) This AD supersedes AD 99-27-12, Amendment 39-11493, Docket No. 99-SW-91-AD (65 FR 346, January 5, 2000).

#### Applicability

(c) This AD applies to Model A109A and A109A II helicopters, with a tail rotor blade (blade), part number (P/N) 109-0132-02-11, -15, and -121, with 400 or more hours time-in-service (TIS), installed, certificated in any category.

#### Reason

(d) Based on the Italian mandatory continued airworthiness information (MCAI) AD, this action contains the same requirement as superseded AD 99-27-12 but narrows the applicability from blade, P/N "109-0132-02—all dash numbers," to specific P/Ns "109-0132-02-11, -15, and -121." Thus, this action does not apply to blades with any other P/N, including newly designated blade, P/N 109-0132-02-125. The actions specified by this AD are intended to continue the requirements to prevent fatigue failure of a blade, loss of a tail rotor, and subsequent loss of control of the helicopter.

#### Actions and Compliance

(e) Required as indicated; unless already done, do the following actions:

(1) Before further flight, dye-penetrant inspect each blade for a crack by following the Compliance Instructions, Part I, of Agusta S.p.A. Bollettino Tecnico No. 109-110, Revision A, dated December 12, 2005 (BT). Thereafter, at intervals not to exceed 100 hours TIS, dye-penetrant inspect each blade for a crack by following the Compliance Instructions, Part III, of the BT. If you find a crack, replace the cracked blade with an airworthy blade before further flight.

(2) Before the first flight each day, visually inspect each blade for a crack using a 3 to 5 power magnifying glass by following the Compliance Instructions, Part II, of the BT. If you find a crack, replace the cracked blade with an airworthy blade before further flight.

#### Differences Between This AD and the MCAI

(f) The MCAI states to comply with the manufacturer's BT. This AD differs from the incorporated portions of the BT as follows:

(1) We refer to the compliance time as hours TIS rather than flight hours.

(2) We do not require you to contact the manufacturer.

#### Other Information

(g) Alternative Methods of Compliance (AMOCs): The Manager, Safety Management Group, Rotorcraft Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Sharon Miles, Aviation Safety Engineer, Regulations and Guidance Group, Fort Worth, Texas 76193-0111, telephone (817) 222-5122, fax (817) 222-5961.

#### Related Information

(h) Mandatory Continuing Airworthiness Information (MCAI) ENAC AD No. 2006-001, Revision 1, dated January 3, 2006, contains related information.

#### Air Transport Association of America (ATA) Tracking Code

(i) Air Transport Association of America (ATA) Code 6410: Main Rotor Blades.

#### Material Incorporated by Reference

(j) You must use the specified portions of Agusta S.p.A. Bollettino Tecnico No. 109-110, Revision A, dated December 12, 2005, to do the actions required.

(1) The Director of the Federal Register approved the incorporation by reference of this service information under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) For service information identified in this AD, contact Agusta, Via Giovanni Agusta, 520 21017 Cascina Costa di Samarate (VA), Italy, telephone 39 0331-229111, fax 39 0331-229605/222595, or at [http://customersupport.agusto.com/technical\\_advice.php](http://customersupport.agusto.com/technical_advice.php).

(3) You may review copies at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas, or 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/cfr/ibr-locations.html>.

Issued in Fort Worth, Texas, on November 7, 2008.

#### Mark R. Schilling,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. E8-27611 Filed 11-24-08; 8:45 am]

BILLING CODE 4910-13-P

## DEPARTMENT OF TRANSPORTATION

## Federal Aviation Administration

## 14 CFR Part 39

[Docket No. FAA-2008-0891 Directorate Identifier 2008-CE-046-AD; Amendment 39-15741; AD 2008-24-01]

RIN 2120-AA64

**Airworthiness Directives; Viking Air Limited DHC-6 Series Airplanes**

**AGENCY:** Federal Aviation Administration (FAA), Department of Transportation (DOT).

**ACTION:** Final rule.

**SUMMARY:** We are adopting a new airworthiness directive (AD) for the products listed above. This AD results from mandatory continuing airworthiness information (MCAI) issued by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as:

Three instances have occurred in which the aircraft took off with pre-mod 6/1676 flight control gust locks still installed, sometimes with disastrous results.

Based on investigation, the FAA and National Transportation Safety Board (NTSB) believe that an attempted takeoff with the gust locks installed could be the cause of a recent accident in Hyannis, Massachusetts. We are issuing this AD to require actions to correct the unsafe condition on these products.

**DATES:** This AD becomes effective December 30, 2008.

On December 30, 2008, the Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD.

**ADDRESSES:** You may examine the AD docket on the Internet at <http://www.regulations.gov> or in person at Document Management Facility, U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200

New Jersey Avenue, SE., Washington, DC 20590.

**FOR FURTHER INFORMATION CONTACT:**

Fabio Buttitta, Aerospace Engineer, FAA, New York Aircraft Certification Office, 1600 Stewart Avenue, Suite 410, Westbury, New York 11590; telephone: (516) 228-7303; fax: (516) 794-5531.

**SUPPLEMENTARY INFORMATION:**

**Discussion**

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to include an AD that would apply to the specified products. That NPRM was published in the *Federal Register* on August 19, 2008 (73 FR 48310). That NPRM proposed to correct an unsafe condition for the specified products. The MCAI states:

Three instances have occurred in which the aircraft took off with pre-mod 6/1676 flight control gust locks still installed, sometimes with disastrous results.

The MCAI, to prevent an attempted take-off with the gust locks installed, requires the incorporation of de Havilland Modification 6/1676 (ensures downward deflection of the elevators when the control locks are engaged) and incorporation of de Havilland Modification 6/1726 (adds to the control lock a warning flag which masks essential flight instruments on the pilot's instrument panel).

**Comments**

We gave the public the opportunity to participate in developing this AD. We have considered the comment received.

**Comment Issue: Proposed AD Deals With an Operational/Pilot Error**

The Aircraft Owners and Pilots Association (AOPA) recommends that the FAA issue a special airworthiness information bulletin (SAIB) instead of an AD. AOPA cites another similar situation where the FAA issued an SAIB for Raytheon Aircraft Company (RAC) (now, Hawker Beechcraft Corporation (HBC)) airplanes instead of an AD, dealing with both operational/pilot error

and the failure of the pilot to remove the control lock before flight. AOPA believes that this is not an unsafe condition under 14 CFR part 39.

The FAA partially agrees with the commenter that in the referenced situation we issued an SAIB instead of an AD. However, we disagree with the commenter that this particular situation should require no more than SAIB action.

This AD action differs from the situation that warranted the SAIB. The SAIB, dated March 11, 2002, for the HBC airplanes was prompted because of operators using makeshift gust locks (common bolts or nails) instead of gust locks provided by the manufacturer. The SAIB recommends use of gust locks that meet the requirements for flight control locks as defined by 14 CFR 23.679 and recommends pilots review their preflight checks. The SAIB also recommends that operators replace older gust locks that locked the controls in the neutral position with newer modified gust locks that locked the controls in the nose down and/or roll input position.

The SAIB applies to the entire line (including commuter category 1900 series) of HBC propeller-driven airplanes, primarily to address accidents that involved gust locks on non-commuter category airplanes. This includes the HBC 1900 series airplanes, which like the DHC-6 series airplanes, are used in commuter operations (14 CFR part 135). The 1900 series airplanes are included as an extra measure to reinforce prudent practice on HBC's entire line of propeller-driven airplanes. It should be noted that the HBC Model 1900 gust lock design always locks the control column in a nose down and/or roll input position.

The following table, *Current Gust Lock Design Differences Between 1900 Series Airplanes and DHC-6 (pre-Mod 6/1676/Mod 6/1726) Series Airplanes*, illustrates the design differences between the two series of airplanes:

CURRENT GUST LOCK DESIGN DIFFERENCES BETWEEN 1900 SERIES AIRPLANES AND DHC-6 (PRE-MOD 6/1676/ MOD 6/1726) SERIES AIRPLANES

1900 Series	DHC-6 Series
Gust lock design pins the control column in a nose-down elevator position that prevents takeoff.	Pre-Mod 6/1676/Mod 6/1726 design of the gust locks pins the control column in a neutral elevator position that allows takeoff.
Rotates the control wheel approximately 15 degrees to the left when the lock is engaged to indicate gust lock engagement.	Control wheel is not rotated as a visual indicator that the gust lock is engaged.
Includes a clamp over the engine control levers with a red warning flag on a chain between the engine control clamp and the control column pin, and a chain connected to the rudder lock pin installed in the floorboards.	Does not include a clamp over the engine control levers or a warning flag.
Design provides an obvious warning that the gust locks are engaged ...	No obvious warning that the gust locks are engaged.

There have been no known accidents of the 1900 series airplanes attributed to failure to remove a gust lock.

The DHC-6 series airplanes are comparable to the 1900 series airplanes and may be used as commuter category airplanes. Before issuance of the MCAI, there were three occurrences of DHC-6 series airplanes attempting take off with pre-Mod 6/1676 gust locks still installed, sometimes with disastrous results. Recently, we had a fatal accident in Hyannis, Massachusetts, where preliminary investigations reveal a pre-Mod 6/1676 gust lock installed.

This AD goes beyond recommending that pilots review and adhere to all pre-flight checks and before take-off procedures. This AD would require operators to incorporate de Havilland Modification 6/1676, which locks the control column forward (elevator nose down position). This reduces the possibility of the airplane becoming airborne should a takeoff be attempted with the gust lock installed. This AD would also require operators to incorporate Mod 6/1726, which adds a warning flag that masks essential flight instruments on the pilot's instrument panel. This gives a more obvious warning to the pilot that the gust locks are installed, minimizing the possibility of an attempted take-off with gust locks installed.

Because this issue has been the cause of past accidents that resulted in the MCAI and could be the cause or a contributing factor to a recent accident, we determined that an unsafe condition exists and the condition is likely to exist or develop in other products of the same type design registered in the United States.

We are not changing the final rule AD action based on this comment.

#### Differences Between This AD and the MCAI or Service Information

We have reviewed the MCAI and related service information and, in general, agree with their substance. But we might have found it necessary to use different words from those in the MCAI to ensure the AD is clear for U.S. operators and is enforceable. In making these changes, we do not intend to differ substantively from the information provided in the MCAI and related service information.

We might also have required different actions in this AD from those in the MCAI in order to follow FAA policies. Any such differences are highlighted in a NOTE within the AD.

#### Costs of Compliance

Based on the service information, we estimate that this AD will affect 42

products of U.S. registry. We also estimate that it will take about 6 work-hours per product to comply with basic requirements of this AD. The average labor rate is \$80 per work-hour. Required parts will cost about \$1,125 per product.

Based on these figures, we estimate the cost of this AD to the U.S. operators to be \$67,410 or \$1,605 per product.

#### 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 AD will not have federalism implications under Executive Order 13132. This AD will 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 AD:*

- (1) Is not a "significant regulatory action" under Executive Order 12866;
- (2) Is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and
- (3) 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.

We prepared a regulatory evaluation of the estimated costs to comply with this AD and placed it in the AD Docket.

#### Examining the AD Docket

You may examine the AD docket on the Internet at <http://www.regulations.gov>; 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 the NPRM, 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.

#### List of Subjects in 14 CFR Part 39

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

#### Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 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:

#### 2008-24-01 Viking Air Limited:

Amendment 39-15741; Docket No. FAA-2008-0891; Directorate Identifier 2008-CE-046-AD.

#### Effective Date

(a) This airworthiness directive (AD) becomes effective December 30, 2008.

#### Affected ADs

(b) None.

#### Applicability

(c) This AD applies to Models DHC-6-1, DHC-6-100, DHC-6-200, and DHC-6-300 airplanes, serial numbers (SNs) 1 through 696, that

- (1) have not had modifications 6/1676 and 6/1726 installed; and
- (2) are certificated in any category.

#### Subject

(d) Air Transport Association of America (ATA) Code 27: Flight Controls.

#### Reason

(e) The mandatory continuing airworthiness information (MCAI) states:

Three instances have occurred in which the aircraft took off with pre-mod 6/1676 flight control gust locks still installed, sometimes with disastrous results.

The MCAI, to prevent an attempted take-off with the gust locks installed, requires the incorporation of de Havilland Modification 6/1676 (ensures downward deflection of the elevators when the control locks are engaged) and incorporation of de Havilland Modification 6/1726 (adds to the control lock a warning flag which masks essential flight instruments on the pilot's instrument panel). Based on investigation, the FAA and National Transportation Safety Board believe

that an attempted takeoff with the gust locks installed could be the cause of a recent accident in Hyannis, Massachusetts.

#### Actions and Compliance

(f) Unless already done, within 6 calendar months after December 30, 2008 (the effective date of this AD), do the following actions using Boeing Canada de Havilland Division Service Bulletin No. 6/508, Revision "A," dated January 31, 1990:

(1) Incorporate de Havilland Modification 6/1676, which assures downward deflection of the elevators when the control locks are engaged.

(2) Incorporate de Havilland Modification 6/1726, which adds to the control lock a warning flag that covers up essential flight instruments on the pilot's instrument panel.

#### FAA AD Differences

**Note:** This AD differs from the MCAI and/or service information as follows: No differences.

#### Other FAA AD Provisions

(g) The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Standards Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Fabio Buttitta, Aerospace Engineer, FAA, New York Aircraft Certification Office, 1600 Stewart Avenue, Suite 410, Westbury, New York 11590; telephone: (516) 228-7303; fax: (516) 794-5531. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(3) *Reporting Requirements:* For any reporting requirement in this AD, under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 et seq.), the Office of Management and Budget (OMB) has approved the information collection requirements and has assigned OMB Control Number 2120-0056.

#### Related Information

(h) Refer to MCAI Transport Canada AD No. CF-90-01, dated January 31, 1990; and Boeing Canada de Havilland Division Service Bulletin No. 6/508, Revision "A," dated January 31, 1990, for related information.

#### Material Incorporated by Reference

(i) You must use Boeing Canada de Havilland Division Service Bulletin No. 6/508, Revision "A," dated January 31, 1990, to do the actions required by this AD, unless the AD specifies otherwise.

(1) The Director of the Federal Register approved the incorporation by reference of

this service information under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) For service information identified in this AD, contact Viking Air Ltd., 9564 Hampden Rd., Sidney, British Columbia, Canada V8L 5V5; telephone: 800-663-8444 or 250-656-7227; fax: 250-656-0673; E-mail: info@vikingair.com; Web: http://www.vikingair.com.

(3) You may review copies at the FAA, Central Region, Office of the Regional Counsel, 901 Locust, Room 506, Kansas City, Missouri 64106; or 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/cfr/ibr-locations.html>.

Issued in Kansas City, Missouri on November 10, 2008.

**James E. Jackson,**

*Acting Manager, Small Airplane Directorate, Aircraft Certification Service.*

[FR Doc. E8-27299 Filed 11-24-08; 8:45 am]

**BILLING CODE 4910-13-P**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 39

[Docket No. FAA-2007-28691; Directorate Identifier 2006-SW-22-AD; Amendment 39-15744; AD 2008-24-04]

RIN 2120-AA64

#### Airworthiness Directives; Eurocopter France Model AS355E, F, F1, F2, and N Helicopters

**AGENCY:** Federal Aviation Administration, DOT.

**ACTION:** Final rule.

**SUMMARY:** This amendment supersedes an existing airworthiness directive (AD) for the specified Eurocopter France (Eurocopter) model helicopters. That AD currently requires certain checks of the magnetic chip detector plug (chip detector) and the main gearbox (MGB) oil-sight glass, certain inspections of the lubrication pump (pump), and replacing the MGB and the pump with an airworthy MGB and pump, if necessary. Also, the AD requires that before a pump or MGB with any hours time-in-service (TIS) can be installed, it must meet the AD requirements. This AD adds all serial-numbered pumps to the applicability and requires using an improved procedure for detecting oil pump wear. This amendment is prompted by additional cases of MGB lubrication pump deterioration and a further investigation that determined that all serial-numbered pumps might be affected and the development of an improved procedure that is more

accurate for detecting oil pump wear earlier. The actions specified by this AD are intended to implement improved procedures to detect a failing MGB oil pump, prevent failure of the MGB pump, seizure of the MGB, loss of drive to an engine and main rotor, and subsequent loss of control of the helicopter.

**DATES:** Effective December 30, 2008.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of December 30, 2008.

**ADDRESSES:** You may get the service information identified in this AD from American Eurocopter Corporation, 2701 Forum Drive, Grand Prairie, TX 75053-4005, telephone (972) 641-3460, fax (972) 641-3527, or at <http://www.eurocopter.com>.

*Examining the Docket:* You may examine the docket that contains this AD, any comments, and other information on the Internet at <http://www.regulations.gov>, or at the Docket Operations office, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC.

**FOR FURTHER INFORMATION CONTACT:** Ed Cuevas, Aviation Safety Engineer, FAA, Rotorcraft Directorate, Safety Management Group, Fort Worth, Texas 76193-0111, telephone (817) 222-5355, fax (817) 222-5961.

**SUPPLEMENTARY INFORMATION:** A proposal to amend 14 CFR part 39 by superseding AD 2003-21-09 R1, Docket No. 2003-SW-10-AD, Amendment 39-14621 (71 FR 31070, June 1, 2006), for the specified Eurocopter model helicopters was published in the **Federal Register** on July 13, 2007 (72 FR 38529). That notice of proposed rulemaking (NPRM) proposed retaining the requirements in AD 2003-21-09 R1 and adding certain part-numbered pumps to the applicability. After we issued the NPRM, the manufacturer developed an improved procedure for monitoring the condition of the MGB lubrication pump. Also, a commenter to the NPRM agreed that the improved procedure is a better way to detect MGB oil pump problems because "sludge on the chip plug can come from sources within the MGB oil system." We agreed with the commenter that the improved procedure is a better way to detect MGB oil pump problems because this process reflects the progressive inefficiency as the oil pump wears as it relates to steady oil temperature and variable outside air temperature (OAT) and issued a supplemental notice of

proposed rulemaking (SNPRM) on June 19, 2008 (73 FR 36821, June 30, 2008). In addition to the proposals from the NPRM, the SNPRM proposed implementing the improved procedure for monitoring the condition of the MGB lubrication pump. No additional comments were received on the SNPRM or the FAA's determination of the cost to the public, and we have determined that air safety and the public interest require the adoption of the rule as proposed in the SNPRM.

The European Aviation Safety Agency (EASA), the Technical Agent for the Member States of the European Community, notified the FAA that an unsafe condition may exist on the specified Eurocopter model helicopters. EASA advises that Eurocopter has developed an improved procedure for monitoring the condition of the MGB lubrication pump.

Eurocopter has issued Alert Service Bulletin No. 05.00.51, dated July 9, 2007 (ASB), specifying the improved procedure. EASA has issued EASA Emergency AD No. 2007-0209E, dated August 6, 2007, in response to the ASB. These helicopter models are manufactured in France and are type certificated for operation in the United States under the provisions of 14 CFR 21.29 and the applicable bilateral agreement. Pursuant to the applicable bilateral agreement, EASA has kept the FAA informed of the situation described above. The FAA has examined the findings of EASA, reviewed all available information, and determined that AD action is necessary for products of these type designs that are certificated for operation in the United States.

We estimate that this AD will affect 80 helicopters of U.S. registry, and the actions will take about:

- 15 minutes to perform the procedures to check the condition of the MGB oil and chip detector plug,
- 4 work hours to remove the MGB and pump,
- 1 work hour to inspect the pump under the 10-hour, 25-hour, and 110-hour time-in-service (TIS) procedures,
- 4 work hours to install a serviceable MGB and pump at an average labor rate of \$80 per work hour, and
- \$4,000 for an overhauled pump and up to \$60,000 for an overhauled MGB per helicopter.

Based on these figures, we estimate the total cost impact of the AD on U.S. operators to be \$107,040 per year, assuming (a) One overhauled MGB and pump is replaced on one helicopter per year, (b) all 80 helicopters operate for 10 days undergoing 10 daily checks and 2 10-hour TIS inspections, and (c) each of the 80 helicopters operate for 260 hours

per year with 20 helicopters receiving the repetitive 25-hour TIS inspection or 10.4 inspections per helicopter per year (260/25) for a total of 208 inspections (20 \* 10.4) and 60 helicopters receiving the repetitive 110-hour TIS inspection or 2.36 inspections per helicopter per year (260/110) for a total of 142 inspections (60 \* 2.36).

#### Regulatory Findings

We have determined that this AD will not have federalism implications under Executive Order 13132. This AD will 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 that the 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); and
3. 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.

We prepared an economic evaluation of the estimated costs to comply with this AD. See the AD docket to examine the economic evaluation.

#### 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.

#### List of Subjects in 14 CFR Part 39

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

#### Adoption of the Amendment

- Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (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. Section 39.13 is amended by removing Amendment 39-14621 (71 FR 31070, June 1, 2006), and by adding a new airworthiness directive (AD), Amendment 39-15744, to read as follows:

#### 2008-24-04 Eurocopter France:

Amendment 39-15744. Docket No. FAA-2007-28691; Directorate Identifier 2006-SW-22-AD. Supersedes AD 2003-21-09 R1, Amendment 39-14621, Docket No. 2003-SW-10-AD.

**Applicability:** Model AS355E, F, F1, F2, and N helicopters, with a main gear box (MGB) lubrication pump (pump), part number (P/N) 355A32-0700-01, 355A32-0700-02, or 355A32-0701-00, any serial number (S/N), certificated in any category.

**Compliance:** Required as indicated.

To detect sludge on the chip detector and dark oil in the MGB, to prevent failure of the MGB pump, seizure of the MGB, loss of drive to an engine and main rotor, and subsequent loss of control of the helicopter, do the following:

(a) Before the first flight of each day and at intervals not to exceed 10 hours time-in-service (TIS), check the MGB magnetic chip detector plug (chip detector) for any sludge. Also, check for dark oil in the MGB oil-sight glass. An owner/operator (pilot) holding at least a private pilot certificate may perform this visual check and must enter compliance into the aircraft maintenance records in accordance with 14 CFR 43.11 and 91.417(a)(2)(v). "Sludge" is a deposit on the chip detector that is typically dark in color and in the form of a film or paste, as compared to metal chips or particles normally found on a chip detector. Sludge may have both metallic or nonmetallic properties, may consist of copper (pinion bearing), magnesium (pump case), and steel (pinion) from the oil pump, and a nonmetallic substance from the chemical breakdown of the oil as it interacts with the metal.

(b) Before further flight, if any sludge is found on the chip detector, remove, open, and inspect the pump.

(c) Before further flight, if the oil appears dark in color when it is observed through the MGB oil-sight glass, take an oil sample. If the oil taken in the sample is dark or dark purple, before further flight, remove, open, and inspect the pump.

**Note 1:** Eurocopter France Alert Service Bulletin No. 05.00.40, Revision 1, dated

January 5, 2006, and Emergency ASB No. 05.00.40, Revision 2, dated December 20, 2006, pertain to the subject of this AD.

(d) Within 25 hours TIS, unless accomplished previously, after operating both engines at normal operating revolutions per minute (RPM) for at least 20 minutes to ensure the MGB oil temperature has stabilized, inspect the oil pump for wear by following the Accomplishment Instructions, paragraph 2.B.2., steps 1. through 6., of Eurocopter Alert Service Bulletin No. 05.00.51, dated July 9, 2007 (ASB). This AD does not require you to send the information to the manufacturer.

(1) Record the outside air temperature (OAT) and rotor speed (NR RPM) and plot the point at which they intersect using the graph in Figure 1 or 2 of the ASB.

(2) If the point on the graph at the intersection of the recorded OAT and the NR RPM falls within:

(i) Zone 3—Before further flight, replace the MGB and pump with an airworthy MGB and pump.

(ii) Zone 2—At intervals not to exceed 25 hours TIS, repeat the inspection procedures by following the Accomplishment Instructions, paragraph 2.B.2. steps 1 through 6, of the ASB. After being classified in "Zone 2," you must obtain two successive inspections separated by at least 24 hours TIS that fall within Zone 1 before you can begin to inspect at intervals not to exceed 110 hours TIS by following paragraph (d)(2)(iii) of this AD for Zone 1.

Note 2: In addition to a worn oil pump, the loss of oil pressure could also be due to a clogged oil filter or cooler, a pinched hose, or an inaccurate pressure switch.

(iii) Zone 1—At intervals not to exceed 110 hours TIS, repeat the inspection procedures by following the Accomplishment Instructions, paragraph 2.B.2., steps 1 through 6, of the ASB.

(3) Compliance with paragraphs (d)(1) and (d)(2) of this AD constitutes terminating action for the checks and inspections required by paragraphs (a), (b), and (c) of this AD.

(e) To request a different method of compliance or a different compliance time for this AD, follow the procedures in 14 CFR 39.19. Contact the Manager, Safety Management Group, FAA, ATTN: Ed Cuevas, Aviation Safety Engineer, Rotorcraft Directorate, Fort Worth, Texas 76193-0111, telephone (817) 222-5355, fax (817) 222-5961.

(f) Do the oil pump inspections by following the specified portions of Eurocopter Alert Service Bulletin No. 05.00.51, dated July 9, 2007. The Director of the Federal Register approved this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from American Eurocopter Corporation, 2701 Forum Drive, Grand Prairie, TX 75053-4005, telephone (972) 641-3460, fax (972) 641-3527, or at <http://www.eurocopter.com>. Copies may be inspected at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas, or 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](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

(g) This amendment becomes effective on December 30, 2008.

Note 3: The subject of this AD is addressed in European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, Emergency AD No. 2006-0378-E, dated December 21, 2006, and AD No. 2007-0209E, dated August 6, 2007.

Issued in Fort Worth, Texas on November 7, 2008.

Mark R. Schilling,  
Acting Manager, Rotorcraft Directorate,  
Aircraft Certification Service.

[FR Doc. E8-27610 Filed 11-24-08; 8:45 am]

BILLING CODE 4910-13-P

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 39

[Docket No. FAA-2008-0911; Directorate Identifier 2008-NM-115-AD; Amendment 39-15739; AD 2008-23-18]

RIN 2120-AA64

#### Airworthiness Directives; Bombardier Model CL-600-2C10 (Regional Jet Series 700, 701 & 702), CL-600-2D15 (Regional Jet Series 705), and CL-600-2D24 (Regional Jet Series 900) Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

**SUMMARY:** We are adopting a new airworthiness directive (AD) for the products listed above. This AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as:

There have been several incidents of shorting and sparks due to de-icing fluid ingress into the cockpit of CL-600-2C10 and CL-600-2D24 aircraft. De-icing fluid can enter between the windshields and side windows, leading to possible damage to the electrical components and wires as it comes into contact with cockpit floodlight electrical connections.

De-icing fluid in contact with cockpit floodlight electrical connections can result in possible arcing and fire. We are issuing this AD to require actions to correct the unsafe condition on these products.

**DATES:** This AD becomes effective December 30, 2008.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of December 30, 2008.

**ADDRESSES:** You may examine the AD docket on the Internet at <http://www.regulations.gov> or in person at the U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC.

**FOR FURTHER INFORMATION CONTACT:** Wing Chan, Aerospace Engineer, Systems and Flight Test Branch, ANE-172, FAA, New York Aircraft Certification Office, 1600 Stewart Avenue, Suite 410, Westbury, New York 11590; telephone (516) 228-7311; fax (516) 794-5531.

#### SUPPLEMENTARY INFORMATION:

##### Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to include an AD that would apply to the specified products. That NPRM was published in the *Federal Register* on August 26, 2008 (73 FR 50254). That NPRM proposed to correct an unsafe condition for the specified products. The MCAI states:

There have been several incidents of shorting and sparks due to de-icing fluid ingress into the cockpit of CL-600-2C10 and CL-600-2D24 aircraft. De-icing fluid can enter between the windshields and side windows, leading to possible damage to the electrical components and wires as it comes into contact with cockpit floodlight electrical connections.

De-icing fluid in contact with cockpit floodlight electrical connections can result in possible arcing and fire. The actions to address the unsafe condition include performing a leak test, applying sealant between the windshields and side windows, and doing related investigative and corrective actions. The related investigative action is performing a leak test after applying sealant. The related corrective action is contacting Bombardier for repair instructions and doing the repair. You may obtain further information by examining the MCAI in the AD docket.

##### Comments

We gave the public the opportunity to participate in developing this AD. We received no comments on the NPRM or on the determination of the cost to the public.

##### Conclusion

We reviewed the available data and determined that air safety and the

public interest require adopting the AD as proposed.

#### Differences Between This AD and the MCAI or Service Information

We have reviewed the MCAI and related service information and, in general, agree with their substance. But we might have found it necessary to use different words from those in the MCAI to ensure the AD is clear for U.S. operators and is enforceable. In making these changes, we do not intend to differ substantively from the information provided in the MCAI and related service information.

We might also have required different actions in this AD from those in the MCAI in order to follow our FAA policies. Any such differences are highlighted in a NOTE within the AD.

#### Costs of Compliance

We estimate that this AD will affect about 254 products of U.S. registry. We also estimate that it will take about 4 work-hours per product to comply with the basic requirements of this AD. The average labor rate is \$80 per work-hour. Based on these figures, we estimate the cost of this AD to the U.S. operators to be \$81,280, or \$320 per product.

#### 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 AD will not have federalism implications under Executive Order 13132. This AD will 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 AD:

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); and
3. 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.

We prepared a regulatory evaluation of the estimated costs to comply with this AD and placed it in the AD docket.

#### 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 the NPRM, 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.

#### List of Subjects in 14 CFR Part 39

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

#### Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 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:

**2008-23-18 Bombardier, Inc. (Formerly Canadair):** Amendment 39-15739. Docket No. FAA-2008-0911; Directorate Identifier 2008-NM-115-AD.

#### Effective Date

(a) This airworthiness directive (AD) becomes effective December 30, 2008.

#### Affected ADs

(b) None.

#### Applicability

(c) This AD applies to Bombardier Model CL-600-2C10 (Regional Jet Series 700, 701 & 702) airplanes, serial numbers 10003 through 10216 inclusive; and Model CL-600-2D15 (Regional Jet Series 705) and CL-600-2D24 (Regional Jet Series 900) airplanes, serial

numbers 15001 through 15040 inclusive; certificated in any category.

#### Subject

(d) Air Transport Association (ATA) of America Code 56: Windows.

#### Reason

(e) The mandatory continuing airworthiness information (MCAI) states:

There have been several incidents of shorting and sparks due to de-icing fluid ingress into the cockpit of CL-600-2C10 and CL-600-2D24 aircraft. De-icing fluid can enter between the windshields and side windows, leading to possible damage to the electrical components and wires as it comes into contact with cockpit floodlight electrical connections.

De-icing fluid in contact with cockpit floodlight electrical connections can result in possible arcing and fire. The actions to address the unsafe condition include performing a leak test, applying sealant between the windshields and side windows, and doing related investigative and corrective actions. The related investigative action is performing a leak test after applying sealant. The related corrective action is contacting Bombardier for repair instructions and doing the repair.

#### Actions and Compliance

(f) Unless already done, do the following actions.

(1) Within 450 flight hours after the effective date of this AD: Perform a leak test in accordance with Part A of the Accomplishment Instructions of Bombardier Alert Service Bulletin A670BA-56-002, Revision A, dated February 26, 2008.

(2) If leakage is detected in the leak test performed in accordance with paragraph (f)(1) of this AD: Prior to further flight, apply sealant between the windshields and side windows and do all applicable related investigative and corrective actions in accordance with Part B of the Accomplishment Instructions of Bombardier Alert Service Bulletin A670BA-56-002, Revision A, dated February 26, 2008. Do all applicable related investigative and corrective actions before further flight.

(3) If there is no leakage detected in the leak test performed in accordance with paragraph (f)(1) of this AD: Within 6 months or 2,000 flight hours after the effective date of this AD, whichever comes first, apply sealant between the windshields and side windows and do all applicable related investigative and corrective actions before further flight in accordance with Part B of the Accomplishment Instructions of Bombardier Alert Service Bulletin A670BA-56-002, Revision A, dated February 26, 2008. Do all applicable related investigative and corrective actions before further flight.

(4) A leak test and application of sealant are also acceptable for compliance with the requirements of paragraphs (f)(1), (f)(2), and (f)(3) of this AD if done before the effective date of this AD in accordance with Bombardier Alert Service Bulletin A670BA-56-002, dated January 7, 2008.

**FAA AD Differences**

**Note 1:** This AD differs from the MCAI and/or service information as follows: No differences.

**Other FAA AD Provisions**

(g) The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, New York Aircraft Certification Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Wing Chan, Aerospace Engineer, Systems and Flight Test Branch, ANE-172, FAA, New York Aircraft Certification Office, 1600 Stewart Avenue, Suite 410, Westbury, New York 11590; telephone (516) 228-7311; fax (516) 794-5531. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(3) *Reporting Requirements:* For any reporting requirement in this AD, under the provisions of the Paperwork Reduction Act, the Office of Management and Budget (OMB) has approved the information collection requirements and has assigned OMB Control Number 2120-0056.

**Related Information**

(h) Refer to MCAI Canadian Airworthiness Directive CF-2008-19, dated May 8, 2008; and Bombardier Alert Service Bulletin A670BA-56-002, Revision A, dated February 26, 2008; for related information.

**Material Incorporated by Reference**

(i) You must use Bombardier Alert Service Bulletin A670BA-56-002, Revision A, dated February 26, 2008, to do the actions required by this AD, unless the AD specifies otherwise.

(1) The Director of the Federal Register approved the incorporation by reference of this service information under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) For service information identified in this AD, contact Bombardier, Inc., 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514-855-5000; fax 514-855-7401; e-mail [thd.crj@aero.bombardier.com](mailto:thd.crj@aero.bombardier.com); Internet <http://www.bombardier.com>.

(3) You may review copies at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or 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](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

Issued in Renton, Washington, on November 6, 2008.

**Stephen P. Boyd,**

*Assistant Manager, Transport Airplane Directorate, Aircraft Certification Service.*

[FR Doc. E8-27169 Filed 11-24-08; 8:45 am]

**BILLING CODE 4910-13-P**

**DEPARTMENT OF TRANSPORTATION****Federal Aviation Administration****14 CFR Part 39**

**[Docket No. FAA-2007-0289; Directorate Identifier 2007-NM-208-AD; Amendment 39-15740; AD 2008-23-19]**

**RIN 2120-AA64**

**Airworthiness Directives; Boeing Model 757 Airplanes**

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Final rule.

**SUMMARY:** We are adopting a new airworthiness directive (AD) for certain Boeing Model 757 airplanes. This AD requires sealing the fasteners on the front and rear spars inside the left and right main fuel tanks and on the rear spar and lower panel of the center fuel tank. This AD also requires inspections of the wire bundle support installations to verify if certain clamps are installed and if Teflon sleeving covers the wire bundles inside the left and right equipment cooling system bays, on the left and right rear spars, and on the left and right front spars; and corrective actions if necessary. This AD results from a fuel system review conducted by the manufacturer. We are issuing this AD to detect and correct improper wire bundle support installation and sleeving and to prevent improperly sealed fasteners in the main and center fuel tanks from becoming an ignition source, in the event of a fault current, which could result in a fuel tank explosion and consequent loss of the airplane.

**DATES:** This AD is effective December 30, 2008.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of December 30, 2008.

**ADDRESSES:** For service information identified in this AD, contact Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124-2207.

**Examining the AD Docket**

You may examine the AD docket on the Internet at <http://www.regulations.gov>; 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 AD, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (telephone 800-647-5527) is the Document Management Facility, U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590.

**FOR FURTHER INFORMATION CONTACT:** Judy Coyle, Aerospace Engineer, Propulsion Branch, ANM-140S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98057-3356; telephone (425) 917-6497; fax (425) 917-6590.

**SUPPLEMENTARY INFORMATION:****Discussion**

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to include an airworthiness directive (AD) that would apply to certain Boeing Model 757 series airplanes. That NPRM was published in the *Federal Register* on December 6, 2007 (72 FR 68764). That NPRM proposed to require sealing the fasteners on the front and rear spars inside the left and right main fuel tanks and on the lower panel of the center fuel tank. That NPRM also proposed to require inspections of the wire bundle support installations to verify if certain clamps are installed and, if Teflon sleeving covers the wire bundles inside the left and right equipment cooling system bays, on the left and right rear spars, and on the left and right front spars; and corrective actions if necessary.

**Comments**

We gave the public the opportunity to participate in developing this AD. We considered the comments received from the four commenters.

**Request for Justification of the NPRM**

Northwest Airlines (NWA) has no objection to the intent of the NPRM, but it states it is not clear that we have shown that the probability of a fuel tank explosion due to unsealed fuel tank fasteners reaches the threshold for justifying the proposed modification. NWA requests that we provide more detail regarding the risk and benefit of the NPRM.

We agree to provide clarification. The unsafe condition encompassed the scenario of single failures (for example, a wire bundle clamp failure that could result in wire bundle contact with the fuel tank causing an ignition source internal to the tank) that place an airplane at risk of a fuel tank explosion.



The in-tank sealant is designed to provide a second level of protection against fuel tank ignition by encapsulating and containing the potential source of ignition. Further, the risk level associated with this single failure scenario was determined to warrant the actions required by this AD. No change to the AD is necessary in this regard.

#### **Request To Clarify the Unsafe Condition**

Boeing requests that we revise paragraph (d) of the NPRM to cover the requirement to do the general visual inspection for wire bundle support installation and sleeving. Boeing states that failures of the wire bundles and shorting to clamps are the prime candidates for the fault current source, and that they should be identified as the unsafe condition.

We agree because accomplishing the general visual inspections for wire bundle supports and sleeving is one of the requirements of this AD. We have revised the Summary and paragraph (d) of this AD accordingly.

#### **Request To Clarify Requirements**

Boeing requests that we revise the Summary of the NPRM to include the requirement to seal the fasteners on the rear spar of the center fuel tank. Boeing states that this action is called out on page 149 in view B of Figure 7 of Boeing Alert Service Bulletin 757-57A0064, dated July 16, 2007.

We agree and have revised the Summary of this AD accordingly. Although the specific location of the "rear spar of the center tank" was inadvertently omitted from the Summary of the NPRM, it was covered by paragraph (f) of the NPRM, which specified accomplishing all of the applicable actions specified in the Accomplishment Instructions of Boeing Alert Service Bulletin 757-57A0064, dated July 16, 2007.

#### **Request To Delay Issuance To Provide Instructions for Maintaining the Design Change**

Continental Airlines (CAL) is concerned that not enough attention has been given to ensure that the changes detailed in Boeing Alert Service Bulletin 757-57A0064, dated July 16, 2007, are preserved for the long-term operation of its Model 757 fleet. CAL states that, other than this service bulletin and some generic information found in the Boeing 757 Maintenance Planning Data (MPD) document, there are no other published "maintenance" documents currently available to show each specific requirement as detailed in the

service bulletin. CAL further states that information detailed by the service bulletin must be available in manuals that are routinely used by maintenance personnel. CAL asserts that making this information available will prevent the inadvertent reversal of the implemented changes, which could lead to violation of the NPRM, in addition to compromising the higher level of safety intended for the Model 757 fleet.

CAL believes the current program, as provided by the service bulletin and proposed by the NPRM, is not ready to be implemented. CAL states that, if the NPRM is mandated as proposed, CAL would not be able to incorporate the modification on its Model 757-200 series airplanes, and a high risk of future de-modification would exist for those airplanes that could be modified. CAL recommends that we coordinate with Boeing regarding its requested changes.

We infer that CAL requests that we delay issuance of the AD until Boeing has revised the applicable maintenance documents to provide detailed information for maintenance personnel to maintain the required design change. We agree with CAL's concern about ensuring that the requirements of this AD are maintained throughout the life of the airplane. We are considering additional rulemaking in this regard. However, we disagree with delaying issuance of the final rule until Boeing has worked through its process to revise the applicable maintenance documents. To delay this action would be inappropriate, since we have determined that an unsafe condition exists and that the actions required by this AD must be mandated to ensure continued safety. However, as a result of this comment, we have initiated discussions with Boeing about including more detail in the Instructions for Continued Airworthiness (ICA) to ensure that the integrity of this AD is maintained throughout the life of an airplane. Those discussions are ongoing at this time. We have not changed the AD in this regard.

#### **Request To Delay Issuance of the AD To Provide Instructions for Modified Airplanes**

CAL states that all of its 41 Model 757-200 series airplanes were modified in the past with a Aviation Partners Boeing (APB) winglet design that incorporated significant changes to the forward and rear spars. CAL states that Boeing has acknowledged that Boeing Alert Service Bulletin 757-57A0064, dated July 16, 2007, does not include instructions for the configuration of CAL's modified airplanes. CAL also

states that Boeing is currently assessing the configuration of CAL's airplanes and that Boeing will respond with an action plan.

We infer that CAL requests that we delay issuance of the AD until Boeing has revised the service bulletin to provide instructions for accomplishing the modification on airplanes equipped with APB winglets installed in accordance with Supplemental Type Certificate (STC) ST01518SE. We disagree with delaying issuance of the final rule because we have determined that an unsafe condition exists and that the actions required by this AD must be mandated to ensure continued safety. Further, we have discussed CAL's concern about the service bulletin instructions with both the airplane and winglet manufacturers. They both indicated that the procedures in the service bulletin, as published, can be accomplished on airplanes equipped with APB winglets installed in accordance with STC ST01518SE. We have not changed the AD in this regard.

#### **Request To Extend Compliance Time**

European Air Transport, on behalf of DHL Air, and NWA request that we extend the compliance time from 60 months to 72 months. European Air Transport states that, due to the high number of work hours needed to accomplish the proposed actions, it plans to do the work during a 4C-check (corresponding to 72 months, 24,000 flight hours, or 12,000 flight cycles, whichever occurs first). European Air Transport also states that a 60-month compliance time would require it to do the proposed actions on some of its airplanes outside the 4C-check, but that a 72-month compliance time will allow it to do the proposed actions on the entire fleet during base maintenance.

NWA states that, due to access requirements, it considers the proposed modification to be consistent with a D-check level of work. NWA also states that it does not understand the substantiation for the 60-month compliance time and believes that doing the work during scheduled fuel tank access will ensure more consistent quality of the modification, as well as reduced costs to industry. NWA also states that it is unaware of any accident or incident that has been attributed to unsealed fuel tank fasteners, or that the risk is such that compliance should be required within 60 months instead of 72 months. NWA believes that a 1-year extension of the compliance time would not have an appreciable impact on safety. NWA further states its request is consistent with the FAA harmonization policy of the aging airplane programs in

accordance with "Fuel Tank Safety Compliance Extension (Final Rule) and Aging Airplane Program Update (Request for Comments)" (69 FR 45936, July 30, 2004).

We do not agree with the request to extend the compliance time. In developing an appropriate compliance time for this action, we considered the urgency associated with the subject unsafe condition and the practical aspect of accomplishing the required modification within a period of time that corresponds to the normal scheduled maintenance for most affected operators. We recognize that operators have different maintenance schedules for accomplishing heavy maintenance on Model 757 airplanes, but at the same time we understand that a 60-month compliance time will accommodate most operators' schedules for that type of work. However, according to the provisions of paragraph (g) of this AD, we may approve requests to adjust the compliance time if the request includes data that prove that the new compliance time would provide an acceptable level of safety. We have not changed the AD in this regard.

#### Conclusion

We reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting the AD with the changes described previously. We also determined that these changes will not increase the economic burden on any operator or increase the scope of the AD.

#### Costs of Compliance

There are about 1,049 airplanes of the affected design in the worldwide fleet. This AD affects about 539 airplanes of U.S. registry. The required actions take up to 545 work hours per airplane depending on the airplane configuration, at an average labor rate of \$80 per work hour. Required parts cost about \$325 per airplane. Based on these figures, the estimated cost of the AD for U.S. operators is up to \$23,675,575, or up to \$43,925 per airplane.

#### 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

This AD will not have federalism implications under Executive Order 13132. This AD will 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 that this AD:*

- (1) Is not a "significant regulatory action" under Executive Order 12866,
- (2) Is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979), and
- (3) 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.

You can find our regulatory evaluation and the estimated costs of compliance in the AD Docket.

#### List of Subjects in 14 CFR Part 39

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

#### Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 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:

**2008-23-19 Boeing:** Amendment 39-15740. Docket No. FAA-2007-0289; Directorate Identifier 2007-NM-208-AD.

#### Effective Date

- (a) This airworthiness directive (AD) is effective December 30, 2008.

#### Affected ADs

- (b) None.

#### Applicability

(c) This AD applies to Boeing Model 757-200, -200CB, -200PF, and -300 series airplanes, certificated in any category; as identified in Boeing Alert Service Bulletin 757-57A0064, dated July 16, 2007.

#### Unsafe Condition

(d) This AD results from a fuel system review conducted by the manufacturer. We are issuing this AD to detect and correct improper wire bundle support installation and sleeving and to prevent improperly sealed fasteners in the main and center fuel tanks from becoming an ignition source, in the event of a fault current, which could result in a fuel tank explosion and consequent loss of the airplane.

#### Compliance

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

#### Fastener Sealing and Inspections

(f) Within 60 months after the effective date of this AD, seal the applicable fasteners and do the general visual inspections of the wire bundle support installations, and do all the applicable corrective actions before further flight, by accomplishing all of the applicable actions specified in the Accomplishment Instructions of Boeing Alert Service Bulletin 757-57A0064, dated July 16, 2007.

#### Alternative Methods of Compliance (AMOCs)

(g)(1) The Manager, Seattle Aircraft Certification Office (ACO), FAA, ATTN: Judy Coyle, Aerospace Engineer, Propulsion Branch, ANM-140S, FAA, Seattle ACO, 1601 Lind Avenue SW., Renton, Washington 98057-3356; telephone (425) 917-6497; fax (425) 917-6590; has the authority to approve AMOCs for this AD, if requested, using the procedures found in 14 CFR 39.19.

(2) To request a different method of compliance or a different compliance time for this AD, follow the procedures in 14 CFR 39.19. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

#### Material Incorporated by Reference

(h) You must use Boeing Alert Service Bulletin 757-57A0064, dated July 16, 2007, to do the actions required by this AD, unless the AD specifies otherwise.

(1) The Director of the Federal Register approved the incorporation by reference of this service information under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124-2207; telephone 206-544-9990; fax 206-766-5682; e-mail [DDCS@boeing.com](mailto:DDCS@boeing.com); Internet <https://www.myboeingfleet.com>.

(3) You may review copies of the service information incorporated by reference at the

FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or 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](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

Issued in Renton, Washington, on October 24, 2008.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E8-27168 Filed 11-24-08; 8:45 am]

BILLING CODE 4910-13-P

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 39

[Docket No. FAA-2008-0889; Directorate Identifier 2008-NM-092-AD; Amendment 39-15738; AD 2008-23-17]

RIN 2120-AA64

#### Airworthiness Directives; Empresa Brasileira de Aeronautica S.A. (EMBRAER) Model ERJ 170 and ERJ 190 Airplanes

**AGENCY:** Federal Aviation Administration (FAA), Department of Transportation (DOT).

**ACTION:** Final rule.

**SUMMARY:** We are adopting a new airworthiness directive (AD) for the products listed above. This AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as:

[E]scape slide system installation [was found with] \* \* \* tie-down straps which are used for escape slide packing [having not been removed]. The non-removal of the tie-down straps does not allow the aircraft door to reach the fully open position and the consequent deployment of the escape slide system in a \* \* \* emergency evacuation, affecting the occupying safety.

The unsafe condition is failure of an evacuation system, which could impede an emergency evacuation and increase the chance of injury to passengers and flightcrew during the evacuation. We are issuing this AD to require actions to correct the unsafe condition on these products.

**DATES:** This AD becomes effective December 30, 2008.

The Director of the Federal Register approved the incorporation by reference

of certain publications listed in this AD as of December 30, 2008.

**ADDRESSES:** You may examine the AD docket on the Internet at <http://www.regulations.gov> or in person at the U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC.

#### FOR FURTHER INFORMATION CONTACT:

Kenny Kaulia, Aerospace Engineer, International Branch, ANM-116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057-3356; telephone (425) 227-2848; fax (425) 227-1149.

#### SUPPLEMENTARY INFORMATION:

##### Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to include an AD that would apply to the specified products. That NPRM was published in the *Federal Register* on August 21, 2008 (73 FR 49362). That NPRM proposed to correct an unsafe condition for the specified products. The MCAI states:

[E]scape slide system installation [was found with] \* \* \* tie-down straps which are used for escape slide packing [having not been removed]. The non-removal of the tie-down straps does not allow the aircraft door to reach the fully open position and the consequent deployment of the escape slide system in a \* \* \* emergency evacuation, affecting the occupying safety.

The unsafe condition is failure of an evacuation system, which could impede an emergency evacuation and increase the chance of injury to passengers and flightcrew during the evacuation. The corrective action involves inspection of the forward and rearward doors' emergency evacuation slide packs for the presence of tie-down straps, and, if applicable, removal of the tie-down straps. You may obtain further information by examining the MCAI in the AD docket.

##### Comments

We gave the public the opportunity to participate in developing this AD. We received no comments on the NPRM or on the determination of the cost to the public.

##### Conclusion

We reviewed the available data and determined that air safety and the public interest require adopting the AD as proposed.

##### Differences Between This AD and the MCAI or Service Information

We have reviewed the MCAI and related service information and, in

general, agree with their substance. But we might have found it necessary to use different words from those in the MCAI to ensure the AD is clear for U.S. operators and is enforceable. In making these changes, we do not intend to differ substantively from the information provided in the MCAI and related service information.

We might also have required different actions in this AD from those in the MCAI in order to follow our FAA policies. Any such differences are highlighted in a NOTE within the AD.

##### Costs of Compliance

We estimate that this AD will affect about 144 products of U.S. registry. We also estimate that it will take about 2 work-hours per product to comply with the basic requirements of this AD. The average labor rate is \$80 per work-hour. Based on these figures, we estimate the cost of this AD to the U.S. operators to be \$23,040, or \$160 per product.

##### 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 AD will not have federalism implications under Executive Order 13132. This AD will 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 AD:*

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); and

3. 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.

We prepared a regulatory evaluation of the estimated costs to comply with this AD and placed it in the AD docket.

#### 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 the NPRM, 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.

#### List of Subjects in 14 CFR Part 39

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

#### Adoption of the Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the FAA amends 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:

**2008-23-17 Empresa Brasileira de Aeronautica S.A. (EMBRAER):** Amendment 39-15738. Docket No. FAA-2008-0889; Directorate Identifier 2008-NM-092-AD.

#### Effective Date

(a) This airworthiness directive (AD) becomes effective December 30, 2008.

#### Affected ADs

(b) None.

#### Applicability

(c) This AD applies to the airplanes specified in paragraphs (c)(1) and (c)(2) of this AD.

(1) EMBRAER Model ERJ 170-100 LR, -100 STD, -100 SE, and -100 SU, -200 LR, -200 STD, and -200 SU airplanes, serial numbers 17000002, 17000004 thru 17000013, and 17000015 thru 17000196, certificated in any category.

(2) EMBRAER Model ERJ 190-100 STD, -100 LR, -100 IGW, -100 ECJ, -200 STD, -200 LR, and -200 IGW airplanes, serial

numbers 19000002, 19000004 thru 19000132, and 19000135, certificated in any category.

#### Subject

(d) Air Transport Association (ATA) of America Code 25: Equipment/Furnishings.

#### Reason

(e) The mandatory continuing airworthiness information (MCAI) states:

[E]scape slide system installation [was found with] \* \* \* tie-down straps which are used for escape slide packing [having not been removed]. The non-removal of the tie-down straps does not allow the aircraft door to reach the fully open position and the consequent deployment of the escape slide system in a \* \* \* emergency evacuation, affecting the occupying safety.

The unsafe condition is failure of an evacuation system, which could impede an emergency evacuation and increase the chance of injury to passengers and flightcrew during the evacuation. The corrective action involves inspection of the forward and rearward doors' emergency evacuation slide packs for the presence of tie-down straps, and, if applicable, removal of the tie-down straps.

#### Actions and Compliance

(f) Unless already done: Within 600 flight hours after the effective date of this AD, carry out a general visual inspection (GVI) of the emergency evacuation slide packs installed on the forward and rearward doors, in accordance with the Accomplishment Instructions of EMBRAER Service Bulletin 170-25-0088, dated December 21, 2007; or 190-25-0062, dated December 21, 2007; as applicable. If tie-down straps are found, they must be cut and removed from the slide pack before further flight.

**Note 1:** For the purposes of this AD, a general visual inspection (GVI) is: "A visual examination of an interior or exterior area, installation, or assembly to detect obvious damage, failure, or irregularity. This level of inspection is made from within touching distance unless otherwise specified. A mirror may be necessary to ensure visual access to all exposed surfaces in the inspection area. This level of inspection is made under normally available lighting conditions such as daylight, hangar lighting, flashlight, or droplight and may require removal or opening of access panels or doors. Stands, ladders, or platforms may be required to gain proximity to the area being checked."

#### FAA AD Differences

**Note 2:** This AD differs from the MCAI and/or service information as follows: No differences.

#### Other FAA AD Provisions

(g) 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. Send information to *Attn:* Kenny Kaulia,

Aerospace Engineer, International Branch, ANM-116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057-3356; telephone (425) 227-2848; fax (425) 227-1149. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(3) *Reporting Requirements:* For any reporting requirement in this AD, under the provisions of the Paperwork Reduction Act, the Office of Management and Budget (OMB) has approved the information collection requirements and has assigned OMB Control Number 2120-0056.

#### Related Information

(h) Refer to MCAI Brazilian Airworthiness Directives 2008-01-03 and 2008-01-04, both effective March 3, 2008; and EMBRAER Service Bulletins 170-25-0088 and 190-25-0062, both dated December 21, 2007; for related information.

#### Material Incorporated by Reference

(i) You must use EMBRAER Service Bulletin 170-25-0088, dated December 21, 2007; or EMBRAER Service Bulletin 190-25-0062, dated December 21, 2007; as applicable; to do the actions required by this AD, unless the AD specifies otherwise.

(1) The Director of the Federal Register approved the incorporation by reference of this service information under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) For service information identified in this AD, contact Empresa Brasileira de Aeronautica S.A. (EMBRAER), Technical Publications Section (PC 060), Av. Brigadeiro Faria Lima, 2170—Putim—12227-901 São Jose dos Campos—SP—BRASIL; telephone: +55 12 3927-5852 or +55 12 3309-0732; fax: +55 12 3927-7546; e-mail: [distrib@embraer.com.br](mailto:distrib@embraer.com.br); Internet: <http://www.flyembraer.com>.

(3) You may review copies at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or 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](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

Issued in Renton, Washington, on November 6, 2008.

**Stephen P. Boyd,**

Assistant Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E8-27170 Filed 11-24-08; 8:45 am]

BILLING CODE 4910-13-P

**DEPARTMENT OF TRANSPORTATION**  
**Federal Aviation Administration**

**14 CFR Part 39**

[Docket No. FAA-2008-0892; Directorate Identifier 2008-CE-049-AD; Amendment 39-15742; AD 2008-24-02]

RIN 2120-AA64

**Airworthiness Directives; Maule Aerospace Technology, Inc. M-4, M-5, M-6, and M-7 Series and Model M-8-235 Airplanes**

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Final rule.

**SUMMARY:** The FAA adopts a new airworthiness directive (AD) for certain Maule Aerospace Technology, Inc. M-4, M-5, M-6, and M-7 series and Model M-8-235 airplanes. This AD requires you to paint the top of the rear elevator control horn, the elevator control cable end attached to the top of the rear control horn, the bottom of the forward elevator control horn, and the elevator control cable end attached to the bottom of the forward control horn. This AD also requires you to insert a supplement into your maintenance program (maintenance manual). This AD results from two reports of accidents where reversed elevator control rigging was a factor. We are issuing this AD to reduce the likelihood of a mechanic rigging the elevator controls backwards, which could result in elevator movement in the opposite direction from control input. This condition could lead to loss of control.

**DATES:** This AD becomes effective on December 30, 2008.

On December 30, 2008, the Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD.

**ADDRESSES:** To get the service information identified in this AD, contact Maule Aerospace Technology, Inc., 2099 Georgia Highway 133 South, Moultrie, Georgia 31788; telephone: (229) 985-2045; fax: (229) 985-2048; e-mail: [engineering@mauleairinc.com](mailto:engineering@mauleairinc.com); Internet: [http://www.mauleairinc.com/service\\_bulletins.htm](http://www.mauleairinc.com/service_bulletins.htm).

To view the AD docket, go to U.S. Department of Transportation, Docket Operations, M-30, West Building

Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590, or on the Internet at <http://www.regulations.gov>. The docket number is FAA-2008-0892; Directorate Identifier 2008-CE-049-AD.

**FOR FURTHER INFORMATION CONTACT:**

Cindy Lorenzen, Aerospace Engineer, One Crown Center, 1895 Phoenix Blvd., Suite 450, Atlanta, Georgia 30349; telephone: (770) 703-6078; fax: (770) 703-6097; e-mail: [cindy.lorenzen@faa.gov](mailto:cindy.lorenzen@faa.gov); or

Gerald Avella, Aerospace Engineer, One Crown Center, 1895 Phoenix Blvd., Suite 450, Atlanta, Georgia 30349; telephone: (770) 703-6066; fax: (770) 703-6097; e-mail: [gerald.avella@faa.gov](mailto:gerald.avella@faa.gov).

**SUPPLEMENTARY INFORMATION:**

**Discussion**

On August 12, 2008, we issued a proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an AD that would apply to certain Maule Aerospace Technology, Inc. M-4, M-5, M-6, and M-7 series and Model M-8-235 airplanes. This proposal was published in the **Federal Register** as a notice of proposed rulemaking (NPRM) on August 19, 2008 (73 FR 48314). The NPRM proposed to require you to paint the top of the rear elevator control horn, the elevator control cable end attached to the top of the rear control horn, the bottom of the forward elevator control horn, and the elevator control cable end attached to the bottom of the forward control horn. The NPRM also proposed to require you to insert a supplement into your maintenance program (maintenance manual).

**Comments**

We provided the public the opportunity to participate in developing this AD. The following presents the comments received on the proposal and FAA's response to each comment:

**Comment Issue No. 1: The AD Should Not Be Issued**

An anonymous commenter suggests that the AD is unnecessary because mechanics should already know to always check the rigging of the flight controls anytime the cables have been disconnected and re-connected. The

commenter requests that we not issue the AD.

While we agree mechanics should always check the rigging of the control cables for proper operation anytime the cables have been re-connected to the airplane, there have been instances where this has not happened and it has led to accidents. To minimize the possibility of incorrect flight control system assembly, this AD requires color coding the cables and control horns, which will provide a visual aid to the mechanic during reassembly.

We are not changing the AD as a result of this comment.

**Comment Issue No. 2: Removal of the Word "Horn" From Paragraph (e)(1)(iii)**

Mr. Geoffrey Sharp comments that the word "horn" does not make sense in the painting instruction requiring painting of "the bottom of the forward elevator control horn." We infer that he is requesting that we remove the word "horn" from paragraph (e)(1)(iii) of the AD.

We do not agree with the comment. The instructions to paint the elevator control horn are correct. The horn is the connecting piece for the control cables. However, upon review we noticed that the word horn was omitted from paragraph (e)(1)(iv) of the proposed AD.

We are changing paragraph (e)(1)(iv) of this AD by adding the word "horn" to the end of the sentence. We have also made this change in the Summary and Discussion sections of this AD.

**Conclusion**

We have carefully reviewed the available data and determined that air safety and the public interest require adopting the AD as proposed except for the changes previously discussed and minor editorial corrections. We have determined that these minor corrections:

- Are consistent with the intent that was proposed in the NPRM for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM.

**Costs of Compliance**

We estimate that this AD affects 1,765 airplanes in the U.S. registry.

We estimate the following costs to do the modification:

Labor cost	Parts cost	Total cost per airplane	Total cost on U.S. operators
1 work-hour × \$80 per hour = \$80	\$20	\$100	\$176,500

**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 AD.

**Regulatory Findings**

We have determined that this AD will not have federalism implications under Executive Order 13132. This AD will 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 that this AD:*

- 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); and
- 3. 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.

We prepared a summary of the costs to comply with this AD (and other information as included in the Regulatory Evaluation) and placed it in the AD Docket. You may get a copy of this summary by sending a request to us at the address listed under **ADDRESSES**. Include "Docket No. FAA-2008-0892; Directorate Identifier 2008-CE-049-AD" in your request.

**List of Subjects in 14 CFR Part 39**

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

**Adoption of the Amendment**

Accordingly, under the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (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. FAA amends § 39.13 by adding a new AD to read as follows:

**2008-24-02 Maule Aerospace Technology, Inc.:** Amendment 39-15742; Docket No. FAA-2008-0892; Directorate Identifier 2008-CE-049-AD.

**Effective Date**

- (a) This AD becomes effective on December 30, 2008.

**Affected ADs**

- (b) None.

**Applicability**

- (c) This AD applies to the following airplane models and serial numbers that are certificated in any category:

Model	Serial Nos.
Bee Dee M-4 .....	All serial numbers.
M-4 .....	All serial numbers.
M-4-180C .....	All serial numbers.
M-4-180V .....	47001T through 47014T.
M-4-210 .....	All serial numbers.
M-4-210C .....	All serial numbers.
M-4-210S .....	All serial numbers.
M-4-220C .....	All serial numbers.
M-4-220S .....	All serial numbers.
M-4C .....	All serial numbers.
M-4S .....	All serial numbers.
M-4T .....	All serial numbers.
M-5-180C .....	All serial numbers.
M-5-200 .....	All serial numbers.
M-5-210C .....	All serial numbers.
M-5-210TC .....	All serial numbers.
M-5-220C .....	All serial numbers.
M-5-235C .....	All serial numbers.
M-6-180 .....	8020C, 8043C, 8065C through 8067C.
M-6-235 .....	7249C, 7356C, 7379C through 7444C, 7446C through 7450C, 7452C through 7459C, 7461C through 7466C, 7468C, 7469C, 7471C through 7475C, 7488C through 7514C, 7516C through 7522C.
M-7-235 .....	4001C through 4132C, 12001C, 12002C.
M-7-235A .....	24001C.
M-7-235B .....	23001C through 23105C.
M-7-235C .....	25001C through 25106C.
M-7-260 .....	26001C through 26021C.
M-7-260C .....	30001C through 30040C.
M-7-420A .....	35001C.
M-7-420AC .....	29001C, 29003C through 29007C.
M-8-235 .....	15001C through 15006C.
MT-7-235 .....	18001C through 18097C, 18099C, 18100C.
MT-7-260 .....	27001C through 27014C.
MT-7-420 .....	51001C, 51002C.
MX-7-160 .....	19001C through 19046C.
MX-7-160C .....	34001C.
MX-7-180 .....	11001C through 11097C.
MX-7-180A .....	20001C through 20064C.
MX-7-180AC .....	33001C through 33010C.

Model	Serial Nos.
MX-7-180B .....	22001C through 22025C, 22027C.
MX-7-180C .....	28001C through 28027C.
MX-7-235 .....	10001C through 10122C.
MX-7-420 .....	13001C through 13003C.
MXT-7-160 .....	17001C through 17008C.
MXT-7-180 .....	14000C through 14125C.
MXT-7-180A .....	21001C through 21096C.

**Unsafe Condition**

(d) This AD results from two reports of accidents where reversed elevator control rigging was a factor. We are issuing this AD

to reduce the likelihood of a mechanic rigging the elevator controls backwards, which could result in elevator movement in the opposite direction from control input. This failure could lead to loss of control.

**Compliance**

(e) To address this problem, you must do the following, unless already done:

Actions	Compliance	Procedures
(1) Using yellow enamel paint, color code the following: (i) the top of the rear elevator control horn; (ii) the elevator control cable end attached to the top of the rear control horn; (iii) the bottom of the forward elevator control horn; and (iv) the elevator control cable end attached to the bottom of the forward control horn	Before the next time the elevator control cable is disconnected for any reason or within the next 12 calendar months after December 30, 2008 (the effective date of this AD), whichever occurs first.	Follow Maule Aerospace Technology, Inc. Mandatory Service Bulletin No. 30, dated March 4, 2008.
(2) Insert the following text into the rigging procedure section of your FAA-approved maintenance program (e.g. maintenance manual): "CAUTION—BEFORE FLIGHT WHENEVER ELEVATOR CABLES ARE RECONNECTED OR NEW CABLES INSTALLED: Always check operation of elevators after a cable reconnect by pulling back on the control and ascertain that the elevators are in the UP position."	Before the next time the elevator control cable is disconnected for any reason or within the next 12 calendar months after December 30, 2008 (the effective date of this AD), whichever occurs first.	Follow Maule Aerospace Technology, Inc. Mandatory Service Bulletin No. 30, dated March 4, 2008. You may insert a copy of this AD or you may insert the text located on the bottom of page 3 of Maule Aerospace Technology, Inc. Mandatory Service Bulletin No. 30, dated March 4, 2008, into the FAA-approved maintenance program (e.g., 1 maintenance manual).

**Alternative Methods of Compliance (AMOCs)**

(f) The Manager, Atlanta 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. Send information to *Attn: Gerald Avella, Aerospace Engineer, One Crown Center, 1895 Phoenix Blvd., Suite 450, Atlanta, Georgia 30349; telephone: (770) 703-6066; fax: (770) 703-6097; e-mail: gerald.avella@faa.gov*. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

**Material Incorporated by Reference**

(g) You must use Maule Aerospace Technology, Inc. Mandatory Service Bulletin No. 30, dated March 4, 2008, to do the actions required by this AD, unless the AD specifies otherwise.

(1) The Director of the Federal Register approved the incorporation by reference of this service information under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) For service information identified in this AD, contact Maule Aerospace Technology, Inc., 2099 Georgia Highway 133 South, Moultrie, Georgia 31788; telephone: (229) 985-2045; fax: (229) 985-2048; e-mail:

*engineering@mauleairinc.com*; Internet: <http://www.mauleairinc.com>.

(3) You may review copies at the FAA, Central Region, Office of the Regional Counsel, 901 Locust, Kansas City, Missouri 64106; or 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](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

Issued in Kansas City, Missouri, on November 10, 2008.

**James E. Jackson,**  
*Acting Manager, Small Airplane Directorate, Aircraft Certification Service.*

[FR Doc. E8-27364 Filed 11-24-08; 8:45 am]

**BILLING CODE 4910-13-P**

**DEPARTMENT OF TRANSPORTATION**

**Federal Aviation Administration**

**14 CFR Part 39**

[Docket No. FAA-2008-0152; Directorate Identifier 2007-NM-348-AD; Amendment 39-15745; AD 2008-24-05]

**RIN 2120-AA64**

**Airworthiness Directives; Boeing Model 737-400, -500, -600, -700, -700C, -800, and -900 Series Airplanes**

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Final rule.

**SUMMARY:** We are adopting a new airworthiness directive (AD) for certain Boeing Model 737-400, -500, -600, -700, -700C, -800, and -900 series airplanes. This AD requires an inspection to determine the part and serial numbers of the windshield wiper motors for the pilot's and first officer's windshields, and doing applicable corrective actions. This AD results from two reports that the left and right windshield wipers stopped working in flight. We are issuing this AD to prevent

failure of the windshield wipers in wet weather, which could result in decreased visibility for the flightcrew.

**DATES:** This AD is effective December 30, 2008.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of December 30, 2008.

**ADDRESSES:** For service information identified in this AD, contact Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124-2207; telephone 206-544-9990; fax 206-766-5682; e-mail [DDCS@boeing.com](mailto:DDCS@boeing.com); Internet <https://www.myboeingfleet.com>.

#### Examining the AD Docket

You may examine the AD docket on the Internet at <http://www.regulations.gov>; 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 AD, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (telephone 800-647-5527) is the Document Management Facility, U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590.

**FOR FURTHER INFORMATION CONTACT:** Nick Wilson, Aerospace Engineer, Cabin Safety and Environmental Systems Branch, ANM-150S, FAA, Seattle Airplane Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98057-3356; telephone (425) 917-6476; fax (425) 917-6590.

#### SUPPLEMENTARY INFORMATION:

##### Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to include an airworthiness directive (AD) that would apply to certain Boeing Model 737-400, -500, -600, -700, -700C, -800, and -900 series airplanes. That NPRM was published in the *Federal Register* on February 8, 2008 (73 FR 7492). That NPRM proposed to require an inspection to determine the part and serial numbers of the windshield wiper motors for the pilot's and first officer's windshields, and the applicable corrective action.

##### Comments

We gave the public the opportunity to participate in developing this AD. We considered the comments received.

#### Request for Clarification of Certain Language

Boeing asks that the language in Note 1 of the NPRM, which specifies "determining the windshield wiper motor has been previously replaced," be changed for clarification to "determining whether the power module replacement has been previously accomplished." Boeing states that the list included as part of Rosemount Aerospace Service Bulletin 2313M-347/2313M-348-30-01, dated June 30, 2006, provides information for determining whether the power module has been replaced with a properly soldered module.

We agree that the language in Note 1 of the AD should be clarified because the part description is different in Boeing Alert Service Bulletin 737-30A1059, dated September 10, 2007, and Boeing Service Bulletin 737-30A1057, Revision 1, dated October 31, 2007 (referred to in the AD as the appropriate sources of service information for accomplishing the specified actions), and Rosemount Aerospace Service Bulletin 2313M-347/2313M-348-30-01, dated June 30, 2006 (referred to as an additional source of service information for determining the part and serial numbers of the windshield wiper motors). Boeing Alert Service Bulletin 737-30A1059, dated September 10, 2007, and Boeing Service Bulletin 737-30A1057, Revision 1, dated October 31, 2007, specify replacing the windshield wiper motor, and Rosemount Aerospace Service Bulletin 2313M-347/2313M-348-30-01, dated June 30, 2006, specifies replacing the power module of the windshield wiper motor. We disagree with using Boeing's suggested wording, which could result in confusion since the Boeing service bulletins specify replacing the motor instead of replacing the power module. We have changed Note 1 for clarification to include the description specified in Rosemount Aerospace Service Bulletin 2313M-347/2313M-348-30-01, dated June 30, 2006.

#### Request for Credit for Previously Accomplished Actions

Boeing also asks that we change paragraph (h) of the NPRM to include credit for Model 737-400 and -500 series airplanes on which the actions specified in Boeing Alert Service Bulletin 737-30A1059, dated September 10, 2007, were done before the effective date of the AD. Boeing states that Boeing Alert Service Bulletin 737-30A1059, dated September 10, 2007, provides instructions for corrective action for those airplanes.

We acknowledge and agree with Boeing's intent that credit should be given for actions done before the effective date of the AD. However, we do not agree to include credit for using the original issue of the service bulletin to do the actions specified in paragraph (h) of the AD. Boeing Alert Service Bulletin 737-30A1059, dated September 10, 2007, is already referred to in paragraph (f) of this AD as the appropriate source of service information for accomplishing the inspection and corrective actions for Model 737-400 and -500 series airplanes. Paragraph (e) of the AD specifies that compliance with the AD before the effective date (comply within the compliance times specified unless already done) meets the requirements of the AD. We have made no change to the AD in this regard.

#### Requests To Clarify Requirements for Maintenance Record Review and Re-Identifying the Wiper Motor Part Number

Southwest Airlines (SWA), KLM Fleet Services, and Airtran Airways request clarification of the review of airplane maintenance records and reidentification of the wiper motor part number, as specified in paragraph (f) of the NPRM.

SWA asks why the wiper motor must be re-identified while on the airplane since the review of airplane maintenance records is acceptable in lieu of an on-airplane inspection of the wiper motor part number and serial number. SWA also notes that the referenced service information requires operators to re-identify the part number of a wiper motor that has been determined to be in good and acceptable working condition. SWA states that re-identifying the part number would be more efficient and convenient if it could be done at the manufacturing facility during maintenance when the motor is removed for another reason.

KLM states that it is unclear if it is still mandatory to re-identify the wiper motor part number within the 60-month compliance time after reviewing the maintenance records, knowing that the wiper motor serial numbers are outside the affected modification range specified in Rosemount Aerospace Service Bulletin 2313M-347/2313M-348-30-01, dated June 30, 2006. KLM adds that intensive work is necessary if the wiper motor must be re-identified even if it is not affected.

AirTran reiterates the views of SWA and KLM and adds that units with replaced modules have eliminated the unsafe condition described in the NPRM. AirTran states that the wiper



motors are located in a difficult location to view or access, and they cannot be re-identified while installed. AirTran notes that gaining access to the airplane, removing the wiper motor, re-identifying the motor, and re-installing the motor is an undue burden on the airlines, since the re-identification does not improve the safety of the airplane. AirTran suggests that the final rule specify that, for airplanes having a wiper motor module that has been replaced, as indicated in Appendix A of Rosemount Aerospace Service Bulletin 2313M-347/2313M-348-30-01, dated June 30, 2006, the part number may be changed at the next shop visit, as opposed to changing the part number in service.

We agree with the commenters' concerns. Operators may review the maintenance records to comply with the AD during the 60-month compliance time proposed in the NPRM, as long as applicable corrective actions are also done in that time. In light of the comments provided, we have determined that, in this case, if the wiper motor is not affected by the requirements of the AD, re-identifying the wiper motor part number is not necessary to ensure an acceptable level of safety. Operators should not be required to remove and replace a part if it is deemed to be an acceptable part. We have added this clarification to paragraph (f) of this AD accordingly.

#### **Request for Clarification of Wiper Motor Replacement Requirement**

SWA asks that the wiper motor replacement be required only if the part number and serial number cannot be read or are listed in Appendix A of Rosemount Aerospace Service Bulletin 2313M-347/2313M-348-30-01, dated June 30, 2006, with the "Module Completed" column marked as "No" (as specified in Steps 1.a. and 1.d., Section 3.B.—Work Instructions) of Boeing Service Bulletin 737-30A1057, Revision 1, dated October 31, 2007.

We agree with SWA. The procedures specified in Steps 1.a. and 1.d. (and in Steps 2.a. and 2.d.) of the Work Instructions already specify replacement of the wiper motor if the part number and serial number cannot be read or are listed in Appendix A of Rosemount Aerospace Service Bulletin 2313M-347/2313M-348-30-01, dated June 30, 2006, with the "Module Completed" column marked as "No". The procedures in Steps 1.b. and 1.c. of the Work Instructions specify re-identification of the part if the part number and serial number are not listed in Appendix A or are listed in Appendix A of Rosemount Aerospace Service Bulletin 2313M-347/

2313M-348-30-01, dated June 30, 2006, with the "Module Completed" column marked as "Yes." The replacement is required only if it meets the conditions specified in Boeing Service Bulletin 737-30A1057, Revision 1, dated October 31, 2007, Steps 1.a. and 1.d. (or Steps 2.a. and 2.d.), of the Work Instructions. Therefore, we have made no change to the AD in this regard.

#### **Request To Clarify Certain Part Numbers in Paragraphs (g) and (i) of the NPRM**

Air Transport Association (ATA) on behalf of its member Delta Airlines states that the part numbers specified in paragraphs (g) and (i) of the NPRM have variations (P/N 2313M347-3 or P/N 2313M348-3), which should be noted in those paragraphs.

We agree with the commenters because the part numbers are the same, the variation is only in the dashes; therefore we have added those alternate part numbers to paragraphs (g) and (i) of this AD for clarification.

#### **Request To Correct Typographical Error in Rosemount Service Bulletin**

ATA on behalf of its member Delta Airlines states that Rosemount Aerospace Service Bulletin 2313M-347/2313M-348-30-01, dated June 30, 2006, has a typographical error in Appendix A as follows: For Model Number 2313M-348-3, serial number (S/N) "M252" should be S/N "M0252." Delta adds that this determination was made in cooperation with Rosemount.

Based on the information provided by the commenter, and confirmation from Rosemount Aerospace, we agree that the serial number specified in Appendix A of Rosemount Aerospace Service Bulletin 2313M-347/2313M-348-30-01, dated June 30, 2006, is incorrect. We have added a new Note 2 to this AD to clarify the correct serial number as follows: For Model Number 2313M-348-3, S/N "M252" should be S/N "M0252." We have been informed that Rosemount Aerospace Service Bulletin 2313M-347/2313M-348-30-01, dated June 30, 2006, is being revised and the correct serial number will be included in the revision.

#### **Request To Clarify Certain Requirements in Boeing Service Bulletin**

ATA on behalf of its member Delta Airlines states that Boeing Service Bulletin 737-30A1057, dated October 6, 2006, referred to an incorrect airplane maintenance manual (AMM) section for the Windshield Wiper Motor System Operational Test. In addition, that service bulletin did not provide wiper

motor condition information in the Work Instructions. That information was provided only in the Compliance section of Boeing Service Bulletin 737-30A1057, dated October 6, 2006.

We infer that the commenters are asking that paragraph (h) of the NPRM be revised to note these corrections; we agree with the commenters. There were mistakes in Boeing Service Bulletin 737-30A1057, dated October 6, 2006, which were corrected in Boeing Service Bulletin 737-30A1057, Revision 1, dated October 31, 2007 (referred to in the AD as the appropriate source of service information for accomplishing the actions). The commenter states that it identified and incorporated the changes, which resulted in the issuance of Boeing Service Bulletin 737-30A1057, Revision 1, dated October 31, 2007. The AMM section specified accomplishing the operational test in Boeing Alert Service Bulletin 737-30A1057, dated October 6, 2006, is AMM 30-42-21/501; the correct AMM section specified for accomplishing the operational test in Boeing Service Bulletin 737-30A1057, Revision 1, dated October 31, 2007, is AMM 30-42-00/501. We have clarified paragraph (h) of this AD to refer to Boeing Service Bulletin 737-30A1057, Revision 1, dated October 31, 2007, to ensure that the mistakes in the original issue of the service bulletin have been addressed.

#### **Request To Extend Compliance Time**

ATA on behalf of its member American Airlines (AAL) notes concern with the 60-month compliance time specified for accomplishing the actions specified in the NPRM. AAL states that its standard maintenance interval is 72 months; therefore, a 60-month compliance time could unnecessarily drive up out-of-service time and related costs. AAL recommends that we extend the compliance time to 72 months to align with industry standard material review board task intervals.

We do not agree to extend the compliance time. In developing an appropriate compliance time for this action, we considered the urgency associated with the subject unsafe condition, the availability of required parts, and the practical aspect of accomplishing the required actions within a period of time that corresponds to the normal scheduled maintenance for most affected operators. In light of these items, we have determined that a 60-month compliance time is appropriate. However, under the provisions of paragraph (j) of the AD, we will consider requests to adjust the compliance time if sufficient data are submitted to substantiate that the new

compliance time would provide an acceptable level of safety. We have made no change to the AD in this regard.

#### Request To Allow an Alternative Method for Part Number Marking

SWA asks that another method of part marking be included in the NPRM. SWA asks why "classification RO" (Rubber Stamp Only per BAC5307) must be used to change the part number on the wiper motor. SWA asks that the NPRM allow another form of acceptable marking for the part number, such as permanent marker.

We agree that any permanent method of part marking is acceptable. We have added a new Note 3 to this AD to clarify that any permanent method is acceptable.

#### Request To Change Parts Installation Paragraph

WestJet asks that paragraph (i) of the NPRM (Parts Installation) be changed as follows: "As of the effective date of this AD, no person may install on any aircraft a Rosemount Aerospace windshield wiper motor having P/N 2313M-347-3 or P/N 2313M-348-3 that has a serial number that is listed in Rosemount Aerospace Service Bulletin 2313M-347/2313M-348-30-01." WestJet states that windshield wiper motors having P/N 2313M-347-3 and P/N 2313M-348-3 with serial numbers outside of the affected modification range, that have not yet been "re-labeled" per Rosemount Aerospace Service Bulletin 2313M-347/2313M-348-30-01, dated June 30, 2006, may be installed on any aircraft. WestJet adds that this change would allow operators to install a "mechanically serviceable" part (that has not yet been "re-labeled") on an aircraft.

We do not agree to change paragraph (h) of the AD. Common industry practice is to control part configuration by part number, not by serial number. While we already agreed that it is not necessary to remove parts from the airplane just to revise the part numbers, we do not agree that it is acceptable to install the subject replacement parts without revising the part number. Ensuring that only parts with correct part numbers are installed on the airplane is an important part of maintaining configuration control and safe operation of the fleet. We have made no change to the AD in this regard.

#### Conclusion

We reviewed the relevant data, considered the comments received, and determined that air safety and the

public interest require adopting the AD with the changes described previously. We also determined that these changes will not increase the economic burden on any operator or increase the scope of the AD.

#### Costs of Compliance

We estimate that this AD affects 767 airplanes of U.S. registry. We also estimate that it takes about 1 work-hour per product to comply with the inspection. The average labor rate is \$80 per work-hour. Based on these figures, we estimate the cost of this AD to the U.S. operators to be \$61,360 or \$80 per product.

#### 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 airplane 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

This AD will not have federalism implications under Executive Order 13132. This AD will 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 that this AD:*

- (1) Is not a "significant regulatory action" under Executive Order 12866,
- (2) Is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979), and
- (3) 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.

You can find our regulatory evaluation and the estimated costs of compliance in the AD Docket.

#### List of Subjects in 14 CFR Part 39

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

#### Adoption of the Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the FAA amends 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:

**2008-24-05 Boeing:** Amendment 39-15745. Docket No. FAA-2008-0152; Directorate Identifier 2007-NM-348-AD.

#### Effective Date

(a) This airworthiness directive (AD) is effective December 30, 2008.

#### Affected ADs

(b) None.

#### Applicability

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

(1) Model 737-400 and -500 series airplanes as identified in Boeing Alert Service Bulletin 737-30A1059, dated September 10, 2007.

(2) Model 737-600, -700, -700C, -800, and -900 series airplanes as identified in Boeing Service Bulletin 737-30A1057, Revision 1, dated October 31, 2007.

#### Unsafe Condition

(d) This AD results from two reports that the left and right windshield wipers stopped working in flight. We are issuing this AD to prevent failure of the windshield wipers in wet weather, which could result in decreased visibility for the flightcrew.

#### Compliance

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

#### Inspection and Corrective Actions if Necessary

(f) Except as provided by paragraph (g) of this AD: Within 60 months after the effective date of this AD, inspect to determine the part number and serial number of the windshield wiper motors for the pilot's and first officer's windshields, and do all applicable corrective actions, by accomplishing all of the applicable actions specified in the Accomplishment Instructions of Boeing Alert Service Bulletin 737-30A1059, dated September 10, 2007 (for Model 737-400 and -500 series airplanes); or Boeing Service Bulletin 737-30A1057, Revision 1, dated October 31, 2007 (for Model 737-600, -700,

-700C, -800, and -900 series airplanes); as applicable. A review of airplane maintenance records is acceptable in lieu of the inspection required by paragraph (f) of this AD if the part number and serial number of the windshield wiper motors can be conclusively determined from that review. Following the inspection or records review, as applicable, for any windshield wiper motor that is found not to be affected by the requirements of this AD, re-identifying the part number is not required.

**Note 1:** Boeing Alert Service Bulletin 737-30A1059, dated September 10, 2007; and Boeing Service Bulletin 737-30A1057, Revision 1, dated October 31, 2007; refer to Rosemount Aerospace Service Bulletin 2313M-347/2313M-348-30-01, dated June 30, 2006, as an additional source of service information for determining whether the windshield wiper motor (identified in the Rosemount service bulletin as the "power module") has been previously replaced and for changing the part number.

**Note 2:** Appendix A of Rosemount Aerospace Service Bulletin 2313M-347/2313M-348-30-01, dated June 30, 2006, identifies an incorrect serial number for Model Number 2313M-348-3. Serial number M252" should be M0252.

**Note 3:** Rosemount Aerospace Service Bulletin 2313M-347/2313M-348-30-01, dated June 30, 2006, specifies marking affected parts with an approved opaque material per BAC5307, classification RO, with an approved permanent marking material; however, for the purposes of this AD, any permanent method of part marking is acceptable.

**Credit for Modification Done According to AD 2003-20-13**

(g) For Model 737-400, -500, -600, -700, and -800 series airplanes: Accomplishing the modification required by paragraph (b) of AD 2003-20-13, amendment 39-13331, is acceptable for compliance with the requirements of paragraph (f) of this AD, provided that no Rosemount Aerospace windshield wiper motor having P/N 2313M-347-3 or P/N 2313M-348-3 (P/N 2313M347-3 or P/N 2313M348-3) has been installed.

**Credit for Actions Done According to Previous Issue of Service Bulletin**

(h) For Model 737-600, -700, -700C, -800, and -900 series airplanes: Actions done before the effective date of this AD in accordance with Boeing Alert Service Bulletin 737-30A1057, dated October 6, 2006, are acceptable for compliance with the requirements of paragraph (f) of this AD; provided that the wiper motor serial number was legible for inspection purposes and the operational test specified in Step 3 in Work Packages 2 and 3 of the Accomplishment Instructions of Boeing Alert Service Bulletin 737-30A1057, Revision 1, dated October 31, 2007, was completed.

**Parts Installation**

(i) As of the effective date of this AD, no person may install Rosemount Aerospace windshield wiper motors having P/N 2313M-347-3 or P/N 2313M-348-3 (P/N

2313M347-3 or P/N 2313M348-3) on any airplane.

**Alternative Methods of Compliance (AMOCs)**

(j)(1) The Manager, Seattle Airplane Certification Office, FAA, ATTN: Nick Wilson, Aerospace Engineer, Cabin Safety and Environmental Systems Branch, ANM-150S, 1601 Lind Avenue, SW., Renton, Washington 98057-3356; telephone (425) 917-6476; fax (425) 917-6590; has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19.

(2) To request a different method of compliance or a different compliance time for this AD, follow the procedures in 14 CFR 39.19. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

**Material Incorporated by Reference**

(k) You must use Boeing Alert Service Bulletin 737-30A1059, dated September 10, 2007; or Boeing Service Bulletin 737-30A1057, Revision 1, dated October 31, 2007, to do the actions required by this AD, unless the AD specifies otherwise.

(1) The Director of the Federal Register approved the incorporation by reference of this service information under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124-2207; telephone 206-544-9990; fax 206-766-5682; e-mail [DACS@baeing.com](mailto:DACS@baeing.com); Internet <https://www.mybaeingfleet.com>.

(3) You may review copies of the service information incorporated by reference at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or 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/cade\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/cade_of_federal_regulations/ibr_locations.html).

Issued in Renton, Washington, on November 10, 2008.

Ali Bahrami,

Manager, Transport Airplane Directorate, Airplane Certification Service.

[FR Doc. E8-27527 Filed 11-24-08; 8:45 am]

BILLING CODE 4910-13-P

**CONSUMER PRODUCT SAFETY COMMISSION**

**16 CFR Part 1500**

**Labeling Requirement for Toy and Game Advertisements; Final Rule**

**Correction**

In rule document E8-26964 beginning on page 67730 in the issue of Monday,

November 17, 2008, make the following correction:

**§1500.20 [Corrected]**

On page 67738, in §1500.20(e)(3), the table and its accompanying footnote text should appear as follows:

Required cautionary statement	Number
16 CFR 1500.19(b)(1) <sup>1</sup> .....	1
16 CFR 1500.19(b)(2) <sup>2</sup> .....	2
16 CFR 1500.19(b)(3)(i) <sup>3</sup> .....	3
16 CFR 1500.19(b)(3)(ii) <sup>4</sup> .....	4
16 CFR 1500.19(b)(4)(i) <sup>5</sup> .....	5
16 CFR 1500.19(b)(4)(ii) <sup>6</sup> .....	6

<sup>1</sup>See figure 1.

<sup>2</sup>See Figure 2.

<sup>3</sup>See Figure 3.

<sup>4</sup>See Figure 4.

<sup>5</sup>See Figure 5.

<sup>6</sup>See Figure 6.

[FR Doc. Z8-26964 Filed 11-24-08; 8:45 am]

BILLING CODE 1505-01-D

**DEPARTMENT OF THE TREASURY**

**Internal Revenue Service**

**26 CFR Part 1**

[TD 9428]

RIN 1545-BD72

**Section 1367 Regarding Open Account Debt**

**Correction**

In rule document E8-24926 beginning on page 62199 in the issue of Monday, October 20, 2008, make the following correction:

**§1.1367-2 [Corrected]**

On page 62203, in the first column, in the sixth full paragraph, in the fourth line, in §1.1367-2(e), "Example 7" should read "Example 7".

[FR Doc. Z8-24926 Filed 11-24-08; 8:45 am]

BILLING CODE 1505-01-D

**DEPARTMENT OF DEFENSE**

**Office of the Secretary**

**32 CFR Part 199**

[DOD-2007-HA-0010; RIN 0720-AB09]

**TRICARE Program; Overpayments Recovery**

AGENCY: Office of the Secretary, DoD.

ACTION: Final rule.

**SUMMARY:** This rule amends the CHAMPUS and TRICARE program

regulation that governs the recoupment of erroneous payments. Specifically, the rule implements changes required by the Debt Collection Improvement Act (DCIA) of 1996 and the revised Federal Claims Collection Standards (FCCS). This final rule is necessary to comply with the DCIA of 1996 and the revised FCCS.

**DATES:** Effective Date: This rule is effective December 26, 2008.

**FOR FURTHER INFORMATION CONTACT:** Gail L. Jones, Medical Benefits and Reimbursement Systems, TRICARE Management Activity, telephone (303) 676-3401.

**SUPPLEMENTARY INFORMATION:**

**Background and Purpose**

On December 23, 1985, the Office of the Secretary of Defense published a final rule in the *Federal Register* (50 FR 52315), clarifying specific procedures and criteria in the assertion, collection or compromise of federal claims and the suspension or termination of collection action on such claims arising under the operation of the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS). Section 199.11, "Overpayments Recovery," addresses claims in favor of the United States arising under the Federal Claims Collection Act (recoupment claims).

On April 26, 1996, the Debt Collection Act of 1982, as amended by the Debt Collection Improvement Act, Public Law 104-134 (110 Stat. 1321-358 et seq.) was enacted into law (as part of the Omnibus Consolidated Rescissions and Appropriations Act of 1996) mainly to increase the collection of non-tax debts owed to the Federal Government. This law centralized the administrative collection of most delinquent non-tax debt at Department of the Treasury (Treasury) Financial Management Service, to increase the efficiency of collection efforts. Government departments and agencies are now required to refer debts to Treasury for centralized administrative offset under the Treasury Offset Program (TOP), and transfer debts to Treasury for collection on the agencies' behalf—a process known as cross servicing.

This final rule implements statutory provisions of the DCIA of 1996 and the revised FCCS, which were jointly issued by Treasury and the Department of Justice (DOJ). The effect of this final rule would avoid the expense of court proceedings for both the government and the debtor, as well as reduce administrative handling, provide greater flexibility to recovery efforts, and promote timely settlements of outstanding federal claims.

**Public Comments**

On December 20, 2007 (72 FR 72307), the Office of the Secretary of Defense provided the public the opportunity to comment on implementing changes required by the DCIA of 1996 and the revised FCCS. Throughout the 60-day comment period, which closed on February 19, 2008, the Department of Defense (DoD) did not receive any public comments. Therefore, within this final rule, the DoD set forth the proposed provisions contained in the December 20, 2007, proposed rule. The proposed rule is adopted without change, as a final rule.

**Section-By-Section Analysis**

- Paragraph (a) provides that it applies to the TRICARE program and CHAMPUS.
- Paragraph (b)(1) adds the DCIA and the revised FCCS, 31 CFR parts 900-904, as authority for collection, as well as Treasury regulations, found at 31 CFR part 285, subpart A, implementing the DCIA and related statutes governing the offset of Federal salaries (5 U.S.C. 5514, 5 CFR part 550, subpart K), administrative offset (31 U.S.C. 3716), administrative offset of tax refunds (31 U.S.C. 3720A) and regulations implementing the offset of military pay under Title 37 U.S.C. 1007(c). The reference to waiver of collection authorized by Section 743 of the National Defense Authorization Act for Fiscal Year 1996 has been deleted. The legislation-authorizing waiver has expired.
- Paragraph (c) reflects that the Director, TRICARE Management Activity (TMA), or a designee, is responsible for ensuring that timely collection action is pursued. The Office of CHAMPUS (OCHAMPUS) has been disestablished. The functions of OCHAMPUS are now being performed by the TMA. The current regulation reflects that agency authority to compromise, suspend, or terminate collection action was limited to claims that did not exceed \$20,000. The rule increases this amount to \$100,000 at paragraph (g), the amount authorized by 31 U.S.C. 3711(a)(2).
- Paragraph (e) delegates the authority to assert, settle, compromise or to suspend or terminate collection on claims arising under the Federal Claims Collection Act to the Director, TMA.
- Paragraph (f)(1) adds a provision that recoupment procedures may be modified or adapted to conform to network agreements and that the recoupment provisions of the rule apply if recoupment under the network agreements is not successful.

- Paragraph (f)(3) requires the TRICARE contractor to first attempt to recover an erroneous payment from another health insurance plan through the contractor's coordination of benefits procedures. If the overpayment cannot be recovered from the other plan, or if the other plan has made payment, the erroneous payment will be recovered from the party that received the erroneous payment from TRICARE.
- Paragraph (f)(6)(iii) specifies that a minimum of one demand letter is required and states that the specific content, timing and number of demand letters may be tailored to the type and amount of debt and the debtor's response, if any.

• Paragraph (f)(6)(ii) of the current regulation states that normally a total of three progressively stronger written demands for payment be made to a debtor at approximately 30-day intervals and that the demands for payment will be made by CHAMPUS fiscal intermediary and OCHAMPUS. This final rule amends this language to reflect that normally the TRICARE contractor will initiate initial collection action to effect recoupment.

• Paragraph (f)(6)(iv) states that the initial or subsequent demand letter(s) may notify debtors of the mandatory requirement to report delinquent debts to credit reporting agencies and to refer delinquent debts to collection agencies, the TOP for collection by administrative offset from Federal tax refunds and other amounts payable by the Government, offset from state payments as well as the requirement that delinquent debts be transferred to Treasury for collection. It also provides that letters may include TMA policies for referring delinquent debts to the DOJ.

• Paragraph (f)(6)(v) deleted language found at Paragraph (f)(6)(iii) of the current regulation, which stated that offset under the provisions of 31 U.S.C. 3716 was not to be used with respect to debts owed by any state or local government. The collection of debts owed by state and local governments through administrative offset is no longer prohibited.

• Paragraph (f)(6)(v)(A) requires eligible non-tax debts delinquent over 180 days be referred to Treasury for centralized administrative offset, unless otherwise exempted from referral. Debts that were formerly referred directly to the Internal Revenue Service for Tax Refund Offset will be referred for centralized administrative offset. It also provides that salary offsets under 5 U.S.C. 5514 that were formerly effected through referral to an employee's paying agency, pursuant to Paragraph (f)(6)(vi)

of 32 CFR 199.11 will be effected through referral for centralized administrative offset.

- Paragraph (f)(6)(vi) implements a mandatory requirement of the DCIA that eligible non-tax debts delinquent over 180 days be transferred to Treasury or a Treasury-Designated Collection Center for collection through cross-servicing, unless otherwise exempted from referral.

- Paragraph (f)(6)(ix) increases the minimum amount of installment payment that may be accepted to \$75.00 per month unless the debtor demonstrates financial hardship. Paragraph (f)(6)(iv) of the current regulation provides that the minimum amount is \$50.00.

- Paragraph (f)(6)(xi) requires TMA to use government-wide collection contracts to obtain debt collection services through private contractors as provided in 31 CFR 901.5(b). The current regulation provides for TMA to contract for such services.

- Paragraph (f)(6)(xii) specifies that Treasury will report debts transferred to it for collection to credit reporting agencies on behalf of TMA.

- Paragraph (g)(1) authorizes the Director, TMA to compromise, suspend or terminate collection action of debts that do not exceed \$100,000 (exclusive of interest, penalties and administrative costs) or less, or such other amount as the Attorney General shall authorize, as provided in 31 CFR 902.1(a). Paragraph (b) of the current regulation limits this authority to \$20,000. Paragraph (g)(3) of the current regulation has been deleted, because the legislation authorizing the waiver has expired.

- Paragraph (h) increases the threshold for referral of cases to the DOJ from \$600 to \$2,500 or such other amount as the Attorney General shall prescribe, as provided in 31 CFR 904.4(a).

#### Regulatory Procedures

##### *Executive Order 12866, "Regulatory Planning and Review"*

Executive Order 12866 requires that a comprehensive regulatory impact analysis be performed on any economically significant regulatory action, defined as one that would result in an annual effect of \$100 million or more on the national economy or which would have other substantial impacts. It has been certified that this final rule is not an economically significant rule; however, it is a regulatory action which has been reviewed by the Office of Management and Budget as required under the provision of E.O. 12866.

##### *Unfunded Mandates Reform Act (Sec. 202, Pub. L. 104-4)*

It has been certified that this rule does not contain a Federal mandate that may result in the expenditure by State, local and tribal governments, in aggregate, or by the private sector, of \$100 million or more in any one year.

##### *Public Law 96-354, "Regulatory Flexibility Act" (5 U.S.C. 601)*

It has been certified that this rule is not subject to the Regulatory Flexibility Act (5 U.S.C. 601) because it would not, if promulgated, have a significant economic impact on a substantial number of small entities. This rule, although not economically significant under E.O. 12866, has been designated as significant and has been reviewed by the Office of Management and Budget as required under the provisions of E.O. 12866. This final rule sets forth changes to conform to the Debt Collection Improvement Act of 1996 (Pub. L. 104-134, 110 Stat. 1321, 1358), as implemented by the Federal Claims Collection Standards, joint regulations issued by the Department of the Treasury and the Department of Justice, 31 CFR parts 900-904.

##### *Public Law 96-511, "Paperwork Reduction Act of 1995" (44 U.S.C. 3501 et seq.)*

It has been certified that this rule does not impose reporting or recordkeeping requirements under the Paperwork Reduction Act of 1995.

##### *Executive Order 13132, Federalism*

It has been certified that this rule does not have federalism implications, as set forth in Executive Order 13132. This rule does not have substantial direct effects on:

- (1) The States;
- (2) The relationship between the National Government and the States; or
- (3) The distribution of power and responsibilities among the various levels of Government.

##### **List of Subjects in 32 CFR Part 199**

Claims, Dental health, Health care, Health insurance, Individuals with disabilities, and Military personnel.

■ Accordingly, 32 CFR Part 199 is amended as follows:

##### **PART 199—[AMENDED]**

■ 1. The authority citation for part 199 continues to read as follows:

**Authority:** 5 U.S.C. 301; 10 U.S.C. chapter 55.

■ 2. Section 199.11 is revised to read as follows:

##### **§ 199.11 Overpayments recovery.**

(a) *General.* Actions to recover overpayments arise when the government has a right to recover money, funds or property from any person, partnership, association, corporation, governmental body or other legal entity, foreign or domestic, except another Federal agency, because of an erroneous payment of benefits under both CHAMPUS and the TRICARE program under § 199.17 of this part. The term "Civilian Health and Medical Program of the Uniformed Services" (CHAMPUS) is defined in 10 U.S.C. 1072(4), and referred to under § 199.17 as the basic CHAMPUS program, otherwise known as TRICARE Standard. The term "TRICARE program" is defined in 10 U.S.C. 1072(7) and is referred to under § 199.17 as the triple-option benefit of TRICARE Prime, TRICARE Extra, and TRICARE Standard. It is the purpose of this section to prescribe procedures for investigation, determination, assertion, collection, compromise, waiver and termination of claims in favor of the United States for erroneous benefit payments arising out of the administration of CHAMPUS and the TRICARE program. For the purpose of this section, references herein to TRICARE beneficiaries, claims, benefits, payments, or appeals shall include CHAMPUS beneficiaries, claims, benefits, payments, or appeals. A claim against several joint debtors arising from a single incident or transaction is considered one claim. The Director, TRICARE Management Activity (TMA), or a designee, may pursue collection against all joint debtors and is not required to allocate the burden of payment between debtors.

(b) *Authority.* (1) *Federal statutory authority.* The Federal Claims Collection Act, 31 U.S.C. 3701, *et seq.*, as amended by the Debt Collection Act of 1982 and the Debt Collection Improvement Act of 1996 (DCIA), provides the basic authority under which claims may be asserted pursuant to this section. The DCIA is implemented by the Federal Claims Collection Standards, joint regulations issued by the Department of the Treasury (Treasury) and the Department of Justice (DOJ) (31 CFR Parts 900-904), that prescribe government-wide standards for administrative collection, offset, compromise, suspension, or termination of agency collection action, disclosure of debt information to credit reporting agencies, referral of debts to private collection contractors for resolution, and referral to the Department of Justice for litigation to

collect debts owed the Federal government. The regulations under this part are also issued under Treasury regulations implementing the DCIA (31 CFR part 285) and related statutes and regulations governing the offset of Federal salaries (5 U.S.C. 5514; 5 CFR part 550, subpart K), administrative offset (31 U.S.C. 3716; 31 CFR part 285, subpart A); administrative offset of tax refunds (31 U.S.C. 3720A) and offset of military pay (37 U.S.C. 1007(c); Volume 7A, Chapter 50 and Volume 7B, Chapter 28 of the Department of Defense Financial Management Regulation, DOD 7000.14-R<sup>1</sup> (DoDFMR)).

(2) *Other authority.* Federal claims may arise under authorities other than the federal statutes, referenced above. These include, but are not limited to:

- (i) State worker's compensation laws.
- (ii) State hospital lien laws.
- (iii) State no-fault automobile statutes.
- (iv) Contract rights under terms of insurance policies.

(c) *Policy.* The Director, TMA, or a designee, shall aggressively collect all debts arising out of its activities. Claims arising out of any incident, which has or probably will generate a claim in favor of the government, will not be compromised, except as otherwise provided in this section, nor will any person not authorized to take final action on the government's claim, compromise or terminate collection action. Title 28 U.S.C. 2415-2416 establishes a statute of limitation applicable to the government where previously neither limitations nor laches were available as a defense. Claims falling within the provisions of this statute will be referred to the Department of Justice without attempting administrative collection action, if such action cannot be accomplished in sufficient time to preclude the running of the statute of limitations.

(d) *Appealability.* This section describes the procedures to be followed in the recovery and collection of federal claims in favor of the United States arising from the operation of TRICARE. Actions taken under this section are not initial determinations for the purpose of the appeal procedures of § 199.10 of this part. However, the proper exercise of the right to appeal benefit or provider status determinations under the procedures set forth in § 199.10 of this part may affect the processing of federal claims arising under this section. Those appeal procedures afford a TRICARE beneficiary or participating provider an opportunity for administrative appellate

review in cases in which benefits have been denied and in which there is an appealable issue. For example, a TRICARE contractor may erroneously make payment for services, which are excluded as TRICARE benefits because they are determined to be not medically necessary. In that event, the contractor will initiate recoupment action, and at the same time, the contractor will offer an administrative appeal as provided in § 199.10 of this part on the medical necessity issue raised by the adverse benefit determination. The recoupment action and the administrative appeal are separate actions. However, in an appropriate case, the pendency of the appeal may provide a basis for the suspension of collection in the recoupment case. If an appeal were resolved entirely in favor of the appealing party, it would provide a basis for the termination of collection action in the recoupment case.

(e) *Delegation.* Subject to the limitations imposed by law or contained in this section, the authority to assert, settle, and compromise or to suspend or terminate collection action arising on claims under the Federal Claims Collection Act has been delegated to the Director, TMA, or a designee.

(f) *Recoupment of erroneous payments.* (1) Erroneous payments are expenditures of government funds, which are not authorized by law or this part. Examples which are sometimes encountered in the administration of TRICARE include mathematical errors, payment for care provided to an ineligible person, payment for care which is not an authorized benefit, payment for duplicate claims, incorrect application of the deductible or co-payment or payment for services which were not medically necessary. Claims in favor of the government arising as the result of the filing of false TRICARE claims or other fraud fall under the cognizance of the Department of Justice. Consequently, procedures in this section apply to such claims only when specifically authorized or directed by the Department of Justice. (See 31 CFR 900.3.) Due to the nature of contractual agreements between network providers and TRICARE prime contractors, recoupment procedures may be modified or adapted to conform to network agreements. The provisions of § 199.11 shall apply if recoupment under the network agreements is not successful.

(2) *Scope.* (i) *General.* Paragraph (f) of this section and the paragraphs following contain requirements and procedures for the assertion, collection or compromise of, and the suspension or termination of collection action on

claims for erroneous payments against a sponsor, patient, beneficiary, provider, physician or other supplier of products or services under TRICARE.

(ii) *Debtor defined.* As used herein, "debtor" means a sponsor, beneficiary, provider, physician, other supplier of services or supplies, or any other person who for any reason has been erroneously paid under TRICARE. It includes an individual, partnership, corporation, professional corporation or association, estate, trust or any other legal entity.

(iii) *Delinquency defined.* A debt is "delinquent" if it has not been paid by the date specified in the initial written demand for payment (that is, the initial written notification) or other applicable contractual agreement, unless other satisfactory payment arrangements have been made by the date specified in the initial written demand for payment. A debt is considered delinquent if at any time after entering into a repayment agreement, the debtor fails to satisfy any obligations under that agreement.

(3) *Other health insurance claims.* Claims arising from erroneous TRICARE payments in situations where the beneficiary has entitlement to an insurance, medical service, health and medical plan, including any plan offered by a third party payer as defined in 10 U.S.C. 1095(h)(1) or other government program, except in the case of a plan administered under Title XIX of the Social Security Act (42 U.S.C. 1396, *et seq.*), through employment, by law, through membership in an organization, or as a student, or through the purchase of a private insurance or health plan, shall be recouped following the procedures in paragraph (f) of this section. If the other plan has not made payment to the beneficiary or provider, the contractor shall first attempt to recover the overpayment from the other plan through the contractor's coordination of benefits procedures. If the overpayment cannot be recovered from the other plan, or if the other plan has made payment, the overpayment will be recovered from the party that received the erroneous payment from TRICARE.

(4) *Claim denials due to clarification or change.* In those instances where claim review results in the denial of benefits previously provided, but now denied due to a change, clarification or interpretation of the public law or this part, no recoupment action need be taken to recover funds expended prior to the effective date of such change, clarification or interpretation.

(5) *Good faith payment.* (i) The Department of Defense, through the Defense Enrollment Eligibility Reporting

<sup>1</sup> Copies may be obtained at <http://www.dtic.mil/whs/directives/>.

System (DEERS), is responsible for establishing and maintaining a file listing of persons eligible to receive benefits under TRICARE. However, it is the responsibility of the Uniformed Services to provide eligible TRICARE beneficiaries with accurate and appropriate means of identification. When sources of civilian medical care exercise reasonable care and precaution identifying persons claiming to be eligible TRICARE beneficiaries, and furnish otherwise covered services and supplies to such persons in good faith, TRICARE benefits may be paid subject to prior approval by the Director, TMA, or a designee, notwithstanding the fact that the person receiving the services and supplies is subsequently determined to be ineligible for benefits. Good faith payments will not be authorized for services and supplies provided by a civilian source of medical care because of its own careless identification procedures.

(ii) When it is determined that a person was not a TRICARE beneficiary, the TRICARE contractor and the civilian source of medical care are expected to make all reasonable efforts to obtain payment or to recoup the amount of the good faith payment from the person who erroneously claimed to be the TRICARE beneficiary. Recoupment of good faith payments initiated by the TRICARE contractor will be processed pursuant to the provisions of paragraph (f) of this section.

(6) *Recoupment procedures.* (i) *Initial action.* When an erroneous payment is discovered, the TRICARE contractor normally will be required to take the initial action to effect recoupment. Such actions will be in accordance with the provisions of this part and the TRICARE contracts and will include a demand (or demands) for refund or an offset against any other TRICARE payment(s) becoming due the debtor. When the efforts of the TRICARE contractor to effect recoupment are not successful within a reasonable time, recoupment cases will be referred to the Office of General Counsel, TMA, for further action in accordance with the provisions of paragraph (f) of this section. All requests to debtors for refund or notices of intent to offset shall be in writing.

(ii) *Demand for payment.* Written demand(s) for payment shall inform the debtor of the following:

(A) The basis for and amount of the debt and the consequences of failing to cooperate to resolve the debt;

(B) The right to inspect and copy TRICARE records pertaining to the debt;

(C) The opportunity to request an administrative review by the TRICARE

contractor; and that such a request must be received by the TRICARE contractor within 90 days from the date of the initial demand letter;

(D) That payment of the debt is due within 30 days from the date of the initial demand notification;

(E) That interest will be assessed on the debt at the Treasury Current Value of Funds rate, pursuant to 31 U.S.C. 3717, and will begin to accrue on the date of the initial demand letter; and that interest will be waived on the debt, or any portion thereof, which is paid within 30 days from the date of the initial demand notification letter;

(F) That administrative costs and penalties will be charged pursuant to 31 CFR 901.9;

(G) That collection by offset against current or subsequent claims or other amounts payable from the government may be taken;

(H) The opportunity to enter into a written agreement to repay the debt;

(I) The name, address, and phone number of a contact person or office that the debtor may contact regarding the debt.

(iii) A minimum of one demand letter is required. However, the specific content, timing and number of demand letters may be tailored to the type and amount of the debt, and the debtor's response, if any. Contractors' demand letters must be mailed or hand-delivered on the same date they are dated.

(iv) The initial or subsequent demand letters may also inform the debtor of the requirement to report delinquent debts to credit reporting agencies and to collection agencies, the requirement to refer debts to the Treasury Offset Program for offset from Federal income tax refunds and other amounts payable by the Government, offset from state payments, the requirement to refer debts to Treasury for collection and TRICARE policies concerning the referral of delinquent debts to the Department of Justice for enforced collection action. The initial or subsequent demand letter may also inform the debtor of TRICARE policies concerning waiver. When necessary to protect the Government's interest (for example to prevent the running of a statute of limitations), written demand may be preceded by other appropriate actions under this regulation, including referral to the Department of Justice for litigation. There should be no undue delay in responding to any communication received from the debtor. Responses to communications from debtors should be made within 30 days of receipt whenever feasible. If prior to the initiation of the demand process or at any time during or after completion of

the demand process, the Director, TMA, or a designee, determines to pursue or is required to pursue offset, the procedures applicable to administrative offset, found at paragraph (f)(6)(v) of this section, must be followed. If it appears that initial collection efforts are not productive or if immediate legal action on the claim appears necessary, the claim shall be referred promptly by the contractor to the Office of General Counsel, TMA.

(v) *Collection by administrative offset.* Collections by offset will be undertaken administratively in every instance when feasible. Collections may be taken by administrative offset under 31 U.S.C. 3716, the common law or other applicable statutory authority. No collection by offset may be undertaken unless the debtor has been sent a written demand for payment, including the procedural safeguards described in paragraph (f)(6)(ii) of this section, unless the failure to take the offset would substantially prejudice the Government's ability to collect the debt, and the time before payment is to be made does not reasonably permit the time for sending written notice. Such prior offset must be promptly followed by sending a written notice and affording the debtor the opportunity for a review by the TRICARE contractor. Examples of erroneous payments include, but are not limited to, claims submitted by individuals ineligible for TRICARE benefits, claims submitted for non-covered services or supplies, claims for which payments by another insurance or health plan reduce TRICARE liability, and from claims made from participating providers in which payment was initially erroneously made to the beneficiary. The resolution of recoupment claims rarely involves issues of credibility or veracity and a review of the written record is ordinarily an adequate means to correct prior mistakes. For this reason, the pre-offset oral hearing requirements of the Federal Claims Collection Standards, 31 CFR 901.3(e) do not apply to the recoupment of erroneous TRICARE payments. However, in instances where an oral hearing is not required, the debtor will be afforded an administrative review if the TRICARE contractor receives a written request for an administrative review within 90 days from the date of the initial demand letter. The appeals procedures described in § 199.10 of this part, afford a TRICARE beneficiary or participating provider an opportunity for an administrative appellate review, including under certain circumstances, the right to an oral hearing before a

hearing officer when an appealable issue exists. TRICARE contractors may take administrative action to offset erroneous payments against other current TRICARE payments owing a debtor. Payments on the claims of a debtor pending at or filed subsequent to the time collection action is initiated should be suspended pending the outcome of the collection action so that these funds will be available for offset. All or part of a debt may be offset depending on the amount available for offset. Any requests for offset received from other agencies and garnishment orders issued by courts of competent jurisdiction will be forwarded to the Office of General Counsel, TMA. Unless otherwise provided by law, administrative offset of payments under the authority of 31 U.S.C. 3716 may not be conducted more than 10 years after the Government's right to collect the debt first accrued, unless facts material to the Government's right to collect the debt were not known and could not reasonably have been known by the TRICARE official or officials charged with the responsibility to discover and collect such debts. This limitation does not apply to debts reduced to judgment. This section does not apply to debts arising under the Social Security Act, except as provided in 42 U.S.C. 404, payments made under the Social Security Act, except as provided for in 31 U.S.C. 3716(c), debts arising under, or payments made under, the Internal Revenue Code, except for offset of tax refunds or tariff laws of the United States; offsets against Federal salaries to the extent these standards are inconsistent with regulations published to implement such offsets under 5 U.S.C. 5514 and 31 U.S.C. 3716; offsets under 31 U.S.C. 3728 against a judgment obtained by a debtor against the United States; offset or recoupment under common law, state law, or federal statutes specifically prohibiting offset or recoupment of particular types of debts or offsets in the course of judicial proceedings, including bankruptcy.

(A) *Referral for centralized administrative offset.* When cost-effective, legally enforceable non-tax debts delinquent over 180 days that are eligible for collection through administrative offset shall be referred to Treasury for administrative offset, unless otherwise exempted from referral. Referrals shall include certification that the debt is past due and legally enforceable and that TMA has complied with all due process requirements of the statute-authorizing offset. Administrative offset, including administrative offset against tax refunds

due debtors under 26 U.S.C. 6402, in accordance with 31 U.S.C. 3720A, shall be effected through referral for centralized administrative offset, after debtors have been afforded at least sixty (60) days notice required in paragraph (f)(6) of this section. Salary offsets shall be effected through referral for centralized administrative offset, after debtors have been afforded due process required by 5 U.S.C. 5514, in accordance with 31 CFR 285.7. Referrals for salary offset shall include certification that the debts are past due, legally enforceable debts and that TMA has complied with all due process requirements under 5 U.S.C. 5514 and applicable agency regulations. The Treasury, Financial Management Service (FMS) may waive the salary offset certification requirement set forth in 31 CFR 285.7, as a prerequisite to submitting the debt to FMS for offset from other payment types. If FMS waives the certification requirement, before an offset occurs, TMA will provide the employee with the notice and opportunity for a hearing as required by 5 U.S.C. 5514 and applicable regulations, and will certify to FMS that the requirements of 5 U.S.C. 5514 and applicable agency regulations have been met. TMA is not required to duplicate notice and administrative review or salary offset hearing opportunities before referring debts for centralized administrative offset when the debtor has been previously given them.

(B) *Referral for non-centralized administrative offset.* Unless otherwise prohibited by law, when centralized administrative offset is not available or appropriate, past due legally enforceable non-tax-delinquent debts that are eligible for referral may be collected through non-centralized administrative offset through a request directly to the payment-authorizing agency. Referrals shall include certification that the debts are past due and that the agency has complied with due process requirements under 31 U.S.C. 3716(a) or other applicable authority and applicable agency regulations concerning administrative offset. Generally, non-centralized administrative offsets will be made on an *ad hoc* case-by-case basis, in cooperation with the agency certifying or authorizing payments to the debtor.

(vi) *Collection by transfer of debts to Treasury or a Treasury-designated debt collection center for collection through cross servicing.* (A) The Director, TMA or a designee, is required to transfer legally enforceable non-tax debts that are delinquent 180 days or more to Treasury for collection through cross-

servicing (31 U.S.C. 3711(g); 31 CFR 285.12.) Debts referred or transferred to Treasury or Treasury-designated debt collection centers shall be serviced, collected, or compromised, or the collection action will be suspended or terminated, in accordance with the statutory requirements and authorities applicable to the collection of such debts. Agencies operating Treasury-designated debt collection centers are authorized to charge a fee for services rendered regarding referred or transferred debts. This fee may be paid out of amounts collected and may be added to the debt as an administrative cost. Referrals will include certification that the debts transferred are valid, legally enforceable debts, that there are no legal bars to collection and that the agency has complied with all prerequisites to a particular collection action under the applicable laws, regulations or policies, unless the agency and Treasury agree that Treasury will do so on behalf of the agency.

(B) The requirement of paragraph (f)(1) of this section does not apply to any debt that:

- (1) Is in litigation or foreclosure.
- (2) Will be disposed of under an approved asset sale program.
- (3) Has been referred to a private collection contractor for a period of time acceptable to Treasury.
- (4) Will be collected under internal offset procedures within 3 years after the debt first became delinquent.
- (5) Is exempt from this requirement based on a determination by the Secretary of the Treasury that exemption for a certain class of debt is in the best interest of the United States.

(vii) *Collection by salary offset.* When a debtor is a member of the military service or a retired member and collection by offset against other TRICARE payments due the debtor cannot be accomplished, and there have been no positive responses to a demand for payment, the Director, TMA, or a designee, may refer the debt for offset from the debtor's pay account pursuant to 37 U.S.C. 1007(c), as implemented by Volume 7A, Chapter 50 and Volume 7B, Chapter 28 of the DoDFMR. Collection from a Federal employee may be effected through salary offset under 5 U.S.C. 5514.

(A) For collections by salary offset the Director, TMA, or designee, will issue written notification, as required by 5 CFR 550.1104(d) at least 30 days before any offsets are taken. In addition, the notification will advise the employee that if he or she retires, resigns or his or her employment ends before collection of the debt is completed, collection may be made from



subsequent payments of any nature due from the United States (e.g., final salary payment, lump-sum leave under 31 U.S.C. 3716 due the employee as of date of separation.) A debtor's involuntary payment of all or part of a debt being collected will not be construed as a waiver of any rights the debtor may have under 5 U.S.C. 5514 or any other provision of contract or law, unless there are statutory or contractual provisions to the contrary or the employee's paying agency is directed by an administrative or judicial order to refund amounts deducted from his or her current pay. No interest will be paid on amounts waived or determined not to be owed unless there are statutory or contractual provisions to the contrary.

(B) *Petition for hearing.* The notice of the proposed offset will advise the debtor of his or her right to petition for a hearing. The petition for hearing must be signed by the debtor or his or her representative and must state whether he or she is contesting debt validity, debt amount and/or the terms of the proposed offset schedule. It must explain with reasonable specificity all the facts, evidence and witnesses, if any (in the case of an oral hearing and a summary of their anticipated testimony), which the debtor believes support his or her position, and include any supporting documentation. If contesting the terms of the proposed offset schedule, the debtor must provide financial information including a completed Department of Justice Financial Statement of Debtor form (OBD-500 or other form prescribed by DOJ), including specific details concerning income and expenses of the employee, his or her spouse and dependents for 1-year period preceding the debt notification and projected income and expenses for the proposed offset period and a statement of the reason why the debtor believes the salary offset schedule will impose extreme financial hardship. Upon receipt of the petition for hearing, the Director, TMA, or a designee, will complete reconsideration. If the Director, TMA, or a designee determines that the debt amount is not owed, that a less amount is owed, or that the terms of the employee's proposed offset schedule are acceptable, it will advise the debtor and request that the employee accept the results of the reconsideration in lieu of a hearing. If the employee declines to accept the results of reconsideration in lieu of a hearing, the debtor will be afforded a hearing. Ordinarily, a petition for hearing and required submissions that are not timely filed, shall be accepted

after expiration of the deadline provided in the notice of the proposed offset, only when the debtor can demonstrate to the Director, TMA, or a designee, that the timely filing of the request was not feasible due to extraordinary circumstances over which the appealing party had no practical control or because of failure to receive notice of the time limit (unless he or she was otherwise aware of it). Each request for an exception to the timely filing requirement will be considered on its own merits. The decision of the Director, TMA, or a designee, on a request for an exception to the timely filing requirement shall be final.

(C) *Extreme financial hardship.* The maximum authorized amount that may be collected through involuntary salary offset is the lesser of 15 percent of the employee's disposable pay or the full amount of the debt. An employee who has petitioned for a hearing may assert that the maximum allowable rate of involuntary offset produces extreme financial hardship. An offset produces an extreme financial hardship if the offset prevents the employee from meeting the costs necessarily incurred for the essential expenses of the employee, employee's spouse and dependents. These essential expenses include costs incurred for food, housing, necessary public utilities, clothing, transportation and medical care. In determining whether the offset would prevent the employee from meeting the essential expenses identified above, the following shall be considered:

- (1) Income from all sources of the employee, the employee's spouse, and dependents;
- (2) The extent to which assets of the employee, employee's spouse and dependents are available to meet the offset and essential subsistence expenses;
- (3) Whether these essential subsistence expenses have been minimized to the greatest extent possible;
- (4) The extent to which the employee or the employee's spouse can borrow money to meet the offset and other essential expenses; and
- (5) The extent to which the employee and the employee's spouse and dependents have other exceptional expenses that should be taken into account and whether these expenses have been minimized.

(D) *Form and content of hearings.* The resolution of recoupment claims rarely involves issues of credibility or veracity and a review of the written record is ordinarily an adequate means to determine the validity or amount of the debt and/or the terms of a proposed

offset schedule. The Director, TMA, or a designee, will determine whether an oral hearing is required. A debtor who has petitioned for a hearing, but who is not entitled to an oral hearing will be given an administrative hearing, based on the written documentation submitted by the debtor and the Director, TMA, or a designee. If the Director, TMA, or a designee, determines that the debtor should be afforded the opportunity for an oral hearing, the debtor may elect to have a hearing based on the written record in lieu of an oral hearing. The Director, TMA, or a designee, will provide the debtor (or his representative) notification of the time, date and location of the oral hearing to be held if the debtor has been afforded an oral hearing. Copies of records documenting the debt will be provided to the debtor or his representative (if they have not been previously provided), at least 3 calendar days prior to the date of the oral hearing. At oral hearings, the only evidence permitted, except oral testimony, will be that which was previously submitted as pre-hearing submissions. At oral hearings, the debtor may not raise any issues not previously raised with TMA. In the absence of good cause shown, a debtor who fails to appear at an oral hearing will be deemed to have waived the right to a hearing and salary offset may be initiated.

(E) *Costs for attendance at oral hearings.* Debtors and their witnesses will bear their own costs for attendance at oral hearings.

(F) *Hearing official's decision.* The Hearing Official's decision will be in writing and will identify the documentation reviewed. It will indicate the amount of debt that he or she determined is valid and shall state the amount of the offset and the estimated duration of the offset. The determination of a hearing official designated under this section is considered an official certification regarding the existence and amount of the debt and/or the terms of the proposed offset schedule for the purposes of executing salary offset under 5 U.S.C. 5514. The Hearing Official's decision must be issued at the earliest practical date, but not later than 60 days from the date the petition for hearing is received by the Office of General Counsel, TMA, unless the debtor requests, and the Hearing Official grants a delay in the proceedings. If a hearing official determines that the debt may not be collected by salary offset, but the Director, TMA, or a designee, finds the debt is still valid, the Director, TMA or a designee, may seek collection through other means, including but not

limited to, offset from other payments due from the United States.

(viii) [Reserved]

(ix) *Collection of installments.* Debts, including interest, penalty and administrative costs shall be collected in one lump sum whenever possible. However, when the debtor is financially unable to pay the debt in one lump sum, the TRICARE contractor or the Director, TMA, or designee, may accept payment in installments. Debtors claiming that lump sum payment will create financial hardship may be required to complete a Department of Justice Financial Statement of Debtor form or provide other financial information that will permit TMA to verify such representations. TMA may also obtain credit reports to assess installment requests. Normally, debtors will make installment payments on a monthly basis. Installment payment shall bear a reasonable relationship to the size of the debt and the debtor's ability to pay. Except when a debtor can demonstrate financial hardship or another reasonable cause exists, installment payments should be sufficient in size and frequency to liquidate the debt in 3 years or less. (31 CFR 901.8(b)). Normally, installment payments of \$75 or less will not be accepted unless the debtor demonstrates financial hardship. Any installment agreement with a debtor in which the total amount of deferred installments will exceed \$750, should normally include an executed promissory agreement. Copies of installment agreements will be retained in the contractor's or TMA, Office of General Counsel's files.

(x) *Interest, penalties, and administrative costs.* Title 31 U.S.C. 3717 and the Federal Claims Collection Standards, 31 CFR 901.9, require the assessment of interest, penalty and administrative costs on delinquent debts. Interest shall accrue from the date the initial debt notification is mailed to the debtor. The rate of interest assessed shall be the rate of the current value of funds to the United States Treasury (the Treasury tax and loan account rate). The collection of interest on the debt or any portion of the debt, which is paid within 30 days after the date on which interest begins to accrue, shall be waived. The Director, TMA, or designee, may extend this 30-day period on a case-by-case basis, if it reasonably determines that such action is appropriate. The rate of interest as initially assessed shall remain fixed for the duration of the indebtedness; except that where the debtor has defaulted on a repayment agreement and seeks to enter into a new agreement, a new interest rate may be set which reflects

the current value of funds to the Treasury at the time the new agreement is executed. Interest shall not be compounded; that is, interest shall not be charged on interest, penalties, or administrative costs required by this section. However, if a debtor defaults on a previous repayment agreement, charges that accrued but were not collected under the defaulted agreement, shall be added to the principal under the new repayment agreement. The collection of interest, penalties and administrative costs may be waived in whole or in part as a part of the compromise of a debt as provided in paragraph (g) of this section. In addition, the Director, TMA, or designee may waive in whole or in part, the collection of interest, penalties, or administrative costs assessed herein if he or she determines that collection would be against equity and good conscience and not in the best interest of the United States. Some situations in which a waiver may be appropriate include:

(A) Waiver of interest consistent with 31 CFR 903.2(c)(2) in connection with a suspension of collection when a TRICARE appeal is pending under § 199.10 of this part where there is a substantial issue of fact in dispute.

(B) Waiver of interest where the original debt arose through no fault or lack of good faith on the part of the debtor and the collection of interest would impose a financial hardship or burden on the debtor. Some examples in which such a waiver would be appropriate include: A debt arising when a TRICARE beneficiary in good faith files and is paid for a claim for medical services or supplies, which are later determined not to be covered benefits, or a debt arising when a TRICARE beneficiary is overpaid as the result of a calculation error on the part of the TRICARE contractor or TMA.

(C) Waiver of interest where there has been an agreement to repay a debt in installments, there is no indication of fault or lack of good faith on the part of the debtor, and the amount of interest is so large in relation to the size of the installments that the debtor can reasonably afford to pay, that it is likely the debt will never be repaid in full. When a debt is paid in installments, the installment payments first will be applied to the payment of outstanding penalty and administrative cost charges, second, to accrued interest and then to principal. Administrative costs incurred as the result of a debt becoming delinquent (as defined in paragraph (f)(2)(iii) of this section) shall be assessed against a debtor. These administrative costs represent the

additional costs incurred in processing and handling the debt because it became delinquent. The calculation of administrative costs should be based upon cost analysis establishing an average of actual additional costs incurred in processing and handling claims against other debtors in similar stages of delinquency. A penalty charge, not exceeding six percent a year, shall be assessed on the amount due on a debt that is delinquent for more than 90 days. This charge, which need not be calculated until the 91st day of delinquency, shall accrue from the date that the debt became delinquent.

(xi) *Referral to private collection agencies.* TMA shall use government-wide debt collection contracts to obtain debt collection services provided by private contractors in accordance with 31 CFR 901.5(b).

(xii) *Reporting delinquent debts to credit reporting agencies.* Delinquent consumer debts shall be reported to credit reporting agencies. Delinquent debts are debts which are not paid or for which satisfactory payment arrangements are not made by the due date specified in the initial debt notification letter, or those for which the debtor has entered into a written payment agreement and installment payments are past due 30 days or longer. Such referrals shall comply with the Bankruptcy Code and the Privacy Act of 1974, 5 U.S.C. 552a, as amended. The provisions of the Privacy Act do not apply to credit bureaus (31 CFR 901.4(1)). There is no requirement to duplicate the notice and review opportunities before referring debts to credit bureaus. Debtors will be advised of the specific information to be transmitted (i.e., name, address, and taxpayer identification number, information about the debt). Procedures developed for such referrals must ensure that an accounting of the disclosures shall be kept which is available to the debtor; that the credit reporting agencies are provided with corrections and annotations of disagreements of the debtor; and that reasonable efforts are made to ensure that the information to be reported is accurate, complete, timely and relevant. When requested by a credit-reporting agency, verification of the information disclosed will be provided promptly. Once a claim has been reviewed and determined to be valid, a complete explanation of the claim will be given the debtor. When the claim is overdue, the individual will be notified in writing that payment is overdue; that within not less than 60 days, disclosure of the claim shall be made to a consumer reporting agency unless

satisfactory payment arrangements are made, or unless the debtor requests an administrative review and demonstrates some basis on which the debt is legitimately disputed; and of the specific information to be disclosed to the consumer reporting agency. The information to be disclosed to the credit reporting agency will be limited to information necessary to establish the identity of the debtor, including name, address and taxpayer identification number; the amount, status and history of the claim; and the agency or program under which the claim arose. Reasonable action will be taken to locate an individual for whom a current address is not available. The requirements of this section do not apply to commercial debts, although commercial debts shall be reported to commercial credit bureaus. Treasury will report debts transferred to it for collection to credit reporting agencies on behalf of the Director, TMA, or a designee.

(xiii) *Use and disclosure of mailing addresses.* In attempting to locate a debtor in order to collect or compromise a debt under this section, the Director, TMA, or a designee, may send a written request to the Secretary of the Treasury, or a designee, for current address information from records of the Internal Revenue Service. TMA may disclose mailing addresses obtained under this authority to other agencies and to collection agencies for collection purposes.

(g) *Compromise, suspension or termination of collection actions arising under the Federal Claims Collection Act.* (1) *Basic considerations.* Federal claims against the debtor and in favor of the United States arising out of the administration of TRICARE may be compromised or collection action taken thereon may be suspended or terminated in compliance with the Federal Claims Collection Act, 31 U.S.C. 3711, as implemented by the Federal Claims Collection Standards, 31 CFR Parts 900-904. The provisions concerning compromise, suspension or termination of collection activity pursuant to 31 U.S.C. 3711 apply to debts, which do not exceed \$100,000 or any higher amount authorized by the Attorney General, exclusive of interest, penalties, and administrative costs, after deducting the amount of partial payments or collections, if any. If, after deducting the amount of any partial payments or collections, the principal amount of a debt exceeds \$100,000, or any higher amount authorized by the Attorney General, exclusive of interest, penalties and administrative costs, the

authority to suspend or terminate rests solely with the DOJ.

(2) *Authority.* TRICARE contractors are not authorized to compromise or to suspend or terminate collection action on TRICARE claims. Only the Director, TMA, or designee or Uniformed Services claims officers acting under the provisions of their own regulations are so authorized.

(3) *Basis for compromise.* A compromise should be for an amount that bears a reasonable relation to the amount that can be recovered by enforced collection procedures, with regard to the exemptions available to the debtor and the time collection will take. A claim may be compromised hereunder if the government cannot collect the full amount if:

(i) The debtor or the estate of a debtor does not have the present or prospective ability to pay the full amount within a reasonable time;

(ii) The cost of collecting the claim does not justify enforced collection of the full amount; or

(iii) The government is unable to enforce collection of the full amount within a reasonable time by enforced collection proceedings; or

(iv) There is significant doubt concerning the Government's ability to prove its case in court for the full amount claimed; or

(v) The cost of collecting the claim does not justify enforced collection of the full amount.

(4) *Basis for suspension.* Collection action may be suspended for the following reasons if future collection action may be sufficiently productive to justify periodic review and action on the claim, considering its size and the amount, which may be realized thereon:

(i) The debtor cannot be located; or

(ii) The debtor's financial condition is expected to improve; or

(iii) The debtor is unable to make payments on the government's claim or effect a compromise at the time, but the debtor's future prospects justify retention of the claim for periodic review and action and;

(A) The applicable statute of limitations has been tolled or started running anew; or

(B) Future collections can be effected by administrative offset, notwithstanding the expiration of the applicable statute of limitations for litigation of claims with due regard to the 10-year limitation for administrative offset under 31 U.S.C. 3716(e)(1); or

(C) The debtor agrees to pay interest on the amount of the debt on which collection action will be temporarily suspended and such temporary suspension is likely to enhance the

debtor's ability fully to pay the principal amount of the debt with interest at a later date.

(iv) Consideration may be given by the Director, TMA, or designee to suspend collection action pending action on a request for a review of the government's claim against the debtor or pending an administrative review under § 199.10 of this part of any TRICARE claim or claims directly involved in the government's claim against the debtor. Suspension under this paragraph will be made on a case-by-case basis as to whether:

(A) There is a reasonable possibility that the debt (in whole or in part) will be found not owing from the debtor;

(B) The government's interest would be protected if suspension were granted by reasonable assurance that the debt would be recovered if the debtor does not prevail; and

(C) Collection of the debt will cause undue hardship.

(5) Collection action may be terminated for one or more of the following reasons:

(i) TMA cannot collect or enforce collection of any substantial amount through its own efforts or the efforts of others, including consideration of the judicial remedies available to the government, the debtor's future financial prospects, and the exemptions available to the debtor under state and federal law;

(ii) The debtor cannot be located, and either;

(iii) The costs of collection are anticipated to exceed the amount recoverable; or

(iv) It is determined that the debt is legally without merit or enforcement of the debt is barred by any applicable statute of limitations; or

(v) The debt cannot be substantiated; or

(vi) The debt against the debtor has been discharged in bankruptcy. Collection activity may be continued subject to the provisions of the Bankruptcy Code, such as collection of any payments provided under a plan of reorganization or in cases when TMA did not receive notice of the bankruptcy proceedings.

(6) In determining whether the debt should be compromised, suspended or terminated, the responsible TMA collection authority will consider the following factors:

(i) Age and health of the debtor; present and potential income; inheritance prospects; the possibility that assets have been concealed or improperly transferred by the debtor; and the availability of assets or income

which may be realized by enforced collection proceedings;

(ii) Applicability of exemptions available to a debtor under state or federal law;

(iii) Uncertainty as to the price which collateral or other property may bring at a forced sale;

(iv) The probability of proving the claim in court because of legal issues involved or because of a bona fide dispute of the facts; the probability of full or partial recovery; the availability of necessary evidence and related pragmatic considerations. Debtors may be required to provide a completed Department of Justice Financial Statement of Debtor form (OBD-500 or such other form that DOJ shall prescribe) or other financial information that will permit TMA to verify debtors' representations. TMA may obtain credit reports or other financial information to enable it independently to verify debtors' representations.

(7) Payment of compromised claims. (i) *Time and manner.* Compromised claims are to be paid in one lump sum whenever possible. However, if installment payments of a compromised claim are necessary, a legally enforceable compromise agreement must be obtained. Payment of the amount that TMA has agreed to accept as a compromise in full settlement of a TRICARE claim must be made within the time and in the manner prescribed in the compromise agreement. Any such compromised amount is not settled until full payment of the compromised amount has been made within the time and manner prescribed. Compromise agreements must provide for the reinstatement of the prior indebtedness, less sums paid thereon, and acceleration of the balance due upon default in the payment of any installment.

(ii) *Failure to pay the compromised amount.* Failure of any debtor to make payment as provided in the compromise agreement will have the effect of reinstating the full amount of the original claim, less any amounts paid prior to default.

(iii) Effect of compromise, waiver, suspension or termination of collection action. Pursuant to the Internal Revenue Code, 26 U.S.C. 6050P, compromises and terminations of undisputed debts totaling \$600 or more for the year will be reported to the Internal Revenue Service in the manner prescribed. Amounts, other than those discharged in bankruptcy, will be included in the debtor's gross income for that year. Any action taken under paragraph (g) of this section regarding the compromise of a federal claim, or waiver or suspension or termination of collection action on a

federal claim is not an initial determination for the purposes of the appeal procedures in § 199.10.

(h) *Referrals for collection.* (1) *Prompt referral.* Federal claims of \$2,500, exclusive of interest, penalties and administrative costs, or such other amount as the Attorney General shall from time to time prescribe on which collection action has been taken under the provisions of this section which cannot be collected or compromised or on which collection action cannot be suspended or terminated as provided herein, will be promptly referred to the Department of Justice for litigation in accordance with 31 CFR part 904. Such referrals shall be made as early as possible consistent with aggressive collection action made by TRICARE contractors and TMA. Referral will be made with sufficient time to bring timely suit against the debtor. Referral shall be made by submission of a completed Claims Collection Litigation Report (CCLR), accompanied by a signed Certificate of Indebtedness. Claims of less than the minimum amount shall not be referred unless litigation to collect such smaller claims is important to ensure compliance with TRICARE's policies or programs; the claim is being referred solely for the purpose of securing a judgment against the debtor, which will be filed as a lien against the debtor's property pursuant to 28 U.S.C. 3201 and returned to the referring office for enforcement; or the debtor has the clear ability to pay the claim and the Government effectively can enforce payment, with due regard for the exemptions available to the debtor under state and Federal law and judicial remedies available to the Government.

(2) *Preservation of evidence.* The Director, TMA, or a designee will take such action as is necessary to ensure that all files, records and exhibits on claims referred, hereunder, are properly preserved.

(i) *Claims involving indication of fraud, filing of false claims or misrepresentation.* Any case in which there is an indication of fraud, the filing of a false claim or misrepresentation on the part of the debtor or any party having an interest in the claim, shall be promptly referred to the Director, TMA, or designee. The Director, TMA, or a designee, will investigate and evaluate the case and either refer the case to an appropriate investigative law enforcement agency or return the claim for other appropriate administrative action, including collection action under this section. Payment on all TRICARE beneficiary or provider claims in which fraud, filing false claims or

misrepresentation is suspected will be suspended until the Director, TMA, or designee, authorizes payment or denial of the claims. Collection action on all claims in which a suspicion of fraud, misrepresentation or filing false claims arises, will be suspended pending referral to the appropriate law enforcement agencies by the Director, TMA, or a designee. Only the Department of Justice has authority to compromise, suspend or terminate collection of such debts.

(ii) [Reserved]

November 18, 2008.

**Patricia Toppings**

*OSD Federal Register Liaison Officer,  
Department of Defense.*

[FR Doc. E8-27959 Filed 11-24-08; 8:45 am]

BILLING CODE 5001-06-P

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 117

[Docket No. USCG-2008-1106]

#### Drawbridge Operation Regulation; Cumberland River, Nashville, TN

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of temporary deviation from regulations.

**SUMMARY:** The Commander, Eighth Coast Guard District has issued a temporary deviation from the regulation governing the operation of the Louisville and Nashville (CSX) Railroad Drawbridge, across the Cumberland River, Mile 190.4, at Nashville, Tennessee. The deviation is necessary to retrofit the bridge with an upgraded rail lift system. This deviation allows the bridge to remain in a closed-to-navigation position for 10 hours each day for a four-day period.

**DATES:** This deviation is effective from 8 a.m. to 6 p.m., December 15-18, 2008.

**ADDRESSES:** Documents indicated in this preamble as being available in the docket are part of docket USCG-2008-1106 and are available online at <http://www.regulations.gov>. They are also available for inspection or copying at two locations: 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, and the Robert A. Young Federal Building, Room 2.107F, 1222 Spruce Street, St. Louis,

MO 63103-2832, between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Roger K. Wiebusch, Bridge Administrator, (314) 269-2378.

**SUPPLEMENTARY INFORMATION:** CSX Transportation Inc. requested a temporary deviation for the Louisville and Nashville Railroad Drawbridge, mile 190.4, at Nashville, Tennessee, across the Cumberland River to close the bridge to navigation. The Louisville and Nashville Railroad Drawbridge currently operates in accordance with 33 CFR 117.5, which states the general requirement that drawbridges shall open promptly and fully for the passage of vessels when a request to open is given in accordance with the subpart. In order to meet the bridge owner's request, the deviation period is 8 a.m. to 6 p.m., December 15-18, 2008 for the draw span to remain in the closed-to-navigation position.

There are no alternate routes for vessels transiting this section of the Cumberland River. The bridge has a vertical clearance of 47 feet above normal pool in the closed-to-navigation position. Navigation on the waterway consists primarily of commercial tows, barge fleeter, and recreational watercraft. The majority of vessels can pass under the bridge in the closed position. On average there may be no more than two openings during a week. This temporary deviation has been coordinated with waterway users and no objections were raised.

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

Dated: November 5, 2008.

**Roger K. Wiebusch,**  
Bridge Administrator.

[FR Doc. E8-27982 Filed 11-24-08; 8:45 am]  
BILLING CODE 4910-15-P

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 117

[USCG-2008-1097]

#### Drawbridge Operation Regulations; Gowanus Canal, Brooklyn, NY, Maintenance

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of temporary deviation from regulations.

**SUMMARY:** The Commander, First Coast Guard District, has issued a temporary deviation from the regulation governing the operation of the Hamilton Avenue Bridge across the Gowanus Canal, mile 1.2, at Brooklyn, New York. Under this temporary deviation the bridge may remain in the closed position for ten days to facilitate bridge maintenance. Vessels that can pass under the draw without a bridge opening may do so at all times.

**DATES:** This deviation is effective from 7 a.m. on November 17, 2008 through 4 p.m. on December 17, 2008.

**ADDRESSES:** Documents indicated in this preamble as being available in the docket are part of docket USCG-2008-1097 and are available online at <http://www.regulations.gov>. They are also available for inspection or copying at two locations: 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, and the First Coast Guard District, Bridge Branch Office, 408 Atlantic Avenue, Boston, Massachusetts 02110, between 7 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Judy Leung-Yee, Project Officer, First Coast Guard District, at (212) 668-7165.

**SUPPLEMENTARY INFORMATION:** The Hamilton Avenue Bridge, across the Gowanus Canal, mile 1.2, at Brooklyn, New York, has a vertical clearance in the closed position of 19 feet at mean high water and 23 feet at mean low water. The Drawbridge Operation Regulations are listed at 33 CFR 117.5. The waterway has seasonal recreational vessels, and commercial vessels of various sizes.

The owner of the bridge, New York City Department of Transportation, requested a temporary deviation to facilitate the mechanical and electrical testing at the bridge.

Under this temporary deviation the Hamilton Avenue Bridge may remain in the closed position as follows: From 7 a.m. on November 17, 2008 through 4 p.m. on November 20, 2008, From 7 a.m. on December 8, 2008 through 4 p.m. on December 10, 2008, from 7 a.m. on December 15, 2008 through 4 p.m. on December 17, 2008. Vessels that can pass under the bridge without a bridge opening may do so at all times.

In accordance with 33 CFR 117.35(e), the bridge must return to its regular operating schedule immediately at the end of the designated time period. This

deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: November 13, 2008.

**Gary Kasso,**

Bridge Program Manager, First Coast Guard District.

[FR Doc. E8-27981 Filed 11-24-08; 8:45 am]

BILLING CODE 4910-15-P

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 165

[Docket No. USCG-2008-1085]

RIN 1625-AA00

#### Safety Zone; Allegheny River, Clinton, PA

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard has established a temporary safety zone extending the entire width of the Allegheny River from mile marker 36.1 to mile marker 36.5. This safety zone is established to protect the general public, marinas, and commercial vessel operators from the hazards associated with the active failure of Lock & Dam #6 (mile marker 36.3). Entry into this zone is prohibited, unless specifically authorized by the Captain of the Port Pittsburgh or a designated representative.

**DATES:** This rule is effective from 1 p.m. on October 30, 2008 until 11:59 p.m. on December 31, 2008.

**ADDRESSES:** Documents indicated in this preamble as being available in the docket are part of docket USCG-2008-1085 and are available online by going to <http://www.regulations.gov>, selecting the Advanced Docket Search option on the right side of the screen, inserting USCG-2008-1085 in the Docket ID box, pressing Enter, and then clicking on the item in the Docket ID column. They are also available for inspection or copying at two locations: 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, and the U.S. Coast Guard Marine Safety Unit Pittsburgh, 100 Forbes Avenue, Suite 1150, Pittsburgh, PA 15222, between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this temporary

rule, call Ensign Douglas Kang Marine Safety Unit Pittsburgh, telephone 412-644-5808 ext. 2108. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

#### SUPPLEMENTARY INFORMATION:

##### Regulatory 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 because immediate action is needed to protect the general public, marinas, and commercial vessel operators from the hazards associated with the active failure of Lock & Dam #6. After an underwater assessment, the Army Corps of Engineers determined that the aforementioned lock and dam is perilously close to catastrophic failure. Such an event could create a navigational hazard to mariners in the form of high water and breakaway debris flowing downriver, and in the form of low pool-water upriver.

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**, since immediate action is needed to protect the general public, marinas, and commercial vessel operators from the hazards associated with the active failure of Lock & Dam #6.

##### Background and Purpose

The Coast Guard is establishing a temporary safety zone extending the entire width of the Allegheny River from mile marker 36.1 to mile marker 36.5. This safety zone is established to protect the general public, marinas, and commercial vessel operators from the hazards associated with the active failure of Lock & Dam #6 (mile marker 36.3).

##### Discussion of Rule

The Coast Guard has established a temporary safety zone extending the entire width of the Allegheny River from mile marker 36.1 to mile marker 36.5. Persons and vessels shall not enter

into, depart from, or move within this safety zone unless specifically authorized by the Captain of the Port Pittsburgh or a designated representative. They may be contacted through Coast Guard Sector Ohio Valley at 1-800-253-7465. This rule is effective from 1 p.m. on October 30, 2008 until 11:59 p.m. on December 31, 2008. The Captain of the Port Pittsburgh will inform the public through broadcast notices to mariners of the enforcement period for the safety zone as well as any changes in the planned schedule.

##### Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

##### Regulatory Planning and Review

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. This expectation is based on the fact that the impacts on routine navigation are expected to be minimal. Notification to the marine community will be made through broadcast notices to mariners.

##### Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601-612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. 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 or anchor in that portion of the Allegheny River from mile marker 36.1 to mile marker 36.5 from 1 p.m. on October 30, 2008 until 11:59 p.m. on December 31, 2008.

This safety zone will not have a significant economic impact on a substantial number of small entities for the following reasons. Although the

safety zone will apply to the entire width of the river, traffic will be allowed to pass through the zone with the permission of the Coast Guard. Before the effective period, we will issue maritime advisories widely available to users of the river.

##### Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104-121), we offer to assist small entities in understanding the rule so that they can better evaluate its effects on them and participate in the rulemaking process.

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.

##### Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

##### Federalism

A rule has implications for federalism under Executive Order 13132. Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

##### 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 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.

**Taking of Private Property**

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

**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.

**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.

**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.

**Energy Effects**

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a "significant energy action" under that order because it is not a "significant regulatory action" under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

**Technical Standards**

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are

technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

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

**Environment**

We have analyzed this rule under Department of Homeland Security Management Directive 5100.1 and Commandant Instruction M16475.ID, 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 under the Instruction that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2-1, paragraph (34)(g), of the Instruction, from further environmental documentation. An environmental analysis checklist and a categorical exclusion determination are available in the docket where indicated under **ADDRESSES**.

**List of Subjects in 33 CFR Part 165**

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, and 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. 1226, 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.

■ 2. Add § 165.T08-033 to read as follows:

**§ 165.T08-033 Safety Zone; Allegheny River, Clinton, PA.**

(a) *Location.* The following area is a Safety Zone: The waters extending the entire width of the Allegheny River from mile marker 36.1 to mile marker 36.5.

(b) *Enforcement Period.* This rule will be enforced from 1 p.m. on October 30, 2008 until 11:59 p.m. on December 31, 2008. The Captain of the Port Pittsburgh or a designated representative will

inform the public through broadcast notices to mariners of the enforcement period for the safety zone as well as any changes in the planned schedule.

(c) *Regulations.* (1) In accordance with the general regulations in § 165.23 of this part, entry into this zone is prohibited unless authorized by the Captain of the Port Pittsburgh.

(2) Persons or vessels requiring entry into or passage through a safety zone must request permission from the Captain of the Port Pittsburgh or a designated representative. They may be contacted through Coast Guard Sector Ohio Valley at 1-800-253-7465.

(3) All persons and vessels shall comply with the instructions of the Captain of the Port Pittsburgh and designated on-scene U.S. Coast Guard patrol personnel. On-scene U.S. Coast Guard patrol personnel includes Commissioned, Warrant, and Petty Officers of the U.S. Coast Guard.

Dated: October 30, 2008.

S.T. Higman,

Lieutenant Commander, U.S. Coast Guard,  
Acting Captain of the Port Pittsburgh.

[FR Doc. E8-27980 Filed 11-24-08; 8:45 am]

BILLING CODE 4910-15-P

**POSTAL REGULATORY COMMISSION****39 CFR Part 3020**

[Docket Nos. MC2009-5 and CP2009-6; Order No. 135]

**Administrative Practice and Procedure, Postal Service**

**AGENCY:** Postal Regulatory Commission.

**ACTION:** Final rule.

**SUMMARY:** The Commission is adding Priority Mail Contract 4 to the Competitive Product List. This action is consistent with changes in a recent law governing postal operations and a related Postal Service request. Republication of the lists of market dominant and competitive products is also consistent with new requirements in the law.

**DATES:** Effective November 25, 2008.

**ADDRESSES:** Submit comments electronically via the Commission's Filing Online system at <http://www.prc.gov>.

**FOR FURTHER INFORMATION CONTACT:** Stephen L. Sharfman, General Counsel, 202-789-6820 and [stephen.sharfman@prc.gov](mailto:stephen.sharfman@prc.gov).

**SUPPLEMENTARY INFORMATION:** *Regulatory History*, 73 FR 66077 (November 6, 2008).

The Postal Service seeks to add a new product identified as Priority Mail

Contract 4 to the Competitive Product List. For reasons discussed below, the Commission approves the Request.

### I. Background

On October 27, 2008, the Postal Service filed a formal request pursuant to 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.* to add Priority Mail Contract 4 to the Competitive Product List. The Postal Service asserts that the Priority Mail Contract 4 product is a competitive product "not of general applicability" within the meaning of 39 U.S.C. 3632(b)(3). This Request has been assigned Docket No. MC2009-5.<sup>1</sup>

The Postal Service contemporaneously filed a contract related to the proposed new product pursuant to 39 U.S.C. 3632(b)(3) and 39 CFR 3015.5. The contract has been assigned Docket No. CP2009-6.

In support of its Request, the Postal Service filed the following materials: (1) A redacted version of the Governors' Decision authorizing the new product which also includes an analysis of the Priority Mail Contract 4;<sup>2</sup> (2) a redacted version of the contract, which, among other things, provides that the contract will expire 2 years from the effective date, which is proposed to be 1 day after the Commission issues all regulatory approvals;<sup>3</sup> (3) requested changes in the Mail Classification Schedule product list;<sup>4</sup> (4) a Statement of Supporting Justification as required by 39 CFR 3020.32;<sup>5</sup> and (5) certification of compliance with 39 U.S.C. 3633(a).<sup>6</sup>

In the Statement of Supporting Justification, Kim Parks, Manager, Sales and Communications, Expedited Shipping, asserts that the service to be provided under the contract will cover its attributable costs, make a positive contribution to institutional costs, and increase contribution toward the requisite 5.5 percent of the Postal

Service's total institutional costs. Request, Attachment D, at 1. W. Ashley Lyons, Manager, Corporate Financial Planning, Finance Department, certifies that the contract complies with 39 U.S.C. 3633(a). *See id.* Attachment E.

The Postal Service filed much of the supporting materials, including the Governors' Decision and the specific Priority Mail Contract 4, under seal. In its Request, the Postal Service maintains that the contract and related financial information, including the customer's name and the accompanying analyses that provide prices, terms, conditions, and financial projections, should remain under seal. *Id.* at 2.

In Order No. 124, the Commission gave notice of the two dockets, appointed a public representative, and provided the public with an opportunity to comment.<sup>7</sup>

### II. Comments

Comments were filed by the Public Representative.<sup>8</sup> No filings were submitted by other interested parties. The Public Representative's comments focus principally on confidentiality and pricing under the contract. Public Representative Comments at 2-3. The Public Representative states that the Postal Service has justified the extent of confidentiality appropriate in this matter. *Id.*

He concludes, *inter alia*, that the contract should generate sufficient revenue to cover the product's attributable costs and contribute to the recovery of total institutional costs assigned to competitive products. *Id.* at 3-4.

### III. Commission Analysis

The Commission has reviewed the contract, the financial analysis provided under seal that accompanies it, and the comments filed by the Public Representative.

**Statutory requirements.** The Commission's statutory responsibilities in this instance entail assigning Priority Mail Contract 4 to either the Market Dominant Product List or to the Competitive Product List. 39 U.S.C. 3642. As part of this responsibility, the Commission also reviews the proposal for compliance with the Postal Accountability and Enhancement Act (PAEA) requirements. This includes, for

proposed competitive products, a review of the provisions applicable to rates for competitive products. 39 U.S.C. 3633.

**Product list assignment.** In determining whether to assign Priority Mail Contract 4 as a product to the Market Dominant Product List or the Competitive Product List, the Commission must consider whether

The Postal Service exercises sufficient market power that it can effectively set the price of such product substantially above costs, raise prices significantly, decrease quality, or decrease output, without risk of losing a significant level of business to other firms or offering similar products.

39 U.S.C. 3642(b)(1). If so, the product will be categorized as market dominant. The competitive category of products shall consist of all other products.

The Commission is further required to consider the availability and nature of enterprises in the private sector engaged in the delivery of the product, the views of those who use the product, and the likely impact on small business concerns. 39 U.S.C. 3642(b)(3).

The Postal Service asserts that its bargaining position is constrained by the existence of other shippers who can provide similar services, thus precluding it from taking unilateral action to increase prices without the risk of losing volume to private companies. Request, Attachment D, at 2-3. The Postal Service also contends that it may not decrease quality or output without risking the loss of business to competitors that offer similar expedited delivery services. *Id.* It further states that the shipper supports the addition of the contract to the product list to effectuate the negotiated contractual terms. *Id.* at 3. Finally, the Postal Service states that the market for expedited delivery services is highly competitive and requires a substantial infrastructure to support a national network. It indicates that large carriers serve this market. Accordingly, the Postal Service states that it is unaware of any small business concerns that could offer comparable service for this customer. *Id.*

No commenter opposes the proposed classification of Priority Mail Contract 4 as competitive. Having considered the statutory requirement and the support offered by the Postal Service, the Commission finds that Priority Mail Contract 4 is appropriately classified as a competitive product and should be added to the Competitive Product List.

**Cost considerations.** The Postal Service's filing seeks to establish a new domestic Priority Mail product. The contract is predicated on unit costs for major mail functions, e.g., window

<sup>1</sup> Request of the United States Postal Service to Add Priority Mail Contract 4 to Competitive Product List and Notice of Establishment of Rates and Class Not of General Applicability, October 27, 2008 (Request).

<sup>2</sup> Attachment A to the Request. The analysis that accompanies the Governors' Decision notes, among other things, that the contract is not risk free, but concludes that the risks are manageable. *See also* Second Errata to Request of the United States Postal Service to Add Priority Mail Contract 4 to Competitive Product List and Notice of Establishment of Rates and Class Not of General Applicability, October 30, 2008. The Postal Service subsequently revised its analysis. *See* Third Errata to Request of the United States Postal Service to Add Priority Mail Contract 4 to Competitive Product List and Notice of Establishment of Rates and Class Not of General Applicability, November 18, 2008.

<sup>3</sup> Attachment B to the Request.

<sup>4</sup> Attachment C to the Request.

<sup>5</sup> Attachment D to the Request.

<sup>6</sup> Attachment E to the Request.

<sup>7</sup> PRC Order No. 124, Notice and Order Concerning Priority Mail Contract 4 Negotiated Service Agreement, October 31, 2008 (Order No. 124).

<sup>8</sup> Public Representative Comments in Response to United States Postal Service Request to Add Priority Mail Contract 4 to Competitive Product List, November 6, 2008 (Public Representative Comments).



service, mail processing, and transportation, based on the shipper's mail characteristics.

The Postal Service contends that adding the Priority Mail Contract 4 product will result in processing Priority Mail pieces that are less costly for the Postal Service than the average Priority Mail piece. *See id.* Attachment A. It believes that its financial analysis shows that these cost savings can be accomplished while ensuring that the contract covers its attributable costs, does not result in subsidization of competitive products by market dominant products, and increases contribution from competitive products. *Id.*, Attachment E, at 1.

Based on the data submitted and the comments received, the Commission finds that Priority Mail Contract 4 should cover its attributable costs (39 U.S.C. 3633(a)(2)), should not lead to the subsidization of competitive products by market dominant products (39 U.S.C. 3633 (a)(1)), and should have a positive effect on competitive products' contribution to institutional costs (39 U.S.C. 3633 (a)(3)). Thus, an initial review of the proposed Priority Mail Contract 4 indicates that it comports with the provisions applicable to rates for competitive products.

The Postal Service shall promptly notify the Commission when the contract terminates, but no later than the actual termination date. The Commission will then remove the contract from the Mail Classification Schedule at the earliest possible opportunity.

In conclusion, the Commission approves Priority Mail Contract 4 as a new product. The revision to the Competitive Product List is shown below the signature of this order and is effective upon issuance of the order.

#### IV. Ordering Paragraphs

##### *It is Ordered:*

1. Priority Mail Contract 4 (MC2009-5 and CP2009-6) is added to the Competitive Product List as a new product under Negotiated Service Agreements, Domestic.

2. The Postal Service shall notify the Commission of the termination date of the contract as discussed in this order.

3. The Secretary shall arrange for the publication of this order in the **Federal Register**.

##### List of Subjects in 39 CFR Part 3020

Administrative practice and procedure; Postal Service.

By the Commission.

Steven W. Williams,  
Secretary.

■ For the reasons stated in the preamble, under the authority at 39 U.S.C. 503, the Postal Regulatory Commission amends 39 CFR part 3020 as follows:

#### PART 3020—PRODUCT LISTS

■ 1. The authority citation for part 3020 continues to read as follows:

**Authority:** 39 U.S.C. 503; 3622; 3631; 3642; 3682.

■ 2. Revise Appendix A to subpart A of part 3020—Mail Classification to read as follows:

#### Appendix A to Subpart A of Part 3020—Mail Classification

##### Schedule

##### Part A—Market Dominant Products

##### 1000 Market Dominant Product List

##### First-Class Mail

Single-Piece Letters/Postcards

Bulk Letters/Postcards

Flats

Parcels

Outbound Single-Piece First-Class Mail

International

Inbound Single-Piece First-Class Mail

International

Standard Mail (Regular and Nonprofit)

High Density and Saturation Letters

High Density and Saturation Flats/Parcels

Carrier Route

Letters

Flats

Not Flat-Machinables (NFM)/Parcels

Periodicals

Within County Periodicals

Outside County Periodicals

Package Services

Single-Piece Parcel Post

Inbound Surface Parcel Post (at UPU rates)

Bound Printed Matter Flats

Bound Printed Matter Parcels

Media Mail/Library Mail

Special Services

Ancillary Services

International Ancillary Services

Address List Services

Caller Service

Change-of-Address Credit Card

Authentication

Confirm

International Reply Coupon Service

International Business Reply Mail Service

Money Orders

Post Office Box Service

Negotiated Service Agreements

HSBC North America Holdings Inc.

Negotiated Service Agreement

Bookspan Negotiated Service Agreement

Bank of America Corporation Negotiated

Service Agreement

The Bradford Group Negotiated Service

Agreement

Market Dominant Product Descriptions

First-Class Mail

[Reserved for Class Description]

Single-Piece Letters/Postcards

[Reserved for Product Description]

Bulk Letters/Postcards

[Reserved for Product Description]

Flats

[Reserved for Product Description]

Parcels

[Reserved for Product Description]

Outbound Single-Piece First-Class Mail

International

[Reserved for Product Description]

Inbound Single-Piece First-Class Mail

International

[Reserved for Product Description]

Standard Mail (Regular and Nonprofit)

[Reserved for Class Description]

High Density and Saturation Letters

[Reserved for Product Description]

High Density and Saturation Flats/Parcels

[Reserved for Product Description]

Carrier Route

[Reserved for Product Description]

Letters

[Reserved for Product Description]

Flats

[Reserved for Product Description]

Not Flat-Machinables (NFM)/Parcels

[Reserved for Product Description]

Periodicals

[Reserved for Class Description]

Within County Periodicals

[Reserved for Product Description]

Outside County Periodicals

[Reserved for Product Description]

Package Services

[Reserved for Class Description]

Single-Piece Parcel Post

[Reserved for Product Description]

Inbound Surface Parcel Post (at UPU rates)

[Reserved for Product Description]

Bound Printed Matter Flats

[Reserved for Product Description]

Bound Printed Matter Parcels

[Reserved for Product Description]

Media Mail/Library Mail

[Reserved for Product Description]

Special Services

[Reserved for Class Description]

Ancillary Services

[Reserved for Product Description]

Address Correction Service

[Reserved for Product Description]

Applications and Mailing Permits

[Reserved for Product Description]

Business Reply Mail

[Reserved for Product Description]

Bulk Parcel Return Service

[Reserved for Product Description]

Certified Mail

[Reserved for Product Description]

Certificate of Mailing

[Reserved for Product Description]

Collect on Delivery

[Reserved for Product Description]

Delivery Confirmation

[Reserved for Product Description]

Insurance

[Reserved for Product Description]

Merchandise Return Service

[Reserved for Product Description]

Parcel Airlift (PAL)

[Reserved for Product Description]

Registered Mail

[Reserved for Product Description]

Return Receipt

[Reserved for Product Description]

Return Receipt for Merchandise

[Reserved for Product Description]

Restricted Delivery  
[Reserved for Product Description]  
Shipper-Paid Forwarding  
[Reserved for Product Description]  
Signature Confirmation  
[Reserved for Product Description]  
Special Handling  
[Reserved for Product Description]  
Stamped Envelopes  
[Reserved for Product Description]  
Stamped Cards  
[Reserved for Product Description]  
Premium Stamped Stationery  
[Reserved for Product Description]  
Premium Stamped Cards  
[Reserved for Product Description]  
International Ancillary Services  
[Reserved for Product Description]  
International Certificate of Mailing  
[Reserved for Product Description]  
International Registered Mail  
[Reserved for Product Description]  
International Return Receipt  
[Reserved for Product Description]  
International Restricted Delivery  
[Reserved for Product Description]  
Address List Services  
[Reserved for Product Description]  
Caller Service  
[Reserved for Product Description]  
Change-of-Address Credit Card  
Authentication  
[Reserved for Product Description]  
Confirm  
[Reserved for Product Description]  
International Reply Coupon Service  
[Reserved for Product Description]  
International Business Reply Mail Service  
[Reserved for Product Description]  
Money Orders  
[Reserved for Product Description]  
Post Office Box Service  
[Reserved for Product Description]  
Negotiated Service Agreements  
[Reserved for Class Description]  
HSBC North America Holdings Inc.  
Negotiated Service Agreement  
[Reserved for Product Description]  
Bookspan Negotiated Service Agreement  
[Reserved for Product Description]  
Bank of America Corporation Negotiated  
Service Agreement  
The Bradford Group Negotiated Service  
Agreement

Part B—Competitive Products

Competitive Product List

Express Mail  
Express Mail  
Outbound International Expedited Services  
Inbound International Expedited Services  
Inbound International Expedited Services 1  
(CP2008-7)

Priority Mail  
Priority Mail  
Outbound Priority Mail International  
Inbound Air Parcel Post

Parcel Select  
Parcel Return Service

International  
International Priority Airlift (IPA)  
International Surface Airlift (ISAL)  
International Direct Sacks—M-Bags  
Global Customized Shipping Services  
Inbound Surface Parcel Post (at non-UPU  
rates)  
International Money Transfer Service

International Ancillary Services  
Special Services  
Premium Forwarding Service  
Negotiated Service Agreements  
Domestic  
Express Mail Contract 1 (MC2008-5)  
Express Mail Contract 2 (MC2009-3 and  
CP2009-4)  
Parcel Return Service Contract 1 (MC2009-  
1 and CP2009-2)  
Priority Mail Contract 1 (MC2008-8 and  
CP2008-26)  
Priority Mail Contract 2 (MC2009-2 and  
CP2009-3)  
Priority Mail Contract 3 (MC2009-4 and  
CP2009-5)  
Priority Mail Contract 4 (MC2009-5 and  
CP2009-6)

Outbound International  
Global Expedited Package Services (GEPS)  
Contracts  
GEPS 1 (CP2008-5, CP2008-11, CP2008-  
12, and CP2008-13, CP2008-18,  
CP2008-19, CP2008-20, CP2008-21,  
CP2008-22, CP2008-23, and CP2008-24)  
Global Plus Contracts  
Global Plus 1 (CP2008-9 and CP2008-10)  
Global Plus 2 (MC2008-7, CP2008-16 and  
CP2008-17)  
Inbound Direct Entry Contracts with  
Foreign Postal Administrations  
(MC2008-6, CP2008-14 and CP2008-15)

Competitive Product Descriptions  
Express Mail  
[Reserved for Group Description]  
Express Mail  
[Reserved for Product Description]  
Outbound International Expedited Services  
[Reserved for Product Description]  
Inbound International Expedited Services  
[Reserved for Product Description]  
Priority  
[Reserved for Product Description]  
Priority Mail  
[Reserved for Product Description]  
Outbound Priority Mail International  
[Reserved for Product Description]  
Inbound Air Parcel Post  
[Reserved for Product Description]  
Parcel Select  
[Reserved for Group Description]  
Parcel Return Service  
[Reserved for Group Description]  
International  
[Reserved for Group Description]  
International Priority Airlift (IPA)  
[Reserved for Product Description]  
International Surface Airlift (ISAL)  
[Reserved for Product Description]  
International Direct Sacks—M-Bags  
[Reserved for Product Description]  
Global Customized Shipping Services  
[Reserved for Product Description]  
International Money Transfer Service  
[Reserved for Product Description]  
Inbound Surface Parcel Post (at non-UPU  
rates)  
[Reserved for Product Description]  
International Ancillary Services  
[Reserved for Product Description]  
International Certificate of Mailing  
[Reserved for Product Description]  
International Registered Mail  
[Reserved for Product Description]  
International Return Receipt  
[Reserved for Product Description]

International Restricted Delivery  
[Reserved for Product Description]  
International Insurance  
[Reserved for Product Description]  
Negotiated Service Agreements  
[Reserved for Group Description]  
Domestic  
[Reserved for Product Description]  
Outbound International  
[Reserved for Group Description]

Part C—Glossary of Terms and  
Conditions [Reserved]

Part D—Country Price Lists for  
International Mail [Reserved]

[FR Doc. E8-27910 Filed 11-24-08; 8:45 am]

BILLING CODE 7710-FW-P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 80

[EPA-HQ-OAR-2005-0161; FRL-8723-3]

RIN 2060-A080

### Regulation of Fuels and Fuel Additives: Modifications to Renewable Fuel Standard Program Requirements

#### Correction

In rule document E8-23131 beginning  
on page 57248 in the issue of Thursday,  
October 2, 2008, make the following  
correction:

#### § 80.1127 [Corrected]

On page 57255, in the second column,  
in § 80.1127(b)(2), the formula should  
appear as follows:

$$D_i = RVO_i - [(\Sigma RINNUM)_i + (\Sigma RINNUM)_{i-1}]$$

[FR Doc. Z8-23131 Filed 11-24-08; 8:45 am]

BILLING CODE 1505-01-D

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Part 73

[DA 08-2453; MB Docket No. 08-127; RM-  
11459]

### Television Broadcasting Services; Madison, WI

AGENCY: Federal Communications  
Commission.

ACTION: Final rule.

**SUMMARY:** The Commission grants a  
petition for rulemaking filed by WMSN  
Licensee, LLC, licensee of station  
WMSN-DT, to substitute DTV channel  
49 for post-transition DTV channel 11 at  
Madison, Wisconsin.

**DATES:** The channel substitution is  
effective December 26, 2008.

**FOR FURTHER INFORMATION CONTACT:** David J. Brown, Media Bureau, (202) 418-1600.

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the Commission's *Report and Order*, MB Docket No. 08-127, adopted October 31, 2008, and released November 5, 2008. The full text of this document is available for public inspection and copying during normal business hours in the FCC's Reference Information Center at Portals II, CY-A257, 445 12th Street, SW., Washington, DC 20554. This document will also be available via ECFS (<http://www.fcc.gov/cgb/ecfs/>). (Documents will be available electronically in ASCII, Word 97, and/or Adobe Acrobat.) This document may be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY-B402, Washington, DC 20554, telephone 1-800-478-3160 or via e-mail [www.BCPIWEB.com](http://www.BCPIWEB.com). To request this document in accessible formats (computer diskettes, large print, audio recording, and Braille), send an e-mail to [fcc504@fcc.gov](mailto:fcc504@fcc.gov) or call the Commission's Consumer and Governmental Affairs Bureau at (202) 418-0530 (voice), (202) 418-0432 (TTY). This document does not contain information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104-13. In addition, therefore, it does not contain any information collection burden "for small business concerns with fewer than 25 employees," pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107-198, see 44 U.S.C. 3506(c)(4). Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

The Commission will send a copy of this *Report and Order* in a report to be sent to Congress and the Government Accountability Office pursuant to the Congressional Review Act, see 5 U.S.C. 801(a)(1)(A).

#### List of Subjects in 47 CFR Part 73

Television, Television broadcasting.  
 ■ For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR Part 73 as follows:

#### PART 73—RADIO BROADCAST SERVICES

■ 1. The authority citation for part 73 continues to read as follows:  
 Authority: 47 U.S.C. 154, 303, 334, 336.

##### § 73.622(i) [Amended]

■ 2. Section 73.622(i), the Post-Transition Table of DTV Allotments

under Wisconsin, is amended by adding DTV channel 49 and removing DTV channel 11 at Madison.

Federal Communications Commission.  
 Clay C. Pendarvis,  
 Associate Chief, Video Division, Media Bureau.

[FR Doc. E8-27990 Filed 11-24-08; 8:45 am]  
 BILLING CODE 6712-01-P

#### FEDERAL COMMUNICATIONS COMMISSION

##### 47 CFR Part 73

[DA 08-2452; MB Docket No. 08-175; RM-11484]

##### Television Broadcasting Services; Bryan, TX

**AGENCY:** Federal Communications Commission.  
**ACTION:** Final rule.

**SUMMARY:** The Commission grants a petition for rulemaking filed by Comcorp of Bryan License Corp., licensee of station KYLE-DT, to substitute DTV channel 29 for post-transition DTV channel 28 at Bryan, Texas.

**DATES:** Effective December 26, 2008.

**FOR FURTHER INFORMATION CONTACT:** David J. Brown, Media Bureau, (202) 418-1600.

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the Commission's *Report and Order*, MB Docket No. 08-175, adopted October 31, 2008, and released November 5, 2008. The full text of this document is available for public inspection and copying during normal business hours in the FCC's Reference Information Center at Portals II, CY-A257, 445 12th Street, SW., Washington, DC 20554. This document will also be available via ECFS (<http://www.fcc.gov/cgb/ecfs/>). (Documents will be available electronically in ASCII, Word 97, and/or Adobe Acrobat.) This document may be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY-B402, Washington, DC 20554, telephone 1-800-478-3160 or via e-mail [www.BCPIWEB.com](http://www.BCPIWEB.com). To request this document in accessible formats (computer diskettes, large print, audio recording, and Braille), send an e-mail to [fcc504@fcc.gov](mailto:fcc504@fcc.gov) or call the Commission's Consumer and Governmental Affairs Bureau at (202) 418-0530 (voice), (202) 418-0432 (TTY). This document does not contain information collection requirements subject to the Paperwork Reduction Act

of 1995, Public Law 104-13. In addition, therefore, it does not contain any information collection burden "for small business concerns with fewer than 25 employees," pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107-198, see 44 U.S.C. 3506(c)(4). Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

The Commission will send a copy of this *Report and Order* in a report to be sent to Congress and the Government Accountability Office pursuant to the Congressional Review Act, see 5 U.S.C. 801(a)(1)(A).

#### List of Subjects in 47 CFR Part 73

Television, Television broadcasting.  
 ■ For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR Part 73 as follows:

#### PART 73—RADIO BROADCAST SERVICES

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334, 336.

##### § 73.622 [Amended]

■ 2. Section 73.622(i), the Post-Transition Table of DTV Allotments under Texas, is amended by adding DTV channel 29 and removing DTV channel 28 at Bryan.

Federal Communications Commission.  
 Clay C. Pendarvis,  
 Associate Chief, Video Division, Media Bureau.

[FR Doc. E8-27993 Filed 11-24-08; 8:45 am]  
 BILLING CODE 6712-01-P

#### DEPARTMENT OF COMMERCE

##### National Oceanic and Atmospheric Administration

##### 50 CFR Part 648

[Docket No. 071212833-8179-02]

RIN 0648-XL76

##### Fisheries of the Northeastern United States; Atlantic Bluefish Fishery; Quota Transfer

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

**ACTION:** Temporary rule; inseason quota transfer.

**SUMMARY:** NMFS announces that the State of Connecticut, the State of Rhode Island, the State of Delaware, and the

State of Maryland are transferring commercial bluefish quota to the State of New York from their 2008 quota. By this action, NMFS adjusts the quotas and announces the revised commercial quota for each state involved.

**DATES:** Effective November 19, 2008, through December 31, 2008.

**FOR FURTHER INFORMATION CONTACT:** Emily Bryant, Fishery Management Specialist, (978) 281-9244, fax (978) 281-9135.

**SUPPLEMENTARY INFORMATION:** Regulations governing the Atlantic bluefish fishery are found at 50 CFR part 648. The regulations require annual specification of a commercial quota that is apportioned among the coastal states from Florida through Maine. The process to set the annual commercial

quota and the percent allocated to each state is described in § 648.160.

Two or more states, under mutual agreement and with the concurrence of the Administrator, Northeast Region, NMFS (Regional Administrator), can transfer or combine bluefish commercial quota under § 648.160(f). The Regional Administrator is required to consider the criteria set forth in § 648.160(f)(1) in the evaluation of requests for quota transfers or combinations.

Connecticut, Rhode Island, Maryland, and Delaware have agreed to transfer 20,000 lb (9,072 kg), 50,000 lb (22,680 kg), 50,000 lb (22,680 kg), and 90,000 lb (40,823 kg), respectively, of their 2008 commercial quotas to New York. The Regional Administrator has determined that the criteria set forth in § 648.160(f)(1) have been met. The

revised bluefish quotas for calendar year 2008 are: New York, 1,157,057 lb (524,832 kg); Connecticut, 77,398 lb (35,107 kg); Rhode Island, 473,649 lb (214,844 kg); Maryland, 180,885 lb (82,048 kg); and Delaware, 54,463 lb (24,704 kg).

**Classification**

This action is taken under 50 CFR part 648 and is exempt from review under Executive Order 12866.

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

Dated: November 18, 2008.

**Emily H. Menashes,**

*Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.*  
[FR Doc. E8-27890 Filed 11-19-08; 4:15 pm]

**BILLING CODE 3510-22-S**

## Proposed Rules

Federal Register

Vol. 73, No. 228

Tuesday, November 25, 2008

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 HOMELAND SECURITY

#### Office of the Secretary

#### 6 CFR Part 5

[Docket No. DHS-2008-0096]

#### Privacy Act of 1974: Implementation of Exemptions; Department of Homeland Security Accident Records

AGENCY: Privacy Office, DHS.

ACTION: Notice of Proposed Rule Making.

**SUMMARY:** The Department of Homeland Security is giving concurrent notice of a revised and updated system of records pursuant to the Privacy Act of 1974 for the Department of Homeland Security Accident Records system of records and this proposed rulemaking. In this proposed rulemaking, the Department proposes to exempt portions of the system of records from one or more provisions of the Privacy Act in connection with providing protective services to the President of the United States and other individuals Section 3056 and 3056A of Title 18.

**DATES:** Comments must be received on or before December 26, 2008.

**ADDRESSES:** You may submit comments, identified by docket number DHS-2008-0096, by one of the following methods:

- *Federal e-Rulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *Fax:* 1-866-466-5370.
- *Mail:* Hugo Teufel III, Chief Privacy Officer, Department of Homeland Security, Washington DC 20528.

*Instructions:* All submissions received must include the agency name and docket number for this notice. All comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided.

*Docket:* For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** For general questions and privacy issues, please contact: Hugo Teufel III (703-235-0780), Chief Privacy Officer, Privacy Office, U.S. Department of Homeland Security, Washington, DC 20528.

#### SUPPLEMENTARY INFORMATION:

*Background:* Pursuant to the savings clause in the Homeland Security Act of 2002, Public Law 107-296, Section 1512, 116 Stat. 2310 (November 25, 2002), the Department of Homeland Security (DHS) and its components and offices have relied on preexisting Privacy Act systems of records notices for the collection and maintenance of records that concern accident records.

As part of its efforts to streamline and consolidate its Privacy Act record systems, DHS is establishing a new agency-wide system of records under the Privacy Act (5 U.S.C. 552a) for DHS accident records. This will ensure that all components of DHS follow the same privacy rules for collecting and handling accident records. DHS will use this system to collect and maintain accident records submitted by DHS personnel and others. In this notice of proposed rulemaking, DHS now is proposing to exempt Accident Records, in part, from certain provisions of the Privacy Act.

The Privacy Act embodies fair information principles in a statutory framework governing the means by which the United States Government collects, maintains, uses, and disseminates personally identifiable information. The Privacy Act applies to information that is maintained in a "system of records." A "system of records" is a group of any records under the control of an agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual. Individuals may request their own records that are maintained in a system of records in the possession or under the control of DHS by complying with DHS Privacy Act regulations, 6 CFR part 5.

The Privacy Act requires each agency to publish in the **Federal Register** a description of the type and character of each system of records that the agency maintains, and the routine uses that are contained in each system in order to make agency recordkeeping practices transparent, to notify individuals

regarding the uses to which personally identifiable information is put, and to assist individuals in finding such files within the agency.

The Privacy Act allows Government agencies to exempt certain records from the access and amendment provisions. If an agency claims an exemption, however, it must issue a Notice of Proposed Rulemaking to make clear to the public the reasons why a particular exemption is claimed.

DHS is claiming exemptions from certain requirements of the Privacy Act for Accident Records. Some information in Accident Records relates to the protective services to the President of the United States or other individuals pursuant to Section 3056 and 3056A of Title 18. These exemptions are needed to protect information relating to DHS activities from disclosure to subjects or others related to these activities. Specifically, the exemptions are required to safeguard records in connection with providing protective services to the President of the United States or other individuals pursuant to Section 3056 and 3056A of Title 18.

In appropriate circumstances, where compliance would not appear to interfere with or adversely affect the law enforcement purposes of this system and the overall law enforcement process, the applicable exemptions may be waived on a case by case basis.

A notice of system of records for Accident Records is also published in this issue of the **Federal Register**.

#### List of Subjects in 6 CFR Part 5

Freedom of information; Privacy.

For the reasons stated in the preamble, DHS proposes to amend Chapter 1 of Title 6, Code of Federal Regulations, as follows:

#### PART 5—DISCLOSURE OF RECORDS AND INFORMATION

1. The authority citation for Part 5 continues to read as follows:

**Authority:** 6 U.S.C. 101 et seq.; Public Law 107-296, 116 Stat. 2135; 5 U.S.C. 301. Subpart A also issued under 5 U.S.C. 552. Subpart B also issued under 5 U.S.C. 552a.

2. Add at the end of Appendix C to Part 5, the following new paragraph 14:

#### Appendix C to Part 5—DHS Systems of Records Exempt From the Privacy Act

\* \* \* \* \*

14. The Department of Homeland Security Accident Records system of records consists of electronic and paper records and will be used by DHS and its components. Accident Records is a repository of information held by DHS in connection with its several and varied missions and functions, including, but not limited to: the enforcement of civil and criminal laws; investigations, inquiries, and proceedings there under; national security and intelligence activities; and protection of the President of the United States or other individuals pursuant to Section 3056 and 3056A of Title 18. Accident Records contains information that is collected by, on behalf of, in support of, or in cooperation with DHS and its components and may contain personally identifiable information collected by other Federal, State, local, tribal, foreign, or international government agencies. Pursuant to 5 U.S.C. 552a(k)(3) this system is exempt from the following provisions of the Privacy Act, subject to the limitations set forth in those subsections: 5 U.S.C. 552a (d). Exemptions from these particular subsections are justified, on a case-by-case basis to be determined at the time a request is made, for the following reasons:

(a) From subsection (d) (Access to Records) because access to the records contained in this system of records could inform the subject of information related to the protection of a President of the United States or other individuals pursuant to Section 3056 and 3056A of Title 18. Permitting access and amendment to such information could disclose security-sensitive information that could be detrimental to homeland security.

Dated: November 18, 2008.

Hugo Teufel III,  
Chief Privacy Officer, Department of  
Homeland Security.

[FR Doc. E8-28061 Filed 11-24-08; 8:45 am]  
BILLING CODE 4410-10-P

## NUCLEAR REGULATORY COMMISSION

### 10 CFR Part 50

[Docket No. PRM-50-84; NRC-2007-0013]

#### Mark Edward Leyse; Consideration of Petition in Rulemaking Process

**AGENCY:** Nuclear Regulatory  
Commission.

**ACTION:** Resolution of petition for  
rulemaking and closure of petition  
docket.

**SUMMARY:** The Nuclear Regulatory  
Commission (NRC) will consider the  
issues raised in a petition for  
rulemaking (PRM) submitted by Mark  
Edward Leyse in the NRC's rulemaking  
process. The petition was dated March  
15, 2007, and was docketed as PRM-50-  
84. The petitioner requests that the NRC  
amend its regulations to require that  
nuclear power reactors be operated in a  
manner to limit the thickness of crud

layers and/or the thickness of oxide  
layers on fuel rod cladding surfaces to  
ensure that the facilities operate in  
compliance with the emergency core  
cooling system (ECCS) acceptance  
criteria. The petitioner also requests that  
the requirements pertaining to ECCS  
evaluation models be amended to  
explicitly require that the steady-state  
temperature distribution and stored  
energy in reactor fuel at the onset of a  
postulated loss-of-coolant accident  
(LOCA) be calculated by factoring in the  
role that the thermal resistance of crud  
and/or oxide layers on fuel cladding  
plays in increasing the stored energy of  
the fuel. Lastly, the petitioner requests  
that the acceptance criteria for analyses  
of ECCS cooling performance for light-  
water nuclear power reactors be  
amended to stipulate a maximum  
allowable percentage of hydrogen  
content in the cladding of fuel rods. The  
NRC will consider the petitioner's first  
two requests in PRM-50-84 because the  
underlying technical considerations  
regarding the effects of crud and oxide  
growth on ECCS analyses noted by the  
petitioner are sufficiently related to an  
ongoing NRC rulemaking activity on  
ECCS analysis acceptance criteria. The  
NRC will consider the petitioner's third  
request because the NRC has already  
initiated rulemaking activities that will  
address the petitioner's underlying  
technical concerns on fuel cladding  
embrittlement.

While the NRC will consider the  
issues raised in the petition in its  
rulemaking process, the petitioner's  
concerns may not be addressed exactly  
as the petitioner has requested. During  
the rulemaking process, the NRC will  
solicit comments from the public and  
will consider all comments before  
issuing a final rule.

**DATES:** The docket for the petition for  
rulemaking PRM-50-84 is closed on  
November 25, 2008.

**ADDRESSES:** You can access publicly  
available documents related to this  
petition for rulemaking using the  
following methods:

*Federal e-Rulemaking Portal:*  
Documents related to the evaluation of  
this petition are assigned to rulemaking  
docket ID: NRC-2006-0013. Further  
NRC action on the issues raised by this  
petition will be considered in the  
rulemaking to establish Performance-  
based ECCS Cladding Acceptance  
Criteria, (RIN 3150-AH42) which has  
been assigned rulemaking docket ID:  
NRC-2008-0332. Information on this  
petition and the related rulemaking can  
be accessed at the Federal rulemaking  
portal, <http://www.regulations.gov>;  
search on rulemaking docket ID: NRC-

2007-0013 and NRC-2008-0332. The  
NRC also tracks all rulemaking actions  
in the "NRC Regulatory Agenda:  
Semiannual Report (NUREG-0936)."

*NRC's Public Document Room (PDR):*  
The public may examine and have  
copied for a fee, publicly available  
documents at the NRC's PDR, Public  
File Area, Room O1-F21, One White  
Flint North, 11555 Rockville Pike,  
Rockville, Maryland.

*NRC's Agencywide Document Access  
and Management System (ADAMS):*  
Publicly available documents created or  
received at the NRC are available  
electronically at the NRC's Electronic  
Reading Room at [http://www.nrc.gov/  
NRC/reading-rm/adams.html](http://www.nrc.gov/NRC/reading-rm/adams.html). From this  
page, the public can gain entry into  
ADAMS, which provides text and image  
files of NRC's public documents. If you  
do not have access to ADAMS or if there  
are any problems in accessing the  
documents located in ADAMS, contact  
the NRC PDR Reference staff at 1-800-  
397-4209, 301-415-4737 or by e-mail to  
[PDR.resource@nrc.gov](mailto:PDR.resource@nrc.gov).

#### FOR FURTHER INFORMATION CONTACT:

Richard Dudley, Mail Stop O12-D3,  
Office of Nuclear Reactor Regulation,  
United States Nuclear Regulatory  
Commission, Washington, DC 20555-  
0001; telephone (301) 415-1116, or e-  
mail [richard.dudley@nrc.gov](mailto:richard.dudley@nrc.gov).

#### SUPPLEMENTARY INFORMATION:

##### The Petition

The NRC received a petition for  
rulemaking (ADAMS Accession No.  
ML070871368) from Mark Edward  
Leyse (the petitioner) dated March 15,  
2007, which was docketed as PRM-50-  
84. The petitioner requested that all  
holders of operating licenses for nuclear  
power plants be required to operate  
such plants at operating conditions (e.g.,  
levels of power production, and light-  
water coolant chemistries) necessary to  
effectively limit the thickness of crud  
and/or oxide layers on fuel rod cladding  
surfaces. On May 23, 2007, the NRC  
published a notice of receipt for this  
petition in the *Federal Register* (72 FR  
28902) and requested public comment.  
The public comment period ended on  
August 6, 2007.

##### NRC Evaluation

The NRC review of this petition and  
evaluation of public comments are  
based upon NRC's understanding of  
several terms used by the petitioner:

1. *Crud* is any foreign substance  
which may become deposited on the  
surface of fuel cladding. This layer can  
impede the transfer of heat. The NRC  
believes that the word "crud" originated  
as an acronym for "Chalk River

Unidentified Deposit", based upon deposits on early test fuels observed at Chalk River Laboratories in Canada. Crud most frequently refers to deposits of tiny iron or nickel metallic particles eroded from pipe and valve surfaces. These particles of stable isotopes may become "activated" or irradiated and transform into radioactive isotopes, such as cobalt-60. In fouling technology today, the term "crud" is generally applied to solid deposits on fuel element heat transfer surfaces (cladding). The NRC staff makes a clear distinction between crud and pure zirconium oxidation layers. Although both materials contain metal oxides, crud does not originate at the fuel rod, while zirconium oxide forms on fuel when the cladding material reacts with oxygen.

2. *Oxide* is a product of the reaction of oxygen with the zirconium cladding material itself. Zirconia, or zirconium dioxide ( $ZrO_2$ ) is one oxidation product which may be found on the exterior surface (and sometimes the interior surface) of zirconium fuel cladding. Although it may be an additional surface layer, formation of oxides also consumes some cladding base material, thereby decreasing metal cladding thickness. Compared to the original metal cladding material, metal oxides usually are more brittle and conduct heat less effectively. In this discussion, the terms "corrosion" and "oxidation" are considered one and the same.

3. *Hydrogen* in a nuclear reactor may be produced by the breakup of coolant water molecules during the oxidation process described previously. Hydrogen may not only be present in the reactor coolant, but may also diffuse into the fuel cladding. It may then either remain in solution or be precipitated as a zirconium hydride. Hydrogen in either form has been found to alter both the material properties and behavior of the cladding material. Formation of zirconium hydrides, such as  $ZrH_2$ , has been found to cause embrittlement of zirconium fuel cladding.

The NRC understands the petitioner as requesting the NRC to conduct rulemaking in three specific areas:

1. Establish regulations that require licensees to operate light water power reactors under conditions that are effective in limiting the thickness of crud and/or oxide layers on zirconium-clad fuel in order to ensure compliance with 10 CFR 50.46(b) ECCS acceptance criteria;

2. Amend current regulations in Appendix K to 10 CFR Part 50 to explicitly require that the steady-state temperature distribution and stored energy in the reactor fuel at the onset of

a postulated LOCA be calculated by factoring in the role that the thermal resistance of crud deposits and/or oxide layers plays in increasing the stored energy in the fuel (these requirements also need to apply to any NRC-approved, best-estimate ECCS evaluation models used in lieu of Appendix K calculations); and

3. Amend § 50.46 to specify a maximum allowable percentage of hydrogen content in cladding.

The NRC will address each of the petitioner's requests below. The NRC will first address the petitioner's third request because the logic used to evaluate the other requests can be more easily understood.

*Proposal 3—Amendment of 10 CFR 50.46, Acceptance Criteria for Emergency Core Cooling Systems for Light-water Nuclear Power Reactors, to include a limit on maximum hydrogen content in cladding.*

The petitioner states that an increase in hydrogen content in cladding contributes to cladding embrittlement. The petitioner cites an April 4, 2001, NRC Advisory Committee on Reactor Safeguards (ACRS) subcommittee meeting on reactor fuels during which an expert from Argonne National Laboratory stated that a reduction of ductility occurs when hydrogen levels reach about 600 to 700 parts-per-million (ppm) in Zircaloy cladding. According to the petitioner, another expert from the Atomic Energy Research Institute stated that a threshold for a reduction of ductility in Zircaloy cladding occurs at even a lower hydrogen level of about 150 to 200 ppm. The petitioner also references an event at Three Mile Island, Unit 1 (TMI-1) during refueling Cycle 10 that involved hydrogen absorption in fuel cladding. The petitioner notes that hydrogen content in the cladding of a rod that did not fail measured 700 ppm at TMI-1 and that this level of hydrogen content in one-cycle cladding is similar to the 800 ppm level measured in fuel cladding at the H.B. Robinson, Unit 2 facility, a pressurized water reactor (PWR). The petitioner states that some of the cladding in TMI-1 Cycle 10 contained levels of hydrogen that Argonne National Laboratory found would have caused a loss of cladding ductility in addition to the embrittlement resulting from excessive oxide levels.

The petitioner also states that absorption of hydrogen would contribute to a loss of cladding ductility during a LOCA along with cladding degradation and massive oxidation. The petitioner cites a failed fuel rod from the TMI-1, Cycle 10 event when hydrogen absorption caused hydrided material to

break away from the outer portions of the cladding. The petitioner believes that the effects of increased stored energy due to a heavy crud layer in the fuel and the severity of cladding oxidation, embrittlement, and resulting fuel degradation during an actual event would be substantially greater than in an ECCS calculation based on clean cladding.

In 2003, the Commissioners directed the NRC staff to undertake rulemaking to amend 10 CFR 50.46 to provide for a more performance-based approach to meeting the ECCS acceptance criteria in § 50.46(b). Technical work to finalize the technical basis for this rulemaking is currently proceeding and includes a study (Research Information Letter 0801, "Technical Basis for Revision of Embrittlement Criteria in 10 CFR 50.46," May 30, 2008, ADAMS accession no. ML081350225; NUREG/CR-6967, "Cladding Embrittlement During Postulated Loss-of-Coolant Accidents," July 2008, ADAMS accession no. ML082130389) of the effects on cladding embrittlement caused by cladding oxidation and hydrogen. Because the NRC is already investigating the need to amend § 50.46 to address hydrogen effects on cladding, the petitioner's request in Proposal 3 will be considered during the current rulemaking. This rulemaking is designated as RIN 3150-AH42 in the "NRC Regulatory Agenda: Semiannual Report (NUREG-0936)." Documents associated with this rule are posted under docket ID: NRC-2008-0332 on the Regulations.gov Web site. Rulemaking will begin when a consensus is reached on the technical basis for the amendments.

*Proposal 1—Establish regulations that require licensees to operate light water power reactors under conditions that effectively limit the thickness of crud and oxide layers on zirconium-clad fuel to ensure compliance with 10 CFR 50.46(b) ECCS acceptance criteria.*

To support the rulemaking request in Proposal 1 of the petition, the petitioner lists sources, such as the Electric Power Research Institute (EPRI) reports, ACRS transcripts, and several journal articles to show that the thermal conductivities of the crud and oxide layers are lower than the thermal conductivity of zirconium metal cladding. The petitioner asserts that because of these lower heat transfer rates, the stored energy within the fuel and the time to transfer stored energy will increase. The petitioner cites several operating instances to support the contention that safety issues can arise from the thermal resistance of crud and oxide layers on fuel cladding. Finally, the petitioner

lists several examples to show that incidents of fuel failures have increased in recent years.

The petitioner's request in Proposal 1 is founded on the potential impact of crud and oxide on ECCS performance evaluations. The NRC generally agrees with the petitioner that crud and oxide formation can impact the thermal response of the fuel system. Hydrogen embrittlement is also an issue in the ongoing rulemaking to revise the ECCS acceptance criteria discussed in Proposal 3 above. The need for any operational restrictions, as requested by the petitioner, would presumably be determined (in part) from these considerations. The NRC believes that the petitioner's Proposal 1 is sufficiently relevant to the ongoing cladding embrittlement rulemaking to warrant consideration in that proceeding. The NRC is accepting the petitioner's Proposal 1 for consideration during the current rulemaking to revise § 50.46(b). In deciding to consider the petitioner's concern in the § 50.46(b) rulemaking, the NRC expresses no position on the specific merits of the petitioner's request and underlying bases. These issues will be addressed separately as part of the rulemaking.

*Proposal 2—Amendment of Appendix K to 10 CFR Part 50, ECCS Evaluation Models I(A)(1), The Initial Stored Energy in the Fuel, to also require the thermal resistance of crud deposits and/or oxide layers as factors in calculations of steady-state temperature distribution and stored energy in the reactor fuel at the onset of a postulated LOCA.*

In this proposal, the petitioner requested that Appendix K to 10 CFR Part 50 be amended to include explicit instructions on how to perform the ECCS performance calculations mentioned above. Also, in lieu of Appendix K calculations, the petitioner requested establishment of a regulation stating that these requirements must also apply to any NRC-approved, best-estimate ECCS evaluation model, as described in NRC Regulatory Guide 1.157. The petitioner states that because layers of crud and/or oxide increase the quantity of stored energy in the fuel, Appendix K to Part 50 should explicitly require that the thermal conductivity of layers of crud and/or oxide be factored into calculations of the stored energy in the fuel. In support of the petition, several references are cited. For example, the petitioner quotes from a letter to the NRC from James F. Klapproth, Manager, Engineering and Technology at General Electric Nuclear Energy (April 8, 2002, ADAMS accession no. ML021020383): "The primary effects of [a] heavy crud layer

during a postulated LOCA would be an increase in the fuel stored energy at the onset of the event, and a delay in the transfer of that stored energy to the coolant during the blowdown phase of the event."

Proposal 2 requests that Appendix K explicitly require consideration of crud and/or oxide layers in the calculation of stored energy used in ECCS performance calculations required by § 50.46. Appendix K provides requirements for one acceptable methodology for performing § 50.46 ECCS performance calculations that must meet the acceptance criteria in § 50.46(b). Similar to Proposal 1 above, the petitioner's request in Proposal 2 is founded on the potential impact of crud and oxide on ECCS performance evaluations. Because the NRC agrees with the petitioner that crud and oxide formation can change the thermal response of the fuel system, it is possible that crud and oxidation layers could also have an impact on cladding hydrogen concentration. Also, because hydrogen uptake and concentration are being considered in the ongoing rulemaking to establish new performance-based ECCS acceptance criteria, consideration of crud and oxidation in that context is appropriate. Thus, the NRC concludes that Proposal 2 is likewise sufficiently relevant to the ongoing rulemaking to warrant consideration in that proceeding. As in the case of the petitioner's Proposal 1, the NRC expresses no position on the specific merits of the petitioner's Proposal 2 and its underlying bases. These issues will be addressed separately as part of the § 50.46(b) rulemaking.

#### *Comparison of PRM-50-84 With Previous Similar Petitions*

PRM-50-84 is the fifth in a series of petitions for rulemaking submitted to the NRC regarding the build-up, analysis, and release of crud on nuclear power plant heat exchange surfaces, and the oxidation of zirconium fuel cladding. Each of the four previous petitions (PRM-50-73 and PRM-50-73A (68 FR 41963; July 16, 2003); PRM-50-76 (70 FR 52893; September 9, 2005); and PRM-50-78 (69 FR 56958; September 23, 2004)) have been denied by the Commission. The NRC evaluated each of the previous petitions and concluded that the requested actions would not contribute to maintaining the public safety or security, nor would it improve the regulatory efficiency and effectiveness. The current petition is being considered because it includes the assertion that the accumulation of crud and oxide deposits will interfere with

effective heat exchange between the cladding and coolant, increase fuel temperatures, and thus, lead to safety problems. Additionally, the NRC's knowledge of the effects of crud, oxidation, and hydrogen content on cladding integrity has increased in the last few years.

In 2003, the NRC initiated work to develop the technical basis for new, performance-based ECCS acceptance criteria that would apply to all zirconium cladding alloys.<sup>1</sup> Laboratory testing was performed on non-irradiated and irradiated zirconium alloys with different burnups to determine what parameters affected cladding embrittlement. On May 30, 2008, the NRC summarized the results of this research effort in a letter (Research Information Letter 0801, "Technical Basis for Revision of Embrittlement Criteria in 10 CFR 50.46," May 30, 2008, ADAMS accession no. ML081350225). The NRC is now evaluating this information to determine if it provides an adequate basis for establishing the new, performance-based ECCS acceptance criteria. Two significant conclusions of this work are that hydrogen content of cladding is an important factor in causing cladding embrittlement and that cladding oxidation is a key contributor to cladding hydrogen content. Because crud and oxide formation can impact the thermal response of the fuel system, it is possible that crud and oxidation layers could also have direct or indirect impacts on cladding hydrogen concentration. Also, because all these factors appear to be interrelated, the NRC will consider all of the phenomena addressed in PRM-50-84 (crud, oxidation, and hydrogen content) in the ongoing rulemaking to establish new performance-based ECCS acceptance criteria in § 50.46(b).

#### **Analysis of Public Comments**

Comments in support of PRM-50-84 were provided by the Union of Concerned Scientists (UCS), two individuals, and the petitioner. The Nuclear Energy Institute and Strategic Teaming and Resource Sharing organization submitted comments in opposition to the petition. A summary of the comments and the NRC's evaluation of those comments follow.

*Comment:* A commenter referenced various technical reports and

<sup>1</sup> The acceptance criteria in the current regulations are specifically applicable to only two cladding alloys, Zircaloy and Zirlo. Fuel designs with other, more advanced cladding alloys must be reviewed on a case-by-case basis and require NRC approval of an exemption to the existing requirements.



operational events to demonstrate that the accumulated hydrogen content of zirconium fuel cladding reduces the ductility of the cladding and increases the possibility that core geometry could change during a LOCA and reduce fuel cooling. (MEL 7-1)

*NRC Response:*

The NRC agrees with the commenter that cladding ductility can be reduced by hydrogen absorption in zirconium cladding. Since 2003, the NRC has been working to develop the technical basis for a new regulation on performance-based ECCS acceptance criteria applicable to the various zirconium cladding alloys. The NRC accepts this aspect of the petitioner's request and will consider hydrogen embrittlement issues during the ongoing rulemaking.

*Comment:* Several commenters referred to numerous technical reports, papers, and articles to document the existence of crud and oxidation layers on light-water reactor fuel cladding and show that the thermal resistance associated with the crud and oxidation layers significantly affects fuel temperatures and ECCS performance. (RHL-1, RHL-2, MEL 6-1, MEL 6-2, MEL 7-1, MEL 7-2, MEL 7-3, RHL 8-2, RHL-10)

*NRC Response:*

The NRC reviewed the technical information provided or referenced by the commenters. The NRC agrees with the commenters that formation of cladding crud and oxide layers is an expected condition at nuclear power plants. However, the amount of accumulated crud and oxidation varies from plant to plant and from one fuel cycle to another. The NRC agrees that crud and/or oxide layers may directly affect the stored energy in the fuel by their thermal resistance as well as indirectly affecting the stored energy through an increase in the fuel rod internal pressure. In addition to the thermal insulating effect of crud, the NRC notes that a crud layer can also change surface topography, which has also been shown to affect cladding oxidation. As part of the ongoing rulemaking on performance-based ECCS analysis acceptance criteria, the NRC will evaluate the effects of these phenomena on cladding hydrogen content and embrittlement to determine their overall significance and if the regulations should be amended in this area.

*Comment:* A commenter asserted that the need to implement PRM-50-84 is shown by analysis of the NRC's February 28, 2006 inspection report on the River Bend Station (ML060600503). The inspection reviewed activities conducted by the licensee related to the

identification and resolution of problems, including calculated higher cladding temperatures in fuel Cycle 8 and the formation of tenacious crud on the fuel rod cladding and fuel rod bowing in River Bend Cycle 11. (RHL-2)

*NRC Response:*

The NRC agrees with the commenter that the River Bend experience shows that exceptionally large accumulations of oxide and crud can have an impact on thermal hydraulic analyses. As part of the ongoing rulemaking on performance-based ECCS analysis acceptance criteria, the NRC will evaluate: (i) The effects of these phenomena on cladding hydrogen content and embrittlement to determine their overall significance, (ii) if such large accumulations are likely to occur under current NRC requirements and industry practices, and (iii) if the NRC's requirements should be amended in this area.

*Comment:* Thermal-hydraulic analyses of ECCS performance approved by the NRC are often inadequate because they may not consider or improperly consider the thermal resistance of accumulated crud and/or oxidation on fuel cladding. Commenters cited examples of plant-specific ECCS analyses and asserted that had crud been properly considered, it is likely that the licensee would not be in compliance with the ECCS analysis acceptance criteria in § 50.46(b). (RHL-2, MEL 7-1, MEL 7-2, MEL 7-3)

*NRC Response:*

Assertions regarding potentially non-compliant ECCS analyses at the facilities mentioned are issues which are separate from resolving a petition for rulemaking on the adequacy of existing regulations. These assertions are not appropriate for consideration in a rulemaking context and are outside the scope of review of this PRM. This information has been referred to the Office Allegation Coordinator to determine the need for additional plant-specific regulatory review.

*Comment:* A commenter cited Generic Safety Issue No. 191 (GSI-191) regarding pressurized water reactors (PWRs), "Assessment of Debris Accumulation on PWR Sump Performance," and a related document, "Peer Review of GSI-191 Chemical Effects Research Program" (NUREG-1861), as justification for the petitioner's conclusion that the current regulations in § 50.46 should be amended. The commenter asserts that these documents discuss the possibilities of incomplete modeling of crud-related thermal properties of fuel cladding. (UCS 3-4)

*NRC Response:*

In GSI-191, the NRC is addressing issues involving PWR containment sump performance and related chemical effects during a loss-of-coolant accident. The GSI-191 issues are different from the long-term buildup of crud and oxidation on reactor fuel which typically occurs during plant operation. The NRC agrees with the commenter that dissolved solids in post-accident cooling water that impinges on hot fuel surfaces could be deposited or precipitated out and could impede heat transfer from the fuel. The evaluation of GSI-191 by the NRC is a separate issue.

*Comment:* A commenter identified two distinguishable layers in BWR fuel cladding deposits: an inner spinel structure and an outer iron oxide structure. The commenter further described the use of zinc in the coolant chemistry of some reactors to reduce radiation buildup on out-of-core surfaces and stated that the potential culprit in cladding overheating could be the tenacious ferrite deposit. Because the thermal conductivity of the ferrite is not known, the commenter concluded that the potential effects of the tenacious layer should be seriously evaluated. (LIN-4)

*NRC Response:*

The NRC has considered the comment and agrees with much of the information provided. The structure and the composition of crud deposits may be complex. Also, the relationship between crud deposition and coolant chemistry is difficult to completely characterize. As part of the ongoing rulemaking on performance-based ECCS analysis acceptance criteria, the NRC will evaluate the effects of these phenomena on cladding hydrogen content and embrittlement to determine their overall significance and if the regulations should be amended in this area.

*Comment:* A commenter referred to an NRC press release regarding an order issued to First Energy Nuclear Operating Company. The order addresses the prompt sharing of information that may be relevant to regulatory activities. The commenter asserted that a proprietary EPRI report, "BWR Fuel Deposit Sample Evaluation, River Bend Cycle 11 Crud Flakes," has information relevant to regulatory activities associated with PRM-50-84. The commenter implied that the River Bend Station licensee should be subject to a similar NRC order requiring that it provide information, such as the EPRI report, to the NRC. (RHL-9)

*NRC Response:*

The NRC reviewed the information about River Bend Cycle 11 provided by the petitioner and commenters and the inspection report (ML060600503)

prepared by the NRC inspection team that investigated the crud occurrences in River Bend Cycles 8 and 11. Although the NRC inspection report referenced the proprietary EPRI report, the NRC staff evaluating PRM-50-84 did not review the EPRI report. Nevertheless, the NRC agrees with the commenter that the River Bend experience shows that exceptionally large accumulations of oxide and crud can have an impact on thermal hydraulic analyses. As part of the ongoing rulemaking on performance-based ECCS analysis acceptance criteria, the NRC will evaluate the effects of these phenomena on cladding hydrogen content and embrittlement to determine their overall significance and if the regulations should be amended in this area.

*Comment:* A commenter opposed granting the petition because the petition relies heavily on abnormal operating experiences at four plants: River Bend (1998-1999 and 2001-2003), Three Mile Island 1 (1995), Palo Verde Unit 2 (1997), and Seabrook (1997), when localized sections of thick crud developed during normal operation. The commenter stated that NRC guidelines in Section 4.2 of the Standard Review Plan (NUREG-0800) do not specify a specific limit on the maximum allowable corrosion thickness, but require the impact of corrosion on the thermal and mechanical performance to be considered in fuel design analysis regarding the design stress and strain limits.

The commenter stated that cladding hydrogen content can have an adverse effect on ductile/brittle behavior of zirconium alloys heated into the beta phase and quenched (as would occur in a LOCA). The hydrogen impact on post-quench cladding ductility is a complex function of the oxidation temperature and pre-quench cooling path. The potential impact of hydrogen on the § 50.46(b) fuel acceptance criteria has been recognized for several years. Experimental programs are underway to assess this impact on current and newer cladding alloys developed to minimize hydrogen build-up during irradiation. The commenter further states that, based on these data, the NRC Office of Nuclear Regulatory Research is developing the technical basis for new performance-based fuel acceptance criteria in § 50.46(b) that include the effects of hydrogen.

In summary, the commenter states that the incidents cited by the petitioner were isolated operational events and would not have been prevented by imposing specific regulatory limits on crud thickness. The industry is actively

pursuing root cause evaluations and has developed corrective actions to mitigate further cases of excessive crud formation. The separate effects of hydrogen on cladding embrittlement will be addressed in future rulemaking to implement new acceptance criteria that are already being developed by the NRC. (NEI 5-1, NEI 5-2, NEI 5-3, NEI 5-4, NEI 5-5, NEI 5-6, NEI 5-7)

*NRC Response:*

The NRC agrees with a great deal of the technical information provided by the commenter and with the commenter's view that new regulations imposing specific regulatory limits on crud thickness would not necessarily have prevented the occurrences of heavy crud deposits resulting from the operational events cited by the petitioner. Nevertheless, formation of cladding crud and oxide layers is an expected condition at nuclear power plants. The thickness of these layers varies from plant to plant. The commenter acknowledged that the hydrogen impact on post-quench cladding ductility is a complex function of the oxidation temperature and pre-quench cooling path, and that these effects will be evaluated in the ongoing rulemaking to develop more performance-based cladding acceptance criteria. Because crud and oxide considerations also have potential impact on these new criteria, the NRC has determined that the petitioner's issues are sufficiently related to the ongoing cladding acceptance criteria rulemaking and should be considered in that proceeding.

*Comment:* Commenters stated that industry-funded research has resulted in chemistry controls, core design constraints, and operational guidance that reduce the susceptibility to heavy crud deposition and that many pressurized water reactors, especially those most susceptible to heavy crud deposition, make extensive use of the industry guidance. Commenters stated that the requested rulemaking would not make a significant contribution to safety because existing regulations and guidance already address consideration of crud-related parameters for core cooling. A commenter stated that NRC and licensee efficiency and effectiveness would be decreased by the requested regulations because significant resources would be required for the NRC to promulgate the rule, for licensees to generate additional information as part of the development of their ECCS evaluation models, and for the NRC to evaluate the licensees' data and analysis. (NEI 5-1, STARS 11-1, NEI 5-2, STARS 11-2, STARS 11-3)

*NRC Response:*

The NRC acknowledges that voluntary industry guidance, if properly implemented by licensees, can be effective in reducing the susceptibility to heavy crud deposition. However, the NRC has determined that crud and oxidation layers can have an impact on cladding hydrogen concentration. Because hydrogen uptake and concentration are being considered in the ongoing rulemaking to establish new performance-based ECCS acceptance criteria, consideration of crud and oxidation in that context is appropriate. If the NRC decides that additional regulations are needed regarding the accumulation of crud and oxidation, the NRC will estimate the additional NRC and licensee burden associated with the proposed changes and evaluate the overall cost-effectiveness of the requirements.

*Late Comment:* On September 5, 2008, after the close of the public comment period on PRM-50-84, the NRC received an additional public comment from Mr. Mark Leyse. The NRC reviewed the information contained in the late comment and determined that it provided no additional information that would affect the NRC's decision to address the issues raised in PRM-50-84 in the ongoing § 50.46(b) rulemaking.

#### Resolution of Petition

The NRC will consider the petitioner's requested rulemaking changes, the underlying issues relevant to the petition, and the comments submitted on PRM-50-84, in the ongoing rulemaking to revise § 50.46(b). This rulemaking is directed at establishing performance-based ECCS acceptance criteria to prevent fuel cladding embrittlement. The petitioner's requested changes and the underlying issues address crud, oxidation, and hydrogen content. These parameters may be factors in hydrogen embrittlement of zirconium cladding, which is being addressed in the § 50.46(b) rulemaking. After the conclusion of the NRC's technical evaluation of the factors relevant to fuel cladding embrittlement, the NRC will determine whether to adopt the petitioner's requested rulemaking changes in the § 50.46(b) rule. If the ongoing work to establish the technical basis for this rulemaking does not support the issuance of a proposed rule, the NRC will issue a supplemental **Federal Register** notice that addresses why the petitioner's requested rulemaking changes were not adopted by the NRC. With this resolution of the petition, the NRC closes the docket for PRM-50-84.

Dated at Rockville, Maryland, this 5th day of November 2008.

For the Nuclear Regulatory Commission.  
**Martin J. Virgilio,**  
*Acting Executive Director for Operations.*  
 [FR Doc. E8-27938 Filed 11-24-08; 8:45 am]  
**BILLING CODE 7590-01-P**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 71

[Docket No. FAA-2008-1186; Airspace  
 Docket No. 08-AGL-12]

#### Proposed Establishment of Class E Airspace; Tower, MN

**AGENCY:** Federal Aviation  
 Administration (FAA), DOT.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** This action proposes to establish Class E airspace at Tower, MN. Controlled airspace is necessary to accommodate new Standard Instrument Approach Procedures (SIAPs) at Tower Municipal Airport, Tower, MN. The FAA is taking this action to enhance the safety and management of Instrument Flight Rules (IFR) aircraft operations at Tower Municipal Airport.

**DATES:** 0901 UTC. Comments must be received on or before January 9, 2009.

**ADDRESSES:** Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12-140, Washington, DC 20590-0001. You must identify the docket number FAA-2008-1186/Airspace Docket No. 08-AGL-12, at the beginning of your comments. You may also submit comments on the Internet at <http://www.regulations.gov>. You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Office (telephone 1-800-647-5527), is on the ground floor of the building at the above address.

**FOR FURTHER INFORMATION CONTACT:** Scott Enander, Central Service Center, Operations Support Group, Federal Aviation Administration, Southwest Region, 2601 Meacham Blvd, Fort Worth, TX 76193-0530; telephone: (817) 222-5582.

#### SUPPLEMENTARY INFORMATION:

##### Comments Invited

Interested parties are invited to participate in this proposed rulemaking

by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. FAA-2008-1186/Airspace Docket No. 08-AGL-12." The postcard will be date/time stamped and returned to the commenter.

#### Availability of NPRMs

An electronic copy of this document may be downloaded through the Internet at <http://www.regulations.gov>. Recently published rulemaking documents can also be accessed through the FAA's web page at [http://www.faa.gov/airports\\_airtraffic/air\\_traffic/publications/airspace\\_amendments/](http://www.faa.gov/airports_airtraffic/air_traffic/publications/airspace_amendments/).

Additionally, any person may obtain a copy of this notice by submitting a request to the Federal Aviation Administration (FAA), Office of Air Traffic Airspace Management, ATA-400, 800 Independence Avenue, SW., Washington, DC 20591, or by calling (202) 267-8783. Communications must identify both docket numbers for this notice. Persons interested in being placed on a mailing list for future NPRM's should contact the FAA's Office of Rulemaking (202) 267-9677, to request a copy of Advisory Circular No. 11-2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedure.

#### The Proposal

This action proposes to amend Title 14, Code of Federal Regulations (14 CFR), Part 71 by establishing Class E airspace for SIAPs operations at Tower Municipal Airport, Tower, MN. The area would be depicted on appropriate aeronautical charts.

Class E airspace areas are published in Paragraph 6005 of FAA Order 7400.9S, dated October 3, 2008, and effective October 31, 2008, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore, (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the U.S. Code. Subtitle 1, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would establish controlled airspace at Tower Municipal Airport, Tower, MN.

#### List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (Air).

#### The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR Part 71 as follows:

#### PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

1. The authority citation for Part 71 continues to read as follows:

**Authority:** 49 U.S.C. 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959-1963 Comp., p. 389.

##### § 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9S, Airspace Designations and Reporting Points, dated October 3, 2008, and effective October 31, 2008, is amended as follows:

Paragraph 6005 Class E Airspace areas extending upward from 700 feet or more above the surface of the earth.

\* \* \* \* \*

#### AGL MN E5 Tower, MN [New]

Tower Municipal Airport, MN  
(lat. 47°49'06" N., long. 92°17'30" W.)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of Tower Municipal Airport, excluding that airspace within Prohibited Area P-205.

\* \* \* \* \*

Issued in Fort Worth, TX on November 14, 2008.

Roger M. Trevino,

Acting Manager, Operations Support Group,  
ATO Central Service Center.

[FR Doc. E8-28034 Filed 11-24-08; 8:45 am]

BILLING CODE 4910-13-P

## CONSUMER PRODUCT SAFETY COMMISSION

### 16 CFR Chapter II

#### Options to Address Crib Safety Hazards; Advance Notice of Proposed Rulemaking; Request for Comments and Information

**AGENCY:** Consumer Product Safety Commission.

**ACTION:** Advance Notice of Proposed Rulemaking.

**SUMMARY:** The Commission is required by section 104 of the Consumer Product Safety Improvement Act of 2008 to examine and assess, in consultation with consumer groups, juvenile product manufacturers, and independent child product engineers and experts, the voluntary standards for, *inter alia*, full size and non-full-size cribs. In particular, the Commission has determined it will examine and assess potential design and durability issues by seeking input and information about hardware systems, other hardware issues, assembly and instructional problems and wood quality/strength issues for full size and non-full-size cribs with stationary or drop-side construction.

This advance notice of proposed rulemaking (ANPR) is being issued to commence the consultative process with stakeholders to examine and assess the effectiveness of the voluntary standards for full size and non-full-size cribs.<sup>1</sup> The Commission solicits written comments concerning the risks of injury associated with full size and non-full-size cribs, possible ways to address these risks,

<sup>1</sup> The Commission voted 2-0 to publish the FR notice as drafted.

and the economic impacts of the various regulatory alternatives.

**DATES:** Comments and submissions in response to this notice must be received by January 26, 2009.

**ADDRESSES:** Comments should be filed by e-mail to [cribsanpr@cpsc.gov](mailto:cribsanpr@cpsc.gov). Comments also may be filed by telefacsimile to (301) 504-0127 or mailed, preferably in five copies, to the Office of the Secretary, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, Maryland 20814; telephone (301) 504-7530. Comments should be captioned ANPR for Options to Address Crib Safety Hazards.

#### FOR FURTHER INFORMATION CONTACT:

Patricia L. Hackett, Directorate for Engineering Sciences, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, Maryland 20814; telephone (301) 504-7577 or e-mail: [phackett@cpsc.gov](mailto:phackett@cpsc.gov).

#### SUPPLEMENTARY INFORMATION:

##### A. Background

###### 1. Voluntary Standards Activity

CPSC staff has participated in ASTM subcommittee activities on cribs since the standards were first developed. While ASTM has made some revisions in response to our input in the past, several staff recommendations regarding crib hardware that this ANPR addresses (Tab A at <http://www.cpsc.gov/library/foia/foia09/brief/ashaz.pdf>) have been considered by the voluntary standards subcommittee, but as of yet, no additional performance requirements have been agreed upon. More recent staff recommendations have involved assembly issues and strength/quality of wood. (Tab B at <http://www.cpsc.gov/library/foia/foia09/brief/ashaz.pdf>).

###### 2. Compliance Activities

The Office of Compliance staff has opened seven investigative cases pertaining to crib hazards since the initiation of the CPSC early warning system (EWS) in November 2007. Five of these investigations resulted in recalls of over 2.5 million cribs and pertain to such issues as drop-side hardware defects, wood quality issues, and dimensional defects. Investigations that are still pending resolution also pertain to drop-side hardware related problems.

##### B. Statutory Authority

Section 104(b)(1)(A) of the Consumer Product Safety Improvement Act of 2008 (CPSIA), Public Law 110-314, August 14, 2008, requires the Commission in consultation with

representatives of consumer groups, juvenile product manufacturers, and independent child product engineers and experts, [to] examine and assess the effectiveness of any voluntary consumer product safety standards for durable infant or toddler products. Because of the amount of information necessary to address the range of technical issues involved in evaluating the hazards posed by cribs, and the amount of time needed by CPSC staff to evaluate that information prior to the Commission issuing a notice of proposed rulemaking under section 104(b)(1)(B), the Commission is using this ANPR as part of the consultation process.

The issuance of this ANPR for purposes of undertaking the consultative process required by section 104(b)(1)(A), does not begin the rulemaking process for full size and non-full-size cribs mandated by section 104(b)(1)(B) of the CPSIA. That will be done when the Commission determines to do so according to its priorities and resources.

##### C. The Product

The Commission has issued mandatory standards under the Federal Hazardous Substances Act (FHSA) for both full-size cribs and non-full-size baby cribs (16 CFR 1508 and 1509 respectively). A full-size crib is defined at 16 CFR 1508 as a bed designed to provide sleeping accommodations for an infant and used in the home, with the following interior dimensions: 71 ± 1.6 centimeters (28 ± 5/8 inches) wide by 133 ± 1.6 centimeters (52 3/8 ± 5/8 inches) long.

A non-full-size crib is defined at 16 CFR 1509 with the same wording as a full-size crib, but with dimensions that are either greater or smaller than the ones contained in 16 CFR 1508. The regulation specifically excludes mesh/net/screen cribs, nonrigidly constructed cribs, cradles, car beds, baby baskets, and bassinets.

##### D. The Risk of Death or Injury

###### 1. Incident Data

Since its inception in November 2007, the CPSC EWS program has led to the evaluation of over 1200 crib incidents and related issues. These include incidents involving hardware systems, assembly errors, wood quality, bedding issues, paint problems, and general design concerns. Since that time, the EWS program has identified many issues with cribs which have led or could lead to entrapment and strangulation. In the last year, CPSC staff has assigned over 250 crib incidents for follow up in-depth

investigations (IDIs), including nine entrapment deaths and many injuries or near misses, where hardware has been the issue.

As a result of EWS review, the Office of Compliance staff has opened seven investigative cases pertaining to crib hazards. Five of these investigations resulted in a recall of over 2.5 million cribs and pertain to such issues as drop side hardware defects, wood quality issues, and dimensional defects. Investigations that are still pending resolution also pertain to drop side hardware related problems.

## 2. Analysis of Incident Data

### a. Drop-Side Cribs and Related Hardware Systems

A review of the incident data and follow up investigations seen in the CPSC EWS program have indicated that cribs with drop sides are the type most likely to experience hardware problems. Due to their design, these cribs contain additional moving parts and have more non-rigid joints or connections between components than non-drop-side cribs. Of particular interest are several incidents where the drop side disengaged in one or more corners due to a variety of reasons, including design defects. These disengagements can go undetected by parents or caregivers and can worsen when the baby pushes or leans against the side of the crib.

With some drop-side-crib designs, because of the presence of the drop side, the rest of the crib can often experience more movement or stresses during foreseeable use than the same crib without a drop side. This can result in problems arising in other components on the crib, such as the mattress-support system, or the stationary-side-hardware connections. Thus, hazards seen on other hardware systems on a drop-side crib might be caused or exacerbated by the design and use of the drop-side system. CPSC staff does not believe that there are adequate performance requirements in either the mandatory or ASTM voluntary standards pertaining to the durability of drop-side systems and related hardware.

### b. Other Hardware Issues

The CPSC EWS program has also uncovered other hardware issues in cribs experienced on both drop-side cribs and non-drop-side cribs. Although some cribs do not have a drop side, they all have mattress-support systems that typically use hardware to connect to the sides of the crib. CPSC staff has reviewed dozens of incident reports from the EWS program relating to mattress support systems, many of which were on drop-side cribs but some that have failed in non-drop-side cribs.

These failures typically involve hardware issues, though some are wood component problems.

Though not as numerous, CPSC staff has also reviewed incident reports of problems with rigidly connected components, such as a bolted connection or a screw-to-metal insert connection between two stationary sides of the crib. These incidents also span both drop-side cribs and non-drop-side cribs.

Missing, damaged or broken hardware can result in the partial separation of a crib component from the rest of the crib. This can generate gaps that may allow an infant's body to pass through and trap the infant at the head or neck, resulting in strangulation deaths. Infants can also suffocate when their head becomes wedged in the space between the crib frame and the mattress.

CPSC staff does not believe that there are adequate performance requirements in either the mandatory or ASTM voluntary standards pertaining to the durability of other crib hardware systems.

### c. Assembly and Instructional Issues

In many incidents, including at least four fatalities, consumer-installed crib components were found to have been installed incorrectly or incompletely. These component installation errors can easily remain undetected by the parents because the crib will still work despite the mis-assembly. CPSC staff's review of various crib assembly instructions shows a varied approach and often inadequate warnings regarding the consequences of a mis-installation. CPSC staff does not believe that there are adequate requirements in either the mandatory or ASTM voluntary standards pertaining to assembly hazards.

### d. Wood Quality/Strength

Another serious hazard uncovered by the CPSC EWS program was a quality/strength issue with wood components. There are no performance requirements in either the CPSC mandatory or ASTM voluntary standards for wood quality and integrity. A wood quality problem can result in a fractured or missing slat, creating a gap that can lead to entrapment. CPSC staff does not believe that there are adequate performance requirements in either the mandatory or ASTM voluntary standards pertaining to wood strength or quality.

## E. Existing Standards

### 1. Summary of CPSC Regulatory Activity

The full-size crib regulation, 16 CFR 1508, was published in 1973 and amended in 1982. The regulation for non-full-size cribs, 16 CFR 1509, was

published in 1976 and amended in 1982. Both standards currently contain requirements pertaining to dimensions, spacing of components, hardware, construction and finishing, assembly instructions, cutouts, identifying marks, warning statements, and compliance declarations. In addition, 16 CFR 1509 contains a requirement regarding mattresses.

On December 16, 1996, the Commission published an ANPR pertaining to crib slat disengagement. The basis for the ANPR was the incident data for an 11-year span, which totaled 138 incidents, including 12 deaths due to entrapment. When slats disengage from the crib-side panel, a gap is left between the remaining slats. A child may be able to get his or her body through the space but not his or her head, resulting in entrapment and potentially severe injury or death.

Following the publication of the ANPR, ASTM International (formerly known as the American Society for Testing and Materials) published a revised standard for full-size cribs (ASTM F 1169-99) in July 1999, which included requirements to address crib-slat integrity. Since that time, the rulemaking has remained open and CPSC staff has been monitoring crib incidents, including slat problems and other potential entrapment hazards.

### 2. Summary of Voluntary Standards Activity

There are several voluntary standards addressing baby cribs. These include, but are not limited to standards issued by the following organizations: ASTM International, Underwriters Laboratories (UL), British Standards Institute (BSI), Health Canada, and the International Organization for Standardization (ISO).

The ASTM crib standards for full size and non-full-size cribs are the ones most widely accepted and conformed to in the U.S. In addition, the Juvenile Product Manufacturers Association (JPMA) has a certification program that manufacturers can join to demonstrate and certify that their products meet current applicable ASTM standards. Members in good standing can display a JPMA certification seal on their products as a symbol that they are certified.

The ASTM standard on full-size cribs (ASTM F 1169) was first published in 1988 and the current version was published in 2007. This standard refers to 16 CFR 1508 and includes several additional requirements, including corner-post-extension dimensions, mattress-support-system requirements, and crib-side-performance requirements. The ASTM standard on

non-full-size cribs (ASTM F 1822) was first published in 1997. In 2002, the standard was combined with the play yard standard, and the current version (ASTM F 406) was published in 2008. This standard has many requirements, some pertaining only to play yards, and others that are very similar to what is in ASTM F 1169, pertaining to rigid sided, non-full-size cribs.

#### F. Solicitation of Information and Comments

CPSC staff is interested in obtaining information and data to help in the possible development of a mandatory regulation. Below, by category, is the information requested:

##### Product Availability:

- Whether there is a crib design on the market that addresses the drop-side and hardware issues identified in Section D above.

- Whether there is a crib concept or patent that addresses the drop-side and hardware issues identified in Section D above.

##### Market Information:

- The U.S. market share of drop-side cribs versus other types of cribs.

- The U.S. market share of domestic manufacturers versus foreign manufacturers.

- The distribution of crib sales by manufacturer and/or retail price for both drop-side and other cribs.

- The models and model numbers of cribs and the annual sales figures for each model from the time such product was made available in the marketplace.

- The names and addresses of manufacturers and distributors who make and sell drop-side and other cribs.

##### Costs of Various Alternatives:

- The costs to manufacturers of redesigning cribs to remove the risk of entrapment and/or the cost of removing these cribs from the market.

- The costs of mandating a testing requirement, a quality control/quality assurance program requirement, a labeling or instructions requirement, and/or recordkeeping requirement (especially for small firms).

- Comparisons of the costs of producing drop-side cribs versus any available substitute products.

- Other information on the potential costs of alternative rules.

##### Benefits of Various Alternatives:

- Comparisons of the utility to consumers of using drop-side cribs versus any available substitute products.

- The benefits of mandating a testing requirement, a quality control/quality assurance program requirement, a labeling or instructions requirement, and/or recordkeeping requirement.

- Other information on the potential benefits of alternative rules.

##### Small Business Impacts:

- The likelihood and nature of any significant economic impact of a rule on small entities.

- Alternatives the Commission should consider, as well as the costs and benefits of those alternatives to minimize the burdens or costs to small entities.

##### Household Data/Information:

- The estimated average expected life of a crib and/or an estimated number of cribs in U.S. households.

- Information or data on the primary reasons consumers purchase and/or use drop-side cribs versus other types of cribs.

- Information concerning consumer use of cribs, specifically, how long they own them, how frequently they use them and for what duration, and product life (in years). Also, information concerning the frequency of resale and/or handing down to other consumers.

##### Foreign Crib Experience:

- Information concerning the types of cribs used in other countries and how the use pattern may be different from that seen in the U.S.

- Injury and death data pertaining to crib uses outside the U.S.

- Standards used by crib manufacturers that market to non-U.S. markets.

##### Incident Data:

- Other crib incident data, not already contained in CPSC data bases, regardless of whether the incident was the fault of the consumer, user, manufacturer, distributor, shipper, retailer or assembler.

- Crib parts replacements information. Including parts sold or offered by the manufacturer, as potential safety problems can often be predicted by looking at the pattern of requests for replacement parts for specific crib models or lines.

- Any studies regarding injuries, deaths, or potential injuries associated with drop-sided vs. non-drop-sided cribs.

##### Other Standards or Testing Requirements:

- Information on other standards not outlined in this ANPR, including test requirements specific to a manufacturer or retailer that should be considered for the mandatory regulation.

- Information concerning experience with crib standards other than the CPSC mandatory regulations and the ASTM standards.

Comments should be filed by e-mail to [cribsanpr@cpsc.gov](mailto:cribsanpr@cpsc.gov). Comments also may be filed by telefacsimile to (301) 504-0127 or mailed, preferably in five copies, to the Office of the Secretary, Consumer Product Safety Commission,

4330 East West Highway, Bethesda, Maryland 20814; telephone (301) 504-7530. Comments should be captioned "ANPR for Options To Address Crib Safety Hazards." All comments and submissions should be received no later than January 26, 2009.

Dated: November 18, 2008.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

[FR Doc. E8-27753 Filed 11-24-08; 8:45 am]

BILLING CODE 6355-01-P

## DEPARTMENT OF EDUCATION

### 34 CFR Part 385

RIN 1820-AB61

[Docket ID ED-2008-OSERS-0010]

#### Rehabilitation Training

**AGENCY:** Office of Special Education and Rehabilitative Services, Department of Education.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Secretary proposes to amend the regulations governing the Rehabilitation Training Program. The amendment is needed to clarify the membership of advisory committees for projects funded under this program.

**DATES:** We must receive your comments on or before December 26, 2008.

**ADDRESSES:** Submit your comments through the Federal eRulemaking Portal or via postal mail, commercial delivery, or hand delivery. We will not accept comments by fax or by e-mail. Please submit your comments only one time, in order to ensure that we do not receive duplicate copies. In addition, please include the Docket ID at the top of your comments.

• *Federal eRulemaking Portal:* Go to <http://www.regulations.gov> to submit your comments electronically. Information on using [Regulations.gov](http://www.regulations.gov), including instructions for accessing agency documents, submitting comments, and viewing the docket, is available on the site under "How To Use This Site."

• *Postal Mail, Commercial Delivery, or Hand Delivery.* If you mail or deliver your comments about the proposed regulation, address them to Ruth Brannon, U.S. Department of Education, 400 Maryland Avenue, SW., room 5052, Potomac Center Plaza (PCP), Washington, DC 20202-2800.

**Privacy Note:** The Department's policy for comments received from members of the public (including those comments submitted by mail, commercial delivery, or hand

delivery) is to make these submissions available for public viewing in their entirety on the Federal eRulemaking Portal at <http://www.regulations.gov>. Therefore, commenters should be careful to include in their comments only information that they wish to make publicly available on the Internet.

**FOR FURTHER INFORMATION CONTACT:**

Ruth Brannon. Telephone: (202) 245-7278 or via Internet:

[ruth.brannon@ed.gov](mailto:ruth.brannon@ed.gov).

If you use a telecommunications device for the deaf (TDD), call the Federal Relay Service (FRS), toll free, at 1-800-877-8339.

Individuals with disabilities can obtain this document in an alternative format (e.g., Braille, large print, audiotape, or computer diskette) on request to the contact person listed under **FOR FURTHER INFORMATION CONTACT**.

**SUPPLEMENTARY INFORMATION:**

**Invitation to Comment**

We invite you to submit comments regarding the proposed regulation. We invite you to assist us in complying with the specific requirements of Executive Order 12866 and its overall requirement of reducing regulatory burden that might result from this proposed regulation. Please let us know of any further opportunities we should take to reduce potential costs or increase potential benefits while preserving the effective and efficient administration of the program.

During and after the comment period, you may inspect all public comments about the proposed regulation by accessing [Regulations.gov](http://Regulations.gov). You may also inspect the comments, in person, in room 5053, Potomac Center Plaza, 550 12th Street, SW., Washington, DC, between the hours of 8:30 a.m. and 4 p.m., Eastern time, Monday through Friday of each week except Federal holidays.

**Assistance to Individuals With Disabilities in Reviewing the Rulemaking Record**

On request, we will supply an appropriate aid, such as a reader or print magnifier, to an individual with a disability who needs assistance to review the comments or other documents in the public rulemaking record for the proposed regulation. If you want to schedule an appointment for this type of aid, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

**Background**

Current 34 CFR 385.40 lists members of minority groups as one of the

categories of mandatory participants on advisory committees for projects funded under the Rehabilitation Training Program. We propose to amend § 385.40 by removing the requirement that a grantee include members of minority groups on its project advisory committee and adding a requirement that a grantee include individuals who are knowledgeable about the needs of individuals with disabilities from diverse groups, including minority groups.

These proposed changes would make 34 CFR 385.40 consistent with the Supreme Court ruling in *Adarand Constructors, Inc. v. Peña*, 515 U.S. 200 (1995), in which the Court held that classifications based upon race or national origin are consistent with equal protection requirements of the Constitution only if they are narrowly tailored measures that further compelling governmental interests. The Secretary believes that current § 385.40 is not consistent with the equal protection requirements because it constitutes a quota based upon race or national origin that is not narrowly tailored in a manner that furthers a compelling government interest.

Thus, these proposed changes are necessary to ensure that grantees do not select individuals to serve on project advisory committees on the basis of their race or national origin. These changes also would add a new requirement that project advisory committees have members who are knowledgeable about the needs of individuals with disabilities from diverse groups, including minority groups. This new requirement would ensure that the committees have broader knowledge of the diverse range of needs of individuals with disabilities.

**Significant Proposed Regulations**

We discuss here the substantive issues regarding the proposed changes. Generally, we do not address proposed regulatory provisions that are technical or otherwise minor in effect.

*Section 385.40* What are the requirements pertaining to the membership of a project advisory committee?

*Statute:* Section 302 of the Rehabilitation Act of 1973, as amended (29 U.S.C. 772), authorizes the Department to provide grants to eligible entities to increase the numbers and upgrade the skills of qualified rehabilitation personnel. Under this authority, the Department implements the Rehabilitation Training Program.

*Current Regulation:* Current § 385.40 requires that, if a project funded under

34 CFR parts 386 through 390 or part 396 (the Rehabilitation Training Program) establishes an advisory committee, its membership must include individuals with disabilities or parents, family members, guardians, advocates, or other authorized representatives of the individuals; members of minority groups; trainees; and providers of vocational rehabilitation and independent living rehabilitation services.

*Proposed Regulation:* Proposed § 385.40 would remove "members of minority groups" and add "individuals who are knowledgeable about the needs of individuals with disabilities from diverse groups, including minority groups."

*Reasons:* The proposed changes would make clear that grantees cannot select project advisory committee members on the basis of their race or national origin. The proposed changes also would achieve the Department's objective for project advisory committees to include individuals who are knowledgeable about the needs of individuals with disabilities from diverse groups. Grantees would be able to select individuals, including individuals who are members of minority groups, as advisory committee members if they possess knowledge of the needs of individuals with disabilities from diverse groups or meet one of the other membership requirements in § 385.40. By no longer constituting a quota based upon race or national origin, this requirement is consistent with the *Adarand* case and the equal protection requirements of the Constitution.

**Executive Order 12866**

Under Executive Order 12866, the Secretary must determine whether this regulatory action is "significant" and therefore subject to the requirements of the Executive order and review by OMB. Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as an action likely to result in a rule that may (1) have an annual effect on the economy of \$100 million or more, or adversely affect a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments, or communities in a material way (also referred to as an "economically significant" rule); (2) create serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) create novel legal or policy issues

arising out of legal mandates, the President's priorities, or the principles set forth in the Executive order. The Secretary has determined that this regulatory action is not significant under the Executive order.

#### 1. Potential Costs and Benefits

Under Executive Order 12866, we have assessed the potential costs and benefits of this regulatory action. The benefits accruing to the Rehabilitation Training Program resulting from this proposed amendment outweigh the costs of making the changes. The proposed regulation would benefit grantees by requiring advisory committees to have members who are knowledgeable about the needs of individuals with disabilities, thereby making the committee a more effective advisor to the grantee. The requirement to select committee members with knowledge of the needs of individuals with disabilities from diverse groups would not impose a cost the grantee would not otherwise incur in the process of creating an advisory committee.

We have also determined that this regulatory action would not unduly interfere with State, local, and tribal governments in the exercise of their governmental functions.

#### 2. Clarity of the Regulations

Executive Order 12866 and the Presidential memorandum on "Plain Language in Government Writing" require each agency to write regulations that are easy to understand.

The Secretary invites comments on how to make the proposed regulation easier to understand, including answers to questions such as the following:

- Are the requirements in the proposed regulation clearly stated?
- Does the proposed regulation contain technical terms or other wording that interferes with its clarity?
- Does the format of the proposed regulation (grouping and order of sections, use of headings, paragraphing, etc.) aid or reduce its clarity?
- Would the proposed regulation be easier to understand if we divided it into more (but shorter) sections? (A "section" is preceded by the symbol "\$" and a numbered heading; for example, § 385.40.)
- Could the description of the proposed regulation in the **SUPPLEMENTARY INFORMATION** section of this preamble be more helpful in making the proposed regulation easier to understand? If so, how?
- What else could we do to make the proposed regulation easier to understand?

To send any comments that concern how the Department could make the proposed regulation easier to understand, see the instructions in the **ADDRESSES** section of this preamble.

#### Regulatory Flexibility Act Certification

The Secretary certifies that the proposed regulation would not have a significant economic impact on a substantial number of small entities. The proposed regulation would affect States and public or nonprofit agencies and organizations, including Indian tribes and institutions of higher education, that are eligible to receive funding under the Rehabilitation Training Program. Some of these entities would be considered small entities according to the U.S. Small Business Administration Size Standards. However, the changes in the proposed regulation would not have a significant economic impact on applicants in terms of the cost of establishing a project advisory committee under this program.

#### Paperwork Reduction Act of 1995

The proposed regulation does not contain any information collection requirements.

#### Intergovernmental Review

This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. One of the objectives of the Executive order is to foster an intergovernmental partnership and a strengthened federalism. The Executive order relies on processes developed by State and local governments for coordination and review of proposed Federal financial assistance.

This document provides early notification of our specific plans and actions for this program.

#### Assessment of Educational Impact

In accordance with section 441 of the General Education Provisions Act, 20 U.S.C. 1221e-4, the Secretary particularly requests comments on whether the proposed regulation would require transmission of information that any other agency or authority of the United States gathers or makes available.

#### Electronic Access to This Document

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To use PDF you must have Adobe Acrobat Reader, which is available free at this site. If you have questions about

using PDF, call the U.S. Government Printing Office (GPO), toll free, at 1-888-293-6498; or in the Washington, DC area at (202) 512-1530.

**Note:** The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: <http://www.gpoaccess.gov/nara/index.html>.

(Catalog of Federal Domestic Assistance Numbers: 84.129 Long Term Training; 84.275 Special Programs, National Clearinghouse of Rehabilitation Training Materials; 84.264 Rehabilitation Continuing Education Programs; 84.160 Training of Interpreters for Deaf Individuals; 84.265 In-Service Training; 84.246 Short Term Training; 84.263 Experimental and Innovative Training; 84.246 Special Programs, Client Assistance Program Training; 84.315 Capacity Building Projects for Traditionally Underserved Populations.)

#### List of Subjects in 34 CFR Part 385

Education, Grant programs—education, Reporting and recordkeeping requirements, Vocational rehabilitation.

Dated: November 20, 2008.

Tracy R. Justesen,

*Assistant Secretary for Special Education and Rehabilitative Services.*

For the reasons discussed in the preamble, the Secretary proposes to amend part 385 of title 34 of the Code of Federal Regulations as follows:

#### PART 385—REHABILITATION TRAINING

1. The authority citation for part 385 is revised to read as follows:

**Authority:** 29 U.S.C. 709(c) and 772, unless otherwise noted.

2. Section 385.40 is revised to read as follows:

#### § 385.40 What are the requirements pertaining to the membership of a project advisory committee?

If a project funded under 34 CFR parts 386 through 390 or 34 CFR part 396 establishes an advisory committee, its membership must include individuals with disabilities or parents, family members, guardians, advocates, or other authorized representatives of the individuals; individuals who are knowledgeable about the needs of individuals with disabilities from diverse groups, including minority groups; trainees; and providers of vocational rehabilitation and independent living rehabilitation services.



(Authority: Sec. 12(c) of the Act; 29 U.S.C. 709(c))  
 [FR Doc. E8-28010 Filed 11-24-08; 8:45 am]  
 BILLING CODE 4000-01-P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 228

[EPA-R10-OW-2008-0826; FRL-8744-8]

### Ocean Dumping; Designation of Ocean Dredged Material Disposal Sites Offshore of the Umpqua River, OR

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed Rule.

**SUMMARY:** EPA is withdrawing an earlier proposal to designate an ocean dredged material disposal site near the mouth of the Umpqua River, Oregon, and is proposing to designate two new ocean dredged material disposal sites located offshore of the Umpqua River, Oregon. EPA's proposed rule was published at 56 FR 49858 (October 2, 1991). Changes since that time to the single site EPA proposed, as well as changes to the ocean dumping program, including changes to the Marine Protection, Research, and Sanctuaries Act, as amended (MPRSA), 33 U.S.C. 1401 to 1445, give rise to EPA's decision to withdraw the October 2, 1991, proposal and to propose two new sites near the mouth of the Umpqua River. The new sites are needed primarily to serve the long-term need for a location to dispose of material dredged from the Umpqua River navigation channel, and to provide a location for the disposal of dredged material for persons who have received a permit for such disposal. The newly designated sites will be subject to ongoing monitoring and management to ensure continued protection of the marine environment.

**DATES:** Comments on this proposed rule must be received by December 26, 2008.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA-R10-OW-2008-0826 by one of the following methods:

- <http://www.regulations.gov>: Follow the on-line instructions for submitting comments.

- **E-mail:**  
*Freedman.Jonathan@epa.gov*.
- **Mail:** Jonathan Freedman, U.S. Environmental Protection Agency, Region 10, Office of Ecosystems, Tribal and Public Affairs (ETPA-083), Aquatic Resources Unit, 1200 Sixth Avenue, Suite 900, Seattle, Washington 98101.

**Instructions:** Direct your comments to Docket ID No. EPA-R10-OW-2008-0826. 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 the Web site, <http://www.regulations.gov>, or through e-mail. 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 e-mail comment directly to EPA without going through the Web site, <http://www.regulations.gov>, your e-mail 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 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 or 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 may not be 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 during normal business hours at the U.S. Environmental Protection Agency, Region 10, Library, 10th Floor, 1200 Sixth Avenue, Suite 900, Seattle, Washington 98101. For access to the documents at the Region 10 Library, contact the Region 10 Library Reference Desk at (206) 553-1289, between the hours of 9 a.m. and 11:30 a.m., and between the hours of 1 p.m. and 4 p.m., Monday through Friday, excluding legal holidays, for an appointment.

#### FOR FURTHER INFORMATION CONTACT:

Jonathan Freedman, U.S. Environmental Protection Agency, Region 10, Office of Ecosystems, Tribal and Public Affairs (ETPA-083), Aquatic Resources Unit, 1200 Sixth Avenue, Suite 900, Seattle, Washington 98101, *phone number:* (206) 553-0266, *e-mail:* [freedman.jonathan@epa.gov](mailto:freedman.jonathan@epa.gov), or contact Jessica Winkler, U.S. Environmental Protection Agency, Region 10, Office of Ecosystems, Tribal and Public Affairs (ETPA-183), Aquatic Resources Unit, 1200 Sixth Avenue, Suite 900, Seattle, Washington 98101, *phone number:* (206) 553-7369, *e-mail:* [winkler.jessica@epa.gov](mailto:winkler.jessica@epa.gov).

#### SUPPLEMENTARY INFORMATION:

##### 1. Potentially Affected Persons

Persons potentially affected by this proposed action include those who seek or might seek permits or approval by EPA to dispose of dredged material into ocean waters pursuant to the Marine Protection, Research, and Sanctuaries Act, as amended (MPRSA), 33 U.S.C. 1401 to 1445. EPA's action would be relevant to persons, including organizations and government bodies seeking to dispose of dredged material in ocean waters offshore of the Umpqua River, Oregon. Currently, the U.S. Army Corps of Engineers (Corps) would be most affected by this proposed action. Potentially affected categories and persons include:

Category	Examples of potentially regulated persons
Federal Government .....	U.S. Army Corps of Engineers Civil Works Projects, and other Federal Agencies.
Industry and General Public .....	Port Authorities, Marinas and Harbors, Shipyards and Marine Repair Facilities, Berth Owners.
State, local and tribal governments .....	Governments owning and/or responsible for ports, harbors, and/or berths, Government agencies requiring disposal of dredged material associated with public works projects.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding persons likely to be affected by this action. For any questions regarding the applicability of this action to a particular person, please refer to the contact person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

## 2. Background

### a. History of Disposal Sites Offshore of the Umpqua River, Oregon

Two ocean dredged material disposal sites, an Interim Site and an Adjusted Site, have been used by the U.S. Army Corps of Engineers (Corps) for disposal of sediments dredged from the Umpqua River navigation project. The Interim Site was included in the list of approved ocean disposal sites for dredged material in the **Federal Register** in 1977 (42 FR 2461). A later realignment of the approach channel to the Umpqua River estuary placed the navigation channel over the Interim Site. In 1991 site, the Adjusted Site was selected by the Corps pursuant to the Corps' authority under Section 103 of the MPRSA. The use of the Interim Site was terminated at that time. Selection of the Adjusted Site was intended to reduce potential hazards associated with navigational conflicts in the channel and associated with

mounding of dredged material at the Interim Site. The selection of the Adjusted Site was also intended to increase long-term disposal site capacity near the mouth of the Umpqua River. EPA concurred on the selection of the Adjusted Site and approved the Corps' request to continue to use the site through the end of the 2008 dredging season. The Adjusted Site is not a suitable candidate for designation by EPA pursuant to Section 102 of the MPRSA because use of the Adjusted Site resulted in mounding that severely limited site capacity. In 1996, shoaling and breaking waves associated with mounding at the Adjusted Site were reported. Subsequently a site utilization study was conducted by the Corps in 1998. That study found evidence of mounding sufficient to warrant serious concern regarding impact on the wave environment near the Umpqua River entrance channel. To address that concern the volume of dredged material placed at the Adjusted Site was reduced from an average annual volume of 188,000 cubic yards (cy) prior to 1999 to an average annual volume of 108,000 cy from 1999 to 2007. EPA determined that alternatives to the Adjusted Site would be needed for long-term disposal capacity near the mouth of the Umpqua River.

### b. Location and Configuration of Proposed Umpqua River Ocean Dredged Material Disposal Sites

Today, EPA withdraws the rule the Agency proposed on October 2, 1991, at 56 FR 49858, to designate an Umpqua River site, and simultaneously proposes to designate two Umpqua River ocean dredged material sites to the north and south, respectively, of the existing Adjusted Site. The coordinates for the two proposed sites are listed below. The figure below shows the location of the Umpqua River ocean dredged material disposal sites (Umpqua River ODMD Sites or Sites) EPA proposes to designate today. The configuration of each Site is expected to allow dredged material disposed in shallower portions of each Site to naturally disperse into the littoral zone without creating mounding conditions that could contribute to adverse impacts to navigation. The proposed configuration will allow EPA to ensure that disposal of dredged material into the Sites will be managed so that as much material as possible is retained in the active littoral drift area to augment shoreline building processes.

The coordinates for the two Umpqua River ODMD Sites, as proposed today, are, in North American Datum 83 (NAD 83):

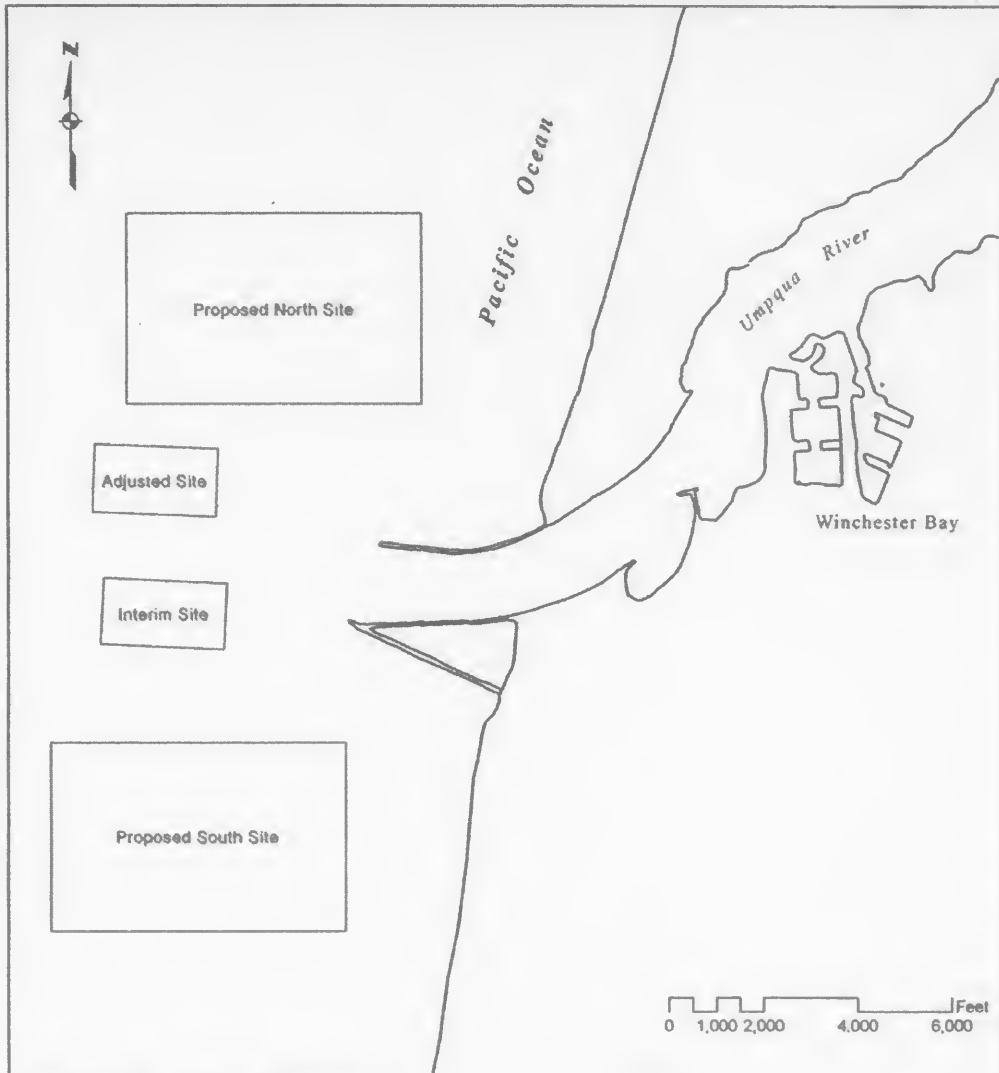
Proposed North Umpqua ODMD Site	Proposed South Umpqua ODMD Site
43° 41' 23.09" N, 124° 14' 20.28" W .....	43° 39' 32.31" N, 124° 14' 35.60" W.
43° 41' 25.86" N, 124° 12' 54.61" W .....	43° 39' 35.23" N, 124° 13' 11.01" W.
43° 40' 43.62" N, 124° 14' 17.85" W .....	43° 38' 53.08" N, 124° 14' 32.94" W.
43° 40' 46.37" N, 124° 12' 52.74" W .....	43° 38' 55.82" N, 124° 13' 08.36" W.

The two proposed Sites are situated in approximately 30 to 120 feet of water located to the north and south of the entrance to the Umpqua River on the southern Oregon Coast (see Figure 1). The recommended dimensions of each of the proposed ocean disposal sites are 6,300 by 4,000 feet. Each disposal site will contain a drop zone, defined by a 500-foot setback inscribed within all sides of the site boundary, reducing the

permissible disposal area to a zone 5,300 feet long by 3,000 feet wide. The drop zone will ensure that dredged material initially stays within each Site. Limited onshore transport of material disposed of at the proposed Sites is expected because of the nature of the prevailing currents and wave transport in the vicinity of the Sites. Net predicted material transport at the proposed Sites is southward in the

summer months and northward during the remainder of the year. These transport mechanisms are expected to move material into the active littoral drift area and to significantly decrease or eliminate mounding as an issue for disposal of dredged material near the mouth of the Umpqua River.

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**Figure 1 is a diagram of the Proposed Section 102 Sites (North and South), the existing Section 103 Adjusted Site, and the historical Interim Site**

*c. Management and Monitoring of the Proposed Sites*

The proposed Umpqua River ODM Sites are expected to receive sediments dredged by the Corps to maintain the federally authorized navigation project at the Umpqua River, Oregon and dredged material from other persons who have obtained a permit for the disposal of dredged material at the Sites. There are no existing Corps permits issued to other entities for use of the 103-Selected site (the Adjusted Site); therefore no permit modifications are required as a result of this action. All persons using the Sites are required to follow the Site Management and Monitoring Plan (SMMP) for the Umpqua River ODM Sites. The SMMP is available as a draft document for review and comment by the public as of today's action proposing the designation of the Umpqua River ODM Sites. The draft SMMP includes management and monitoring requirements to ensure that dredged materials disposed at the Sites are suitable for disposal, addresses management of the Sites to ensure mounding does not occur, and addresses the timing of disposal events to minimize interference with other uses of ocean waters in the vicinity of the proposed Sites.

*d. MPRSA Criteria*

In proposing to designate the Umpqua River ODM Sites, EPA assessed the proposed action against the criteria of the MPRSA, with particular emphasis on the general and specific regulatory criteria of 40 CFR Part 228, to determine if designation of the proposed sites satisfies those criteria.

*General Criteria (40 CFR 228.5)*

*(1) Sites must be selected to minimize interference with other activities in the marine environment, particularly avoiding areas of existing fisheries or shellfisheries, and regions of heavy commercial or recreational navigation (40 CFR 228.5(a)).*

EPA's assessment of information available at the time of this proposed rule included a review of the potential for interference with navigation, recreation, shellfisheries, aquatic resources, commercial fisheries, protected geologic features, and cultural and/or historically significant areas. The proposed Sites are located away from the approach to the Umpqua River entrance channel and are unlikely to cause interference with navigation near the mouth of the Umpqua River. Commercial crab and salmon fishing have the potential to take place in the proposed Sites because of overlapping

disposal and fishing seasons, but conflicts are not anticipated based on past history of fishing and disposal operations. Other recreational users, for example, surfers, boarders, and divers, may use the near-shore area in the vicinity of the proposed Sites. These recreationists are not expected to generate heavy recreational navigation use with the potential to conflict with disposal operations at the proposed South Site.

*(2) Sites must be situated such that temporary perturbations to water quality or other environmental conditions during initial mixing caused by disposal operations would be reduced to normal ambient levels or undetectable contaminant concentrations or effects before reaching any beach, shoreline, marine sanctuary, or known geographically limited fishery or shellfishery (40 CFR 228.5(b)).*

Based on EPA's review of modeling, monitoring data, analysis of sediment quality, and history of use, no detectable contaminant concentrations or water quality effects, e.g., suspended solids, would be expected to reach any beach, shoreline, or other area outside of the proposed Sites. All dredged material proposed for disposal will be evaluated according to 40 CFR 227.13 and only suitable material can be disposed of at the site. Modeling work performed by the Corps demonstrates that water column turbidity would be expected to dissipate for an anticipated 97% of the coarser material within a few minutes of disposal, while the remaining 3% of the material, which would be classified as fine-grained, would be expected to dissipate within a half hour. Over time, some of the suitable disposed material would be expected to migrate into the littoral system, and potentially to coastal shorelines. Bottom movement of material, based on historic trends near the mouth of the Umpqua River, is expected to show a net movement to the north at the depth of the disposal sites with rapid dispersion after movement.

*(3) If Site designation studies show that any interim disposal sites do not meet the site selection criteria, use of such sites shall be terminated as soon as any alternate site can be designated (40 CFR 228.5(c)).*

Use of the Interim Site near the proposed Umpqua River Sites was terminated upon selection of the 103-selected site, the Adjusted Site, by the Corps. Use of the Adjusted Site terminated at the end of the 2008 dredging season. There are no selected or designated sites remaining near the mouth of the Umpqua River. The designation of the proposed Sites is necessary because no location for the

disposal of dredged material exists in the vicinity of the proposed Sites at this time.

*(4) The sizes of disposal sites will be limited in order to localize for identification and control any immediate adverse impacts, and to permit the implementation of effective monitoring and surveillance to prevent adverse long-range impacts. Size, configuration, and location are to be determined as part of the disposal site evaluation (40 CFR 228.5(d)).*

EPA sized the proposed Sites to meet this criterion. The proposed Sites tend to be moderately dispersive in the near-shore area and less dispersive farther from shore. The Sites were designed to be large enough to minimize the potential for adverse mounding and to allow for a minimum twenty-year capacity. Effective monitoring of the proposed Sites is necessary and annual bathymetric surveys are anticipated for each Site. Those surveys are expected to be used to document the fate of the dredged material disposed at the Sites and to provide information for active management of the Sites.

*(5) EPA will, wherever feasible, designate ocean dumping sites beyond the edge of the continental shelf and other such sites where historical disposal has occurred (40 CFR 228.5(e)).*

The proposed Sites would be located near where historic disposal has occurred with only minimal impact to the environment. Locations off the continental shelf in the Pacific Ocean as a general rule are inhabited by stable benthic and pelagic ecosystems on steeper gradients that are not well adapted to the type of frequent disturbance events that would occur if disposal of dredged material took place. Monitoring and surveillance of a site located beyond the edge of the continental shelf would be challenging and would present safety concerns for crew transporting the material to be disposed and monitoring the site. In addition, dredged material disposed at a location beyond the continental shelf would not be available to the littoral system. The loss of material would potentially have a negative impact the mass balance of the system with a resulting negative impact on erosion/accretion patterns along this limited area of coastline near the Umpqua River.

*Specific Criteria (40 CFR 228.6)*

*(1) Geographical Position, Depth of Water, Bottom Topography and Distance from Coast (40 CFR 228.6(a)(1)).*

Based on the data available at the time of this proposal, the geographical position, including the depth of the

proposed Sites, bottom topography, and distance from the coastline in the vicinity of the proposed Sites, will not cause adverse effects to the marine environment. Based on EPA's understanding of the currents at the proposed Sites and their influence on the movement of material in the area, there is a high likelihood that much of the material disposed at the Sites will be transported to the littoral system. This movement is expected to allow for long-term disposal without creation of adverse mounding conditions at either of the proposed Sites.

To help avoid adverse mounding at either of the proposed Sites, the site management strategy will include placing the majority of dredged material in shallower portions of the Sites closer to shore, where the material can quickly return to the regional littoral sediment system. Disposal runs will be managed to avoid multiple dumps in any location to further minimize mounding. Management is likely to include establishing "cells" along the nearshore boundary and assigning numbers of "dumps" to each cell to minimize material accumulation and avoid excessive or persistent mounding. Disposal will also be offset between the two proposed Sites to allow for maximum dispersal of material and minimal impact to each Site. In the shallower portion of the Sites, it is anticipated that disposal would still lead to the formation of temporary mounds on the bottom. Material placed in the deeper portions of the Sites (the outer, or seaward third) is expected to remain within Site boundaries for a longer time (a few years depending on depth and storm events) and could form more persistent, but still temporary, features.

(2) *Location in Relation to Breeding, Spawning, Nursery, Feeding, or Passage Areas of Living Resources in Adult or Juvenile Phases (40 CFR 228.6(a)(2)).*

The proposed Sites are not located in exclusive breeding, spawning, nursery or feeding areas for adult or juvenile phases of living resources. Many near-shore pelagic organisms are found in the water column over the proposed Sites, but these organisms are found in the water column off most of the Pacific coast and are not unique to the proposed Sites. Benthic fauna common to near-shore, sandy, wave-influenced regions that are found along the Pacific coast are also found at the proposed Sites, and are generally well-suited to survive in this dynamic environment and have been found to adapt well to natural and human perturbations. Benthic communities are expected to rapidly recolonize in the event of

burying after disposal. Near the proposed Sites, a variety of pelagic and demersal fish species, as well as shellfish, are found. Anadromous salmonids are found at all seasons in the near-shore area off the mouth of the Umpqua River. Seals and sea lions also inhabit the lower Umpqua River and coastal area. Habitat in the near-shore area and shoreline of the Umpqua River entrance channel supports a variety of avian species. Whales and sea turtles are present seasonally offshore of the coastline in this area, but are generally observed further offshore than the proposed Sites. Modeling of the water column over the proposed Sites indicates that turbidity from a disposal event would be expected to dissipate rapidly and that avoidance behavior by any species in the proposed Sites, or in the surrounding area, at the time of a disposal event would be short-term.

(3) *Location in Relation to Beaches and Other Amenity Areas (40 CFR 228.6(a)(3)).*

The proposed Sites, although located in close proximity to the Umpqua River navigation channel, are located a sufficient distance offshore to avoid adverse impacts to beaches and other amenity areas. The local beaches support tourism, and recreational and commercial fishing. Transportation of dredges or barges to and from the proposed Sites to dispose of dredged material is expected to be coordinated so as to avoid disturbance of other activities near the Umpqua River entrance channel. Dredged material disposed of at the proposed Sites is expected to disperse into the littoral system, with a possible positive effect over time of reducing erosion of coastal beaches. The proposed North ODMD Site is 3,100 feet from the north jetty and 3,000 feet from the nearest beach. The proposed South ODMD Site is 2,400 feet from the south jetty and 2,100 feet from the nearest beach. There are no rocks or pinnacles in the vicinity of either site. The Oregon Dunes National Recreation Area, a part of the Siuslaw National Forest, is located on the beach adjacent to the proposed South ODMD Site, but does not extend into the water. The dunes in the Recreation Area are used for off-highway vehicle use, hiking, photography, fishing, canoeing, horseback riding and camping. Use of the proposed South ODMD Site is not expected to interfere with any of those upland uses.

The ocean area north and south of the south jetty is utilized for wave-dependent near shore recreation, such as surfing, diving, kayaking, boogie-boarding, skim boarding, and body surfing. It is possible that some of these

uses may overlap with the proposed Sites, resulting in temporary usage conflict during disposal activities. The proposed Umpqua River ODMD Sites were sized and located in order to provide long-term capacity for the disposal of dredged material without causing any impacts to the wave environment at, or near, the proposed Sites. Site monitoring and adaptive management, as described in the draft SMMP, will address possible future mounding. The use of the proposed Sites is not expected to change the wave conditions for any of the recreational uses referenced above.

(4) *Types and Quantities of Wastes Proposed to be Disposed of, and Proposed Methods of Release, including Methods of Packing the Waste, if any (40 CFR 228.6(a)(4)).*

Dredged material found suitable for ocean disposal pursuant to the regulatory criteria for dredged material or characterized by chemical and biological testing and found suitable for disposal into ocean waters will be the only material allowed to be disposed of at the proposed Sites. No material defined as "waste" under the MPRSA will be allowed to be disposed of at the proposed Sites. The dredged material expected to be disposed of at the Sites will be predominantly marine sand, far removed from known sources of contamination. The physical and chemical analyses of material from the Umpqua River Navigation Channel and boat basin access channel indicate both are suitable for open water disposal. The material from the boat basin access channel contains a higher percentage of fines than the material from the navigation channel, however, the material has been found suitable for disposal at the proposed Sites.

With respect to proposed methods of releasing material at the proposed Sites, material will be released just below the surface from hopper dredges or dump barges. The dredges will be required to be under power and to slowly transit the disposal location during disposal. This method of release is expected to spread material at the Sites to minimize mounding and to minimize impacts to the benthic community and other species in the Sites at the time of a disposal event.

(5) *Feasibility of Surveillance and Monitoring (40 CFR 228.6(a)(5)).*

Monitoring and surveillance at the proposed Sites are expected to be feasible and readily performed from small surface research vessels. The proposed Sites are accessible for bathymetric and side-scan sonar surveys. At a minimum, it is expected that annual bathymetric surveys will be

conducted at each of the proposed Sites to confirm that no unacceptable mounding is taking place within either Site or its immediate vicinity. Routine monitoring is expected to concentrate on examining how the distribution of material in the near-shore portions of the Sites is working to minimize mounding of material and to examine how the distribution of material augments littoral processes.

(6) *Dispersion, Horizontal Transport and Vertical Mixing Characteristics of the Area, including Prevailing Current Direction and Velocity, if any* (40 CFR 228.6(a)(6)).

Dispersion, horizontal transport and vertical mixing characteristics of the area at and in the vicinity of the proposed Sites indicate that the marine sands and fluvial gravels from the Umpqua River distribute away from the river mouth rapidly. The beaches do not show significant accretion or loss, suggesting the system is in equilibrium and that littoral transport is in balance. The bottom current records suggest a bias in transport to the north. Fine grained material tends to remain in suspension and to experience rapid offshore transport compared to other sediment sizes. Sediment transport of sand-sized material or coarser tends to be moved directly as bedload but is occasionally suspended by wave action near the seafloor.

(7) *Existence and Effects of Current and Previous Discharges and Dumping in the Area (including Cumulative Effects)* (40 CFR 228.6(a)(7)).

The two Sites proposed in today's action have not been used before for any type of disposal activity. The Interim and Adjusted Sites experienced significant adverse mounding which decreased capacity and suitability for designation. EPA's evaluation of historical data and modeling conducted by the Corps concluded that past disposal operations have not resulted in unacceptable environmental degradation. Future disposal of dredged material is not expected to result in unacceptable environmental degradation at the proposed Sites or in the vicinity of the proposed Sites. Although mounding is a potential effect, bathymetric surveys will be conducted at the proposed Sites. The draft SMMP includes requirements, including preventative steps, for managing the proposed Sites to address any potential mounding issues.

(8) *Interference with Shipping, Fishing, Recreation, Mineral Extraction, Desalination, Fish and Shellfish Culture, Areas of Special Scientific Importance and Other Legitimate Uses of the Ocean* (40 CFR 228.6(a)(8)).

Designation of the proposed Sites is not expected to interfere with shipping, fishing, recreation or other legitimate uses of the ocean. Disposals at the new Sites will be managed according to the SMMP to minimize interference with other legitimate uses of the ocean through careful timing and staggering of disposals in the near-shore portion of the proposed Sites. Commercial and recreational fishing and commercial navigation are the primary uses for which such timing will be needed. No plans for mineral extraction offshore of the Umpqua River are planned or proposed for this area. Wave-dependent near-shore recreation, such as surfing, diving, kayaking, boogie-boarding, skim boarding, and body surfing, may possibly overlap with the proposed Sites, resulting in temporary usage conflict during disposal activities. The proposed Sites will be managed to minimize such potential conflicts. The use of the proposed Sites is not expected to change the wave conditions for any of the recreational uses referenced above. Two wave energy projects are in the preliminary permitting phases near the proposed Sites. One wave energy project, referred to as the Reedsport Wave Energy Project, is proposed for installation approximately 5 miles north of the Umpqua River. The Reedsport Wave Energy Project is north of the proposed North Umpqua River ODMD Site and no conflicts between that project and the use of the North site are expected. A second project, the Douglas County Wave and Tidal Energy Project, is proposed to be located both in the ocean waters near the proposed Sites and on the south jetty structure at the mouth of the Umpqua River. Final dimensions and configuration for the Douglas County project are not yet known, therefore, it is unknown whether the proposed project would present any usage conflicts with the proposed Umpqua River ODMD Sites. Project proponents for both of these wave energy projects have received a preliminary permit and filed a notice of intent to file a license application with FERC. Fish and shellfish culture operations are not under consideration for the area. There are no known areas of scientific importance in the vicinity of the proposed Site.

(9) *The Existing Water Quality and Ecology of the Sites as Determined by Available Data or Trend Assessment of Baseline Surveys* (40 CFR 228.6(a)(9)).

EPA has not identified any adverse water quality impacts from ocean disposal of dredged material based on water and sediment quality analyses conducted in the study area of the

proposed Sites and based on experience with past disposals near the mouth of the Umpqua River. Fisheries and benthic data show the ecology of the area to be that of a mobile sand community typical of the Oregon Coast.

(10) *Potentiality for the Development or Recruitment of Nuisance Species in the Disposal Site* (40 CFR 228.6(a)(10)).

Nuisance species, considered as any undesirable organism not previously existing at a location, have not been observed at, or in the vicinity of, the proposed Sites. Material expected to be disposed at the proposed Sites has been classified as uncontaminated marine sands similar to the sediment present at the Sites. Some fine-grained material, finer than natural background, may also be disposed. While this finer-grained material could have the potential to attract nuisance species to the proposed Sites, no such recruitment has occurred in the past at either the Interim or the Adjusted Site. The draft SMMP includes specific biological monitoring requirements, which will act to identify any nuisance species, and management requirements, allowing EPA to direct special studies and/or operational changes to address the issue if it arises.

(11) *Existence at or in Close Proximity to the Site of any Significant Natural or Cultural Feature of Historical Importance* (40 CFR 228.6(a)(11)).

No significant cultural features have been identified at, or in the vicinity of, the proposed Sites. As discussed further below, EPA coordinated with Oregon's State Historic Preservation Officer and with Tribes in the vicinity of the proposed Sites to identify any cultural features. None were identified. No shipwrecks were observed or documented within the proposed Sites or their immediate vicinity.

*e. National Environmental Policy Act (NEPA); Magnuson-Stevens Act (MSA); Marine Mammal Protection Act (MMPA); Coastal Zone Management Act (CZMA); Endangered Species Act (ESA); National Historic Preservation Act (NHPA)*

(1) NEPA

Section 102 of the National Environmental Policy Act of 1969, as amended (NEPA), 42 U.S.C. 4321 to 4370f, requires that Federal agencies prepare an Environmental Impact Statement (EIS) for major Federal actions significantly affecting the quality of the human environment. NEPA does not apply to EPA designations of ocean disposal sites under the MPRSA because the courts have exempted EPA's actions under the MPRSA from the procedural

requirements of NEPA through the functional equivalence doctrine. Under that doctrine, as EPA discussed most recently in the Agency's final rule reviewing the NEPA regulations, the courts reasoned that actions under the MPRSA are functionally equivalent to the analysis required under NEPA because such actions are undertaken with full consideration of environmental impacts and with opportunities for public involvement. See 72 FR 53653, September 19, 2007. EPA has, by policy, determined that the preparation of non-EIS NEPA documents for certain EPA regulatory actions, including actions under the MPRSA, is appropriate. EPA's "Notice of Policy and Procedures for Voluntary Preparation of NEPA Documents," (Voluntary NEPA Policy), 63 FR 58045, (October 29, 1998), sets out both the policy and procedures EPA uses when preparing such environmental review documents. EPA's 2007 revisions to 40 CFR Part 6 provided the framework EPA used to prepare the voluntary NEPA documents for this proposed action.

EPA's primary voluntary NEPA document for designating the proposed Sites is the Draft *Umpqua River, Oregon Ocean Dredged Material Disposal Sites Evaluation Study and Environmental Assessment, 2008* (EA), jointly prepared by EPA and the Corps. The EA and its Technical Appendices, which are part of the docket for today's proposed action, provide the threshold environmental review for the proposed designation of the two Sites. The information from the EA is used extensively, above, in the discussion of the ocean dumping criteria. Because EPA's Voluntary NEPA Policy does not require the preparation of an EIS for this proposed action, the EA prepared for designating the two proposed Sites is available for public comment and a final EA will be made available at the time of final rulemaking. Persons interested in commenting on this EA should do so at this time. There may not be another opportunity to comment.

#### (2) MSA and MMPA

In the spring of 2008, EPA initiated consultation with the National Marine Fisheries Service (NMFS) concerning essential fish habitat and protected marine mammals. EPA prepared an essential fish habitat (EFH) assessment pursuant to Section 305(b), 16 U.S.C. 1855(b), of the Magnuson-Stevens Act, as amended (MSA), 16 U.S.C. 1801 to 1891d. NMFS is also reviewing EPA's EFH assessment and ESA Biological Assessment for purposes of the Marine Mammal Protection Act of 1972, as amended (MMPA), 16 U.S.C. 1361 to

1389. Consultation under both MMPA and MSA is still underway, but is expected to conclude before EPA takes any action to finalize today's proposed rule. Persons interested in commenting on this issue should do so at this time. There may not be another opportunity to comment.

#### (3) CZMA

EPA initiated consultation with the state of Oregon on coastal zone management issues in June and July of 2008. EPA prepared a consistency determination for the Oregon Ocean and Coastal Management Program (OCMP) to meet the requirements of the Coastal Zone Management Act, as amended, (CZMA), 16 U.S.C. 1451 to 1465, and will submit that determination formally to the Oregon Department of Land Conservation and Development (DLCD) for review.

#### (4) ESA

EPA initiated informal consultation with NMFS and the U.S. Fish and Wildlife Service on its action to designate the Umpqua River ODMD Sites beginning in the spring of 2008. EPA prepared a Biological Assessment to assess the potential effects of designating the two Umpqua River Sites on aquatic and wildlife species to determine whether or not its action might adversely affect species listed as endangered or threatened and/or adversely modify or destroy their designated critical habitat. EPA found that its action would not be likely to adversely affect aquatic or wildlife species listed pursuant to the Endangered Species Act, as amended (ESA), 16 U.S.C. 1531 to 1544, or the critical habitat of such species. EPA found that site designation does not have a direct impact on any of the identified ESA species but also found that indirect impacts associated with reasonably foreseeable future disposal activities had to be considered. These indirect impacts included a short-term increase in suspended solids and turbidity in the water column when dredged material was disposed at the new Sites and an accumulation of material on the ocean floor when material was disposed at the Sites. EPA concluded that while its action may affect ESA-listed species, the action would not be likely to adversely affect ESA-listed species or critical habitat.

The U.S. Fish and Wildlife Service (USFWS) concurred with EPA's finding that EPA's action to designate the proposed Umpqua River ODMD Sites would not likely adversely affect listed species or critical habitat. Consultation with the USFWS for this proposed

action is complete. The National Marine Fisheries Service (NMFS) is still reviewing the proposed action, but consultation with NMFS is expected to be completed before EPA takes any action to finalize today's proposed rule. EPA specifically requests that any comments concerning ESA be made at this time. This may be the only opportunity for interested persons to comment on this issue.

#### (5) NHPA

EPA initiated consultation with the State of Oregon's Historic Preservation Officer (SHPO) to address National Historic Preservation Act, as amended (NHPA), 16 U.S.C. 470 to 470a-2, which requires Federal agencies to take into account the effect of their actions on districts, sites, buildings, structures, or objects, included in, or eligible for inclusion in the National Register. EPA determined that no historic properties were affected, or would be affected, by the proposed designation of the Sites. EPA did not find any historic properties within the geographic area of the proposed Sites. This determination was based on an extensive review of the National Register of Historic Districts in Oregon, the Oregon National Register list and an assessment of cultural resources near the proposed Sites: Side scan sonar of the proposed Sites did not reveal the presence of any shipwrecks or other cultural or historic properties. This consultation is expected to be completed before EPA takes any action to finalize today's proposed rule. EPA specifically requests that any comments concerning NHPA be made at this time. This may be the only opportunity for interested persons to comment on this issue.

### 3. Statutory and Executive Order Reviews

This rule proposes to designate two ocean dredged material disposal sites pursuant to Section 102 of the MPRSA. This rule complies with applicable executive orders and statutory provisions as follows:

#### (1) Executive Order 12866

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether the regulatory action is "significant," and therefore subject to OMB review and the requirements of the Executive Order. The Executive Order defines "significant regulatory action" as one that is likely to result in a rule that may: (1) Have an annual effect on the economy of \$100 million or more, or adversely affect in a material way, the economy, a sector of the economy,

productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. EPA has determined that this proposed rule is not a "significant regulatory action" under the terms of Executive Order 12866 and is therefore not subject to OMB review.

#### (2) Paperwork Reduction Act

This proposed action does not impose an information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*, because this proposed rule does not establish or modify any information or recordkeeping requirements for the regulated community and only seeks to authorize the pre-existing requirements under State law and imposes no additional requirements beyond those imposed by State law.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing, and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

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. The OMB control numbers for EPA's regulations in Title 40 of the CFR are listed in 40 CFR Part 9.

#### (3) Regulatory Flexibility

The Regulatory Flexibility Act (RFA), generally requires Federal agencies to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act

or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions. For purposes of assessing the impacts of today's rule on small entities, small entity is defined as: (1) A small business defined by the Small Business Administration's size regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district, or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field. EPA has determined that this action will not have a significant economic impact on small entities because the proposed rule will only have the effect of regulating the location of sites to be used for the disposal of dredged material in ocean waters. After considering the economic impacts of today's rule, I certify that this action will not have a significant economic impact on a substantial number of small entities. EPA continues to be interested in the potential impacts of the proposed rule on small entities and welcomes comments on issues related to such impacts.

#### (4) Unfunded Mandates Reform Act

This action contains no Federal mandates under the provisions of Title II of the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1531 to 1538, for state, local, or tribal governments or the private sector. This action imposes no new enforceable duty on any State, local, or tribal governments or the private sector. Therefore, this action is not subject to the requirements of sections 202 or 205 of the UMRA. This action is also not subject to the requirements of section 203 of the UMRA because it contains no regulatory requirements that might significantly or uniquely affect small government entities. Those entities are already subject to existing permitting requirements for the disposal of dredged material in ocean waters.

#### (5) Executive Order 13132: Federalism

Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in

the Executive Order to include regulations 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 various levels of government." This rule does not have federalism implications. It 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 various levels of government, as specified in Executive Order 13132. This rule proposes to designate two sites for the disposal of dredged material in ocean waters. Thus, Executive Order 13132 does not apply to this rule. In the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between EPA and State and local governments, EPA specifically solicits comment on this proposed rule from State and local officials.

#### (6) Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This proposed rule does not have tribal implications, as specified in Executive Order 13175 because the designation of the two dredged material disposal Sites will not have a direct effect on 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. Thus, Executive Order 13175 does not apply to this rule. Although Executive Order 13175 does not apply to this proposed rule, EPA consulted with tribal officials in the development of this rule, particularly as the proposed rule relates to potential impacts to historic or cultural resources. EPA specifically solicits additional comment on this proposed rule from tribal officials.

#### (7) Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997) as applying only to those regulatory actions that concern health or safety risks, such that the analysis required under section 5-501 of the Executive Order has the potential to influence the regulation. This action is not subject to Executive Order 13045 because it does not establish an environmental standard intended to mitigate health or safety risks. The proposed action concerns the designation of two Sites and would only have the effect of providing designated locations to use for ocean disposal of



dredged material pursuant to section 102(c) of the MPRSA.

*(8) Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use*

This action is not subject to Executive Order 13211, "Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) because it is not a "significant regulatory action" as defined under Executive Order 12866.

*(9) National Technology Transfer and Advancement Act*

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 ("NTTAA"), Public Law 104-113, section 12(d) (15 U.S.C. 272), directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards. The proposed action includes environmental monitoring and measurement as described in EPA's draft SMMP. EPA will not require the use of specific, prescribed analytic methods for monitoring and managing the proposed Sites once designated. Rather, the Agency plans to allow the use of any method, whether it constitutes a voluntary consensus standard or not, that meets the monitoring and measurement criteria discussed in the SMMP. EPA welcomes comments on this aspect of the proposed rulemaking and, specifically, invites the public to identify potentially-applicable voluntary consensus standards and to explain why such standards should be used in this regulation.

*(10) Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low Income Populations*

Executive Order 12898 (59 FR 7629 (Feb. 16, 1994)) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or

environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States. EPA has determined that this proposed rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it does not affect the level of protection provided to human health or the environment. EPA has assessed the overall protectiveness of designating the proposed disposal Sites against the criteria established pursuant to the MPRSA to ensure that any adverse impact on the environment will be mitigated to the greatest extent practicable.

**List of Subjects in 40 CFR Part 228**

Environmental protection, Water pollution control.

**Authority:** This action is issued under the authority of Section 102 of the Marine Protection, Research, and Sanctuaries Act, as amended, 33 U.S.C. 1401, 1411, 1412.

Dated: November 14, 2008.

**Elin D. Miller,**

*Regional Administrator, Region 10.*

**PART 228—[AMENDED]**

For the reasons set out in the preamble, Chapter I of title 40 is proposed to be amended as set forth below:

1. The authority citation for part 228 continues to read as follows:

**Authority:** 33 U.S.C. 1412 and 1418

2. Section 228.15 is amended by adding paragraph (n)(7) to read as follows:

**§ 228.15 Dumping sites designated on a final basis.**

\* \* \* \* \*

(n) \* \* \*

(7) Umpqua River, OR—North and South Dredged Material Disposal Sites.

(i) North Umpqua River Site.

(A) *Location:* 43°41'23.09" N, 124°14'20.28" W; 43°41'25.86" N, 124°12'54.61" W; 43°40'43.62" N, 124°14'17.85" W; 43°40'46.37" N, 124°12'52.74" W.

(B) *Size:* Approximately 1.92 kilometers long and 1.22 kilometers wide, with a drop zone which is defined as a 500-foot setback inscribed within all sides of the site boundary, reducing the permissible disposal area to a zone 5,300 feet long by 3,000 feet wide.

(C) *Depth:* Ranges from approximately 9 to 37 meters

(D) *Primary Use:* Dredged material

(E) *Period of Use:* Continuing Use

(F) *Restrictions:* (1) Disposal shall be limited to dredged material determined

to be suitable for ocean disposal according to 40 CFR 227.13, from the Umpqua River navigation channel and adjacent areas;

(2) Disposal shall be managed by the restrictions and requirements contained in the currently-approved Site Management and Monitoring Plan (SMMP);

(3) Monitoring, as specified in the SMMP, is required.

(ii) South Umpqua River Site

(A) *Location:* 43°39'32.31" N, 124°14'35.60" W; 43°39'35.23" N, 124°13'11.01" W; 43°38'53.08" N, 124°14'32.94" W; 43°38'55.82" N, 124°13'08.36" W.

(B) *Size:* Approximately 1.92 kilometers long and 1.22 kilometers wide, with a drop zone which is defined as a 500-foot setback inscribed within all sides of the site boundary, reducing the permissible disposal area to a zone 5,300 feet long by 3,000 feet wide.

(C) *Depth:* Ranges from approximately 9 to 37 meters

(D) *Primary Use:* Dredged material

(E) *Period of Use:* Continuing Use

(F) *Restrictions:* (1) Disposal shall be limited to dredged material determined to be suitable for ocean disposal according to 40 CFR 227.13, from the Umpqua River navigation channel and adjacent areas;

(2) Disposal shall be managed by the restrictions and requirements contained in the currently-approved Site Management and Monitoring Plan (SMMP);

(3) Monitoring, as specified in the SMMP, is required.

\* \* \* \* \*

[FR Doc. E8-27967 Filed 11-24-08; 8:45 am]

BILLING CODE 6560-50-P

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 271**

[EPA-R05-RCRA-2008-0712; FRL-8744-9]

**Wisconsin: Final Authorization of State Hazardous Waste Management Program Revision**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** Wisconsin has applied to EPA for final authorization of the changes to its hazardous waste program under the Resource Conservation and Recovery Act (RCRA). EPA has reviewed Wisconsin's application and has preliminarily determined that these changes satisfy all requirements needed to qualify for final authorization, and is

proposing to authorize the State's changes. This proposal authorizes Wisconsin for new regulations which they have not been previously authorized for.

**DATES:** Comments on this proposed rule must be received on or before *December 26, 2008*.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA-R05-RCRA-2008-0712 by one of the following methods: *http://www.regulations.gov*: Follow the online instructions for submitting comments.

*E-mail: gromnicki.jean@epa.gov.*

*Mail:* Jean Gromnicki, Wisconsin Regulatory Specialist, LR-8J, U.S. EPA, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604.

*Instructions:* Direct your comments to Docket ID Number EPA-R05-RCRA-2008-0712. 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 *www.regulations.gov* or e-mail. The *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 e-mail comment directly to EPA without going through *www.regulations.gov*, your e-mail 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 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 or 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.epagov/epahome/dockets.htm*.

*Docket:* All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some of the 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. You may view and copy Wisconsin's application from 9 a.m. to 4 p.m. at the following addresses: U.S. EPA, Region 5, LR-8J, 77 West Jackson Boulevard, Chicago, Illinois, contact: Jean Gromnicki (312) 886-6162; or Wisconsin Department of Natural Resources, 101 S. Webster Street, Madison, Wisconsin, contact: Patricia Chabot (608) 264-6015.

**FOR FURTHER INFORMATION CONTACT:** Jean Gromnicki, Wisconsin Regulatory Specialist, U.S. EPA, Region 5, LR-8J, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886-6162, e-mail *gromnicki.jean@epa.gov*.

#### **SUPPLEMENTARY INFORMATION:**

##### **A. Why Are Revisions to State Programs Necessary?**

States which have received final authorization from EPA under RCRA Section 3006(b), 42 U.S.C. 6926(b), must maintain a hazardous waste program that is equivalent to, consistent with, and no less stringent than, the Federal program. As the Federal program changes, States must change their programs and ask EPA to authorize the changes. Changes to State programs may be necessary when Federal or State statutory or regulatory authority is modified or when certain other changes occur. Most commonly, States must change their programs because of changes to EPA's regulations in 40 Code of Federal Regulations (CFR) parts 124, 260 through 266, 268, 270, 273 and 279.

##### **B. What Decisions Have We Made in This Rule?**

We conclude that Wisconsin's application to revise its authorized program meets all of the statutory and regulatory requirements established by RCRA. Therefore, we propose to grant Wisconsin final authorization to operate its hazardous waste program with the changes described in the authorization application. Wisconsin has responsibility for permitting Treatment, Storage, and Disposal Facilities (TSDFs) within its borders (except in Indian Country) and for carrying out the aspects of the RCRA program described in its revised program application, subject to the limitations of the Hazardous and Solid Waste Amendments of 1984 (HSWA). New Federal requirements and prohibitions imposed by Federal regulations that EPA promulgates under the authority of

HSWA take effect in authorized States before they are authorized for the requirements. Thus, EPA will implement those requirements and prohibitions in Wisconsin, including issuing permits, until the State is granted authorization to do so.

##### **C. What Is the Effect of This Authorization Decision?**

The effect of this decision is that a facility in Wisconsin subject to RCRA will now have to comply with the authorized State requirements instead of the equivalent Federal requirements in order to comply with RCRA. Wisconsin has enforcement responsibilities under its State hazardous waste program for violations of such program, but EPA retains its authority under RCRA sections 3007, 3008, 3013, and 7003, which include, among others, authority to:

1. Do inspections, and require monitoring, tests, analyses or reports.
2. Enforce RCRA requirements and suspend or revoke permits.
3. Take enforcement actions regardless of whether the State has taken its own actions.

This action does not impose additional requirements on the regulated community because the regulations for which Wisconsin is being authorized by today's action are already effective, and are not changed by today's action.

##### **D. What Happens If EPA Receives Comments That Oppose This Action?**

If EPA receives comments that oppose this authorization, we will address all public comments in a later **Federal Register**. You may not have another opportunity to comment. If you want to comment on this authorization, you must do so at this time.

##### **E. What Has Wisconsin Previously Been Authorized for?**

Wisconsin initially received final authorization on January 30, 1986, effective January 31, 1986 (51 FR 3783) to implement the RCRA hazardous waste management program. We granted authorization for changes to their program on May 23, 1989, effective June 6, 1989 (54 FR 15029), on November 22, 1989, effective January 22, 1990 (54 FR 48243), on April 24, 1992, effective April 24, 1992 (57 FR 15029), on June 2, 1993, effective August 2, 1993 (58 FR 31344), on August 4, 1994, effective October 4, 1994 (59 FR 39971), on August 5, 1999, effective October 4, 1999 (64 FR 42630), and on June 26, 2002, effective June 26, 2002 (67 FR 43002).

**F. What Changes Are We Authorizing With This Action?**

On April 29, 2008, Wisconsin submitted a final complete program revision application, seeking

authorization of their changes in accordance with 40 CFR 271.21. We now make a final decision, subject to receipt of written comments that oppose this action, that Wisconsin's hazardous waste program revision satisfies all of

the requirements necessary to qualify for final authorization. Therefore, we propose to grant Wisconsin final authorization for the following program changes:

TABLE 1—WISCONSIN'S ANALOGS TO THE FEDERAL REQUIREMENTS

Description of Federal Requirement (include checklist #, if relevant)	FEDERAL REGISTER date and page (and/or RCRA statutory authority)	Analogous state authority
Technical Amendments to the Universal Treatment Standards and Treatment Standards for Organic Toxicity Characteristic Wastes and Newly Listed Waste; Checklist 137.1.	January 3, 1995; 60 FR 242.	NR 660.30, 660.31, 660.32, 660.33, 661.02, 664.0001, 665.0001, 266.023, 266.100, 266 Appendix XIII, NR 668.01, 668.02, 668.07, 668.09, 668.38, 668.40, 668.41, 668.42, 668.43, 668.45, 668.46, 668.48, 668 Appendix IV, 668 Appendix V, 668 Appendix X; Effective August 1, 2006.
Hazardous Waste Management System; Carbamate Production Identification and Listing of Hazardous Waste; and CERCLA Hazardous Substance Designation and Reportable Quantities; Correction; Checklist 140.1.	April 17, 1995; 60 FR 19165.	NR 661.03, 661.32, 661.33, 661 Appendix VII, 661 Appendix VIII; Effective August 1, 2006.
As amended; Checklist 140.2 .....	May 12, 1995; 60 FR 25619.	
Land Disposal Restrictions Phase III-Decharacterized Wastewaters, Carbamate Wastes and Spent Potliners; Checklist 151.1.	April 8, 1996; 61 FR 15660	NR 668.01, 668.02, 668.03, 668.07, 668.08, 668.09, 668.39, 668.40, 668.42, 668.44, 668.48, 668 Appendix XI; Effective August 1, 2006.
As amended; Checklist 151.2 .....	April 30, 1996; 61 FR 19117.	
As amended; Checklist 151.3 .....	June 28, 1996; 61 FR 33680.	
As amended; Checklist 151.4 .....	July 10, 1996; 61 FR 36419	
As amended; Checklist 151.5 .....	August 26, 1996; 61 FR 43924.	
As amended; Checklist 151.6 .....	February 19, 1997; 62 FR 7502.	
Imports and Exports of Hazardous Waste: Implementation of OECD Council Decision; Checklist 152.	April 12, 1996; 61 FR 16289.	NR 661.06, 662.010, 662.190, 662.053, 662.56, 662.058, 662.080, 662.081, 662.082, 662.083, 662.084, 662.085, 662.086, 662.087, 662.088, 662.089, 663.10, 663.20, 664.0012, 664.0071, 665.0012, 665.0071, 666.70, 673.20, 673.40, 673.56, 673.70; Effective August 1, 2006.
Hazardous Waste Treatment, Storage, and Disposal Facilities and Hazardous Waste Generators; Organic Air Emission Standards for Tanks, Surface Impoundments and Containers; Checklist 154.	November 25, 1996; 61 FR 59931.	NR 660.11, 661.06, 662.034, 662.192, 664.0013, 664.0015, 664.0073, 664.0077, 664.0179, 664.0200, 664.0232, 664.0601, 664.1030, 664.1033, 664.1034, 664.1035, 664.1050, 664.1055, 664.1058, 664.1064, 664.1080, 664.1081, 664.1082, 664.1083, 664.1084, 664.1085, 664.1086, 664.1087, 664.1088, 664.1089, 664.1090, 664.1091, 665.0001, 665.0013, 665.0015, 665.0073, 665.0077, 665.0178, 665.0202, 665.0231, 665.1030, 665.1033, 665.1034, 665.1035, 665.1050, 665.1055, 665.1058, 665.1064, 665.1080, 665.1081, 665.1082, 665.1083, 665.1084, 665.1085, 665.1086, 665.1087, 665.1088, 665.1089, 665.1090, 665.1091, 665 Appendix VI, 670.004, 670.014, 670.015, 670.016, 670.017, 670.027; Effective August 1, 2006.
As amended; Checklist 154.1 .....	December 6, 1994; 59 FR 62896.	
As amended; Checklist 154.2 .....	May 19, 1995; 60 FR 26828.	
As amended; Checklist 154.3 .....	September 29, 1995; 60 FR 50426.	
As amended; Checklist 154.4 .....	November 13, 1995; 60 FR 56952.	
As amended; Checklist 154.5 .....	February 9, 1996; 61 FR 4903.	
As amended; Checklist 154.6 .....	June 5, 1996; 61 FR 28508	
Warfarin & Zinc Phosphide Listing; Checklist 7 .....	May 10, 1984; 49 FR 19922.	NR 661.33; Effective August 1, 2006.
Lime-Stabilized Pickle Liquor Sludge; Checklist 8 .....	June 5, 1984; 49 FR 23284	NR 661.03; Effective August 1, 2006.
Household Waste; Checklist 9 .....	November 13, 1984; 49 FR 44978.	NR 661.04; Effective August 1, 2006.

TABLE 1—WISCONSIN'S ANALOGS TO THE FEDERAL REQUIREMENTS—Continued

Description of Federal Requirement (include checklist #, if relevant)	FEDERAL REGISTER date and page (and/or RCRA statutory authority)	Analogous state authority
Satellite Accumulation; Checklist 12 .....	December 20, 1984; 49 FR 49568.	NR 662.034, 662.192; Effective August 1, 2006.
Financial Responsibility; Settlement Agreement (Amendment to Checklist 24's Optional Designation of 264.113 and 265.113); Checklist 24A.	June 26, 1990; 55 FR 25976.	NR 660.10, 664.0110, 664.0111, 664.0112, 664.0113, 664.0114, 664.0115, 664.0116, 664.0117, 664.0118, 664.0119, 664.0120, 664.0141, 664.0142, 664.0143, 664.0144, 664.0145, 664.0147, 664.0151, 665.0110, 665.0111, 665.0112, 665.0113, 665.0114, 665.0115, 665.0116, 665.0117, 665.0118, 665.0119, 665.0120, 665.0140, 665.0141, 665.0142, 665.0143, 665.0144, 665.0145, 665.0147, 670.014, 670.042, 670.072; Effective August 1, 2006.
Liability Requirements for Hazardous Waste Facilities; Corporate Guarantee; Checklist 43.	November 18, 1987; 52 FR 44314.	NR 664.0147, 664.0151, 665.0147; Effective August 1, 2006.
HSWA Codification Rule 2; Corrective Action for Injection Wells; 44C.	December 1, 1987; 52 FR 45788.	NR 665.01, 670.060; Effective August 1, 2006.
Changes to Part 124 Not Accounted for by Present Checklists; Checklist 70.	January 4, 1989; 54 FR 246.	NR 670.403, 670.406, 670.405, 670.410, 670.412; Effective August 1, 2006.
Toxicity Characteristics Revisions (Correction 1); Checklist 74.1.	June 29, 1990; 55 FR 26986.	NR 661.04, 661.08, 661.24, 661.30, 261 Appendix II, 664.0301, 665.0221, 665.0273, 665 Appendix I; Effective August 1, 2006.
Burning of Hazardous Waste in Boilers and Industrial Furnaces; Checklist 85.	February 21, 1991; 56 FR 7134.	NR 660.10, 660.11, 661.02, 661.04, 261.06, 664.0112, 664.0340, 665.0112, 665.0113, 665.0340, 666.100, 666.101, 666.102, 666.103, 666.104, 666.105, 666.106, 666.107, 666.108, 666.109, 666.110, 666.111, 666.112, 266 Appendices I, II, III, IV, V, VI, VII, VIII, IX, and X, 670.022, 670.042/Appendix I, 670.066, 670.072, 670.073; Effective August 1, 2006.
Burning of Hazardous Waste in Boilers and Industrial Furnaces; Corrections and Technical Amendments I; Checklist 94.	July 17, 1991; 56 FR 32688	NR 661.03, 661.06, 665.0370, 666.040, 666.100, 666.102, 666.103, 666.104, 666.106, 666.107, 666.108, 666.109, 666.110, 666.112, 666 Appendices I, II, III, IV, VII, VIII, IX and X, Appendix A to Appendix X, Appendix B to Appendix X, Appendix C to Appendix X, 670.022, 670.042, 670.066, 670.073; Effective August 1, 2006.
Burning of Hazardous Waste in Boilers and Industrial Furnaces; Corrections and Technical Amendments II; Checklist 96.	August 27, 1991; 56 FR 42504.	NR 661.02, 665.0112, 665.0113, 666.100, 666.102, 666.103, 666.104, 666.108, 666.109, 666.110, 666.111, 666.112, 666 Appendix IX, Appendix XI, Appendix XII; Effective August 1, 2006.
Exports of Hazardous Waste; Technical Correction; Checklist 97.	September 4, 1991; 56 FR 43704.	NR 662.053, 662.190, 662.056; Effective August 1, 2006.
Burning of Hazardous Waste in Boilers and Industrial Furnaces; Technical Amendment III; Checklist 111.	August 25, 1992; 57 FR 38558.	NR 660.10, 660.20, 661.02, 664.0001, 665.0001, 666.100, 666.101, 666.103, 666.104, 666.106, 666.107, 666.108, 666.112, 666 Appendix IX; Effective August 1, 2006.
Burning of Hazardous Waste in Boilers and Industrial Furnaces; Amendment IV; Checklist 114.	September 30, 1992; 57 FR 44999.	NR 666.103, 666 Appendix IX; Effective August 1, 2006.
"Mixture" and "Derived-From" Rules; Response to Court Remand; Checklist 117A.	March 3, 1992; 57 FR 7628	NR 661.03; Effective August 1, 2006.
"Mixture" and "Derived-From" Rules; Technical Correction; Checklist 117A.1.	June 1, 1992; 57 FR 23062	NR 661.03; Effective August 1, 2006.
"Mixture" and "Derived-From" Rules; Final Rule; Checklist 117A.2.	October 30, 1992; 57 FR 49278.	NR 661.03; Effective August 1, 2006.
Land Disposal Restrictions for ignitable and Corrosive Characteristic Wastes Whose Treatment Standards Were Vacated; Checklist 124.	May 24, 1993; 58 FR 29860.	NR 664.0001, 665.0001, 668.01, 668.02, 668.07, 668.09, 668.37, 668.40, 668.41, 668.42, 668.43, 670.042; Effective August 1, 2006.
Requirements for Preparation, Adoption and Submittal of Implementation Plans; Checklist 125.	July 20, 1993; 58 FR 38816	NR 660.11, 666.104, 666.106, 666 Appendix X; Effective August 1, 2006.
Burning of Hazardous Waste in Boilers and Industrial Furnaces; Checklist 127.	November 9, 1993; 58 FR 59598.	NR 666.112, 266 Appendix VII; Effective August 1, 2006.
Recordkeeping Instructions; Checklist 131 .....	March 24, 1994; 59 FR 13891.	NR 664 Appendix I/Table I & II, 665 Appendix I/Table I & II; Effective August 1, 2006.
Solid Waste, Hazardous Waste, Oil Discharge and Superfund Programs; Removal of Legally Obsolete Rules; Checklist 144.	June 29, 1995; 60 FR 33912.	NR 661.31, 666.103, 666.104, 670.002, 670.010; Effective August 1, 2006.
Criteria for Classification of Solid Waste Disposal Facilities and Practices; Identification and Listing of Hazardous Waste; Requirements for Authorization of State Hazardous Waste Programs; Checklist 153.	July 1, 1996; 61 FR 34252	NR 661.05; Effective August 1, 2006.

TABLE 1—WISCONSIN'S ANALOGS TO THE FEDERAL REQUIREMENTS—Continued

Description of Federal Requirement (include checklist #, if relevant)	FEDERAL REGISTER date and page (and/or RCRA statutory authority)	Analogous state authority
Land Disposal Restrictions Phase III—Emergency Extension of the K088 Capacity Variance; Checklist 155.	January 14, 1997; 62 FR 1992.	NR 668.39; Effective August 1, 2006.
Military Munitions Rule: Hazardous Waste Identification and Management; Explosives Emergencies; Manifest Exemption for Transport of Hazardous Waste on Right-of-Ways on Contiguous Properties; Checklist 156.	February 12, 1997; 62 FR 6622.	NR 660.10, 661.02, 662.010, 662.190, 662.020, 662.191, 663.10, 664.0001, 664.0070, 664.1200, 664.1201, 664.1202, 665.0001, 665.0070, 665.1200, 665.1201, 665.1202, 666.200, 666.201, 666.202, 666.203, 666.204, 666.205, 666.206, 667.001, 670.042; Effective August 1, 2006.
Land Disposal Restrictions—Phase IV: Treatment Standards for Wood Preserving Wastes, Paperwork Reduction and Streamlining, Exemptions from RCRA for Certain Processed Materials; and Miscellaneous Hazardous Waste Provisions; Checklist 157.	May 12, 1997; 62 FR 25998.	NR 661.01, 661.02, 661.04, 661.06, 668.01, 668.04, 668.07, 668.09, 668.30, 668.40, 668.42, 668.44, 668 Appendix VI, VII, VIII; Effective August 1, 2006.
Hazardous Waste Management System; Testing and Monitoring Activities; Checklist 158.	June 13, 1997; 62 FR 32452.	NR 660.11, 664.1034, 664.1063, 664 Appendix IX, 665.1034, 665.1063, 666.104, 666.106, 266.107, 266 Appendix IX; Effective August 1, 2006.
Hazardous Waste Management System; Carbamate Production, Identification and Listing of Hazardous Waste; Land Disposal Restrictions; Checklist 159.	June 17, 1997; 62 FR 32974.	NR 661.32/table, 661.33, 661 Appendix VII and VIII, 668.39, 668.40/table; Effective August 1, 2006.
Land Disposal Restrictions Phase III—Emergency Extension of the K088 National Capacity Variance; Checklist 160.	July 14, 1997; 62 FR 37694	NR 668.39; Effective August 1, 2006.
Second Emergency Revision of the Land Disposal Restrictions (LDR) Treatment Standards for Listed Hazardous Waste From Carbamate Production; Checklist 161.	August 28, 1997; 62 FR 45568.	NR 668.40, 668.48; Effective August 1, 2006.
Clarification of Standards for Hazardous Waste LDR Treatment Variances; Checklist 162.	December 5, 1997; 62 FR 64504.	NR 668.44; Effective August 1, 2006.
Organic Air Emissions Standards for Tanks, Surface Impoundments, and Containers; Clarification and Technical Amendment; Checklist 163.	December 8, 1997; 62 FR 64636.	NR 664.0015, 664.0073, 664.1030, 664.1031, 664.1033, 664.1050, 664.1060, 664.1062, 664.1064, 664.1080, 664.1082, 664.1083, 664.1084, 664.1085, 664.1086, 664.1087, 664.1089, 665.0015, 665.0073, 665.1030, 665.1033, 665.1050, 665.1060, 665.1062, 665.1064, 665.1080, 665.1081, 665.1082, 665.1083, 665.1084, 665.1085, 665.1086, 665.1087, 665.1088, 665.1090, 670.014; Effective August 1, 2006.
Kraft Mill Steam Stripper Condensate Exclusion; Checklist 164.	April 15, 1998; 63 FR 18504.	NR 661.04; Effective August 1, 2006.
Recycled Used Oil Management Standards; Technical Correction and Clarification; Checklist 166.	May 6, 1998; 63 FR 24963	NR 661.05, 661.06, 679.10; 679.22, 679.45, 679.54, 679.64, 679.74; Effective August 1, 2006
As amended; Checklist 166.1 .....	July 14, 1998; 63 FR 37780	
Land Disposal Restrictions Phase IV—Treatment Standards for Metal Wastes and Mineral Processing Wastes; Checklist 167A.	May 26, 1998; 63 FR 28556.	NR 668.02, 668.03, 668.34, 668.40, 668.48; Effective August 1, 2006.
Land Disposal Restrictions Phase IV—Hazardous Soils Treatment Standards and Exclusions; Checklist 167B.	May 26, 1998; 63 FR 28556.	NR 668.02, 668.07, 668.44, 668.49; Effective August 1, 2006.
Land Disposal Restrictions Phase IV—Corrections; Checklist 167C.	May 26, 1998; 63 FR 28556.	NR 668.04, 668.07, 668.40, 668.42, 668.45, 668.48, 668 Appendix VII/Table 1, Appendix VII/Table 2, Appendix VIII; Effective August 1, 2006.
As amended; Checklist 167C.1 .....	June 8, 1998; 63 FR 31266	
Mineral Processing Secondary Materials Exclusion; Checklist 167D.	May 26, 1998; 63 FR 58556.	NR 661.02, 661.03, 661.04; Effective August 1, 2006.
Bevill Exclusion Revisions and Clarification; checklist 167E.	May 26, 1998; 63 FR 28556.	NR 661.03, 661.04; Effective August 1, 2006.
Exclusion of Recycled Wood Preserving Wastewaters; Checklist 167F.	May 26, 1998; 63 FR 28556.	NR 261.04; Effective August 1, 2006.
Hazardous Waste Combustors Revised Standards; Checklist 168.	June 19, 1998; 63 FR 33782.	NR 661.04, 661.38, 670.042, 670.072; Effective August 1, 2006.
Petroleum Refining Process; Checklist 169 .....	August 6, 1998; 63 FR 42110.	NR 661.03, 661.04, 661.06, 661.31, 661.32, 261, 668.35, 668.40 Appendix VII; Effective August 1, 2006.
Land Disposal Restrictions—Phase IV; Checklist 170 .....	August 31, 1998; 63 FR 46332.	NR 668.40; Effective August 1, 2006.
Emergency Revisions of LDR Treatment Standards; Checklist 171.	September 4, 1998; 63 FR 47409.	NR 668.40, 668.48; Effective August 1, 2006.
Emergency Revisions of LDR Treatment Standards; Checklist 172.	September 9, 1998; 63 FR 48124.	NR 668.34; Effective August 1, 2006.
Land Disposal Restrictions Treatment Standards (Spent Potliners); Checklist 173.	September 24, 1998; 63 FR 51254.	NR 668.39, 668.40; Effective August 1, 2006.

TABLE 1—WISCONSIN'S ANALOGS TO THE FEDERAL REQUIREMENTS—Continued

Description of Federal Requirement (include checklist #, if relevant)	FEDERAL REGISTER date and page (and/or RCRA statutory authority)	Analogous state authority
Standards Applicable to Owners/Operators of Closed and Closing Hazardous Waste Management Facilities: Post-Closure Permit Requirement and Closure Process; Checklist 174.	October 22, 1998; 63 FR 56710.	NR 664.0090, 664.0110, 664.0112, 664.0118, 664.0140, 665.0090, 665.0110, 665.0112, 665.0118, 665.0121, 665.0140, 670.001, 670.014, 670.028; Effective August 1, 2008.
Hazardous Remediation Waste Management Requirements; Checklist 175.	November 30, 1998; 63 FR 65874.	NR 660.10, 661.04, 664.0001, 664.0073, 664.0101, 664.0552, 664.0553, 664.0554, 665.0001, 668.02, 668.50, 670.002, 670.011, 670.042, 670.068, 670.073, 670.079, 670.080, 670.085, 670.090, 670.095, 670.100, 670.105, 670.110, 670.115, 670.120, 670.125, 670.130, 670.135, 670.140, 670.145, 670.150, 670.155, 670.160, 670.165, 670.170, 670.175, 670.180, 670.185, 670.190, 670.195, 670.200, 670.205, 670.210, 670.215, 670.220, 670.225, 670.230; Effective August 1, 2006.
Universal Waste Rule Technical Amendment; Checklist 176.	December 24, 1998; 63 FR 71225.	NR 666.80, 673.06; Effective August 1, 2006.
Organic Air Emission Standards; Checklist 177 .....	January 21, 1999; 64 FR 3381.	NR 662.034, 662.192, 664.1031, 664.1080, 664.1083, 664.1084, 664.1086, 665.1080, 665.1084, 665.1085, 665.1087; Effective August 1, 2006.
Petroleum Refining Process Wastes; Checklist 178 .....	February 11, 1999; 64 FR 6806.	NR 661.04; Effective August 1, 2006.
Land Disposal Restrictions Phase IV—Technical Corrections and Clarifications to Treatment Standards; Checklist 179.	May 11, 1999; 64 FR 25408.	NR 661.02, 661.04, 662.034, 662.192, 668.02, 668.07, 668.09, 668.40, 668.48, 668.49; Effective August 1, 2006.
Guidelines Establishing Test Procedures for the Analysis of Oil and Grease and Non-Polar Material Under the CWA and RCRA; Checklist 180.	May 14, 1999; 64 FR 26315.	NR 660.11; Effective August 1, 2006.
Universal Waste: Lamp Rule; Checklist 181 .....	July 6, 1999; 64 FR 36466	NR 660.10, 661.09, 664.0001, 665.0001, 668.01, 670.001, 673.01, 673.02, 673.03, 673.04, 673.05, 673.06, 673.07, 673.08, 673.09, 673.10, 673.13, 673.14, 673.30, 673.32, 673.33, 673.34, 673.50, 673.60, 673.81; Effective August 1, 2006.
NESHAPS: Final Standards for Hazardous Air Pollutants for Hazardous Waste Combustors; Checklist 182.	September 30, 1999; 64 FR 52827.	NR 660.10, 661.38, 664.0340, 664.0601, 665.0340, 666.100, 666.101, 666.105, 666.112, 266 Appendix VIII, 670.019, 670.022, 670.042, 670.062, 670.066; Effective August 1, 2006.
As amended; Checklist 182.1 .....	November 19, 1999; 64 FR 63209.	NR 661.32, 662.034, 662.192, 668.07, 668.40, 668.49; Effective August 1, 2006.
Land Disposal Restrictions; Wood Preserving Wastes, Metal Wastes, Zinc Micronutrients Fertilizer, etc.; Corrections; Checklist 183.	October 20, 1999; 64 FR 56469.	NR 662.034, 662.192; Effective August 1, 2006.
Wastewater Treatment Sludges from the Metal Finishing Industry; 180 Day Accumulation Time; Checklist 184.	March 8, 2000; 65 FR 12378.	NR 661.32 Table, 661.33 Table, 661 Appendix VII and VIII, 668.40, 668.48; Effective August 1, 2006.
Organobromine Production Wastes; Checklist 185 .....	March 17, 2000; 65 FR 14472.	NR 661.31, 668 Appendix VII; Effective August 1, 2006.
Organobromine Production Waste and Petroleum Refining Process Waste—Clarification; Checklist 187.	June 8, 2000; 65 FR 36365	NR 661.38, 664.0340, 670.042; Effective August 1, 2006.
NESHAPS: Final Standards for Hazardous Air Pollutants for Hazardous Waste Combustors; Technical Corrections; Checklist 188.	July 10, 2000; 65 FR 42292	NR 661.38, 664.0340, 670.042; Effective August 1, 2006.
As amended; Checklist 188.1 .....	May 14, 2001; 66 FR 24270.	NR 661.32, 661 Appendix VII and VIII, 668.33, 668.40, 668.48; Effective August 1, 2006.
As amended; Checklist 188.2 .....	July 3, 2001; 66 FR 35087	NR 661.32, 661 Appendix VII and VIII, 668.33, 668.40, 668.48; Effective August 1, 2006.
Hazardous Waste Management System; Identification and Listing of Hazardous Waste; Chlorinated Aliphatics Production Wastes; Land Disposal Restrictions for Newly Identified Wastes; and CERCLA Hazardous Substance Designation and Reportable Quantities; Checklist 189.	November 8, 2000; 65 FR 67068.	NR 668.32, 668.48, 668.49, 668 Appendix III; Effective August 1, 2006.
Deferral of Phase IV Standards for PCBs as a Constituent Subject to Treatment in Soil; Checklist 190.	December 26, 2000; 65 FR 81373.	NR 666.210, 666.220, 666.225, 666.230, 666.235, 666.240, 666.245, 666.250, 666.255, 666.260, 666.305, 666.310, 666.315, 666.320, 666.325, 666.330, 666.335, 666.340, 666.345, 666.350, 666.355, 666.360; Effective August 1, 2006.
Storage, Treatment, Transportation, and Disposal of Mixed Waste; Checklist 191.	May 16, 2001; 66 FR 27218.	NR 661.03; Effective August 1, 2006.
Mixture and Derived-From Rule Revisions; Checklist 192A.	May 16, 2001; 66 FR 27266.	NR 661.03; Effective August 1, 2006.

TABLE 1—WISCONSIN'S ANALOGS TO THE FEDERAL REQUIREMENTS—Continued

Description of Federal Requirement (include checklist #, if relevant)	FEDERAL REGISTER date and page (and/or RCRA statutory authority)	Analogous state authority
Land Disposal Restrictions Correction; Checklist 192B ...	May 16, 2001; 66 FR 27266.	NR 268 Appendix VII/Table 1; Effective August 1, 2006.
Change of EPA Mailing Address; Checklist 193 .....	June 28, 2001; 66 FR 34374.	NR 660.11; Effective August 1, 2006.
Correction to the Hazardous Waste Identification Rule (HWIR): Revisions to the Mixture and Derived-From Rules; Checklist 194.	October 3, 2001; 66 FR 50332.	NR 661.03; Effective August 1, 2006.
Inorganic Chemical Manufacturing Wastes Identification and Listing; Checklist 195.	November 20, 2001; 66 FR 58258.	NR 661.04, 661.32, 661 Appendix VII, 668.36, 668.40 Table; Effective August 1, 2006.
As amended 195.1 .....	April 9, 2002; 67 FR 17119	
CAMU Amendments; Checklist 196 .....	January 22, 2002; 67 FR 2962.	NR 660.10, 664.0550, 664.0551, 664.0552, 664.0554, 664.0555; Effective August 1, 2006.
Hazardous Air Pollutant Standards for Combustors Interim Standards; Checklist 197.	February 13, 2002; 67 FR 6792.	NR 664.0340, 665.0340, 666.100, 670.019, 670.022, 670.062, 670.066, 670.235; Effective August 1, 2006.
Hazardous Air Pollutant Standards for Combustors; Corrections; Checklist 198.	February 14, 2002; 67 FR 6968.	NR 666.100, 670.042; Effective August 1, 2006.
Vacatur of Mineral Processing Spent Materials Being Reclaimed as Solid Wastes and TCLP Used with MGP Waste; Checklist 199.	March 13, 2002; 67 FR 11251.	NR 661.02, 661.04, 661.24; Effective August 1, 2006.
Zinc Fertilizers Made From Recycled Hazardous Secondary Materials; Checklist 200.	July 24, 2002; 67 FR 48393	NR 661.04, 666.020, 668.40; Effective August 1, 2006.
Land Disposal Restrictions: National Treatment Variance to Designate New Treatment Subcategories for Radioactively Contaminated Cadmium-, Mercury-, and Silver-Containing Batteries; Checklist 201.	October 7, 2002; 67 FR 62618.	NR 668.40/Table; Effective August 1, 2006.
NESHAP: Standards for Hazardous Air Pollutants for Hazardous Waste Combustors—Corrections; Checklist 202.	December 19, 2002; 67 FR 77687.	NR 670.019, 670.022, 670.062, 670.066; Effective August 1, 2006.
Hazardous Waste System; Modification of the Hazardous Waste Manifest System; Final Rule; Checklist 207.	March 4, 2005; 70 FR 10776.	NR 660.10, 661.07, 662.020, 662.191, 662.021, 662.190, 662.027, 662.032, 662.033, 662.034, 662.192, 662.054, 662.60, 662 Appendix, 662 Appendix/8700–22, 662 Appendix/8700–22A, 663.20, 663.21, 664.0070, 664.0071, 664.0072, 664.0076, 665.0070, 665.0071, 665.0072, 665.0076; Effective April 1, 2007.
As amended; Checklist 207.1 .....	June 16, 2005; 70 FR 35034.	

### G. Where Are the Revised State Rules Different From the Federal Rules?

These practices are prohibited in Wisconsin: Underground Injection (40 CFR part 144), and Land Treatment (40 CFR 270.20). Wisconsin also does not provide for Permit by Rule (40 CFR 270.60). Wisconsin does not allow automatic authorization under the permit modification regulations found in 40 CFR 270.42(b)(6). The 10 year Remedial Action Plan, or RAP (40 CFR 270.79 *et seq.*) is replaced by a 5 year Remediation Variance (NR670.079).

These Wisconsin regulations are more stringent: 662.220(5)(c,d), 662.220(6)(c,d,f), and 670.030 (annual report required instead of a biennial report).

Wisconsin maintains different financial regulations, that allow for additional equivalent financial mechanisms (664.0143), do not allow the net worth test for closure under Part 665, and maintain some more stringent insurance requirements under

664.0143(5)(h), 664.0147(1)(a)(3), and 665.0147(1)(a)(3).

The following Wisconsin regulations have no Federal Counterpart: 666.081, 666.900 through 666.910, and 673.11. On the converse, there are no Wisconsin provisions for 40 CFR 268.5, 268.44 (other than 268.44(h)), and 270.3 as these are Federal non-delegable provisions.

### H. Who Handles Permits After the Authorization Takes Effect?

Wisconsin will issue permits for all the provisions for which it is authorized and will administer the permits it issues. EPA will continue to administer any RCRA hazardous waste permits or portions of permits which we issued prior to the effective date of this authorization until they expire or are terminated. We will not issue any more new permits or new portions of permits for the provisions listed in the Table above after the effective date of this authorization. EPA will continue to

implement and issue permits for HSWA requirements for which Wisconsin is not yet authorized.

### I. How Does This Action Affect Indian Country (18 U.S.C. 1151) in Wisconsin?

Wisconsin is not authorized to carry out its hazardous waste program in "Indian Country," as defined in 18 U.S.C. 1151. Indian Country includes:

1. All lands within the exterior boundaries of Indian reservations within the State of Wisconsin;
2. Any land held in trust by the U.S. for an Indian tribe; and
3. Any other land, whether on or off an Indian reservation that qualifies as Indian Country.

Therefore, this action has no effect on Indian Country. EPA will continue to implement and administer the RCRA program in Indian Country.

### J. What Is Codification and Is EPA Codifying Wisconsin's Hazardous Waste Program as Authorized in This Rule?

Codification is the process of placing the State's statutes and regulations that comprise the State's authorized hazardous waste program into the Code of Federal Regulations. We do this by referencing the authorized State rules in 40 CFR part 272. Wisconsin's rules, up to and including those revised June 7, 1991, as corrected August 19, 1991, have previously been codified through the incorporation-by-reference effective February 4, 1992 (57 FR 4162). We reserve the amendment of 40 CFR part 272, subpart KK for the codification of Wisconsin's program changes until a later date.

### K. Statutory and Executive Order Reviews

This proposed rule only authorizes hazardous waste requirements pursuant to RCRA 3006 and imposes no requirements other than those imposed by State law (see **SUPPLEMENTARY INFORMATION**, Section A. Why are Revisions to State Programs Necessary?). Therefore this rule complies with applicable executive orders and statutory provisions as follows:

#### 1. Executive Order 18266: Regulatory Planning Review

The Office of Management and Budget has exempted this rule from its review under Executive Order 12866 (58 FR 51735, October 4, 1993).

#### 2. Paperwork Reduction Act

This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

#### 3. Regulatory Flexibility Act

After considering the economic impacts of today's rule on small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), I certify that this rule will not have a significant economic impact on a substantial number of small entities.

#### 4. Unfunded Mandates Reform Act

Because this rule approves pre-existing requirements under State law and does not impose any additional enforceable duty beyond that required by State law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4).

#### 5. Executive Order 13132: Federalism

Executive Order 13132 (64 FR 43255, August 10, 1999) does not apply to this rule because it will not have federalism implications (*i.e.*, 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).

#### 6. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Executive Order 13175 (65 FR 67249, November 9, 2000) does not apply to this rule because it will not have tribal implications (*i.e.*, substantial direct effects on one or more Indian tribes, or 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.)

#### 7. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

This rule is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it is not economically significant as defined in Executive Order 12866 and because the EPA does not have reason to believe the environmental health or safety risks addressed by this action present a disproportionate risk to children.

#### 8. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This rule is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not a significant regulatory action as defined in Executive Order 12866.

#### 9. National Technology Transfer Advancement Act

EPA approves State programs as long as they meet criteria required by RCRA, so it would be inconsistent with applicable law for EPA, in its review of a State program, to require the use of any particular voluntary consensus standard in place of another standard that meets requirements of RCRA. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply to this rule.

#### 10. Executive Order 12988

As required by section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996), in issuing this rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize

potential litigation, and provide a clear legal standard for affected conduct.

#### 11. Executive Order 12630: Evaluation of Risk and Avoidance of Unanticipated Takings

EPA has complied with Executive Order 12630 (53 FR 8859, March 18, 1988) by examining the takings implications of the rule in accordance with the Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings issued under the executive order.

#### 12. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low Income Populations

Because this rule proposes authorization of pre-existing State rules and imposes no additional requirements beyond those imposed by State law and there are no anticipated significant adverse human health or environmental effects, the rule is not subject to Executive Order 12898 (59 FR 7629, February 16, 1994).

#### List of Subjects in 40 CFR Part 271

Environmental protection, Administrative practice and procedure, Confidential business information, Hazardous materials transportation, Hazardous waste, Indians-lands, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements.

**Authority:** This action is issued under the authority of sections 2002(a), 3006 and 7004(b) of the Solid Waste Disposal Act as amended 42 U.S.C. 6912(a), 6926, 6974(b).

Dated: October 23, 2008.

Walter W. Kovalick, Jr.

Acting Regional Administrator, United States Environmental Protection Agency, Region 5.

[FR Doc. E8-27971 Filed 11-24-08; 8:45 am]

BILLING CODE 6560-50-P

## DEPARTMENT OF HOMELAND SECURITY

### Transportation Security Administration

49 CFR Parts 1515, 1520, 1522, 1540, 1542, 1544, and 1550

[Docket No. TSA-2008-0021]

RIN 1652-AA53

### Large Aircraft Security Program, Other Aircraft Operator Security Program, and Airport Operator Security Program

AGENCY: Transportation Security Administration, DHS.



**ACTION:** Proposed rule; extension of comment period.

**SUMMARY:** The Transportation Security Administration (TSA) is extending the comment period on the notice of proposed rulemaking (NPRM) regarding the Large Aircraft Security Program (LASP) published on October 30, 2008. TSA has received and decided to grant the request for an extension of the comment period for an additional sixty (60) days. The comment period will now end on February 27, 2009, instead of December 29, 2008.

**DATES:** The comment period for the proposed rule at 73 FR 64790, October 30, 2008, is extended until February 27, 2009.

**ADDRESSES:** You may submit comments, identified by the TSA docket number to this rulemaking, to the Federal Docket Management System (FDMS), a government-wide, electronic docket management system, using any one of the following methods:

**Electronically:** You may submit comments through the Federal eRulemaking portal at <http://www.regulations.gov>. Follow the online instructions for submitting comments.

**Mail, In Person, or Fax:** Address, hand-deliver, or fax your written comments to the Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12-140, Washington, DC 20590-0001; Fax 202-493-2251. The Department of Transportation (DOT), which maintains and processes TSA's official regulatory dockets, will scan the submission and post it to FDMS.

See **SUPPLEMENTARY INFORMATION** for format and other information about comment submissions.

**FOR FURTHER INFORMATION CONTACT:** For program questions: Erik Jensen, Assistant General Manager, Policy and Plans, Office of General Aviation, TSNM, TSA-28, Transportation Security Administration, 601 South 12th Street, Arlington, VA 22202-4220; telephone (571) 227-2401; facsimile (571) 227-2918; e-mail [LASP@dhs.gov](mailto:LASP@dhs.gov).

For questions regarding Sensitive Security Information (SSI): Andrew Colsky, Director, SSI Office, Office of the Special Counselor (OSC), TSA-31, Transportation Security Administration, 601 South 12th Street, Arlington, VA 22202-4220; telephone (571) 227-3513; facsimile (571) 227-2945; e-mail [SSI@dhs.gov](mailto:SSI@dhs.gov).

**SUPPLEMENTARY INFORMATION:**

**Comments Invited**

TSA invites interested persons to participate in this action by submitting written comments, data, or views. We also invite comments relating to the economic, environmental, energy, or federalism impacts that might result from this action. See **ADDRESSES** above for information on where to submit comments.

With each comment, please identify the docket number at the beginning of your comments. TSA encourages commenters to provide their names and addresses. The most helpful comments reference a specific portion of the document, explain the reason for any recommended change, and include supporting data. You may submit comments and material electronically, in person, by mail, or fax as provided under **ADDRESSES**, but please submit your comments and material by only one means. If you submit comments by mail or delivery, submit them in an unbound format, no larger than 8.5 by 11 inches, suitable for copying and electronic filing.

If you would like TSA to acknowledge receipt of comments submitted by mail, include with your comments a self-addressed, stamped postcard on which the docket number appears. We will stamp the date on the postcard and mail it to you.

TSA will file in the public docket all comments received by TSA, except for comments containing confidential information and sensitive security information (SSI)<sup>1</sup>. TSA will consider all comments received on or before the closing date for comments and will consider comments filed late to the extent practicable. The docket is available for public inspection before and after the comment closing date.

**Handling of Confidential or Proprietary Information and Sensitive Security Information (SSI) Submitted in Public Comments**

Do not submit comments that include trade secrets, confidential commercial or financial information, or SSI to the public regulatory docket. Please submit such comments separately from other comments on the action. Comments containing this type of information should be appropriately marked as containing such information and submitted by mail to the address listed

<sup>1</sup> "Sensitive Security Information" or "SSI" is information obtained or developed in the conduct of security activities, the disclosure of which would constitute an unwarranted invasion of privacy, reveal trade secrets or privileged or confidential information, or be detrimental to the security of transportation. The protection of SSI is governed by 49 CFR part 1520.

**FOR FURTHER INFORMATION CONTACT** section.

Upon receipt of such comments, TSA will not place the comments in the public docket and will handle them in accordance with applicable safeguards and restrictions on access. TSA will hold documents containing SSI, confidential business information, or trade secrets in a separate file to which the public does not have access, and place a note in the public docket that TSA has received such materials from the commenter. If TSA determines, however, that portions of these comments may be made publicly available, TSA may include a redacted version of the comment in the public docket. If TSA receives a request to examine or copy information that is not in the public docket, TSA will treat it as any other request under the Freedom of Information Act (FOIA) (5 U.S.C. 552) and the Department of Homeland Security's (DHS') FOIA regulation found in 6 CFR part 5.

**Reviewing Comments in the Docket**

Please be aware that anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual who submitted the comment (or signed the comment, if submitted on behalf of an association, business, labor union, etc.). You may review the applicable Privacy Act Statement published in the **Federal Register** on April 11, 2000 (65 FR 19477), or you may visit <http://DocketInfo.dot.gov>.

You may review TSA's electronic public docket on the Internet at <http://www.regulations.gov>. In addition, DOT's Docket Management Facility provides a physical facility, staff, equipment, and assistance to the public. To obtain assistance or to review comments in TSA's public docket, you may visit this facility between 9 a.m. to 5 p.m., Monday through Friday, excluding legal holidays, or call (202) 366-9826. This docket operations facility is located in the West Building Ground Floor, Room W12-140 at 1200 New Jersey Avenue, SE., Washington, DC 20590.

**Availability of the Notice of Proposed Rulemaking and Comments Received**

You can get an electronic copy using the Internet by—

- (1) Searching the electronic Federal Docket Management System (FDMS) Web page at <http://www.regulations.gov>;
- (2) Accessing the Government Printing Office's Web page at <http://www.gpoaccess.gov/fr/index.html>; or
- (3) Visiting TSA's Security Regulations Web page at <http://www.regulations.gov>

[www.tsa.gov](http://www.tsa.gov) and accessing the link for "Research Center" at the top of the page.

In addition, copies are available by writing or calling the individual in the **FOR FURTHER INFORMATION CONTACT** section. Make sure to identify the docket number of this rulemaking.

#### Comment Period Extension

On October 30, 2008 (73 FR 64790), TSA published an NPRM on the Large Aircraft Security Program, Other Aircraft Operator Security Program, and Airport Operator Security Program. The NPRM has a 60-day comment period that would have ended on December 29, 2008. In a request dated October 30, 2008, the National Business Aviation Association (NBAA) and the Aircraft Owners and Pilots Association (AOPA) requested an extension of the deadline for filing comments on the LASP NPRM from December 29, 2008 to February 27, 2009. See Docket Item No. TSA-2008-0021-0018. NBAA and AOPA believe that the original 60-day comment period is insufficient time to provide TSA with substantive answers to the questions posed in the proposal or for community education and feedback.

TSA has decided to grant NBAA and AOPA's requests for an extension and, therefore, is extending the comment period for an additional sixty (60) days. The comment period will now be a total of 120 days and will end on February 27, 2009. This extension will allow the aviation industry and other interested entities and individuals additional time to complete their comments on the NPRM.

Issued in Arlington, Virginia, on November 19, 2008.

**Kip Hawley,**  
Assistant Secretary.

[FR Doc. E8-28011 Filed 11-24-08; 8:45 am]

BILLING CODE 9110-05-P

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

#### 50 CFR Part 679

[Docket No. 080103016-8417-01]

RIN 0648-AW40

#### Fisheries of the Exclusive Economic Zone Off Alaska; Revise Maximum Retainable Amounts of Groundfish Using Arrowtooth Flounder as a Basis Species in the Gulf of Alaska

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

**ACTION:** Proposed rule; request for comments.

**SUMMARY:** NMFS proposes a regulatory amendment to revise the maximum retainable amounts (MRAs) of groundfish using arrowtooth flounder as a basis species in the Gulf of Alaska. This action would increase the MRAs from 0 percent to 20 percent for deep-water flatfish, rex sole, flathead sole, shallow-water flatfish, Atka mackerel, and skates; from 0 percent to 5 percent for aggregated rockfish; and from 0 percent to 1 percent for sablefish. The intended effect of this action is to reduce regulatory discards of otherwise marketable groundfish in the arrowtooth flounder fishery. This action is intended to promote the goals and objectives of the Magnuson-Stevens Fishery Conservation and Management Act, the Fishery Management Plan for Groundfish of the Gulf of Alaska, and other applicable law.

**DATES:** Comments must be received no later than December 26, 2008.

**ADDRESSES:** Send written comments to Sue Salvesson, Assistant Regional Administrator, Sustainable Fisheries Division, Alaska Region, NMFS, Attn: Ellen Sebastian, Records Officer. You may submit comments, identified by "RIN 0648-AW40" by any one of the following methods:

- **Electronic Submissions:** Submit all electronic public comments via the Federal eRulemaking Portal website at <http://www.regulations.gov>.

- **Mail:** P.O. Box 21668, Juneau, AK 99802.

- **Fax:** (907) 586-7557.

- **Hand delivery to the Federal Building:** 709 West 9<sup>th</sup> Street, Room 420A, Juneau, AK.

All comments received are part of the public record and will be posted to <http://www.regulations.gov> without change. All Personal Identifying Information (e.g., name, address) voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information.

NMFS will accept anonymous comments (enter "N/A" in the required fields, if you wish to remain anonymous). Attachments to electronic comments must be in Microsoft Word, Excel, WordPerfect, or Adobe portable document file (pdf) formats to be accepted.

Copies of the Environmental Assessment/Regulatory Impact Review/Initial Regulatory Flexibility Analysis (EA/RIR/IRFA) prepared for this action are available from the NMFS Alaska Region at the address above or from the

Alaska Region Web site at <http://www.fakr.noaa.gov/sustainablefisheries.htm>.

**FOR FURTHER INFORMATION CONTACT:** Tom Pearson, 907-481-1780.

#### SUPPLEMENTARY INFORMATION:

##### Background

NMFS manages the groundfish fisheries in the exclusive economic zone in the Gulf of Alaska (GOA) under the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP). The North Pacific Fishery Management Council (Council) prepared the FMP under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), 16 U.S.C. 1801 *et seq.* Regulations governing U.S. fisheries and implementing the FMP appear at 50 CFR parts 600 and 679.

Regulations at (679.20(e) establish maximum retainable amount (MRA) percentages for groundfish species and species groups. These MRA percentages establish the amount of a species closed to directed fishing that may be retained onboard a vessel, relative to the amounts of other groundfish open to directed fishing retained onboard the vessel. MRA percentages serve as a management tool to slow down the rate of harvest and reduce the incentive for targeting a species closed to directed fishing. MRAs also allow for retention of incidentally caught species instead of requiring regulatory discards of species closed to directed fishing. MRA percentages do not reflect a natural incidental catch rate, but rather, reflect a balance between the recognized need to slow harvest rates, minimize the potential for discards, and, in some cases, provide an increased opportunity to harvest available total allowable catch (TAC) through limited targeting activity.

In 1994, and after it became apparent that several groundfish stocks as well as halibut were impacted, NMFS published an emergency interim rule to prohibit the use of arrowtooth flounder as a basis species for the purpose of retaining groundfish (59 FR 6222, February 10, 1994). This action prevented exceeding the overfishing limit of Pacific ocean perch and thornyhead rockfish. Also, it prevented premature fishery closures due to reaching the halibut prohibited species catch (PSC) limit. At the time the emergency rule was published, several vessel operators were deliberately targeting arrowtooth flounder to provide a basis for the retention of highly valued groundfish species, such as sablefish, which were closed to directed fishing. After landing, the retained arrowtooth

flounder was either discarded or made into fish meal. The prohibition was made permanent in 1995 (60 FR 40304, August 8, 1995).

By 1995, a limited market for arrowtooth flounder had begun to develop. In 1997, the MRAs for pollock and Pacific cod using arrowtooth flounder as a basis species were increased from 0 to 5 percent to reduce regulatory discards without providing an incentive to intentionally target an MRA species that is closed to directed fishing (62 FR 11109, March 11, 1997). This action was successful in reducing discards required by regulation and reduced the number of violation notices issued by the Office of Enforcement for exceeding the MRAs of pollock and Pacific cod. Since 1997, the incidental catch of pollock and Pacific cod in the arrowtooth flounder fishery has not increased from previous average rates. In 2006, as part of Amendment 69 to the FMP, which revised the formula used to establish the TAC for the (other species) complex, the MRA for (other species) (using arrowtooth flounder as a basis species) was increased from 0 to 20 percent (71 FR 12626, March 13, 2006). This action was also taken to reduce discards required by regulation.

In October 2006, the Council received a proposal from industry to increase the MRAs for several groundfish species using arrowtooth flounder as a basis species because arrowtooth flounder is now a viable target fishery. Effort by the trawl fleet to improve retention of groundfish species is constrained by the current MRAs. In addition, to support the increased catch of arrowtooth flounder, the annual TAC for arrowtooth flounder was increased from 5,000 mt to 8,000 mt in the Western GOA in 2001 and has remained at that level since then. The arrowtooth flounder TAC was increased from 25,000 mt to 30,000 mt in the Central GOA in 2007 and remained at that level in 2008. Total catch of arrowtooth flounder in the GOA, including both directed fishing and incidental catch in other groundfish fisheries, has increased from 16,247 mt in 1997 to 25,340 mt in 2007. Over the same period the retention of arrowtooth flounder in all trawl fisheries has increased from 18 percent to 58 percent of the total catch of arrowtooth flounder in the GOA, an indication of a growing market for arrowtooth flounder. In the 2006 directed arrowtooth flounder fishery in the GOA, 82 percent of arrowtooth flounder catch was retained.

The Council took final action in October 2007, and selected the industry's proposal as its preferred alternative. The proposed action would revise the GOA Retainable Percentages

listed in Table 10 to part 679 to increase the MRAs for selected groundfish species using arrowtooth flounder as a basis species. The MRAs for deep-water flatfish, rex sole, flathead sole, shallow-water flatfish, Atka mackerel, and skates would be increased from 0 percent to 20 percent; the MRA for aggregated rockfish would be increased from 0 percent to 5 percent; and the MRA for sablefish would be increased from 0 percent to 1 percent. The MRAs for pollock, Pacific cod, (other species), (and forage fish using arrowtooth flounder as a basis species) would not be changed.

The proposed MRAs are higher than the percentages of the groundfish catch from 2003 to 2006 associated with the directed arrowtooth flounder fishery for Atka mackerel, deep-water flatfish, flathead sole, rex sole, shallow-water flatfish, and skates, and lower for aggregated rockfish. Because the proposed MRAs are higher than the previously reported incidental catch amounts, this action would allow some increased catch of Atka mackerel, deep-water flatfish, flathead sole, rex sole, shallow-water flatfish, and rockfish without exceeding the TAC amounts established for these species.

The draft Environmental Assessment prepared for this action concluded that the proposed increase of the MRAs for selected species of groundfish using arrowtooth as a basis species would not affect any groundfish stock or any other component of the physical or biological environment. Under this proposed action, the MRAs for groundfish in the arrowtooth flounder fishery would be increased from current levels and greater amounts of groundfish closed to directed fishing could be retained in the arrowtooth flounder fishery instead of discarded. However, even though the amounts of groundfish retained in the arrowtooth flounder fishery would increase, total removals of each species would still be within the TAC levels for each species and would be further constrained by halibut PSC limitations that often close directed fishing for groundfish by vessels using trawl gear. The impacts of the harvest strategies and resulting TAC amounts were analyzed in the 2007 Alaska Groundfish Harvest Final Specifications Environmental Impact Statement available at <http://www.fakr.noaa.gov>.

The proposed rule would revise § 679.20(f)(2) to remove the requirement that arrowtooth flounder may not be used as a basis species to calculate retainable amounts of other groundfish species.

Minor editorial revisions would be made to Table 10 to part 679. The words "shallow water" and "deep water"

would be revised to "shallow-water" and "deep-water" to standardize the preferred spelling of these terms.

In note 1 to Table 10, the term "shortraker/rougheye" (171) would be removed because NMFS no longer has a species category or code in Table 2a to part 679 for the combination of shortraker and rougheye rockfish.

Note 10 to Table 10 lists the species included in the aggregated forage fish category. The word "families" in the parentheses following the term "Aggregated forage fish" would be replaced with the word "taxa" because all species of the order Euphausiacea (krill) also are included in the list of aggregated forage fish. The word taxa refers to more general groupings of similar organisms and includes taxonomic families and orders.

#### Classification

Pursuant to section 304 (b)(1)(A) and 305 (d) of the Magnuson-Stevens Act, the NMFS Assistant Administrator has determined that this proposed rule is consistent with the FMP, other provisions of the Magnuson-Stevens Act, and other applicable law, subject to further consideration after public comment.

This proposed rule has been determined to be not significant for the purposes of Executive Order 12866.

An initial regulatory flexibility analysis (IRFA) was prepared, as required by section 603 of the Regulatory Flexibility Act (RFA). The IRFA describes the economic impact this proposed rule, if adopted, would have on small entities. A description of the action, why it is being considered, and the legal basis for this action are contained at the beginning of this section in the preamble and in the SUMMARY section of the preamble. A copy of the EA/RIR/IRFA analysis is available from NMFS (see ADDRESSES).

The Small Business Administration has defined all fish-harvesting or hatchery businesses that are independently owned and operated, not dominant in their field of operation, and have annual receipts less than \$4.0 million as small businesses. In addition, seafood processors with 500 employees or fewer, wholesale industry members with 100 employees or fewer, not-for-profit enterprises, and government jurisdictions with a population of 50,000 or less are considered small entities. NMFS has determined that a "substantial number" of small entities would generally be 20 percent of the total universe of small entities affected by the regulation. A regulation would have a "significant negative impact" on these small entities if it reduced annual

gross revenues by more than 5 percent, increased total costs of production by more than 5 percent or resulted in compliance costs for small entities by at least 10 percent compared with compliance costs as a percent of sales for large entities.

The IRFA estimated that 18 trawl catcher vessels participating in the arrowtooth flounder fishery qualify as "small entities" for purposes of the Regulatory Flexibility Act. None of the catcher/processors participating in the arrowtooth flounder fishery qualify as small entities.

Three alternatives were analyzed for their impact. Alternative 1, the status quo or no action alternative, would leave the MRAs for groundfish in the arrowtooth flounder fishery unchanged from current levels, and would continue to require fishermen to discard otherwise marketable groundfish.

Alternative 2, the Council's preferred alternative brought forward as a proposal from the industry, would increase the MRAs for some species of groundfish in the arrowtooth flounder fishery in order to reduce discards of otherwise marketable fish without raising allocation concerns with respect to pollock, Pacific cod, rockfish, and sablefish. Alternative 3, developed by NMFS and Council staff, would increase

the MRAs for groundfish species caught in the arrowtooth flounder fishery to levels estimated to cover incidental catch of these species. Under Alternative 3 the MRAs for deep-water flatfish (5 percent), rex sole (10 percent), flathead sole (15 percent), shallow-water flatfish (5 percent), Atka mackerel (5 percent), and skates (10 percent) would be lower than the 20 percent proposed under Alternative 2.

Alternatives 2 and 3 would provide an opportunity to retain additional, economically valuable groundfish species in the arrowtooth flounder directed fishery. This would be beneficial to the affected small entities. The benefits to small entities under Alternative 2, the preferred alternative, would be slightly greater than under Alternative 3. No negative impacts on small entities are associated with either Alternative 2 or 3.

This proposed rule contains no additional collection-of-information requirements subject to review and approval by OMB under the Paperwork Reduction Act.

The analysis did not reveal any Federal rules that duplicate, overlap, or conflict with the proposed action.

#### List of Subjects in 50 CFR Part 679

Alaska, Fisheries.

Dated: November 20, 2008.

**Samuel D. Rauch III**

*Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.*

For the reasons set out in the preamble, 50 CFR part 679 is proposed to be amended as follows:

#### PART 679—FISHERIES OF THE EXCLUSIVE ECONOMIC ZONE OFF ALASKA

1. The authority citation for part 679 continues to read as follows:

**Authority:** 16 U.S.C. 773 *et seq.*; 1801 *et seq.*; 3631 *et seq.*; Pub. L. 108-447.

2. In § 679.20, revise the first sentence of paragraph (f)(2) to read as follows:

#### § 679.20 General limitations.

\* \* \* \* \*

(f) \* \* \*

(2) *Retainable amounts.* Any groundfish species for which directed fishing is closed may not be used to calculate retainable amounts of other groundfish species. \* \* \*

\* \* \* \* \*

3. Revise Table 10 to 50 CFR part 679 to read as follows:

BILLING CODE 3510-22-S

Table 10 to Part 679--Gulf of Alaska Retainable Percentages

Code	BASIS SPECIES Species	INCIDENTAL CATCH SPECIES (for DSR caught on catcher vessels in the SEO, see § 679.20(j) <sup>6</sup> )											Skates (11)	Aggregated forage fish <sup>(10)</sup>	Other species (7)	
		Pollock	Pacific cod	DW flat <sup>(2)</sup>	Rex sole	Flathead sole	SW Flat (3)	Arrowtooth	Sablefish	Aggregated rockfish <sup>(6)</sup>	SR/RE ERA <sup>(1)</sup>	DSR SEO (C/Ps only) (9)				Alaska mackerel
110	Pacific cod	20	na <sup>9</sup>	20	20	20	20	35	1	5	(1)	10	20	2	20	20
121	Arrowtooth	5	5	20	20	20	20	na <sup>9</sup>	1	5	0	0	20	2	20	20
122	Flathead sole	20	20	20	20	na <sup>9</sup>	20	35	7	15	7	1	20	2	20	20
125	Rex sole	20	20	20	na <sup>9</sup>	20	20	35	7	15	7	1	20	2	20	20
136	Northern rockfish	20	20	20	20	20	20	35	7	15	7	1	20	2	20	20
141	Pacific ocean perch	20	20	20	20	20	20	35	7	15	7	1	20	2	20	20
143	Thornyhead	20	20	20	20	20	20	35	7	15	7	1	20	2	20	20
152/ 151	Shortraker/ rougheye <sup>(1)</sup>	20	20	20	20	20	20	35	7	15	na <sup>9</sup>	1	20	2	20	20
193	Alta mackerel	20	20	20	20	20	20	35	1	5	(1)	10	na <sup>9</sup>	2	20	20
270	Pollock	na <sup>9</sup>	20	20	20	20	20	35	1	5	(1)	10	20	2	20	20
710	Sablefish	20	20	20	20	20	20	35	na <sup>9</sup>	15	7	1	20	2	20	20
Flatfish, deep-water <sup>(2)</sup>		20	20	na <sup>9</sup>	20	20	20	35	7	15	7	1	20	2	20	20
Flatfish, shallow-water <sup>(3)</sup>		20	20	20	20	na <sup>9</sup>	20	35	1	5	(1)	10	20	2	20	20
Rockfish, other <sup>(4)</sup>		20	20	20	20	20	20	35	7	15	7	1	20	2	20	20
Rockfish, pelagic <sup>(5)</sup>		20	20	20	20	20	20	35	7	15	7	1	20	2	20	20
Rockfish, DSR-SEO <sup>(6)</sup>		20	20	20	20	20	20	35	7	15	7	na <sup>9</sup>	20	2	20	20
Skates <sup>(11)</sup>		20	20	20	20	20	20	35	1	5	(1)	10	20	2	na <sup>9</sup>	20
Other species <sup>(7)</sup>		20	20	20	20	20	20	35	1	5	(1)	10	20	2	20	na <sup>9</sup>
Aggregated amount of non-groundfish species		20	20	20	20	20	20	35	1	5	(1)	10	20	2	20	20

Notes to Table 10 to Part 679	
1	Shortraker/rougheye rockfish SR/RE shortraker rockfish (152) rougheye rockfish (151) SR/RE ERA shortraker/rougheye rockfish in the Eastern Regulatory Area. Where numerical percentage is not indicated, the retainable percentage of SR/RE is included under Aggregated Rockfish
2	Deep-water flatfish Dover sole, Greenland turbot, and deep-sea sole
3	Shallow-water flatfish Flatfish not including deep-water flatfish, flathead sole, rex sole, or arrowtooth flounder means slope rockfish and demersal shelf rockfish
4	Western Regulatory Area Central Regulatory Area West Yakutat District Southeast Outside District means slope rockfish Slope rockfish S. aurora (aurora) S. melanostomus (blackgill) S. paucispinus (bocaccio) S. goodii (chillipepper) S. grameri (darkblotch) S. elongatus (greenstriped) S. variegatus (harlequin) S. wilsoni (pygmy) S. babcocki (redbanded) S. pronger (redstripe) S. zacentrus (sharpchin) S. jordani (shortbelly) S. gilliatii (dusky) S. pinniger (canary) S. nebulosus (china) S. saurus (copper) S. brevispinis (silvergrey) S. diplorea (spimose) S. saxicola (stripetail) S. miniatus (vermilion) S. reedi (yellowmouth) S. flavidus (yellowtail) S. ruberrimus (yelloweye)
5	Pelagic shelf rockfish In the Eastern GOA only. Slope rockfish also includes S. polvspinosus (Northern)
6	Demersal shelf rockfish (DSR) S. entomelas (widow) S. maliger (quillback) S. helvomatellatus (rosethorn) S. nigrocinctus (tiger) DSR-SEO = Demersal shelf rockfish in the Southeast Outside District The operator of a catcher vessel that is required to have a Federal fisheries permit, or that harvests IFQ halibut with hook and line or jig gear, must retain and land all DSR that is caught while fishing for groundfish or IFQ halibut in the SEO. Limits on sale and requirements for disposal of DSR are set out at § 679.20 (j).
7	Other species sculpins octopus sharks squid
8	Aggregated rockfish Means rockfish of the genera <i>Sebastes</i> and <i>Sebastes</i> defined at § 679.2 except in: Southeast Outside District (SEO) where DSR is a separate category for those species marked with a numerical percentage Eastern Regulatory Area (ERA) where SR/RE is a separate category for those species marked with a numerical percentage

Notes to Table 10 to Part 679	
9	N/A not applicable Aggregated forage fish (all species of the following taxa)
10	Bristlemouths, lightfishes, and anglemouths (family <u>Gomostomatidae</u> )
	Capelin smelt (family <u>Osmeriidae</u> )
	Deep-sea smelts (family <u>Bathylagidae</u> )
	Eulachon smelt (family <u>Osmeriidae</u> )
	Gunnels (family <u>Pholidae</u> )
	Krill (order <u>Euphausiacea</u> )
	Laternfishes (family <u>Myctophidae</u> )
	Pacific herring (family <u>Clupeidae</u> )
	Pacific sand fish (family <u>Trichostomidae</u> )
	Pacific sand lance (family <u>Ammodytidae</u> )
	Pricklebacks, war-bonnets, ceblennyis, cockscombs, and Shannys (family <u>Sichaeidae</u> )
	Surf smelt (family <u>Osmeriidae</u> )
	209
	516
	773
511	
207	
800	
772	
235	
206	
774	
208	
515	
11	Skates Species and Groups
	Big Skates
	702
	Longnose Skates
	701
	Other Skates
	700

**DEPARTMENT OF COMMERCE****National Oceanic and Atmospheric Administration****50 CFR Part 680**

RIN 0648-AW97

**Fisheries of the Exclusive Economic Zone Off Alaska; Bering Sea and Aleutian Islands Crab Rationalization Program**

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

**ACTION:** Notice of availability of fishery management plan amendment; request for comments.

**SUMMARY:** Congress amended the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) to require the Secretary of Commerce to approve the Bering Sea/Aleutian Islands Crab Rationalization Program (CR Program). The CR Program allocates Bering Sea and Aleutian Islands crab resources among harvesters, processors, and coastal communities. Amendment 28 would modify the Fishery Management Plan for Bering Sea/Aleutian Islands King and Tanner Crabs (FMP) and the CR Program to allow unlimited post-delivery transfers of all classes of individual fishing quota and individual processing quota. This action is necessary to improve the flexibility to the fleet, reduce the number of violations for overages, reduce enforcement costs, and allow for more complete harvest of allocations. This action is intended to promote the goals and objectives of the Magnuson-Stevens Act, the FMP, and other applicable laws.

**DATES:** Comments on the amendment must be received by November 25, 2008.

**ADDRESSES:** Send comments to Sue Salvesson, Assistant Regional Administrator, Sustainable Fisheries Division, Alaska Region, NMFS, Attn: Ellen Sebastian. You may submit comments, identified by "RIN 0648-AW97," by any one of the following methods:

• **Electronic Submissions:** Submit all electronic public comments via the FedereleRulemaking Portal website at <http://www.regulations.gov>.

• **Mail:** P. O. Box 21668, Juneau, AK 99802.

• **Fax:** (907) 586-7557.

• **Hand delivery to the Federal Building:** 709 West 9<sup>th</sup> Street, Room 420A, Juneau, AK.

All comments received are a part of the public record and will generally be posted to <http://www.regulations.gov> without change. All personal identifying information (e.g., name, address) voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information.

NMFS will accept anonymous comments (enter N/A in the required fields, if you wish to remain anonymous). Attachments to electronic comments will be accepted in Microsoft Word, Excel, WordPerfect, or Adobe portable document file (pdf) formats only.

The proposed rule to implement Amendment 28 to the FMP was categorically excluded from the need to prepare an environmental assessment under the National Environmental Policy Act. Copies of Amendment 28, the categorical exclusion memorandum, the Regulatory Impact Review/Initial Regulatory Flexibility Analysis (RIR/IRFA) for this action, as well as the Environmental Impact Statement prepared for the Crab Rationalization Program may be obtained from the NMFS Alaska Region at the address above or from the Alaska Region website at <http://alaskafisheries.noaa.gov>.

**FOR FURTHER INFORMATION CONTACT:** Glenn Merrill, 907-586-7459, or Julie Scheurer, 907-586-7356.

**SUPPLEMENTARY INFORMATION:** The Magnuson-Stevens Act requires that each regional fishery management council submit any fishery management plan amendment it prepares to NMFS for review and approval, disapproval, or partial approval by the Secretary of Commerce. The Magnuson-Stevens Act also requires that NMFS, upon receiving a fishery management plan amendment, immediately publish a notice in the *Federal Register* announcing that the amendment is available for public review and comment. This notice announces that proposed Amendment 28 to the Fishery Management Plan for Bering Sea/Aleutian Islands King and Tanner Crabs is available for public review and comment.

The king and Tanner crab fisheries in the exclusive economic zone of the Bering Sea and Aleutian Islands (BSAI) are managed under the FMP. The FMP was prepared by the North Pacific Fishery Management Council (Council) under the Magnuson-Stevens Act. Amendments 18 and 19 amended the FMP to include the CR Program. Regulations implementing Amendments 18 and 19 were published on March 2,

2005 (70 FR 10174), and are located at 50 CFR part 680.

The Council submitted Amendment 28 to the FMP for Secretarial review. Amendment 28 would make minor changes to the FMP to allow unlimited transfers of individual fishing quota (IFQ) and individual processing quota (IPQ) to cover overages.

Under the CR Program, NMFS issued quota share (QS) to persons based on their qualifying harvest histories in the BSAI crab fisheries during a specific time period. Each year, the QS issued to a person yields an amount of IFQ in pounds of raw crab as a proportion of the total QS pool in a crab fishery. There are four types of IFQ: Class A, Class B, C shares, and catcher processor vessel owner IFQ. Similarly, crab processors were issued processor quota share that yields annual IPQ. Class A IFQ is subject to regional delivery requirements. Crab harvested with Class A IFQ must be delivered to processors with an equivalent amount of IPQ available. This proposed amendment would primarily affect holders of Class A IFQ.

Under existing regulations, harvesters are prohibited from exceeding the amount of IFQ that is issued to them, either individually, or to their cooperative (see § 680.7(e)(2)), and processors are prohibited from receiving more IFQ than the amount of unused IPQ that they hold (see regulations at § 680.7(a)(5)). If a harvester delivers more crab than the amount of IFQ that he holds, he has violated existing regulations, commonly known as an overage. Overages can occur either through deliberate actions, or more commonly through unintentional errors. Generally, overages of less than 3 percent are subject to forfeiture of the overage, with larger or repeat violations subject to additional penalties at the discretion of NOAA Office for Law Enforcement.

Amendment 28, if approved, would allow post-delivery transfers to cover overages of IPQ as well as all classes of IFQ. There would be no limit on the size of a post-delivery transfer or on the number of post-delivery transfers a person could undertake. However, a person could not begin a new fishing trip if any of the IFQ accounts of the IFQ permits used on a vessel were negative or zero, and no person could have a negative balance in an IFQ or IPQ account after June 30, the end of a crab fishing year. The Council recommended Amendment 28 to the FMP to improve flexibility to the fleet, reduce the number of violations for overages, reduce enforcement costs, and allow more complete harvest of allocations.



The RIR/IRFA prepared for this action describes in detail the costs and benefits of the proposed amendment (see **ADDRESSES** for availability). All of the directly regulated entities would be expected to benefit from this action relative to the status quo because the proposed amendment would allow greater flexibility and a longer time period over which to account for overages.

Public comments are being solicited on proposed Amendment 28 through the end of the comment period (see **DATES**). NMFS intends to publish in the **Federal Register** and seek public

comment on a proposed rule that would implement Amendment 28, following NMFS' evaluation of the proposed rule under the Magnuson-Stevens Act. Public comments on the proposed rule must be received by the end of the comment period on Amendment 28 to be considered in the approval/disapproval decision on Amendment 28. All comments received by the end of the comment period on Amendment 28, whether specifically directed to the FMP amendment or the proposed rule, will be considered in the decision to approve or disapprove the amendment. Comments received after that date will

not be considered in the decision on the amendment. To be considered, comments must be received, not just postmarked or otherwise transmitted, by the close of business on the last day of the comment period.

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

Dated: November 19, 2008.

**Emily H. Menashes**

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

[FR Doc. E8-28015 Filed 11-24-08; 8:45 am]

**BILLING CODE 3510-22-S**

## Notices

Federal Register

Vol. 73, No. 228

Tuesday, November 25, 2008

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

#### Forest Service

#### Black Hills National Forest, Bearlodge Ranger District, Sundance, WY—Rattlesnake Forest Management Project

**AGENCY:** Forest Service, USDA.

**ACTION:** Revised Notice of Intent to Prepare an Environmental Impact Statement.

**SUMMARY:** This notice of intent revises the previously published notice of intent for the Rattlesnake Project (73 FR 65284, Nov. 3, 2008). Due to a printing error, the previously published notice contained an incorrect electronic mail address. This notice corrects the address and extends the comment due date.

The Forest Service will prepare an environmental impact statement (EIS) on a proposal to implement multiple resource management actions in the Rattlesnake Project Area to implement the amended Black Hills National Forest Land and Resource Management Plan. The proposed action includes approximately 11,000 acres of commercial timber harvest, 5,000 acres of non-commercial vegetation management, 6,000 acres of prescribed burning, three miles of road construction, road improvements, and watershed improvements. Prescribed burning is proposed in a roadless area.

**DATES:** Comments concerning the scope of the analysis must be received by December 22, 2008. The draft EIS is expected to be available for public review in March 2009, and the final EIS is expected to be completed by June 2009.

**ADDRESSES:** Send written comments to Rattlesnake Project, c/o Content Analysis Group, 172 E. 500 S., Bountiful, UT 84010. Fax number: (801) 397-1605. Electronic mail: [bhnf@contentanalysisgroup.com](mailto:bhnf@contentanalysisgroup.com). Comments may be hand-delivered to the

Bearlodge Ranger District office, 101 South 21st Street, Sundance, Wyoming, between the hours of 8 a.m. and 4:30 p.m., Monday through Friday, excluding federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Elizabeth Krueger, Resource Planner, Bearlodge Ranger District, Black Hills National Forest. Telephone number: (307) 283-1361.

#### SUPPLEMENTARY INFORMATION:

##### Purpose of and Need for Action

The purpose of actions proposed under the Rattlesnake Forest Management Project is to provide biologically diverse ecosystems, protect basic resources, and provide for sustained commodity uses by reducing crown fire hazard and wildfire threats to private property, reducing risk of mountain pine beetle infestation, producing commercial timber now and creating conditions for future timber production, conserving and enhancing big game winter range, enhancing forest structural diversity, and conserving and enhancing late successional landscapes.

##### Proposed Action

The Rattlesnake Project Area covers approximately 42,171 acres of National Forest System land and 3,935 acres of interspersed private land east of Sundance, Wyoming. To reduce wildfire hazard, the Forest Service proposes to thin pine stands, construct fuel breaks, reduce fuels adjacent to populated areas and across the landscape, reduce pine competition with aspen and birch stands, and conduct prescribed burning. To reduce risk of beetle infestation, activities would include thinning and regeneration of pine stands. To produce commercial timber and create conditions for future timber production, proposed activities include regeneration and shelterwood removal in pine stands, thinning of merchantable and submerchantable pine, and reduction of bur oak competition. To conserve and enhance winter range, activities would include uneven-age management of pine stands, reduction of pine and oak competition with desirable forage, and prescribed burning. To enhance forest structural diversity, the proposal includes regeneration harvest in pine and conservation of stands that could develop into late successional forest. Road construction, repair, and improvement would occur in support of

these activities. New roads would be closed following harvest, and existing roads not part of the National Forest System could also be closed in conjunction with this project. To conserve and enhance late successional landscapes (management area 3.7), the Forest Service would conduct prescribed burning. Other proposed enhancement activities include watershed improvement through road and stream rehabilitation.

The Rattlesnake Project Area includes the 7,944-acre Sand Creek Roadless Area. Most of the Sand Creek area is unsuitable for timber harvest, and new road construction is prohibited in much of the area by Forest Plan direction, severely limiting opportunities for mechanical treatment. The Forest Service considers access to the area by commercial equipment impractical at this time and has chosen to focus on objectives that could be achieved by non-commercial means. As a result, the only action proposed in the Sand Creek Roadless Area is prescribed burning (2,386 acres), with the purpose of promoting late successional forest attributes.

##### Background

The Rattlesnake Project area encompasses the area of the Cement Project. The Forest Service approved the Cement Project on February 20, 2004. The project was litigated. Following a July 2005 wildfire that substantially altered forest conditions in the Cement Project area, the Forest Service withdrew the project. The complaint was subsequently dismissed in April 2006.

In the course of the withdrawal of the Cement Project decision and dismissal of the complaint, the Forest Service made several commitments regarding any new proposal in the Cement Project Area. These commitments pertained to addressing certain changed conditions; developing the range of alternatives; and soliciting and considering public comment on the new proposal. The Forest Service intends to honor these commitments in the analysis process for the Rattlesnake Project.

The Rattlesnake Project Area includes the Cement Project Area but is a new and separate proposal from the earlier Cement Project. Initial planning for the Rattlesnake Project began in October 2007 with a review of existing forest conditions and amended Forest Plan

direction for management of the area. Circumstances affecting National Forest System lands in the Rattlesnake Project Area have changed substantially since 2004. (1) The Phase II Amendment to the Forest Plan was approved on October 31, 2005. This amendment altered management direction for the Black Hills National Forest, including the Rattlesnake Project area, by adding broad-scale objectives increasing management emphasis on hazardous fuels, forest structural diversity, and habitat for rare species. These changes directly affect the type and extent of vegetation management actions the Forest Service takes in the Black Hills. (2) The Cement Fire of July 2005 burned 2,079 acres of National Forest System land in the Rattlesnake Project area. Approximately 77 percent of this area burned at moderate or high intensity, resulting in the mortality of an estimated 1,925,300 cubic feet of sawtimber. (3) Population adjacent to the Rattlesnake Project Area has increased in the last four years with subdivision of the Red Canyon Ranch. These developments could be affected by hazardous fuel conditions in the project area. (4) Mountain pine beetle populations have increased dramatically in an area about five miles south of the Rattlesnake Project area, causing high levels of pine mortality on several hundred acres. This infestation has the potential to spread to the Rattlesnake area. (5) The Forest Service has issued new regulations implementing the National Forest Management Act. These new regulations replace earlier direction under which the Cement Project decision was analyzed and approved. The new planning regulations make it clear that they have minimal application at the project level. This project would be conducted in accordance with the requirements of the new regulations.

#### Responsible Official

Steve Kozel, District Ranger, Bearlodge Ranger District, Black Hills National Forest, 101 South 21st Street, PO Box 680, Sundance, Wyoming 82729.

#### Nature of Decision To Be Made

The decision to be made is whether to approve the proposed action or alternatives at this time. No Forest Plan amendments are proposed.

#### Scoping Process

Comments and input regarding the proposed action are being requested from the public and other interested parties in conjunction with this notice of intent. The comment period will be open for thirty days, beginning on the

date of publication of this notice of intent. Response to the draft EIS will be sought from the interested public beginning approximately in March 2009.

#### Comment Requested

This notice of intent initiates the scoping process, which guides development of the environmental impact statement. It is our desire to involve interested parties in identifying the issues related to proposed activities. Comments will assist in identification of key issues and opportunities to develop project alternatives and mitigation measures.

#### Early Notice of Importance of Public Participation in Subsequent Environmental Review:

A draft EIS will be prepared for comment. The comment period on the draft EIS will extend 45 days from the date the Environmental Protection Agency publishes the notice of availability in the **Federal Register**. This notice is expected to appear in February 2009.

The Forest Service believes, at this early stage, it is important to give reviewers notice of several court rulings related to public participation in the environmental review process. First, reviewers of draft EISs must structure their participation in the environmental review of the proposal so that it is meaningful and alerts an agency to the reviewer's position and contentions (*Vermont Yankee Nuclear Power Corp. v. NRDC*, 435 U.S. 519, 553 (1978)). Also, environmental objections that could be raised at the draft EIS stage but that are not raised until after completion of the final EIS may be waived or dismissed by the courts (*City of Angoon v. Hodel*, 803 F.2d 1016, 1022 (9th Cir. 1986) and *Wisconsin Heritages, Inc. v. Harris*, 490 F. Supp. 1334, 1338 (E.D. Wis. 1980)). Because of these court rulings, it is very important that those interested in this proposed action participate by the close of the 45-day comment period so that substantive comments and objections are made available to the Forest Service at a time when it can meaningfully consider them and respond to them in the final EIS.

To assist the Forest Service in identifying and considering issues and concerns on the proposed action, comments on the draft EIS should be as specific as possible. It is also helpful if comments refer to specific pages or chapters of the draft EIS. Comments may also address the adequacy of the draft EIS or the merits of the alternatives formulated and discussed in the statement. Reviewers may wish to refer to the Council on Environmental Quality Regulations for implementing

the procedural provisions of the National Environmental Policy Act at 40 CFR 1503.3 in addressing these points. Comments received, including the names and addresses of those who comment, will be considered part of the public record on this proposal and will be available for public inspection.

(Authority: 40 CFR 1501.7 and 1508.22; Forest Service Handbook 1909.15, Section 21)

Dated: November 17, 2008.

**Craig Bobzien,**

*Forest Supervisor.*

[FR Doc. E8-27840 Filed 11-24-08; 8:45 am]

BILLING CODE 3410-11-M

## DEPARTMENT OF COMMERCE

### International Trade Administration

A-533-824

#### Polyethylene Terephthalate Film, Sheet, and Strip from India: Final Results of Antidumping Duty Administrative Review

**AGENCY:** Import Administration, International Trade Administration, Department of Commerce.

**SUMMARY:** On August 6, 2008, the Department of Commerce (the Department) published in the **Federal Register**, the preliminary results of this administrative review of Polyethylene Terephthalate Film, Sheet, and Strip (PET Film). See *Polyethylene Terephthalate Film, Sheet, and Strip from India: Preliminary Results of and Partial Recession of the Antidumping Duty Administrative Review*, 73 FR 45699 (August 6, 2008) (*Preliminary Results*). The review covers one respondent, Jindal Poly Films Limited (Jindal). The period of review (POR) is July 1, 2006, through June 30, 2007. We invited interested parties to submit comments on our *Preliminary Results*. Based on our analysis of the comment received, we have made a change to our calculations with respect to the treatment of duty drawback. For the final dumping margins see the "Final Results of Review" section below.

**EFFECTIVE DATE:** November 25, 2008.

**FOR FURTHER INFORMATION CONTACT:** Martha Douthit, AD/CVD Operations, Office 6, Import Administration, International Trade Administration, Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230; telephone: (202) 482-5050.

**SUPPLEMENTARY INFORMATION:**

## Background

Since the publication of the *Preliminary Results*, the following event has occurred. On August 25, 2008, Jindal timely submitted a case brief commenting on the calculations with respect to duty drawback. Petitioners, Dupont Teijin Films, Mitsubishi Polyester Film Of America, Toray Plastics (America), Inc., and SKC America, Inc. did not file a case or rebuttal brief.

## Scope of the Order

The products covered by the antidumping duty order are all gauges of raw, pretreated, or primed PET film, whether extruded or coextruded. Excluded are metallized films and other finished films that have had at least one of their surfaces modified by the application of a performance-enhancing resinous or inorganic layer of more than 0.00001 inches thick. Imports of PET film are currently classifiable in the Harmonized Tariff Schedule of the United States (HTSUS) under item number 3920.62.00.90. HTSUS subheadings are provided for convenience and customs purposes. The written description of the scope of the antidumping duty order is dispositive.

On August 25, 2003, the Department determined, in a scope ruling, that tracing and drafting film is outside of the scope of the order. See *Notice of Scope Ruling*, 70 FR 24533 (May 10, 2005).

## Analysis of Comment Received

The sole issue raised in the case brief by a party to this proceeding is addressed in the Memorandum from Stephen J. Claeys, Deputy Assistant Secretary for Import Administration, to David M. Spooner, Assistant Secretary for Import Administration, Issue and Decision Memorandum for the Final Results of Administrative Review of the Antidumping Duty Order on PET Film from India, (Decision Memorandum), dated concurrently with this notice, which is hereby adopted by this notice. The sole issue raised concerns the treatment of duty drawback. Parties can find a complete discussion of this issue in this public memorandum which is on file in the Central Records Unit, room 1117 of the Department of Commerce building. In addition, a complete version of the Decision Memorandum can be accessed directly on the Internet at: <http://ia.ita.doc.gov/frn>. The paper copy and the electronic version of the Decision Memorandum are identical in content.

## Changes Since the Preliminary Results

Based on the comment received from Jindal, we have made a change to the margin calculations used in the *Preliminary Results*. The adjustment is discussed in detail in the Decision Memorandum.

## Final Results of Review

We determine that the following weighted average antidumping margin exists for the period July 1, 2006, through June 30, 2007.

Manufacturer/Exporter	Weighted-Average Margin
Jindal Poly Films Limited (Jindal) .....	0.00 percent ( <i>de minimis</i> )

## Assessment

The Department shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries pursuant to section 751(a)(1)(B) of the Tariff Act of 1930, as amended (the Act). Pursuant to 19 CFR 351.106(c)(2), we will instruct CBP to liquidate without regard to antidumping duties any entries for which the assessment rate is *de minimis* (i.e., less than 0.50 percent). The Department intends to issue assessment instructions directly to CBP 15 days after the date of publication of these final results of review.

The Department clarified its "automatic assessment" regulation on May 6, 2003 (68 FR 23954). See *Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties*, 68 FR 23954 (May 6, 2003). This clarification will apply to entries of subject merchandise during the POR produced by any of the companies for which we are rescinding this review, and for which each no-shipment respondent did not know its merchandise would be exported by another company to the United States. In such instances, we will instruct CBP to liquidate unreviewed entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction.

## Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date, consistent with section 751(a)(2)(C) of the Act: (1) the cash deposit rate will be zero for Jindal; (2)

if the exporter is not a firm covered in this review, but was covered in a previous review or the original less than fair value (LTFV) investigation, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (3) if the exporter is not a firm covered in this review, a prior review, or the original LTFV investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; and (4) if neither the exporter nor the manufacturer is a firm covered in this or any previous review conducted by the Department, the cash deposit rate will continue to be the "All Others" rate established in the original LTFV investigation, adjusted for the export subsidy rate found in the companion countervailing duty investigation, which results in a rate of 5.71 percent. See *Certain Polyethylene Terephthalate Film, Sheet, and Strip from India: Final Results of Antidumping Duty Administrative Review*, 70 FR 8072 (February 17, 2005). These cash deposit requirements, when imposed, shall remain in effect until further notice.

## Notification to Importers

This notice also serves as the final reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

## Notification Regarding Administrative Protective Order

This notice also serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO as explained in the APO itself. See 19 CFR 351.305(a)(3). Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of the APO is a sanctionable violation.

This notice is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: November 17, 2008.

David M. Spooner,

Assistant Secretary for Import Administration.

[FR Doc. E8-28018 Filed 11-24-08; 8:45 am]

BILLING CODE 3510-DS-S

## DEPARTMENT OF COMMERCE

### International Trade Administration

[A-823-808]

#### Certain Cut-to-Length Carbon Steel Plate From Ukraine; Preliminary Results of Full Sunset Review of the Suspension Agreement

**AGENCY:** Import Administration, International Trade Administration, Department of Commerce.

**ACTION:** Notice of Preliminary Results of the Full Sunset Review of the Suspension Agreement on Certain Cut-to-Length Carbon Steel Plate from Ukraine.

**SUMMARY:** On August 1, 2008, the Department of Commerce ("the Department") initiated a sunset review of the suspended antidumping duty investigation on certain cut-to-length carbon steel plate ("CTL plate") from Ukraine pursuant to section 751(c) of the Tariff Act of 1930, as amended ("the Act"). See *Initiation of Five-year ("Sunset") Review*, 73 FR 44968 (August 1, 2008) ("Initiation Notice"). On the basis of notices of intent to participate filed on behalf of domestic interested parties and adequate substantive comments filed on behalf of domestic and respondent interested parties, the Department is conducting a full (240-day) review. As a result of this review, the Department preliminarily finds that termination of the suspended antidumping duty investigation on CTL plate from Ukraine would likely lead to continuation or recurrence of dumping at the levels indicated in the Preliminary Results of Review section of this notice.

**DATES:** *Effective Date:* November 25, 2008.

**FOR FURTHER INFORMATION CONTACT:** Judith Rudman or Jay Carreiro, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230, telephone: (202) 482-0192 or (202) 482-3674.

#### SUPPLEMENTARY INFORMATION:

##### History of the Suspension Agreement

On December 3, 1996, the Department initiated an antidumping duty

investigation under section 732 of the Tariff Act of 1930 ("the Act") on certain cut-to-length carbon steel plate ("CTL plate") from Ukraine. See *Initiation of Antidumping Duty Investigations: Certain Cut-to-Length Carbon Steel Plate from the People's Republic of China, Ukraine, the Russian Federation, and the Republic of South Africa*, 61 FR 64051 (December 3, 1996). On June 11, 1997, the Department preliminarily determined that CTL plate from Ukraine was being, or was likely to be, sold in the United States at less than fair value. See *Preliminary Determination of Sales at Less Than Fair Value; Certain Cut-to-Length Carbon Steel Plate from Ukraine*, 62 FR 31958 (June 11, 1997).

The Department suspended the antidumping duty investigation on October 24, 1997, on the basis of an agreement by the Government of Ukraine to restrict the volume of direct and indirect exports of CTL plate to the United States in order to prevent the suppression or undercutting of price levels of U.S. domestic like products. See *Suspension of Antidumping Duty Investigation: Certain Cut-to-Length Carbon Steel Plate From Ukraine*, 62 FR 61766 (November 19, 1997). Thereafter, the Department completed its investigation and published in the **Federal Register** its final determination of sales at less than fair market value. In the final determination, the Department calculated weighted-average dumping margins of 81.43 percent for JSC Azovstal Iron & Steel Works ("Azovstal"), 155.00 percent for JSC Ilyich Iron & Steel Works ("Ilyich"), and 237.91 for "all other" Ukrainian manufacturers, producers, and exporters of the subject merchandise. See *Notice of Final Determination of Sales at Less Than Fair Value: Certain Cut-to-Length Carbon Steel Plate From Ukraine*, 62 FR 61754 (November 19, 1997). A Suspension Agreement ("Agreement") remains in effect for all manufacturers, producers, and exporters of CTL plate from Ukraine.<sup>1</sup>

#### Background

On August 1, 2008, the Department initiated a sunset review of the suspended antidumping duty investigation on CTL plate from Ukraine, pursuant to section 751(c) of the Act. See *Initiation Notice*, 73 FR

<sup>1</sup> On September 29, 2008, a revised Suspension Agreement was signed by representatives of Ukrainian CTL plate producers. This agreement became effective November 1, 2008, and replaces the previous non-market economy agreement, and amendments to it, that have been in effect since 1997. For more information, see [http://www.trade.gov/press/press\\_releases/2008/ukraine\\_092908.asp](http://www.trade.gov/press/press_releases/2008/ukraine_092908.asp).

44968. The Department received notices of intent to participate on behalf of ArcelorMittal USA, SSAB North America Division, Evraz S.A. Oregon Steel Mills and Evraz S.A. Claymont, and Nucor Corporation (collectively, "domestic interested parties"), within the applicable deadline specified in section 351.218(d)(1)(i) of the Department's regulations. See *Notices of Intent to Participate for ArcelorMittal USA, Inc.* (August 18, 2008) and *SSAB North America Division; Evraz S.A. Oregon Steel Mills; and Evraz S.A. Claymont* (August 15, 2008). Domestic interested parties claimed interested-party status under section 771(9)(C) of the Act as producers of the domestic like products. In addition, domestic interested parties assert that they are not related to a foreign producer/exporter and are not importers, or related to importers, of the subject merchandise.

The Department also received complete substantive responses from the domestic interested parties within the 30-day deadline specified in the Department's regulations under section 351.218(d)(3)(i). See *Collective Substantive Response for ArcelorMittal USA, SSAB North America Division, Evraz S.A. Oregon Steel Mills and Evraz S.A. Claymont, and Nucor Corporation* (August 29, 2008). On September 2, 2008, the Department received a complete substantive response from Azovstal Iron & Steel Works ("Azovstal") and Ilyich Iron & Steel Works ("Ilyich") (collectively, "respondent interested parties"). See *Substantive Response for Azovstal and Ilyich* (September 2, 2008). Respondent interested parties assert that they participated fully in the original investigation and have exported CTL plate from Ukraine in accordance with the terms and conditions of the Agreement. Respondent interested parties claimed interested-party status under section 771(9)(A) of the Act as foreign manufacturers, producers, and exporters of CTL plate from Ukraine. Domestic interested parties did not submit rebuttal responses.

After examining the substantive responses from all parties, on September 22, 2008, the Department determined that the domestic interested parties' and respondent interested parties' responses were adequate, consistent with the requirements of 19 CFR 351.218(e). See *Letter from Edward C. Yang, Director, AD/CVD Operations, China/NME Group, Import Administration, to Robert Carpenter, Director, Office of Investigations, International Trade Commission* (September 22, 2008). Because the responses of both domestic and respondent interested parties

constituted adequate responses to the notice of initiation, the Department is conducting a full (240-day) sunset review in accordance with 19 CFR 351.218(e)(1)(i). The Department will issue final results of review not later than March 29, 2009.

#### Scope of Review

The products covered by the Agreement include hot-rolled iron and non-alloy steel universal mill plates (*i.e.*, flat-rolled products rolled on four faces or in a closed box pass, of a width exceeding 150 mm but not exceeding 1250 mm and of a thickness of not less than 4 mm, not in coils and without patterns in relief), of rectangular shape, neither clad, plated nor coated with metal, whether or not painted, varnished, or coated with plastics or other nonmetallic substances; and certain iron and non-alloy steel flat-rolled products not in coils, of rectangular shape, hot-rolled, neither clad, plated, nor coated with metal, whether or not painted, varnished, or coated with plastics or other nonmetallic substances, 4.75 mm or more in thickness and of a width which exceeds 150 mm and measures at least twice the thickness. Included as subject merchandise in the Agreement are flat-rolled products of nonrectangular cross-section where such cross-section is achieved subsequent to the rolling process (*i.e.*, products which have been "worked after rolling") for example, products which have been beveled or rounded at the edges. This merchandise is currently classified in the Harmonized Tariff Schedule of the United States (HTS) under item numbers 7208.40.3030, 7208.40.3060, 7208.51.0030, 7208.51.0045, 7208.51.0060, 7208.52.0000, 7208.53.0000, 7208.90.0000, 7210.70.3000, 7210.90.9000, 7211.13.0000, 7211.14.0030, 7211.14.0045, 7211.90.0000, 7212.40.1000, 7212.40.5000, and 7212.50.0000. Although the HTS subheadings are provided for convenience and customs purposes, the written description of the scope of the Agreement is dispositive. Specifically excluded from subject merchandise within the scope of this Agreement is grade X-70 steel plate.

#### Analysis of Comments Received

All issues raised by parties to this sunset review are addressed in the Issues and Decision Memorandum ("Decision Memorandum") from Ronald K. Lorentzen, Deputy Assistant Secretary, Policy and Negotiations, Import Administration, to David M. Spooner, Assistant Secretary, Import

Administration, dated November 17, 2008, which is adopted by this notice. The issues discussed in the Decision Memorandum include the likelihood of continuation or recurrence of dumping and the magnitude of the margins likely to prevail were the suspended antidumping duty investigation to be terminated. Parties may find a complete discussion of all issues raised in this review and the corresponding recommendations in this public memorandum, which is on file in the Central Records Unit, room B-1117, of the main Commerce building. In addition, a complete version of the Decision Memorandum can be accessed directly on the Web at <http://ia.ita.doc.gov/frn>. The paper copy and electronic version of the Decision Memorandum are identical in content.

#### Preliminary Results of Review

We preliminarily determine that termination of the suspended antidumping duty investigation on CTL plate from Ukraine would likely lead to a continuation or recurrence of dumping at the following percentage weighted-average margins:

Manufacturer/producer/exporter	Weighted-average margin percentage
Azovstal .....	81.43
Ilyich .....	155.00
Ukraine-wide .....	237.91

#### Public Comment

An interested party may request a hearing within 30 days of publication of these preliminary results. See 19 CFR 351.310(c). Interested parties may submit case briefs no later than 50 days after publication of these preliminary results. See 19 CFR 351.309(c)(1)(i). Rebuttal briefs, limited to issues raised in the case briefs, may be filed no later than 5 days after the due date for filing case briefs. See 19 CFR 351.309(d)(1). Any hearing, if requested, will be held 2 days after the due date for filing rebuttal briefs, or the first business day thereafter, unless the Department alters the date. The Department will issue the final results of this sunset review, including the results of our analysis of the issues raised in any written comments or at a hearing, if requested, no later than March 29, 2009.

We are issuing and publishing this notice in accordance with sections 751(c), 752(c), and 777(i)(1) of the Tariff Act.

Dated: November 17, 2008.

David M. Spooner,  
Assistant Secretary for Import  
Administration.

[FR Doc. E8-28019 Filed 11-24-08; 8:45 am]  
BILLING CODE 3510-DS-P

#### DEPARTMENT OF COMMERCE

##### National Oceanic and Atmospheric Administration

##### Science Advisory Board (SAB); Draft Report of the NOAA Science Advisory Board Social Science Working Group

**AGENCY:** Office of Oceanic and Atmospheric Research (OAR), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

**ACTION:** Notice of availability of report and request for public comment.

**SUMMARY:** NOAA Research (OAR) publishes this notice on behalf of the NOAA Science Advisory Board (SAB) to announce the availability of the draft report of the SAB Social Science Working Group (here called SSWG) for public comment. The draft report of the SSWG has been prepared pursuant to the request initiated from the NOAA for an external panel of experts to carry out an independent review of current social science research conducted by NOAA and examine how the results of the research are being developed and incorporated into the operations of NOAA.

**DATES:** Comments on this draft report must be received by December 26, 2008.

**ADDRESSES:** The draft report of the SSWG will be available on the NOAA Science Advisory Board Web site at <http://www.sab.noaa.gov/Reports/SSWG.pdf>. The public is encouraged to submit comments electronically to [noaa.sab.comments@noaa.gov](mailto:noaa.sab.comments@noaa.gov). For individuals who do not have access to the Internet, comments may be submitted in writing to: NOAA Science Advisory Board (SAB), c/o Dr. Cynthia Decker, 1315 East-West Highway-R/SAB, Silver Spring, Maryland 20910.

**FOR FURTHER INFORMATION CONTACT:** Dr. Cynthia Decker, Executive Director, Science Advisory Board, NOAA, 1315 East-West Highway-R/SAB, Silver Spring, Maryland 20910. (Phone: 301-734-1156, Fax: 301-713-1459) during normal business hours of 9 a.m. to 5 p.m. Eastern Time, Monday through Friday, or visit the NOAA SAB Web site at <http://www.sab.noaa.gov>.

**SUPPLEMENTARY INFORMATION:** As part of its charge, the SSWG was tasked to examine social science related research

efforts by NOAA. The SSWG was requested to develop findings and recommendations to enhance NOAA's social science research capabilities. The complete terms of reference for the working group can be found at [http://www.sab.noaa.gov/Working\\_Groups/current/socialscience/SAB%20SSWG07\\_ToR\\_FINAL.pdf](http://www.sab.noaa.gov/Working_Groups/current/socialscience/SAB%20SSWG07_ToR_FINAL.pdf). The SAB is chartered under the Federal Advisory Committee Act and is the only Federal Advisory Committee with the responsibility to advise the Under Secretary of Commerce for Oceans and Atmosphere on long- and short-term strategies for research, education, and application of science to resource management and environmental assessment and prediction.

NOAA welcomes all comments on the content of this draft report. We also request comments on any inconsistencies perceived within the report, and possible omissions of important topics or issues. This draft report is issued for comment only and is not intended for external purposes. For any inadequacies noted within the draft report, please propose specific remedies. Suggested changes will be incorporated where appropriate, and a final report will be posted on the SAB Web site.

Please follow these instructions for preparing and submitting comments. Using the format guidance described below will facilitate the comments process and assure that all comments are appropriately considered. Overview comments should be provided first and should be numbered. Comments that are specific to particular pages, paragraphs or lines of the section should follow any overview comments and should identify the page and line numbers to which they apply. Please number each page of your comments.

Dated: November 20, 2008.

**Mark E. Brown,**

*Chief Financial Officer, Office of Oceanic and Atmosphere Research, National Oceanic and Atmospheric Administration.*

[FR Doc. E8-28008 Filed 11-24-08; 8:45 am]

BILLING CODE 3510-22-P

**DEPARTMENT OF COMMERCE**

**National Oceanic and Atmospheric Administration**

RIN 0648-XL66

**Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Regulatory Amendment to the Fishery Management Plan for the Reef Fish Resources of the Gulf of Mexico**

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

**ACTION:** Notice of intent (NOI) to prepare a draft environmental impact statement (DEIS); notice of scoping meetings; request for comments.

**SUMMARY:** NMFS, Southeast Region, in collaboration with the Gulf of Mexico Fishery Management Council (Council), intends to prepare a DEIS to describe and analyze management alternatives to be included in a regulatory action taken under the Fishery Management Plan for the Reef Fish Resources of the Gulf of Mexico (Reef Fish FMP). These alternatives will consider measures to reduce the incidental take of sea turtles by the bottom longline component of the reef fish fishery. The purpose of this NOI is to solicit public comments on the scope of issues to be addressed in the DEIS.

**DATES:** Written comments on the scope of issues to be addressed in the DEIS must be received by NMFS by December 26, 2008. Scoping meetings will be held in December 2008. See **SUPPLEMENTARY INFORMATION** for specific dates and times.

**ADDRESSES:** Written comments on the scope of the DEIS, suggested alternatives and potential impacts, and requests for additional information on the action should be sent to Peter Hood, NMFS, Southeast Regional Office, 263 13th Avenue South, St. Petersburg, FL 33701-5511; telephone (727) 824-5305; fax (727) 824-5308. Comments may also be sent by e-mail to [0648-XL66@noaa.gov](mailto:0648-XL66@noaa.gov). Requests for information packets and for sign language interpretation or other auxiliary aids should be directed to the Gulf of Mexico Fishery Management Council, 2203 North Lois Avenue, Suite 1100, Tampa, FL 33607; telephone: (813) 348-1630; fax: (813) 348-1711; Web site: [www.gulfcouncil.org](http://www.gulfcouncil.org). Requests may also be sent by e-mail to [Carrie.Simmons@gulfcouncil.org](mailto:Carrie.Simmons@gulfcouncil.org).

**FOR FURTHER INFORMATION CONTACT:** Peter Hood, phone: (727) 824-5305; fax:

(727) 824-5308; e-mail: [Peter.Hood@noaa.gov](mailto:Peter.Hood@noaa.gov).

**SUPPLEMENTARY INFORMATION:** A 2005 Biological Opinion on the Gulf of Mexico (Gulf) reef fish fishery concluded the fishery's continued authorization is not likely to jeopardize the continued existence of any species listed under the Endangered Species Act (ESA). The Incidental Take Statement (ITS) anticipated takes of 85 loggerhead sea turtles over a three-year period for the bottom longline portion of the reef fish fishery and 203 loggerhead sea turtles for the entire fishery. Take was also anticipated for other sea turtle species and smalltooth sawfish.

Beginning in 2006, NMFS has required vessels participating in the Gulf reef fish fishery to carry observers if selected to participate in the observer program. Observer data is collected from reef fish vessels as well as shark bottom longline vessels that also participate in the reef fish fishery. Currently, the program covers one percent of the fishery. From July 2006 through December 2007, observers documented 16 loggerhead sea turtles and 2 unidentified hardshell sea turtles captured by longlines targeting reef fish in the eastern Gulf. Only 44 percent of captured sea turtles were released alive. Based on these data and levels of effort from logbooks, NMFS estimated 902 hardshell sea turtle takes occurred during the 18-month study period in the eastern Gulf by reef fish bottom longline vessels.

According to the ESA, reinitiation of a consultation on the effect a federal action has on listed species is necessary when "the amount or extent of taking specified in the ITS is exceeded." The 18-month estimates from the NMFS study for bottom longlines in the eastern Gulf exceed the anticipated takes for all gear in the entire Gulf for three years. Accordingly, the Southeast Regional Office, Sustainable Fisheries Division, requested reinitiation of consultation for the Gulf reef fish fishery on September 3, 2008.

At its October 2008 meeting, the Council decided to initiate regulatory action including measures to reduce the incidental take of sea turtles by the bottom longline component of the reef fish fishery. NMFS, in collaboration with the Council, will develop a DEIS to evaluate alternatives to accomplish this reduction. Those alternatives include, but are not limited to: a "no action" alternative; alternatives to develop time/area closures; alternatives for gear or bait modification; alternatives to expand the observer

program; and alternatives for effort limitation.

In accordance with NOAA's Administrative Order 216-6, Section 5.02(c), the Council has identified this preliminary range of alternatives as a means to initiate discussion for scoping purposes only. These preliminary issues may not represent the full range of issues that eventually will be evaluated in the Environmental Impact Statement.

The Council has scheduled the following scoping meetings to provide the opportunity for additional public input:

1. Tuesday, December 9, 2008 Hilton Garden Inn, 1101 US Highway 231, Panama City, FL 32405, phone: 850-392-1093;

2. Wednesday, December 10, 2008 City of Madeira Beach, 300 Municipal Drive, Madeira Beach, FL 33708, phone: 727-391-9951.

Copies of the scoping document are available from the Council or can be downloaded from the Council Web site (see **ADDRESSES**).

All scoping meetings will begin at 7 p.m. The meetings will be physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to the Council (see **ADDRESSES**).

Once the DEIS associated with the regulatory action is completed, it will be filed with the Environmental Protection Agency (EPA). The EPA will publish a notice of availability of the DEIS for public comment in the **Federal Register**. The DEIS will have a 45-day comment period. This procedure is pursuant to regulations issued by the Council on Environmental Quality (CEQ) for implementing the procedural provisions of the National Environmental Policy Act (NEPA; 40 CFR parts 1500-1508) and to NOAA's Administrative Order 216-6 regarding NOAA's compliance with NEPA and the CEQ regulations.

NMFS will consider public comments received on the DEIS in developing the final environmental impact statement (FEIS) and before adopting final management measures for the action. NMFS will submit both the final measures and the supporting FEIS to the Secretary of Commerce (Secretary) for review as per the Magnuson-Stevens Fishery Conservation and Management Act.

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

Dated: November 20, 2008.

**Emily H. Menashes,**

*Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.*  
[FR Doc. E8-28017 Filed 11-24-08; 8:45 am]

**BILLING CODE 3510-22-S**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

RIN 0648-XK83

#### Incidental Takes of Marine Mammals During Specified Activities; Marine Seismic Surveys in the Southwest Pacific Ocean, January-February, 2009

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

**ACTION:** Notice; proposed incidental take authorization; request for comments.

**SUMMARY:** NMFS has received an application from the Lamont-Doherty Earth Observatory (L-DEO) for an Incidental Harassment Authorization (IHA) to take small numbers of marine mammals, by harassment, incidental to conducting a seismic survey in the southwest Pacific Ocean. Pursuant to the Marine Mammal Protection Act (MMPA), NMFS requests comments on its proposal to authorize L-DEO to take, by Level B harassment only, small numbers of marine mammals incidental to conducting a marine seismic survey during January through February, 2009.

**DATES:** Comments and information must be received no later than December 26, 2008.

**ADDRESSES:** Comments on the application should be addressed to Michael Payne, Chief, Permits, Conservation and Education Division, Office of Protected Resources, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910-3225. The mailbox address for providing email comments is [PR1.0648-XK83@noaa.gov](mailto:PR1.0648-XK83@noaa.gov). Comments sent via e-mail, including all attachments, must not exceed a 10-megabyte file size.

A copy of the application containing a list of the references used in this document may be obtained by writing to the address specified above, telephoning the contact listed below (see **FOR FURTHER INFORMATION CONTACT**), or visiting the internet at: <http://www.nmfs.noaa.gov/pr/permits/incidental.htm>.

Documents cited in this notice may be viewed, by appointment, during regular business hours, at the aforementioned address.

**FOR FURTHER INFORMATION CONTACT:** Jeannine Cody or Ken Hollingshead, Office of Protected Resources, NMFS, (301) 713-2289.

**SUPPLEMENTARY INFORMATION:**

## Background

Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce to allow, upon request, the incidental, but not intentional, taking of marine mammals by United States citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, a notice of a proposed authorization is provided to the public for review.

Authorization for incidental taking shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s), will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses, and if the permissible methods of taking and requirements pertaining to the mitigation, monitoring and reporting of such takings are set forth. NMFS has defined "negligible impact" in 50 CFR 216.103 as "...an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival."

Section 101(a)(5)(D) of the MMPA established an expedited process by which citizens of the United States can apply for an authorization to incidentally take small numbers of marine mammals by harassment. Except with respect to certain activities not pertinent here, the MMPA defines "harassment" as:

any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild ["Level A harassment"]; or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering ["Level B harassment"].

Section 101(a)(5)(D) establishes a 45-day time limit for NMFS' review of an application followed by a 30-day public notice and comment period on any proposed authorizations for the incidental harassment of small numbers of marine mammals. Within 45 days of the close of the comment period, NMFS must either issue or deny issuance of the authorization.

## Summary of Request

On August 18, 2008, NMFS received an application from L-DEO for the taking by Level B harassment only, of small numbers of 29 species of marine mammals incidental to conducting, with



research funding from the National Science Foundation (NSF), a marine seismic survey within the Exclusive Economic Zone (EEZ) of Tonga in the southwest Pacific Ocean during January through February 2009.

L-DEO proposes to tomographically image the crust and uppermost mantle of the Eastern Lau Spreading Center (ELSC). The survey area is approximately 42 kilometers (km) offshore from Tonga in water depths ranging from 1000 - 2600 meters (m). L-DEO chose to survey the ELSC because it provides the best site to study the complete range of spreading center processes, magma storage and thermal systems. This study is part of NSF's RIDGE 2000 program, which was developed to facilitate the study of mid-ocean ridges and back-arc spreading centers. These areas mark the boundaries where oceanic plates separate from one another. Around the mid-ocean ridges, heat from the mantle drives vast hydrothermal systems that influence ocean water chemistry and nourish enormous ecosystems. These data are integral to understanding how mid-ocean ridges influence global climatic conditions and to understanding plate tectonic processes and their effects on earthquake occurrence and distribution.

#### Description of the Specified Activity

The planned survey will involve one source vessel, the R/V *Marcus G. Langseth* (*Langseth*), a seismic vessel owned by the NSF. The proposed project is scheduled to commence on January 14, 2009, and end on February 21, 2009. The vessel will depart Nuku'alofa, Tonga on January 14, 2009 for a one-day transit to the study area in the Lau Basin in the southwest Pacific Ocean (between 19–21° S. and 175–176° W.).

To obtain high-resolution three-dimensional (3D) structures of the Lau Basin's magmatic systems and thermal structures, the *Langseth* will deploy a towed array of 36 airguns with a total discharge volume of approximately 6,600 cubic inches (in<sup>3</sup>). The *Langseth* will also deploy 55 to 64 Ocean Bottom Seismometers (OBS) for the survey. As the airgun array is towed along the survey lines, the OBS will receive the returning acoustic signals and record them internally for later analysis. In addition to the OBS, L-DEO may use a relatively short (up to 6-km) hydrophone streamer to receive the returning acoustic signals and transfer the data to the on-board processing system.

The seismic survey effort (e.g., equipment testing, startup, line changes,

repeat coverage of any areas, and equipment recovery) will require approximately 19 days to complete 42 transects of variable lengths, totaling 3650 km and will include approximately 456 hours of airgun operation. Please see L-DEO's application for more detailed information. The proposed seismic transects will provide a tomographical image in three dimensions of the physical properties of the crust and uppermost mantle of this area. The exact dates of the activities will depend on logistics, weather conditions, and the need to repeat some lines if data quality is substandard.

#### Vessel Specifications

The *Langseth*, operated by L-DEO, was designed as a seismic research vessel, with a propulsion system designed to be as quiet as possible to avoid interference with the seismic signals. The vessel, which has a length of 71.5 m (235 feet (ft)); a beam of 17.0 m (56 ft); a maximum draft of 5.9 m (19 ft); and a gross tonnage of 2925, can accommodate up to 55 people. The ship is powered by two Bergen BRG-6 diesel engines, each producing 3550 horsepower (hp), which drive the two propellers directly. Each propeller has four blades, and the shaft typically rotates at 750 revolutions per minute. The vessel also has an 800 hp bowthruster, which is not used during seismic acquisition. The operation speed during seismic acquisition is typically 7.4B9.3 km/h (4–5 knots). When not towing seismic survey gear, the *Langseth* can cruise at 20B24 km/h (11–13 knots). The *Langseth* has a range of 25,000 km (13,499 nautical miles). The *Langseth* will also serve as the platform from which vessel-based marine mammal (and sea turtle) observers will watch for animals before and during airgun operations.

#### Acoustic Source Specifications

##### Seismic Airguns

The full airgun array for the survey consists of 36 airguns (a mixture of Bolt 1500LL and Bolt 1900LLX airguns ranging in size from 40 to 360 in<sup>3</sup>), with a total volume of approximately 6,600 in<sup>3</sup> and a firing pressure of 1900 pounds per square inch (psi). The airgun array will fire every 400 m or 180 seconds. The dominant frequency component is 2–188 Hertz (Hz).

The array configuration consists of four identical linear arrays or strings, with 10 airguns on each string; the first and last airguns will be spaced 16 m (52 ft) apart. For each operating string, nine airguns will be fired simultaneously,

whereas the tenth is kept in reserve as a spare, to be turned on in case of failure of another airgun. The four airgun strings will be distributed across an approximate area of 24H16 m (79 x 52 ft) behind the *Langseth* and will be towed approximately 50–100 m (164–328 ft) behind the vessel at a tow-depth of 9–12 m (29.5–39.4 ft). The airgun array will fire for a brief (0.1 second (s)) pulse every 180 s. The array will remain silent at all other times.

#### Multibeam Echosounder

The *Langseth* will operate a Simrad EM120 multibeam echosounder (MBES) simultaneously during airgun operations to map characteristics of the ocean floor. The hull-mounted MBES emits brief pulses of mid- or high-frequency (11.25–12.6 kHz) sound in a fan-shaped beam that extends downward and to the sides of the ship. The beamwidth is 1° fore-aft and 150° athwartship. The maximum source level is 242 dB re 1  $\mu\text{Pa}\cdot\text{m}$  (root mean square (rms)). For deep-water operation, each "ping" consists of nine successive fan-shaped transmissions, each 15 millisecond (ms) in duration and each ensonifying a sector that extends 1° fore/aft. The nine successive transmissions span an overall cross-track angular extent of about 150°, with 16 ms gaps between the pulses for successive sectors. A receiver in the overlap area between two sectors would receive two 15–ms pulses separated by a 16–ms gap. In shallower water, the pulse duration is reduced to 5 or 2 ms, and the number of transmit beams is also reduced. The ping interval varies with water depth, from approximately 5 s at 1000 m (3,281 ft) to 20 s at 4000 m (13,124 ft).

#### Sub-bottom Profiler

The *Langseth* will operate a sub-bottom profiler (SBP) continuously throughout the cruise with the MBES. An SBP operates at mid- to high frequencies and is generally used simultaneously with an MBES to provide information about the sedimentary features and bottom topography. SBP pulses are directed downward at typical frequencies of approximately 3–18 kHz. However, the dominant frequency component of the SBP is 3.5 kHz which is directed downward in a narrow beam by a hull-mounted transducer on the vessel. The SBP output varies with water depth from 50 watts in shallow water to 800 watts in deep water and has a normal source output (downward) of 200 dB re 1  $\mu\text{Pa}\cdot\text{m}$  and a maximum source level output (downward) of 204 dB re 1  $\mu\text{Pa}\cdot\text{m}$ .

The SBP used aboard the *Langseth* uses seven beams simultaneously, with a beam spacing of up to 15 degrees (°) and a fan width up to 30°. Pulse duration is 0.4 100 ms at intervals of 1 s; a common mode of operation is to broadcast five pulses at 1-s intervals followed by a 5-s pause.

#### Characteristics of Airgun Pulses

Discussion of the characteristics of airgun pulses has been provided in Appendix B of L-DEO's application and in previous **Federal Register** notices (see 69 FR 31792, June 7, 2004; 71 FR 58790, October 5, 2006; 72 FR 71625, December 18, 2007; or 73 FR 52950, September 12, 2008). Reviewers are referred to those documents for additional information.

#### Safety Radii

To aid in estimating the number of marine mammals that are likely to be taken, pursuant to the MMPA, and in developing effective mitigation measures, NMFS applies certain acoustic thresholds that indicate the received level at which Level A or Level B harassment would occur in marine mammals were exposed, see Table 1.

Source and Volume	Tow Depth (m)	Predicted RMS Distances (m)		
		190 dB	180 dB	160 dB
Single Bolt airgun 40 in <sup>3</sup>	9-12	12	40	385
4 strings 36 airguns 6600 in <sup>3</sup>	9	300	950	6000
	12	340	1120	6850

Table 1. Predicted distances to which sound levels  $\geq$  190, 180, and 160 dB re 1  $\mu$  Pa might be received in deep (>1000 m; 3280 ft) water from the 36 airgun array during the seismic survey, January - February, 2009.

The distance from the sound source at which an animal would be exposed to these different received sound levels may be estimated and is typically referred to as safety radii. These safety radii are specifically used to help NMFS estimate the number of marine mammals likely to be harassed by the proposed activity and in deciding how close a marine mammal may approach an operating sound source before the applicant will be required to power-down or shut down the sound source.

During this study, all survey efforts will take place in deep (greater than 1000 m, 3820 ft) water. The L-DEO model does not allow for bottom interactions, and thus is most directly applicable to deep water and to relatively short ranges. L-DEO has summarized the modeled distances for the planned airgun configuration in Table 1 which shows the distances at which four rms sound levels (190 decibel (dB), 180 dB, and 160 dB) are expected to be received from the 36-airgun array and a single airgun operating in water greater than 1000 m (3,820 ft) in depth.

The calculated distances are expected to overestimate the actual distances to the corresponding Sound Pressure Levels (SPL), given the deep-water

results of Tolstoy *et al.* (2004a,b). Additional information regarding how the safety radii were calculated and how the empirical measurements were used to correct the modeled numbers may be found in Section I and Appendix A of L-DEO's application.

The conclusion that the model predictions in Table 1 are precautionary, relative to actual 180 and 190 dB (rms) radii, is based on empirical data from the acoustic calibration of different airgun configurations than those used on the *Langseth* (cf. Tolstoy *et al.*, 2004a,b); that sound source verification study was done in the northern Gulf of Mexico. L-DEO has recently (late 2007/early 2008) conducted a more extensive acoustic calibration study of the *Langseth*'s 36-airgun array, also in the northern Gulf of Mexico (LGL Ltd. 2006; Holst and Beland, 2008). Distances where various sound levels (e.g., 190, 180, and 160 dB re 1  $\mu$ Pa (rms) were received are being determined for various airgun configurations and water depths. Those results are not yet available. However, the empirical data from the 2007/2008 calibration study will be used to refine the exclusion zones proposed above for use during survey, if the data are

appropriate and available at the time of the survey.

#### Description of Marine Mammals in the Activity Area

Twenty-nine marine mammal species may occur off the coast of Tonga, including 21 odontocetes (toothed cetaceans, such as dolphins), and 8 mysticetes (baleen whales). Pinnipeds are unlikely to be encountered in or near the Lau Basin survey area where seismic operations will occur, and are, therefore, not addressed further in this document. Five of these species are listed as endangered under the U.S. Endangered Species Act (ESA), including the humpback (*Megaptera novaeangela*), sei (*Balaenoptera borealis*), fin (*Balaenoptera physalus*), blue (*Balaenoptera musculus*), and sperm (*Physeter macrocephalus*) whales. This IHA will only address requested take authorizations for cetaceans as L-DEO does not expect to encounter pinnipeds that far offshore in the study area. Thus L-DEO is not requesting any takes for pinnipeds in this IHA.

Table 2 below outlines the species, their habitat and abundance in the proposed survey area, and the requested number of takes by both instances and individuals.

Species	Habitat	Abundance in the SW Pacific	Occurrence in the Survey Area	Maximum Estimate of Individuals	Best Estimate of Individuals	Best Estimate of Exposures	Approx. % of Regional Population
				Request		Instances	
<b>Mysticetes</b>							
Humpback whale*	Nearshore waters	6,200	Rare	3	1	3	0.01
Sei whale*	Offshore, pelagic	12,000	Common	3	1	3	0.01

Species	Habitat	Abundance in the SW Pacific	Occurrence in the Survey Area	Maximum Estimate of Individuals	Best Estimate of Individuals	Best Estimate of Exposures	Approx. % of Regional Population
				Request		Instances	
Fin whale*	Pelagic, continental slope	3,031	Uncommon	3	1	3	0.03
Blue whale*	Pelagic, coastal	756	Uncommon	3	1	3	0.12
Pygmy right whale	Coastal, oceanic	0	Common	3	1	3	N.A.
Minke whale	Pelagic, coastal	155,000	Rare in Jan.	3	1	3	0.001
Dwarf minke whale	Coastal	N.A.	N.A.	3	1	3	N.A.
Bryde's whale	Pelagic, coastal	16,500	Common	14	4	15	0.02
<b>Odontocetes</b>							
Sperm whale*	Pelagic, deep seas	22,700	Common	22	6	22	0.03
Pygmy sperm whale	Deep waters off the shelf	N.A.	Common	353	96	358	N.A.
Dwarf Sperm whale	Deep waters off the shelf	11,200	Uncommon	353	96	358	0.85
Cuvier's beaked whale	Pelagic	20,000	Common	40	17	64	0.09
Southern bottlenose whale	Pelagic	N.A.	Rare	0	0	0	N.A.
Longman's beaked whale	Pelagic	N.A.	Uncommon	16	7	26	N.A.
Blainville's beaked whale	Pelagic	25,300	Common	40	17	64	0.07
Ginkgo-toothed beaked whale	Pelagic	25,300	Rare	16	7	26	0.03
Rough-toothed dolphin	Deep water	145,900	Uncommon	1,649	857	3,214	0.59
Bottlenose dolphin	Coastal, oceanic	243,500	Common	330	171	643	0.07
Pantropical spotted dolphin	Coastal, pelagic	1,298,400	Uncommon	1,649	857	3,214	0.07
Spinner dolphin	Coastal, pelagic	1,019,300	Rare	3,298	1,714	6,428	0.17
Striped dolphin	Continental shelf	1,918,000	Rare	330	171	643	0.01
Fraser's dolphin	Waters > 1000 m	289,300	Rare	989	514	1,929	0.18
Short-beaked common dolphin	Shelf, pelagic	2,210,900	Common	330	171	643	0.01
Risso's dolphin	Waters > 1000 m	175,800	Common	330	171	643	0.10
Melon-headed whale	Oceanic	45,400	Uncommon	152	43	163	0.10
Pygmy killer whale	Deep, pantropical	38,900	Uncommon	30	9	33	0.02
False killer whale	Pelagic	39,800	Uncommon	91	26	98	0.07
Killer whale	Widely distributed	8,500	Common	61	17	65	0.20
Short-finned pilot whale	Pelagic	160,200	Common	61	17	65	0.01

Species	Habitat	Abundance in the SW Pacific	Occurrence in the Survey Area	Maximum Estimate of Individuals	Best Estimate of Individuals	Best Estimate of Exposures	Approx. % of Regional Population
				Request		Instances	
<b>Total</b>				10,173	4,997	18,735	

Table 2. Abundance, preferred habitat, and commonness of the marine mammal species that may be encountered during the proposed survey within the Lau Basin survey area. The far right columns indicate the estimated number of each species that will be exposed to 160 dB based on best and maximum density estimates. NMFS believes that, when mitigation measures are taken into consideration, the activity is likely to result in take of numbers of animals less than those indicated by the column titled Maximum Estimate of Exposures - Request.

\* Federally listed endangered species.

Detailed information regarding the status and distribution of these marine mammals may be found in sections III and IV of L-DEO's application.

#### Potential Effects of the Proposed Activity on Marine Mammals

##### Summary of Potential Effects of Airgun Sounds on Marine Mammals

The effects of sounds from airguns might include one or more of the following: tolerance, masking of natural sounds, behavioral disturbance, temporary or permanent hearing impairment, or non-auditory physical or physiological effects (Richardson *et al.*, 1995; Gordon *et al.*, 2004; Nowacek *et al.*, 2007; Southall *et al.*, 2007). Permanent hearing impairment, in the unlikely event that it occurred, would constitute injury, but temporary threshold shift (TTS) is not an injury (Southall *et al.*, 2007). Although the possibility cannot be entirely excluded, it is unlikely that the project would result in any cases of temporary or permanent hearing impairment, or any significant non-auditory physical or physiological effects. Some behavioral disturbance is expected, but is expected to be localized and short-term. These effects are discussed below, but also in further detail in Appendix B of L-DEO's application.

##### Tolerance

Numerous studies have shown that pulsed sounds from airguns are often readily detectable in the water at distances of many kilometers. A summary of the characteristics of airgun pulses, is provided in Appendix B of L-DEO's application. Several studies have also shown that marine mammals at distances more than a few kilometers from operating seismic vessels often show no apparent response (tolerance) (see Appendix B of L-DEO's application). That is often true even in cases when the pulsed sounds must be readily audible to the animals based on measured received levels and the hearing sensitivity of that mammal group. Although various baleen whales, toothed whales, and (less frequently) pinnipeds have been shown to react

behaviorally to airgun pulses under some conditions, at other times mammals of all three types have shown no overt reactions. In general, pinnipeds usually seem to be more tolerant of exposure to airgun pulses than cetaceans, with the relative responsiveness of baleen and toothed whales being variable.

##### Masking

Introduced underwater sound may, through masking, reduce the effective communication distance of a marine mammal species if the frequency of the source is close to that used as a signal by the marine mammal, and if the anthropogenic sound is present for a significant fraction of the time (Richardson *et al.*, 1995).

Masking effects of pulsed sounds (even from large arrays of airguns) on marine mammal calls and other natural sounds are expected to be limited, although there are very few specific data on this. Because of the intermittent nature (one pulse every 180 seconds) and low duty cycle of seismic pulses, animals can emit and receive sounds in the relatively quiet intervals between pulses. However, in exceptional situations, reverberation occurs for much or the entire interval between pulses (e.g., Simard *et al.*, 2005; Clark and Gagnon, 2006) which could mask calls. Some baleen and toothed whales are known to continue calling in the presence of seismic pulses, and their calls can usually be heard between the seismic pulses (e.g., Richardson *et al.*, 1986; McDonald *et al.*, 1995; Greene *et al.*, 1999; Nieuwkerk *et al.*, 2004; Smultea *et al.*, 2004; Holst *et al.*, 2005a,b, 2006). In the northeastern Pacific Ocean, blue whale calls have been recorded during a seismic survey off Oregon (McDonald *et al.*, 1995). Among odontocetes, there has been one report that sperm whales ceased calling when exposed to pulses from a very distant seismic ship (Bowles *et al.*, 1994), but more recent studies found that they continued calling in the presence of seismic pulses (Madsen *et al.*, 2002c; Tyack *et al.*, 2003; Smultea *et al.*, 2004; Holst *et al.*, 2006; Jochens *et al.*, 2006). Dolphins and porpoises

commonly are heard calling while airguns are operating (e.g., Gordon *et al.*, 2004; Smultea *et al.*, 2004; Holst *et al.*, 2005a,b; Potter *et al.*, 2007). The sounds important to small odontocetes are predominantly at much higher frequencies than are the dominant components of airgun sounds, thus limiting the potential for masking. In general, masking effects of seismic pulses are expected to be minor, given the normally intermittent nature of seismic pulses and the *Langseth* being the only seismic vessel operating in the area for a limited time. Masking effects on marine mammals are discussed further in Appendix B of L-DEO's application.

##### Disturbance Reactions

Disturbance includes a variety of effects, including subtle to conspicuous changes in behavior, movement, and displacement. Based on NMFS (2001, p. 9293), NRC (2005), and Southall *et al.* (2007), we assume that simple exposure to sound, or brief reactions that do not disrupt behavioral patterns in a potentially significant manner, do not constitute harassment or "taking". By potentially significant, we mean "in a manner that might have deleterious effects to the well-being of individual marine mammals or their populations".

Reactions to sound, if any, depend on species, state of maturity, experience, current activity, reproductive state, time of day, and many other factors (Richardson *et al.*, 1995; Wartzok *et al.*, 2004; Southall *et al.*, 2007). If a marine mammal does react briefly to an underwater sound by changing its behavior or moving a small distance, the impacts of the change are unlikely to be significant to the individual, *let alone* the stock or population. However, if a sound source displaces marine mammals from an important feeding or breeding area for a prolonged period, impacts on individuals and populations could be significant. Given the many uncertainties in predicting the quantity and types of impacts of noise on marine mammals, it is common practice to estimate how many mammals would be present within a particular distance of

industrial activities and exposed to a particular level of industrial sound. In most cases, this approach likely overestimates the numbers of marine mammals that would be affected in some biologically-important manner.

The sound criteria used to estimate how many marine mammals might be disturbed to some biologically-important degree by a seismic program are based primarily on behavioral observations of a few species. Detailed studies have been done on humpback and sperm whales. Less detailed data are available for some other species of baleen whales, and small toothed whales, but for many species there are no data on responses to marine seismic surveys.

#### •Baleen Whales

Baleen whales generally tend to avoid operating airguns, but avoidance radii are quite variable. Whales are often reported to show no overt reactions to pulses from large arrays of airguns at distances beyond a few kilometers, even though the airgun pulses remain well above ambient noise levels out to much longer distances. However, as reviewed in Appendix B of L-DEO's application, baleen whales exposed to strong noise pulses from airguns often react by deviating from their normal migration route and/or interrupting their feeding and moving away. In the cases of migrating gray and bowhead whales, the observed changes in behavior appeared to be of little or no biological consequence to the animals. They simply avoided the sound source by displacing their migration route to varying degrees, but within the natural boundaries of the migration corridors.

Studies of gray (*Eshrichtius robustus*), bowhead (*Balena mysticetes*), and humpback whales have shown that seismic pulses with received levels of 160-170 dB re 1  $\mu$ Pa (rms) seem to cause obvious avoidance behavior in a substantial fraction of the animals exposed (Richardson *et al.*, 1995). In many areas, seismic pulses from large arrays of airguns diminish to those levels at distances ranging from 4-15 km (2.5-9.3 mi) from the source. A substantial proportion of the baleen whales within those distances may show avoidance or other strong behavioral reactions to the airgun array. Subtle behavioral changes sometimes become evident at somewhat lower received levels, and studies summarized in Appendix B of L-DEO's application have shown that some species of baleen whales, notably bowhead and humpback whales, at times show strong avoidance at received levels lower than 160-170 dB re 1  $\mu$ Pa (rms).

Responses of humpback whales to seismic surveys have been studied during migration, on summer feeding grounds, and on Angolan winter breeding grounds; there has also been discussion of effects on the Brazilian wintering grounds. McCauley *et al.* (1998, 2000a) studied the responses of humpback whales off Western Australia to a full-scale seismic survey with a 16-airgun, 2678-in<sup>3</sup> array, and to a single 20-in<sup>3</sup> airgun with source level 227 dB re 1  $\mu$ Pa m (peak to peak). McCauley *et al.* (1998) documented that avoidance reactions began at 5-8 km (3-5 mi) from the array, and that those reactions kept most pods approximately 3-4 km (1.8-2.5 mi) from the operating seismic boat. McCauley *et al.* (2000a) noted localized displacement during migration of 4-5 km (2.5-3.1 mi) by traveling pods and 7-12 km (4.3-7.5 mi) by more sensitive resting pods of cow-calf pairs. Avoidance distances with respect to the single airgun were smaller but consistent with the results from the full array in terms of the received sound levels. The mean received level for initial avoidance of an approaching airgun was 140 dB re 1  $\mu$ Pa (rms) for humpback pods containing females, and at the mean closest point of approach distance the received level was 143 dB re 1  $\mu$ Pa (rms). The initial avoidance response generally occurred at distances of 5-8 km (3.1-4.9 mi) from the airgun array and 2 km (1.2 mi) from the single airgun. However, some individual humpback whales, especially males, approached within distances of 100-400 m (328-1312 ft), where the maximum received level was 179 dB re 1  $\mu$ Pa (rms).

Humpback whales on their summer feeding grounds in southeast Alaska did not exhibit persistent avoidance when exposed to seismic pulses from a 1.64-L (100-in<sup>3</sup>) airgun (Malme *et al.*, 1985). Malme *et al.* reported that some of the humpbacks seemed startled at received levels of 150-169 dB re 1 FPa and concluded that there was no clear evidence of avoidance, despite the possibility of subtle effects, at received levels up to 172 re 1  $\mu$ Pa on an approximate rms basis. It has been suggested that South Atlantic humpback whales wintering off Brazil may be displaced or even strand upon exposure to seismic surveys (Engel *et al.*, 2004). The evidence for this was circumstantial and subject to alternative explanations (IAGC, 2004). Also, the evidence was not consistent with subsequent results from the same area of Brazil (Parente *et al.*, 2006), or with direct studies of humpbacks exposed to seismic surveys in other areas and seasons. After

allowance for data from subsequent years, there was "no observable direct correlation" between strandings and seismic surveys (IWC, 2007:236).

Various species of Balaenoptera (blue, sei, fin, and minke whales) have occasionally been reported in areas ensounded by airgun pulses (Stone, 2003; MacLean and Haley, 2004; Stone and Tasker, 2006). Sightings by observers on seismic vessels off the United Kingdom from 1997 to 2000 suggest that, during times of good sightability, sighting rates for mysticetes (mainly fin and sei whales) were similar when large arrays of airguns were shooting vs. silent (Stone, 2003; Stone and Tasker, 2006). However, these whales tended to exhibit localized avoidance, remaining significantly further (on average) from the airgun array during seismic operations compared with non-seismic periods (Stone and Tasker, 2006). In a study off Nova Scotia, Moulton and Miller (2005) found little difference in sighting rates (after accounting for water depth) and initial sighting distances of balaenopterid whales when airguns were operating versus silent. However, there were indications that these whales were more likely to be moving away when seen during airgun operations. Similarly, ship-based monitoring studies of blue, fin, sei and minke whales offshore of Newfoundland (Orphan Basin and Laurentian Sub-basin) found no more than small differences in sighting rates and swim directions during seismic vs. non-seismic periods (Moulton *et al.*, 2005, 2006a,b).

Data on short-term reactions by cetaceans to impulsive noises are not necessarily indicative of long-term or biologically significant effects. It is not known whether impulsive sounds affect reproductive rate or distribution and habitat use in subsequent days or years. However, gray whales have continued to migrate annually along the west coast of North America with substantial increases in the population over recent years, despite intermittent seismic exploration (and much ship traffic) in that area for decades (Appendix A in Malme *et al.*, 1984; Richardson *et al.*, 1995; Angliss and Outlaw, 2008). The western Pacific gray whale population did not seem affected by a seismic survey in its feeding ground during a previous year (Johnson *et al.*, 2007). Similarly, bowhead whales have continued to travel to the eastern Beaufort Sea each summer, and their numbers have increased notably, despite seismic exploration in their summer and autumn range for many

years (Richardson *et al.*, 1987; Angliss and Outlaw, 2008).

#### Toothed Whales

Little systematic information is available about reactions of toothed whales to noise pulses. Few studies similar to the more extensive baleen whale/seismic pulse work summarized above and (in more detail) in Appendix B of L-DEO's application have been reported for toothed whales. However, there are recent systematic studies on sperm whales (Jochens *et al.*, 2006; Miller *et al.*, 2006), and there is an increasing amount of information about responses of various odontocetes to seismic surveys based on monitoring studies (e.g., Stone, 2003; Smultea *et al.*, 2004; Moulton and Miller, 2005; Bain and Williams, 2006; Holst *et al.*, 2006; Stone and Tasker, 2006; Potter *et al.*, 2007; Weir, 2008).

Seismic operators and marine mammal observers on seismic vessels regularly see dolphins and other small toothed whales near operating airgun arrays, but in general there is a tendency for most delphinids to show some avoidance of operating seismic vessels (e.g., Goold, 1996a,b,c; Calambokidis and Osmek, 1998; Stone, 2003; Moulton and Miller, 2005; Holst *et al.*, 2006; Stone and Tasker, 2006; Weir, 2008). Some dolphins seem to be attracted to the seismic vessel and floats, and some ride the bow wave of the seismic vessel even when large arrays of airguns are firing (e.g., Moulton and Miller, 2005). Nonetheless, small toothed whales more often tend to head away, or to maintain a somewhat greater distance from the vessel, when a large array of airguns is operating than when it is silent (e.g., Stone and Tasker, 2006; Weir, 2008). In most cases the avoidance radii for delphinids appear to be small, on the order of 1 km less, and some individuals show no apparent avoidance. The beluga (*Delphinapterus leucas*) is a species that (at times) shows long-distance avoidance of seismic vessels. Aerial surveys conducted in the southeastern Beaufort Sea during summer found that sighting rates of beluga whales were significantly lower at distances 10–20 km (6.2–12.4 mi) compared with 20–30 km (12.4–18.6 mi) from an operating airgun array, and observers on seismic boats in that area rarely see belugas (Miller *et al.*, 2005; Harris *et al.*, 2007).

Captive bottlenose dolphins (*Tursiops truncatus*) and beluga whales exhibited changes in behavior when exposed to strong pulsed sounds similar in duration to those typically used in seismic surveys (Finneran *et al.*, 2000, 2002, 2005). However, the animals

tolerated high received levels of sound before exhibiting aversive behaviors.

Results for porpoises depend on species. The limited available data suggest that harbor porpoises (*Phocoena phocoena*) show stronger avoidance of seismic operations than do Dall's porpoises (*Phocoenoides dalli*) (Stone, 2003; MacLean and Koski, 2005; Bain and Williams, 2006; Stone and Tasker, 2006). Dall's porpoises seem relatively tolerant of airgun operations (MacLean and Koski, 2005; Bain and Williams, 2006), although they too have been observed to avoid large arrays of operating airguns (Calambokidis and Osmek, 1998; Bain and Williams, 2006). This apparent difference in responsiveness of these two porpoise species is consistent with their relative responsiveness to boat traffic and some other acoustic sources (Richardson *et al.*, 1995; Southall *et al.*, 2007).

Most studies of sperm whales exposed to airgun sounds indicate that the sperm whale shows considerable tolerance of airgun pulses (e.g., Stone, 2003; Moulton *et al.*, 2005, 2006a; Stone and Tasker, 2006; Weir, 2008). In most cases the whales do not show strong avoidance, and they continue to call (see Appendix B of L-DEO's application for review). However, controlled exposure experiments in the Gulf of Mexico indicate that foraging behavior was altered upon exposure to airgun sound (Jochens *et al.*, 2006).

There are almost no specific data on the behavioral reactions of beaked whales to seismic surveys. However, northern bottlenose whales (*Hyperoodon ampullatus*) continued to produce high-frequency clicks when exposed to sound pulses from distant seismic surveys (Laurinoll and Cochrane, 2005; Simard *et al.*, 2005). Most beaked whales tend to avoid approaching vessels of other types (e.g., Wursig *et al.*, 1998). They may also dive for an extended period when approached by a vessel (e.g., Kasuya, 1986). Thus, it is likely that beaked whales would also show strong avoidance of an approaching seismic vessel, although this has not been documented explicitly.

There are increasing indications that some beaked whales tend to strand when naval exercises involving mid-frequency sonar operation are ongoing nearby (e.g., Simmonds and Lopez-Jurado, 1991; Frantzis, 1998; NOAA and USN, 2001; Jepson *et al.*, 2003; Hildebrand, 2005; Barlow and Gisiner, 2006; see also the "Strandings and Mortality" subsection, later). These strandings are apparently at least in part a disturbance response, although auditory or other injuries or other

physiological effects may also be involved. Whether beaked whales would ever react similarly to seismic surveys is unknown (see "Strandings and Mortality", below). Seismic survey sounds are quite different from those of the sonar in operation during the above-cited incidents.

Odontocete reactions to large arrays of airguns are variable and, at least for delphinids and Dall's porpoises, seem to be confined to a smaller radius than has been observed for the more responsive of the mysticetes, belugas, and harbor porpoises (refer to Appendix B in L-DEO's application).

#### Hearing Impairment and Other Physical Effects

Temporary or permanent hearing impairment is a possibility when marine mammals are exposed to very strong sounds, and temporary threshold shift (TTS) has been demonstrated and studied in certain captive odontocetes and pinnipeds exposed to strong sounds (reviewed in Southall *et al.*, 2007). However, there has been no specific documentation of TTS *let alone* permanent hearing damage, i.e., permanent threshold shift (PTS), in free-ranging marine mammals exposed to sequences of airgun pulses during realistic field conditions. To avoid the potential for injury, NMFS has determined that cetaceans and pinnipeds should not be exposed to pulsed underwater noise at received levels exceeding, respectively, 180 and 190 dB re 1  $\mu\text{Pa}_{\text{rms}}$ . As summarized above, data that are now available imply that TTS is unlikely to occur unless odontocetes (and probably mysticetes as well) are exposed to airgun pulses stronger than 180 dB re 1  $\mu\text{Pa}$  (rms).

Several aspects of the planned monitoring and mitigation measures for this project are designed to detect marine mammals occurring near the airgun array, and to avoid exposing them to sound pulses that might, at least in theory, cause hearing impairment. In addition, many cetaceans and (to a limited degree) pinnipeds and sea turtles are likely to show some avoidance or the area with high received levels of airgun sound. In those cases, the avoidance responses of the animals themselves will reduce or (most likely) avoid any possibility of hearing impairment.

Non-auditory physical effects might also occur in marine mammals exposed to strong underwater pulsed sound. Possible types of non-auditory physiological effects or injuries that might (in theory) occur in mammals close to a strong sound source include stress, neurological effects, bubble

formation, and other types of organ or tissue damage. It is possible that some marine mammal species (i.e., beaked whales) may be especially susceptible to injury and/or stranding when exposed to strong pulsed sounds. However, as discussed below, there is no definitive evidence that any of these effects occur even for marine mammals in close proximity to large arrays of airguns. It is unlikely that any effects of these types would occur during the proposed project given the brief duration of exposure of any given mammal, the deep water in the survey area, and the planned monitoring and mitigation measures (see below). The following subsections discuss in somewhat more detail the possibilities of TTS, PTS, and non-auditory physical effects.

#### Temporary Threshold Shift (TTS)

TTS is the mildest form of hearing impairment that can occur during exposure to a strong sound (Kryter, 1985). While experiencing TTS, the hearing threshold rises and a sound must be stronger in order to be heard. At least in terrestrial mammals, TTS can last from minutes or hours to (in cases of strong TTS) days. For sound exposures at or somewhat above the TTS threshold, hearing sensitivity in both terrestrial and marine mammals recovers rapidly after exposure to the noise ends. Few data on sound levels and durations necessary to elicit mild TTS have been obtained for marine mammals, and none of the published data concern TTS elicited by exposure to multiple pulses of sound. Available data on TTS in marine mammals are summarized in Southall *et al.* (2007).

For toothed whales exposed to single short pulses, the TTS threshold appears to be, to a first approximation, a function of the energy content of the pulse (Finneran *et al.*, 2002, 2005). Sound exposure level (SEL), which takes into account the duration of the sound, is the metric used to measure energy and uses the units dB re 1  $\mu\text{Pa}^2\cdot\text{s}$ , as opposed to SPL, which is the pressure metric used in the rest of this document (units - dB re 1  $\mu\text{Pa}$ ). Given the available data, the received energy level of a single seismic pulse (with no frequency weighting) might need to be approximately 186 dB re 1  $\mu\text{Pa}^2\cdot\text{s}$  (i.e., 186 dB SEL or approximately 196 201 dB re 1  $\mu\text{Pa}$  (rms)) in order to produce brief, mild TTS. Exposure to several strong seismic pulses that each have received levels near 190 dB re 1  $\mu\text{Pa}$  (rms) might result in cumulative exposure of approximately 186 dB SEL and thus slight TTS in a small odontocete, assuming the TTS threshold is (to a first approximation) a function

of the total received pulse energy. The distances from the Langseth's airguns at which the received energy level (per pulse, flat-weighted) would be expected to be 190 dB re 1  $\mu\text{Pa}$  (rms) or above, are shown in Table 1. Levels 190 dB re 1  $\mu\text{Pa}$  (rms) or above are expected to be restricted to radii no more than 340 m (1115.5 ft) (Table 1) from the 36-airgun array. For an odontocete closer to the surface, the maximum radius with 190 dB re 1  $\mu\text{Pa}$  (rms) or above, would be smaller.

The above TTS information for odontocetes is derived from studies on the bottlenose dolphin and beluga. There is no published TTS information for other types of cetaceans. However, preliminary evidence from a harbor porpoise exposed to airgun sound suggests that its TTS threshold may have been lower (Lucke *et al.*, 2007).

For baleen whales, there are no data, direct or indirect, on levels or properties of sound that are required to induce TTS. The frequencies to which baleen whales are most sensitive are assumed to be lower than those to which odontocetes are most sensitive, and natural background noise levels at those low frequencies tend to be higher. As a result, auditory thresholds of baleen whales within their frequency band of best hearing are believed to be higher (less sensitive) than are those of odontocetes at their best frequencies (Clark and Ellison, 2004). From this, it is suspected that received levels causing TTS onset may also be higher in baleen whales (Southall *et al.*, 2007). In any event, no cases of TTS are expected given three considerations: (1) the low abundance of baleen whales in most parts of the planned study area; (2) the strong likelihood that baleen whales would avoid the approaching airguns (or vessel) before being exposed to levels high enough for TTS to occur; and (3) the mitigation measures that are planned.

In pinnipeds, TTS thresholds associated with exposure to brief pulses (single or multiple) of underwater sound have not been measured. Initial evidence from more prolonged (non-pulse) exposures suggested that some pinnipeds (harbor seals in particular) incur TTS at somewhat lower received levels than do small odontocetes exposed for similar durations (Kastak *et al.*, 1999, 2005; Ketten *et al.*, 2001). The TTS threshold for pulsed sounds has been indirectly estimated as being an SEL of approximately 171 dB re 1  $\mu\text{Pa}^2\cdot\text{s}$  (Southall *et al.*, 2007), which would be equivalent to a single pulse with received level of approximately 181 186 dB re 1  $\mu\text{Pa}$  (rms), or a series of pulses for which the highest rms

values are a few dB lower. However, pinnipeds are not expected to occur in or near the planned study area.

#### Permanent Threshold Shift (PTS)

When PTS occurs, there is physical damage to the sound receptors in the ear. In severe cases, there can be total or partial deafness, while in other cases; the animal has an impaired ability to hear sounds in specific frequency ranges (Kryter, 1985). There is no specific evidence that exposure to pulses of airgun sound can cause PTS in any marine mammal, even with large arrays of airguns. However, given the possibility that mammals close to an airgun array might incur at least mild TTS, there has been further speculation about the possibility that some individuals occurring very close to airguns might incur PTS (Richardson *et al.*, 1995, p. 372ff). Single or occasional occurrences of mild TTS are not indicative of permanent auditory damage. Relationships between TTS and PTS thresholds have not been studied in marine mammals, but are assumed to be similar to those in humans and other terrestrial mammals. PTS might occur at a received sound level at least several decibels above that inducing mild TTS if the animal were exposed to strong sound pulses with rapid rise time—see Appendix B of L-DEO's application. Based on data from terrestrial mammals, a precautionary assumption is that the PTS threshold for impulse sounds (such as airgun pulses as received close to the source) is at least 6 dB higher than the TTS threshold on a peak-pressure basis, and probably greater than 6 dB (Southall *et al.*, 2007:441–4) estimated that received levels would need to exceed the TTS threshold by at least 15 dB for there to be risk of PTS. Thus, for cetaceans they estimate that the PTS threshold might be a mammal-weighted (M-weighted) SEL (for the sequence of received pulses) of approximately 198 dB re 1  $\mu\text{Pa}^2\cdot\text{s}$  (15 dB higher than the TTS threshold for an impulse), where the SEL value is accumulated over the sequence of pulses. Additional assumptions had to be made to derive a corresponding estimate for pinnipeds, as the only available data on TTS-thresholds in pinnipeds pertain to non-impulse sound. Southall *et al.* (2007) estimate that the PTS threshold could be a cumulative  $M_{pw}$ -weighted SEL of approximately 186 dB re 1  $\mu\text{Pa}^2\cdot\text{s}$  in the harbor seal exposed to impulse sound. The PTS threshold for the California sea lion and northern elephant seal the PTS threshold would probably be higher, given the higher TTS thresholds in those species.

Southall *et al.* (2007) also note that, regardless of the SEL, there is concern about the possibility of PTS if a cetacean or pinniped received one or more pulses with peak pressure exceeding 230 or 218 dB re 1 FPa (peak), respectively. A peak pressure of 230 dB re 1  $\mu$ Pa (3.2 bar $\cdot$ m, 0-peak) would only be found within a few meters of the largest (360 in<sup>3</sup>) airgun in the planned airgun array (Caldwell and Dragoset, 2000). A peak pressure of 218 dB re 1  $\mu$ Pa could be received somewhat farther away; to estimate that specific distance, one would need to apply a model that accurately calculates peak pressures in the nearfield around an array of airguns.

Given the higher level of sound necessary to cause PTS as compared with TTS, it is considerably less likely that PTS would occur. Baleen whales generally avoid the immediate area around operating seismic vessels, as do some other marine mammals and sea turtles. The planned monitoring and mitigation measures, including visual monitoring, PAM, power downs, and shut downs of the airguns when mammals are seen within or approaching the exclusion zones, will further reduce the probability of exposure of marine mammals to sounds strong enough to induce PTS.

#### Non-auditory Physiological Effects

Non-auditory physiological effects or injuries that theoretically might occur in marine mammals exposed to strong underwater sound include stress, neurological effects, bubble formation, resonance, and other types of organ or tissue damage (Cox *et al.*, 2006; Southall *et al.*, 2007). Studies examining such effects are limited. However, resonance (Gentry, 2002) and direct noise-induced bubble formation (Crum *et al.*, 2005) are not expected in the case of an impulsive source like an airgun array. If seismic surveys disrupt diving patterns of deep-diving species, this might perhaps result in bubble formation and a form of the bends, as speculated to occur in beaked whales exposed to sonar. However, there is no specific evidence of this upon exposure to airgun pulses.

In general, very little is known about the potential for seismic survey sounds (or other types of strong underwater sounds) to cause non-auditory physical effects in marine mammals. Such effects, if they occur at all, would presumably be limited to short distances and to activities that extend over a prolonged period. The available data do not allow identification of a specific exposure level above which non-auditory effects can be expected (Southall *et al.*, 2007), or any meaningful quantitative predictions of

the numbers (if any) of marine mammals that might be affected in those ways. Marine mammals that show behavioral avoidance of seismic vessels, including most baleen whales, some odontocetes, and some pinnipeds, are especially unlikely to incur non-auditory physical effects. Also, the planned mitigation measures, including shut downs of the airguns, will reduce any such effects that might otherwise occur.

#### Strandings and Mortality

Marine mammals close to underwater detonations of high explosives can be killed or severely injured, and the auditory organs are especially susceptible to injury (Ketten *et al.*, 1993; Ketten, 1995). However, explosives are no longer used for marine seismic research or commercial seismic surveys, and have been replaced entirely by airguns or related non-explosive pulse generators. Airgun pulses are less energetic and have slower rise times, and there is no specific evidence that they can cause serious injury, death, or stranding even in the case of large airgun arrays. However, the association of mass strandings of beaked whales with naval exercises and, in one case, an L-DEO seismic survey (Malakoff, 2002; Cox *et al.*, 2006), has raised the possibility that beaked whales exposed to strong pulsed sounds may be especially susceptible to injury and/or behavioral reactions that can lead to stranding (e.g., Hildebrand, 2005; Southall *et al.*, 2007).

Specific sound-related processes that lead to strandings and mortality are not well documented, but may include: (1) swimming in avoidance of a sound into shallow water; (2) a change in behavior (such as a change in diving behavior) that might contribute to tissue damage, gas bubble formation, hypoxia, cardiac arrhythmia, hypertensive hemorrhage or other forms of trauma; (3) a physiological change such as a vestibular response leading to a behavioral change or stress-induced hemorrhagic diathesis, leading in turn to tissue damage; and (4) tissue damage directly from sound exposure, such as through acoustically mediated bubble formation and growth or acoustic resonance of tissues. There are increasing indications that gas-bubble disease (analogous to the bends), induced in supersaturated tissue by a behavioral response to acoustic exposure, could be a pathologic mechanism for the strandings and mortality of some deep-diving cetaceans exposed to sonar. However, the evidence for this remains circumstantial and associated with exposure to naval mid-frequency sonar, not seismic

surveys (Cox *et al.*, 2006; Southall *et al.*, 2007).

Seismic pulses and mid-frequency sonar signals are quite different, and some mechanisms by which sonar sounds have been hypothesized to affect beaked whales are unlikely to apply to airgun pulses. Sounds produced by airgun arrays are broadband impulses with most of the energy below 1 kHz. Typical military mid-frequency sonars emit non-impulse sounds at frequencies of 2 to 10 kHz, generally with a relatively narrow bandwidth at any one time. A further difference between seismic surveys and naval exercises is that naval exercises can involve sound sources on more than one vessel. Thus, it is not appropriate to assume that there is a direct connection between the effects of military sonar and seismic surveys on marine mammals. However, evidence that sonar signals can, in special circumstances, lead (at least indirectly) to physical damage and mortality (e.g., Balcomb and Claridge, 2001; NOAA and USN, 2001; Jepson *et al.*, 2003; Fernandez *et al.*, 2004, 2005; Hildebrand, 2005; Cox *et al.*, 2006) suggests that caution is warranted when dealing with exposure of marine mammals to any high-intensity pulsed sound.

There is no conclusive evidence of cetacean strandings or deaths at sea as a result of exposure to seismic surveys, but a few cases of strandings in the general area where a seismic survey was ongoing have led to speculation concerning a possible link between seismic surveys and strandings. Suggestions that there was a link between seismic surveys and strandings of humpback whales in Brazil (Engel *et al.*, 2004) were not well founded (IAGC, 2004; IWC, 2007). In September 2002, there was a stranding of two Cuvier's beaked whales (*Ziphius cavirostris*) in the Gulf of California, Mexico, when the L-DEO vessel R/V *Maurice Ewing* was operating a 20-airgun, 8490-in<sup>3</sup> airgun array in the general area. The link between the stranding and the seismic surveys was inconclusive and not based on any physical evidence (Hogarth, 2002; Yoder, 2002). Nonetheless, the Gulf of California incident plus the beaked whale strandings near naval exercises involving use of mid-frequency sonar suggests a need for caution in conducting seismic surveys in areas occupied by beaked whales until more is known about effects of seismic surveys on those species (Hildebrand, 2005). No injuries of beaked whales are anticipated during the proposed study because of: (1) the high likelihood that any beaked whales nearby would avoid the approaching



vessel before being exposed to high sound levels; (2) the proposed monitoring and mitigation measures; and (3) differences between the sound sources operated by L-DEO and those involved in the naval exercises associated with strandings.

#### *Possible Effects of Multibeam Echosounder (MBES) Signals*

The Simrad EM120 12-kHz MBES will be operated from the source vessel continuously during the planned study. Sounds from the MBES are very short pulses, occurring for 2-15 ms once every 5-20 s, depending on water depth. Most of the energy in the sound pulses emitted by this MBES is at frequencies near 12 kHz, and the maximum source level is 242 dB re 1  $\mu\text{Pa}\cdot\text{m}$  (rms). The beam is narrow ( $1^\circ$ ) in fore-aft extent and wide ( $150^\circ$ ) in the cross-track extent. Each ping consists of nine successive fan-shaped transmissions (segments) at different cross-track angles. Any given mammal at depth near the trackline would be in the main beam for only one or two of the nine segments. Also, marine mammals that encounter the Simrad EM120 are unlikely to be subjected to repeated pulses because of the narrow fore aft width of the beam and will receive only limited amounts of pulse energy because of the short pulses. Animals close to the ship (where the beam is narrowest) are especially unlikely to be ensonified for more than one 2-15 ms pulse (or two pulses if in the overlap area). Similarly, Kremser *et al.* (2005) noted that the probability of a cetacean swimming through the area of exposure when an MBES emits a pulse is small. The animal would have to pass the transducer at close range and be swimming at speeds similar to the vessel in order to receive the multiple pulses that might result in sufficient exposure to cause TTS.

Navy sonars that have been linked to avoidance reactions and stranding of cetaceans: (1) generally have longer pulse duration than the Simrad EM120, and (2) are often directed close to omnidirectionally versus more downward for the Simrad EM120. The area of possible influence of the MBES is much smaller a narrow band below the source vessel. The duration of exposure for a given marine mammal can be much longer for naval sonar.

Marine mammal communications will not be masked appreciably by the MBES signals given the low duty cycle of the echosounder and the brief period when an individual mammal is likely to be within its beam. Furthermore, in the case of baleen whales, the MBES signals (12 kHz) do not overlap with the

predominant frequencies in the calls, which would avoid any significant masking.

Behavioral reactions of free-ranging marine mammals to sonar, echosounders, and other sound sources appear to vary by species and circumstance. Observed reactions have included silencing and dispersal by sperm whales (Watkins *et al.*, 1985), increased vocalizations and no dispersal by pilot whales (*Globicephala* spp.) (Rendell and Gordon, 1999), and the previously-mentioned beachings by beaked whales. During exposure to a 21-25 kHz sonar with a source level of 215 dB re 1  $\mu\text{Pa}\cdot\text{m}$ , gray whales reacted by orienting slightly away from the source and being deflected from their course by approximately 200 m (Frankel, 2005). When a 38-kHz echosounder and a 150-kHz acoustic Doppler current profiler were transmitting during studies in the Eastern Tropical Pacific, baleen whales showed no significant responses, while spotted and spinner dolphins were detected slightly more often and beaked whales less often during visual surveys (Gerrodette and Pettis, 2005).

Captive bottlenose dolphins exhibited changes in behavior when exposed to 1-s tonal signals at frequencies similar to those that will be emitted by the MBES used by L-DEO, and to shorter broadband pulsed signals. Behavioral changes typically involved what appeared to be deliberate attempts to avoid the sound exposure (Schlundt *et al.*, 2000; Finneran *et al.*, 2002; Finneran and Schlundt, 2004). The relevance of those data to free-ranging odontocetes is uncertain, and in any case, the test sounds were quite different in duration as compared with those from an MBES.

Because of the unlikelihood of an animal being exposed to more than one or two very brief pulses, NMFS does not expect the operation of the MBES to result in the harassment of any marine mammals.

#### *Possible Effects of the Sub-bottom Profiler Signals*

An SBP may be operated from the source vessel at times during the planned study. Sounds from the sub-bottom profiler are very short pulses, occurring for 1-4 ms once every second. Most of the energy in the sound pulses emitted by the SBP is at 3.5 kHz, and the beam is directed downward in a narrow beam with a spacing of up to 15 and a fan width up to 30°. The sub-bottom profiler on the *Langseth* has a maximum source level of 204 dB re 1  $\mu\text{Pa}\cdot\text{m}$ . Kremser *et al.* (2005) noted that the probability of a cetacean swimming through the area of exposure when a

bottom profiler emits a pulse is small—even for an SBP more powerful than that on the *Langseth* if the animal was in the area, it would have to pass the transducer at close range and in order to be subjected to sound levels that could cause TTS.

Marine mammal communications will not be masked appreciably by the sub-bottom profiler signals given their directionality and the brief period when an individual mammal is likely to be within its beam. Furthermore, in the case of most baleen whales, the SBP signals do not overlap with the predominant frequencies in the calls, which would avoid significant masking.

Marine mammal behavioral reactions to other pulsed sound sources are discussed above, and responses to the SBP are likely to be similar to those for other pulsed sources if received at the same levels. However, the pulsed signals from the SBP are considerably weaker than those from the MBES. Therefore, behavioral responses would not be expected unless marine mammals were to approach very close to the source. This is not expected to occur because of the mitigation measures and the likely avoidance behaviors of marine mammals.

It is unlikely that the SBP produces pulse levels strong enough to cause hearing impairment or other physical injuries even in an animal that is (briefly) in a position near the source. The SBP is usually operated simultaneously with other higher-power acoustic sources. Many marine mammals will move away in response to the approaching higher-power sources or the vessel itself before the mammals would be close enough for there to be any possibility of effects from the less intense sounds from the SBP. In the case of mammals that do not avoid the approaching vessel and its various sound sources, mitigation measures that would be applied to minimize effects of other sources would further reduce or eliminate any minor effects of the SBP.

#### *Possible Effects of the Acoustic Release Signals*

The acoustic release transponder used to communicate with the OBS uses frequencies of 9-13 kHz. Once the OBS is ready to be retrieved, an acoustic release transponder interrogates the OBS at a frequency of 9-11 kHz, and a response is received at a frequency of 9-13 kHz. These signals will be used very intermittently. The source level of the release signal is 190 dB re 1  $\mu\text{Pa}$  at 1 m. An animal would have to pass by the OBS at close range when the signal is emitted in order to be exposed to any

pulses at that level. The sound is expected to undergo a spreading loss of approximately 40 dB in the first 100 m (328 ft). Thus, any animals located 100 m (328 ft) or more from the signal will be exposed to very weak signals (less than 150 dB) that are not expected to have any effects. The signal is used only for short intervals to interrogate and trigger the release of the OBS and consists of pulses rather than a continuous sound. Given the short duration use of this signal and rapid attenuation in seawater it is unlikely that the acoustic release signals would significantly affect marine mammals or sea turtles through masking, disturbance, or hearing impairment. Any effects likely would be negligible given the brief exposure at presumable low levels.

### Proposed Monitoring and Mitigation Measures

#### Monitoring

L-DEO proposes to sponsor marine mammal monitoring during the present project, in order to implement the proposed mitigation measures that require real-time monitoring, and to satisfy the anticipated monitoring requirements of the IHA. L-DEO's proposed Monitoring Plan is described below this section. L-DEO understands that this monitoring plan will be subject to review by NMFS, and that refinements may be required. The monitoring work described here has been planned as a self-contained project independent of any other related monitoring projects that may be occurring simultaneously in the same regions. L-DEO is prepared to discuss coordination of its monitoring program with any related work that might be done by other groups insofar as this is practical and desirable.

#### Vessel-based Visual Monitoring

Marine mammal observers (MMOs) will be based aboard the seismic source vessel and will watch for marine mammals and turtles near the vessel during daytime airgun operations and during any start-ups at night. The MMOs will also watch for marine mammals and turtles near the seismic vessel for at least 30 minutes (min) prior to the start of airgun operations after an extended shut down. When feasible, MMOs will also observe during daytime periods when the seismic system is not operating for comparison of sighting rates and behavior with versus without airgun operations. Based on MMOs' observations, the airguns will be powered down or shut down when marine mammals are observed within or

about to enter a designated exclusion zone (EZ). The EZ is a region in which a possibility exists of adverse effects on animal hearing or other physical effects.

During seismic operations in the Lau Basin, at least three MMOs will be based aboard the *Langseth*. MMOs will be appointed by L-DEO with NMFS' concurrence. At least one MMO, and when practical two MMOs, will monitor marine mammals and turtles near the seismic vessel during ongoing daytime operations and nighttime start ups of the airguns. Use of two simultaneous observers will increase the proportion of the animals present near the source vessel that are detected. MMOs will be on duty in shifts of duration no longer than 4 hours (h). Other crew will also be instructed to assist in detecting marine mammals and turtles and implementing mitigation requirements (if practical). Before the start of the seismic survey the crew will be given additional instruction regarding how to do so.

The *Langseth* is a suitable platform for marine mammal and turtle observations. When stationed on the observation platform, the eye level will be approximately 18 m (59 ft) above sea level, and the observer will have a good view around the entire vessel. During daytime, the MMOs will scan the area around the vessel systematically with reticle binoculars (e.g., 7 50 Fujinon), Big-eye binoculars (25 150), and with the naked eye. During darkness, night vision devices (NVDs) will be available (ITT F500 Series Generation 3 binocularimage intensifier or equivalent), when required. Laser rangefinding binoculars (Leica LRF 1200 laser rangefinder or equivalent) will be available to assist with distance estimation. Those are useful in training observers to estimate distances visually, but are generally not useful in measuring distances to animals directly; that is done primarily with the reticles in the binoculars.

The vessel-based monitoring will provide data to estimate the numbers of marine mammals exposed to various received sound levels, to document any apparent disturbance reactions or lack thereof, and thus to estimate the numbers of mammals potentially "taken" by harassment. It will also provide the information needed in order to power down or shut down the airguns at times when mammals and turtles are present in or near the safety radii. When a sighting is made, the following information about the sighting will be recorded:

1. Species, group size, age/size/sex categories (if determinable), behavior when first sighted and after initial

sighting, heading (if consistent), bearing and distance from seismic vessel, sighting cue, apparent reaction to the airguns or vessel (e.g., none, avoidance, approach, paralleling, etc.), and behavioral pace.

2. Time, location, heading, speed, activity of the vessel, sea state, visibility, and sun glare.

The data listed under (2) will also be recorded at the start and end of each observation watch, and during a watch whenever there is a change in one or more of the variables.

All observations and power-downs or shut downs will be recorded in a standardized format. Data will be entered into a custom database using a notebook computer. The accuracy of the data entry will be verified by computerized validity data checks as the data are entered and by subsequent manual checking of the database. Preliminary reports will be prepared during the field program and summaries forwarded to the operating institution's shore facility and to NSF weekly or more frequently.

Results from the vessel-based observations will provide:

1. The basis for real-time mitigation (airgun power-down or shut-down).
2. Information needed to estimate the number of marine mammals potentially taken by harassment, which must be reported to NMFS per terms of MMPA authorizations or regulations.
3. Data on the occurrence, distribution, and activities of marine mammals and turtles in the area where the seismic study is conducted.
4. Data on the behavior and movement patterns of marine mammals and turtles seen at times with and without seismic activity.

#### Passive Acoustic Monitoring

Passive acoustic monitoring (PAM) will take place to complement the visual monitoring program. Visual monitoring typically is not effective during periods of bad weather or at night, and even with good visibility, is unable to detect marine mammals when they are below the surface or beyond visual range. Acoustical monitoring can be used in addition to visual observations to improve detection, identification, localization, and tracking of cetaceans. The acoustic monitoring will serve to alert visual observers (if on duty) when vocalizing cetaceans are detected. It is only useful when marine mammals call, but it can be effective either by day or by night, and does not depend on good visibility. It will be monitored in real time so that the visual observers can be advised when cetaceans are detected. When bearings (primary and mirror-

image) to calling cetacean(s) are determined, the bearings will be relayed to the visual observer to help him/her sight the calling animal(s).

The PAM system consists of hardware (i.e., hydrophones) and software. The "wet end" of the system consists of a low-noise, towed hydrophone array that is connected to the vessel by a "hairy" faired cable. The array will be deployed from a winch located on the back deck. A deck cable will connect from the winch to the main computer lab where the acoustic station and signal conditioning and processing system will be located. The lead-in from the hydrophone array is approximately 400 m (1312 ft) long, and the active part of the hydrophone array is approximately 56 m (184 ft) long. The hydrophone array is typically towed at depths less than 20 m (66 ft).

The towed hydrophones will be monitored 24 h per day while at the seismic survey area during airgun operations, and during most periods when the *Langseth* is underway while the airguns are not operating. One MMO will monitor the acoustic detection system at any one time, by listening to the signals from two channels via headphones and/or speakers and watching the real-time spectrographic display for frequency ranges produced by cetaceans. MMOs monitoring the acoustical data will be on shift for 16 h at a time. Besides the visual MMOs, an additional MMO with primary responsibility for PAM will also be aboard. All MMOs are expected to rotate through the PAM position, although the most experienced with acoustics will be on PAM duty more frequently.

When a vocalization is detected while visual observations are in progress, the acoustic MMO will contact the visual MMO immediately, to alert him/her to the presence of cetaceans (if they have not already been seen), and to allow a power down or shut down to be initiated, if required. The information regarding the call will be entered into a database. The data to be entered include an acoustic encounter identification number, whether it was linked with a visual sighting, date, time when first and last heard and whenever any additional information was recorded, position and water depth when first detected, bearing if determinable, species or species group (e.g., unidentified dolphin, sperm whale), types and nature of sounds heard (e.g., clicks, continuous, sporadic, whistles, creaks, burst pulses, strength of signal, etc.), and any other notable information. The acoustic detection can also be recorded for further analysis.

#### Mitigation

L-DEO's mitigation procedures are based on protocols used during previous L-DEO seismic research cruises as approved by NMFS, and on best practices recommended in Richardson *et al.* (1995), Pierson *et al.* (1998), and Weir and Dolman (2007). The measures are described in detail below this section.

#### Proposed Safety Zones

As noted earlier, L-DEO modeled received sound levels for the 36-airgun array and for a single 1900LL 40-in<sup>3</sup> airgun (which will be used during power downs), in relation to distance and direction from the airguns. Based on the modeling for deep water, the distances from the source where sound levels are predicted to be 190, 180, and 160 dB re 1 FPa (rms) were determined (Table 1). The 180- and 190-dB radii vary with tow depth of the airgun array and range up to 1120 m and 340 m, respectively. The 180- and 190-dB levels are shut-down criteria applicable to cetaceans and pinnipeds, respectively, as specified by NMFS (2000); these levels were used to establish the safety zones. If the MMO detects marine mammal(s) or turtle(s) within or about to enter the appropriate safety radii, the airguns will be powered down (or shut down if necessary) immediately (see below).

#### Mitigation During Operations

Mitigation measures that will be adopted during the L-DEO survey include: (1) speed or course alteration, provided that doing so will not compromise operational safety requirements; (2) power-down procedures; (3) shut-down procedures; (4) ramp-up procedures; and (5) special procedures for species of particular concern.

**Speed or Course Alteration** – If a marine mammal or sea turtle is detected outside the safety zone and, based on its position and the relative motion, is likely to enter the safety zone, the vessel's speed and/or direct course may be changed. This would be done if practicable while minimizing the effect on the planned science objectives. The activities and movements of the marine mammal or sea turtle (relative to the seismic vessel) will then be closely monitored to determine whether the animal is approaching the applicable safety zone. If the animal appears likely to enter the safety zone, further mitigative actions will be taken, i.e., either further course alterations or a power down or shut down of the airguns. Typically, during seismic

operations that use hydrophone streamers, the source vessel is unable to change speed or course and one or more alternative mitigation measures (see below) will need to be implemented.

**Power-down Procedures** – A power-down involves decreasing the number of airguns in use such that the radius of the 180-dB (or 190-dB) zone is decreased to the extent that marine mammals or turtles are no longer in or about to enter the safety zone. A power-down of the airgun array can also occur when the vessel is moving from one seismic line to another. During a power-down for mitigation, one airgun will be operated. The continued operation of one airgun is intended to alert marine mammals and turtles to the presence of the seismic vessel in the area. In contrast, a shut-down occurs when all airgun activity is suspended.

If a marine mammal or turtle is detected outside the safety zone but is likely to enter the safety radius, and if the vessel's speed and/or course cannot be changed to avoid having the animal enter the safety radius, the airguns will be powered down before the animal is within the safety radius. Likewise, if a mammal or turtle is already within the safety zone when first detected, the airguns will be powered down immediately. During a power-down of the airgun array, the 40-in<sup>3</sup> airgun will be operated. If a marine mammal or turtle is detected within or near the smaller safety radius around that single airgun (Table 1), it will be shut down (see next subsection).

Following a power-down, airgun activity will not resume until the marine mammal or turtle has cleared the safety zone. The animal will be considered to have cleared the safety zone if it: (1) is visually observed to have left the safety zone; or (2) has not been seen within the zone for 15 min in the case of small odontocetes; or (3) has not been seen within the zone for 30 min in the case of mysticetes and large odontocetes, including sperm, pygmy sperm, dwarf sperm, and beaked whales; or (4) the vessel has moved outside the safety zone for turtles, i.e., approximately 5 to 20 min, depending on the sighting distance, vessel speed, and tow-depth.

**Shut-down Procedures** – During a power down, the operating airgun(s) will be shut down if a marine mammal or turtle is seen within or approaching the exclusion zone for a single airgun. Shut-downs will be implemented (1) if an animal enters the exclusion zone of the single airgun after a power-down has been initiated, or (2) if an animal is initially seen within the exclusion zone of a single airgun when more than one airgun (typically the full array) is

operating. Airgun activity will not resume until the marine mammal or turtle has cleared the EZ, or until the visual marine mammal observer (MMVO) is confident that the animal has left the vicinity of the vessel. Criteria for judging that the animal has cleared the EZ will be as described in the preceding subsection.

**Ramp-up Procedures** – A ramp-up procedure will be followed when the airgun array begins operating after a specified period without airgun operations or when a power-down has exceeded that period. It is proposed that, for the present cruise, this period would be approximately 9 min. This period is based on the largest modeled 180-dB radius for the 36-airgun array (see Table 1) in relation to the planned speed of the *Langseth* while shooting the airguns. Similar periods (approximately 8–10 min) were used during previous L-DEO surveys.

Ramp-up will begin with the smallest gun in the array (40 in<sup>3</sup>). Airguns will be added in a sequence such that the source level of the array will increase in steps not exceeding 6 dB per 5-min period over a total duration of about 35 min. During ramp-up, the MMOs will monitor the safety zone and if marine mammals or turtles are sighted, a course/speed change, power down, or shut down will be implemented as though the full array were operational.

If the complete safety zone has not been visible for at least 30 min prior to the start of operations in either daylight or nighttime, ramp-up will not commence unless at least one airgun (40 in<sup>3</sup> or similar) has been operating during the interruption of seismic survey operations. Given these provisions, it is likely that the airgun array will not be ramped up from a complete shut-down at night or in thick fog, because the outer part of the safety zone for that array will not be visible during those conditions. If one airgun has operated during a power-down period, ramp-up to full power will be permissible at night or in poor visibility, on the assumption that marine mammals and turtles will be alerted to the approaching seismic vessel by the sounds from the single airgun and could move away if they choose. Ramp-up of the airguns will not be initiated if a sea turtle or marine mammal is sighted within or near the applicable safety zones during the day or close to the vessel at night.

**Shutdown if Injured or Dead Whale is Found** – In the unanticipated event that any cases of marine mammal injury or mortality are found and are judged likely to have resulted from these activities, L-DEO will cease operating

seismic airguns and report the incident to the Office of Protected Resources, NMFS immediately.

#### Reporting

L-DEO will submit a report to NMFS within 90 days after the end of the cruise. The report will describe the operations that were conducted and sightings of marine mammals and turtles near the operations. The report will provide full documentation of methods, results, and interpretation pertaining to all monitoring. The 90-day report will summarize the dates and locations of seismic operations, and all marine mammal and turtle sightings (dates, times, locations, activities, associated seismic survey activities). The report will also include estimates of the number and nature of exposures that could result in "takes" of marine mammals by harassment or in other ways.

All injured or dead marine mammals (regardless of cause) must be reported to NMFS as soon as practicable. Report should include species or description of animal, condition of animal, location, time first found, observed behaviors (if alive) and photo or video, if available.

#### Estimated Take by Incidental Harassment

Because of the mitigation measures that will be required and the likelihood that some cetaceans will avoid the area around the operating airguns of their own accord, NMFS does not expect any marine mammals to approach the sound source close enough to be injured (Level A harassment). All anticipated takes would be "takes by Level B harassment", as described previously, involving temporary behavioral modifications or low-level physiological effects.

Estimates of the numbers of marine mammals that might be affected are based on consideration of the number of marine mammals that could be disturbed appreciably by approximately 3,650 km of seismic surveys during the proposed seismic program in the Lau Basin, Tonga. Few systematic aircraft- or ship-based surveys have been conducted for marine mammals in offshore waters of the South Pacific Ocean, and the species of marine mammals that occur there are not well known. L-DEO's estimates are based on species accounts in part derived from Reeves *et al.* (1999), who summarized distribution information from the area served by the South Pacific Regional Environment Programme (SPREP). The SPREP region covers a vast area of the Pacific Ocean between the Tropic of Capricorn and the Equator from Papua

New Guinea (140° E) to Pitcairn Island (130° W).

It should be noted that the estimates of exposures to various sound levels assume that the surveys will be completed; in fact, the planned number of line-kilometers has been increased by 25 percent to accommodate lines that may need to be repeated, equipment testing, etc. Furthermore, any marine mammal sightings within or near the designated safety zone will result in the power or shut down of seismic operations as a mitigation measure. Thus, the following estimates of the numbers of marine mammals potentially exposed to 160-dB sounds are precautionary, and probably overestimate the actual numbers of marine mammals that might be involved. These estimates assume that there will be no weather, equipment, or mitigation delays, which is highly unlikely.

The anticipated radii of influence of the MBES and SBP are less than those for the airgun array. It is assumed that, during simultaneous operations of the airgun array and the other sources, any marine mammals close enough to be affected by the MBES or SBP would already be affected by the airguns. However, whether or not the airguns are operating simultaneously with the other sources, marine mammals are expected to exhibit no more than short-term and inconsequential responses to the MBES and SBP given their characteristics (e.g., narrow downward-directed beam) and other considerations (see Possible Effects of Multibeam Echosounder Signals and Possible Effects of the Subbottom Profiler Signals). Such reactions are not considered to constitute "taking" (NMFS 2001). Therefore, no additional allowance is included for animals that might be affected by sound sources other than airguns.

#### Density Estimates

The basis for estimating the densities of marine mammals in the proposed study area is discussed in section VII of L-DEO's application. The density estimates used in this assessment are from one of Longhurst's (2007) biogeographic provinces north of the survey area that is oceanographically similar to the province in which the seismic activities will take place. Some of the surveys conducted by Ferguson and Barlow (2001) in the Eastern Tropical Pacific (ETP) during 1986–1996 are in Longhurst's (2007) North Pacific Tropical Gyre Province, which is similar to the South Pacific Subtropical Gyre (SPSG), in which the proposed seismic survey will occur. The similarities are: (1) they are both low-nitrate, low-

chlorophyll regions of the oceans with numerous coral reefs, and (2) upwelled nutrients by islands are used by corals and do not increase pelagic productivity. The species assemblages that occur in the southwest Pacific Ocean will be different than those sighted during the surveys in the ETP. However, the overall abundance of species groups with generally similar habitat requirements are expected to be roughly similar.

#### Potential Number of Exposures to Sound Levels at or above 160 dB

L-DEO's "best estimate" of the potential number of exposures of cetaceans, absent any mitigation measures, to seismic sounds with received levels at or above 160 dB re 1  $\mu$ Pa (rms) is 18,735 (Table 2). L-DEO's "maximum estimate" of the potential number of exposures of cetaceans, with mitigation measures, to seismic sounds with received levels at or above 160 dB re 1  $\mu$ Pa(rms) is 10,173 (Table 2). It is assumed that marine mammals exposed to airgun sounds this strong might change their behavior sufficiently to be considered "taken by harassment".

The number of potential exposures to sound levels at or above 160 dB re 1  $\mu$ Pa (rms) were calculated by multiplying the expected average species density (see section VII of L-DEO's application) times the anticipated minimum area (17,525 km<sup>2</sup>, 10,889 mi<sup>2</sup>) to be ensonified to that level during airgun operations including overlap.

The area expected to be ensonified was determined by entering the planned survey lines into a MapInfo Geographic Information System (GIS), using the GIS to identify the relevant areas by "drawing" the applicable 160-dB buffer around each seismic line, and then calculating the total area within the buffers. Areas where overlap occurred (because of closely-spaced lines) were included when estimating the number of exposures.

#### Number of Individual Cetaceans Exposed to Sound Levels at or above 160 dB

L-DEO's "best estimate" of the potential number of different individuals that could be exposed to airgun sounds with received levels at or above 160 dB re 1  $\mu$ Pa (rms) on one or more occasions is 4,997. That total includes 11 baleen whales, four of which are considered endangered under the ESA: one humpback whale, one blue whale, one sei whale, and one fin whale, which would represent small numbers of the regional populations (Table 2). In addition, six sperm whales (also listed as endangered under the

ESA) could be exposed during the survey, as well as 48 beaked whales (Table 2).

The spinner dolphin is estimated to be the most common species in the area, with a best estimate of 1,714 spinner dolphins exposed to sound levels at or above 160 dB re 1- $\mu$ Pa(rms).

Based on numbers of animals encountered during previous L-DEO seismic surveys, the likelihood of the successful implementation of the required mitigation measures, and the likelihood that some animals will avoid the area around the operating airguns, NMFS believes that L-DEO's airgun seismic testing program may result in the Level B harassment of some lower number of individual marine mammals (a few times each) than is indicated by the column titled, Maximum Estimate of Exposures - Request, in Table 2. L-DEO has asked for authorization for take of their "maximum estimate" of numbers for each species. Though NMFS believes that take of the requested numbers is unlikely, we still find these numbers small relative to the population sizes.

#### Potential Effects on Habitat

The proposed seismic survey will not result in any permanent impact on habitats used by marine mammals, or to the food sources they use. The main impact issue associated with the proposed activity will be temporarily elevated noise levels and the associated direct effects on marine mammals.

The *Langseth* will deploy and retrieve approximately 55-64 OBS. The OBS anchors will remain upon equipment recovery. Although OBS placement will disrupt a very small area of seafloor habitat and may disturb benthic invertebrates, the impacts are expected to be localized and transitory. The vessel will deploy the OBS in such a way that creates the least disturbance to the area. Thus, it is not expected that the placement of OBS would have adverse effects beyond naturally occurring changes in this environment, and any effects of the planned activity on marine mammal habitats and food resources are expected to be negligible.

*Effects on Fish and Invertebrates* - One reason for the adoption of airguns as the standard energy source for marine seismic surveys is that, unlike explosives, they have not been associated with large-scale fish kills. However, existing information on the impacts of seismic surveys on marine fish and invertebrate populations is very limited.

There are three types of potential effects of exposure to seismic surveys: (1) pathological, (2) physiological, and (3) behavioral. Pathological effects

involve lethal and temporary or permanent sublethal injury. Physiological effects involve temporary and permanent primary and secondary stress responses, such as changes in levels of enzymes and proteins. Behavioral effects refer to temporary and (if they occur) permanent changes in exhibited behavior (e.g., startle and avoidance behavior). The three categories are interrelated in complex ways. For example, it is possible that certain physiological and behavioral changes could potentially lead to an ultimate pathological effect on individuals (i.e., mortality).

The specific received sound levels at which permanent adverse effects to fish potentially could occur are little studied and largely unknown. Furthermore, the available information on the impacts of seismic surveys on marine fish is from studies of individuals or portions of a population; there have been no studies at the population scale. The studies of individual fish have often been on caged fish that were exposed to airgun pulses in situations not representative of an actual seismic survey. Thus, available information provides limited insight on possible real-world effects at the ocean or population scale. This makes drawing conclusions about impacts on fish problematic because, ultimately, the most important issues concern effects on marine fish populations, their viability, and their availability to fisheries.

The existing body of information on the impacts of seismic survey sound on marine invertebrates is also very limited. However, benthic invertebrates in the Lau Basin are not expected to be affected by seismic operations, as sound levels from the airguns will diminish dramatically by the time the sound reaches the ocean floor at a depth of approximately 2250 m (7382 ft).

There is some unpublished and very limited evidence of the potential for adverse effects on invertebrates. Based on the physical structure of their sensory organs, marine invertebrates appear to be specialized to respond to particle displacement components of an impinging sound field and not to the pressure component (Popper *et al.*, 2001). The only information available on the impacts of seismic surveys on marine invertebrates involves studies of individuals; there have been no studies at the population scale. Thus, available information provides limited insight on possible real-world effects at the regional or ocean scale. The most important aspect of potential impacts concerns how exposure to seismic survey sound ultimately affects invertebrate populations and their

viability, including availability to fisheries. More detailed information on studies of potential impacts of sounds on fish and invertebrates is provided in Appendix E of L-DEO's application.

#### Negligible Impact Determination

NMFS has preliminarily determined, provided that the aforementioned mitigation and monitoring measures are implemented, that the impact of conducting a seismic program in the southwest Pacific Ocean may result, at worst, in a temporary modification in behavior and/or low-level physiological effects (Level B Harassment) of small numbers of certain species of marine mammals. While behavioral and avoidance reactions may be made by these species in response to the resultant noise from the airguns, these behavioral changes are expected to have a negligible impact on the affected species and stocks of marine mammals.

While the number of potential incidental harassment takes will depend on the distribution and abundance of marine mammals in the area of seismic operations, the number of potential harassment takings is estimated to be relatively small in light of the population size (see Table 2). NMFS anticipates the actual take of individuals to be lower than the numbers depicted in the table, because those numbers do not reflect either the implementation of the mitigation numbers or the fact that some animals will avoid the sound at levels lower than those expected to result in harassment. Additionally, mitigation measures require that the *Langseth* avoid any areas where marine mammals are concentrated.

In addition, no take by death and/or serious injury is anticipated, and the potential for temporary or permanent hearing impairment will be avoided through the incorporation of the required mitigation measures described in this document. This conclusion is supported by: (1) the likelihood that, given sufficient notice through slow ship speed and ramp-up of the seismic array, marine mammals are expected to move away from a noise source that it is annoying prior to its becoming potentially injurious; (2) TTS is unlikely to occur, especially in odontocetes, until levels above 180 dB re 1  $\mu$ Pa (rms) are reached; (3) the fact that injurious levels of sound are only likely very close to the vessel; and (4) the monitoring program developed to avoid injury will be sufficient to detect (using visual detection and PAM), with reasonable certainty, all marine mammals within or entering the identified safety zones.

#### Endangered Species Act (ESA)

Under section 7 of the ESA, the National Science Foundation (NSF) has begun consultation on this proposed seismic survey. NMFS will also consult internally on the issuance of an IHA under section 101(a)(5)(D) of the MMPA for this activity. Consultation will be concluded prior to a determination on the issuance of an IHA.

#### National Environmental Policy Act (NEPA)

On September 22, 2005 (70 FR 55630), NSF published a notice of intent to prepare a Programmatic Environmental Impact Statement/Overseas Environmental Impact Statement (EIS/OES) to evaluate the potential environmental impacts associated with the use of seismic sources in support of NSF-funded research by U.S. academic scientists. NMFS agreed to be a cooperating agency in the preparation of the EIS/OEIS. This EIS/OEIS has not been completed. Therefore, in order to meet NSF's and NMFS' NEPA requirements for the proposed activity and issuance of an IHA to L-DEO, the NSF has prepared an Environmental Assessment of a Marine Geophysical Survey by the *Langseth* in the southwest Pacific Ocean off the coast of Tonga. NMFS is reviewing that document and will either adopt NSF's EA or conduct a separate NEPA analysis, as necessary, prior to making a determination of the issuance of the IHA. NMFS has posted NSF's EA on its website at <http://www.nmfs.noaa.gov/pr/permits/incidental.htm#applications>.

#### Preliminary Conclusions

Based on the preceding information, and provided that the proposed mitigation and monitoring are incorporated, NMFS has preliminarily concluded that the proposed activity will incidentally take, by level B behavioral harassment only, small numbers of marine mammals. The provision requiring that the activities not have an unmitigable adverse impact on the availability of the affected species or stock for subsistence uses does not apply for this proposed action. No take by Level A harassment (injury) or death is anticipated and harassment takes should be at the lowest level practicable due to incorporation of the mitigation measures proposed in this document.

#### Proposed Authorization

NMFS proposes to issue an IHA to L-DEO for a marine seismic survey in the southwest Pacific Ocean during January-February, 2009, provided the previously

mentioned mitigation, monitoring, and reporting requirements are incorporated.

Dated: November 18, 2008.

James H. Lecky,

Director, Office of Protected Resources,  
National Marine Fisheries Service.

[FR Doc. E8-27895 Filed 11-25-08; 8:45 am]

BILLING CODE 3510-22-S

#### DEPARTMENT OF COMMERCE

##### National Oceanic and Atmospheric Administration

[Docket Number: 0811191487-81488-01]

RIN: 0648-XL97

##### National Weather Service (NWS); NOAA Science Advisory Board's Environmental Information Services Working Group

**AGENCY:** National Weather Service (NWS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

**ACTION:** Notice of solicitation for members of the NOAA Science Advisory Board's Environmental Information Services Working Group.

**SUMMARY:** The Under Secretary of Commerce for Oceans and Atmosphere requested the NOAA Science Advisory Board (SAB) to obtain input from a standing working group, the Environmental Information Services Working Group (EISWG), as a mechanism to address interactions between NOAA and its Partners. The initial focus of the EISWG is to advise on issues raised and enhance effective collaboration between the National Weather Service and its partners. The composition of the Working Group will reflect those interests.

The EISWG will be composed of 15-18 members, who, by reason of knowledge, experience or training, are especially qualified to represent users of NOAA environmental information services, including, but not limited to, the commercial weather industry (both value-added and end-users), academia, and the media. Membership may also include representatives of federal, state and regional government agencies and non-governmental agencies. NOAA is requesting nominations for membership in the SAB EISWG.

**DATES:** Nominations must be received by January 23, 2009.

**ADDRESSES:** Nominations should be submitted electronically to ([noaa.sab.eiswg@noaa.gov](mailto:noaa.sab.eiswg@noaa.gov)).

**FOR FURTHER INFORMATION CONTACT:** Jennifer Sprague, 301-713-0217.

**SUPPLEMENTARY INFORMATION:** The complete Terms of Reference of this working group can be found on the NOAA Science Advisory Board Web site: [http://www.sab.noaa.gov/Working\\_Groups/standing/index.html](http://www.sab.noaa.gov/Working_Groups/standing/index.html).

At this time, NOAA is soliciting for up to eighteen members qualified to represent users of NOAA environmental information services, including, but not limited to, the commercial weather industry (both value-added and end-users), academia, and the media. Membership may also include representatives of federal, state and regional government agencies and non-governmental agencies. Members should have a credible science background, and an operational knowledge of federal agencies and interactions with state and local partners. The Working Group will convene 2-3 times over a year following the initial meeting. It will not advise NOAA directly, but, instead, will advise the SAB, which will deliberate on the Working Group's input before advising NOAA.

The intent is to select the membership of the group from the suggested candidates; however, the SAB retains the prerogative to propose members to the working group who were not nominated if it deems this necessary to achieve the desired balance. Once selected, the members' names will be posted at <http://www.sab.noaa.gov>.

The NOAA SAB has advised that the establishment of EISWG should be an interim solution. One year after the first meeting of the EISWG, the NOAA SAB will evaluate the effectiveness of this Working Group as a mechanism for obtaining advice on partnership issues relating to environmental information services. Following that evaluation, the SAB will recommend other steps as deemed necessary.

**Nominations:** Anyone is eligible to nominate and self-nominations will be accepted. Nominations should provide: (1) The nominee's full name, title, institutional affiliation, and contact information; (2) the nominee's area(s) of expertise; and (3) a concise Curriculum Vitae (CV) or resume that covers education, experience, relevant publications and summarizes how this expertise addresses the EISWG terms of reference.

Dated: November 20, 2008.

**David Murray,**

*Director, Management and Organization Division, Office of the Chief Financial Officer, National Weather Service, National Oceanic and Atmospheric Administration.*

[FR Doc. E8-27973 Filed 11-24-08; 8:45 am]

BILLING CODE 3510-22-P

## CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

### Information Collection; Submission for OMB Review, Comment Request

**AGENCY:** Corporation for National and Community Service.

**ACTION:** Notice.

**SUMMARY:** The Corporation for National and Community Service (hereinafter the "Corporation"), has submitted a public information collection request (ICR) entitled the Disaster Response Cooperative Agreement Application Package to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995, Public Law 104-13, (44 U.S.C. Chapter 35). Copies of this ICR, with applicable supporting documentation, may be obtained by calling the Corporation for National and Community Service, Phil Shaw, Office of Emergency Management at 202-606-6697. Individuals who use a telecommunications device for the deaf (TTY-TDD) may call (202) 565-2799 between 8:30 a.m. and 5 p.m. eastern time, Monday through Friday.

**ADDRESSES:** Comments may be submitted, identified by the title of the information collection activity, to the Office of Information and Regulatory Affairs, Attn: Ms. Katherine Astrich, OMB Desk Officer for the Corporation for National and Community Service, by any of the following two methods within 30 days from the date of publication in this **Federal Register**:

- (1) By fax to: (202) 395-6974, Attention: Ms. Katherine Astrich, OMB Desk Officer for the Corporation for National and Community Service; and
- (2) Electronically by e-mail to: [Katherine\\_T\\_Astrich@omb.eop.gov](mailto:Katherine_T_Astrich@omb.eop.gov).

**SUPPLEMENTARY INFORMATION:** The OMB is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Corporation, 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;
- Propose ways to enhance the quality, utility, and clarity of the information to be collected; and
- Propose 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, e.g., permitting electronic submissions of responses.

### Comments

A 60-day public comment Notice was published in the **Federal Register** on February 12, 2008. This comment period ended April 12, 2008. No public comments were received from this notice.

**Description:** The Disaster Response Cooperative Agreement allows an existing Corporation grantee to establish a legal framework with the Corporation to support disaster response activities assigned by a FEMA Mission Assignment. Programs operating under a Cooperative Agreement can receive reimbursement of expenses accrued while on disaster assignment.

The Corporation seeks to develop a new Disaster Response Cooperative Agreement (DRCA) Application. When developed, the application will revise/clarify the application review and clearance process. It will also expand data collection to support enhanced asset mapping efforts.

**Type of Review:** New Information Collection.

**Agency:** Corporation for National and Community Service.

**Title:** Disaster Response Cooperative Agreement Application.

**OMB Number:** None.

**Agency Number:** None.

**Affected Public:** Existing grantees and CNCS supported programs.

**Total Respondents:** 100 annually.

**Frequency:** One (1) time.

**Average Time per Response:** 2 hours.

**Estimated Total Burden Hours:** 200 hours.

**Total Burden Cost (capital/startup):** None.

**Total Burden Cost (operating/maintenance):** None.

Dated: November 17, 2008.

**Kristin McSwain,**

*Acting Chief Operations Officer, Corporation for National and Community Service.*

[FR Doc. E8-27906 Filed 11-24-08; 8:45 am]

BILLING CODE 6050--SS-P

## DEPARTMENT OF DEFENSE

### Office of the Secretary

[Docket ID DoD-2008-OS-0145]

### Proposed Collection; Comment Request

**AGENCY:** United States Military Entrance Processing Command (USMEPCOM), Officer of the Under Secretary of

Defense (Personnel and Readiness) (Military Personnel Policy), DoD.

**ACTION:** Notice.

In compliance with Section 3506(c)(2)(A) of the *Paperwork Reduction Act of 1995*, the United States Military Entrance Processing Command (USMEPCOM), Officer of the Under Secretary of Defense (Personnel and Readiness) (Military Personnel Policy) announces the following public information collection and seeks public comment on the provisions thereof. 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 shall have practical utility; (b) the accuracy of the agency's estimate of burden of the proposed information collection; (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.

**DATES:** Consideration will be given to all comments received by January 26, 2009.

**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, 1160 Defense Pentagon, Washington, DC 20301-1160.

*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:** To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to: HQ USMEPCOM Program Analysis and Evaluation Directorate, ATTN: Ms. M. Lou Wetzel, 2834 Green Bay Road, North Chicago, IL 60064-3094; call at 847-688-3680, extension 7234 or e-mail at [lou.wetzel@mepcom.army.mil](mailto:lou.wetzel@mepcom.army.mil).

*Title, Associated Form, and OMB Control Number:* USMEPCOM MEPS Customer Satisfaction Survey, OMB Control Number 0704-TBD.

*Needs and Uses:* This information collection requirement is necessary to aid the MEPS in evaluating effectiveness of current policies and core processes, identifying unmet customer needs, and allocating resources more efficiently.

*Affected Public:* Individuals or households.

*Annual Burden Hours:* 10,000 hours.

*Number of Respondents:* 60,000.

*Responses per Respondent:* 1.

*Average Burden per Response:* 10 minutes.

*Frequency:* On occasion.

#### SUPPLEMENTARY INFORMATION:

#### Summary of Information Collection

USMEPCOM, with headquarters in North Chicago, Ill., is a joint service command staffed with civilians and military from all five branches of service. The command, through its network of 65 Military Entrance Processing Stations, determines whether applicants are qualified for enlistment based on standards set by each of the services. USMEPCOM Regulation 601-23, *Enlistment Processing*, directs the information collection requirement for all 65 Military Entrance Processing Stations (MEPS) to obtain timely feedback on MEPS core processes. This web-based tool will allow MEPS to efficiently administer voluntary surveys on a routine basis to their primary customer, the applicants, for military service. This information collection requirement is necessary to aid the MEPS in evaluating effectiveness of current policies and core processes, identifying unmet customer needs, and allocating resources more efficiently.

Dated: November 18, 2008.

Patricia L. Toppings,

*OSD Federal Register Liaison Officer,  
Department of Defense.*

[FR Doc. E8-27945 Filed 11-24-08; 8:45 am]

BILLING CODE 5001-06-P

#### DEPARTMENT OF DEFENSE

#### Office of the Secretary

[Docket ID DoD-2008-OS-0141]

#### Proposed Collection; Comment Request

**AGENCY:** Defense Finance and Accounting Service, DoD.

**ACTION:** Notice.

**SUMMARY:** In compliance with Section 3506(c)(2)(A) of the *Paperwork Reduction Act of 1995*, the Defense Finance and Accounting Service announces the proposed extension of a public information collection and seeks

public comment on the provisions thereof. 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 shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed information collection; (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.

**DATES:** Consideration will be given to all comments received by January 26, 2009.

**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, 1160 Defense Pentagon, Washington, DC 20301-1160.

*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:** To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Defense Finance and Accounting Service—8899 East 56th Street, Attn: George Glammeyer, Department 3300, Indianapolis, IN 46249-3300, or call George Glammeyer 317-510-2282.

*Title, Associated Form, and OMB Number:* Waiver/Remission of Indebtedness Application, DD Form 2789; OMB Control Number 0730-0009.

*Needs and Uses:* Used by current or former DoD civilian employees or military members to request waiver or remission of an indebtedness owed to the Department of Defense. Under 5 U.S.C. 5584, 10 U.S.C. 2774, and 32 U.S.C. 716, certain debts arising out of erroneous payments may be waived. Under 10 U.S.C. 4837, 10 U.S.C. 6161, and 10 U.S.C. 9837, certain debts may be remitted. Information obtained through this form is used in



adjudicating the request for waiver or remission.

*Affected Public:* Individuals or households.

*Annual Burden Hours:* 9,200 hours.

*Number of Respondents:* 6400.

*Responses per Respondent:* 1.

*Average Burden per Response:* 1.4375 hours.

*Frequency:* On occasion.

**SUPPLEMENTARY INFORMATION:**

**Summary of Information Collection**

The referenced United States Code sections on waivers provide for an avenue of relief for individuals who owe debts to the United States which resulted from erroneous payments. Criteria for waiver of a debt includes a determination that there is no indication of fraud, misrepresentation, fault, or lack of good faith on the part of the individual owing the debt or any other person interested in obtaining a waiver. Information obtained through the proposed collection is needed in order to adjudicate the waiver request under the law.

Dated: November 18, 2008.

Patricia L. Toppings,  
OSD Federal Register Liaison Officer,  
Department of Defense.

[FR Doc. E8-27947 Filed 11-24-08; 8:45 am]

BILLING CODE 5001-06-P

**DEPARTMENT OF DEFENSE**

**Office of the Secretary**

[Docket ID DoD-2008-OS-0146]

**Proposed Collection; Comment Request**

**AGENCY:** Office of the Under Secretary of Defense (Personnel and Readiness), DOD.

**ACTION:** Notice.

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Under Secretary of Defense (Personnel and Readiness) announces the following proposed extension of a public information collection and seeks public comment on the provisions thereof. 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 shall have practical utility; (b) the accuracy of the agency's estimate of burden of the proposed information collection; (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.

**DATES:** Consideration will be given to all comments received by January 26, 2009.

**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, 1160 Defense Pentagon, Washington, DC 20301-1160.

*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:** To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Department of Defense Education Activity, *Attn:* Dr. Sandra D. Emblar, 4040 North Fairfax Drive, Arlington, VA 22203-1635, or call at (703) 588-3175.

*Title and OMB Control Number:*

Department of Defense Education Activity (DODEA) Evaluation and Program Surveys—Generic; OMB Control Number 0704-0437.

*Needs and Uses:* The Department of Defense Education Activity (DODEA) has a need to conduct a variety of one-time surveys, interviews, and focus groups on an as-needed basis. The population for these data collections will be limited to students and parents of students attending DODEA schools. These information collections are necessary to measure DODEA's progress on the goals set forth in the Community Strategic Plan, and to assess parent and student input on school policies and procedures. These data collections will include, but are not limited to, school operations and procedures (such as school uniforms, transportation, school calendar), school facilities, curricular and instructional needs and effectiveness, programmatic needs and effectiveness, and extra-curricular and co-curricular activities. The information sought by these data collections will allow DODEA to quickly have access to the information necessary to determine overall effectiveness, increase

efficiency, and obtain valuable input from parents and students on new and existing policies and procedures. Data collection instruments to include burden hours and supporting documentation will be submitted to the DOD Clearance Officer and OMB for final approval as they become available.

*Affected Public:* Individuals or households.

*Annual Burden Hours:* 1,041.

*Number of Respondents:* 2,500.

*Responses per Respondent:* 1.

*Average Burden per Response:* 25 minutes.

*Frequency:* On occasion.

**SUPPLEMENTARY INFORMATION:**

**Summary of Information Collection**

The following categories will be included in this data collection.

*School procedures and policies.*

These data collections will gather information from DODEA students and parents on issues related to the everyday operational processes and policies of the school. These data collections will include, but will not be limited to, information on the school calendar, school uniforms, school transportation, school lunch, school facilities (i.e., gymnasiums, cafeterias, and playgrounds). These data collections will allow DODEA to immediately identify or determine the extent of student and parent concerns and to quickly gather suggestions for improvement from parents and students.

*School curriculum.* These data collections will gather information from students and parents on the curricular availability and instructional practices in DODEA schools. These data collections will include, but will not be limited to, course offerings, availability and use of curricular materials, instructional practices, and availability and use of educational technology. These data collections will also gather information on the perceived effectiveness of the school curriculum.

*Program effectiveness and operations.* These data collections will gather opinions from students and parents on the provision, needs, and effectiveness of non-curricular programs and support services, such as counseling, special education services, gifted education, English as a Second Language Services, Physical and Occupational Therapy, and in-school medical services. These data collections will help assess the extent to which support services are available and accessible, as well as help determine the effectiveness and additional needs of support programs.

*Extra-curricular and co-curricular activities.* These data collections will

provide information from students and parents on the availability, effectiveness, and perceived needs of school extra-curricular and co-curricular activities. These data collections will help determine the extent to which the athletic interests of DODEA students are being met by the current offerings, and assess the effectiveness of such activities. These data collections will also help determine the extent to which the dramatic, artistic, musical, and academic interests of DODEA students are being met, and determine the future needs of such programs.

Dated: November 18, 2008.

**Patricia L. Toppings**,  
OSD Federal Register Liaison Officer,  
Department of Defense.  
[FR Doc. E8-27948 Filed 11-24-08; 8:45 am]  
BILLING CODE 5001-06-P

## DEPARTMENT OF DEFENSE

### Office of the Secretary

[Docket ID: DoD-2008-HA-0143]

#### Existing Collection; Comment Request

**AGENCY:** Office of the Assistant Secretary of Defense for Health Affairs, DoD.

**ACTION:** Notice.

In compliance with Section 3506(c)(2)(A) of the *Paperwork Reduction Act of 1995*, the Office of the Assistant Secretary of Defense for Health Affairs announces the proposed extension of a public information collection and seeks public comment on the provisions thereof. 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 shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed information collection; (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.

**DATES:** Consideration will be given to all comments received by January 26, 2009.

**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, 1160 Defense Pentagon, Washington, DC 20301-1160.

**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:

To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to TRICARE Management Activity Program, Policy and Benefits Branch, Attn: Mr. Jody Donehoo, 5111 Leesburg Pike, Suite 810, Falls Church, VA 22041-3206, or call 703-681-0039.

**Title; Associated Form; and OMB Number:** Continued Health Care Benefit Program, DD Form 2837; OMB Control Number 0704-0364.

**Needs and Uses:** The continuing information collection requirement is necessary for individuals to apply for enrollment in the Continued Health Care Benefit Program (CHCBP). The CHCBP is a program of temporary health care benefit coverage that is made available to eligible individuals who lose health care coverage under the Military Health System (MHS).

**Affected Public:** Individuals or households.

**Annual Burden Hours:** 625.

**Number of Respondents:** 2,500.

**Responses per Respondent:** 1.

**Average Burden per Response:** .25 hours.

**Frequency:** On occasion.

#### SUPPLEMENTARY INFORMATION:

##### Summary of Information Collection

Respondents are individuals who are or were beneficiaries of the Military Health System (MHS) and who desire to enroll in the CHCBP following their loss of entitlement to health care coverage in the MHS. These beneficiaries include the active duty service member or former service member (who, for purposes of this notice shall be referred to as "service member"), an un-married former spouse of a service member, an unmarried child of a service member who ceases to meet the requirements for being considered a dependent, and a child placed for adoption or legal custody with the service member.

In order to be eligible for health care coverage under CHCBP, an individual

must first enroll in CHCBP. DD Form 2837 is used as the information collection vehicle for that enrollment. The CHCBP is a legislatively mandated program and it is anticipated that the program will continue indefinitely.

Dated: November 18, 2008.

**Patricia L. Toppings**,  
OSD Federal Register, Liaison Officer,  
Department of Defense.  
[FR Doc. E8-27955 Filed 11-24-08; 8:45 am]  
BILLING CODE 5001-06-P

## DEPARTMENT OF DEFENSE

### Office of the Secretary

[Docket ID DoD-2008-HA-0144]

#### Proposed Collection; Comment Request

**AGENCY:** Office of the Assistant Secretary of Defense for Health Affairs, DoD.

**ACTION:** Notice.

In compliance with Section 3506(c)(2)(A) of the *Paperwork Reduction Act of 1995*, the Office of the Assistant Secretary of Defense for Health Affairs announces a proposed public information collection and seeks public comment on the provisions thereof. 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 shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed information collection; (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.

**DATES:** Consideration will be given to all comments received by January 26, 2009.

**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, 1160 Defense Pentagon, Washington, DC 20301-1160.

**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:** To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Office of the Assistant Secretary of Defense for Health Affairs, Force Health Protection and Readiness, ATTN: Ms. Caroline Miner, 5113 Leesburg Pike, Suite 901, Falls Church, Virginia 22041, or call Force Health Protection and Readiness, at 703-578-8500 or 1-800-754-2132.

**Title; Associated Form; and OMB Number:** Survey of Experiences with the Human Subjects Review Process; OMB Control Number 0720-TBD.

**Needs and Uses:** This information collection aligns with the Military Health System objectives to foster research innovations and to transform the infrastructure to eliminate redundancies and increase desired outcomes. The proposed information collection will enable the Office of the Under Secretary of Defense for Personnel and Readiness, Human Research Protection Program to assess the effectiveness of current review processes and facilitate efforts to measure and improve the overall efficiency and effectiveness of the program.

**Affected Public:** Individuals or households.

**Annual Burden Hours:** 500.

**Number of Respondents:** 1000.

**Responses per Respondent:** 1.

**Average Burden per Response:** 30 minutes.

**Frequency:** On occasion.

#### SUPPLEMENTARY INFORMATION:

##### Summary of Information Collection

Respondents are researchers who may have submitted a research protocol to an Office of the Under Secretary of Defense for Personnel and Readiness institution for human subjects review within the past year. The survey will ask respondents about the number and types of approvals required for their research and the amount of time taken to obtain the required reviews and approvals.

Dated: November 18, 2008.

**Patricia L. Toppings,**  
OSD Federal Register Liaison Officer,  
Department of Defense.

[FR Doc. E8-27957 Filed 11-24-08; 8:45 am]

BILLING CODE 5001-06-P

## DEPARTMENT OF DEFENSE

### Office of the Secretary

[Docket ID DoD-2008-OS-0142]

#### Proposed Collection; Comment Request

**AGENCY:** Defense Finance and Accounting Service, DoD.

**ACTION:** Notice.

**SUMMARY:** In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Defense Finance and Accounting Service announces the proposed extension of a public information collection and seeks public comment on the provisions thereof. 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 shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed information collection; (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.

**DATES:** Consideration will be given to all comments received by January 26, 2009.

**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, 1160 Defense Pentagon, Washington, DC 20301-1160.

**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:** To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Defense Finance and Accounting Service—Cleveland, Attn: Ms. Theresa A Matthes, DFAS-CL/JFRA, 1240 E. 9th Street, Cleveland, OH 44199, or call Ms. Theresa A Matthes, (216) 204-2383.

**Title, Associated Form, and OMB Number:** Custodianship Certification to Support Claim on Behalf of Minor Children of Deceased Members of the Armed Forces, DD Form 2790, OMB Control Number 0730-0010.

**Needs and Uses:** Per DoD Financial Management Regulation, 7000.14-R Volume 7B, Chapter 46, paragraph 460103A(1), an annuity for a minor child is paid to the legal guardian, or, if there is no legal guardian, to the natural parent who has care, custody, and control of the child as the custodian, or to a representative payee of the child. An annuity may be paid directly to the child when the child is considered to be of majority age under the law in the state of residence. The child then is considered an adult for annuity purposes and a custodian or legal fiduciary is not required.

**Affected Public:** Individuals or households.

**Annual Burden Hours:** 120 hours.

**Number of Respondents:** 300.

**Responses per Respondent:** 1.

**Average Burden per Response:** 24 minutes.

**Frequency:** On occasion.

#### SUPPLEMENTARY INFORMATION:

##### Summary of Information Collection

The form is used by the Directorate of Retired and Annuity Pay, Defense Finance and Accounting Service—Cleveland, (DFAS-CL) in order to pay the annuity to the correct person on behalf of a child under the age of majority. If the form with the completed certification is not received, the annuity payments are suspended. Since the funds for annuity are paid by members there are no consequences to the Federal Government.

November 18, 2008

**Patricia L. Toppings,**  
OSD Federal Register Liaison Officer,  
Department of Defense.

[FR Doc. E8-27958 Filed 11-24-08; 8:45 am]

BILLING CODE 5001-06-P

## DEPARTMENT OF DEFENSE

### GENERAL SERVICES ADMINISTRATION

#### NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000-0010]

#### Federal Acquisition Regulation; Information Collection; Progress Payments

**AGENCIES:** Department of Defense (DOD), General Services Administration (GSA).

and National Aeronautics and Space Administration (NASA).

**ACTION:** Notice of request for public comments regarding an extension to an existing OMB clearance.

**SUMMARY:** Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Federal Acquisition Regulation (FAR) Secretariat will be submitting to the Office of Management and Budget (OMB) a request to review and approve extension of a currently approved information collection requirement concerning progress payments. The clearance currently expires on March 31, 2009.

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the FAR, and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology. **DATES:** Submit comments on or before January 26, 2009.

**ADDRESSES:** Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to the General Services Administration, FAR Secretariat (VPR), 1800 F Street, NW., Room 4041, Washington, DC 20405.

**FOR FURTHER INFORMATION CONTACT:** Edward Chambers, Procurement Analyst, Contract Policy Division, GSA (202) 501-3221.

**SUPPLEMENTARY INFORMATION:**

**A. Purpose**

Certain Federal contracts provide for progress payments to be made to the contractor during performance of the contract. The requirement for certification and supporting information are necessary for the administration of statutory and regulatory limitation on the amount of progress payments under a contract. The submission of supporting cost schedules in an optional procedure that, when the contractor elects to have a group of individual orders treated as a single contract for progress payments purposes, is necessary for the administration of

statutory and regulatory requirements concerning progress payments.

**B. Annual Reporting Burden**

*Respondents:* 27,000.  
*Responses Per Respondent:* 32.  
*Annual Responses:* 864,000.  
*Hours Per Response:* .55.  
*Total Burden Hours:* 475,000.

**OBTAINING COPIES OF**

**PROPOSALS:** Requesters may obtain a copy of the information collection documents from the General Services Administration, FAR Secretariat (VPR), Room 4035, 1800 F Street, NW., Washington, DC 20405, telephone (202) 501-4755. Please cite OMB Control No. 9000-0010, Progress Payments, in all correspondence.

Dated: November 14, 2008.

**Al Matera,**

*Director, Office of Acquisition Policy.*

[FR Doc. E8-27894 Filed 11-24-08; 8:45 am]

**BILLING CODE 6820-EP-S**

**DEPARTMENT OF DEFENSE**

**Department of the Air Force**

[Docket ID USAF-2008-0036]

**Proposed Collection; Comment Request**

**AGENCY:** United States Air Force Logistics Transformation Office (HQ USAF/A4IT), DoD.

**ACTION:** Notice.

In compliance with Section 3506(c)(2)(A) of the *Paperwork Reduction Act of 1995*, the United States Air Force Logistics Transformation Office announces a proposed public information collection and seeks public comment on the provisions thereof. 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 shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed information collection; (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.

**DATES:** Consideration will be given to all comments received by January 26, 2009.

**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, 1160 Defense Pentagon, Washington, DC 20301-1160.

*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:** To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to United States Air Force Logistics Transformation Office (HQ USAF/A4IT [HQ 754ELSG/EC]), *Attn:* [Ms. Dorothy Ander], 4375 Chidlaw Rd., Area A, Bldg 262, Room S008, Post 1Q, WPAFB, OH 45433-5006, or call HQ USAF/A4IT, Logistics Transformation Office, at 937-904-0793.

*Title; Associated Form; and OMB Number:* Expeditionary Combat Support System (ECSS) Readiness Survey; OMB Control Number 0701-TBD.

*Needs and Uses:* The information collection requirement is necessary to measure the knowledge and acceptance of the new system by potential users and their managers. The results will be used to gauge the effectiveness of program activities and identify necessary course corrections.

*Affected Public:* Business or other for profit.

*Annual Burden Hours:* 924 hours.

*Number of Respondents:* 2767.

*Responses per Respondent:* 2.

*Average Burden per Response:* 10 minutes.

*Frequency:* Annually.

**SUPPLEMENTARY INFORMATION:**

**Summary of Information Collection**

Respondents are U.S. Air Force contractors that use, provide information to, or use information from any of the current U.S. Air Force logistics computer systems; along with all other government personnel that use these systems. Responders will voluntarily complete a survey that asks about their knowledge and acceptance of the new system. The results will be used to gauge the effectiveness of program activities and identify necessary course corrections to ensure all personnel have received the information and education needed to transition to the new systems, policies, processes, and procedures.

Dated: November 18, 2008.

Patricia L. Toppings,  
OSD Federal Register Liaison Officer,  
Department of Defense.

[FR Doc. E8-27949 Filed 11-24-08; 8:45 am]

BILLING CODE 5001-06-P

## DEPARTMENT OF DEFENSE

### Department of the Army

[Docket ID USA-2008-0080]

#### Proposed Collection; Comment Request

**AGENCY:** Office of the Administrative Assistant to the Secretary of the Army, (OAA-AAHS), DoD.

**ACTION:** Notice.

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Department of the Army announces a proposed extension of a public information collection and seeks public comment on the provisions thereof. 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 shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed information collection; (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.

**DATES:** Consideration will be given to all comments received by January 26, 2009.

**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, 1160 Defense Pentagon, Washington, DC 20301-1160.

*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:** To request more information on this

proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Department of the Army, Human Resources Command, Officer Personnel Management Directorate (AHRC-OPD-A), 200 Stovall Street, Alexandria, Virginia 22332, (Attn: Denise Camacho), or call Department of the Army Reports clearance officer at (703) 428-6440.

*Title, Associated Form, and OMB Number:* Application and Contract for Establishment of a Junior Reserve Officers' Training Corps Unit, DA Form 3126, OMB Control Number 0702-0021.

*Needs and Uses:* Educational institutions which desire to host a Junior ROTC unit may make application using DA Form 3126. The program provides unique educational opportunities for young citizens through their participation in a federally sponsored course while pursuing a civilian education. Participating students develop citizenship, leadership and communication skills, knowledge of the rule of the U.S. Army in support of national objectives, as well as an appreciation for the importance of physical fitness. The organization of units established by the Department of the Army at public and private secondary schools is provided under 10 U.S.C. 2031 and 32 CFR 542.

*Affected Public:* Not-For-Profit institutions.

*Annual Burden Hours:* 70.

*Number of Respondents:* 70.

*Responses per Respondent:* 1.

*Average Burden per Response:* 1 hour.

*Frequency:* On occasion.

#### SUPPLEMENTARY INFORMATION:

##### Summary of Information Collection

The DA Form 3126 is initiated by the school desiring to host a unit and is countersigned by a representative of the Secretary of the Army. The contract is necessary to establish a mutual agreement between the secondary institution and the U.S. Government. The Commanding General, Human Resources Command, is responsible for administering the JROTC program and overall policy. Region commanders are responsible for operating and administering the JROTC commanders. Data provided on the application is used to determine which factor as: (1) Receipt of signed applications and agreements; (2) enrollment potential; (3) capacity of the institution to conduct the program; (4) accreditation status; (5) ability to comply with statutory and contractual requirements; and (6) fair and equitable distribution of units throughout the nation.

Dated: November 18, 2008.

Patricia L. Toppings,  
OSD Federal Register, Liaison Officer,  
Department of Defense.

[FR Doc. E8-27946 Filed 11-24-08; 8:45 am]

BILLING CODE 5001-06-P

## DEPARTMENT OF DEFENSE

### Department of the Army

[Docket ID USA-2008-0078]

#### Proposed Collection; Comment Request

**AGENCY:** Office of the Administrative Assistant to the Secretary of the Army, (OAA-RPA), DoD.

**ACTION:** Notice.

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Department of the Army announces a proposed extension of a public information collection and seeks public comment on the provisions thereof. 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 shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed information collection; (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.

**DATES:** Consideration will be given to all comments received by January 26, 2009.

**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, 1160 Defense Pentagon, Washington, DC 20301-1160.

*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:** To request more information on this

proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to Military Surface Deployment and Distribution Command, 709 Ward Drive, Bldg. 1990, Scott Air Force Base, IL 62225-1604, Attn: SDDC-IMP-T, Station 1E164-44 (Carlos Alvarado), or call Department of the Army Reports clearance officer at (703) 428-6440.

*Title, Associated Form, and OMB Number:* Transportation Discrepancy Report; DD Form 361; OMB Control Number 0702-0124.

*Needs and Uses:* DD Form 361 is essential for documenting any loss, damage, or other discrepancy, which may result from the movement of Government freight by commercial transportation companies (carries). The form is ordinarily completed by the Federal agencies for which the transportation service is provided. However, in a small minority of cases (Approximately 9%), contractor personnel acting for the government may be required to complete this form.

*Affected Public:* Business or other for profit.

*Annual Burden Hours:* 1,434.

*Number of Respondents:* 1,434.

*Responses per Respondent:* 1.

*Average Burden per Response:* 1 hour.

*Frequency:* On occasion.

#### SUPPLEMENTARY INFORMATION:

##### Summary of Information Collection

DD Form 361 is essential for documenting any loss, damage, or other discrepancy, which may result from the movement of Government freight by commercial transportation companies (carries). As insurers of goods transported under the bill of lading contract carriers are responsible to the extent provided by law, for the delivery of goods as tendered by or for the Government.

Dated: November 18, 2008

**Patricia L. Toppings,**

*OSD Federal Register Liaison Officer,  
Department of Defense.*

[FR Doc. E8-27960 Filed 11-24-08; 8:45 am]

BILLING CODE 5001-06-P

## DEPARTMENT OF ENERGY

### Methane Hydrate Advisory Committee

**AGENCY:** Office of Fossil Energy,  
Department of Energy.

**ACTION:** Notice of Open Meeting.

This notice announces a meeting of the Methane Hydrate Advisory Committee. Federal Advisory

Committee Act (Pub. L. 92-463, 86 Stat. 770) requires that notice of these meetings be announced in the **Federal Register**.

**DATES:** Monday, December 22, 2008, 2 to 3:30 p.m.

**ADDRESSES:** TMS, Inc., 955 L'Enfant Plaza North, SW., Suite 1500, Washington, DC 20024.

**FOR FURTHER INFORMATION CONTACT:** Edith Allison, U.S. Department of Energy, Office of Oil and Natural Gas, Washington, DC 20585. Phone: 202-586-1023.

#### SUPPLEMENTARY INFORMATION:

*Purpose of the Committee:* The purpose of the Methane Hydrate Advisory Committee is to provide advice on potential applications of methane hydrate to the Secretary of Energy, and assist in developing recommendations and priorities for the Department of Energy Methane Hydrate Research and Development Program.

##### *Tentative Agenda:*

- Welcome and introductions.
- Discussion of whether a subcommittee should be formed to visit the new Secretary of Energy to discuss Committee's positions as stated in the previously-developed transition documents.
- Selection of visit subcommittee and potential dates, if required.

*Public Participation:* The meeting is open to the public. The Chairman of the Committee will conduct the meeting to facilitate the orderly conduct of business. 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 Edith Allison at the address or telephone number listed above. You must make your request for an oral statement at least five business days prior to the meeting, and reasonable provisions will be made to include the presentation on the agenda. Public comment will follow the 10 minute rule.

*Minutes:* The minutes of this meeting will be available for public review and copying within 60 days at the Freedom of Information Public Reading Room, Room 1G-033, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC, between 9 a.m. and 4 p.m., Monday through Friday, except federal holidays.

Issued at Washington, DC, on November 20, 2008.

**Rachel Samuel,**

*Deputy Committee Management Officer.*

[FR Doc. E8-27943 Filed 11-24-08; 8:45 am]

BILLING CODE 6450-01-P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

[Docket No. CP09-20-000]

#### Avista Corporation; Notice of Application

November 19, 2008.

Take notice that on November 6, 2008, Avista Corporation (Avista), 1411 East Mission Avenue, Spokane, Washington 99202, filed in Docket No. CP09-20-000, an application pursuant to Section 7(f) of the Natural Gas Act (NGA) requesting the determination of a service area within which Avista may, without further Commission authorization, enlarge or expand its natural gas distribution facilities. Avista also requests: (i) A finding that Avista qualifies as a local distribution company (LDC) for the purposes of section 311 of the Natural Gas Policy Act of 1978 (NGPA); (ii) a waiver of the Commission's accounting and reporting requirements and other regulatory requirements ordinarily applicable to natural gas companies under the NGA and the NGPA; and (iii) such further relief as the Commission may deem appropriate, all as more fully set forth in the application which is on file with the Commission and open to public inspection. This filing may also be viewed on the Commission's Web site 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. For assistance, call (866) 208-3676 or TTY, (202) 502-8659.

Any questions regarding this application should be directed to Michael G. Andrea, Staff Attorney at Avista Corporation, 1411 East Mission Avenue, MSC-23, Spokane, Washington 99202, or by calling (509) 495-2564 (telephone); (509) 777-5468 (fax), [michael.andrea@avistacorp.com](mailto:michael.andrea@avistacorp.com) or Paul Korman, Van Ness Feldman, PC, 1050 Thomas Jefferson Street, Washington, DC 20007; (202) 298-1830 (telephone) or (202) 338-2361 (fax), [pik@vnf.com](mailto:pik@vnf.com).

Pursuant to section 157.9 of the Commission's rules, 18 CFR 157.9, within 90 days of this Notice the Commission staff will either: Complete its environmental assessment (EA) and place it into the Commission's public record (eLibrary) for this proceeding, or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS)

or EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date stated below, file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit 14 copies of filings made with the Commission and must mail a copy to the applicant and to every other party in the proceeding. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commenters will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commenters will not be required to serve copies of filed

documents on all other parties.

However, the non-party commenters will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

Motions to intervene, protests and comments may be filed electronically via the internet in lieu of paper; see 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the "e-Filing" link. The Commission strongly encourages electronic filings.

*Comment Date:* December 10, 2008.

**Kimberly D. Bose,**  
Secretary.

[FR Doc. E8-27924 Filed 11-24-08; 8:45 am]  
BILLING CODE 6717-01-P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

[Project No. 2743-065]

#### Four Dam Pool Power Agency; Kodiak Electric Association, Inc.; Notice of Application for Transfer of License, and Soliciting Comments, Motions To Intervene, and Protests

November 19, 2008.

On October 6, 2008, Four Dam Pool Power Agency (Transferor) and Kodiak Electric Association, Inc. (Transferee) filed an application, for transfer of license of the Terror Lake Project, located on the Kizhuyak River in Kodiak, Alaska.

Applicants seek Commission approval to transfer the license for the Four Dam Pool Power Agency to Kodiak Electric Association, Inc.

*Applicant Contact:* Mr. William H. Prentice, Ater Wynne LLP, 222 SW Columbia Street, Suite 1800, Portland, OR 97201-6618, phone (503) 226-1191 and Mr. Darron Scott, General Manager, Kodiak Electric Association, Inc., P.O. Box 787, Kodiak, AK 99615-0787.

*FERC Contact:* Robert Bell, (202) 502-6062.

Deadline for filing comments, motions to intervene: 30 days from the issuance of this notice. Comments, motions to intervene, and notices of intent may be filed electronically via the Internet. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the "e-Filing" link. If unable to be filed electronically, documents may be paper-filed. To paper-file, an original and eight copies should be

mailed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. 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>. More information about this project 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-2743-065) in the docket number field to access the document. For assistance, call toll-free 1-866-208-3372.

**Kimberly D. Bose,**  
Secretary.

[FR Doc. E8-27923 Filed 11-24-08; 8:45 am]  
BILLING CODE 6717-01-P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

#### Combined Notice of Filings #1

September 30, 2008.

Take notice that the Commission received the following electric corporate filings:

*Docket Numbers:* EC08-127-000.

*Applicants:* Puget Sound Energy, Inc., Mint Farm Energy Center LLC.

*Description:* Joint Application of Mint Farm Energy Center LLC and Puget Sound Energy, Inc. Under Section 203 of the FPA and Request for Expedited Action.

*Filed Date:* 09/26/2008.

*Accession Number:* 20080926-5119.

*Comment Date:* 5 p.m. Eastern Time on Friday, October 17, 2008.

Take notice that the Commission received the following exempt wholesale generator filings:

*Docket Numbers:* EG08-98-000.

*Applicants:* Elbow Creek Wind Project LLC.

*Description:* Self Certification Notice as an Exempt Wholesale Generator of Elbow Creek Wind Project LLC.

*Filed Date:* 09/29/2008.

*Accession Number:* 20080929-5002.

*Comment Date:* 5 p.m. Eastern Time on Monday, October 20, 2008.

Take notice that the Commission received the following electric rate filings:

*Docket Numbers:* ER08-1214-001; ER08-1215-001; ER08-1216-001.

*Applicants:* Wisconsin Electric Power Company.

*Description:* Wisconsin Electric Power Co. submits an executed Settlement Agreement and associated documents.

*Filed Date:* 09/12/2008.

*Accession Number:* 20080912-4012.

*Comment Date:* 5 p.m. Eastern Time on Tuesday, October 07, 2008.

*Docket Numbers:* ER08-1315-001.

*Applicants:* Florida Power & Light Company.

*Description:* Florida Power & Light Company submits an amendment to their 7/28/08 filing to address an inquiry from FERC Staff re the nature of the facilities specifically whether the facilities to be installed by FPL etc.

*Filed Date:* 09/11/2008.

*Accession Number:* 20080916-0098.

*Comment Date:* 5 p.m. Eastern Time on Thursday, October 09, 2008.

Take notice that the Commission received the following open access transmission tariff filings:

*Docket Numbers:* OA08-9-002.

*Applicants:* PJM Interconnection, L.L.C.

*Description:* Compliance Amendment.

*Filed Date:* 09/29/2008.

*Accession Number:* 20080929-5141.

*Comment Date:* 5 p.m. Eastern Time on Monday, October 20, 2008.

Any person desiring to intervene or to protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. It is not necessary to separately intervene again in a subdocket related to a compliance filing if you have previously intervened in the same docket. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. In reference to filings initiating a new proceeding, interventions or protests submitted on or before the comment deadline need not be served on persons other than the Applicant.

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 14 copies of the intervention or protest to the Federal Energy Regulatory Commission,

888 First St. NE., Washington, DC 20426.

The filings in the above proceedings 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 e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail [FERCOnlineSupport@ferc.gov](mailto:FERCOnlineSupport@ferc.gov), or call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

**Nathaniel J. Davis, Sr.,**

*Deputy Secretary.*

[FR Doc. E8-27904 Filed 11-24-08; 8:45 am]

BILLING CODE 6717-01-P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

[Docket No. EL09-11-000]

#### Interstate Power and Light Company, Complainant, v. ITC Midwest, LLC, Respondent; Notice of Complaint

November 19, 2008.

Take notice that on November 18, 2008, Interstate Power and Light Company (Complainant) filed, pursuant to section 206 of the Federal Power Act, 16 U.S.C. 824(e), and section 206 of the Commission's Rules of Practice and Procedure, 18 CFR 358.206, a formal complaint against ITC Midwest, LLC (Respondent) seeking relief from the Respondent's implementation of its formula rate for FERC-jurisdictional transmission service for 2009 and beyond.

The Complainant certifies that copies of the complaint were served on the contacts for the Respondent as listed on the Commission's list of Corporate Officials.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. The Respondent's answer and all interventions, or protests must be filed on or before the comment date.

The Respondent's answer, motions to intervene, and protests must be served on the Complainants.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the "eFiling" link at <http://www.ferc.gov>. Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at <http://www.ferc.gov>, using the "eLibrary" link and is 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 e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail [FERCOnlineSupport@ferc.gov](mailto:FERCOnlineSupport@ferc.gov), or call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

*Comment Date:* 5 p.m. Eastern Time on December 8, 2008.

**Kimberly D. Bose,**

*Secretary.*

[FR Doc. E8-27921 Filed 11-24-08; 8:45 am]

BILLING CODE 6717-01-P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

[Docket Nos. EG08-87-000, EG08-88-000, EG08-89-000, EG08-90-000, EG08-91-000]

#### Crystal Lake Wind, LLC, Crystal Lake Wind II, LLC, Osceola Windpower II, LLC, Story Wind, LLC, Noble Great Plains Windpark, LLC; Notice of Effectiveness of Exempt Wholesale Generator Status

November 19, 2008.

Take notice that during the month of October 2008, the status of the above-captioned entities as Exempt Wholesale Generators Companies became effective by operation of the Commission's regulations 18 CFR 366.7(a).

**Kimberly D. Bose,**

*Secretary.*

[FR Doc. E8-27919 Filed 11-24-08; 8:45 am]

BILLING CODE 6717-01-P



## DEPARTMENT OF ENERGY

Federal Energy Regulatory  
Commission

[ Docket Nos. EC08-91-000, EC08-91-001 ]

**Horizon Asset Management, Inc.;  
Order Clarifying Jurisdiction Over  
Certain Investment Adviser Activities  
Under Section 203(A)(2) of the Federal  
Power Act, Allowing Affected  
Investment Entities a 90-Day Filing  
Period, and Acting On Requests for  
Blanket Authorizations**

Issued November 20, 2008.

*Before Commissioners:* Joseph T. Kelliher, Chairman; Suedeen G. Kelly, Marc Spitzer, Philip D. Moeller, and Jon Wellingshoff.

1. On May 19, 2008, as amended on September 25, 2008,<sup>1</sup> Horizon Asset Management (Horizon) filed a request for a disclaimer of jurisdiction by the Commission that would relieve Horizon of the obligation to obtain prior Commission authorization under section 203 of the Federal Power Act (FPA)<sup>2</sup> for acquisitions of the securities of certain public utility holding companies or certain electric utility operating companies. In the alternative, Horizon requests blanket authorizations, under sections 203(a)(1) and 203(a)(2) of the FPA: (1) For Horizon to instruct or advise on the acquisition on behalf of Account Holders, as defined below, of securities of public utilities or public utility holding companies, and (2) for public utilities or public utility holding companies to sell securities to Horizon on behalf of the Account Holders. Horizon also requests retroactive authorization for the holdings in excess of 10 percent of the voting shares of Reliant Energy, Inc. (Reliant), Sierra Pacific Power (Sierra Pacific), and Aquila, Inc. (Aquila).

2. In this order the Commission clarifies an aspect of its jurisdiction under the "purchase, acquire, or take any security" clause of FPA section 203(a)(2). We also deny the request for a disclaimer of jurisdiction, dismiss the request for blanket authorization under section 203(a)(1) as unnecessary, and find that the request for blanket authorization under section 203(a)(2) is consistent with the public interest. We grant the blanket authorization under section 203(a)(2), subject to reporting and record retention conditions, for a period of three years. We deny the

request for retroactive approval of Horizon's holdings in excess of 10 percent of the voting shares of Reliant, Sierra Pacific, and Aquila but, in light of the previous lack of clarity regarding our interpretation of the scope of section 203(a)(2), we determine not to impose sanctions for Horizon's failure to file for prior approval of these acquisitions of securities.

3. Having now clarified our interpretation of the Commission's jurisdiction under the "purchase, acquire, or take any security" clause of section 203(a)(2), however, we caution Horizon and other similar investment advisers that they may face possible monetary or other sanctions if they fail to obtain advance approval under section 203(a)(2) of similar acquisitions of securities. Further, we remind investment companies and advisers that if they participate or have a role in other types of acquisitions of securities of public utility companies or public utility holding companies and it is not clear to them whether section 203(a)(2) approval is needed for those types of transactions, they have the option of seeking a jurisdictional determination from the Commission through a declaratory order or other appropriate procedural mechanism prior to engaging in the transactions.

4. Because not all investment companies and advisers may have been aware of our interpretation of the Commission's jurisdiction under the "purchase, acquire, or take any security" clause of section 203(a)(2) to require prior authorization for the acquisition of public utility securities as discussed in this order, we will allow any such affected entity to file within 90 days of the date of publication of this order in the **Federal Register** an application requesting such authorization.

**I. Background****A. Description of Applicant**

5. Horizon is an investment adviser registered with the Securities and Exchange Commission (SEC).<sup>3</sup> Horizon states that its primary business is the management and direction of separately managed accounts. These accounts are owned by individuals and entities (Account Holders) and are generally "in

the hands of" account custodians (typically, one of the large banking institutions). The vast majority of the separately managed accounts are "discretionary accounts," which means that Horizon has the exclusive authority to manage the account and instruct the custodian to add or reduce positions in the account. Horizon states that the Account Holder is the actual owner of all the stock in the account and is listed in the relevant stock registries as the owner. Horizon earns a fee for its management of the account.

6. Horizon states that it is the general partner and investment adviser of certain hedge funds and it is a subadviser to certain mutual funds. In one instance, Horizon has been delegated the right to vote shares in the fund. Of the total amount Horizon has under management, roughly 90 percent is in separately managed accounts. Horizon states that it employs a variety of strategies in its activities as an investment adviser, which permits an investor to select the strategy of choice for the direction of his or her separately managed account or to select a hedge fund that embodies the strategy.

7. Horizon states that its Account Holders previously held the authority to vote the shares in their accounts (absent a provision in the management agreement between Horizon and the Account Holder to the contrary). But several years ago, at the request of Account Holders, Horizon began inserting a provision in the management agreement under which the Account Holder delegated the right to vote the shares in his or her account to Horizon.

8. Horizon states it has filed as an exempt holding company under the Public Utility Holding Company Act of 2005 (PUHCA 2005)<sup>4</sup> and Commission form FERC-65A with respect to its accounts holding more than 10 percent of the voting securities of Reliant, Sierra Pacific, and Aquila.

9. Each Account Holder is a separate legal person or entity. Horizon states that it does not control any of the Account Holders. Each Account Holder has delegated to Horizon the responsibility for supervising and managing the securities portfolio of that account. The delegated responsibilities include both the purchase and sale of the securities as well as the voting rights proxies. Horizon states that in exercising the voting rights it generally defers to Institutional Shareholder Services, Inc. (Institutional Shareholder

<sup>1</sup> The May 19, 2008, filing is the original application (Original Application). The September 25, 2008, filing is an amendment to the Application (Amendment) and also provides answers to a deficiency letter from Commission staff (Answer).

<sup>2</sup> 16 U.S.C. 824b (2006).

<sup>3</sup> Under the Investment Advisers Act of 1940, an investment adviser is any person who, for compensation, engages in the business of advising others, either directly or through publications or writings, as to the value of securities or as to the advisability of investing in, purchasing, or selling securities, or who, for compensation and as part of a regular business, issues or promulgates analyses or reports concerning securities. 15 U.S.C. 80b-2(a)(11) (2006).

<sup>4</sup> 42 U.S.C. 16451 *et seq.* (2006).

Services)<sup>5</sup> but retains the option to override its decisions. Horizon maintains that Account Holders are passive investors with respect to ownership interests in utilities and will be unable to exercise control.

#### *B. Request for Disclaimer of Jurisdiction or Blanket Authorization*

10. Horizon's application contains two basic requests that are posed in the alternative. First, Horizon requests that the Commission disclaim jurisdiction over its account management activities that involve the acquisition of holding company or utility securities that otherwise would be subject to Commission approval under FPA section 203. Alternatively, Horizon seeks permanent blanket authorization under FPA sections 203(a)(1) and 203(a)(2) for: (i) Horizon to engage in account management activities involving the acquisition of the voting securities of any public utility, electric utility company, transmitting utility, or holding company in a holding company system that includes an electric utility company or transmitting utility; and (ii) utilities or holders of utility voting securities to sell their securities to Horizon or its agents in transactions that fall within the scope of its account management activities, subject to certain conditions. Horizon proposes the following conditions to its requested blanket authorization that are intended to prevent the exercise of control over jurisdictional facilities:

(1) Horizon will only manage the securities of publicly-traded utilities on behalf of Account Holders and all acquisitions of securities made pursuant to the authorizations shall be securities of publicly-traded utilities;<sup>6</sup>

(2) The shares of any public utility or public utility holding company in an individual Horizon account shall be less than 10 percent of the issued voting securities of such public utility or public utility holding company;

(3) Horizon shall maintain its policies and comply with applicable statutory prohibitions against exercising control over companies whose securities are acquired for Horizon Account Holders, and Horizon will not change such policies in the future;

(4) Horizon will maintain its eligibility to make Schedule 13G filings with the SEC pursuant to SEC rules under the Securities and Exchange Act

<sup>5</sup> Institutional Shareholder Services is an entity who performs proxy voting functions for a number of registered investment advisers and other entities.

<sup>6</sup> Horizon defines "publicly traded utilities" as utilities whose common stock is traded on the New York Stock Exchange, the American Stock Exchange, or the NASDAQ.

of 1934<sup>7</sup> and, when appropriate, will make such 13G filings with respect to securities of public utilities and public utility holding companies and contemporaneously file a copy with the Commission.<sup>8</sup> Further, Horizon shall file with the Commission any comment or deficiency letters received from the SEC that concern Schedule 13G-related compliance audits conducted by the SEC. Those filings shall be made in this docket or in appropriate sub-dockets of this docket;

(5) Horizon will not take action which would require it to make a Schedule 13D filing with the SEC with respect to the securities of any public utility or public utility holding company;

(6) Horizon will include language in its Form ADV,<sup>9</sup> its Policies and Procedures Manual, its annual letter to Account Holders, and all future Account Holder Agreements explicitly providing that Horizon shall not exercise the shareholder voting rights delegated to Horizon by Account Holders, or act in any other way, to exercise control over any public utility or any public utility holding company. Horizon shall not change or withdraw this language without providing the Commission with at least 90 days notice;

(7) The shares of any public utility or public utility holding company over which Horizon and any affiliated entity have voting power shall not exceed 19.99 percent of the voting securities of

<sup>7</sup> 15 U.S.C. 78a *et seq.* (2000) (1934 Act).

<sup>8</sup> Under the Securities Exchange Act of 1934, 15 U.S.C. 78a *et seq.* (2000 & Supp V 2005), and the SEC's regulations under that statute, 17 CFR 240.13-1 *et seq.*, when a person acquires, directly or indirectly, beneficial ownership of five percent or more of any class of securities of a publicly-traded company, that person must file a disclosure report with the SEC on either a Schedule 13D or 13G. While there are other distinguishing characteristics, the fundamental difference is usually the "investment intent" of the investor, which can change at any time and then be acted upon after 10 days. A Schedule 13D must be filed when the owner of the securities holds the securities "with the purpose or effect of changing or influencing the control of the issuer" or if ownership "equals or exceeds 20 percent of the class of equity securities." 17 CFR 240.13-1(c). In order to qualify to file a Schedule 13G, the filer must be able to certify that it "has acquired such securities in the ordinary course of business and not with the purpose nor with the effect of changing or influencing the control of the issuer, nor in connection with or as a participant in any transaction having such purpose or effect." 17 CFR 240.13-1(b)(1)(i). The commitment not to influence control is not permanent. Under SEC rules, once a Schedule 13G has been filed, a person can change its intent and begin to exert control or commence acquiring additional securities with the intention of exerting control 10 days after filing Schedule 13D. 17 CFR 240.13-1(c).

<sup>9</sup> A Form ADV is a SEC form used to register an investment adviser under the Investment Advisers Act.

such public utility or public utility holding company;

(8) Horizon shall retain the records of its transactions concerning public utility securities as required under the Investment Advisers Act of 1940 (Investment Advisers Act).<sup>10</sup>

(9) Horizon shall generally defer to Institutional Shareholder Services voting recommendations and will exercise its voting power in a way that is consistent with its fiduciary duties to its Account Holders but, in any case, shall maintain readily auditable records of the voting of the shares of public utilities or public utility holding companies in its accounts; and

(10) Horizon shall provide the Commission with a quarterly report within 45 days of the end of each calendar quarter of the holdings of securities of public utilities and public utility holding companies as of the last day of the calendar quarter stated in terms of the number of shares held as of the end of the quarter and as a percentage of the outstanding shares.

## **II. Notice of Filings and Responsive Pleadings**

11. Notice of the Original Application was published in the **Federal Register**, 73 FR 31,085 (2008), with interventions and protests due on or before June 9, 2008. None was filed. Notice of the Amendment and Answer was published in the **Federal Register**, 73 FR 58,222 (2008), with interventions and protests due on or before October 16, 2008. None was filed.

## **III. Discussion**

### *A. Disclaimer of Jurisdiction*

#### **1. Horizon's Request**

12. Horizon states that it is an investment adviser that directs acquisitions of stock for its account holders and maintains that this activity does not bring it within the Commission's jurisdiction under FPA section 203. Horizon notes that section 203(a)(2) applies to holding companies that "purchase, acquire, or take" utility or holding company securities, and it argues that it does not engage in these activities. Horizon points out that the FPA does not define the terms "purchase," "acquire," or "take," and its analysis focuses on the meaning that should be attributed to them.<sup>11</sup> It

<sup>10</sup> 15 U.S.C. 80b-2(a)(11).

<sup>11</sup> The text of section 203(a)(2) reads as follows: No holding company in a holding company system that includes a transmitting utility or an electric utility shall purchase, acquire, or take any security with a value in excess of \$10,000,000 of, or, by any means whatsoever, directly or indirectly, merge or consolidate with, a transmitting utility, an

maintains that in interpreting these terms, the Commission should begin by assuming that their ordinary meaning expresses their legislative purpose, and they should be viewed in the light of the "object and policy" of the statute.<sup>12</sup> Horizon finds their ordinary meaning in various dictionary definitions, and it maintains that those definitions show that it has not purchased, taken or acquired any securities in the course of its business activities.

13. According to Horizon, to "purchase" means "to obtain by buying,"<sup>13</sup> to "obtain for money or by paying a price,"<sup>14</sup> or to "acqui[re] by one's own or another's act \* \* \* rather than by descent or inheritance."<sup>15</sup> Horizon argues that these definitions do not apply to it because it does not obtain or buy the securities in the accounts it manages. Instead, it directs stock trading companies to buy or obtain securities for its Account Holders.

14. Horizon states that to "acquire" is normally defined as "[t]o gain possession or control of; to get or obtain,"<sup>16</sup> or to "get or gain by one's own efforts[;] to come to have as one's own; get possession of."<sup>17</sup> Horizon argues that it is its Account Holders who acquire the securities in the course of its business operations.

15. Finally, Horizon argues that it does not "take" public utility securities by virtue of its role as investment adviser because that would require a finding that it "obtain[s] possession or control" of, or "transfer[s] to [it]self," the public utility securities.<sup>18</sup>

16. Horizon follows this discussion of dictionary definitions with several observations on differences between the language in section 203(a)(1) and section 203(a)(2), as well as the treatment of direct and indirect acquisitions of securities under section 203(a)(2). Horizon notes that the Commission has acknowledged that section 203(a)(1)(A) contains broad, catch-all language regarding the scope of transactions that it covers, and section

203(a)(2) has no similar language. Specifically, section 203(a)(1)(A) requires Commission authorization for a public utility to sell, lease, or otherwise dispose of certain facilities, and section 203(a)(2) requires Commission authority to purchase, acquire, or take certain securities. In other words, section 203(a)(2) does not contain additional language such as "or otherwise obtain."<sup>19</sup> Horizon concludes that the absence of such language counsels against a finding that section 203(a)(2) is intended to confer jurisdiction over the type of activity it engages in.

17. Horizon also notes that the Commission has concluded that the first clause of section 203(a)(2), which pertains to securities acquisitions, addresses direct and not indirect acquisitions. Horizon maintains that in its case any direct acquisitions are made by its Account Holders, and it is not a parent holding company of its Account Holders or any of the stock trading companies that purchase the securities held in the accounts.

18. Horizon states that it does not own, legally or beneficially, the public utility securities in the accounts it manages, and it is not a beneficial owner of public utility securities under section 13(d) of the 1934 Act or the SEC's regulations under that statute because those securities are not acquired with "the purpose or effect of changing or influencing control of the issuer."<sup>20</sup> This is because the public utility securities acquired by the Account Holders at Horizon's direction are not acquired with the purpose or effect of changing or influencing control of the issuer.<sup>21</sup> Horizon states that as an

investment adviser, Horizon does not directly or indirectly own or acquire securities of public utilities in the accounts it manages; it does not itself purchase those securities on behalf of the account holders; and it does not have the authority to manage, direct, or control the day-to-day operations of any public utilities. While Horizon states in its May 19, 2008 application that it does not exercise the voting rights delegated to it and instead delegates those rights to Institutional Shareholder Services,<sup>22</sup> Horizon suggests in its September 25, 2008 amendment to its application that Institutional Shareholder Services simply provides voting recommendations.<sup>23</sup>

19. Horizon distinguishes itself from other investment companies that have received blanket authorizations under section 203(a)(2) based on three considerations.<sup>24</sup> First, those companies conceded that they or their affiliates were purchasers or acquirers of securities because they made the purchases or acquisitions themselves. Horizon states that it does not purchase securities as a broker.

20. Horizon argues that the other applicants either did not raise the issue of jurisdiction or simply conceded it or requested that the Commission assume jurisdiction. Horizon, on the other hand, does not request that the Commission assume jurisdiction and argues that it does not purchase or acquire utility or holding company securities. Finally, Horizon maintains that certain of these other applicants sought blanket authorization not only for an investment adviser but also for affiliated mutual funds that an investment adviser manages. These mutual funds clearly own or acquire the stock in question. By contrast, Horizon states that it is not seeking authorization for any of its Account Holders.

21. Horizon next argues that even if it were deemed to purchase, acquire, or take public utility securities, it should be excluded from the FPA's definition of a holding company. Horizon states that the FPA incorporates the definition of a holding company found in the Energy Policy Act of 2005 (EPAct 2005).<sup>25</sup> It notes that a holding company is defined there as a company that

electric utility company, or a holding company in a holding company system that includes a transmitting utility, or an electric utility company, with a value in excess of \$10,000,000 without first having secured an order of the Commission authorizing it to do so.

<sup>16</sup> U.S.C. 824b(a)(2) (2006).

<sup>12</sup> Application at 6.

<sup>13</sup> Application at 6 (citing *Webster's New World Dictionary*, Third College Ed.) at 1091 (1994)).

<sup>14</sup> *Id.*

<sup>15</sup> *Id.* (citing *Black's Law Dictionary* at 1270 (8th deluxe ed. 2004)).

<sup>16</sup> *Id.* (citing *Black's Law Dictionary* at 25).

<sup>17</sup> *Id.* (citing *Webster's New World Dictionary* at 12).

<sup>18</sup> *Id.* (citing *Black's Law Dictionary* at 1492; *Webster's New World Dictionary* at 1364).

<sup>19</sup> *Id.* at 7 (citing *Phelps Dodge Corporation*, 121 FERC ¶ 61,251, at P 19 (2007)).

<sup>20</sup> *Id.* at 7-8 (citing *Goldman Sachs Group*, 121 FERC ¶ 61,059, at n.33 (2007) (*Goldman Sachs*) (citing 17 CFR 240.16a-1(a)(1)).

<sup>21</sup> We note that Horizon has represented that it is a beneficial owner with respect to Schedule 13G filings made for holdings of Aquila, Reliant, Allegheny Energy Inc., and Sierra Pacific. See *Horizon Asset Management, Inc.*, Form Schedule 13G, Statement of acquisition of beneficial ownership by individuals, (filed Feb. 20, 2008) <http://www.sec.gov/Archives/edgar/data/66960/000105682308000003/horizonthirteenagayle22008.txt>; *Horizon Asset Management, Inc.*, Form Schedule 13G, Statement of acquisition of beneficial ownership by individuals, (filed Feb. 20, 2008) <http://www.sec.gov/Archives/edgar/data/1056823/000105682308000007/horizonthirteenagayle22008.txt>; *Horizon Asset Management, Inc.*, Form Schedule 13G, Statement of acquisition of beneficial ownership by individuals, (filed Mar. 6, 2008) <http://www.sec.gov/Archives/edgar/data/3673/000105682308000012/horizonthirteenagayle32008.txt>; *Horizon Asset Management, Inc.*, Form Schedule 13G/A, Statement of acquisition of beneficial ownership by individuals [amend], (filed Mar. 10, 2008) <http://www.sec.gov/Archives/edgar/data/741508/000105682308000013/horizonthirteenagayle22008.txt>.

<sup>22</sup> Application at 8.

<sup>23</sup> September 25, 2008 Amendment at 4.

<sup>24</sup> Horizon seeks to distinguish itself from the companies dealt with in *Capital Research & Mgmt. Co.*, 116 FERC ¶ 61,267 (2006) (CRMC); *Goldman Sachs*, supra n.20; *Morgan Stanley*, 121 FERC ¶ 61,060 (2007) (*Morgan Stanley*); *Legg Mason, Inc.*, 121 FERC ¶ 61,061, at P 18 (2007) (*Legg Mason*); *T. Rowe Price Group Inc.*, 119 FERC ¶ 62,048 (2007).

<sup>25</sup> 42 U.S.C. 16451(b) (2006).

directly or indirectly owns, controls, or holds with power to vote 10 percent or more of the outstanding voting securities of a public utility company or a holding company of a public utility company. Horizon argues that it does not directly or indirectly own, control, or hold any outstanding voting securities of public utility companies or holding companies in the accounts it manages, and it therefore does not fall within the definition. To the extent that Horizon is delegated any voting power, it re-delegates that power to Institutional Shareholder Services. Horizon notes that the Commission can find a company that does not meet the definition of a holding company to be a holding company if the company exerts a "controlling influence" over the management of any public utility company or holding company. Horizon maintains that it exercises no such influence, and it has no plans to do so.

22. Horizon states that while it made a filing with the Commission on form FERC-65A providing notice of its status as a holding company, this was done out of an abundance of caution under PUHCA 2005, not the FPA, and the filing should have not determined whether Horizon is a holding company under the FPA. Horizon also states that it is not evident that its actions in filing a form FERC-65A can confer jurisdiction on the Commission or that Horizon can concede jurisdiction even if it wished to do so.

#### 2. Commission Determination

23. As an initial matter, we note that in certain respects this case represents an issue of first impression because the Commission has not previously clearly addressed the meaning of "to purchase, acquire or take any security" under FPA section 203(a)(2). While the Commission has acted on a number of requests for blanket authorizations to purchase, acquire or take securities, it either has been clear in those contexts that entities would be "purchasing, acquiring or taking" securities within the common (dictionary) meaning of those terms, or entities have filed for approval as a precautionary matter and the Commission has acted without analysis or discussion of these statutory terms. In particular, the Commission has not specifically opined on whether an investment adviser is considered to be an entity that "purchases, acquires, or takes" securities in circumstances where the adviser is not itself a security account holder, the security account holders have delegated the power to vote securities to the financial adviser, but the financial adviser generally defers to another entity that it engages

to vote the securities (as in this case, discussed below, Institutional Shareholder Services). The Commission for the first time in this docket addresses the meaning of the "purchase, acquire, or take any security" clause of FPA section 203(a)(2).

24. Horizon starts from the premise that because the FPA does not define the terms "purchase," "acquire," or "take," one must assume that their legislative purpose is expressed in their ordinary meaning viewed in light of the "object and policy" of the statute. Horizon discusses the dictionary definitions of these terms, but it fails to view them in light of the underlying purpose of section 203(a)(2) and the interrelationship between this section and PUHCA 2005. Instead of attempting to place the ordinary meanings of these terms in their statutory context, Horizon considers the meaning of "purchase, acquire, or take," in the abstract, *i.e.*, as they are presented in the dictionary, then claims that it does not engage in any of the actions described in the dictionary, and finally argues in the alternative that even if it does engage in these actions, it is not a holding company for these purposes. This approach is particularly problematic when dealing with terms as general as "purchase," "acquire," or "take" since the meaning of these terms can vary widely depending on the context in which they appear.

25. The relevant context here is one where a *holding company* purchases, acquires, or takes something, and this means that we must first address Horizon's assertion that it is not a holding company for purposes of the Federal Power Act. Only when that question is answered can one determine whether, in light of the purpose underlying FPA section 203(a)(2), it is reasonable to conclude that Horizon's activities fall within the "purchase, acquire, or take" language of section 203(a)(2). Horizon argues that it is not a holding company, *i.e.*, it does not directly or indirectly own, control, or hold with power to vote 10 percent or more of a public utility company or holding company's voting securities, because it does not purchase, acquire or take such securities.<sup>26</sup> However, the terms "purchase," "acquire," or "take" do not appear in the definition of a holding company, and therefore whether Horizon is a holding company must be decided independently of them based on the applicable statutory definition.

26. The facts that Horizon presents make it clear that it is a holding

company. Section 203(a)(6) of the FPA states that for purposes of section 203, the term holding company has the meaning given to it in PUHCA 2005.<sup>27</sup>

27. PUHCA 2005 defines a holding company in section 1262(8)(i) as a company that "directly or indirectly owns, controls, or holds, with power to vote," 10 percent or more of the outstanding voting securities of a public-utility company or of a holding company of any public-utility company.<sup>28</sup> Horizon's Account Holders have delegated to it the power to vote the securities in question, and it therefore holds those securities with the power to vote them. Horizon's choice to defer in most cases to Institutional Shareholder Services on how to vote the securities does not alter the fundamental facts because it has reserved the right to override the recommendations of Institutional Shareholder Services and, in any case, Horizon nowhere suggests that the delegation is irrevocable.

28. Horizon in fact concurs with our determination because it has previously conceded in filings made at the Commission that it "is a holding company under PUHCA 2005 because, in its capacity as investment adviser to certain accounts it has power to vote more than ten percent of the outstanding voting securities of Aquila, Inc."<sup>29</sup> Horizon now states that its filings were made out of an abundance of caution under PUHCA 2005, not the FPA, and it therefore should not be found to be a holding company under the FPA. For the reasons stated above, we disagree that Horizon does not fall within the PUHCA 2005 definition of holding company. Further, as noted above, section 203(a)(6) of the FPA states that for purposes of section 203, the term holding company has the meaning given to it in PUHCA 2005. To be a holding company for purposes of

<sup>27</sup> 16 U.S.C. 824b(a)(6) (2006).

<sup>28</sup> The applicable statutory definition states that the term "holding company" means:

(i) Any company that directly or indirectly owns, controls, or holds, with power to vote, 10 percent or more of the outstanding voting securities of a public-utility company or of a holding company of any public-utility company; and

(ii) Any person, determined by the Commission, after notice and opportunity for hearing, to exercise directly or indirectly (either alone or pursuant to an arrangement or understanding with one or more persons) such a controlling influence over the management or policies of any public-utility company or holding company as to make it necessary or appropriate for the rate protection of utility customers with respect to rates that such person be subject to the obligations, duties, and liabilities imposed by this subtitle upon holding companies.

<sup>29</sup> See June 15, 2006 filing by Horizon in Docket No. PH06-90-000.

<sup>26</sup> Application at 10.

PUHCA 2005 is therefore to be a holding company for purposes of FPA section 203(a)(2).

29. We thus reject the claim that Horizon's filing of a form FERC-65A is not indicative of whether Horizon is a holding company under the FPA. Horizon nowhere references in its original form FERC-65A filing that it filed out of an abundance of caution and makes the claim for the first time here. Horizon has previously conceded, and does not dispute here, that it holds 10 percent or more of a holding company's voting securities with power to vote. In light of this, Horizon is a holding company under PUHCA 2005 and, by virtue of section 203(a)(6), it is also a holding company for purposes of section 203(a)(2).

30. We also reject Horizon's argument that it is not a holding company because it does not exert any controlling influence over the management of any public utility company or holding company. PUHCA 2005 treats as a holding company any company that directly or indirectly owns, controls, or holds with power to vote 10 percent or more of the voting securities of a public utility company or of a public utility holding company. Such companies are deemed to be holding companies regardless of whether the facts of their particular situation prevent them from exercising control. While the PUHCA 2005 definition of holding company also gives the Commission additional powers to determine an entity to be a holding company where it has a controlling influence over management or policies of a public utility company, this authority pertains to situations where the entity does not fall within the formal definition of a holding company set forth in PUHCA 2005 section 1262(8)(A)(i), but there is nevertheless a reason to treat that entity as a holding company. Since Horizon falls within the formal definition, there is no reason to consider whether Horizon "controls" a public-utility company for purposes of determining that it is a holding company.

31. Having concluded that Horizon is a public utility holding company, we now turn to whether the activities in which it engages constitute the purchase, acquisition, or taking of securities within the meaning of FPA section 203(a)(2). While we agree that dictionary definitions are a starting point of the analysis where, as here, the terms "purchase, acquire, or take" are not defined in either the FPA or PUHCA, nevertheless the terms must also be given meaning in light of the statutory context and purposes of FPA section 203(a)(2). Taking into account

the simultaneous repeal of PUHCA 1935 and enactment of additional corporate review authority in the FPA—and specifically the addition of section 203(a)(2) of the FPA which pertains to certain public utility holding company investments—the Commission concludes that it is reasonable to read the terms "purchase, acquire, or take" sufficiently broadly to permit the Commission to adequately protect energy customers of public-utility companies and transmitting utilities. EAct 2005's repeal of PUHCA 1935 and enactment of a "books and records" holding company statute in the form of PUHCA 2005 were intended to remove certain barriers to investment in the electric industry. However, at the same time, Congress added section 203(a)(2) to the FPA to ensure adequate Federal oversight of certain holding company transactions involving public-utility companies and transmitting utilities. Were the Commission to interpret new section 203(a)(2) to exclude the types of investment activities engaged in by Horizon or by similar investment advisers that, like Horizon, are holding companies, it is possible that such holding companies could exercise control over public-utility companies or transmitting utilities in a way that harms energy customers.<sup>30</sup>

32. If the critical mark of a holding company is that it owns, controls, or holds securities with power to vote them, then what it means to purchase, acquire or take securities must be considered in light of that fact. As Horizon notes, to "acquire" is normally defined as "[t]o gain possession or control of; to get or obtain."<sup>31</sup> or to "get or gain by one's own efforts[;] to come to have as one's own; get possession of."<sup>32</sup> It also notes that to take something means, in part, to "obtain possession or control" of it.<sup>33</sup> We do not see how Horizon could hold securities with power to vote them if it did not gain possession or control of them, *i.e.*, if it did not "acquire" or "take" them.<sup>34</sup>

<sup>30</sup> With regard to the consumer protection purposes of EAct 2005, Senator Bingaman stated:

I am a strong supporter of section 1289 [the section of EAct 2005 that is codified at FPA section 203(a)(2)] because I believe it is vital, especially since we are repealing the Public Utility Holding Company Act [of 1935], that FERC be given the authority it needs to protect U.S. consumers. In my opinion, section 1289 gives FERC the appropriate authority to ensure that utility mergers and acquisition do not adversely impact consumers.

151 Cong. Rec. S9359 (daily ed. July 29, 2005) (statement of Sen. Bingaman).

<sup>31</sup> See *supra* n.15.

<sup>32</sup> See *supra* n.16.

<sup>33</sup> See *supra* n.18.

<sup>34</sup> We note in this connection that while Horizon sometimes states that it "delegates" the power to vote the shares it holds to Institutional Shareholder

The fact that Horizon does not acquire all the rights in the bundle of rights that constitute a property interest in these securities does not mean that it does not acquire them for purposes of section 203(a)(2). What matters is that it acquires rights that bring it within the definition of, and thus make it, a holding company, *i.e.* voting rights. Moreover, such rights could (but may not necessarily) result in the exercise of control over a public utility company. It is thus reasonable to conclude that Congress intended section 203(a)(2) to require Commission approval of such securities transactions and to find that Horizon acquires the securities for purposes of section 203(a)(2). We believe this interpretation is consistent with the protective, prophylactic purpose of section 203(a)(2) and that this authority can be exercised in a way that balances both the investment and consumer protection purposes envisioned in the EAct 2005 amendments.

33. Finally, while we recognize that FPA section 203(a)(2) does not contain broad, catch-all language such as "or otherwise obtain securities" (*i.e.*, broad language to parallel the "or otherwise dispose" language of FPA section 203(a)(1)), we do not find this determinative of the specific issue before us. Nor do we find determinative the fact that the Commission has found that section 203(a)(2) applies to direct rather than indirect acquisitions. Our conclusion here rests on our finding that Horizon itself, and not an entity in which Horizon has an interest, acquires and holds the securities with the power to vote.

#### B. Blanket Authorization Under Section 203

34. Section 203(a) of the FPA provides that the Commission must approve a transaction if it finds that the transaction "will be consistent with the public interest."<sup>35</sup> The Commission's analysis of whether a transaction is consistent with the public interest generally involves consideration of three factors: (1) The effect on competition; (2) the effect on rates; and (3) the effect on regulation.<sup>36</sup> In

Services, there is no evidence of a delegation of legal rights or powers. On the contrary, as noted above, Horizon retains the power to override Institutional Shareholder Services' voting recommendations. In addition, Horizon represents in the Schedule 13G filings it has made in connection with its holdings of Reliant, Sierra Pacific, and Aquila that it has "sole voting power" with respect to these shares. See *supra* n.21.

<sup>35</sup> 16 U.S.C. 824b (2006).

<sup>36</sup> See *Inquiry Concerning the Commission's Merger Policy Under the Federal Power Act: Policy*

addition, EPAct 2005 amended section 203 to specifically require that the Commission also determine that the transaction will not result in cross-subsidization of a non-utility associate company or the pledge or encumbrance of utility assets for the benefit of an associate company, unless the Commission determines that the cross-subsidization, pledge, or encumbrance will be consistent with the public interest.<sup>37</sup> The Commission's regulations establish verification and informational requirements for applicants that seek a determination that a transaction will not result in inappropriate cross-subsidization or pledge or encumbrance of utility assets.<sup>38</sup>

35. As discussed below, we dismiss Horizon's request for blanket authorization under section 203(a)(1) as unnecessary. We also find Horizon's request for blanket authorization under section 203(a)(2) to be consistent with the public interest and approve that request for a period of three years. In addition, we deny the request for retroactive approval under section 203(a)(2) of Horizon's holdings in excess of 10 percent of the outstanding voting shares of Reliant, Sierra Pacific, and Aquila.

#### 1. Blanket Authorization Under Section 203(a)(1)

36. Horizon requests blanket authority under section 203(a)(1) for utilities or holders of utility voting securities to sell such securities to Horizon or, on behalf of the Account Holders, to entities acting on the basis of Horizon's instructions or advice subject to certain conditions.<sup>39</sup>

*Statement*, Order No. 592, 61 FR 68,595 (1996), FERC Stats. & Regs. ¶ 31,044 (1996), *reconsideration denied*, Order No. 592-A, 62 FR 33,341 (1997), 79 FERC ¶ 61,321 (1997) (*Merger Policy Statement*); see also *Revised Filing Requirements Under Part 33 of the Commission's Regulations*, Order No. 642, 65 FR 70,983 (2000), FERC Stats. & Regs., Regulations Preambles July 1996-Dec. 2000 ¶ 31,111 (2000), *order on reh'g*, Order No. 642-A, 66 FR 16,121 (2001), 94 FERC ¶ 61,289 (2001); see also *Transactions Subject to Federal Power Act Section 203*, Order No. 669, 71 FR 1348 (2006), FERC Stats. & Regs. ¶ 31,200 (2005), *order on reh'g*, Order No. 669-A, 71 FR 28,422 (2006), FERC Stats. & Regs. ¶ 31,214 (2006) (*Order No. 669-A*), *order on reh'g*, Order No. 669-B, 71 FR 42,579 FERC Stats. & Regs. ¶ 31,225 (2006).

<sup>37</sup> 16 U.S.C. 824b(a)(4) (2006).

<sup>38</sup> 18 CFR 33.2(j) (2008).

<sup>39</sup> Section 203(a)(1) reads as follows:

(1) No public utility shall, without first having secured an order of the Commission authorizing it to do so—

(A) Sell, lease, or otherwise dispose of the whole of its facilities subject to the jurisdiction of the Commission, or any part thereof of a value in excess of \$10,000,000;

37. We dismiss the request for blanket authorization under section 203(a)(1) as unnecessary.<sup>40</sup> We have clarified that transactions that do not transfer control of a public utility or jurisdictional facilities do not fall within the "or otherwise dispose" language of section 203(a)(1)(A) and thus do not require approval under section 203(a)(1)(A).<sup>41</sup> With the conditions imposed in granting Horizon's request for section 203(a)(2) authorization, we find that the transactions under the blanket authorization requested by Horizon will not result in the change in control of a public utility or jurisdictional facilities, or the sale, lease or merger of a public utility or jurisdictional facilities.<sup>42</sup> Therefore, we dismiss, as unnecessary, Horizon's request for authorization under section 203(a)(1).

#### 2. Analysis Under Section 203(a)(2)

##### a. Effect on Competition

##### i. Horizon's Analysis

38. Horizon requests blanket authorization under section 203(a)(2) for the acquisition of securities of public utilities, electric utility companies, transmitting utilities or a holding company in a holding company system that includes an electric utility company or transmitting utility subject to certain conditions. Horizon argues that the proposed blanket authorizations will not adversely affect competition because the commitments it makes in the application, Horizon's fiduciary obligation, the internal policies it has in place, as well as applicable securities law, will prevent Horizon from exercising control over the companies in which it invests.

39. Horizon states that under section 13 of the 1934 Act,<sup>43</sup> any person acquiring more than five percent of the

(B) Merge or consolidate, directly or indirectly, such facilities or any part thereof with those of any other person, by any means whatsoever;

(C) Purchase, acquire, or take any security with a value in excess of \$10,000,000 of any other public utility; or

(D) Purchase, lease, or otherwise acquire an existing generation facility—

(i) That has a value in excess of \$10,000,000; and  
(ii) That is used for interstate wholesale sales and over which the Commission has jurisdiction for ratemaking purposes.

16 U.S.C. 824b(a)(1) (2006).

<sup>40</sup> See *Legg Mason*, 121 FERC ¶ 61,061 at P 18.

<sup>41</sup> *FPA section 203 Supplemental Policy Statement*, FERC Stats. & Regs. ¶ 31,253 at P 37 (2007).

<sup>42</sup> We note that the transactions under the blanket authorization requested by Horizon pursuant to section 203(a)(2) do not implicate sections 203(a)(1)(C) or 203(a)(1)(D), which apply to public utilities' acquisitions of public utility securities and generating facilities.

<sup>43</sup> 15 U.S.C. 78m (2000).

beneficial ownership of any class of equity securities traded on a public exchange must file with the SEC on either Schedule 13D or 13G providing certain information concerning the acquirer's intentions and purposes with respect to the acquisition. Schedule 13G requires the filer to certify that the securities in question have been acquired

In the ordinary course of \* \* \* [its] business and not with the purpose nor with the effect of changing or influencing the control of the issuer, nor in connection with or as a participant in any transaction having such a purpose or effect \* \* \*.<sup>44</sup>

40. Horizon states that, if the intentions of a filer of a Schedule 13G change, the filer must notify the SEC of this fact and wait for a "cooling off" period<sup>45</sup> before attempting to exercise control over the security issuer. Horizon also states that the SEC has provided guidance that makes it clear that any activity designed to replace the issuing company's management or influence the day-to-day commercial conduct of its business constitutes an attempt to control and therefore renders the acquiring person ineligible to file Schedule 13G.

41. Horizon states that it currently notifies the SEC of reportable transactions under the 1934 Act using Schedule 13G, and it is completely prohibited from exercising control over any public utility whose securities are covered by the Schedule 13G filing. The filing of Schedule 13G by a person having the intention or purpose of exercising control over the issuer is said to be a violation of the 1934 Act and exposes the filer to possible civil and criminal liability. Horizon states that it has never had and does not now have any intention to exercise control over any public utility or public utility holding company.

42. As noted above, Horizon commits to maintain its eligibility to make Schedule 13G filings with the SEC pursuant to SEC rules under the 1934 Act and, when appropriate, will make such 13G filings with respect to securities of public utilities and public utility holding companies and contemporaneously file a copy with the Commission. Horizon also will file with the Commission any comment or deficiency letters received from the SEC that concern Schedule 13G-related compliance audits conducted by the SEC.

43. Horizon also states that, as a registered investment adviser, it could

<sup>44</sup> 17 CFR 240.13d-1(b)(1)(i) (2008).

<sup>45</sup> Under 17 CFR 240.13d-1(e)(2), the "cooling off" period is 10 days.

also be subject to an enforcement action under the Investment Advisers Act<sup>46</sup> if it exercised control over any public utility. Horizon states that under the Investment Advisers Act, investment advisers are required to provide full disclosure of material information to investors. If Horizon were or was planning to be "in the energy business," or a "public utility," or if Horizon were engaging in or was planning to engage in acts which would render it ineligible to file Schedule 13G, this information would have to be disclosed to investors. In addition, as a registered investment adviser regulated by the SEC, Horizon states that it is required to provide Part II of its Form ADV (or a document containing at a minimum the information contained in Part II) to its current and prospective clients, which must include a disclosure of all material facts and information so that an investor can make an informed investment decision. Further, as a fiduciary, Horizon states that it is obligated to make sure that the information contained in its Form ADV does not omit information regarding its investment strategies that a reasonable investor would find relevant.

44. In addition, Horizon has proposed the conditions, listed in P 8 above, that are intended to prevent the exercise of control over jurisdictional facilities.

#### ii. Commission Determination

45. When combined with other factors, the Commission has previously relied upon an applicants' filing of Schedule 13G, along with the associated regulatory and enforcement regime administered by the SEC, to ensure that the applicant would not exercise control over public utilities or public utility holding companies.<sup>47</sup> Horizon similarly proposes use of Schedule 13G along with other measures as support for its request for blanket authorization under section 203(a)(2). Under the conditions Horizon proposes, all security purchases made pursuant to the requested blanket authorization will be of publicly traded securities for which Horizon will maintain eligibility to file Schedule 13G. Horizon states that it has never filed a Schedule 13D and proposes the condition that it will not take action which would require it to file a Schedule 13D with the SEC with respect to the securities of any public utility or public utility holding company. Horizon also commits to maintain its policies and to comply with applicable statutory

prohibitions against exercising control over companies whose securities are acquired for Horizon Account Holders.

46. Horizon also proposes to include language in its Form ADV, its Policies and Procedures Manual, its annual letter to Account Holders, and all future Account Holder Agreements explicitly providing that Horizon shall not exercise the shareholder voting rights delegated to Horizon by Account Holders, or act in any other way, to exercise control over any public utility or any public utility holding company.<sup>48</sup> With that language in place, actions by Horizon in violation of it would subject Horizon to potential legal action by both the SEC and the Account Holders, in addition to appropriate action by the Commission.

47. We will accept Horizon's proposed conditions restricting the holdings of the voting securities of any public utility or public utility holding company to less than 10 percent in an individual Horizon account and to no more than 19.99 percent for Horizon or any affiliated entity having voting power, since these conditions are similar to limits on ownership that the Commission has placed on holdings of public utilities or public utility holding companies by firms who are investment advisers or engage in similar activities.<sup>49</sup> The Commission will require the 19.99 percent limit on holdings for Horizon or any affiliated entity having voting power to be interpreted as the maximum which Horizon and affiliated entities may cumulatively hold.

48. Efforts by Horizon to use its voting power from security holdings to exercise control over public utilities or public utility holding companies will be further limited by Horizon's proposed condition that it will exercise its voting power in a way that is consistent with its fiduciary duties to its Account Holders, and to maintain readily auditable records of the voting of the shares.

49. We will also accept Horizon's commitment to file contemporaneously with the Commission a copy of relevant Schedule 13G filings made to the SEC, and to file with the Commission any comment or deficiency letters received from the SEC. We will also accept Horizon's commitment to provide the Commission with quarterly reports of

<sup>46</sup>Horizon pledges not to change or withdraw the language without providing the Commission with a least 90 days notice. We will accept that commitment. If prior authorization under section 203 is necessary, the Commission will require Horizon to file an appropriate application under section 203.

<sup>49</sup>See, e.g., *Legg Mason*, 121 FERC ¶ 61,061 at P 22 and *CRMC*, 116 FERC ¶ 61,267 at P 20.

security holdings of public utilities and public utility holding companies. We will also require that any changes in the information provided on the initial Schedule 13G be reflected in an annual amended filing due within 45 days of the end of each calendar year. With this additional requirement, the Schedule 13G-related filings and quarterly informational filings of the holdings of securities are similar to those previously required of firms similar to Horizon which requested blanket authorizations under section 203.<sup>50</sup> In addition, records that may be useful in any future audit will be accessible though Horizon's proposal to keep records of its transactions concerning public utility securities as required by the Investment Advisers Act. We accept this commitment.

50. We find that, with the conditions proposed by Horizon and accepted here, as modified above, Horizon will be unable to exercise control over the public utilities and public utility holding companies whose securities are acquired under the blanket authorization requested under section 203(a)(2). Thus, we find that the transactions under that requested blanket authorization have no adverse effect on competition.

#### b. Effect on Rates

##### i. Horizon's Analysis

51. Horizon argues that the acquisition of securities pursuant to the requested blanket authorization will have no adverse effect on rates of wholesale customers or retail electric service customers because, as Horizon will not acquire or exercise control over any utility, it will have no role in the setting of rates by such entities. Further, Horizon argues that acquisition of securities pursuant to the requested blanket authorization will not affect the market-based or cost-based rates of the utilities in which the Account Holders will be investing.

##### ii. Commission Determination

52. We find that the transactions under the blanket authorization requested by Horizon under section 203(a)(2) will not have an adverse effect on rates for the reasons set forth by Horizon above.

#### c. Effect on Regulation

##### i. Horizon's Analysis

53. Horizon argues that the acquisition of securities pursuant to the

<sup>50</sup>See, e.g., *Legg Mason*, 121 FERC ¶ 61,061 at P 30, *CRMC*, 116 FERC ¶ 61,267 at P 30, and *Ecofin Holdings Limited*, 120 FERC ¶ 61,189 at P 41 (2007).

<sup>46</sup>15 U.S.C. 80b-1 *et seq.* (2000).

<sup>47</sup>See, e.g., *Legg Mason*, 121 FERC ¶ 61,061 at P 26-30; *Goldman Sachs*, 121 FERC ¶ 61,059 at P 30-41; *Morgan Stanley*, 121 FERC ¶ 61,060 at P 37-49; *CRMC*, 116 FERC ¶ 61,267 at P 16-20.

requested blanket authorization will have no adverse effect on regulation either by the Commission or by state regulatory authorities because the acquisition will not result in any change in the activities, corporate structure, or control of a utility that might affect its jurisdictional status under either federal or state law. Horizon further argues that, because no exercise of control is involved, Horizon is and will be in no position to cause a utility to take action which would have an adverse effect on regulation.

#### ii. Commission Determination

54. We find that the transactions under the blanket authorization requested by Horizon under section 203(a)(2) will not have an adverse effect on regulation for the reasons set forth by Horizon above.

#### d. Cross-subsidization

##### i. Horizon's Analysis

55. Horizon argues that the acquisition of securities pursuant to the requested blanket authorization will not result in cross-subsidization of a non-utility associate company or the pledge or encumbrance of utility assets for the benefit of an associate company because Horizon and the Account Holders will be non-controlling investors in utilities with no ability to improperly cause or direct the utilities in which they have an interest to cross-subsidize their non-utility associate companies or to pledge or encumber their assets.

56. Horizon further states that the transactions pursuant to the requested blanket authorization will not result in any: (1) Transfers of facilities between a traditional public utility associate company that has captive ratepayers or that owns or provides transmission service over jurisdictional transmission facilities, and an associate company; (2) new issuances of securities by traditional public utility associate companies that have captive customers or that own or provide transmission service over jurisdictional transmission facilities, for the benefit of an associate company; (3) new pledges or encumbrances of assets of a traditional public utility associate company that has captive customers or that owns or provides transmission service over jurisdictional transmission facilities, for the benefit of an associate company; or (4) new affiliate contracts between non-utility associate companies and traditional public utility associate companies that have captive customers or that own or provide transmission service over jurisdictional transmission facilities, other than non-power goods

and services agreements subject to review under sections 205 and 206 of the FPA.

#### ii. Commission Determination

57. We find that the transactions under the blanket authorization requested by Horizon under section 203(a)(2) will not result in cross-subsidization or the pledge or encumbrance of utility assets for the benefit of an associate company for the reasons set forth by Horizon above.

#### e. Authorization Period

##### i. Applicant's Request

58. Horizon requests the Commission to grant a permanent blanket authorization.

##### ii. Commission Determination

59. We will grant Horizon's blanket authorization for a three-year period, rather than on a permanent basis. We find that a three-year limitation balances Horizon's need to operate under the requested authorizations with our duty to provide adequate regulatory oversight under section 203 of the FPA, particularly as we continue to gain experience with FPA section 203(a)(2) authorizations. Accordingly, the authorizations expire three years from the date of this order, without prejudice to requests to extend the authorizations.

#### f. Request for Retroactive Authorization

##### i. Horizon's Request

60. Horizon requests retroactive authorization for the holdings in excess of 10 percent of the voting shares of Reliant, Sierra Pacific, and Aquila. Horizon states that the decision to direct the accounts under its management to acquire stock of Reliant, Sierra Pacific, and Aquila was in no way an indication of any intention to exercise control over such companies. Horizon states that its investment decision in this regard was motivated solely by its analysis of the value of those securities as passive investments.

##### ii. Commission Determination

61. Section 203(a)(2) of the FPA requires Commission approval before a public utility holding company purchases, acquires, or takes any security (with a value in excess of \$10 million) of a transmitting utility, an electric utility company, or a public utility holding company in a holding company system that includes a transmitting utility or an electric utility company having a value in excess of \$10 million. Acquiring securities without prior Commission authorization is directly contrary to statutory

requirements. Therefore, the Commission denies the request for retroactive approval under 203(a)(2) of Horizon's holdings in excess of 10 percent of the voting shares of Reliant, Sierra Pacific, and Aquila. Although we are denying retroactive approval, we recognize that prior to this case the Commission had not directly or clearly addressed the scope and meaning of the "purchase, acquire, or take any security" clause of section 203(a)(2) and therefore we will not impose sanctions on Horizon for failing to obtain advance Commission approval in these circumstances. Now that we have clarified our jurisdiction, however, Horizon and all similar companies that acquire or hold securities on behalf of account holders are on notice that we consider the types of transactions described in Horizon's petition to be jurisdictional under FPA section 203(a)(2), thus requiring prior approval, and we will consider sanctions including possible monetary penalties to companies that do not obtain advance approval. Finally, we remind companies that if there is any question as to whether particular securities acquisitions fall under section 203(a)(2), they may seek a determination from the Commission through a petition for a declaratory order or other appropriate procedural mechanism.

62. As noted above, because not all investment companies and advisers may have been aware of our interpretation of the Commission's jurisdiction under the "purchase, acquire, or take any security" clause of section 203(a)(2) to require prior authorization for the acquisition of public utility securities as discussed in this order, we will allow any such affected entity to file within 90 days of the date of the publication of this order in the **Federal Register** an application requesting such authorization. After that time, the failure to make a timely filing may result in subjecting the entity in question to sanctions.

#### *The Commission orders:*

(A) The Commission rejects the request for a disclaimer of jurisdiction. The Commission also denies the request for retroactive approval under section 203(a)(2) of Horizon's holdings in excess of 10 percent of the voting shares of Reliant, Sierra Pacific, and Aquila. In addition, the Commission hereby dismisses the request for blanket authorization under FPA section 203(a)(1) and grants the request for blanket authorization under section 203(a)(2) for a period of three years from the date of this order, without prejudice to requests to extend the authorization, as discussed in the body of the order.



(B) Transactions under the blanket authorizations are subject to the terms and conditions and quarterly reporting requirements and for the purposes set forth in the Application, as discussed and modified in the body of this order.

(C) The foregoing authorizations are without prejudice to the authority of the Commission or any other regulatory body with respect to rates, service, accounts, valuation, estimates, or determinations of costs, or any other matter whatsoever now pending or which may come before the Commission.

(D) Nothing in this order shall be construed to imply acquiescence in any estimate or determination of costs or any valuation of property claimed or asserted.

(E) The Commission retains authority under sections 203(b) and 309 of the FPA to issue supplemental orders as appropriate.

(F) Horizon is subject to audit to determine whether it is in compliance with the representations, conditions and requirements upon which the authorizations are herein granted and with applicable Commission rules, regulations and policies. In the event of a violation, the Commission may take action within the scope of its oversight and enforcement authority.

(G) Horizon shall file with the Commission, for informational purposes, contemporaneously with filing at the SEC the Schedule 13G filings made with the SEC that are relevant to the authorizations granted in this order. Any changes in the information provided on the initial Schedule 13G must be reflected in an annual amended filing due within 45 days of the end of each calendar year. Horizon shall file with the Commission any comment or deficiency letters received from the SEC that concern Schedule 13G-related compliance audits conducted by the SEC. Such filings shall be made in this docket or in appropriate sub-dockets of this docket.

(H) Horizon shall file with the Commission, for informational purposes, within 45 days of the end of each calendar quarter, a quarterly report of securities of public utilities and public utility holding companies as of the last day of the calendar quarter stated in terms of the number of shares held as of the end of the quarter and as a percentage of the outstanding shares.

(I) Horizon shall retain the records of its transactions concerning public utility securities as required under the Investment Advisers Act.

(J) Horizon must inform the Commission, within 30 days, of any material change in circumstances that

would reflect a departure from the facts, policies, and procedures the Commission relied upon in granting the request and specifying the terms and conditions under which the blanket authorization, as set forth in section 33.1(c)(5) of the Commission's regulations, will be available to them.

(K) The Secretary is directed to publish a copy of this order in the **Federal Register**.

By the Commission.

**Kimberly D. Bose,**  
Secretary.

[FR Doc. E8-27984 Filed 11-24-08; 8:45 am]  
BILLING CODE 6717-01-P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

[Docket No. ER02-2001-009; Docket No. ER07-559-000]

**Before Commissioners: Joseph T. Kelliher, Chairman; Suedeen G. Kelly, Marc Spitzer, Philip D. Moeller, and Jon Wellinghoff; Electric Quarterly Reports, Flat Earth Energy, LLC Order on Intent To Revoke Market-Based Rate Authority**

November 20, 2008.

1. Section 205 of the Federal Power Act (FPA), 16 U.S.C. 824d (2000), and 18 CFR part 35 (2008), require, among other things, that all rates, terms, and conditions of jurisdictional services be filed with the Commission. In Order No. 2001, the Commission revised its public utility filing requirements and established a requirement for public utilities, including power marketers, to file Electric Quarterly Reports summarizing the contractual terms and conditions in their agreements for all jurisdictional services (including market-based power sales, cost-based power sales, and transmission service) and providing transaction information (including rates) for short-term and long-term power sales during the most recent calendar quarter.<sup>1</sup>

2. Commission staff's review of the Electric Quarterly Report submittals indicates that one utility with authority to sell electric power at market-based rates has failed to file its Electric Quarterly Reports. This order notifies this public utility that its market-based

rate authorization will be revoked unless it complies with the Commission's requirements within 15 days of the date of issuance of this order.

3. In Order No. 2001, the Commission stated that,

[i]f a public utility fails to file a[n] Electric Quarterly Report (without an appropriate request for extension), or fails to report an agreement in a report, that public utility may forfeit its market-based rate authority and may be required to file a new application for market-based rate authority if it wishes to resume making sales at market-based rates.<sup>2</sup>

4. The Commission further stated that,

[o]nce this rule becomes effective, the requirement to comply with this rule will supersede the conditions in public utilities' market-based rate authorizations, and failure to comply with the requirements of this rule will subject public utilities to the same consequences they would face for not satisfying the conditions in their rate authorizations, including possible revocation of their authority to make wholesale power sales at market-based rates.<sup>3</sup>

5. Pursuant to these requirements, the Commission has revoked the market-based rate tariffs of several market-based rate sellers that failed to submit their Electric Quarterly Reports.<sup>4</sup>

6. As noted above, Commission staff's review of the Electric Quarterly Report submittals identified one public utility with authority to sell power at market-based rates that failed to file Electric Quarterly Reports through the third quarter of 2008. Commission staff contacted this entity to remind it of its regulatory obligations.<sup>5</sup> Nevertheless, the public utility listed in the caption of this order has not met those obligations.<sup>6</sup> Accordingly, this order notifies this public utility that its market-based rate authorization will be revoked unless it complies with the Commission's requirements within 15 days of the issuance of this order.

7. In the event that the above-captioned market-based rate seller has already filed its Electric Quarterly Report in compliance with the Commission's requirements, its inclusion herein is inadvertent. Such market-based rate seller is directed, within 15 days of the date of issuance of this order, to make a filing with the

<sup>2</sup> Order No. 2001 at P 222.

<sup>3</sup> *Id.* at P 223.

<sup>1</sup> *Revised Public Utility Filing Requirements*, Order No. 2001, FERC Stats. & Regs. ¶ 31,127, *reh'g denied*, Order No. 2001-A, 100 FERC ¶ 61,074, *reconsideration and clarification denied*, Order No. 2001-B, 100 FERC ¶ 61,342, *order directing filings*, Order No. 2001-C, 101 FERC ¶ 61,314 (2002) *order directing filings*, Order No. 2001-D, 102 FERC ¶ 61,334 (2003).

<sup>4</sup> See, e.g., *Electric Quarterly Reports*, 73 FR 31,460 (June 2, 2008); *Electric Quarterly Reports*, 115 FERC ¶ 61,073 (2006); *Electric Quarterly Reports*, 114 FERC ¶ 61,171 (2006).

<sup>5</sup> See *Flat Earth Energy, LLC*, Docket No. ER07-559-000 (October 7, 2008) (unpublished letter order).

<sup>6</sup> According to the Commission's records, the company subject to this order last filed its Electric Quarterly Reports for the 1st quarter of 2008.

Commission identifying itself and providing details about its prior filings that establish that it complied with the Commission's Electric Quarterly Report filing requirements.

8. If the above-captioned market-based rate seller does not wish to continue having market-based rate authority, it may file a notice of cancellation with the Commission pursuant to section 205 of the FPA to cancel its market-based rate tariff.

*The Commission orders:*

(A) Within 15 days of the date of issuance of this order, the public utility listed in the caption of this order shall file with the Commission all delinquent Electric Quarterly Reports. If the public utility fails to make this filing, the Commission will revoke that public utility's authority to sell power at market-based rates and will terminate its electric market-based rate tariff. The Secretary is hereby directed, upon expiration of the filing deadline in this order, to promptly issue a notice, effective on the date of issuance, listing the public utility whose tariff has been revoked for failure to comply with the requirements of this order and the Commission's Electric Quarterly Report filing requirements.

(B) The Secretary is hereby directed to publish this order in the **Federal Register**.

By the Commission.

**Kimberly D. Bose,**  
Secretary.

[FR Doc. E8-27992 Filed 11-24-08; 8:45 am]

BILLING CODE 6717-01-P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

[Docket No. PL09-2-000]

#### Material Changes in Facts That Require Notifications Under Commission Regulations Under the Public Utility Holding Company Act of 2005; Order Clarifying Requirement To Notify Commission of Material Changes in Facts Under the Public Utility Holding Company Act of 2005 and Allowing 45-Day Filing Period for Updated Notifications

Issued November 20, 2008.

*Before Commissioners:* Joseph T. Kelliher, Chairman; Suedeen G. Kelly; Marc Spitzer; Philip D. Moeller; and Jon Wellinghoff.

1. The Commission's regulations under the Public Utility Holding Company Act of 2005 (PUHCA 2005)<sup>1</sup>

currently require persons that meet the definition of a holding company set forth at 18 CFR 366.1 (2008) to notify the Commission of their status as a holding company no later than 30 days after they become a holding company.<sup>2</sup> The Commission's PUHCA 2005 regulations also provide exemptions from or waivers of requirements that apply to holding companies.<sup>3</sup> The companies that receive certain of these exemptions or waivers are required to notify the Commission of material changes in facts that may affect the exemption or waiver.<sup>4</sup> It has come to the Commission's attention that we may not have provided sufficient clarity regarding an aspect of the scope of this filing requirement and the purpose of this order is to clarify and provide guidance on certain filings that need to be made under this regulation.

2. The exemptions in question apply to a number of entities, including certain passive investors and certain utility operating companies, as well as to certain classes of transactions. Qualifying entities or classes of transactions are exempt from the requirements concerning access to books and records found at section 366.2, as well as the accounting, record-retention, and reporting requirements of sections 366.21, 366.22, and 366.23 of the Commission's regulations.<sup>5</sup> To receive one or more of these exemptions, a person must file an exemption notification with the Commission, *i.e.*, FERC-65A. The exemption is deemed granted if the Commission does not take action on the notification within 60 days.<sup>6</sup> Persons that do not qualify for an exemption under the regulations may petition for a declaratory order granting one.<sup>7</sup>

3. The waivers in question apply to holding companies that have single-state holding company systems, as defined in section 366.3(c)(1) of the Commission's regulations, as well as investors in independent transmission-only companies and holding companies with 100 MW of generation or less that is used for their own load or sales to affiliated end users.<sup>8</sup> Qualifying entities receive a waiver of the accounting, record-retention, and reporting requirements found in sections 366.21, 366.22 and 366.23 of the Commission's regulations.<sup>9</sup> To receive one or more of

these waivers, a person must file a waiver notification with the Commission, *i.e.*, FERC-65B. The waiver is deemed granted if the Commission does not take action on the notification within 60 days.<sup>10</sup> Persons that do not qualify for a waiver under the regulations may petition for a declaratory order granting one.<sup>11</sup>

4. The Commission's regulations specify that if there is any material change in facts that may affect an exemption or waiver of the type described above, the person that received the exemption or waiver must notify the Commission of the change within 30 days of the material change. At that time the person must (i) submit a new FERC-65A, FERC-65B, or petition for declaratory order; (ii) file a written explanation why the material change in facts does not affect the exemption or waiver; or (iii) notify the Commission that it no longer seeks to maintain its exemption or waiver.<sup>12</sup>

5. The Commission's regulations require only notification of those material changes in facts that may affect an exemption or waiver, but they do not otherwise state when a notification is required. The Commission wishes to clarify one type of change in facts that should in all cases be the subject of a notification. If a holding company that has previously filed an exemption or waiver notification, *i.e.*, FERC-65A or FERC-65B, or that has received an exemption or waiver through a declaratory order, becomes a holding company with respect to an *additional* public-utility company or holding company of any public-utility company (*i.e.*, obtains the power to vote 10 percent or greater of the voting securities of an *additional* company), that holding company should file with the Commission a notification of material change in facts that describes the additional public-utility company or holding company of any public-utility company and otherwise complies with the requirements of section 366.4(d)(1) of the Commission's regulations by selecting one of the three possible courses of action set forth in that section. This filing should be made *whether or not* a change has occurred with respect to the basis on which the exemption or waiver was granted.<sup>13</sup> We

<sup>10</sup> *Id.* § 366.4(c)(1).

<sup>11</sup> *Id.* § 366.4(c)(2); *accord id.* § 366.3(d).

<sup>12</sup> *Id.* § 366.4(d).

<sup>13</sup> For example, if a holding company received an exemption from the PUHCA 2005 regulations on the basis of its status as a passive investor of the type identified in 18 CFR 366.3(b)(2)(i), it should notify the Commission whenever it acquires as a passive investor interests in an additional public-utility company or holding company that, upon

<sup>1</sup> 42 U.S.C. 16451 *et seq.* (2006).

<sup>2</sup> 18 CFR 366.4(a)(1) (2008).

<sup>3</sup> *Id.* § 366.3.

<sup>4</sup> *Id.* § 366.4(d).

<sup>5</sup> *Id.* § 366.3(b).

<sup>6</sup> *Id.* § 366.4(b)(1).

<sup>7</sup> *Id.* § 366.4(b)(3); *accord id.* § 366.3(d).

<sup>8</sup> *Id.* § 366.3(c).

<sup>9</sup> *Id.* § 366.4(c).

note that the FERC-65 filing requirements are intended, in part, to serve an informational purpose,<sup>14</sup> and the addition of a new subsidiary company that is a public-utility company or holding company of a public-utility company represents a material fact that should be reported to the Commission.

6. Because not all holding companies may have been interpreting the Commission's regulations to require such filings where the basis on which their exemption or waiver was granted has not changed, and because the Commission has not previously clarified this requirement for notifications of material changes in fact, we will allow all such companies to file within 45 days of the date of publication of this order in the **Federal Register** a notification of change in material facts which updates the Commission on any investments of 10 percent or more of the voting securities of a public-utility company or holding company of a public-utility company since the time the exemption or waiver was granted. The Secretary is directed to publish a copy of this order in the **Federal Register**.

By the Commission.

**Kimberly D. Bose,**  
Secretary.

[FR Doc. E8-27985 Filed 11-24-08; 8:45 am]  
BILLING CODE 6717-01-P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

[Docket No. CP98-150-012]

#### Millennium Pipeline Company, L.L.C.; Notice of Petition To Amend

November 19, 2008.

Take notice that on November 17, 2008, Millennium Pipeline Company, L.L.C. (Millennium), One Blue Hill Plaza, Seventh Floor, P.O. Box 1565, Pearl River, New York 10965, filed in Docket No. CP98-150-012, a petition to amend the certificate of public convenience and necessity issued on December 21, 2006 in Docket No. CP98-150-006, *et al.* It is stated that Millennium seeks authority to amend its certificate authorization to allow it to implement a contingency plan to acquire, construct, and operate

additional facilities if it is unable to complete the horizontal directional drill at the East Branch of the Delaware River or at Wheeler Creek in time to make its facilities available for service prior to December 31, 2008. Specifically, Millennium requests authorization to (1) decrease the diameter of the pipeline facilities to be constructed at Wheeler Creek from 30 inches to 24 inches, and permanently provide service utilizing the reduced diameter facilities; (2) delay completion of the horizontal directional drill (HDD) at the East Branch of the Delaware River until no later than September 30, 2009; (3) acquire from Columbia two 10-inch diameter pipelines and a small segment of one 12-inch diameter pipeline located to the west of the two 10-inch lines (Crossing Facilities) which Columbia is authorized to abandon in place; (4) construct limited facilities, including approximately 850 feet of 12-inch pipeline, cathodic protection equipment and overpressure protection facilities, necessary to interconnect Columbia's Crossing Facilities with Millennium's newly constructed 30-inch diameter mainline at the East Branch of the Delaware River; and (5) provide service utilizing the Crossing Facilities until such time as Millennium completes the HDD or implements an approved alternative at the East Branch of the Delaware River. It is stated that the requested authorizations would only be implemented if Millennium determines that either of the HDDs would not be completed in time to permit Millennium to make its system available for service prior to December 31, 2008.

It is also stated that if Millennium is able to complete one HDD, but not the other HDD, Millennium would only implement the authorization that applies to the HDD it is unable to complete, all as more fully set forth in the petition to amend which is on file with the Commission and open to public inspection. This filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site 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. For assistance, contact FERC Online Support at [FERCOnlineSupport@ferc.gov](mailto:FERCOnlineSupport@ferc.gov) or toll free at (866) 208-3676; or for TTY, contact (202) 502-8659.

Any initial questions regarding Millennium's proposal in this petition should be directed to counsel for Millennium, Daniel F. Collins or Letitia W. McKoy, Fulbright & Jaworski, L.L.P., 801 Pennsylvania Avenue, NW.,

Washington, DC 20004; telephone (202) 662-4586 (Daniel) or (202) 662-4668 (Letitia), fax (202) 662-4643.

Pursuant to section 157.9 of the Commission's rules, 18 CFR 157.9, within 90 days of this Notice the Commission staff will either: complete its environmental assessment (EA) and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Persons who wish to comment only on the environmental review of this

acquisition, becomes a "subsidiary company," as defined in 18 CFR 366.1, of the passive investor. This filing should be made even if the holding company continues to qualify for an exemption as a passive investor.

<sup>14</sup> *Id.* § 366.4(a)(2).

project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commenters will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commenters will not be required to serve copies of filed documents on all other parties. However, the non-party commenters will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the "eFiling" link at <http://www.ferc.gov>. Persons unable to file electronically should submit the original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

*Comment Date:* November 26, 2008.

**Kimberly D. Bose,**  
Secretary.

[FR Doc. E8-27918 Filed 11-24-08; 8:45 am]  
BILLING CODE 6717-01-P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

[Docket No. OR08-14-000]

#### Cimmarron Gathering, L.P.; Notice of Request for Temporary Waiver of Tariff Filing and Reporting Requirements

November 19, 2008.

Take notice that on August 12, 2008, Cimmarron Gathering, L.P. (Cimmarron) tendered for filing an application for temporary waiver of the filing and reporting requirements of section 6 and section 20 of the Interstate Commerce Act.

In support thereof, Cimmarron states that its pipeline is a small crude oil line connecting Cimmarron's Pinkston Station in Texas to its Hewitt and Elmore stations in Oklahoma. Cimmarron further states that it owns 100 percent of the throughput transported on the pipeline. Cimmarron also states that there are no intermediate points on the pipeline and that no third party has requested the construction of any such intermediate point or

otherwise expressed interest in becoming a shipper on the pipeline.

Any person desiring to intervene or to protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. It is not necessary to separately intervene again in a subdocket related to a compliance filing if you have previously intervened in the same docket. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. In reference to filings initiating a new proceeding, interventions or protests submitted on or before the comment deadline need not be served on persons other than the Applicant.

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 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First St., NE., Washington, DC 20426.

The filings in the above proceedings 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 e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail [FERCOnlineSupport@ferc.gov](mailto:FERCOnlineSupport@ferc.gov) or call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

*Comment Date:* 5 p.m. Eastern Time December 5, 2008.

**Kimberly D. Bose,**  
Secretary.

[FR Doc. E8-27922 Filed 11-24-08; 8:45 am]  
BILLING CODE 6717-01-P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

[Docket No. RP09-8-000]

#### Tuscarora Gas Transmission Company; Notice of Technical Conference

November 19, 2008.

Take notice that the Commission will convene a technical conference in the above-referenced proceeding on Thursday, December 11, 2008, at 10 a.m. (EDT), in a room to be designated at the offices of the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

The Commission's October 31, 2008 Order<sup>1</sup> in Docket No. RP09-8-000 directed that a technical conference be held to address the issues raised by Tuscarora Gas Transmission Company's (Tuscarora) October 1, 2008 tariff filing. At the conference, Commission Staff and interested persons will have the opportunity to discuss all of the issues raised by Tuscarora's filing.

FERC conferences are accessible under section 508 of the Rehabilitation Act of 1973. For accessibility accommodations please send an e-mail to [accessibility@ferc.gov](mailto:accessibility@ferc.gov) or call toll free (866) 208-3372 (voice) or (202) 502-8659 (TTY), or send a fax to (202) 208-2106 with the required accommodations.

All interested persons are permitted to attend. For further information please contact Timothy Duggan at (202) 502-8326 or e-mail [Timothy.Duggan@ferc.gov](mailto:Timothy.Duggan@ferc.gov).

**Kimberly D. Bose,**  
Secretary.

[FR Doc. E8-27917 Filed 11-24-08; 8:45 am]  
BILLING CODE 6717-01-P

## ENVIRONMENTAL PROTECTION AGENCY

[EPA-R09-OAR-2008-0819; FRL-8744-6]

#### Adequacy Status of Motor Vehicle Emissions Budgets in Submitted Eight-Hour Ozone Early Progress Plan for Eastern Kern County for Transportation Conformity Purposes; California

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of Adequacy.

**SUMMARY:** In this notice, EPA is notifying the public that the Agency has

<sup>1</sup> Tuscarora Gas Transmission Co., 125 FERC ¶ 61,133 (2008).

found that the motor vehicle emissions budgets for 8-hour ozone in the Eastern Kern County 8-hour Ozone Early Progress Plan are adequate for transportation conformity purposes. On March 24, 2008, the California Air Resources Board submitted a revision to the California State Implementation Plan (SIP) containing Early Progress Plans for the 8-hour ozone standard for five California areas, including the Eastern Kern County nonattainment area. As a result of our adequacy finding, the Kern Council of Governments and the U.S. Department of Transportation must use these budgets in future conformity analyses once the finding becomes effective.

**DATES:** This finding is effective December 10, 2008.

**FOR FURTHER INFORMATION CONTACT:** Karina O'Connor, U.S. EPA, Region IX, Air Division (AIR-2), 75 Hawthorne Street, San Francisco, CA 94105-3901; (775) 833-1276 or [oconnor.karina@epa.gov](mailto:oconnor.karina@epa.gov).

**SUPPLEMENTARY INFORMATION:**

Throughout this document, whenever "we," "us," or "our" is used, we mean EPA.

Today's notice is simply an announcement of a finding that we have already made. EPA Region IX sent a letter to the California Air Resources Board on November 10, 2008 stating that the motor vehicle emissions budgets for year 2008 in the submitted SIP containing an early progress plan for the Eastern Kern 8-hour ozone nonattainment area are adequate. The finding is available at EPA's conformity website: <http://www.epa.gov/otaq/stateresources/transconf/adequacy.htm>. The adequate motor vehicle emissions budgets are provided in the following table:

**MOTOR VEHICLE EMISSIONS BUDGETS,  
SUMMER PLANNING INVENTORY**

Budget year	Volatile organic compounds <sup>1</sup> (tons per day)	Nitrogen oxides (tons per day)
2008 .....	5	18

<sup>1</sup> The plan uses a comparable State term, reactive organic gases (ROG).

Transportation conformity is required by Clean Air Act section 176(c). EPA's conformity rule requires that transportation plans, transportation improvement programs, and projects conform to state air quality implementation plans (SIPs) and establishes the criteria and procedures for determining whether or not they do.

Conformity to a SIP means that transportation activities will not produce new air quality violations, worsen existing violations, or delay timely attainment of the national ambient air quality standards.

The criteria by which we determine whether a SIP's motor vehicle emission budgets are adequate for conformity purposes are outlined in 40 CFR 93.118(e)(4). We have described our process for determining the adequacy of submitted SIP budgets in our July 1, 2004 preamble starting at 69 FR 40038 and we used the information in these resources in making our adequacy determination. Please note that an adequacy review is separate from EPA's completeness review, and should not be used to prejudge EPA's ultimate approval action for the SIP. Even if we find a budget adequate, the SIP could later be disapproved.

**Authority:** 42 U.S.C. 7401 *et seq.*

Dated: November 14, 2008.

**Keith Takata,**

*Acting Regional Administrator, Region IX.*

[FR Doc. E8-27968 Filed 11-24-08; 8:45 am]

**BILLING CODE 6560-50-P**

**ENVIRONMENTAL PROTECTION  
AGENCY**

[EPA-HQ-OA-2008-0701; FRL-8744-7]

**Agency Information Collection  
Activities; Proposed Collection;  
Comment Request; Focus Groups as  
Used by EPA for Economics Projects  
(Renewal); EPA ICR No. 2205.02, OMB  
Control No. 2090-0028**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** In compliance with the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), this document announces that an Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval. This is a request to renew an existing approved collection. The ICR, which is abstracted below, describes the nature of the information collection and its estimated burden and cost.

**DATES:** Additional comments may be submitted on or before December 26, 2008.

**ADDRESSES:** Submit your comments, referencing Docket ID No. EPA-HQ-OA-2008-0701, to (1) EPA online using [www.regulations.gov](http://www.regulations.gov) (our preferred method), by e-mail to [oei.docket@epa.gov](mailto:oei.docket@epa.gov), or by mail to: EPA

Docket Center, Environmental Protection Agency, Office of Environmental Information, Environmental Protection Agency, Mailcode: 28221T, 1200 Pennsylvania Ave., NW., Washington, DC 20460, and (2) OMB by mail to: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th Street, NW., Washington, DC 20503.

**FOR FURTHER INFORMATION CONTACT:**

Nathalie Simon, National Center for Environmental Economics, Office of Policy Economics and Innovation, (1809T), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: 202-566-2347; fax number: 202-566-2363; e-mail address: [simon.nathalie@epa.gov](mailto:simon.nathalie@epa.gov).

**SUPPLEMENTARY INFORMATION:** EPA has submitted the following ICR to OMB for review and approval according to the procedures prescribed in 5 CFR 1320.12. On September 23, 2008 (73 FR 54798), EPA sought comments on this ICR pursuant to 5 CFR 1320.8(d). EPA received no comments. Any additional comments on this ICR should be submitted to EPA and OMB within 30 days of this notice.

EPA has established a public docket for this ICR under Docket ID No. EPA-HQ-OA-2008-0701, which is available for online viewing at [www.regulations.gov](http://www.regulations.gov), or in person viewing at the Office of Environmental Information (OEI) Docket in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The EPA/DC 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 Reading Room is 202-566-1744, and the telephone number for the OEI Docket is 202-566-1752.

Use EPA's electronic docket and comment system at [www.regulations.gov](http://www.regulations.gov), to submit or view public comments, access the index listing of the contents of the docket, and to access those documents in the docket that are available electronically. Once in the system, select "docket search," then key in the docket ID number identified above. Please note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing at [www.regulations.gov](http://www.regulations.gov) as EPA receives them and without change, unless the comment contains copyrighted material, confidential business information (CBI), or other

information whose public disclosure is restricted by statute. For further information about the electronic docket, go to [www.regulations.gov](http://www.regulations.gov).

**Title:** Focus Groups as Used by EPA for Economics Projects (Renewal).

**ICR numbers:** EPA ICR No. 2205.02, OMB Control No. 2090-0028.

**ICR Status:** This ICR is scheduled to expire on November 30, 2008. Under OMB regulations, the Agency may continue to conduct or sponsor the collection of information while this submission is pending at OMB. 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. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register** when approved, are listed in 40 CFR part 9, are displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers in certain EPA regulations is consolidated in 40 CFR part 9.

**Abstract:** The Environmental Protection Agency (EPA) is seeking renewal of a generic information collection request (ICR) for the conduct of focus groups and one-on-one interviews related to survey development for economics projects. Focus groups are groups of individuals brought together for moderated discussions on a specific topic or issue. These groups are typically formed to gain insight and understanding of attitudes and perceptions held by the public surrounding a particular issue. One-on-one interviews, as the term implies, are individual interviews in which a respondent is generally asked to review materials and provide feedback on their content and design as well as the thought processes that the materials invoke. Focus groups and one-on-one interviews (hereafter referred to collectively as "focus groups") used as a qualitative research tool have three major purposes:

- To better understand respondents' attitudes, perceptions and emotions in response to specific topics and concepts;
- To obtain respondent information useful for better defining variables and measures in later quantitative studies; and
- To further explore findings obtained from quantitative studies.

Through these focus groups, the Agency will be able to gain a more in-depth understanding of the public's attitudes, beliefs, motivations and

feelings regarding specific issues and will provide invaluable information regarding the quality of draft survey instruments. Focus group discussions are necessary and important steps in the design of a quality survey. The target population for the focus group discussions will vary by project, but will generally include members of the general public. Participation in the focus groups will be completely voluntary. Each focus group will fully conform to federal regulations—specifically the Privacy Act of 1974 (5 U.S.C. 552a), the Hawkins-Stafford Amendments of 1988 (Pub. L. 100-297), and the Computer Security Act of 1987.

**Burden Statement:** The annual public reporting and recordkeeping burden for this collection of information is estimated to average 2.33 hours per response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements which have subsequently changed; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

**Respondents/Affected Entities:** Individuals.

**Estimated Number of Respondents:** 337.

**Frequency of Response:** Once.

**Estimated Total Annual Hour Burden:** 786.

**Estimated Total Annual Cost:** \$22,385, includes \$0 annualized capital or O&M costs.

**Changes in the Estimates:** There is a decrease of 214 hours in the annual estimated burden currently identified in the OMB Inventory of Approved ICR Burdens. This decrease is based on new estimates provided by the program offices at EPA on their projected use of focus groups.

Dated: November 19, 2008.

**John Moses,**  
Acting Director, Collection Strategies  
Division.

[FR Doc. E8-27965 Filed 11-24-08; 8:45 am]  
BILLING CODE 6560-50-P

## ENVIRONMENTAL PROTECTION AGENCY

### Gulf of Mexico Program Policy Review Board; Notice of Charter Renewal

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice of Charter Renewal.

Notice is hereby given that the Environmental Protection Agency (EPA) has determined that, in accordance with the provisions of the Federal Advisory Committee Act (FACA), 5 U.S.C. App. 2, the Gulf of Mexico Program Policy Review Board (GMPPRB) is a necessary committee which is in the public interest.

Accordingly, GMPPRB will be renewed for an additional two-year period. The purpose of GMPPRB is to provide advice and recommendations to the Administrator of EPA on issues associated with plans to improve and protect the water quality and living resources of the Gulf of Mexico.

Inquiries may be directed to Gloria Car, Designated Federal Officer, U.S. EPA, Gulf of Mexico Program Office (Mail Code: EPAIGMPO), Stennis Space Center, MS, 39529, Telephone (228) 688-2421, or [car.gloria@epa.gov](mailto:car.gloria@epa.gov).

Dated: November 18, 2008.

**Benjamin Grumbles,**  
Assistant Administrator, Office of Water.  
[FR Doc. E8-27857 Filed 11-24-08; 8:45 am]  
BILLING CODE 6560-50-M

## ENVIRONMENTAL PROTECTION AGENCY

[FRL-8744-5]

### Federal Agency Hazardous Waste Compliance

**AGENCY:** Environmental Protection Agency.

**ACTION:** Notice of twenty-third update of the Federal Agency Hazardous Waste Compliance Docket.

**SUMMARY:** Since 1988, the U.S. Environmental Protection Agency (EPA) has maintained a Federal Agency Hazardous Waste Compliance Docket ("the Docket") under Section 120(c) of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). Section 120(c) requires EPA to establish a Docket that contains certain information reported to EPA by Federal facilities that manage hazardous waste or from which a reportable quantity of hazardous substances has been released. The Docket is used to identify Federal facilities that should be evaluated to determine if they pose a

threat to public health or welfare and the environment and to provide a mechanism to make this information available to the public. The Docket contains information that is submitted by Federal facilities under the following authorities: CERCLA Section 103, and RCRA Sections 3005, 3010 and 3016. EPA is required to publish a list of newly reported facilities in the **Federal Register**.

CERCLA Section 120(d) requires that EPA take steps to assure that a Preliminary Assessment (PA) be completed for those sites identified in the Docket and that the evaluation and listing of sites with a PA be completed within a reasonable time frame. The PA is designed to provide information for EPA to consider when evaluating the site for potential response action or listing on the National Priorities List (NPL).

Today's notice identifies the Federal facilities not previously listed on the Docket and reported to EPA since the last update of the Docket (72 FR 46218) on August 17, 2007. In addition to the list of additions to the Docket, this notice includes a section with revisions of the previous Docket list. The revisions in this update include 33 additions and 53 deletions since the previous update, as well as numerous other corrections to the Docket list. At the time of publication of this notice, the new total number of Federal facilities listed on the Docket is 2,271.

**DATES:** This list is current as of November 4, 2008.

**FOR FURTHER INFORMATION CONTACT:** Electronic versions of the Docket and more information on its implementation can be obtained at <http://www.epa.gov/fedfac/documents/docket.htm> by clicking on the link for *Update #23 to the Federal Agency Hazardous Waste Compliance Docket*.

#### **SUPPLEMENTARY INFORMATION:**

##### **Table of Contents**

- 1.0 Introduction
- 2.0 Regional Docket Coordinators
- 3.0 Revisions of the Previous Docket
- 4.0 Process for Compiling the Updated Docket
- 5.0 Facilities Not Included
- 6.0 Facility Status Reporting, Including NFRAP Status Updates
- 7.0 Information Contained on Docket Listing

##### **1.0 Introduction**

Section 120(c) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), 42 United States Code (U.S.C.) 9620(c), as amended by the Superfund Amendments and

Reauthorization Act of 1986 (SARA), requires the U.S. Environmental Protection Agency (EPA) to establish the Federal Agency Hazardous Waste Compliance Docket ("Docket"). The Docket contains information on Federal facilities that is submitted by Federal agencies to EPA under Sections 3005, 3010, and 3016 of the Resource Conservation and Recovery Act (RCRA), 42 U.S.C. 6925, 6930, and 6937, and under Section 103 of CERCLA, 42 U.S.C. 9603. Specifically, RCRA Section 3005 establishes a permitting system for certain hazardous waste treatment, storage, and disposal (TSD) facilities; RCRA Section 3010 requires waste generators, transporters and TSD facilities to notify EPA of their hazardous waste activities; and RCRA Section 3016 requires Federal agencies to submit biennially to EPA an inventory of their Federal hazardous waste facilities. CERCLA Section 103(a) requires the owner or operator of a vessel or onshore or offshore facility to notify the National Response Center (NRC) of any spill or other release of a hazardous substance that equals or exceeds a reportable quantity (RQ), as defined by CERCLA Section 101. Additionally, CERCLA Section 103(c) requires facilities that have "stored, treated, or disposed of" hazardous wastes and where there is "known, suspected, or likely releases" of hazardous substances to report their activities to EPA.

*The Docket serves three major purposes:* (1) To identify all Federal facilities that must be evaluated to determine whether they pose a risk to human health and the environment sufficient to warrant inclusion on the National Priorities List (NPL); (2) to compile and maintain the information submitted to EPA on such facilities under the provisions listed in Section 120(c) of CERCLA; and (3) to provide a mechanism to make the information available to the public.

The initial list of Federal facilities to be included on the Docket was published in the **Federal Register** on February 12, 1988 (53 FR 4280). Since then, updates to the Docket have been published on November 16, 1988 (54 FR 46364); December 15, 1989 (54 FR 51472); August 22, 1990 (55 FR 34492); September 27, 1991 (56 FR 49328); December 12, 1991 (56 FR 64898); July 17, 1992 (57 FR 31758); February 5, 1993 (58 FR 7298); November 10, 1993 (58 FR 59790); April 11, 1995 (60 FR 18474); June 27, 1997 (62 FR 34779); November 23, 1998 (63 FR 64806); June 12, 2000 (65 FR 36994); December 29, 2000 (65 FR 83222); October 2, 2001 (66 FR 50185); July 1, 2002 (67 FR 44200);

January 2, 2003 (68 FR 107); July 11, 2003 (68 FR 41353); December 15, 2003 (68 FR 240); July 19, 2004 (69 FR 42989); December 20, 2004 (69 FR 75951); October 25, 2005 (70 FR 61616); and August 17, 2007 (72 FR 46218). This notice constitutes the twenty-third update of the Docket.

Today's notice provides some background information on the Docket. Additional information on the Docket requirements and implementation are found in the Docket Reference Manual, Federal Agency Hazardous Waste Compliance Docket found at <http://www.epa.gov/fedfac/documents/docket.htm> or obtained by calling the Regional Docket Coordinators listed below. Today's notice also provides changes to the list of sites included on the Docket in four areas: (1) Additions, (2) Deletions, (3) Corrections, and (4) No Further Remedial Action Planned (NFRAP) Status Changes. Specifically, additions are newly identified Federal facilities that have been reported to EPA since the last update and now are included on the Docket; the deletions section lists Federal facilities that EPA is deleting from the Docket;<sup>1</sup> the corrections section lists changes in the information about the Federal facilities already listed on the Docket; and the section updating the NFRAP status lists the Federal facilities whose NFRAP status has changed since the last Docket update.

The information submitted to EPA on each Federal facility is maintained in the Docket repository located in the EPA Regional office of the Region in which the facility is located; for a description of the information required under those provisions, see 53 FR 4280 (February 12, 1988). Each repository contains the documents submitted to EPA under the reporting provisions and correspondence relevant to the reporting provisions for each facility.

##### **2.0 Regional Docket Coordinators**

Contact the following Docket coordinators for information on Regional Docket repositories:

Gerardo Millán-Ramos (HBS), U.S. EPA Region 1, #1 Congress St., Suite 1100, Boston, MA 02114-2023, (617) 918-1377.

Helen Shannon (ERRD), U.S. EPA Region 2, 290 Broadway, 18th Floor, New York, NY 10007-1866, (212) 637-4260 or Alida Karas (ERRD), U.S. EPA Region 2, 290 Broadway, New York, NY 10007-1866, (212) 637-4276.

<sup>1</sup> See Section 3.2 for the criteria for being deleted from the Docket.

- Cesar Lee (3HS50), U.S. EPA Region 3, 1650 Arch Street, Philadelphia, PA 19107, (215) 814-3205.
- Donna Webster (4SF-FFB), U.S. EPA Region 4, 61 Forsyth St., SW, Atlanta, GA 30303, (404) 562-8870.
- Michael Chrystof (SR-6)), U.S. EPA Region 5, 77 W. Jackson Blvd., Chicago, IL 60604, (312) 353-3705.
- Philip Ofosu (6SF-RA), U.S. EPA Region 6, 1445 Ross Avenue, Dallas, TX 75202-2733, (214) 665-3178.
- D. Karla Asberry (MO/KS RB), U.S. EPA Region 7, 901 N. Fifth Street, Kansas City, KS 66101, (913) 551-7595.
- Stan Zawistowski (EPR-F), U.S. EPA Region 8, 1595 Wynkoop Street, Denver, CO 80202 (303) 312-6255
- Carol Weinstein (SFD-6-1), U.S. EPA Region 9, 75 Hawthorne Street, San Francisco, CA 94105, (415) 972-3083 or Debbie Schechter (SFD-6-1), U.S. EPA Region 9, 75 Hawthorne Street, San Francisco, CA 94105, (415) 972-3093.
- Monica Lindeman (ECL, ABU # 1), U.S. EPA Region 10, 1200 Sixth Avenue, Seattle, WA 98101, (206) 553-5113 or Ken Marcy (ECL, ABU # 1), U.S. EPA Region 10, 1200 Sixth Avenue, Seattle, WA 98101, (206) 463-1349.

### 3.0 Revisions of the Previous Docket

This section includes a discussion of the additions, deletions, corrections, and NFRAP status changes to the list of Docket facilities since the previous Docket update.

#### 3.1 Additions

Today, 33 Federal facilities are being added to the Docket, primarily because of new information obtained by EPA (for example, recent reporting of a facility pursuant to RCRA Sections 3005, 3010, or 3016 or CERCLA Section 103). CERCLA Section 120, as amended by the Defense Authorization Act of 1997, specifies that EPA take steps to assure that a Preliminary Assessment (PA) be completed within a reasonable time frame for those Federal facilities that are included on the Docket. Among other things, the PA is designed to provide information for EPA to consider when evaluating the site for potential response action or listing on the NPL.

#### 3.2 Deletions

Today, 53 Federal facilities are being deleted from the Docket. There are no statutory or regulatory provisions that address deletion of a facility from the Docket. However, if a facility is incorrectly included on the Docket, it may be deleted from the Docket; this may be appropriate for a facility for which there was an incorrect report

submitted for hazardous waste activity under RCRA (e.g., 40 CFR 262.44); a facility that was not Federally-owned or operated at the time of the listing; facilities included more than once (i.e., redundant listings); or when multiple facilities are combined under one listing. Facilities being deleted no longer will be subject to the requirements of CERCLA Section 120(d).

#### 3.3 Corrections

Changes necessary to correct the previous Docket were identified by both EPA and Federal agencies. The corrections include changes in addresses or spelling, corrections of the recorded name and ownership of a Federal facility, and additional reporting mechanisms used to include a facility on the Docket. In addition, some changes in the names of Federal facilities were made to establish consistency in the Docket or between CERCLIS and the Docket. For each Federal facility for which a correction has been entered, the original entry (designated by an "o"), as it appeared in previous Docket updates, is shown directly below the corrected entry (designated by a "c") for easy comparison. Today, information is being corrected for 27 facilities.

#### 3.4 NFRAP Status Changes

Today's update to the Docket includes a chart showing 7 sites with changes in their NFRAP status. When a Federal facility listed on the Docket provides a PA (and if warranted a Site Inspection (SI)) for a site to EPA, EPA evaluates the site in accordance with the Hazard Ranking System (HRS) to determine whether the site scores sufficiently high to warrant NPL listing. If EPA determines that the facility or site does not pose a threat sufficient to warrant Superfund action, EPA typically will designate the site status as NFRAP under Superfund.

A decision not to take further response/remedial action under the Superfund program usually is based on a finding that there is no significant threat to human health or the environment, and EPA would not propose to list the site on the NPL at that time. If new or additional information becomes available suggesting that the site may warrant further evaluation, EPA will re-evaluate the site accordingly. This decision does not preclude any further action at the Federal facility or site by another EPA program, the State or other Federal agency. Generally, NFRAP status pertains to sites included in the CERCLIS Inventory.

An "N" in this chart designates the site as NFRAP.

#### 4.0 Process for Compiling the Updated Docket

In compiling the newly reported Federal facilities for the update being published today, EPA extracted the names, addresses, and identification numbers of facilities from four EPA databases—ERNS, the Biennial Inventory of Federal Agency Hazardous Waste Activities, the Resource Conservation and Recovery Information System (RCRAInfo), and the Superfund Comprehensive Environmental Response, Compensation, and Liability Information System (CERCLIS)—that contain information about Federal facilities submitted under the four provisions listed in CERCLA Section 120(c).

EPA assures the quality of the information on the Docket by conducting extensive evaluation of the current Docket list with the information obtained from the databases identified above to determine which Federal facilities were, in fact, newly reported and qualified for inclusion on the update. EPA is also striving to correct errors for Federal facilities that were previously reported. For example, state-owned or privately owned facilities that are not operated by the Federal government may have been included. Such problems are sometimes caused by procedures historically used to report and track Federal facilities data. EPA is working to resolve them. Representatives of Federal agencies are asked to write to EPA's Docket coordinator at the following address if revisions of this update information are necessary: Tim Mott, Federal Agency Hazardous Waste Compliance Docket Coordinator, Federal Facilities Restoration and Reuse Office (Mail Code 5106P), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460.

#### 5.0 Facilities Not Included

*Certain categories of facilities may not be included on the Docket, such as:* (1) Federal facilities formerly owned by a Federal agency that at the time of consideration was not Federally-owned or operated; (2) Federal facilities that are small quantity generators (SQGs) that have never generated more than 1,000 kg of hazardous waste in any month; (3) Federal facilities that are solely hazardous waste transportation facilities, as reported under RCRA Section 3010; and (4) Federal facilities that have mixed mine or mill site ownership. An EPA policy issued in June, 2003 provided guidance for a site-



by-site evaluation as to whether "mixed ownership" mine or mill sites, created as a result of the General Mining Law of 1872 and never reported under Section 103(a), should be included on the Docket. For purposes of that guidance, mixed ownership mine or mill sites are those located partially on private land and partially on public land. This guidance is found at <http://www.epa.gov/fedfac/pdf/mixownrshpmine.pdf>. The guidance for not including these facilities may change; facilities now not included may be added at some point if EPA determines that they should be included.

**6.0 Facility NPL Status Reporting, Including NFRAP Status**

EPA typically tracks the NPL status of Federal facilities listed on the Docket. An updated list of the NPL status of all Docket facilities, as well as their NFRAP status, is available at <http://www.epa.gov/fedfac/documents/docket.htm>.

**7.0 Information Contained on Docket Listing**

The updated information is provided in four tables. The first table is a list of new Federal facilities that are being added on the Docket. The second is a list of Federal facilities that are being deleted from the Docket. The third contains corrections of information included on the Docket. The fourth table lists updates to NFRAP status.

The facilities listed in each table are organized by state and then grouped alphabetically within each state by the Federal agency responsible for the facility. Under each state heading is listed, the name and address of the facility, the Federal agency responsible for the facility, the statutory provision(s) under which the facility was reported to EPA, and a code. Each Federal facility listed in the update has been assigned a code that indicates a specific reason for the addition, deletion, or correction. The code key precedes the lists.

The statutory provisions under which a facility is reported are listed in a column titled "Reporting Mechanism." Applicable mechanisms are listed for each facility: for example Sections 3010, 3016, 103(c), or Other. "Other" has been added as a reporting mechanism to

indicate those Federal facilities that otherwise have been identified to have releases or threat of releases of hazardous substances. The National Contingency Plan 40 CFR 300.405 addresses discovery or notification and outlines what constitutes discovery of a hazardous substance release, and states that a release may be discovered in several ways, including (1) A report submitted in accordance with Section 103(a) of CERCLA, *i.e.*, reportable quantities codified at 40 CFR part 302; (2) A report submitted to EPA in accordance with Section 103(c) of CERCLA; (3) Investigation by government authorities conducted in accordance with Section 104(e) of CERCLA or other statutory authority; (4) Notification of a release by a Federal or state permit holder when required by its permit; (5) Inventory or survey efforts or random or incidental observation reported by government agencies or the public; (6) Submission of a citizen petition to EPA or the appropriate Federal facility requesting a preliminary assessment, in accordance with Section 105(d) of CERCLA; (7) A report submitted in accordance with Section 311(b)(5) of the CWA; and (8) Other sources. As a policy matter, EPA generally believes it is appropriate for Federal facilities identified through the CERCLA discovery and notification process to be included on the Docket.

The complete list of Federal facilities that now make up the Docket and the NPL and NFRAP status are available to interested parties and can be obtained at <http://www.epa.gov/fedfac/documents/docket.htm> by clicking on the link for *Federal Agency Hazardous Waste Compliance Docket Update #23* or by calling Tim Mott, the EPA HQ Docket Coordinator at (703) 603-8807. As of today, the total number of Federal facilities that appear on the Docket is 2,273.

Dated: November 7, 2008.

**John E. Reeder,**  
Director, Federal Facilities Restoration and Reuse Office, Office of Solid Waste and Emergency Response.

**Docket Codes**

*Categories for Deletion of Facilities*

- (1) Small-Quantity Generator.

- (2) Never Federally Owned and/or Operated.
- (3) Formerly Federally Owned and/or Operated but not at time of listing.
- (4) No Hazardous Waste Generated.
- (5) (This code is no longer used.)
- (6) Redundant Listing/Site on Facility.
- (7) Combining Sites Into One Facility/ Entries Combined.
- (8) Does Not Fit Facility Definition.
- (9) (This code is no longer used.)
- (10) (This code is no longer used.)
- (11) (This code is no longer used.)
- (12) (This code is no longer used.)
- (13) (This code is no longer used.)
- (14) (This code is no longer used.)

*Categories for Addition of Facilities*

- (15) Small-Quantity Generator with either a RCRA 3016 or CERCLA 103 Reporting Mechanism.
- (16) One Entry Being Split Into Two (or more)/ Federal Agency Responsibility Being Split.
- (17) New Information Obtained Showing That Facility Should Be Included.
- (18) Facility Was a Site on a Facility That Was Disbanded; Now a Separate Facility.
- (19) Sites Were Combined Into One Facility.
- (19A) New currently Federally owned and/or operated Facility site.

*Categories for Corrections of Information About Facilities*

- (20) Reporting Provisions Change.
- (20A) Typo Correction/Name Change/ Address Change.
- (21) Changing Responsible Federal Agency. (If applicable, new responsible Federal agency must submit proof of previously performed PA, which is subject to approval by EPA.)
- (22) Changing Responsible Federal Agency and Facility Name. (If applicable, new responsible Federal agency must submit proof of previously performed PA, which is subject to approval by EPA.)
- (23) New Reporting Mechanism Added at Update.
- (24) Reporting Mechanism Determined To Be Not Applicable After Review of Regional Files.

**FEDERAL AGENCY HAZARDOUS WASTE COMPLIANCE DOCKET UPDATE #23—ADDITIONS**

Facility name	Address	City	State	Zip code	Agency	Reporting mechanism	Code
Transportation Security Administration at LAX.	5757 W Century Blvd .....	Los Angeles	CA ...	90045	Homeland Security .....	3010 .....	19A

## FEDERAL AGENCY HAZARDOUS WASTE COMPLIANCE DOCKET UPDATE #23—ADDITIONS—Continued

Facility name	Address	City	State	Zip code	Agency	Reporting mechanism	Code
Federal Correctional Institution Herlong.	741 925 Herlong Access Rd ...	Herlong .....	CA ...	96113	Justice .....	3010 .....	19A
Pond Mine .....	Sec 3, T12N R10E MDBM .....	Forest Hill ..	CA ...	95631	Interior—Bureau of Land Management.	103a .....	19A
Kelly Silver Mine .....	Hwy 395 .....	Red Mountain.	CA ...	93558	Interior—Bureau of Land Management.	103a .....	19A
Poore Mine .....	Benedict Canyon Lane .....	Nevada Co.	CA ...	.....	Interior—Bureau of Land Management.	103a .....	19A
USN Undersea Warfare Center.	801 Clematis St .....	West Palm Beach.	FL ...	33401	Navy .....	3010 .....	19A
USDA FS Caribou-Targhee NF: Smoky Canyon Mine Site.	Smoky Canyon Rd/FS Rd 110, 24 mi E of Soda Springs, T8S R45E Sec 24, 25 & 36; T8S R46E Sec 17, 18, 19, 20, 29, 30, 31 & 32; T9S R46E Sec 6, 7 & 18; T9S R45E Sec 1, 12 & 13, Boise Meridian.	Soda Springs.	ID ....	83276	Agriculture—Forest Service .....	Other .....	19A
USDOJ BLM Idora Mine and Mill Site.	Carbon Center Road, 10 mi SE of Pritchard, 10 mi N of Wallace, T49N R5E Sec 30.	Wallace .....	ID ....	83873	Interior—Bureau of Land Management.	Other .....	19A
USDA FS Boise NF: Belshazzar Mine.	Granite Creek Road, 3 mi W of Placerville, T7N R4E Sec 17, Boise Meridian.	Placerville ..	ID ....	83666	Agriculture—Forest Service .....	Other .....	19A
U.S. Army Corps of Engineers, Rock Island District, Lock and Dam 12.	.....	Hanover Township.	IL ....	61041	Corps of Engineers, Civil .....	3016 .....	19A
U.S. Army Corps of Engineers, Cape Cod Canal, Bourne Bridge Lead Abatement Project.	40 Academy Drive .....	Buzzards Bay.	MA ..	02532	Corps of Engineers, Civil .....	3010 .....	19A
VA Medical Center ...	1400 VFW Parkway .....	West Roxbury.	MA ..	02132	Veterans Affairs .....	3010 .....	19A
U.S. VA Medical Center Brockton.	940 Belmont St .....	Brockton .....	MA ..	02401	Veterans Affairs .....	3010 .....	19A
Aberdeen Proving Ground (Michaelsville Landfill).	Off Rte 40 .....	Aberdeen ...	MD ..	21005	Army .....	103c .....	17
VA Medical Center—St Cloud.	4801 Veterans Dr .....	St. Cloud ....	MN ..	56303	Veterans Affairs .....	3010 .....	19A
National Geospatial-Intelligence Agency.	3200 South 2nd Street .....	St. Louis .....	MO ..	63118	NGA—St. Louis .....	3010, 103c	17
Old Saint Louis Base	Foot of Iron St. & Mississippi River.	St Louis .....	MO ..	63111-2336	Homeland Security—Coast Guard.	103c .....	19A
Overton Gravel Pit Trespass Site.	¼ Mi W OF Hwy 169 .....	Overton .....	NV ...	89040	Interior—Bureau of Reclamation.	3010 .....	19A
Samuel S Stralton VA Medical Center.	113 Holland Ave .....	Albany .....	NY ...	12208	Veterans Affairs .....	3010 .....	19A
USNAVY Boardman Naval Weapons Systems Training Site.	Bombing Range Road, 6 mi S of Boardman.	Boardman ..	OR ..	97818	Navy .....	Other .....	19A
Letterkenny Army Depot (PDO Area).	N Franklin Street .....	Franklin County.	PA ...	17201	Army .....	103c .....	17
USPFO for Tennessee ARNG.	HQ (STARC) Houston Barracks.	Nashville ....	TN ...	37204	Army .....	3010 .....	19A
Naval Support Activity Mid-South.	Willis Gate @ Navy Road .....	Millington ....	TN ...	38054	Navy .....	3010 .....	19A
Camp Williams .....	5 Mi W of Lehi .....	Lehi .....	UT ...	84043	Army .....	103c .....	19A
Pershing Project—Blanding Launch Complex.	7 Mi SW of Blanding .....	Blanding .....	UT ...	84511	Army .....	103c .....	19A
King Edward Mine ...	18 Mi NW of Blanding .....	Blanding .....	UT ...	84511	Agriculture—Forest Service .....	103c .....	19A
UTTR South Wendover AFAR-AL501.	5 Mi SW of Wendover .....	Wendover ..	UT ...	84083	Air Force .....	.....	19A
St. Juliens Creek Annex (U.S. Navy).	Victory Boulevard .....	Chesapeake	VA ...	23323	Navy .....	103c .....	17

## FEDERAL AGENCY HAZARDOUS WASTE COMPLIANCE DOCKET UPDATE #23—ADDITIONS—Continued

Facility name	Address	City	State	Zip code	Agency	Reporting mechanism	Code
COE—Civil Lower Granite Dam.	Granite-Almota Road, 21 mi SW of Colfax, T14N R43E Sec 29.	Colfax .....	WA ..	99111	Corps of Engineers, Civil .....	3010 .....	19A
USDOJ BR Hazardous Waste Site.	T19N R23E SEC 31, Willamette Meridian, 25 mi W of George, 35 mi SW of Quincy.	Quincy .....	WA ..	98848	Interior—Bureau of Reclamation.	3010 .....	19A
USHS CG Burrows Island Light Station.	SW side of Burrows Island, 5 mi SW of Anacortes.	Anacortes ...	WA ..	98221	Homeland Security—Coast Guard.	3010 .....	19A
USDOJ BIA Signal Peak Ranger Station.	BIA 140 Rd-Signal Peak Road, 24 mi SW of White Swan, T9N R13E Sec 25, Willamette Meridian.	White Swan	WA ..	98952	Interior—Bureau of Indian Affairs.	3010 .....	19A
USDA FS Mt. Baker-Snoqualmie NF: Rainy Mine & Mill Site.	FS Rd 5640, 12 mi NE of North Bend, T24N R10E Sec 9 & 16, Willamette Meridian.	North Bend	WA ..	98045	Agriculture—Forest Service .....	Other .....	19A

## FEDERAL AGENCY HAZARDOUS WASTE COMPLIANCE DOCKET UPDATE #23—CORRECTIONS

Facility name	Address	City	State	Zip code	Agency	Reporting mechanism	Code
c-BLM Chaffee County Landfill.	T.51.N.R.8.E. Sec.21, U.S. Hwy 285 10M North of Salida.	Salida .....	CO ..	81201	Interior—Bureau of Land Management.	103c .....	20A
o-BLM Chaffee County Landfill.	T.51.N.R.8.E. Sec.21, U.S. Hwy 285 10M North of Salida.	Salida .....	CO ..	.....	Interior—Bureau of Land Management.	103c.	
c-BLM Eagle County Landfill.	T.4. N.R.83.W. Sec.10 & 11 ....	Eagle .....	CO ..	81613	Interior—Bureau of Land Management.	103c .....	20A
o-BLM Eagle County Landfill.	T.4. N.R.83.W. Sec.10 & 11 ....	.....	CO ..	.....	Interior—Bureau of Land Management.	103c.	
c-BLM Fremont .....	T.48.N.R.12.E. Sec.19 .....	Cotopaxi .....	CO ..	81223	Interior—Bureau of Land Management.	103c .....	20A
o-BLM Fremont .....	T.48.N.R.12.E. Sec.19 .....	Cata Paxi ...	CO ..	.....	Interior—Bureau of Land Management.	103c.	
c-BLM Kremmling Dump.	T.1.N.R.80.E. Sec.9 .....	Kremmling ..	CO ..	80459	Interior—Bureau of Land Management.	103c .....	20A
o-BLM Kremmling Dump.	T.1.N.R.80.E. Sec.9 .....	Kremmling ..	CO ..	.....	Interior—Bureau of Land Management.	103c.	
c-BLM Maybell Dump	.....	Maybell .....	CO ..	81640	Interior—Bureau of Land Management.	103c .....	20A
o-BLM Maybell Dump	.....	Moffatt County.	CO ..	.....	Interior—Bureau of Land Management.	103c.	
c-BLM San Miguel Landfill #1.	T.44.N.R.15.W. Sec.26 .....	Naturita .....	CO ..	81422	Interior—Bureau of Land Management.	103c .....	20A
o-BLM San Miguel Landfill #1.	T.44.N.R.15.W. Sec.26 .....	Nataurita ....	CO ..	.....	Interior—Bureau of Land Management.	103c.	
c-Cortez Organizational Maintenance Shop.	PO Box E .....	Cortez .....	CO ..	81321	Army .....	3016 .....	20A
o-Cortez Organizational Maintenance Shop.	PO Box E .....	Cortez .....	CO ..	.....	Army .....	3016.	
c-National Water Quality Laboratory.	5293 Ward Rd .....	Denver .....	CO ..	80002	Interior .....	3010 3016 103c.	20A
o-National Water Quality Laboratory.	5293 Ward Rd .....	Denver .....	CO ..	80225	Interior .....	3010 3016 103c.	
c-Shriever AFS Transformer Storage Area.	500 Navstar St .....	Colorado Springs.	CO ..	80912	Air Force .....	103a .....	20A
o-Shriever AFS Transformer Storage Area.	500 Navstar St .....	Colorado Springs.	CO ..	.....	Air Force .....	103a.	
c-Defense Industrial Plant Equipment.	Old Rt. 1, P.O. Box 532, 6675 Sherman Road.	Atchison .....	KS ...	66002	Army .....	103c .....	21
o-Defense Industrial Plant Equipment.	Old Rt. 1, P.O. Box 532, 6675 Sherman Road.	Atchison .....	KS ...	66002	Defense Logistics Agency .....	103c.	
c-BLM Illegal Airstrip John Greytak.	Section 6 T.11N.R.27.E .....	Flatwillow ...	MT ..	59059	Interior—Bureau of Land Management.	103c .....	20A

## FEDERAL AGENCY HAZARDOUS WASTE COMPLIANCE DOCKET UPDATE #23—CORRECTIONS—Continued

Facility name	Address	City	State	Zip code	Agency	Reporting mechanism	Code
o-BLM Illegal Airstrip John Greytak.	Section 6 T.11N.R.27.E .....	Flatwillow ...	MT ..	.....	Interior—Bureau of Land Management.	103c.	
c-BLM Roundup Landfill.	1.5 Miles Northwest of Roundup.	Roundup ....	MT ..	59072	Interior—Bureau of Land Management.	103c .....	20A
o-BLM Roundup Landfill.	1.5 Miles Northwest of Roundup.	Roundup ....	MT ..	.....	Interior—Bureau of Land Management.	103c.	
c-BLM Sluice Gulch Leaking Adit.	T.6.SR.15.W. Sec.5 .....	Phillipsburg	MT ..	59858	Interior—Bureau of Land Management.	103c .....	20A
o-BLM Sluice Gulch Leaking Adit.	T.6.SR.15.W. Sec.5 .....	.....	MT ..	.....	Interior—Bureau of Land Management.	103c.	
c-BLM Steamboat Point.	T.25.N.R.10.E. Sec.18 PMM ...	Loma .....	MT ..	59460	Interior—Bureau of Land Management.	103c .....	20A
o-BLM Steamboat Point.	T.25.N.R.10.E. Sec.18 PMM ...	Loma .....	MT ..	.....	Interior—Bureau of Land Management.	103c.	
c-Precious Metals Plating.	Star Route Box 85 .....	Bonner .....	MT ..	59823	Housing and Urban Development.	103c 3010 ..	20A
o-Precious Metals Plating.	Star Route Box 85 .....	Bonner .....	MT ..	.....	Housing and Urban Development.	103c 3010.	
c-Tucson/Hebrew Academy.	NW 1/4 Section 26, T 37N, R 9W.	Port of Del Bonita.	MT ..	59427	Interior .....	103c .....	20A
o-Tucson/Hebrew Academy.	NW 1/4 Section 26, T 37N, R 9W.	.....	MT ..	.....	Interior .....	103c.	
c-Montana Air National Guard OMS #2.	International Airport .....	Missoula ....	MT ..	59801	Air Force .....	3010 .....	20A
o-Montana Air National Guard OMS #2.	International Airport .....	Great Falls	MT ..	59401	Air Force .....	3010.	
c-USDA Biosciences Research Lab.	1605 W. College St. ....	Fargo .....	ND ..	58105	Agriculture .....	3010 3016 103c.	20A
o-North Dakota Agricultural Experiment Station.	1605 W. College St. ....	Fargo .....	ND ..	58105	Agriculture .....	3010 3016 103c.	
c-Stanley R Mickelsen Safeguard Complex (RSL-4) Remote Sprint LA.	1 Mile Southwest of Fairdale ...	Fairdale .....	ND ..	58229	Air Force .....	103c .....	20A
o-Stanley R Mickelsen Safeguard Complex (RSL-4) Remote Sprint LA.	1 Mile Southwest of Fairdale ...	Fairdale .....	ND ..	58205	Air Force .....	103c.	
c-Air Force Real Property Agency (formerly Griffiss Air Force Base).	153 Brooks Rd .....	Rome .....	NY ...	13441	Air Force .....	3005 3010 3016 103c.	20A
o-Griffiss Air Force Base.	153 Brooks Rd .....	Rome .....	NY ...	13441	Air Force .....	3005 3010 3016 103c.	
c-Letterkenny Army Depot (SE Area).	N Franklin St Ext .....	Chambersburg.	PA ...	17201	Army .....	3005 3010 3016 103c 103a.	20A
o-Letterkenny Army Depot.	N Franklin St Ext .....	Chambersburg.	PA ...	17201	Army .....	3005 3010 3016 103c 103a.	
c-American Fork Canyon/Uinta National.	.....	Pleasant Grove.	UT ...	84062	.....	103c .....	20A
o-American Fork Canyon/Uinta National.	.....	Pleasant Grove.	UT ...	84601	.....	103c.	
c-USFS Santaquin Mudslide.	1 Mile Northeast of Santaquin	Santaquin ...	UT ...	84401	Agriculture .....	103c 3016 ..	20A
o-USFS Santaquin Mudslide.	1 Mile Northeast of Santaquin	Santaquin ....	UT ...	84401	Agriculture .....	103c 3016.	

## FEDERAL AGENCY HAZARDOUS WASTE COMPLIANCE DOCKET UPDATE #23—CORRECTIONS—Continued

Facility name	Address	City	State	Zip code	Agency	Reporting mechanism	Code
c-Langley Air Force Base/NASA Langley Research Center.	Off State Highway 187 .....	Hampton ....	VA ...	23665	NASA .....	3010 3016 103c.	20A
o-Langley Research Center.	Mail Stop 453 .....	Hampton ....	VA ...	23665	NASA .....	3010 3016 103c.	
c-Naval Amphibious Base Little Creek.	Shore Drive (U.S. Route 60) ...	Virginia Beach.	VA ...	23455	Navy .....	3005 3010 3016 103c 103a.	20A
o-Little Creek Naval Amphibious Base.	Little Creek .....	Norfolk .....	VA ...	23521	Navy .....	3005 3010 3016 103c 103a.	
c-NWS Yorktown—Cheatham Annex.	Cheatham Annex, Naval Supply Center.	Yorktown ....	VA ...	23185	Navy .....	3005 3010 3016 103c.	20A
o-Williamsburg Naval Supply Center Cheatham Annex.	Naval Supply Center, Norfolk ..	Williamsburg.	VA ...	23185	Navy .....	3005 3010 3016 103c.	
c-Naval Weapons Station—Yorktown.	US Naval Weapons Station .....	Yorktown ....	VA ...	23690	Navy .....	3005 3010 3016 103c.	20A
o-Yorktown Naval Weapons Station.	N/A .....	Yorktown ....	VA ...	23691	Navy .....	3005 3010 3016 103c.	

## FEDERAL AGENCY HAZARDOUS WASTE COMPLIANCE DOCKET UPDATE #23—DELETIONS

Facility name	Address	City	State	Zip code	Agency	Reporting mechanism	Code
PRI South Pacific Inc.	Utulei .....	Pago Pago	AS ...	96799	.....	- 3010 .....	2
Triumph Air Repair Inc.	4010 S 43rd Pl .....	Phoenix ....	AZ ...	85040	.....	- 3010 .....	2
DEA Apache Junction.	1891 South Apache .....	Apache Junction.	AZ ...	.....	Justice .....	103a .....	2
DEA Ashfork .....	12 M. SE of Ashfork .....	Ashfork ....	AZ ...	.....	Justice .....	103a .....	2
DEA Mesa .....	1764 North Mesa Drive .....	Mesa .....	AZ ...	.....	Justice .....	103a .....	2
DEA Sierra Vista ...	1031 East Acacia .....	Sierra Vista	AZ ...	.....	Justice .....	103a .....	2
DEA Phoenix .....	10809 North 40th Street .....	Phoenix ....	AZ ...	.....	Justice .....	103a 103c .....	2
Hu Hu Kam Memorial Hospital.	PHS Indian Health Service ...	Sacaton ...	AZ ...	85247	Health and Human Services	3010 .....	1
BR Davis Dam .....	St. Highway 68, 3 Mi N of City.	Bullhead City.	AZ ...	86430	.....	3010 .....	1
BR Yuma .....	South Side of Levey Road ...	Yuma .....	AZ ...	.....	Interior .....	103a .....	1
Hassayampa/Lynx Creek Abandoned Mines.	5 Miles SE Prescott-Prescott Natl Forest.	Prescott ....	AZ ...	86301	Agriculture .....	103c 3016 103a .....	6
BR-Golden Falcon Site.	23rd St at Ave C .....	Yuma .....	AZ ...	85364	.....	103c .....	6
Shasta-Trinity NF: Lakeshore Landfill.	2400 Washington Avenue ....	Redding ....	CA ...	96001	Agriculture .....	103c 3016 .....	7
Camp Roberts Training Site.	Hwy 101 .....	Camp Roberts.	CA ...	93451	Army .....	3010 .....	7
Pacific Environs-Johnston Atoll.	APO .....	San Francisco.	CA ...	96305	Air Force .....	3016 .....	6
George Air Force Base-Superior Valley Range.	S13 14 24 T305 R46E .....	China Lake	CA ...	99999	Air Force .....	103c 3005 .....	7
LAAFB Fort MacArthur Annex.	2400 Pacific Avenue .....	San Pedro	CA ...	90731	Air Force .....	3016 103c .....	7
Los Angeles Air Force Base.	2400 Pacific Ave .....	Los Angeles.	CA ...	90009	Air Force .....	3010 .....	7
Aerospace Corporation.	2400 EL Segundo Blvd .....	El Segundo	CA ...	90245	Defense Logistics Agency ....	3010 .....	7

## FEDERAL AGENCY HAZARDOUS WASTE COMPLIANCE DOCKET UPDATE #23—DELETIONS—Continued

Facility name	Address	City	State	Zip code	Agency	Reporting mechanism	Code
Tustin Marine Corps Air Station-Helicopter.	USMC Air Station .....	Tustin .....	CA ...	92710-5001	Navy .....	3005 3010 103c ...	7
Action Battery Manufacturing Company.	4700-02 W Rosecrans .....	Hawthorne	CA ...	90250	.....	-3010 .....	2
Carlsbad Narcotics Task Force.	2461 Impala .....	Carlsbad ...	CA ...	92008	Justice .....	103a .....	6
MCLB Barstow .....	3 Miles East of Barstow on I40.	Barstow ....	CA ...	92311	Navy .....	3005 3010 3016 103c 103a.	6
Naval Facilities Engineering Service Center.	560 Center Drive .....	Port Huene- neme.	CA ...	91766	Navy .....	3010 103a 103c 3016.	6
Express Cleaners ..	1170 Arnold Dr # 140 .....	Martinez ....	CA ...	94553	.....	-3010 .....	2
Garage, State of California.	570 Ellis .....	San Fran- cisco.	CA ...	94109	.....	-3010 .....	2
General Chemical Company.	5568 Schaefer Ave .....	Chino .....	CA ...	91710	.....	-3010 .....	2
Lemon Grove Camera.	7848 Broadway .....	Lemon, Grove.	CA ...	92045	.....	-3010 .....	2
Lester Miller Farm	Miller Rd North of Hahn Road.	Arbuckle ...	CA ...	95912	.....	-3016 .....	2
Los Angeles County of, Mechanical Dept.	1100 N Eastern Ave .....	Los Ange- les.	CA ...	90063	.....	-3010 .....	2
Performance West Petroleum.	2065 Martin Ave #106 .....	Santa Clara.	CA ...	95050	.....	-3010 .....	2
Prototype Concepts Inc.	1945 Placentia Ave .....	Costa Mesa.	CA ...	92627	.....	-3010 .....	2
Radionics Inc .....	1800 Abbott .....	Salinas .....	CA ...	93901	.....	-3010 .....	2
Santa Barbara County Roadyard.	4415 Cathedral Oaks Road ..	Santa Bar- bara.	CA ...	93110	.....	-3010 .....	2
Royce Del Metals ..	North Blosser & West Main St.	Santa Maria.	CA ...	.....	Corps of Engineers, Civil .....	103a .....	2
Cottonwood Station	40 Silverwood .....	Summit Valley.	CA ...	92387	.....	-3010 .....	1
Logistics Support Center.	1310 Cucamonga Ave .....	Ontario .....	CA ...	91761	.....	-3010 .....	1
BR Cachuna O&M Board.	Cachuna Lake .....	Santa Bar- bara.	CA ...	93105	Interior .....	3010 .....	1
Los Angeles Federal Reserve Bank.	950 S Grand .....	Los Ange- les.	CA ...	90015	Federal Reserve Board .....	3010 .....	1
Los Angeles Federal Reserve Bank.	409 W Olympic Blvd .....	Los Ange- les.	CA ...	90015	Federal Reserve Board .....	3010 .....	1
San Francisco Federal Reserve Bank.	101 Market Street .....	San Fran- cisco.	CA ...	94105	Federal Reserve Board .....	3010 .....	1
Delta Airlines-Denver.	Stapleton Airport .....	Denver .....	CO ..	80238	.....	-3010 103c .....	2
FPSD Pistol Range	4th St & M St SW .....	Washington	DC ..	20407	General Services Administra- tion.	3010 .....	6
Wahiawa NCTAMS EASTPAC.	Off Center St Oahu Island ...	Wahiawa ...	HI ...	96786	Navy .....	103c 3010 .....	6
Ritchie Rubbleville	2001 Ritchie Marlboro High- way.	Upper Marlboro.	MD ..	.....	Navy .....	103a .....	2
Assayers Laboratories.	2155 Last Chance Rd .....	Elko .....	NV ...	89801	.....	-3010 .....	2
Norfolk Facility .....	200 Ligon Street .....	Norfolk .....	VA ...	.....	-Navy .....	103a .....	2
Fine Petroleum .....	2801 St Julian Ave .....	Norfolk .....	VA ...	23510	EPA .....	3010 .....	2
Goodwin Junkyard	Route 659 Kings Cove Road/ Box 98.	Carrollton ..	VA ...	22314	.....	-3010 103c .....	2
Langley Air Force Base.	1 CSG/DE .....	Langley AFB.	VA ...	23665	Air Force .....	3005 3010 3016 103c 103a.	6
Manchester Tank & Equipment Co.	Air Park Dr Rte 684 .....	Petersburg	VA ...	23803	.....	-3010 .....	2
Fauquier County Landfill.	Route 674 .....	Fauquier ...	VA ...	22186	.....	-103c .....	2

## FEDERAL AGENCY HAZARDOUS WASTE COMPLIANCE DOCKET UPDATE #23—DELETIONS—Continued

Facility name	Address	City	State	Zip code	Agency	Reporting mechanism	Code
Cheyenne Organizational Maintenance Shop #4.	P.O. Box 1709 .....	Cheyenne	WY ..	82003	.....	-3016 .....	6
BLM Granby Landfill.	2.N.77.W.Sec.26827 .....	Granby .....	CO ..	80480	Interior—Bureau of Land Management.	103c .....	N
Baltimore Postal Service Vehicle Maintenance.	60 W Oliver Street .....	Baltimore ..	MD ..	21201	Postal Service .....	3010 .....	N
U.S. Medical Federal Bureau of Prisons.	1900 W. Sunshine .....	Springfield	MO ..	65801	Justice .....	103c .....	N
Marquand (ex) Gap Filler Annex.	NW ¼ Section 18, T32N, R8E.	Marquand	MO ..	63655	Agriculture .....	3016 .....	N
Lynn Keller Farm ...	Sec 6 T16N R8E .....	Cedar Bluffs.	NE ...	68015	Agriculture .....	3016 .....	N
Yorktown Reserve Training Center.	Route 238 SE Corner of York Co.	Yorktown ..	VA ...	23690	Homeland Security .....	3010 .....	N
Robert C. Byrd Locks and Dam.	RT 2 .....	Apple Grove.	WV ..	25502	Corps of Engineers, Civil .....	103a .....	N

[FR Doc. E8-27972 Filed 11-24-08; 8:45 am]

BILLING CODE 6560-50-P

**FARM CREDIT ADMINISTRATION****Farm Credit Administration Board; Regular Meeting****AGENCY:** Farm Credit Administration.**SUMMARY:** Notice is hereby given, pursuant to the Government in the Sunshine Act (5 U.S.C. 552b(e)(3)), of the regular meeting of the Farm Credit Administration Board (Board).**DATE AND TIME:** The regular meeting of the Board will be held at the offices of the Farm Credit Administration in McLean, Virginia, on December 11, 2008, from 9 a.m. until such time as the Board concludes its business.**FOR FURTHER INFORMATION CONTACT:** Roland E. Smith, Secretary to the Farm Credit Administration Board, (703) 883-4009, TTY (703) 883-4056.**ADDRESSES:** Farm Credit Administration, 1501 Farm Credit Drive, McLean, Virginia 22102-5090.**SUPPLEMENTARY INFORMATION:** Parts of this meeting of the Board will be open to the public (limited space available), and parts will be closed to the public. In order to increase the accessibility to Board meetings, persons requiring assistance should make arrangements in advance. The matters to be considered at the meeting are:**Open Session****A. Approval of Minutes**

- November 13, 2008.

**B. New Business**

- April Meeting Date Change.

- Inflation Adjustments to the Civil Money Penalties—Final Rule.

**C. Reports**

- FCS Building Association Quarterly Report.

**Closed Session\***

- OSMO Supervisory and Oversight Activities.

Dated: November 20, 2008.

**Roland E. Smith,***Secretary, Farm Credit Administration Board.*

[FR Doc. E8-28118 Filed 11-21-08; 4:15 pm]

BILLING CODE 6705-01-P

**GENERAL SERVICES ADMINISTRATION****Multiple Award Schedule Advisory Panel; Notification of Public Advisory Panel Meetings****AGENCY:** U.S. General Services Administration (GSA).**ACTION:** Notice.**SUMMARY:** The U.S. General Services Administration (GSA) Multiple Award Schedule Advisory Panel (MAS Panel), a Federal Advisory Committee, will hold a public meeting on the following date: Monday, December 8, 2008. GSA utilizes the MAS program to establish long-term Governmentwide contracts with responsible firms to provide Federal, State, and local government customers with access to a wide variety of commercial supplies (products) and services.

\* Session Closed-Exempt pursuant to 5 U.S.C. 552b(c)(8) and (9).

The MAS Panel was established to develop advice and recommendations on MAS program pricing policies, provisions, and procedures in the context of current commercial pricing practices. The Panel will be developing recommendations for MAS program pricing provisions for the acquisition of (1) professional services; (2) products; (3) total solutions which consist of professional services and products; and (4) non professional services. In developing the recommendations, the Panel will, at a minimum, address these 5 questions for each of the 4 types of acquisitions envisioned above: (1) Where does competition take place?; (2) If competition takes place primarily at the task/delivery order level, does a fair and reasonable price determination at the MAS contract level really matter?; (3) If the Panel consensus is that competition is at the task order level, are the methods that GSA uses to determine fair and reasonable prices and maintain the price/discount relationship with the basis of award customer(s) adequate?; (4) If the current policy is not adequate, what are the recommendations to improve the policy/guidance; and (5) If fair and reasonable price determination at the MAS contract level is not beneficial and the fair and reasonable price determination is to be determined only at the task/delivery order level, then what is the GSA role?

To that end, the Panel would like to hear from the many stakeholders of the MAS program. The MAS program stakeholders include, but not limited to, ordering agency contracting officers, GSA contracting officers, schedule contract holders, Congress, program

managers, General Accountability Office, and Federal agency Inspector General Offices. The panel is particularly interested in stakeholder views as to how the issues discussed above may relate differently to the purchase of goods, services, or goods and services that are configured to propose an integrated solution to an agency's needs. Written comments may be submitted at any time in accordance with the guidance below.

The meeting will be held at U.S. General Services Administration, Federal Acquisition Service, 2200 Crystal Drive, Room L1301, Arlington, VA 22202. The location is within walking distance of the Crystal City metro stop. The meeting start time is 9:00 a.m., and will adjourn no later than 5:00 p.m.

For presentations before the Panel, the following guidance is provided:

**Oral comments:** The Panel will no longer entertain oral presentations.

**Written Comments:** Written comments must be received ten (10) business days prior to the meeting date so that the comments may be provided to the Panel for their consideration prior to the meeting. Comments should be supplied to Ms. Brooks at the address/contact information noted below in the following format: one hard copy with original signature and one electronic copy via email in Microsoft Word.

Subsequent meeting dates, locations, and times will be published at least 15 days prior to the meeting date.

**FOR FURTHER INFORMATION CONTACT:** Information on the Panel meetings, agendas, and other information can be obtained at [www.gsa.gov/masadvisorypanel](http://www.gsa.gov/masadvisorypanel) or you may contact Ms. Pat Brooks, Designated Federal Officer, Multiple Award Schedule Advisory Panel, U.S. General Services Administration, 2011 Crystal Drive, Suite 911, Arlington, VA 22205; telephone 703 605-3406, Fax 703 605-3454; or via email at [mas.advisorypanel@gsa.gov](mailto:mas.advisorypanel@gsa.gov).

**AVAILABILITY OF MATERIALS:** All meeting materials, including meeting agendas, handouts, public comments, and meeting minutes will be posted on the MAS Panel website at [www.gsa.gov/masadvisorypanel](http://www.gsa.gov/masadvisorypanel) or [www.gsa.gov/masap](http://www.gsa.gov/masap).

**MEETING ACCESS:** Individuals requiring special accommodations at any of these meetings should contact Ms. Brooks at least ten (10) business days prior to the meeting date so that appropriate arrangements can be made.

Dated: November 19, 2008

**David A. Drabkin,**

*Deputy Chief Acquisition Officer, Office of the Chief Acquisition Officer, General Services Administration.*

[FR Doc. E8-27951 Filed 11-24-08; 8:45 am]

**BILLING CODE 6820-EP-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Public Consultation Meeting of the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight

**AGENCY:** Department of Health and Human Services, Office of the Secretary.

**ACTION:** Notice.

**SUMMARY:** The U.S. Department of Health and Human Services is hereby giving notice that the Trans-Federal Task Force on Biosafety and Biocontainment Oversight will be holding a public consultation meeting. The meeting is open to the public.

**DATES:** The Trans-Federal Task Force on Biosafety and Biocontainment Oversight will hold a public consultation meeting on December 8, 2008 from 8:30 a.m. to 5 p.m. EST and December 9, 2008 from 8:30 a.m. to 2:45 p.m. EST.

**ADDRESSES:** The Bethesda North Marriott Hotel and Conference Center, 5701 Mariemell Road, North Bethesda, MD 20852. Phone: 301-822-9200.

**FOR FURTHER INFORMATION CONTACT:** CAPT Theresa Lawrence, Ph.D., Office of Medicine, Science and Public Health, Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services, 330 C Street, SW., Room 5008C, Washington, DC 20447; phone: 202-401-5879; fax: 202-205-8494; e-mail address: [biosafetytaskforce@hhs.gov](mailto:biosafetytaskforce@hhs.gov).

**SUPPLEMENTARY INFORMATION:** The Federal government established the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight to undertake an intensive analysis of the current framework of biosafety and biocontainment oversight of research activities involving infectious agents and toxins in high- and maximum-containment research facilities. The Task Force envisions effective comprehensive local and Federal oversight that protects laboratory workers, public health, agriculture, and the environment while fostering progress in life sciences research. The Task Force is chaired by officials from the U.S. Department of Health and Human Services and the U.S.

Department of Agriculture and is comprised of representatives from a broad range of Federal departments and agencies that have responsibility for, and oversight of, the management of biohazard risks.

**Background:** The Task Force's purpose is to "explore methods to improve biosafety oversight in the United States to include a review of mechanisms by which the Federal Government can ensure safe working conditions in laboratories handling infectious agents." This public consultation meeting will allow the Task Force to obtain individual input from members of the public on several aspects of biosafety and biocontainment oversight in the U.S. The meeting's dialogue will focus on a series of questions on which the U.S. Government would specifically like to solicit comment. These questions concern such matters as the identification of gaps in the current oversight framework and options for improvement, including how to optimize biosafety and biocontainment oversight while simultaneously protecting laboratory workers, public health, agriculture, and the environment. The agenda and questions for discussion will be available prior to the meeting at the Web site <http://www.hhs.gov/aspr/omsp/biosafetytaskforce/index.html>. All public comments and recommendations will be considered by the Task Force.

**Availability of Materials:** The agenda and other materials will be posted on the Task Force's Web site at <http://www.hhs.gov/aspr/omsp/biosafetytaskforce/index.html> prior to the meeting.

**Procedures for Providing Public Input:** Public participation in this meeting of the Task Force is encouraged. Interested members of the public may attend the meeting in person or participate by public teleconference. Any member of the public wishing to obtain information regarding participation by teleconference should consult the Web site: <http://www.hhs.gov/aspr/omsp/biosafetytaskforce/index.html> or contact CAPT Theresa Lawrence (preferably by e-mail) for more information. Interested members of the public may submit relevant written or oral information for the Task Force to consider. Oral and written information that is submitted may be made available to the public; therefore, we request that statements do not include private or proprietary information. Oral Statements: Thirty minutes will be available each day of the meeting for public comment. In general, each speaker (or group of speakers) requesting an oral



presentation will be limited to three minutes. To be placed on the public speaker list, interested parties should contact CAPT Theresa Lawrence in writing (preferably via e-mail), by November 28, 2008. Written Statements: In general, individuals or groups may file written comments with the Task Force. All written comments must be received prior to December 12, 2008 and should be sent to CAPT Theresa Lawrence (preferably by e-mail with "Task Force Public Comment" as the subject line). Individuals needing special assistance should notify CAPT Theresa Lawrence (preferably by e-mail) by November 28, 2008.

Dated: November 18, 2008.

**RADM William C. Vanderwagen,**  
*Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services.*

[FR Doc. E8-28013 Filed 11-24-08; 8:45 am]  
**BILLING CODE 4150-37-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2008-D-0588]

#### Compliance Policy Guide Sec. 540.700 Processed and/or Blended Seafood Products (CPG 7108.16); Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of revised Compliance Policy Guide Sec. 540.700 Processed and/or Blended Seafood Products (CPG 7108.16) (the CPG). The CPG provides guidance for FDA staff on FDA's labeling requirements for processed and blended seafood products.

**DATES:** Submit written or electronic comments regarding the CPG at any time.

**ADDRESSES:** Submit written comments on the CPG to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>. Submit written requests for single copies of the CPG to the Division of Compliance Policy (HFC-230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 240-632-6861. See

the **SUPPLEMENTARY INFORMATION** section for electronic access to the CPG.

**FOR FURTHER INFORMATION CONTACT:** Catalina Ferre-Hockensmith, Center for Food Safety and Applied Nutrition (HFS-820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2371.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In the *Federal Register* of July 26, 1985 (50 FR 30523), FDA made available Compliance Policy Guide 7108.16, which was subsequently renumbered and renamed Compliance Policy Guide Sec. 540.700 Processed and/or Blended Seafood Products (CPG 7108.16). FDA has revised the CPG. The CPG provides guidance for FDA staff on FDA's labeling requirements for processed and blended seafood products. The CPG also contains information that may be useful to the regulated industry and to the public.

FDA is issuing the revisions to the CPG as Level 2 guidance under FDA's good guidance practices regulation (21 CFR 10.115). Consistent with FDA's good guidance practices regulation, the agency will accept comments on the CPG at any time. The CPG represents the agency's 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.

##### II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

##### III. Electronic Access

Persons with access to the Internet may obtain the CPG from FDA's Office of Regulatory Affairs history page. It may be accessed at [http://www.fda.gov/ora/compliance\\_ref/cpg/cpgfod/cpg540-700.html](http://www.fda.gov/ora/compliance_ref/cpg/cpgfod/cpg540-700.html).

Dated: November 14, 2008.

**Michael A. Chappell,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. E8-27969 Filed 11-24-08; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HOMELAND SECURITY

### Welcome to the DHS Enterprise e-Recruitment System

**AGENCY:** Office of the Chief Human Capital Officer, DHS.

**ACTION:** 60-Day Notice and request for comments; Information Collection submission for OMB Review.

**SUMMARY:** The Department of Homeland Security, Office of the Chief Human Capital Officer has submitted the following information collection request (ICR) 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 January 26, 2009. This process is conducted in accordance with 5 CFR 1320.1.

**ADDRESSES:** Comments and questions about this Information Collection Request should be forwarded to the Office of the Chief Human Capital Officer, Attn: Mabeline Hall for the Department of Homeland Security/CHCO, 245 Murray Lane SW., Building 410, Washington, DC 20528.

**FOR FURTHER INFORMATION CONTACT:** Mabeline Hall, 202-357-8272 (this is not a toll free number).

**SUPPLEMENTARY INFORMATION:** The Department of Homeland Security (DHS), Office of the Chief Human Capital Officer (OCHCO) is implementing an enterprise e-Recruitment system for DHS. The use of an automated recruitment solution is necessary to meet mission critical needs of DHS and comply with the 45-day hiring model under the President's Management Agenda.

Technology-enabled recruitment can deliver both time savings and improved results. Based on an internal inventory of DHS human resource (HR) systems, more than 50 systems are currently used

by DHS components to perform hiring/recruitment related activities. As part of the effort to consolidate and modernize the HR systems, the OCHCO is leading an effort to consolidate towards an automated enterprise solution that can contribute to material improvements in the overall hiring process.

Working in close collaboration, OCHCO's Human Capital Business System (HCBS) and Human Capital units defined the key project goals. The overall vision for the e-Recruitment initiative is to implement a state-of-the-art system that automates hiring/recruitment processes across DHS and seamlessly integrates with other related DHS services.

The Office of Management and Budget is particularly interested in comments which:

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.

This collection is designed to further allow DHS to plan recruitment efforts based on workforce analytics regarding turnover rates and expected budget/FTE allocations; proactively recruit for anticipated vacancies to reduce the time-to-hire; automate employee referrals, applications, pre-screening, resume management, candidate tracking, and candidate rating and ranking; provide applicant workflow, communications, interview management, reference/background checking, and "on-boarding" services; provide regulatory and analytical reports for both recruiters and hiring managers. Response by applicants is optional. Any information obtained by DHS will be used only for evaluating applicants for job opportunities by rating and ranking the applications based upon the qualifications and skills outlined by the job vacancy announcement. All responses are treated in a highly confidential manner

and responses may be verified for accuracy and completeness.

#### Analysis

AGENCY: Department of Homeland Security, Office of the Chief Human Capital Officer.

Title: DHS Enterprise e-Recruitment System.

OMB Number: 1601-New.

Frequency: On-going collection.

Affected Public: All individuals anticipating applying for an employment opportunity with the Department of Homeland Security Headquarters Division.

Number of Respondents: 10,000.

Estimated Time Per Respondent: 2 Hours.

Total Burden Hours: 10,000 x 2 = 20,000.

Total Burden Cost (capital/startup): \$20,341,958.00.

Total Burden Cost (operating/maintaining): \$39,845,675.00.

Dated: November 18, 2008.

Richard Mangogna,  
Chief Information Officer.

[FR Doc. E8-28036 Filed 11-24-08; 8:45 am]

BILLING CODE 4410-10-P

## DEPARTMENT OF HOMELAND SECURITY

### Office of the Secretary

[Docket No. DHS-2008-0136]

### Privacy Act of 1974; Department of Homeland Security General Training Records System of Records

AGENCY: Privacy Office, DHS.

ACTION: Notice of Privacy Act system of records.

**SUMMARY:** In accordance with the Privacy Act of 1974, the Department of Homeland Security is giving notice that it proposes to update one record system titled, DHS/ALL-003 Department of Homeland Security General Training Records. Categories of individuals, categories of records, routine uses, and exemptions of this system of records notice have been updated to better reflect the Department's updated general training record systems. Additionally, the Department will be issuing a Final Rule on the exemptions elsewhere in the **Federal Register** concurrent with the publishing of this updated System of Records Notice. This updated system will be included in the Department of Homeland Security's inventory of record systems.

**DATES:** Comments must be received on or before December 26, 2008.

**ADDRESSES:** You may submit comments, identified by docket number DHS-2008-0136 by one of the following methods:

- *Federal e-Rulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *Fax:* 1-866-466-5370.
- *Mail:* Hugo Teufel III, Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528.

- *Instructions:* All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change and may be read at <http://www.regulations.gov>, including any personally identifiable information provided.

- *Docket:* For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** For general questions and privacy issues please contact: Hugo Teufel III (703-235-0780), Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

The Department of Homeland Security (DHS) is updating and reissuing an agency-wide system of records under the Privacy Act (5 U.S.C. 552a) for DHS general training records. This system collects and maintains training records on current and former Departmental employees, contractors, and other individuals.

In accordance with the Privacy Act of 1974, DHS is giving notice that it proposes to update one record system titled, DHS/ALL-003 Department of Homeland Security General Training Records (71 FR 26767 May 8, 2006). Categories of individuals have been updated to include volunteers and contractors; other participants in training programs, including instructors, course developers, observers, and interpreters; categories of records have been updated to include more extensive records for processing and tracking training activities; routine uses have been updated to allow for the sharing of information for an audit of the Department or its components; to share with the supervisor of those individuals seeking training as it relates to the individual's fitness and qualifications for training and to provide training status; and to allow for sharing in the event the Department has a possible loss of personally identifiable information. Additionally, the Department will be

issuing a Final Rule on the exemptions elsewhere in the **Federal Register** concurrent with the publishing of this updated System of Records Notice. This updated system will be included in DHS's inventory of record systems.

## II. Privacy Act

The Privacy Act embodies fair information principles in a statutory framework governing the means by which the United States Government collects, maintains, uses, and disseminates individuals' records. The Privacy Act applies to information that is maintained in a "system of records." A "system of records" is a group of any records under the control of an agency for which information is retrieved by the name of an individual or by some identifying number, symbol, or other identifying particular assigned to the individual. In the Privacy Act, an individual is defined to encompass United States citizens and legal permanent residents. As a matter of policy, DHS extends administrative Privacy Act protections to all individuals where systems of records maintain information on U.S. citizens, lawful permanent residents, and visitors. Individuals may request access to their own records that are maintained in a system of records in the possession or under the control of DHS by complying with DHS Privacy Act regulations, 6 CFR Part 5.

The Privacy Act requires each agency to publish in the **Federal Register** a description denoting the type and character of each system of records that the agency maintains, and the routine uses that are contained in each system in order to make agency record keeping practices transparent, to notify individuals regarding the uses to which their records are put, and to assist individuals to more easily find such files within the agency. Below is the description of the DHS Mailing and Other Lists System of Records.

In accordance with 5 U.S.C. 552a(r), DHS has provided a report of this updated system of records to the Office of Management and Budget and to Congress.

### SYSTEM OF RECORDS

DHS/All-003.

#### SYSTEM NAME:

Department of Homeland Security General Training Records.

#### SECURITY CLASSIFICATION:

Unclassified.

#### SYSTEM LOCATION:

Records are maintained at several Headquarters locations and in

component offices of the Department of Homeland Security, in both Washington, DC and field locations.

#### AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The Homeland Security Act of 2002, Pub. L. 107-296, 6 U.S.C. 121; Federal Records Act, 44 U.S.C. 3101; 6 CFR Part 5; 5 U.S.C. app. 3; 5 U.S.C. 301 and Ch. 41; Executive Order 11348, as amended by Executive Order 12107; and Executive Order 9397 (SSN).

#### CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Current and former employees of DHS, volunteers and contractors; any individual who is or has been an employee of DHS and who has applied for, participated in or assisted with a training program; any other Federal employee or private individual, including contractors and others, who has participated in or assisted with training programs recommended, sponsored or operated by the Department of Homeland Security; and other participants in training programs, including instructors, course developers, observers, and interpreters.

#### CATEGORIES OF RECORDS IN THE SYSTEM:

The system includes all records pertaining to training, including:

- Individual's name;
- Date of birth;
- Social security number;
- Address;
- Phone numbers;
- Email addresses;
- Occupation;
- Nomination forms;
- Registration forms;
- Course rosters and sign-in sheets;
- Instructor lists;
- Schedules;
- Payment records, including financial, travel and related expenditures;
- Examination and testing materials;
- Grades and student evaluations;
- Course and instructor critiques;
- Equipment issued to trainees and other training participants; and other reports pertaining to training; and
  - Individuals who apply for but are not accepted for training.

#### PURPOSE:

This record system will collect and document training given to DHS employees, contractors, and others who are provided DHS training. This system will provide DHS with a means to track the particular training that is provided, identify training trends and needs, monitor and track the expenditure of training and related travel funds, schedule training classes and programs, schedule instructors, track training

items issued to students, assess the effectiveness of training, identify patterns, respond to requests for information related to the training of DHS personnel and other individuals, and facilitate the compilation of statistical information about training.

#### ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, all or a portion of the records of information contained in this system may be disclosed outside Department of Homeland Security (DHS) as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

A. To the Department of Justice or other Federal agency conducting litigation or in proceedings before any court, adjudicative or administrative body, when it is necessary to the litigation and one of the following is a party to the litigation or has an interest in such litigation:

1. DHS or any component thereof;
2. Any employee of DHS in his/her official capacity;
3. Any employee of DHS in his/her individual capacity where DOJ or DHS has agreed to represent the employee; or
4. The United States or any agency thereof, is a party to the litigation or has an interest in such litigation, and DHS determines that the records are both relevant and necessary to the litigation and the use of such records is compatible with the purpose for which DHS collected the records.

B. To a congressional office from the record of an individual in response to an inquiry from that congressional office made at the request of the individual to whom the record pertains.

C. To the National Archives and Records Administration or other Federal government agencies pursuant to records management inspections being conducted under the authority of 44 U.S.C. 2904 and 2906.

D. To an agency, organization, or individual for the purpose of performing audit or oversight operations as authorized by law, but only such information as is necessary and relevant to such audit or oversight function.

E. To appropriate agencies, entities, and persons when:

1. DHS suspects or has confirmed that the security or confidentiality of information in the system of records has been compromised;
2. The Department has determined that as a result of the suspected or confirmed compromise there is a risk of harm to economic or property interests,

identity theft or fraud, or harm to the security or integrity of this system or other systems or programs (whether maintained by DHS or another agency or entity) or harm to the individual that rely upon the compromised information; and

3. The disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with DHS's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm.

F. To contractors and their agents, grantees, experts, consultants, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for DHS, when necessary to accomplish an agency function related to this system of records. Individuals provided information under this routine use are subject to the same Privacy Act requirements and limitations on disclosure as are applicable to DHS officers and employees.

G. To an appropriate Federal, State, tribal, local, international, or foreign law enforcement agency or other appropriate authority charged with investigating or prosecuting a violation or enforcing or implementing a law, rule, regulation, or order, where a record, either on its face or in conjunction with other information, indicates a violation or potential violation of law, which includes criminal, civil, or regulatory violations and such disclosure is proper and consistent with the official duties of the person making the disclosure.

H. To a Federal, State, tribal, local or foreign government agency or professional licensing authority in response to its request, in connection with the hiring or retention of an employee, the issuance of a security clearance, the reporting of an investigation of an employee, the letting of a contract, or the issuance or status of a license, grant, or other benefit by the requesting entity, to the extent that the information is relevant and necessary to the requesting entity's decision on the matter.

I. To educational institutions or training facilities for purposes of enrollment and verification of employee attendance and performance.

J. To the Equal Employment Opportunity Commission, Merit Systems Protection Board, Office of the Special Counsel, Federal Labor Relations Authority, or Office of Personnel Management or to arbitrators and other parties responsible for processing any personnel actions or conducting administrative hearings or

appeals, or if needed in the performance of authorized duties.

K. To the Department of Justice or a consumer reporting agency for further action on a delinquent debt when circumstances warrant.

L. To employers to the extent necessary to obtain information pertinent to the individual's fitness and qualifications for training and to provide training status.

M. To the news media and the public, with the approval of the Chief Privacy Officer in consultation with counsel, when there exists a legitimate public interest in the disclosure of the information or when disclosure is necessary to preserve confidence in the integrity of DHS or is necessary to demonstrate the accountability of DHS's officers, employees, or individuals covered by the system, except to the extent it is determined that release of the specific information in the context of a particular case would constitute an unwarranted invasion of personal privacy.

**DISCLOSURE TO CONSUMER REPORTING AGENCIES:**

Yes.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Records in this system are stored electronically or on paper in secure facilities in a locked drawer behind a locked door. The records are stored on magnetic disc, tape, digital media, and CD-ROM.

**RETRIEVABILITY:**

Data may be retrieved by the individual's name, social security number, or other personal identifier.

**SAFEGUARDS:**

Records in this system are safeguarded in accordance with applicable rules and policies, including all applicable DHS automated systems security and access policies. Strict controls have been imposed to minimize the risk of compromising the information that is being stored. Access to the computer system containing the records in this system is limited to those individuals who have a need to know the information for the performance of their official duties and who have appropriate clearances or permissions.

**RETENTION AND DISPOSAL:**

Records are maintained and disposed in accordance with National Archives and Records Administration General Records Schedule, No. 1.

**SYSTEM MANAGER(S) AND ADDRESS:**

For Headquarters components of the Department of Homeland Security, the System Manager is the Director of Departmental Disclosure, Department of Homeland Security, Washington, DC 20528. For components of the Department of Homeland Security, the System Manager can be found at <http://www.dhs.gov/foia> under "contacts."

**NOTIFICATION PROCEDURE:**

Individuals seeking notification of and access to any record contained in this system of records, or seeking to contest its content, may submit a request in writing to the component's FOIA Officer, whose contact information can be found at <http://www.dhs.gov/foia> under "contacts." If an individual believes more than one component maintains Privacy Act records concerning him or her the individual may submit the request to the Chief Privacy Officer, Department of Homeland Security, 245 Murray Drive, SW., Building 410, STOP-0550, Washington, DC 20528.

When seeking records about yourself from this system of records or any other Departmental system of records your request must conform with the Privacy Act regulations set forth in 6 CFR Part 5. You must first verify your identity, meaning that you must provide your full name, current address and date and place of birth. You must sign your request, and your signature must either be notarized or submitted under 28 U.S.C. 1746, a law that permits statements to be made under penalty of perjury as a substitute for notarization. While no specific form is required, you may obtain forms for this purpose from the Director, Disclosure and FOIA, <http://www.dhs.gov> or 1-866-431-0486. In addition you should provide the following:

- An explanation of why you believe the Department would have information on you,
- Identify which component(s) of the Department you believe may have the information about you,
- Specify when you believe the records would have been created,
- Provide any other information that will help the FOIA staff determine which DHS component agency may have responsive records,
- If your request is seeking records pertaining to another living individual, you must include a statement from that individual certifying his/her agreement for you to access his/her records.

Without this bulleted information the component(s) will not be able to conduct an effective search, and your

request may be denied due to lack of specificity or lack of compliance with applicable regulations.

**RECORD ACCESS PROCEDURE:**

See "Notification Procedure" above.

**CONTESTING RECORD PROCEDURES:**

See "Notification Procedure" above.

**RECORD SOURCE CATEGORIES:**

Information originates within DHS and from the individual to whom the record pertains.

**EXEMPTIONS CLAIMED FOR THE SYSTEM:**

The Secretary of Homeland Security has exempted certain records in this system on the basis of 5 U.S.C. 552a(k)(6) in order to preserve the objectivity and fairness of testing and examination material.

Dated: November 18, 2008.

Hugo Teufel III,

Chief Privacy Officer, Department of Homeland Security.

[FR Doc. E8-28037 Filed 11-24-08; 8:45 am]

BILLING CODE 4410-10-P

**DEPARTMENT OF HOMELAND SECURITY**

**Office of the Secretary**

[Docket No. DHS-2008-0092]

**Privacy Act of 1974; Department of Homeland Security Mailing and Other Lists System of Records**

**AGENCY:** Privacy Office; DHS.

**ACTION:** Notice of Privacy Act system of records.

**SUMMARY:** In accordance with the Privacy Act of 1974, the Department of Homeland Security is giving notice that it proposes to update one record system titled, DHS/ALL-002 Department of Homeland Security Mailing and Other Lists System. Categories of records have been changed to reflect the removal of emergency contact information which has been moved to the Emergency Personnel Location System of Records (October 17, 2008). The routine uses of this system of records have been updated to include the ability to share information for audits; for breach mitigation; with Federal, State and local agencies; with the Department of Justice; and with the news media. This updated system will be included in DHS's inventory of record systems.

**DATES:** Written comments must be submitted on or before December 26, 2008.

**ADDRESSES:** You may submit comments, identified by docket number DHS-

2008-0092 by one of the following methods:

• **Federal e-Rulemaking Portal:** <http://www.regulations.gov>. Follow the instructions for submitting comments.

• **Fax:** 1-866-466-5370.

• **Mail:** Hugo Teufel III, Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528.

• **Instructions:** All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change and may be read at <http://www.regulations.gov>, including any personally identifiable information provided.

• **Docket:** For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** For general questions and privacy issues please contact: Hugo Teufel III (703-235-0780), Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

The Department of Homeland Security (DHS) is updating and reissuing an agency-wide system of records under the Privacy Act (5 U.S.C. 552a) for DHS mailing and other lists. These lists are used to facilitate mailings to multiple addressees and other activities in furtherance of DHS duties. DHS and its components and offices use the system to account for all persons appearing on mailing lists collected and maintained throughout DHS to facilitate mailings to multiple addressees and other activities in furtherance of DHS duties.

In accordance with the Privacy Act of 1974, DHS is giving notice that it proposes to update one record system titled, DHS/ALL-002 Department of Homeland Security Mailing and Other Lists System (69 FR 70460 December 9, 2004). Categories of records have been changed to reflect the removal of emergency contact information which has been moved to Emergency Personnel Location System of Records (73 FR 61888 October 17, 2008). The routine uses of this system of records have been changed to reflect the addition of information sharing for audits of the Department and its components; for breach mitigation to prevent the unauthorized use or disclosure of information and to prepare for privacy related incidents; with Federal, State and local agencies related to tracking and completion of training;

with the Department of Justice; with the news media. This updated system will be included in DHS's inventory of record systems.

**II. Privacy Act**

The Privacy Act embodies fair information principles in a statutory framework governing the means by which the United States Government collects, maintains, uses, and disseminates individuals' records. The Privacy Act applies to information that is maintained in a "system of records." A "system of records" is a group of any records under the control of an agency for which information is retrieved by the name of an individual or by some identifying number, symbol, or other identifying particular assigned to the individual. In the Privacy Act, an individual is defined to encompass United States citizens and legal permanent residents. As a matter of policy, DHS extends administrative Privacy Act protections to all individuals where systems of records maintain information on U.S. citizens, lawful permanent residents, and visitors. Individuals may request access to their own records that are maintained in a system of records in the possession or under the control of DHS by complying with DHS Privacy Act regulations, 6 CFR Part 5.

The Privacy Act requires each agency to publish in the *Federal Register* a description denoting the type and character of each system of records that the agency maintains, and the routine uses that are contained in each system in order to make agency recordkeeping practices transparent, to notify individuals regarding the uses to which their records are put, and to assist individuals to more easily find such files within the agency. Below is the description of the DHS Mailing and Other Lists System of Records.

In accordance with 5 U.S.C. 552a(r), DHS has provided a report of this updated system of records to the Office of Management and Budget and to Congress.

**SYSTEM OF RECORDS  
DHS/ALL-002**

**SYSTEM NAME:**

Department of Homeland Security Mailing and Other Lists System of Records.

**SECURITY CLASSIFICATION:**

Unclassified.

**SYSTEM LOCATION:**

This system of records is located in the Department of Homeland Security,

Washington, DC 20528, as well as in the component DHS offices.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

All persons appearing on mailing lists maintained throughout DHS to facilitate mailings to multiple addressees and other activities in furtherance of DHS duties. These lists include persons who have requested DHS material; members of the news media who have provided contact information; persons who serve on DHS boards and committees other than those covered by the Federal Advisory Committee Act which are covered under DHS/ALL 009 Advisory Committees (73 FR 57639), and other individuals having business with DHS who have provided contact information; individuals who enter contests sponsored by DHS; contractors or other individuals who work or attend meetings at DHS; and other persons who attend or have an interest in DHS programs, contests, exhibits, conferences, training courses, and similar events.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Categories of records in this system include:

- Individual's name;
- Age;
- School grade; (where appropriate)
- School name; (where appropriate)
- Telephone numbers;
- E-mail address;
- Mailing address;
- Position/title;
- Business affiliation (where appropriate);
- Other contact information provided to DHS by individuals covered by this system of records; and
- Computer-generated identifier or case number where created in order to retrieve information.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

5 U.S.C. 301; 44 U.S.C. 3101.

**PURPOSE(S):**

The system is maintained for the purpose of mailing informational literature or responses to those who request it; maintaining lists of individuals who attend meetings; maintaining information regarding individuals who enter contests sponsored by DHS; and for other purposes for which mailing or contact lists may be created.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, all or a

portion of the records of information contained in this system may be disclosed outside Department of Homeland Security (DHS) as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

- A. To the Department of Justice or other Federal agency conducting litigation or in proceedings before any court, adjudicative or administrative body, when it is necessary to the litigation and one of the following is a party to the litigation or has an interest in such litigation:
1. DHS or any component thereof;
  2. Any employee of DHS in his/her official capacity;
  3. Any employee of DHS in his/her individual capacity where DOJ or DHS has agreed to represent the employee; or
  4. The United States or any agency thereof, is a party to the litigation or has an interest in such litigation, and DHS determines that the records are both relevant and necessary to the litigation and the use of such records is compatible with the purpose for which DHS collected the records.

B. To a congressional office from the record of an individual in response to an inquiry from that congressional office made at the request of the individual to whom the record pertains.

C. To the National Archives and Records Administration or other Federal government agencies pursuant to records management inspections being conducted under the authority of 44 U.S.C. 2904 and 2906.

D. To an agency, organization, or individual for the purpose of performing audit or oversight operations as authorized by law, but only such information as is necessary and relevant to such audit or oversight function.

E. To appropriate agencies, entities, and persons when:

1. DHS suspects or has confirmed that the security or confidentiality of information in the system of records has been compromised;
2. The Department has determined that as a result of the suspected or confirmed compromise there is a risk of harm to economic or property interests, identity theft or fraud, or harm to the security or integrity of this system or other systems or programs (whether maintained by DHS or another agency or entity) or harm to the individual that rely upon the compromised information; and
3. The disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with DHS's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm.

F. To contractors and their agents, grantees, experts, consultants, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for DHS, when necessary to accomplish an agency function related to this system of records. Individuals provided information under this routine use are subject to the same Privacy Act requirements and limitations on disclosure as are applicable to DHS officers and employees.

G. To an appropriate Federal, State, tribal, local, international, or foreign law enforcement agency or other appropriate authority charged with investigating or prosecuting a violation or enforcing or implementing a law, rule, regulation, or order, where a record, either on its face or in conjunction with other information, indicates a violation or potential violation of law, which includes criminal, civil, or regulatory violations and such disclosure is proper and consistent with the official duties of the person making the disclosure.

J. To the news media and the public, with the approval of the Chief Privacy Officer in consultation with counsel, when there exists a legitimate public interest in the disclosure of the information or when disclosure is necessary to preserve confidence in the integrity of DHS or is necessary to demonstrate the accountability of DHS's officers, employees, or individuals covered by the system, except to the extent it is determined that release of the specific information in the context of a particular case would constitute an unwarranted invasion of personal privacy.

**DISCLOSURE TO CONSUMER REPORTING AGENCIES:**

None.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Records in this system are stored electronically or on paper in secure facilities in a locked drawer behind a locked door. The records are stored on magnetic disc, tape, digital media, and CD-ROM.

**RETRIEVABILITY:**

Information typically will be retrieved by an identification number assigned by computer or case number where created for tracking purposes, by e-mail address, or by name of an individual.

**SAFEGUARDS:**

Records in this system are safeguarded in accordance with

applicable rules and policies, including all applicable DHS automated systems security and access policies. Strict controls have been imposed to minimize the risk of compromising the information that is being stored. Access to the computer system containing the records in this system is limited to those individuals who have a need to know the information for the performance of their official duties and who have appropriate clearances or permissions.

#### RETENTION AND DISPOSAL:

Some records are retained and disposed of in accordance with the National Archives and Records Administration's General Records Schedule 12 (Communications Records). Other records are retained and disposed of in accordance with General Records Schedule 1. Files may be retained for up to three years or less depending on the record. For records that may be used in litigation, the files related to that litigation will be retained for three years after final court adjudication.

#### SYSTEM MANAGER AND ADDRESS:

For Headquarters components of the Department of Homeland Security, the System Manager is the Director of Departmental Disclosure, Department of Homeland Security, Washington, DC 20528. For components of the Department of Homeland Security, the System Manager can be found at <http://www.dhs.gov/foia> under "contacts."

#### NOTIFICATION PROCEDURE:

Individuals seeking notification of and access to any record contained in this system of records, or seeking to contest its content, may submit a request in writing to the component's FOIA Officer, whose contact information can be found at <http://www.dhs.gov/foia> under "contacts." If an individual believes more than one component maintains Privacy Act records concerning him or her the individual may submit the request to the Chief Privacy Officer, Department of Homeland Security, 245 Murray Drive, SW., Building 410, STOP-0550, Washington, DC 20528.

When seeking records about yourself from this system of records or any other Departmental system of records your request must conform with the Privacy Act regulations set forth in 6 CFR Part 5. You must first verify your identity, meaning that you must provide your full name, current address and date and place of birth. You must sign your request, and your signature must either be notarized or submitted under 28 U.S.C. 1746, a law that permits

statements to be made under penalty of perjury as a substitute for notarization. While no specific form is required, you may obtain forms for this purpose from the Director, Disclosure and FOIA, <http://www.dhs.gov> or 1-866-431-0486. In addition you should provide the following:

- An explanation of why you believe the Department would have information on you,
- Identify which component(s) of the Department you believe may have the information about you,
- Specify when you believe the records would have been created,
- Provide any other information that will help the FOIA staff determine which DHS component agency may have responsive records,
- If your request is seeking records pertaining to another living individual, you must include a statement from that individual certifying his/her agreement for you to access his/her records.

Without this bulleted information the component(s) will not be able to conduct an effective search, and your request may be denied due to lack of specificity or lack of compliance with applicable regulations.

#### RECORD ACCESS PROCEDURES:

See "Notification procedure" above.

#### CONTESTING RECORD PROCEDURES:

See "Notification procedure" above.

#### RECORD SOURCE CATEGORIES:

Information contained in this system is obtained from affected individuals/organizations, public source data, other government agencies and/or information already in other DHS records systems.

#### EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

Dated: November 18, 2008.

**Hugo Teufel III,**

*Chief Privacy Officer, Department of Homeland Security.*

[FR Doc. E8-28053 Filed 11-24-08; 8:45 am]

BILLING CODE 4410-10-P

## DEPARTMENT OF HOMELAND SECURITY

### Office of the Secretary

[Docket No. DHS-2008-0005]

### Privacy Act of 1974; Department of Homeland Security Accident Records System of Records

**AGENCY:** Privacy Office, DHS.

**ACTION:** Notice of Privacy Act system of records.

**SUMMARY:** In accordance with the Privacy Act of 1974 and as part of the Department of Homeland Security's ongoing effort to review and update legacy system of record notices, the Department of Homeland Security is giving notice that it proposes to consolidate two legacy record systems: Treasury/CS.002-Accident Reports (October 18, 2001), Treasury/CS.151-Motor Vehicle Accident Reports (October 18, 2001), and is no longer depending upon the DOE-38, Occupational and Industrial Accident Records (June 28, 1995) system of records. The Department of Homeland Security is issuing a Department-wide system of records to cover accident records. This system will allow the Department of Homeland Security to collect and maintain records that concern individuals, both Department employees and non-employees, who have been injured on Department property, or while performing their official duties. Categories of individuals, categories of records, routine uses and exemptions of these legacy system of records notices have been consolidated and updated to better reflect the Department's accident record systems. Additionally, a Notice of Proposed Rulemaking will be published elsewhere in the **Federal Register** concurrent with this System of Records. This consolidated system, titled Accident Records, will be included in the Department of Homeland Security's inventory of record systems.

**DATES:** Submit comments on or before December 26, 2008. This new system will be effective December 26, 2008.

**ADDRESSES:** You may submit comments, identified by docket number DHS-2008-0005 by one of the following methods:

- *Federal e-Rulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *Fax:* 1-866-466-5370.
- *Mail:* Hugo Teufel III, Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528.

• *Instructions:* All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change and may be read at <http://www.regulations.gov>, including any personal information provided.

- *Docket:* For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** For general questions and privacy issues please contact: Hugo Teufel III (703-

235-0780), Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

Pursuant to the savings clause in the Homeland Security Act of 2002, Public Law 107-296, Section 1512, 116 Stat. 2310 (November 25, 2002), the Department of Homeland Security (DHS) and its components and offices have relied on preexisting Privacy Act systems of records notices for the collection and maintenance of records that concern individuals, both DHS employees and non-employees, who have been injured on DHS property, or while performing their official duties.

As part of its efforts to streamline and consolidate its records systems, DHS is establishing a consolidated system of records under the Privacy Act (5 U.S.C. 552a) for these accident records. This will ensure that all components of DHS follow the same privacy rules for collecting and maintaining accident records. The collection and maintenance of this information will assist DHS in meeting its obligation to address accident claims for which the agency may be responsible.

In accordance with the Privacy Act of 1974 and as part of DHS's ongoing effort to review and update legacy system of record notices, DHS is giving notice that it proposes to consolidate two legacy record systems: Treasury/CS.002-Accident Reports (66 FR 52984 October 18, 2001), Treasury/CS.151-Motor Vehicle Accident Reports (66 FR 52984 October 18, 2001), and is no longer depending on DOE-38, Occupational and Industrial Accident Records (60 FR 33510 June 28, 1995) system of records. DHS is issuing a DHS-wide system of records to cover accident records. This system will allow DHS to collect and maintain records that concern individuals, both DHS employees and non-employees, who have been injured on DHS property, or while performing their official duties. Categories of records, routine uses and exemptions of these legacy system of records notices have been consolidated and updated to better reflect the Department's accident record systems. Additionally, a Notice of Proposed Rulemaking will be published elsewhere in the **Federal Register** concurrent with this System of Records. This consolidated system, titled Accident Records, will be included in the Department of Homeland Security's inventory of record systems.

**II. Privacy Act**

The Privacy Act embodies fair information principles in a statutory framework governing the means by which the United States Government collects, maintains, uses, and disseminates individuals' records. The Privacy Act applies to information that is maintained in a "system of records." A "system of records" is a group of any records under the control of an agency for which information is retrieved by the name of an individual or by some identifying number, symbol, or other identifying particular assigned to the individual. In the Privacy Act, an individual is defined to encompass United States citizens and legal permanent residents. As a matter of policy, DHS extends administrative Privacy Act protections to all individuals where systems of records maintain information on U.S. citizens, lawful permanent residents, and visitors. Individuals may request access to their own records that are maintained in a system of records in the possession or under the control of DHS by complying with DHS Privacy Act regulations, 6 CFR Part 5.

The Privacy Act requires each agency to publish in the **Federal Register** a description denoting the type and character of each system of records that the agency maintains, and the routine uses that are contained in each system in order to make agency record keeping practices transparent, to notify individuals regarding the uses of their records, and to assist individuals to more easily find such files within the agency. Below is the description of the Accident Records System of Records.

In accordance with 5 U.S.C. 552a(r), DHS has provided a report of this new system of records to the Office of Management and Budget (OMB) and to Congress.

**System of Records:**

DHS/ALL-006

**SYSTEM NAME:**

Department of Homeland Security Accident Records

**SECURITY CLASSIFICATION:**

Unclassified.

**SYSTEM LOCATION:**

Records are maintained at several Headquarters locations and in component offices of DHS, in both Washington, DC, and field locations.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Categories of individuals covered by this system include DHS employees or

contractors and non-employees who have been injured on DHS property, or while performing their official duties. DHS employees or other individuals who file claims seeking benefits under the Federal Employee Compensation Act File (FECA) are covered by DOL/GOVT-1 Workers' Compensation Programs, Federal Employee Compensation Act File, and are not included in this DHS system.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Categories of records in this system include:

- Injured person's name;
- Individual's age;
- Job title;
- Length of employment and current position;
- Employee classification;
- Home address;
- Telephone number;
- Accident and investigation reports;
- Accident and/or report number;
- Date of accident;
- Place of accident;
- Nature of accident;
- Operator license;
- Insurance information;
- Description of injury;
- Description of vehicles involved (title, make, year, license number, driver), if applicable;
- Type of treatment given;
- Description of the damaged property;
- Root cause analysis;
- Safety and health programs involved;
- Records of injuries and illnesses;
- Physicians' reports;
- Incident analysis;
- Short-term and long-term preventive actions taken;
- Correspondence involving insurance claims; and
- Witness, suspect, subject information.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

5 U.S.C. 301; The Federal Records Act, 44 U.S.C. 3101; Section 19 of Occupational Health & Safety Act of 1970; 5 U.S.C. 8101-8150, 8191-8193; Executive Order 11807.

**PURPOSE(S):**

The purpose of this system is to document accidents that occur on DHS property or while an employee or contractor is on official duty.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, all or a portion of the records of information



contained in this system may be disclosed outside DHS as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

A. To the Department of Justice (including United States Attorney Offices) or other Federal agency conducting litigation or in proceedings before any court, adjudicative or administrative body when it is necessary to the litigation and one of the following is a party to the litigation or has an interest in such litigation:

1. DHS or any component thereof;
2. Any employee of DHS in his/her official capacity;
3. Any employee of DHS in his/her individual capacity where the Department of Justice or DHS has agreed to represent the employee; or
4. The United States or any agency thereof, is a party to the litigation or has an interest in such litigation, and DHS determines that the records are both relevant and necessary to the litigation and the use of such records is compatible with the purpose for which DHS collected the records.

B. To a congressional office from the record of an individual in response to an inquiry from that congressional office made at the request of the individual to whom the record pertains.

C. To the National Archives and Records Administration or other Federal government agencies pursuant to records management inspections being conducted under the authority of 44 U.S.C. §§ 2904 and 2906.

D. To an agency, organization, or individual for the purpose of performing audit or oversight operations as authorized by law, but only such information as is necessary and relevant to such audit or oversight function.

E. To appropriate agencies, entities, and persons when:

1. DHS suspects or has confirmed that the security or confidentiality of information in the system of records has been compromised;
2. The Department has determined that as a result of the suspected or confirmed compromise there is a risk of harm to economic or property interests, identity theft or fraud, or harm to the security or integrity of this system or other systems or programs (whether maintained by DHS or another agency or entity) or harm to the individual who relies upon the compromised information; and
3. The disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with DHS's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm.

F. To contractors and their agents, grantees, experts, consultants, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for DHS, when necessary to accomplish an agency function related to this system of records. Individuals provided information under this routine use are subject to the same Privacy Act requirements and limitations on disclosure as are applicable to DHS officers and employees.

G. To an appropriate Federal, State, tribal, local, international, or foreign law enforcement agency or other appropriate authority charged with investigating or prosecuting a violation or enforcing or implementing a law, rule, regulation, or order, where a record, either on its face or in conjunction with other information, indicates a violation or potential violation of law, which includes criminal, civil, or regulatory violations and such disclosure is proper and consistent with the official duties of the person making the disclosure.

H. To the employee's beneficiary in the event of death following the accident or injury or to the employee's agent in case of disability.

I. To a court, magistrate, or administrative tribunal in the course of presenting evidence, including disclosures to opposing counsel or witnesses in the course of civil discovery, litigation, or settlement negotiations or in connection with criminal law proceedings or in response to a subpoena from a court of competent jurisdiction.

J. To third parties during the course of law enforcement investigation to the extent necessary to obtain information pertinent to the investigation, provided disclosure is appropriate to the proper performance of the official duties of the officer making the disclosure.

K. To appropriate Federal, State, local, tribal, or foreign governmental agencies or multilateral governmental organizations for the purpose of protecting the vital interests of a data subject or other persons, including to assist such agencies or organizations in preventing exposure to or transmission of a communicable or quarantinable disease or to combat other significant public health threats; appropriate notice will be provided of any identified health threat or risk.

L. To Department of Labor for processing and adjudicating claims under the Federal Employee's Compensation Act or other workmen's compensation claims.

M. To the news media and the public, with the approval of the Chief Privacy Officer in consultation with counsel,

when there exists a legitimate public interest in the disclosure of the information or when disclosure is necessary to preserve confidence in the integrity of DHS or is necessary to demonstrate the accountability of DHS's officers, employees, or individuals covered by the system, except to the extent it is determined that release of the specific information in the context of a particular case would constitute an unwarranted invasion of personal privacy.

**DISCLOSURE TO CONSUMER REPORTING AGENCIES:**

None.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Records in this system are stored electronically or on paper in secure facilities in a locked drawer behind a locked door. The records are stored on magnetic disc, tape, digital media, and CD-ROM.

**RETRIEVABILITY:**

Records may be retrieved by name, accident and/or report number, and/or date of accident.

**SAFEGUARDS:**

Records in this system are safeguarded in accordance with applicable rules and policies, including all applicable DHS automated systems security and access policies. Strict controls have been imposed to minimize the risk of compromising the information that is being stored. Access to the computer system containing the records in this system is limited to those individuals who have a need to know the information for the performance of their official duties and who have appropriate clearances or permissions.

**RETENTION AND DISPOSAL:**

Records are destroyed six years after a case is closed, in accordance with National Archives and Records Administration General Records Schedule 10, Item 5.

**SYSTEM MANAGER AND ADDRESS:**

For Headquarters and components of DHS, the System Manager is the Director of Departmental Disclosure, Department of Homeland Security, Washington, DC 20528. For components of DHS, the System Manager can be found at <http://www.dhs.gov/foia> under "contacts."

**NOTIFICATION PROCEDURE:**

Individuals seeking notification of and access to any record contained in

this system of records, or seeking to contest its content, may submit a request in writing to the Headquarters or component's FOIA Officer, whose contact information can be found at <http://www.dhs.gov/foia> under "contacts." If an individual believes more than one component maintains Privacy Act records concerning him or her the individual may submit the request to the Chief Privacy Officer, Department of Homeland Security, 245 Murray Drive, SW., Building 410, STOP-0550, Washington, DC 20528.

When seeking records about yourself from this system of records or any other Departmental system of records your request must conform with the Privacy Act regulations set forth in 6 CFR Part 5. You must first verify your identity, meaning that you must provide your full name, current address and date and place of birth. You must sign your request, and your signature must either be notarized or submitted under 28 U.S.C. 1746, a law that permits statements to be made under penalty of perjury as a substitute for notarization. While no specific form is required, you may obtain forms for this purpose from the Director, Disclosure and FOIA, <http://www.dhs.gov> or 1-866-431-0486. In addition you should provide the following:

- An explanation of why you believe the Department would have information on you,
- Identify which component(s) of the Department you believe may have the information about you,
- Specify when you believe the records would have been created,
- Provide any other information that will help the FOIA staff determine which DHS component agency may have responsive records,
- If your request is seeking records pertaining to another living individual, you must include a statement from that individual certifying his/her agreement for you to access his/her records.

Without this bulleted information the component(s) may not be able to conduct an effective search, and your request may be denied due to lack of specificity or lack of compliance with applicable regulations.

**RECORD ACCESS PROCEDURES:**

See "Notification Procedure" above.

**CONTESTING RECORD PROCEDURES:**

See "Notification Procedure" above.

**RECORD SOURCE CATEGORIES:**

Information originates with individuals, including employees and contractors, who have been injured on DHS property or while excising their

official duties. Police reports, witness reports, statements from employees' supervisors, doctors' reports, reports of investigations conducted DHS, and/or insurance claims may also be included.

**EXEMPTIONS CLAIMED FOR THE SYSTEM:**

The Secretary of Homeland Security has exempted this system from subsections (d) of the Privacy Act pursuant to 5 U.S.C. 552a(k)(3).

Dated: November 18, 2008.

**Hugo Teufel III,**

*Chief Privacy Officer, Department of Homeland Security.*

[FR Doc. E8-28057 Filed 11-24-08; 8:45 am]

**BILLING CODE 4410-10-P**

**DEPARTMENT OF HOMELAND SECURITY**

**Coast Guard**

[USCG-2008-1144]

**Towing Safety Advisory Committee; Notice of Open Teleconference Meeting**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of meeting.

**SUMMARY:** This notice announces a teleconference of the Towing Safety Advisory Committee (TSAC). The purpose of this teleconference is for TSAC to discuss and vote on three documents/issues: (1) Task Statement 08-02 regarding clarification of the Apprentice Mate (Steersman) license; (2) the revised report of the Economic Analysis sub-group of the Towing Vessel Inspection Working Group; and (3) a revised Resolution from the Commercial/Recreational Boating Interface Working Group.

**DATES:** The teleconference call will take place on Tuesday December 16, 2008, from 12:30 p.m. until 2:30 p.m. Eastern Time. The meeting may close early if all business is finished. Requests to make oral presentations should reach the Coast Guard on or before December 9, 2008.

**ADDRESSES:** Committee members and the public may participate by dialing 1-877-950-5410; when prompted, enter participant passcode 9876776 followed by the [#] key. Public participation is welcomed; however, the number of teleconference lines is limited and available on a first-come, first-served basis. Members of the public may also participate by coming to Room 1303, U.S. Coast Guard Headquarters, 2100 Second Street, SW., Washington, DC 20593-0001. This Notice and documents identified in the

Supplementary Information section as being available in the docket may be viewed in our online docket, USCG-2008-1144 at <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** For questions on this notice, contact Mr. Gerald Miente, Assistant Designated Federal Officer (ADFO), TSAC, telephone 202-372-1401, fax 202-372-1926, or e-mail [gerald.p.miente@uscg.mil](mailto:gerald.p.miente@uscg.mil).

**SUPPLEMENTARY INFORMATION:** TSAC advises, consults with, and makes recommendations to the Secretary DHS on matters relating to shallow-draft inland and coastal waterway navigation and towing safety. Notice of this meeting is given under the Federal Advisory Committee Act, 5 U.S.C. App. 2 (Pub. L. 92-463). The subject documents are available on the Internet at [www.regulations.gov](http://www.regulations.gov) under the docket number USCG-2008-1144. Once on the Web site, enter the docket number, and click "Go."

**Agenda of Meeting**

- Welcome and Opening Remarks—TSAC Chairman.
- Discussion and voting on the revision and acceptance of draft Task Statement 08-02 "Apprentice Mate" (Steersman).
- Discussion and voting on the approval of a Supplementary Report from the Economic Analysis Subgroup.
- Discussion and voting on the approval of a revised resolution from the Commercial/Recreational Boating Interface Working Group.
- Public comment period (as time permits).
- Meeting adjourned.

**Procedural**

This meeting is open to the public. Please note that the meeting may adjourn early if all business is finished. At the Chair's discretion, members of the public may make oral presentations during the meeting. If you would like to make an oral presentation at the meeting, please notify Mr. Miente no later than December 9, 2008. Written material for distribution at a meeting should reach the Coast Guard no later than December 9, 2008. If you would like a copy of your material distributed to each member of the committee in advance of a meeting, please submit material electronically via e-mail to the ADFO no later than December 9, 2008.

**Information on Services for Individuals With Disabilities**

For information on facilities or services for individuals with disabilities

or to request special assistance at the meetings, contact Mr. Miente as soon as possible.

Dated: November 20, 2008.

**Howard L. Hime,**

*Acting Director of Commercial Regulations and Standards.*

[FR Doc. E8-27983 Filed 11-24-08; 8:45 am]

BILLING CODE 4910-15-P

## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

[FEMA-1809-DR]

#### Missouri; Major Disaster and Related Determinations

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Notice.

**SUMMARY:** This is a notice of the Presidential declaration of a major disaster for the State of Missouri (FEMA-1809-DR), dated November 13, 2008, and related determinations. **DATES:** *Effective Date:* November 13, 2008.

**FOR FURTHER INFORMATION CONTACT:** Peggy Miller, Disaster Assistance Directorate, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646-3886.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given that, in a letter dated November 13, 2008, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121-5207 (the Stafford Act), as follows:

I have determined that the damage in certain areas of the State of Missouri resulting from severe storms, flooding, and a tornado during the period of September 11-24, 2008, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121-5207 (the Stafford Act). Therefore, I declare that such a major disaster exists in the State of Missouri.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Individual Assistance and Public Assistance in the designated areas and Hazard Mitigation throughout the State. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Hazard Mitigation and Other Needs Assistance will be limited to 75 percent of the total eligible costs.

Federal funds provided under the Stafford Act for Public Assistance also will be limited to 75 percent of the total eligible costs, except for any particular projects that are eligible for a higher Federal cost-sharing percentage under the FEMA Public Assistance Pilot Program instituted pursuant to 6 U.S.C. 777.

Further, you are authorized to make changes to this declaration to the extent allowable under the Stafford Act.

The time period prescribed for the implementation of section 310(a), Priority to Certain Applications for Public Facility and Public Housing Assistance, 42 U.S.C. 5153, shall be for a period not to exceed six months after the date of this declaration.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Michael L. Karl, of FEMA, is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas of the State of Missouri have been designated as adversely affected by this major disaster:

Boone, Callaway, Chariton, Lewis, Lincoln, Linn, Marion, Osage, Schuyler, St. Charles, St. Louis, Stone, Taney, Texas, and Webster Counties and the Independent City of St. Louis, for Individual Assistance.

Adair, Audrain, Barry, Bollinger, Butler, Callaway, Cape Girardeau, Carter, Chariton, Christian, Clark, Crawford, Dent, Douglas, Dunklin, Howard, Howell, Knox, Lewis, Lincoln, Linn, Madison, Maries, Marion, Miller, New Madrid, Oregon, Ozark, Perry, Ralls, Ray, Reynolds, Ripley, Schuyler, Scotland, Scott, Shannon, Shelby, St. Genevieve, Stoddard, Stone, Sullivan, Taney, Texas, Wayne, Webster, and Wright Counties, for Public Assistance.

All counties and the Independent City of St. Louis within the State of Missouri are eligible to apply for assistance under the Hazard Mitigation Grant Program.

(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.)

**R. David Paulison,**

*Administrator, Federal Emergency Management Agency.*

[FR Doc. E8-27912 Filed 11-24-08; 8:45 am]

BILLING CODE 9111-23-P

## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

[FEMA-1800-DR]

#### Illinois; Amendment No. 5 to Notice of a Major Disaster Declaration

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Notice.

**SUMMARY:** This notice amends the notice of a major disaster declaration for the State of Illinois (FEMA-1800-DR), dated October 3, 2008, and related determinations.

**DATES:** *Effective Date:* November 18, 2008.

**FOR FURTHER INFORMATION CONTACT:** Peggy Miller, Disaster Assistance Directorate, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646-3886.

**SUPPLEMENTARY INFORMATION:** The notice of a major disaster declaration for the State of Illinois is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of October 3, 2008.

Will and Woodford Counties for Public Assistance (already designated for Individual Assistance).

Bureau, Cass, Greene, Kendall, Macoupin, Montgomery and Scott Counties for Public Assistance.

(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.)

**R. David Paulison,**

*Administrator, Federal Emergency Management Agency.*

[FR Doc. E8-27913 Filed 11-24-08; 8:45 am]

BILLING CODE 9111-23-P

**DEPARTMENT OF HOMELAND SECURITY****Federal Emergency Management Agency****[FEMA-3295-EM]****Louisiana; Amendment No. 1 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 Louisiana (FEMA-3295-EM), dated September 11, 2008, and related determinations.

**DATES:** *Effective Date:* November 7, 2008.

**FOR FURTHER INFORMATION CONTACT:**

Peggy Miller, Disaster Assistance Directorate, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646-3886.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given that the incident period for this emergency is closed effective November 7, 2008.

(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.)

**R. David Paulison,**  
*Administrator, Federal Emergency Management Agency.*

[FR Doc. E8-27966 Filed 11-24-08; 8:45 am]

**BILLING CODE 9111-23-P****DEPARTMENT OF HOMELAND SECURITY****Federal Emergency Management Agency****[FEMA-1792-DR]****Louisiana; Amendment No. 6 to Notice of a Major Disaster Declaration****AGENCY:** Federal Emergency Management Agency, DHS.**ACTION:** Notice.

**SUMMARY:** This notice amends the notice of a major disaster declaration for the State of Louisiana (FEMA-1792-DR), dated September 13, 2008 and related determinations.

**DATES:** *Effective Date:* November 7, 2008.

**FOR FURTHER INFORMATION CONTACT:**

Peggy Miller, Disaster Assistance Directorate, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646-3886.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given that the incident period for this disaster is closed effective November 7, 2008.

(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.)

**R. David Paulison,**  
*Administrator, Federal Emergency Management Agency.*

[FR Doc. E8-27964 Filed 11-24-08; 8:45 am]

**BILLING CODE 9111-23-P****DEPARTMENT OF HOMELAND SECURITY****U.S. Customs and Border Protection****Notice of Issuance of Final Determination Concerning Multifunctional Machines**

**AGENCY:** U.S. Customs and Border Protection, Department of Homeland Security.

**ACTION:** Notice of final determination.

**SUMMARY:** This document provides notice that U.S. Customs and Border Protection ("CBP") has issued a final determination concerning the country of origin of certain multifunctional machines which may be offered to the United States Government under a government procurement contract. Based upon the facts presented, in the final determination CBP concluded that Japan is the country of origin of the multifunctional machines for purposes of U.S. Government procurement.

**DATES:** The final determination was issued on November 7, 2008. A copy of the final determination is attached. Any party-at-interest, as defined in 19 CFR 177.22(d), may seek judicial review of this final determination within December 26, 2008.

**FOR FURTHER INFORMATION CONTACT:**

Karen S. Greene, Valuation and Special Programs Branch, Regulations and Rulings, Office of International Trade (202-572-8838).

**SUPPLEMENTARY INFORMATION:** Notice is hereby given that on, pursuant to subpart B of part 177, Customs Regulations (19 CFR part 177, subpart B), CBP issued a final determination concerning the country of origin of certain multifunctional machines which may be offered to the United States Government under a government procurement contract. This final determination, in HQ H020516, was issued at the request of Sharp Electronics Corporation under procedures set forth at 19 CFR part 177, subpart B, which implements Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. 2511-18). In the final determination, CBP concluded that, based upon the facts presented, certain articles will be substantially transformed in Japan. Therefore, CBP found that Japan is the country of origin of the finished articles for purposes of U.S. Government procurement.

Section 177.29, Customs Regulations (19 CFR 177.29), provides that notice of final determinations shall be published in the **Federal Register** within 60 days of the date the final determination is issued. Section 177.30, CBP Regulations (19 CFR § 177.30), provides that any party-at-interest, as defined in 19 CFR 177.22(d), may seek judicial review of a final determination within 30 days of publication of such determination in the **Federal Register**.

Dated: November 20, 2008.

**Sandra L. Bell,**  
*Executive Director, Office of Regulations and Rulings, Office of International Trade.*

**HQ H020516**

November 7, 2008.

OT: RR:CTF:VS H020516 KSG.  
Mr. Edmund Baumgartner, Esq., Pillsbury Winthrop Shaw Pittman LLP, 1540 Broadway, New York, NY 10036.  
Re: U.S. Government Procurement; country of origin of multifunctional machines; substantial transformation.  
Dear Mr. Baumgartner:

This is in response to your letter, dated November 26, 2007, requesting a final determination on behalf of Sharp Electronics Corporation ("Sharp")

pursuant to subpart B of 19 CFR Part 177.

Under these regulations, which implement Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. 2511 *et seq.*), CBP issues country of origin advisory rulings and final determinations as to whether an article is or would be a product of a designated country or instrumentality for the purposes of granting waivers of certain "Buy American" restrictions in U.S. law or practice for products offered for sale to the U.S. Government.

This final determination concerns the country of origin of certain multifunctional machines that Sharp may sell to the U.S. Government. We note that Sharp is a party-at-interest within the meaning of 19 CFR 177.22(d)(1) and is entitled to request this final determination. A conference was held on this matter at Headquarters on August 25, 2008.

#### Facts:

This case involves the Sharp Andromeda II J-models (Sharp model # AR-M257J, AR-M317J). These models have monochrome copying, printing, faxing and scanning functions. Model #AR-M257J and ARM-317J are designed to print 25 and 31 pages per minute.

Sharp Corporation, Sharp's parent company ("Sharp Japan") developed the Andromeda J-models in Japan; all the engineering, development, design and art work processes were developed in Japan.

There are 8 main subassemblies that compose the Andromeda II J-models. Two subassemblies involve processing in Japan: The multifunctional printer ("MFP") control unit and process unit. Subassemblies made in China include: The laser scanner unit ("LSU"); transfer unit; the MFP cabinet unit; the developer unit ("DV") unit; fusing unit; and the reversible single pass feeder ("RSPF").

The MFP control unit is the combination of a printed circuit board with a number of sophisticated integrated circuits. The flash read-only memory ("ROM"), which you state is the primary component, is manufactured in Japan. The CPU, the integrated circuit for the main control unit ("MCU"), and the printed wiring board ("PCB") for the integrated memory controller, which you state are the key parts of the control printer boards, are produced in Japan. Other components such as diodes, resistors and capacitors are installed on the control printer board in China.

The process unit subassembly houses the drum used for creating images. The

drum is produced and installed in Japan using parts made in China, such as the flanges and the gear. Assembly in China includes integration of the drum support frame and the main charger unit.

The LSU unit creates text or images on the photoconductor drum. The LSU unit is assembled in China. The laser diode and the synchronous lenses, which you state are critical components, are produced in Japan.

The transfer unit uses a roller to place the image created on the drum onto the paper. This unit is assembled in China. The transfer rollers are made in Japan.

The MPF cabinet unit is the outer body of the multifunctional system. Several parts are made in Japan including the motor driver, parts of the scanner, the application-specific integrated circuits ("ASIC"), the CPU, the flash ROM and the program for the ASIC. You state that when the unit leaves China, it is not functional because there is no process unit, transfer unit or fusing unit. You state that the core parts for forming the images, such as the main board, the transfer unit, the DV unit and the process unit, are installed in Japan.

The DV unit is used to transfer toner evenly over the latent image created on the drum unit. The unit is assembled in China. The developer (iron powder beads), the toner cartridge and the toner are produced in Japan.

The fusing unit is used to fix the transferred image onto paper. It is assembled in China. Certain components such as the fusing gear, the separator pawl and thermostat, which you state are critical, are produced and tested in Japan.

Lastly, the RSPF transports the original document to the part of the machine used for scanning the image. It is assembled in China.

The final assembly of the machines takes place in Japan. Sharp Japan starts with a MFP cabinet unit subassembly and assembles the key subassemblies described above into the cabinet by screws. The flash ROM is installed into the slot on the rear of the MFP cabinet unit and fixed with screws. The Andromeda II J-models consist of 2914 pieces of parts, and over 30 percent of them are assembled in Japan.

Extensive testing and final inspection and packaging of the units for shipment to the U.S. occurs in Japan.

The imported J-models are classified in subheading 8443.31 of the Harmonized Tariff Schedule of the United States ("HTSUS"). The subassemblies imported into Japan are classified in subheading 8443.99.5015, HTSUS.

#### Issue

What is the country of origin of the subject multifunctional machines for the purpose of U.S. Government procurement?

#### Law and Analysis

Pursuant to Subpart B of Part 177, 19 CFR 177.21 *et seq.*, which implements Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. 2511 *et seq.*), CBP issues country of origin advisory rulings and final determinations as to whether an article is or would be a product of a designated country or instrumentality for the purposes of granting waivers of certain "Buy American" restrictions in U.S. law or practice for products offered for sale to the U.S. Government.

Under the rule of origin set forth under 19 U.S.C. 2518(4)(B):

An article is a product of a country or instrumentality only if (i) it is wholly the growth, product, or manufacture of that country or instrumentality, or (ii) in the case of an article which consists in whole or in part of materials from another country or instrumentality, it has been substantially transformed into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was so transformed.

See also 19 CFR 177.22(a).

In determining whether the combining of parts or materials constitutes a substantial transformation, the determinative issue is the extent of operations performed and whether the parts lose their identity and become an integral part of the new article. *Belcrest Linens v. United States*, 573 F. Supp. 1149 (Ct. Int'l Trade 1983), *aff'd*, 741 F.2d 1368 (Fed. Cir. 1984). Assembly operations that are minimal or simple, as opposed to complex or meaningful, will generally not result in a substantial transformation. See C.S.D. 80-111, C.S.D. 85-25, C.S.D. 89-110, C.S.D. 89-118, C.S.D. 90-51, and C.S.D. 90-97. In C.S.D. 85-25, 19 Cust. Bull. 844 (1985), CBP held that for purposes of the Generalized System of Preferences ("GSP"), the assembly of a large number of fabricated components onto a printed circuit board in a process involving a considerable amount of time and skill resulted in a substantial transformation. In that case, in excess of 50 discrete fabricated components (such as resistors, capacitors, diodes, integrated circuits, sockets, and connectors) were assembled. Whether an operation is complex and meaningful depends on the nature of the operation, including the number of components assembled, number of different operations, time, skill level required, attention to detail, quality control, the value added to the

article, and the overall employment generated by the manufacturing process.

The courts and CBP have also considered the essential character of the imported article in making these determinations. See *Uniroyal, Inc. v. United States*, 542 F. Supp. 1026, 3 CIT 220, 224–225 (1982) (where it was determined that imported uppers were the essence of a completed shoe) and *National Juice Products Association, et al v. United States*, 628 F. Supp. 978, 10 CIT 48, 61 (1986) (where the court addressed each of the factors (name, character, and use) in finding that no substantial transformation occurred in the production of retail juice products from manufacturing concentrate).

In order to determine whether a substantial transformation occurs when components of various origins are assembled into completed products, CBP considers the totality of the circumstances and makes such determinations on a case-by-case basis. The country of origin of the item's components, extent of the processing that occurs within a country, and whether such processing renders a product with a new name, character, and use are primary considerations in such cases. Additionally, factors such as the resources expended on product design and development, extent and nature of post-assembly inspection and testing procedures, and worker skill required during the actual manufacturing process will be considered when determining whether a substantial transformation has occurred. No one factor is determinative.

CBP has held in a number of cases involving similar merchandise that complex and meaningful assembly operations involving a large number of components result in a substantial transformation. In Headquarters Ruling Letter ("HRL") 563491 (February 8, 2007), CBP addressed the country of origin of certain digital color multifunctional systems manufactured by Sharp and assembled in Japan of various Japanese—and Chinese—origin parts. In that ruling, CBP determined that color multifunctional systems were a product of Japan based on the fact that "although several subassemblies are assembled in China, enough of the Japanese subassemblies and individual components serve major functions and are high in value, in particular, the transfer belt, control box unit, application-specific integrated circuits, charged couple device, and laser diodes." Further CBP found that the testing and adjustments performed in Japan were technical and complex and the assembly operations that occurred in Japan were sufficiently complex and

meaningful. Thus, through the product assembly and testing and adjustment operations, the individual components and subassemblies of Japanese and foreign-origin were subsumed into a new and distinct article of commerce that had a new name, character, and use. See also HRL 562936, dated March 17, 2004.

In HRL 561734, dated March 22, 2001, CBP held that certain multifunctional machines (consisting of printer, copier, and fax machines) assembled in Japan were a product of that country for the purposes of U.S. government procurement. The multifunctional machines were assembled from 227 parts (108 parts obtained from Japan, 92 from Thailand, 3 from China, and 24 from other countries) and eight subassemblies, each of which was assembled in Japan. See also HRL 561568, dated March 22, 2001.

Counsel states that the engineering, design and development of these machines takes place entirely in Japan. A number of components that are claimed to be critical such as the flash ROM, CPU, ASIC's, transfer roller, a charge-coupled device ("CCD"), synchronous lenses, laser diodes, drums, developer and toner are made in Japan. The final assembly and adjustment/alignment/testing procedures required for these J-model are also performed in Japan and claimed to be extremely sophisticated. Counsel states that unless the J-models are properly adjusted and aligned, they do not become marketable products and this adjustment process requires a high level of technical skills.

We agree that the J-models discussed in this ruling are considered a product of Japan. As noted above, the engineering, design and development of the multifunctional machines occurs in Japan. Moreover, a substantial portion of the components and assemblies are of Japanese origin. Sharp describes many of these components as critical. We note that several of the components used in the Chinese-origin subassemblies are of Japanese origin. Further, the processing that occurs in Japan is complex and meaningful, requiring the assembly of a large number of components, that results in a new and distinct article of commerce with a new name, character and use. As Japan is the final country of production and a substantial amount of work is performed there, we find that the Andromeda II-J multifunctional machines are products of Japan for the purposes of U.S. Government procurement.

#### Holding

Based on the facts of this case, we find that the processing in Japan substantially transforms the non-Japanese components. Therefore, the country of origin of the Sharp Andromeda II J-model multifunctional machines is Japan for purposes of U.S. Government procurement.

Notice of this final determination will be given in the **Federal Register**, as required by 19 CFR 177.29. Any party-at-interest other than the party which requested this final determination may request, pursuant to 19 CFR 177.31 that CBP reexamine the matter anew and issue a new final determination. Pursuant to 19 CFR 177.30, any party-at-interest may, within 30 days after publication of the **Federal Register** Notice referenced above, seek judicial review of this final determination before the Court of International Trade.

Sincerely, Sandra L. Bell  
Executive Director, Office of  
Regulations and Rulings, Office of  
International Trade

[FR Doc. E8–28014 Filed 11–24–08; 8:45 am]  
BILLING CODE 9111–14–P

#### DEPARTMENT OF THE INTERIOR

##### Fish and Wildlife Service

[FWS–R8–ES–2008–N0296; 1112–000–81420–F2]

##### Habitat Conservation Plan for Pacific Gas & Electric Company's Operation, Maintenance, and Minor New Construction Activities in the North Coast, Central Coast, Sacramento Valley, and Sierra Regions, California

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Notice of intent to prepare an environmental impact statement and notice of public scoping meetings.

**SUMMARY:** Pursuant to the National Environmental Policy Act (NEPA), we, the U.S. Fish and Wildlife Service (Service), are issuing this notice to advise the public that we intend to gather information necessary to prepare, in coordination with the California Department of Fish and Game (DFG) and Pacific Gas & Electric Company (PG&E), a joint Environmental Impact Statement/Environmental Impact Report (EIS/EIR) on the PG&E Multiple-Region (North Coast, Central Coast, Sacramento Valley, Sierra) Operations, Maintenance, and Minor New Construction Habitat Conservation Plan (HCP). The HCP is being prepared under Section 10(a)(1)(B) of the Federal Endangered

Species Act of 1973, as amended (Act). PG&E intends to request a permit to cover 75 species federally listed as threatened or endangered and 34 unlisted species that may become listed during the term of the permit. The permit is needed to authorize incidental take of listed species that could occur as a result of implementing activities covered under the HCP.

The Service provides this notice to:

- (1) Describe the proposed action and possible alternatives;
- (2) advise other Federal and State agencies, affected Tribes, and the public of our intent to prepare an EIS/EIR;
- (3) announce the initiation of a public scoping period;
- and (4) obtain suggestions and information on the scope of issues and alternatives to be included in the EIS/EIR.

**DATES:** We must receive your written comments on or before December 26, 2008. We will hold a public meeting on Thursday, December 4, 2008, 2 p.m. to 4 p.m., Sacramento CA.

A Web conference is scheduled for the same date as the public meeting, from 5 p.m. to 7 p.m. Conference Title: PG&E Multiple Region HCP EIS/EIR Scoping. In order to hear the audio for the conference, you must dial: 877-741-4242, and enter passcode: 1495039, for the operator or automated response system. If needed, dial 0 for technical assistance. First you must test your browser for compatibility at the following URL prior to the web event date: <https://www112.livemeeting.com/cc/test2007/join?id=LiveMeeting2007Test&role=attend&cn=user&pw=&recording&agreement=accepted&placewareLicenseCookie=true>

Please note that this is only the browser check link and not the link to the actual event. Once you have

successfully joined the test meeting, you may exit. Second, join conference 10 minutes prior to event start: <https://www.livemeeting.com/cc/vcc/join?id=w1495039&role=attend&pw=A149503>. If you have problems entering the conference using the above link, please type in the meeting URL: <https://www119.livemeeting.com/cc/vcc/join> and enter the Meeting ID: w1495039, and Entry Code: A149503, when prompted.

**ADDRESSES:** The public meeting will be held at the following location: Thursday, December 4, 2008, at the Evelyn Moore Community Center, 1402 Dickson Street, Sacramento, CA.

Information, written comments, or questions related to the preparation of the EIS/EIR and NEPA process should be submitted to Eric Tattersall, Chief, Conservation Planning and Recovery Division, U.S. Fish and Wildlife Service, Sacramento Fish and Wildlife Office, 2800 Cottage Way, W-2605, Sacramento, California 95825; Fax 916-414-6713.

**FOR FURTHER INFORMATION CONTACT:** Eric Tattersall, Chief, Conservation Planning and Recovery Division, at the Sacramento Fish and Wildlife Office at 916-414-6600.

**SUPPLEMENTARY INFORMATION:**

**Reasonable Accommodation**

Persons needing reasonable accommodations in order to attend and participate in the public meeting should contact Eric Tattersall at 916-414-6600 as soon as possible. In order to allow sufficient time to process requests, please submit them at least 1 week before the public meeting. Information regarding this proposed action is available in alternative formats upon request.

**Background**

Section 9 of the Act and Federal regulations prohibit the "take" of fish and wildlife species listed as endangered or threatened. Under the Act, the following activities are defined as take: To harass, harm, pursue, hunt, shoot, wound, kill, trap, capture or collect listed animal species, or attempt to engage in such conduct [16 U.S.C. 1532(19)]. However, under Section 10(a) of the Act, we may issue permits to authorize "incidental take" of listed species. "Incidental take" is defined by the Act as take that is incidental to, and not the purpose of, carrying out an otherwise lawful activity. Regulations governing permits for threatened species and endangered species, respectively, are at 50 CFR 17.32 and 50 CFR 17.22.

Take of listed plant species is not prohibited under the Act and cannot be authorized under a Section 10(a)(1)(B) permit. However, plant species may be included on a permit in recognition of conservation benefits provided for them under the HCP. All species included on the permit would receive assurances under the Service's "No Surprises" regulation 50 CFR 17.22(b)(5) and 17.32(b)(5).

Currently, PG&E intends to request a permit for 109 species under the HCP: 75 listed and 34 unlisted species (covered species) (Table 1). This proposed species list may change during the development of the HCP. Specific PG&E regions in the Plan Area are abbreviated as follows: CC = Central Coast, NC = North Coast, S = Sierra, and SV = Sacramento Valley. Categories of listing status (Federal, under the Act) are abbreviated as follows: N = not listed, D = de-listed, C = candidate, T = threatened, and E = endangered.

TABLE 1—PROPOSED COVERED SPECIES

Species	PG&E regions				Listing status*
	CC	NC	S	SV	
<b>Invertebrates</b>					
Conservancy fairy shrimp ( <i>Branchinecta conservatio</i> )				X	E
Vernal pool fairy shrimp ( <i>Branchinecta lynchi</i> )	X			X	T
Ohlone tiger beetle ( <i>Cicindela ohlone</i> )	X				E
Valley elderberry longhorn beetle ( <i>Desmocerus californicus dimorphus</i> )				X	T
Smith's blue butterfly ( <i>Euphilotes enoptes smithi</i> )	X				E
Kern primrose sphinx moth ( <i>Euproserpinus euterpe</i> )	X				T
Morro shoulderband snail ( <i>Helminthoglypta walkeriana</i> )	X				E
Vernal pool tadpole shrimp ( <i>Lepidurus packardii</i> )	X			X	E
Lotis blue butterfly ( <i>Lycæides argyrognomon lotis</i> )		X			E
Shasta crayfish ( <i>Pacifastacus fortis</i> )		X			E
Mount Hermon June beetle ( <i>Polyphylla barbata</i> )	X				E
Behren's silverspot butterfly ( <i>Speyeria zerene behrensi</i> )		X			E
Zayante band-winged grasshopper ( <i>Trimerotropis infantilis</i> )	X				E
<b>Amphibians:</b>					
California tiger salamander—Central California Distinct Population Segment ( <i>Ambystoma californiense</i> )			X	X	T

TABLE 1—PROPOSED COVERED SPECIES—Continued

Species	PG&E regions				Listing status <sup>1</sup>
	CC	NC	S	SV	
California tiger salamander—Santa Barbara County Distinct Population Segment ( <i>Ambystoma californiense</i> )	X				E
Santa Cruz long-toed salamander ( <i>Ambystoma macrodactylum croceum</i> )	X				E
Tehachapi slender salamander ( <i>Batrachoseps stebbinsi</i> )	X				N
Arroyo toad ( <i>Bufo californicus</i> )	X				E
Shasta salamander ( <i>Hydromantes shastae</i> )		X		X	N
California red-legged frog ( <i>Rana aurora draytonii</i> )	X	X	X	X	T
Foothill yellow-legged frog ( <i>Rana boylei</i> )		X		X	N
Mountain yellow-legged frog ( <i>Rana muscosa</i> )			X		C
Southern torrent salamander ( <i>Rhyacotriton variegatus</i> )		X			N
Reptiles:					
Western pond turtle ( <i>Clemmys-Actinemys</i> <i>marmorata</i> )	X	X		X	N
Blunt-nosed leopard lizard ( <i>Gambelia silus</i> )	X				E
Giant garter snake ( <i>Thamnophis gigas</i> )				X	T
Birds:					
Tricolored blackbird ( <i>Agelaius tricolor</i> )	X	X	X	X	N
Golden eagle ( <i>Aquila chrysaetos</i> )	X	X	X	X	N
Western burrowing owl ( <i>Athene cunicularia</i> )	X			X	N
Marbled murrelet ( <i>Brachyramphus marmoratus</i> )	X	X			T
Swainson's hawk ( <i>Buteo swainsoni</i> )				X	N
Western snowy plover—Pacific Coast Population ( <i>Charadrius alexandrinus nivosus</i> )	X	X			T
Western yellow-bill cuckoo ( <i>Coccyzus americanus occidentalis</i> )	X			X	C
Willow flycatcher ( <i>Empidonax traillii</i> )	X			X	E
Southwestern willow flycatcher ( <i>Empidonax traillii eximius</i> )	X				N
American peregrine falcon ( <i>Falco peregrinus anatum</i> )		X	X	X	D
Bald eagle ( <i>Haliaeetus leucocephalus</i> )	X	X	X	X	D
California black rail ( <i>Laterallus jamaicensis coturniculus</i> )	X	X		X	N
California brown pelican ( <i>Pelecanus occidentalis californicus</i> )	X				E**
Purple martin ( <i>Progne subis</i> )				X	N
California clapper rail ( <i>Rallus longirostris obsoletus</i> )	X	X		X	E
Great gray owl ( <i>Strix nebulosa</i> )		X	X	X	N
Northern spotted owl ( <i>Strix occidentalis caurina</i> )		X		X	T
Least Bell's vireo ( <i>Vireo bellii pusillus</i> )	X				E
Mammals:					
San Joaquin antelope ground squirrel ( <i>Ammospermophilus nelsoni</i> )	X				N
Point Arena mountain beaver ( <i>Apodontia rufa nigra</i> )		X			E
Giant kangaroo rat ( <i>Dipodomys ingens</i> )	X				E
Fisher—West Coast Distinct Population Segment ( <i>Martes pennanti</i> )		X	X	X	C
San Joaquin kit fox ( <i>Vulpes macrotis mutica</i> )	X			X	E
Plants:					
McDonald's rock-cress ( <i>Arabis mcdonaldiana</i> )		X			E
Hearst's Manzanita ( <i>Arctostaphylos hookeri</i> ssp. <i>hearstiorum</i> )	X				N
Morro Manzanita ( <i>Arctostaphylos morroensis</i> )	X				T
Marsh sandwort ( <i>Arenaria paludicola</i> )	X				E
Coastal dunes milk-vetch ( <i>Astragalus tener</i> var. <i>titi</i> )	X				E
San Benito evening-primrose ( <i>Camissonia benitensis</i> )	X				T
California jewel-flower ( <i>Caulanthus californicus</i> )	X				E
Hearst's ceanothus ( <i>Ceanothus hearstiorum</i> )	X				N
Maritime ceanothus ( <i>Ceanothus maritimus</i> )	X				N
Purple amole ( <i>Chlorogalum purpureum</i> )—includes both <i>Chlorogalum purpureum</i> var. <i>purpureum</i> and <i>Chlorogalum purpureum</i> var. <i>reductum</i>	X				T
Howell's spineflower ( <i>Chorizanthe howellii</i> )		X			E
Ben Lomond spineflower ( <i>Chorizanthe pungens</i> var. <i>hartwegiana</i> )	X				E
Monterey spineflower ( <i>Chorizanthe pungens</i> var. <i>pungens</i> )	X				T
Scott's Valley spineflower ( <i>Chorizanthe robusta</i> var. <i>hartwegii</i> )	X				E
Robust spineflower ( <i>Chorizanthe robusta</i> var. <i>robusta</i> )	X				E
Chorro Creek bog thistle ( <i>Cirsium fontinale</i> var. <i>obispoense</i> )	X				E
La Graciosa thistle ( <i>Cirsium loncholepis</i> )	X				E
Pismo clarkia ( <i>Clarkia speciosa</i> ssp. <i>immaculata</i> )	X				E
Salt marsh bird's-beak ( <i>Cordylanthus maritimus</i> ssp. <i>maritimus</i> )	X				E
Palmate-bracted bird's beak ( <i>Cordylanthus palmatus</i> )				X	E
Seaside bird's-beak ( <i>Cordylanthus rigidus</i> ssp. <i>littoralis</i> )	X				N
Santa Cruz cypress ( <i>Cupressus abramsiana</i> )	X				E
Gowen cypress ( <i>Cupressus goveniana</i> ssp. <i>goveniana</i> )	X				T
Gaviota tarplant ( <i>Deinandra increscens</i> ssp. <i>villosa</i> )	X				E
Indian Knob mountain balm ( <i>Eriodictyon altissimum</i> )	X				E
Lompoc yerba santa ( <i>Eriodictyon capitatum</i> )	X				E
Butterworth's buckwheat ( <i>Eriogonum butterworthianum</i> )	X				N
Red Mountain (Kelloggs') buckwheat ( <i>Eriogonum kelloggii</i> )		X			C
Loch Lomond button-celery ( <i>Eryngium constancei</i> )		X			E



TABLE 1—PROPOSED COVERED SPECIES—Continued

Species	PG&E regions				Listing status*
	CC	NC	S	SV	
Menzies' wallflower ( <i>Erysimum menziesii</i> )—includes both.					
<i>Erysimum menziesii</i> ssp. <i>eurekaense</i> and <i>Erysimum menziesii</i> ssp. <i>yadonii</i>		X			E
Santa Cruz wallflower ( <i>Erysimum teretifolium</i> )	X				E
Monterey gilia ( <i>Gilia tenuiflora</i> ssp. <i>arenaria</i> )	X				E
Santa Cruz tarplant ( <i>Holocarpha macradenia</i> )	X				T
Burke's goldfields ( <i>Lasthenia burkei</i> )		X			E
Contra Costa goldfields ( <i>Lasthenia conjugens</i> )		X		X	E
Beach layia ( <i>Layia carnosa</i> )		X		X	E
Western lily ( <i>Lilium occidentale</i> )		X			E
Nipomo Mesa lupine ( <i>Lupinus nipomensis</i> )	X				E
Tidestrom's (clover) lupine ( <i>Lupinus tidestromii</i> )	X				E
San Joaquin woolly-threads ( <i>Monolopia congdonii</i> )	X				E
Few-flowered navarretia ( <i>Navarretia leucocephala</i> ssp. <i>pauciflora</i> )		X			E
Many-flowered navarretia ( <i>Navarretia leucocephala</i> ssp. <i>plieantha</i> )		X			E
Lake County stonecrop ( <i>Parvisedum leiocarpum</i> )		X			E
Dudley's lousewort ( <i>Pedicularis dudleyi</i> )	X				N
White-rayed pentachaeta ( <i>Pentachaeta bellidiflora</i> )	X				E
Yadon's pipeira ( <i>Piperia yadonii</i> )	X				E
San Francisco popcorn-flower ( <i>Plagiobothrys diffusus</i> )	X				N
Santa Lucia mint ( <i>Pogogyne clareana</i> )	X				N
Scott's Valley polygonum ( <i>Polygonum hickmanii</i> )	X				E
Hickman's cinquefoil ( <i>Potentilla hickmanii</i> )	X				N
Gambel's watercress ( <i>Rorippa gambellii</i> )	X				E
Adobe sanicle ( <i>Sanicula maritime</i> )	X				N
Red Mountain stonecrop ( <i>Sedum eastwoodiae</i> )		X			C
Cuesta Pass checkerbloom ( <i>Sidalcea hickmanii</i> ssp. <i>anomala</i> )	X				N
Parish's checkerbloom ( <i>Sidalcea hickmanii</i> ssp. <i>parishii</i> )	X				C
California seablite ( <i>Suaeda californica</i> )	X				E
Santa Ynez false lupine ( <i>Thermopsis macrophylla</i> )	X				N
Kneeland Prairie penny-cress ( <i>Thlaspi californicum</i> )		X			E
Pacific Grove clover ( <i>Trifolium polyodon</i> )	X				N
Monterey clover ( <i>Trifolium trichocalyx</i> )	X				E

NOTES:

\* Species with listing status of D or N are included in the Plan as covered species, in case they become listed during the course of the HCP.

\*\* The California brown pelican was proposed for delisting by the Service on February 20, 2008 (73 FR 9408).

The Plan Area includes approximately 550,000 acres and includes the right-of-way surrounding gas and electric transmission and distribution facilities, the lands owned by PG&E and/or subject to PG&E easements for these facilities, private access routes associated with PG&E's activities, future minor new construction areas, and mitigation areas for impacts resulting from PG&E's activities. The Plan Area includes the network of PG&E facilities in 36 counties, including 18 counties within the Sacramento Valley region, 20 counties within the Sierra region (of which 12 overlap with Sacramento Valley), 6 counties within the Central Coast region, and 4 counties within the North Coast region. The Sacramento Valley region includes the following counties: Tuolumne, Calaveras, Amador, Sacramento, Yolo, Sutter, Butte, Glenn, Yuba, El Dorado, Placer, Nevada, Sierra, Plumas, Colusa, Tehama, Trinity, and Shasta. The counties within the Sierra region include: Modoc, Siskiyou, Lassen, Shasta, Tehama, Butte, Plumas, Sierra,

Nevada, Placer, Yuba, El Dorado, Amador, Calaveras, Alpine, Tuolumne, Mariposa, Madera, Fresno, and Tulare. The Central Coast region consists of the following counties: Santa Cruz, San Benito, Monterey, San Luis Obispo, Santa Barbara, and Kern. The North Coast region consists of the following counties: Humboldt, Trinity, Mendocino, and Lake.

Activities that may be covered under the HCP include a variety of tasks associated with the operation, maintenance, and minor new construction of PG&E's gas and electric transmission and distribution system, as mandated for public safety by the California Public Utilities Commission, the California Energy Commission, and the California Department of Transportation. More specifically, these activities may include: gas pipeline protection, recoating, repair, and replacement; electric line protection, repair, reconductoring, and replacement; electric pole repair/replacement; vegetation management to maintain clearances around facilities; and minor construction for new gas and

electric extensions. The HCP would not cover operation, maintenance, or construction of power generation facilities. The Service, DFG, and PG&E are now considering components of a conservation program in the HCP. These components would include measures to avoid, minimize, and mitigate take, such as preservation, restoration, and enhancement of habitat. The HCP will also include measures for monitoring and adaptive management. This conservation program would focus on providing long-term protection of covered species by protecting biological communities in the Plan Area. The Service anticipates that PG&E will request a permit duration of 50 years.

**Environmental Impact Statement/ Report**

The joint document will be prepared in compliance with NEPA and the California Environmental Quality Act (CEQA). The Service and DFG will prepare the EIS/EIR, the Service will be responsible for the scope and content of the document for NEPA purposes, and DFG will be responsible for the scope

and content of the CEQA document, as the State lead agency pursuant to CEQA and the permitting entity pursuant to the California Endangered Species Act and Fish and Game Code 2081.

The EIS/EIR will consider the proposed action (i.e., the issuance of a Section 10(a)(1)(B) permit under the Act based on the proposed HCP) and a reasonable range of alternatives. A detailed description of the proposed action and alternatives will be included in the EIS/EIR. It is anticipated that several alternatives will be developed, which may vary by the level of conservation, impacts caused by the proposed activities, permit area, covered species, or a combination of these factors. Additionally, a No Action alternative will be considered. Under the No Action alternative, the Service would not issue a Section 10(a)(1)(B) permit.

The EIS/EIR will also identify potentially significant impacts on land use and planning, agricultural resources, biological resources, aesthetics, geology and soils, water resources, cultural resources, transportation and circulation, noise and vibration, air quality, public health/environmental hazards, recreation, environmental justice, socioeconomic, and other environmental issues that could occur directly or indirectly with implementation of the proposed action and alternatives. For all potentially significant impacts, the EIS/EIR will identify mitigation measures, where feasible, to reduce these impacts to a level below significance.

This notice of intent is being furnished in accordance with 40 CFR Sections 1501.2, 1501.7, 1506.6, and 1508.22 to obtain suggestions, comments, and useful information from other agencies and the public on the scope of the proposed EIS/EIR, including the significant environmental issues deserving of study, the range of actions, the range of alternatives, and the range of impacts to be considered. Written comments from interested parties are invited to ensure that all issues related to the proposed Section 10(a)(1)(B) incidental take permit application are identified. Comments will only be accepted in written form. You may submit written comments by mail, facsimile transmission, or in person (see ADDRESSES). Before including your address, phone number, e-mail 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: November 18, 2008.

**Richard E. Sayers,**

*Acting Deputy Regional Director, California and Nevada Region, Sacramento, California.*

[FR Doc. E8-27925 Filed 11-24-08; 8:45 am]

BILLING CODE 4310-55-P

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

[CO-922-09-1310-FI; COC68089]

#### Notice of Proposed Reinstatement of Terminated Oil and Gas Lease

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice of Proposed Reinstatement of Terminated Oil and Gas Lease.

**SUMMARY:** Under the provisions of 30 U.S.C. 188(d) and (e), and 43 CFR 3108.2-3(a) and (b)(1), the Bureau of Land Management (BLM) received a petition for reinstatement of oil and gas lease COC68089 from the following companies: (1) Delta Petroleum Corp., (2) Gasconade Oil Co., (3) Helm Energy LLC, and (4) Riggs Oil and Gas Corp., for lands in San Miguel County, Colorado. The petition was filed on time and was accompanied by all the rentals due since the date the lease terminated under the law.

**FOR FURTHER INFORMATION CONTACT:** Bureau of Land Management, Milada Krasilinec, Land Law Examiner, Branch of Fluid Minerals Adjudication, at 303.239.3767.

**SUPPLEMENTARY INFORMATION:** The lessee has agreed to the amended lease terms for rentals and royalties at rates of \$10.00 per acre or fraction thereof, per year and 16 $\frac{2}{3}$  percent, respectively. The lessee has paid the required \$500 administrative fee and \$163 to reimburse the Department for the cost of this **Federal Register** notice. The lessees have met all the requirements for reinstatement of the lease as set out in Section 31(d) and (e) of the Mineral Lands Leasing Act of 1920 (30 U.S.C. 188), and the Bureau of Land Management is proposing to reinstate lease COC68089 effective April 1, 2008, under the original terms and conditions of the lease and the increased rental and royalty rates cited above.

Dated: November 18, 2008.

**Milada Krasilinec,**  
*Land Law Examiner.*

[FR Doc. E8-27898 Filed 11-24-08; 8:45 am]

BILLING CODE 4310-JB-P

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

[CO-922-09-1310-FI; COC68150]

#### Notice of Proposed Reinstatement of Terminated Oil and Gas Lease

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice of Proposed Reinstatement of Terminated Oil and Gas Lease.

**SUMMARY:** Under the provisions of 30 U.S.C. 188(d) and (e), and 43 CFR 3108.2-3(a) and (b)(1), the Bureau of Land Management (BLM) received a petition for reinstatement of oil and gas lease COC68150 from the following companies: (1) Delta Petroleum Corp., (2) Gasconade Oil Co., (3) Helm Energy, LLC, and (4) Riggs Oil and Gas Corp., for lands in San Miguel County, Colorado. The petition was filed on time and was accompanied by all the rentals due since the date the lease terminated under the law.

**FOR FURTHER INFORMATION CONTACT:** Bureau of Land Management, Milada Krasilinec, Land Law Examiner, Branch of Fluid Minerals Adjudication, at 303.239.3767.

**SUPPLEMENTARY INFORMATION:** The lessee has agreed to the amended lease terms for rentals and royalties at rates of \$10.00 per acre or fraction thereof, per year and 16 $\frac{2}{3}$  percent, respectively. The lessee has paid the required \$500 administrative fee and \$163 to reimburse the Department for the cost of this **Federal Register** notice. The lessees have met all the requirements for reinstatement of the lease as set out in section 31(d) and (e) of the Mineral Lands Leasing Act of 1920 (30 U.S.C. 188), and the Bureau of Land Management is proposing to reinstate lease COC68150 effective April 1, 2008, under the original terms and conditions of the lease and the increased rental and royalty rates cited above.

Dated: November 18, 2008.

**Milada Krasilinec,**  
*Land Law Examiner.*

[FR Doc. E8-27899 Filed 11-24-08; 8:45 am]

BILLING CODE 4310-JB-P

**DEPARTMENT OF THE INTERIOR****Bureau of Land Management**

[CO-922-09-1310-FI; COC68149]

**Notice of Proposed Reinstatement of Terminated Oil and Gas Lease****AGENCY:** Bureau of Land Management, Interior.**ACTION:** Notice of proposed reinstatement of terminated oil and gas lease.

**SUMMARY:** Under the provisions of 30 U.S.C. 188(d) and (e), and 43 CFR 3108.2-3(a) and (b)(1), the Bureau of Land Management (BLM) received a petition for reinstatement of oil and gas lease COC68149 from the following companies: (1) Delta Petroleum Corp., (2) Gasconade Oil Co., (3) Helm Energy, LLC, and (4) Riggs Oil and Gas Corp., for lands in San Miguel County, Colorado. The petition was filed on time and was accompanied by all the rentals due since the date the lease terminated under the law.

**FOR FURTHER INFORMATION CONTACT:** Bureau of Land Management, Milada Krasilinec, Land Law Examiner, Branch of Fluid Minerals Adjudication, at 303-239-3767.

**SUPPLEMENTARY INFORMATION:** The lessee has agreed to the amended lease terms for rentals and royalties at rates of \$10.00 per acre or fraction thereof, per year and 16 2/3 percent, respectively. The lessee has paid the required \$500 administrative fee and \$163 to reimburse the Department for the cost of this *Federal Register* notice. The lessees have met all the requirements for reinstatement of the lease as set out in Section 31(d) and (e) of the Mineral Lands Leasing Act of 1920 (30 U.S.C. 188), and the Bureau of Land Management is proposing to reinstate lease COC68149 effective April 1, 2008, under the original terms and conditions of the lease and the increased rental and royalty rates cited above.

Dated: November 18, 2008.

Milada Krasilinec,

Land Law Examiner.

[FR Doc. E8-27900 Filed 11-24-08; 8:45 am]

BILLING CODE 4310-JB-P

**DEPARTMENT OF THE INTERIOR****Bureau of Land Management**

[CO-922-09-1310-FI; COC68148]

**Notice of Proposed Reinstatement of Terminated Oil and Gas Lease****AGENCY:** Bureau of Land Management, Interior.**ACTION:** Notice of proposed reinstatement of terminated oil and gas lease.

**SUMMARY:** Under the provisions of 30 U.S.C. 188(d) and (e), and 43 CFR 3108.2-3(a) and (b)(1), the Bureau of Land Management (BLM) received a petition for reinstatement of oil and gas lease COC68148 from the following companies: (1) Delta Petroleum Corp., (2) Gasconade Oil Co., (3) Helm Energy, LLC, and (4) Riggs Oil and Gas Corp., for lands in San Miguel County, Colorado. The petition was filed on time and was accompanied by all the rentals due since the date the lease terminated under the law.

**FOR FURTHER INFORMATION CONTACT:** Bureau of Land Management, Milada Krasilinec, Land Law Examiner, Branch of Fluid Minerals Adjudication, at 303-239-3767.

**SUPPLEMENTARY INFORMATION:** The lessee has agreed to the amended lease terms for rentals and royalties at rates of \$10.00 per acre or fraction thereof, per year and 16 2/3 percent, respectively. The lessee has paid the required \$500 administrative fee and \$163 to reimburse the Department for the cost of this *Federal Register* notice. The lessees have met all the requirements for reinstatement of the lease as set out in Section 31(d) and (e) of the Mineral Lands Leasing Act of 1920 (30 U.S.C. 188), and the Bureau of Land Management is proposing to reinstate lease COC68148 effective April 1, 2008, under the original terms and conditions of the lease and the increased rental and royalty rates cited above.

Dated: November 18, 2008.

Milada Krasilinec,

Land Law Examiner.

[FR Doc. E8-27902 Filed 11-24-08; 8:45 am]

BILLING CODE 4310-JB-P

**DEPARTMENT OF THE INTERIOR****Bureau of Land Management**

[COC 28270]

**Public Land Order No. 7717; Partial Revocation of Secretarial Order Dated October 26, 1906; Colorado****AGENCY:** Bureau of Land Management, Interior.**ACTION:** Public Land Order.

**SUMMARY:** This order partially revokes a withdrawal insofar as it affects 160 acres of National Forest System land withdrawn from all forms of appropriation under the public lands laws, including the mining laws and

reserved for use by the Forest Service as the Coon Creek Ranger Station within the Grand Mesa National Forest. This order also opens the land to sale under the authority of Public Law 107-63.

**DATES:** *Effective Date:* December 26, 2008.

**FOR FURTHER INFORMATION CONTACT:** John D. Beck, BLM Colorado State Office, 2850 Youngfield Street, Lakewood, Colorado 80215-7093, 303-239-3882.

**SUPPLEMENTARY INFORMATION:** This action makes the land available for sale under the authority of Section 329 of the Department of the Interior and Related Agencies Appropriation Act, 2002 (Pub. L. 107-63) in connection with the Forest Service's Pilot Conveyance Program for excess Forest Service structures.

**Order**

By virtue of the authority vested in the Secretary of the Interior by Section 204 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714 (2000), it is ordered as follows:

1. The Secretarial Order dated October 26, 1906, which withdrew National Forest System lands from appropriation under the public land laws, including the mining laws and reserved them for use by the Forest Service as Ranger Stations, is hereby revoked only insofar as it affects the following described land:

**Grand Mesa National Forest Coon Creek Ranger Station Sixth Principal Meridian**T. 11 S., R. 96 W.,  
sec. 16, NE¼.

The area described contains 160 acres in Mesa County.

2. The land described in Paragraph 1 is hereby opened to sale in accordance with Section 329 of the Department of the Interior and Related Agencies Appropriation Act, 2002 (Pub. L. 107-63).

Dated: November 10, 2008.

C. Stephen Allred,

Assistant Secretary—Land and Minerals Management.

[FR Doc. E8-28009 Filed 11-24-08; 8:45 am]

BILLING CODE 3410-11-P

**DEPARTMENT OF THE INTERIOR****National Park Service****Notice of Intent to Repatriate Cultural Items: Peabody Museum of Natural History, Yale University, New Haven, CT****AGENCY:** National Park Service, Interior.**ACTION:** Notice.

Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3005, of the intent to repatriate cultural items in the possession of the Peabody Museum of Natural History, Yale University, New Haven, CT, that meet the definition of "unassociated funerary objects" under 25 U.S.C. 3001.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003 (d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the cultural items. The National Park Service is not responsible for the determinations in this notice.

The cultural items are two shell beads described as "burial wampum."

In 1913, the Peabody Museum of Natural History received two shell beads described as "Two pieces of Wampum. Indian. From a grave in Cayuga County, New York." The cultural items were donated to the museum by Robert W. Curtis of Stratford, CT.

Cayuga County, NY, is in the traditional territory of the Onondaga Nation. No other documentation about the cultural items exists in the museum's records. Based on the geographic origin of the beads, the catalog description of the items as burial associations, and consultation with representatives of the Onondaga Nation of New York, the cultural items were determined to be unassociated funerary objects and culturally affiliated to the Onondaga Nation of New York.

Officials of the Peabody Museum of Natural History have determined that, pursuant to 25 U.S.C. 3001 (3)(B), the two cultural items described above are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony and are believed, by a preponderance of the evidence, to have been removed from a specific burial site of a Native American individual. Officials of the Peabody Museum of Natural History also have determined that, pursuant to 25 U.S.C. 3001 (2), there is a relationship of shared group identity that can be reasonably traced between the unassociated funerary objects and the Onondaga Nation of New York.

Representatives of any other Indian tribe that believes itself to be culturally affiliated with the unassociated funerary objects should contact the Director, Peabody Museum of Natural History, P.O. Box 208118, 170 Whitney Avenue, New Haven, CT 06520-8118, telephone (203) 432-3753, before December 26,

2008. Repatriation of the unassociated funerary objects to the Onondaga Nation of New York may proceed after that date if no additional claimants come forward.

The Peabody Museum of Natural History is responsible for notifying the Onondaga Nation of New York that this notice has been published.

Dated: October 28, 2008

**Sherry Hutt,**

*Manager, National NAGPRA Program.*

[FR Doc. E8-28038 Filed 11-24-08; 8:45 am]

BILLING CODE 4312-50-S

## DEPARTMENT OF THE INTERIOR

### National Park Service

#### **Notice of Intent to Repatriate Cultural Items: U.S. Department of Agriculture, Forest Service, Coronado National Forest, Tucson, AZ and Arizona State Museum, University of Arizona, Tucson, AZ; Correction**

**AGENCY:** National Park Service, Interior.

**ACTION:** Notice; correction.

Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3005, of the intent to repatriate cultural items in the possession of the U.S. Department of Agriculture, Forest Service, Coronado National Forest, Tucson, AZ, and in the possession of the Arizona State Museum, University of Arizona, Tucson, AZ, that meet the definition of "objects of cultural patrimony" under 25 U.S.C. 3001.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003 (d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

This notice corrects the number of cultural items with the addition of one object of cultural patrimony, which was found in Arizona State Museum's collection after the publication of a Notice of Intent to Repatriate in the **Federal Register** on November 20, 2007 (FR Doc E7-22671, Page 65354).

In the **Federal Register** of November 20, 2007, the notice is corrected by substituting the following for paragraph 3:

The 59 cultural items are part of an archeological collection known as the Pinaleno Cotton Cache. The 59 cultural

items are 2 caches of raw, native cotton, 3 ceramic jars, 3 ceramic bowls, 2 coiled basketry bowls, 1 coiled basketry pot stand, and 48 botanical and faunal items.

Representatives of any other Indian tribe that believes itself to be culturally affiliated with the objects of cultural patrimony should contact Dr. Frank E. Wozniak, NAGPRA Coordinator, Southwestern Region, USDA Forest Service, 333 Broadway Blvd., SE, Albuquerque, NM 87102, telephone (505) 842-3238, before December 26, 2008. Repatriation of the objects of cultural patrimony to the Tohono O'odham Nation of Arizona may proceed after that date if no additional claimants come forward.

The Coronado National Forest is responsible for notifying the Ak Chin Indian Community of the Maricopa (Ak Chin) Indian Reservation, Arizona; Gila River Indian Community of the Gila River Indian Reservation, Arizona; Hopi Tribe of Arizona; Salt River Pima-Maricopa Indian Community of the Salt River Reservation; and the Tohono O'odham Nation of Arizona that this notice has been published.

Dated: October 31, 2008

**Sherry Hutt,**

*Manager, National NAGPRA Program.*

[FR Doc. E8-28040 Filed 11-24-08; 8:45 am]

BILLING CODE 4312-50-S

## DEPARTMENT OF THE INTERIOR

### National Park Service

#### **Notice of Inventory Completion: U.S. Department of Defense, Army Corps of Engineers, Portland District, Portland, OR and University of Oregon Museum of Natural and Cultural History, Eugene, OR**

**AGENCY:** National Park Service, Interior.

**ACTION:** Notice.

Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains for which the University of Oregon Museum of Natural and Cultural History, Eugene, OR, and U.S. Department of Defense, Army Corps of Engineers, Portland District, Portland, OR, have joint responsibility. The human remains were removed from an undetermined location in Benton County, OR, during an Army Corps of Engineers-sponsored development project.

This notice is published as part of the National Park Service's administrative

responsibilities under NAGPRA, 25 U.S.C. 3003 (d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.

A detailed assessment of the human remains was made by the University of Oregon Museum of Natural and Cultural History and U.S. Army Corps of Engineers. Portland District professional staff in consultation with representatives of the Confederated Tribes of the Grand Ronde Community of Oregon and Confederated Tribes of the Siletz Reservation, Oregon.

In 1951, human remains representing a minimum of eight individuals were removed from an undetermined location in Benton County, OR, by the Army Corps of Engineers during construction of a levee near the Willamette River. The location, referred to as "Fir Grove," was situated somewhere between Albany and Corvallis, OR. Following their removal from the area, the human remains were transferred to the University of Oregon for preservation. No known individuals were identified. No associated funerary objects are present.

Museum accession notes indicate that stone tools and cultural objects were found in association with the human remains, but none of the cultural items were transferred to the University of Oregon Museum. Based on distinctive osteological evidence and the documented association of the human remains with the observed artifacts, the individuals have been determined to be Native American.

Ethnographic records suggest the area between present-day Albany and Corvallis, OR, was occupied by Kalapuya bands during the early Contact Period. The human remains described above are believed to have been removed from an area within or near the traditional lands of the Kalapuyan peoples whose descendants are members of the present-day Confederated Tribes of the Grand Ronde Community of Oregon and Confederated Tribes of the Siletz Reservation, Oregon.

The Confederated Tribes of the Grand Ronde Community of Oregon include at least 26 tribes and bands whose ancestral homelands span western Oregon, southwestern Washington and northern California. The Grand Ronde tribes and bands include the Rogue River, Umpqua, Chasta, Kalapuya, Molala, Clackamas, Salmon River, Tillamook, and Nestucca, as well as other, smaller groups. At the time of contact, the individual groups spoke 30

dialects of the Athapascan, Chinookan, Kalapuyan, Takelman, Molalan, Sahaptin, Salishan, and Shastan language families. In 1856–1857, the U.S. Government forcibly relocated the Grand Ronde peoples to the Grand Ronde Reservation, located at the headwaters of the South Yamhill River in Yamhill and Polk Counties, OR. The Confederated Tribes of the Grand Ronde Community of Oregon were first incorporated in 1935, terminated from Federal recognition in 1954, and restored to recognized status in 1983.

The Confederated Tribes of the Siletz Reservation, Oregon, are a confederation of 30 bands whose ancestral territory ranged along the entire Oregon coast and Coast Range, inland to the main divide of the Cascade Range and southward to the Rogue River watershed. The principal tribes include the Clatsop, Chinook, Klickitat, Molala, Kalapuya, Tillamook, Alosea, Siuslaw/Lower Umpqua, Coos, Coquille, Upper Umpqua, Tututni, Chetco, Tolowa, Takelma or Upper Rogue River, Galice/Applegate, and Shasta. The ancestors of the Confederated Tribes of the Siletz Reservation spoke at least 10 different base languages, many of which had strong dialectic divisions even within the same language. In general, five linguistic stocks – Salish, Yakonan, Kusan, Takelman, and Athapascan – are represented by the tribes. The tribes were forcibly removed from their homelands in 1855 by the U.S. Government and placed on the Siletz and Grand Ronde reservations. After having their tribal status terminated from Federal recognition in 1954, the Confederated Tribes of the Siletz Reservation, Oregon were officially restored to recognized status in 1977.

Officials of the U.S. Army Corps of Engineers, Portland District have determined that, pursuant to 25 U.S.C. 3001 (9–10), the human remains described above represent the physical remains of at least eight individuals of Native American ancestry. Officials of the U.S. Army Corps of Engineers, Portland District have also determined that, pursuant to 25 U.S.C. 3001 (2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and the Confederated Tribes of the Grand Ronde Community of Oregon and/or Confederated Tribes of the Siletz Reservation, Oregon.

Representatives of any other Indian tribe that believes itself to be culturally affiliated with the human remains should contact Daniel Mulligan, NAGPRA Coordinator, Environmental Resources Branch, U.S. Army Corps of Engineers, Portland District, P.O. Box

2946, Portland, OR 97208–2946, telephone (503) 808–4768, before December 26, 2008. Repatriation of the human remains to the Confederated Tribes of the Grand Ronde Community of Oregon and/or Confederated Tribes of the Siletz Reservation, Oregon, may proceed after that date if no additional claimants come forward.

The U.S. Army Corps of Engineers, Portland District is responsible for notifying the Confederated Tribes of the Grand Ronde Community of Oregon and Confederated Tribes of the Siletz Reservation, Oregon that this notice has been published.

Dated: October 30, 2008

**Sherry Hutt,**

*Manager, National NAGPRA Program.*

[FR Doc. E8–28005 Filed 11–24–08; 8:45 am]

BILLING CODE 4312–50–S

## DEPARTMENT OF THE INTERIOR

### National Park Service

#### Notice of Inventory Completion: Anchorage Museum at Rasmuson Center, Anchorage, AK

**AGENCY:** National Park Service, Interior.

**ACTION:** Notice.

Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains in the possession of the Anchorage Museum at Rasmuson Center, Anchorage, AK. The human remains were removed from near Point Hope and Point Barrow, AK.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003 (d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.

A detailed assessment of the human remains was made by the Anchorage Museum at Rasmuson Center professional staff. Consultations with representatives from the Village of Anaktuvuk Pass; Arctic Slope Regional Corporation; Atkasuk Village (Atkasook); Native Village of Barrow Inupiat Traditional Government; Kaktovik Village; Native Village of Nuiqsut; Native Village of Point Hope; Native Village of Point Lay; and Village of Wainwright have yet to occur.

On an unknown date, human remains representing a minimum of two

individuals were removed from areas in or around Point Hope and Point Barrow, AK, by Colonel M.R. "Muktuk" Marston of Anchorage, AK. In 1955, Col. Marston donated the human remains to the Cook Inlet Historical Society. In 1968, the Cook Inlet Historical Society donated their collection to the Anchorage Museum at Rasmuson Center. In 2008, the ownership of the Cook Inlet Historical Society collection was transferred to the Municipality of Anchorage and placed into the custody of the Anchorage Museum Association, governing body of the Anchorage Museum at Rasmuson Center. No known individuals were identified. No associated funerary objects are present.

Col. Marston collected Native American human remains and objects over a 15 year period in northern Alaska. Based on the donor's history and general provenience of removal, the human remains are reasonably determined to be of Native American descent and closely related to the Inupiat people. Specifically, the human remains are from an area traditionally used by the descendants of the Inupiat that are members of the Village of Anaktuvuk Pass; Arctic Slope Regional Corporation; Atkasuk Village (Atkasook); Native Village of Barrow Inupiat Traditional Government; Kaktovik Village; Native Village of Nuiqsut; Native Village of Point Hope; Native Village of Point Lay; and Village of Wainwright.

Officials of the Anchorage Museum at Rasmuson Center have determined that, pursuant to 25 U.S.C. 3001 (9-10), the human remains described above represent the physical remains of two individuals of Native American ancestry. Officials of the Anchorage Museum at Rasmuson Center also have determined that, pursuant to 25 U.S.C. 3001 (2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and Village of Anaktuvuk Pass; Arctic Slope Regional Corporation; Atkasuk Village (Atkasook); Native Village of Barrow Inupiat Traditional Government; Kaktovik Village; Native Village of Nuiqsut; Native Village of Point Hope; Native Village of Point Lay; and Village of Wainwright.

Representatives of any other Indian tribe that believes itself to be culturally affiliated with the human remains should contact Darian LaTocha, Collections Manager, Anchorage Museum at Rasmuson Center, 121 West 7th Avenue, Anchorage, AK 99501, telephone (907) 343-6197, before December 26, 2008. Repatriation of the human remains to the Village of

Anaktuvuk Pass; Arctic Slope Regional Corporation; Atkasuk Village (Atkasook); Native Village of Barrow Inupiat Traditional Government; Kaktovik Village; Native Village of Nuiqsut; Native Village of Point Hope; Native Village of Point Lay; and Village of Wainwright may proceed after that date if no additional claimants come forward.

The Anchorage Museum at Rasmuson Center is responsible for notifying the Village of Anaktuvuk Pass; Arctic Slope Regional Corporation; Atkasuk Village (Atkasook); Native Village of Barrow Inupiat Traditional Government; Kaktovik Village; Native Village of Nuiqsut; Native Village of Point Hope; Native Village of Point Lay; and Village of Wainwright that this notice has been published.

Dated: October 23, 2008

**Sherry Hutt,**

*Manager, National NAGPRA Program.*

[FR Doc. E8-28003 Filed 11-24-08; 8:45 am]

**BILLING CODE 4312-50-5**

## DEPARTMENT OF THE INTERIOR

### National Park Service

#### Notice of Inventory Completion: Anchorage Museum at Rasmuson Center, Anchorage, AK

**AGENCY:** National Park Service, Interior.

**ACTION:** Notice.

Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains in the possession of Anchorage Museum at Rasmuson Center, Anchorage, AK. The human remains were removed from a site approximately 80 miles from Kodiak, AK.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003 (d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.

A detailed assessment of the human remains was made by the Anchorage Museum at Rasmuson Center professional staff. Consultations with representatives from the Akhiok-Kaguyak, Inc.; Ayakulik, Inc.; Kaguyak Village; Koniag, Inc.; Native Village of Larsen Bay; and Uyak, Incorporated have yet to occur.

At an unknown date, human remains representing a minimum of one individual were removed from "about eighty miles from Kodiak, near Amik Bay" in Kodiak Island, AK, by Kathy Whitman of Anchorage. On May 4, 1971, Ms. Whitman donated the human remains to the Anchorage Museum. Sometime after it was collected, masking tape was used to stabilize the lower mandible. No known individual was identified. No associated funerary objects are present.

The Anchorage Museum's records report the human remains were found near "Amik Bay" in Kodiak. According to multiple references, Amik Bay is not recorded as a place name. However, there is an Amik Island at the mouth of Moser Bay, which is in Alitak Bay, and is approximately 80 miles from Kodiak. Although it is uncertain where the human remains were precisely collected and whether they were found without the means of conducting excavations, it is reasonably believed that the location is Alitak Bay and not "Amik Bay," as stated in the museum accession records. Based on their age, the human remains are reasonably believed to be of Native American descent and closely related to the Alutiiq people. Specifically, the human remains are from an area traditionally used by the members of Akhiok-Kaguyak, Inc.; Native Village of Akhiok; Ayakulik, Inc.; Kaguyak Village; Koniag, Inc.; Native Village of Larsen Bay; and Uyak, Inc.

Officials of the Anchorage Museum at Rasmuson Center have determined that, pursuant to 25 U.S.C. 3001 (9-10), the human remains described above represent the physical remains of one individual of Native American ancestry. Officials of the Anchorage Museum at Rasmuson Center also have determined that, pursuant to 25 U.S.C. 3001 (2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and Akhiok-Kaguyak, Inc.; Native Village of Akhiok; Ayakulik, Inc.; Kaguyak Village; Koniag, Inc.; Native Village of Larsen Bay; and Uyak, Inc.

Representatives of any other Indian tribe that believes itself to be culturally affiliated with the human remains should contact Darian LaTocha, Collections Manager, Anchorage Museum at Rasmuson Center, 121 West 7th Avenue, Anchorage, AK 99501, telephone (907) 343-6197, before December 26, 2008. Repatriation of the human remains to the Akhiok-Kaguyak, Inc.; Native Village of Akhiok; Ayakulik, Inc.; Kaguyak Village; Koniag, Inc.; Native Village of Larsen Bay; and Uyak, Inc. may proceed after that date if no additional claimants come forward.

The Anchorage Museum at Rasmuson Center is responsible for notifying Akhiok-Kaguyak, Inc.; Native Village of Akhiok; Ayakulik, Inc.; Kaguyak Village; Koniag, Inc.; Native Village of Larsen Bay; and Uyak, Inc. that this notice has been published.

Dated: October 23, 2008

**Sherry Hutt,**

*Manager, National NAGPRA Program.*

[FR Doc. E8-28004 Filed 11-24-08; 8:45 am]

BILLING CODE 4312-50-5

## DEPARTMENT OF THE INTERIOR

### National Park Service

**Notice of Inventory Completion:  
Phoebe A. Hearst Museum of  
Anthropology, University of California,  
Berkeley, Berkeley, CA**

**AGENCY:** National Park Service, Interior.

**ACTION:** Notice.

Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and associated funerary objects in the control of the Phoebe A. Hearst Museum of Anthropology, University of California, Berkeley, Berkeley, CA. The human remains and associated funerary objects were removed from Amador and Calaveras Counties, CA.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003 (d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

An assessment of the human remains, catalogue records, and relevant associated documents was made by the Phoebe A. Hearst Museum of Anthropology professional staff in consultation with representatives of the Buena Vista Rancheria of Me-Wuk Indians of California; Cher-Ae Heights Indian Community of the Trinidad Rancheria, California; Chicken Ranch Rancheria of Me-Wuk Indians of California; Ione Band of Miwok Indians of California; Jackson Rancheria of Me-Wuk Indians of California; Shingle Springs Band of Miwok Indians, Shingle Springs Rancheria (Verona Tract), California; Tuolumne Band of Me-Wuk Indians of the Tuolumne Rancheria of California; and United Auburn Indian

Community of the Auburn Rancheria of California.

In 1952 and 1953, human remains representing a minimum of 65 individuals (29 catalogue records) were removed from CA-Cal-83, a site located on the eastern slope of Golden Gate Hill in Calaveras County, CA, by E. Treganza of the University of California Archaeological Survey. The human remains and associated funerary objects were accessioned into the museum between 1952 and 1953 (Accessions UCAS 175 and UCAS 233 respectively). No known individuals were identified. The 15,213 associated funerary objects are 2 balls, 14,663 beads, 5 belt fragments, 9 animal bones, 8 bottle fragments, 1 bowl, 1 brush, 1 buckle, 39 buttons, 1 cane fragment, 1 clasp, 4 cloth fragments, 2 coins, 10 colored fragments, 1 container, 12 copper fragments, 1 cordage, 5 crystals, 1 cylinder, 1 disc, 10 metal objects, 1 file, 13 lithics, 13 eating utensils, 4 handles, 1 heel, 13 knives, 2 mirrors, 1 mortar, 14 iron nails, 23 obsidian flakes and fragments, 2 lumps of ochre, 94 ornaments, 2 pebbles, 79 pendants, 1 pestle, 4 pins, 1 point, 3 projectile points, 1 rivet, 2 rock fragments, 5 scissors fragments, 13 scrapers, 25 sequins, 44 shells, 10 shoe fragments, 1 string, 11 textile fragments, 1 thimble, 8 tubes, 1 twig, 17 whistles, 21 wood fragments, 1 shovel blade, and 3 soil samples.

In 1950, human remains representing a minimum of 12 individuals (12 catalogue records) were removed from CA-Ama-3 (Bamert Cave), a site located on a hill overlooking the Camanche Reservoir in Amador County, CA, by R.F. Heizer and A.E. Treganza. The human remains and associated funerary objects were accessioned into the museum in that same year. No known individuals were identified. The one associated funerary object is the burial encasement of the individual in catalogue record no. 1-164179a, which includes coiled basketry, twined burden basket, tule reed mat, milkweed cordage, and grass lining.

Chronological information is available for the human remains, associated funerary objects, and other site-specific artifacts present at both CA-Cal-83 and CA-Ama-3. One radiocarbon date (on charcoal) and the presence of artifacts such as coins (minted in 1856) and casket hardware (patented in 1865) indicate that these locations were still in use for burial purposes in historic times. The two sites are located in the aboriginal territory of the Northern Sierra Miwok as indicated by ethnographic and linguistic data. In addition, oral history and native folklore

contain numerous geographic references to these parts of Calaveras and Amador Counties. The archeological evidence for the region is indicative of cultural continuity from 1500 BP, with the expansion of the ancestral Miwok into the Sierra, to the emergence of the historic Sierra Miwok after 750 BP. The Amador Phase (750-150BP) contains archeological traits that are consistent with ethnographic Sierra Miwok culture. Descendants of the Northern Sierra Miwok are members of the Buena Vista Rancheria of Me-Wuk Indians of California; Cher-Ae Heights Indian Community of the Trinidad Rancheria, California; Chicken Ranch Rancheria of Me-Wuk Indians of California; Ione Band of Miwok Indians of California; Jackson Rancheria of Me-Wuk Indians of California; Shingle Springs Band of Miwok Indians, Shingle Springs Rancheria (Verona Tract), California; Tuolumne Band of Me-Wuk Indians of the Tuolumne Rancheria of California; and United Auburn Indian Community of the Auburn Rancheria of California.

Officials of the Phoebe A. Hearst Museum of Anthropology have determined that, pursuant to 25 U.S.C. 3001 (9-10), the human remains described above represent the physical remains of 77 individuals of Native American ancestry. Officials of the Phoebe A. Hearst Museum of Anthropology have also determined that, pursuant to 25 U.S.C. 3001 (3)(A), that the 15,214 objects described above are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony. Lastly, officials of the Phoebe A. Hearst Museum of Anthropology have determined that, pursuant to 25 U.S.C. 3001 (2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and associated funerary objects and the Buena Vista Rancheria of Me-Wuk Indians of California; Cher-Ae Heights Indian Community of the Trinidad Rancheria, California; Chicken Ranch Rancheria of Me-Wuk Indians of California; Ione Band of Miwok Indians of California; Jackson Rancheria of Me-Wuk Indians of California; Shingle Springs Band of Miwok Indians, Shingle Springs Rancheria (Verona Tract), California; Tuolumne Band of Me-Wuk Indians of the Tuolumne Rancheria of California; and United Auburn Indian Community of the Auburn Rancheria of California.

Representatives of any other Indian tribe that believes itself to be culturally affiliated with the human remains and associated funerary objects should

contact Judd King, Interim Director of the Phoebe A. Hearst Museum of Anthropology, University of California, Berkeley, CA 94720, before December 26, 2008. Repatriation of the human remains and associated funerary objects to the Buena Vista Rancheria of Me-Wuk Indians of California; Cher-Ae Heights Indian Community of the Trinidad Rancheria, California; Chicken Ranch Rancheria of Me-Wuk Indians of California; Ione Band of Miwok Indians of California; Jackson Rancheria of Me-Wuk Indians of California; Shingle Springs Band of Miwok Indians, Shingle Springs Rancheria (Verona Tract), California; Tuolumne Band of Me-Wuk Indians of the Tuolumne Rancheria of California; and United Auburn Indian Community of the Auburn Rancheria of California may proceed after that date if no additional claimants come forward.

The Phoebe A. Hearst Museum of Anthropology is responsible for notifying the Buena Vista Rancheria of Me-Wuk Indians of California; Cher-Ae Heights Indian Community of the Trinidad Rancheria, California; Chicken Ranch Rancheria of Me-Wuk Indians of California; Ione Band of Miwok Indians of California; Jackson Rancheria of Me-Wuk Indians of California; Shingle Springs Band of Miwok Indians, Shingle Springs Rancheria (Verona Tract), California; Tuolumne Band of Me-Wuk Indians of the Tuolumne Rancheria of California; and United Auburn Indian Community of the Auburn Rancheria of California that this notice has been published.

Dated: October 23, 2008

**Sherry Hutt,**

*Manager, National NAGPRA Program.*

[FR Doc. E8-28006 Filed 11-24-08; 8:45 am]

BILLING CODE 4312-50-S

## DEPARTMENT OF THE INTERIOR

### National Park Service

#### **Notice of Inventory Completion: U.S. Department of the Interior, U.S. Fish and Wildlife Service, Region 7, Anchorage, AK**

**AGENCY:** National Park Service, Interior.

**ACTION:** Notice.

Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains in the possession of the U.S. Department of the Interior, U.S. Fish and Wildlife Service, Region 7, Anchorage, AK. The human remains

were removed from Krugloi Point, Agattu Island, AK.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003 (d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.

A detailed assessment of the human remains was made by U.S. Fish and Wildlife Service, Region 7 professional staff with assistance from the Alaska State Office of History and Archaeology and University of Alaska, Anchorage, in consultation with representatives of the Aleut Corporation, Ounalashka Corporation, and Unangan Repatriation Commission, a non-Federally recognized Native Alaskan advisory group.

In 1949, human remains representing a minimum of one individual, were removed from Krugloi Point, Agattu Island, AK, during research permitted to T.P. Bank and supervised in the field by A.C. Spaulding. The human remains gathered by the expedition were sent to the University of Michigan, Ann Arbor, MI, and then to the University of Alaska Fairbanks. In 2002, the human remains were moved to the Museum of the Aleutians at the request of the Ounalashka Corporation. No known individual was identified. No associated funerary objects are present.

Radiocarbon dates from unworked pieces of wood associated with the human remains, but not considered to be funerary objects, were run at the University of Michigan, Michigan Memorial-Phoenix Project Radiocarbon Laboratory. The samples yielded dates of  $2500 \pm 300$  years and  $2630 \pm 300$  years ago (Spaulding 1962). The burial context and physical traits of the human remains are consistent with those observed for pre-contact Aleut populations. Skeletal morphology of present-day Aleut populations is similar to that of prehistoric populations and demonstrates biological and cultural affiliation between present-day Aleut groups and prehistoric populations in the Aleutian Islands.

After Russian contact with the Aleutians in 1751, the population declined precipitously. By the 1760s, all Near Islanders had moved into a single village on Attu Island. During World War II, the villagers of Attu were interred in Japan and at war's end the survivors were resettled in the village on Atka. The Unangan Repatriation Commission provided the Fish and Wildlife Service with a list of islands

and their culturally affiliated village corporations and tribal entities. The Ounalashka Corporation claimed ownership and affiliation with the entire T.P. Bank collection including human remains, and were also consulted, but were determined not to have cultural affiliation with the human remains removed from Agattu Island. The Aleut Corporation is responsible for human remains from islands without strong village claims. Agattu Island is accordingly represented and reasonably determined by officials of the U.S. Fish and Wildlife Service, Region 7 to have a shared group relationship to members of the Aleut Corporation.

Officials of the U.S. Fish and Wildlife Service, Region 7 have determined that, pursuant to 25 U.S.C. 3001 (9-10), the human remains described above represent the physical remains of one individual of Native American ancestry. Officials of the U.S. Fish and Wildlife Service, Region 7 also have determined that, pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and the Aleut Corporation.

Representatives of any other Indian tribe that believes itself to be culturally affiliated with the human remains should contact Debra Corbett, U.S. Fish and Wildlife Service, 1011 East Tudor Road, Anchorage, AK 99503, telephone (907) 786-3399, before December 26, 2008. Repatriation of the human remains to the Aleut Corporation may proceed after that date if no additional claimants come forward.

U.S. Fish and Wildlife Service, Region 7 is responsible for notifying the Aleut Corporation, Ounalashka Corporation, and Unangan Repatriation Commission, a non-Federally recognized Native Alaskan advisory group, that this notice has been published.

Dated: October 28, 2008

**Sherry Hutt,**

*Manager, National NAGPRA Program.*

[FR Doc. E8-28001 Filed 11-24-08; 8:45 am]

BILLING CODE 4312-50-S

## DEPARTMENT OF THE INTERIOR

### National Park Service

#### **Notice of Inventory Completion: University of Oregon, Oregon State Museum of Anthropology, Eugene, OR**

**AGENCY:** National Park Service, Interior.

**ACTION:** Notice.

Notice is here given in accordance with the Native American Graves Protection and Repatriation Act



(NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains in the possession of the University of Oregon, Oregon State Museum of Anthropology, Eugene, OR. The human remains were removed from an unknown site in Oregon.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.

A detailed assessment of the human remains was made by Oregon State Museum of Anthropology professional staff in consultation with representatives of the Confederated Tribes of the Siletz Reservation, Oregon.

At an unknown date, human remains representing one individual were removed from an unknown site in Oregon. The human remains were donated to the museum by a private donor. No known individual was identified. No associated funerary objects are present.

The human remains are determined to be Native American based on skeletal evidence. According to museum records, the human remains are that of a "Siletz Indian." No other documentation is available. Based on this information, the human remains are reasonably believed to be Siletz. The Siletz are represented by the Confederated Tribes of the Siletz Reservation, Oregon.

Officials of the Oregon State Museum of Anthropology have determined that, pursuant to 25 U.S.C. 3001 (9-10), the human remains described above represent the physical remains of one individual of Native American ancestry. Officials of the Oregon State Museum of Anthropology also have determined that, pursuant to 25 U.S.C. 3001 (2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and the Confederated Tribes of the Siletz Reservation, Oregon.

Representatives of any other Indian tribe that believes itself to be culturally affiliated with the human remains should contact Pamela Endzweig, Director of Collections, Oregon State Museum of Anthropology, 1224 University of Oregon, Eugene, OR 97403-1224, telephone (541) 346-5120, before December 26, 2008. Repatriation of the human remains to the Confederated Tribes of the Siletz Reservation, Oregon may proceed after

that date if no additional claimants come forward.

Oregon State Museum of Anthropology is responsible for notifying the Confederated Tribes of the Siletz Reservation, Oregon that this notice has been published.

Dated: October 23, 2008

**Sherry Hutt,**

Manager, National NAGPRA Program.

[FR Doc. E8-28007 Filed 11-24-08; 8:45 am]

BILLING CODE 4312-50-S

## INTERNATIONAL TRADE COMMISSION

[Inv. No. 337-TA-660]

### In the Matter of: Certain Active Comfort Footwear; Notice of Investigation

**AGENCY:** U.S. International Trade Commission.

**ACTION:** Institution of investigation pursuant to 19 U.S.C. 1337.

**SUMMARY:** Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on October 22, 2008, under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, on behalf of Masai Marketing & Trading AG of Romanshorn, Switzerland and Masai USA Corp. of Hailey, Idaho. A supplement to the complaint was filed on November 7, 2008. The complaint, as supplemented, alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation, of certain active comfort footwear that infringes certain claims of U.S. Patent Nos. 6,341,432. The complaint, as supplemented, further alleges that an industry in the United States exists as required by subsection (a)(2) of section 337.

The complainants request that the Commission institute an investigation and, after the investigation, issue an exclusion order and cease and desist orders.

**ADDRESSES:** The complaint and supplement, except for any confidential information contained therein, are 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., Room 112, Washington, DC 20436, telephone 202-205-2000. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202-

205-1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 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>.

#### FOR FURTHER INFORMATION CONTACT:

Heidi E. Strain, Esq., Office of Unfair Import Investigations, U.S. International Trade Commission, telephone (202) 205-2606.

**Authority:** The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2008).

**Scope of Investigation:** Having considered the complaint, the U.S. International Trade Commission, on November 19, 2008, ordered that—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation, of certain active comfort footwear that infringes one or more of claims 1, 2, 5, 6, 8, 12, 21, 23, 24, 28, and 30 of U.S. Patent No. 6,341,432, and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(2) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainants are: Masai Marketing & Trading AG, Badstrasse 14, CH-8590 Romanshorn, Switzerland; Masai USA Corp., 515 North River, Hailey, Idaho 83333.

(b) The respondents are the following entities alleged to be in violation of section 337, and are the parties upon which the complaint is to be served: RYN Korea Co., Ltd., Yuk-Sam Dong, 667-8, Poong-Chun Building 1st Floor, Kang-Nam, Seoul, Korea; Main d/b/a WalkingShoesPlus.com, 928 S. Western Avenue #235, Los Angeles, California 90006; Feet First Inc., 5030 Champion

Boulevard #F7, Polo Club Shoppes, Boca Raton, Florida 33496.

(c) The Commission investigative attorney, party to this investigation, is

Heidi E. Strain, Esq., Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street, SW., Room 401, Washington, DC 20436; and

(3) For the investigation so instituted, Paul J. Luckern, Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(d) and 210.13(a), such responses will be considered by the Commission if received not later than 20 days after the date of service by the Commission of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Issued: November 19, 2008.

**William R. Bishop,**

*Acting Secretary to the Commission.*

[FR Doc. E8-27942 Filed 11-24-08; 8:45 am]

BILLING CODE 7020-02-P

## INTERNATIONAL TRADE COMMISSION

[Investigation No. 731-TA-1145 (Final)]

### Certain Steel Threaded Rod From China

**AGENCY:** United States International Trade Commission.

**ACTION:** Scheduling of the final phase of an antidumping investigation.

**SUMMARY:** The Commission hereby gives notice of the scheduling of the final phase of antidumping investigation No. 731-TA-1145 (Final) under section 735(b) of the Tariff Act of 1930 (19 U.S.C. 1673d(b)) (the Act) to determine

whether an industry in the United States is materially injured or threatened with material injury, or the establishment of an industry in the United States is materially retarded, by reason of less-than-fair-value imports from China of certain steel threaded rod, provided for in subheading 7318.15.50 of the Harmonized Tariff Schedule of the United States.<sup>1</sup>

For further information concerning the conduct of this phase of the investigation, hearing procedures, and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201), and part 207, subparts A and C (19 CFR part 207).

**DATES:** *Effective Date:* October 8, 2008.

**FOR FURTHER INFORMATION CONTACT:**

Joanna Lo (202-205-1888), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202-205-1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202-205-2000. General information concerning the Commission may also be obtained by accessing its Internet server (<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>.

**SUPPLEMENTARY INFORMATION:**

**Background.**—The final phase of this investigation is being scheduled as a result of an affirmative preliminary determination by the Department of Commerce that imports of certain steel threaded rod from China are being sold in the United States at less than fair value within the meaning of section 733 of the Act (19 U.S.C. 1673b). The investigation was requested in a petition filed on March 5, 2008, by Vulcan Threaded Products, Inc., Pelham, AL.

<sup>1</sup> For purposes of this investigation, the Department of Commerce has defined the subject merchandise as "steel threaded rod. Steel threaded rod is certain threaded rod, bar, or studs, of carbon quality steel, having a solid, circular cross section, of any diameter, in any straight length, that have been forged, turned, cold-drawn, cold-rolled, machine straightened, or otherwise cold-finished, and into which threaded grooves have been applied. In addition, the steel threaded rod, bar, or studs subject to this investigation are non-headed and threaded along greater than 25 percent of their total length. A variety of finishes or coatings, such as plain oil finish as a temporary rust protectant, zinc coating (i.e., galvanized, whether by electroplating or hot-dipping), paint, and other similar finishes and coatings, may be applied to the merchandise."

**Participation in the investigation and public service list.**—Persons, including industrial users of the subject merchandise and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in the final phase of this investigation as parties must file an entry of appearance with the Secretary to the Commission, as provided in section 201.11 of the Commission's rules, no later than 21 days prior to the hearing date specified in this notice. A party that filed a notice of appearance during the preliminary phase of the investigation need not file an additional notice of appearance during this final phase. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the investigation.

**Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list.**—Pursuant to section 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in the final phase of this investigation available to authorized applicants under the APO issued in the investigation, provided that the application is made no later than 21 days prior to the hearing date specified in this notice. Authorized applicants must represent interested parties, as defined by 19 U.S.C. 1677(9), who are parties to the investigation. A party granted access to BPI in the preliminary phase of the investigation need not reapply for such access. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

**Staff report.**—The prehearing staff report in the final phase of this investigation will be placed in the nonpublic record on February 5, 2009, and a public version will be issued thereafter, pursuant to section 207.22 of the Commission's rules.

**Hearing.**—The Commission will hold a hearing in connection with the final phase of this investigation beginning at 9:30 a.m. on February 25, 2009, at the U.S. International Trade Commission Building. Requests to appear at the hearing should be filed in writing with the Secretary to the Commission on or before February 16, 2009. A nonparty who has testimony that may aid the Commission's deliberations may request permission to present a short statement at the hearing. All parties and nonparties desiring to appear at the hearing and make oral presentations should attend a prehearing conference to be held at 9:30 a.m. on February 18, 2009, at the U.S. International Trade

Commission Building. Oral testimony and written materials to be submitted at the public hearing are governed by sections 201.6(b)(2), 201.13(f), and 207.24 of the Commission's rules. Parties must submit any request to present a portion of their hearing testimony *in camera* no later than 7 business days prior to the date of the hearing.

**Written submissions.**—Each party who is an interested party shall submit a prehearing brief to the Commission. Prehearing briefs must conform with the provisions of section 207.23 of the Commission's rules; the deadline for filing is February 12, 2009. Parties may also file written testimony in connection with their presentation at the hearing, as provided in section 207.24 of the Commission's rules, and posthearing briefs, which must conform with the provisions of section 207.25 of the Commission's rules. The deadline for filing posthearing briefs is March 4, 2009; witness testimony must be filed no later than three days before the hearing. In addition, any person who has not entered an appearance as a party to the investigation may submit a written statement of information pertinent to the subject of the investigation, including statements of support or opposition to the petition, on or before March 4, 2009. On March 18, 2009, the Commission will make available to parties all information on which they have not had an opportunity to comment. Parties may submit final comments on this information on or before March 20, 2009, but such final comments must not contain new factual information and must otherwise comply with section 207.30 of the Commission's rules. All written submissions must conform with the provisions of section 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's rules do not authorize filing of submissions with the Secretary by facsimile or electronic means, except to the extent permitted by section 201.8 of the Commission's rules, as amended, 67 FR 68036 (November 8, 2002). Even where electronic filing of a document is permitted, certain documents must also be filed in paper form, as specified in II (C) of the Commission's Handbook on Electronic Filing Procedures, 67 FR 68168, 68173 (November 8, 2002).

Additional written submissions to the Commission, including requests pursuant to section 201.12 of the Commission's rules, shall not be accepted unless good cause is shown for accepting such submissions, or unless

the submission is pursuant to a specific request by a Commissioner or Commission staff.

In accordance with sections 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the investigation must be served on all other parties to the investigation (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

**Authority:** This investigation is being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.21 of the Commission's rules.

Issued: November 18, 2008.

By order of the Commission.

**William R. Bishop,**

*Acting Secretary to the Commission.*

[FR Doc. E8-27911 Filed 11-24-08; 8:45 am]

BILLING CODE 7020-02-P

## INTERNATIONAL TRADE COMMISSION

[Investigation No. 332-502]

### Sub-Saharan African Textile and Apparel Inputs: Potential for Competitive Production

**AGENCY:** United States International Trade Commission.

**ACTION:** Institution of investigation.

**SUMMARY:** Pursuant to section 3(c)(1) of Public Law 110-436, An Act to extend the Andean Trade Preference Act, and for other purposes ("the Act"), and pursuant to section 332(g) of the Tariff Act of 1930 (19 U.S.C. 1332(g)), the U.S. International Trade Commission (Commission) has instituted investigation No. 332-502, *Sub-Saharan African Textile and Apparel Inputs: Potential for Competitive Production*.

#### DATES:

*January 15, 2009:* Deadline for filing request to appear at the public hearing.

*January 17, 2009:* Deadline for filing pre-hearing briefs and statements.

*January 29, 2009:* Public hearing.

*February 12, 2009:* Deadline for filing post-hearing briefs and statements.

*February 24, 2009:* Deadline for filing all other written submissions.

*May 15, 2009:* Transmittal of Commission report to the appropriate congressional committees and the Comptroller General.

**ADDRESSES:** All Commission offices, including the Commission's hearing rooms, are located in the United States International Trade Commission

Building, 500 E Street, SW., Washington, DC. All written submissions should be addressed to the Secretary, United States International Trade Commission, 500 E Street, SW., Washington, DC 20436. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at <http://www.usitc.gov/secretary/edis.htm>.

#### FOR FURTHER INFORMATION CONTACT:

Project leader Kimberlie Freund (202-708-5402 or

[kimberlie.freund@usitc.gov](mailto:kimberlie.freund@usitc.gov)) or deputy

project leader Joshua Levy (202-205-

3236 or [joshua.levy@usitc.gov](mailto:joshua.levy@usitc.gov)) for

information specific to this

investigation. For information on the

legal aspects of this investigation,

contact William Gearhart of the

Commission's Office of the General

Counsel (202-205-3091 or

[william.gearhart@usitc.gov](mailto:william.gearhart@usitc.gov)). The media

should contact Margaret O'Laughlin,

Office of External Relations (202-205-

1819 or [margaret.olaughlin@usitc.gov](mailto:margaret.olaughlin@usitc.gov)).

Hearing-impaired individuals may

obtain information on this matter by

contacting the Commission's TDD

terminal at 202-205-1810. General

information concerning the Commission

may also be obtained by accessing its

Internet site (<http://www.usitc.gov>).

Persons with mobility impairments who

will need special assistance in gaining

access to the Commission should

contact the Office of the Secretary at

202-205-2000.

**Background:** On October 16, 2008, the

President signed into law Public Law

No. 110-436, An Act to extend the

Andean Trade Preference Act, and for

other purposes. Section 3(c)(1) of the

Act requires the Commission to conduct

a review to identify yarns, fabrics, and

other textile and apparel inputs that

through new or increased investment or

other measures can be produced

competitively in beneficiary sub-

Saharan African (SSA) countries (as

defined in section 506A(c) of the Trade

Act of 1974, 19 U.S.C. 2466a(c)). The

Act requires the Commission to report

the results of its review to the House

Committee on Ways and Means and the

Senate Committee on Finance (the

committees), and the Comptroller

General, not later than 7 months after

enactment of the law (by May 15, 2009).

Section 3(c)(2) of the Act requires the

Comptroller General to submit a report

to the committees based on the

Commission's report and other available

information not later than 90 days after

receiving the Commission's report. The

Comptroller General's report is to

include recommendations for changes

in U.S. trade preference programs,

including the African Growth and Opportunity Act (19 U.S.C. 3701) and amendments made by that act, to provide incentives to increase investment and other measures to improve the competitiveness of beneficiary SSA countries in the production of yarns, fabrics, and other textile and apparel inputs identified in the Commission's report, including changes to requirements relating to rules of origin under such programs.

The Commission also instituted this investigation pursuant to section 332(g) of the Tariff Act of 1930 to facilitate docketing of submissions and public access to Commission records through the Commission's EDIS electronic records system.

**Public Hearing:** A public hearing in connection with this investigation will be held at the U.S. International Trade Commission Building, 500 E Street, SW., Washington, DC, beginning at 9:30 a.m. on January 29, 2009. Requests to appear at the public hearing should be filed with the Secretary not later than 5:15 p.m., January 15, 2009, in accordance with the requirements in the "Submissions" section below. All pre-hearing briefs and statements should be filed not later than 5:15 p.m., January 17, 2009, and all post-hearing briefs and statements responding to matters raised at the hearing should be filed not later than 5:15 p.m., February 12, 2009. In the event that, as of the close of business on January 15, 2009, no witnesses are scheduled to appear at the hearing, the hearing will be canceled. Any person interested in attending the hearing as an observer or nonparticipant may call the Office of the Secretary (202-205-2000) after January 15, 2009, for information concerning whether the hearing will be held.

**Written Submissions:** In lieu of or in addition to participating in the hearing, interested parties are invited to submit written statements concerning this investigation. All written submissions should be addressed to the Secretary and should be received not later than 5:15 p.m., February 24, 2009. All written submissions must conform with the provisions of section 201.8 of the Commission's *Rules of Practice and Procedure* (19 CFR 201.8). Section 201.8 of the rules requires that a signed original (or a copy designated as an original) and fourteen (14) copies of each document be filed. In the event that confidential treatment of the document is requested, at least four (4) additional copies must be filed, in which the confidential information must be deleted (see the following paragraph for further information regarding confidential business

information). The Commission's rules do not authorize filing submissions with the Secretary by facsimile or electronic means, except to the extent permitted by section 201.8 of the rules (see *Handbook for Electronic Filing Procedures*, [http://www.usitc.gov/secretary/fed\\_reg\\_notices/rules/documents/handbook\\_on\\_electronic\\_filing.pdf](http://www.usitc.gov/secretary/fed_reg_notices/rules/documents/handbook_on_electronic_filing.pdf)); persons with questions regarding electronic filing should contact the Secretary at 202-205-2000. Any submission that contains confidential business information must also conform with the requirements of section 201.6 of the Commission's *Rules of Practice and Procedure* (19 CFR 201.6). Section 201.6 of the rules requires that the cover of the document and the individual pages be clearly marked as to whether they are the "confidential" or "non-confidential" version, and that the confidential business information be clearly identified by means of brackets. All written submissions, except for confidential business information, will be made available in the Office of the Secretary for inspection by interested parties. The Commission anticipates that the report it sends to the committees and the Comptroller General in this investigation will be made available to the public in its entirety. Consequently, the report that the Commission sends to the committees and the Comptroller General will not contain any confidential business information. Any confidential business information received by the Commission in this investigation and used in preparing its report will not be published in a manner that would reveal the operations of the firm supplying the information.

By order of the Commission.

Issued: November 19, 2008.

**William R. Bishop,**

*Acting Secretary to the Commission.*

[FR Doc. E8-27903 Filed 11-24-08; 8:45 am]

BILLING CODE 7020-02-P

## DEPARTMENT OF JUSTICE

### Antitrust Division

#### **United States v. Inbev NV/SA; Proposed Final Judgment and Competitive Impact Statement**

Notice is hereby given pursuant to the Antitrust Procedures and Penalties Act, 15 U.S.C. 16(b)-(h), that a proposed Final Judgment, Hold Separate Stipulation and Order, and Competitive Impact Statement have been filed with the United States District Court for the District of Columbia in *United States v.*

*InBev NV/SA*, Civ. Action No. 08-cv-01965. On November 14, 2008, the United States filed a Complaint alleging that the proposed acquisition by InBev NV/SA of Anheuser-Busch Companies, Inc., would violate section 7 of the Clayton Act, 15 U.S.C. 18. The Complaint alleges that the acquisition would substantially reduce competition for sale of beer in the Buffalo, Rochester, and Syracuse, New York metropolitan areas. The proposed Final Judgment, filed at the same time as the Complaint, requires InBev to divest Labatt USA and grant a perpetual license to the acquirer to brew and sell Labatt brand beer for consumption throughout the United States.

Copies of the Complaint, proposed Final Judgment, and Competitive Impact Statement are available for inspection at the Department of Justice, Antitrust Division, Antitrust Documents Group, 450 Fifth Street, NW., Suite 1010, Washington, DC 20530 (202-514-2481), on the Department of Justice Web site (<http://www.usdoj.gov/atr>), and at the Office of the Clerk of the United States District Court for the District of Columbia. Copies of these materials may be obtained from the Antitrust Division upon request and payment of the copying fee set by Department of Justice regulations.

Public comment is invited within 60 days of the date of this notice. Such comments, and responses thereto, will be published in the *Federal Register* and filed with the Court. Comments should be directed to Joshua H. Soven, Chief, Litigation I Section, Antitrust Division, Department of Justice, 1401 H Street, NW., Suite 4000, Washington, DC 20530 (202-307-0001).

**Patricia A. Brink,**

*Deputy Director, Office of Operations.*

United States of America, 1401 H Street, NW.,—Suite 4000, Washington, DC 20530. Plaintiff, v. Inbev N.V./S.A.

Brouwerijplein 1, 3000 Leuven, Belgium, Inbev USA LLC, 50 Fountain Plaza—Suite 900, Buffalo, NY 14202, and Anheuser-Busch Companies, Inc., One Busch Place, St. Louis, MO 63118, Defendants. Case: 1:08-cv-01965, Assigned to: Robertson, James, Assign. Date: 11/14/2008. Description: Antitrust.

#### **Complaint**

The United States of America, acting under the direction of the Attorney General of the United States, brings this civil action to enjoin the proposed acquisition of Anheuser-Busch Companies, Inc. ("Anheuser-Busch") by InBev N.V./S.A. ("InBev") and to obtain

other equitable relief. The United States alleges as follows:

#### I. Nature of the Action

1. On July 13, 2008, Anheuser-Busch and InBev entered into an Agreement and Plan of Merger pursuant to which InBev intends to acquire 100 percent of the voting securities of Anheuser-Busch in a transaction valued at approximately \$52 billion. Anheuser-Busch is the largest brewing company in the United States, accounting for approximately 50 percent of beer sales in the country. Its best selling brands are Bud Light and Budweiser. Belgium-based InBev is the second-largest brewer in the world. InBev's best-selling brands in the United States are Labatt, Stella Artois, and Becks. The proposed acquisition of Anheuser-Busch by InBev would create the world's largest brewing company with annual revenues of over \$36 billion.

2. In three regions of upstate New York, the proposed acquisition would significantly increase the level of concentration in the market and substantially reduce competition by combining InBev's Labatt brands and Anheuser-Busch's Budweiser brands.

3. In the Buffalo metropolitan area ("Buffalo") and the Rochester metropolitan area ("Rochester"), the proposed acquisition would increase Anheuser-Busch's share of the beer market from approximately 24 percent to approximately 45 percent, producing a highly concentrated market dominated by two firms—the combined InBev/Anheuser-Busch and MillerCoors (a joint venture between SABMiller and Coors Brewing Co.). MillerCoors has approximately a 26 percent share of the Buffalo and Rochester beer markets and no other firm has more than a five percent share.

4. The proposed acquisition would also create a highly concentrated beer market in the Syracuse metropolitan area ("Syracuse"). In Syracuse, the proposed acquisition would increase Anheuser-Busch's share of the beer market from approximately 28 percent to approximately 41 percent, with MillerCoors controlling approximately 28 percent. As in Buffalo and Rochester, no other firm has more than a five percent share of the beer market in Syracuse.

5. The proposed acquisition would eliminate substantial head-to-head competition between Anheuser-Busch's Budweiser and InBev's Labatt brands in Buffalo, Rochester, and Syracuse.

6. The significant increase in market concentration that the proposed acquisition would produce in the Buffalo, Rochester, and Syracuse

geographic markets, combined with the loss of head-to-head competition, is likely to substantially lessen competition, in violation of section 7 of the Clayton Act, resulting in higher prices for beer for consumers.

#### II. Jurisdiction and Venue

7. The United States brings this action under section 15 of the Clayton Act, as amended, 15 U.S.C. 25, to prevent and restrain Defendants from violating section 7 of the Clayton Act, 15 U.S.C. 18. This Court has subject matter jurisdiction over this action pursuant to section 15 of the Clayton Act, 15 U.S.C. 25 and 28 U.S.C. 1331, 1337(a), and 1345.

8. Defendants Anheuser-Busch and InBev produce and sell beer in the flow of interstate commerce, and their production and sale of beer substantially affect interstate commerce. Defendants Anheuser-Busch and InBev transact business and are found in the District of Columbia, through, among other things, selling beer to customers in this District. Venue is proper for Anheuser-Busch in this District under 15 U.S.C. 22. Venue is proper in the District of Columbia for Defendant InBev, a Belgian corporation, under 28 U.S.C. 1391(d).

#### III. The Defendants

9. Anheuser-Busch, a Delaware corporation headquartered in St. Louis, Missouri, is the largest brewer in the United States and accounts for approximately 50 percent of beer sales nationwide. Anheuser-Busch operates 12 breweries in the United States. Anheuser-Busch's best-selling brands are Budweiser and Bud Light.

10. Belgium-based InBev is the second-largest brewer in the world, but does not operate any breweries in the United States. InBev's best-selling brands in the United States are Stella, Becks, Bass, and Labatt. Most of InBev's brands, including Stella, Becks, and Bass, are imported, marketed, and sold in the United States by Anheuser-Busch pursuant to a 2006 import agreement ("Anheuser-Busch/InBev import agreement"). InBev's Labatt brands are excluded from the Anheuser-Busch/InBev import agreement. The Labatt brands are brewed in Canada by InBev's subsidiary, Labatt Brewing Company Limited, and are imported and sold in the United States by InBev's subsidiary, InBev USA d/b/a Labatt USA ("IUSA"). Although InBev's overall market share in the United States is small (approximately two percent), the geographic markets are local, and Labatt brand beers account for a significant

portion of the Buffalo, Rochester, and Syracuse beer markets.

11. In Buffalo and Rochester, IUSA accounts for approximately 21 percent of beer sales and Anheuser-Busch accounts for approximately 24 percent of beer sales. In Syracuse, IUSA and Anheuser-Busch account for approximately 13 percent and 28 percent of beer sales, respectively. Combined, Anheuser-Busch and InBev would account for approximately 45 percent of beer sales in Buffalo and Rochester, and over 41 percent of beer sales in Syracuse.

#### IV. Relevant Markets

##### A. Relevant Product Market

12. Beer is an alcoholic beverage that is substantially differentiated from other alcoholic beverages by taste, quality, alcohol content, image, and price.

13. Neither the price of wine nor the price of spirits significantly influences or constrains the price of beer. Purchasers of beer are unlikely to reduce their purchases of beer in response to a small but significant and non-transitory increase in the price of beer to an extent that would make such a price increase unprofitable.

14. Beer is a line of commerce and a relevant product market within the meaning of section 7 of the Clayton Act.

##### B. Relevant Geographic Markets

15. Beer is sold to consumers in local geographic markets through a three-tier distribution system in New York and throughout the United States. Brewers such as InBev and Anheuser-Busch sell beer to wholesalers (often known as "distributors"), which, in turn, sell to retailers. In New York and throughout the United States, distributors' contracts with brewers contain territorial limits and prohibit distributors from selling outside their territories.

16. Distributors cannot sell a brewer's products outside their territories without violating their contracts with the brewer. This allows brewers to charge different prices in different locales for the same package and brand of beer, and prevents individual distributors (and retailers) from defeating such price differences through arbitrage.

17. Brewers develop beer pricing and promotion strategies on a "local" market basis, based on an assessment of local competitive conditions, local demand for the brewers' beer, and local brand strength.

18. Brewers selling beer in a metropolitan area would be able to increase the price of beer by a small but significant and non-transitory amount

without losing sufficient sales to make such a price increase unprofitable.

19. The metropolitan areas of Buffalo, Rochester, and Syracuse constitute three separate, relevant geographic markets for the sale of beer within the meaning of section 7 of the Clayton Act.

#### V. Likely Anticompetitive Effects

20. The relevant beer markets are highly concentrated. In Buffalo and Rochester, the top three brewers: Anheuser-Busch, MillerCoors, and InBev (USA)—account for approximately 24 percent, 26 percent, and 21 percent of the beer market, respectively. In Syracuse, Anheuser-Busch, MillerCoors and IUSA account for approximately 28 percent, 28 percent, and 13 percent of the beer market, respectively.

21. If the proposed acquisition is permitted to occur, the beer markets in Buffalo and Rochester would become substantially more concentrated. The combined firm would control at least 45 percent of beer sales. The merged firm and MillerCoors would control over 70 percent of beer sales. Using a standard concentration measure called the Herfindahl-Herschman Index (or "HHI," defined and explained in Appendix A), the proposed acquisition would produce an HHI increase of approximately 1020 and a post-acquisition HHI of approximately 2790 in Buffalo and Rochester.

22. If the proposed acquisition is permitted to occur, the Syracuse beer market also would become substantially more concentrated. The combined firm would control approximately 41 percent of the market, and the top two brewers—the merged firm and MillerCoors—would account for approximately 69 percent of beer sales. The proposed acquisition in Syracuse would produce an HHI increase of approximately 750 and a post-acquisition HHI of approximately 2580.

23. In Buffalo, Rochester, and Syracuse, the proposed acquisition would eliminate significant head-to-head competition between InBev's Labatt brands and Anheuser-Busch's Budweiser brands. Currently, InBev (through its IUSA subsidiary) and Anheuser-Busch compete in the relevant geographic markets through price discounts and various forms of promotions.

24. The significant increase in market concentration that the proposed acquisition would produce in the Buffalo, Rochester, and Syracuse geographic markets, combined with the loss of head-to-head competition, is likely to substantially lessen competition in violation of section 7 of

the Clayton Act, resulting in higher prices for beer for consumers.

#### VI. Absence of Countervailing Factors

25. Responses from other competitors or new entry is not likely to prevent the likely anticompetitive effects of the proposed acquisition. Competition from other competitors is insufficient to prevent a small but significant and non-transitory price increase implemented by the Defendants in those markets from being profitable. Entry of a significant new competitor into the marketplace is particularly unlikely because a new entrant would not possess the highly-important brand acceptance necessary to succeed.

26. The anticompetitive effects of the proposed acquisition are not likely to be eliminated or mitigated by any efficiencies that may be achieved by the acquisition.

#### VII. Violation Alleged

27. The United States hereby incorporates paragraphs 1 through 26.

28. The proposed acquisition of Anheuser-Busch by InBev would likely substantially lessen competition in interstate trade and commerce, in violation of section 7 of the Clayton Act, 15 U.S.C. 18, and would likely have the following effects, among others:

(a) Actual and potential competition between Anheuser-Busch and InBev (through its IUSA subsidiary) for beer sales in the relevant geographic markets would be eliminated; and

(b) Competition generally in the relevant geographic markets for beer would be substantially lessened.

#### Prayer for Relief

The United States requests:

1. That the proposed acquisition be adjudged to violate section 7 of the Clayton Act, 15 U.S.C. 18;

2. That the Defendants be permanently enjoined and restrained from carrying out the proposed acquisition or from entering into or carrying out any other agreement, understanding, or plan by which Anheuser-Busch would acquire, be acquired by, or merge with, any of the other Defendants;

3. That the United States be awarded costs of this action; and

4. That the United States have such other relief as the Court may deem just and proper.

Respectfully submitted,

/s/  
Deborah A. Garza (DC Bar No. 395259),  
Acting Assistant Attorney General.

/s/  
Patricia A. Brink,  
Deputy Director, Office of Operations.

/s/  
Joshua H. Soven,  
Chief (DC Bar No. 436633).

/s/  
Joseph M. Miller,  
Assistant Chief (DC Bar No. 439965),  
Litigation I Section, (202) 307-0827.

/s/  
Mitchell H. Glende,  
Barry L. Creech (DC Bar No. 421070),  
Scott I. Fitzgerald,  
Tiffany Joseph-Daniels (DC Bar No. 481878),  
Ryan Kantor,  
David C. Kelly,  
Karl D. Knutsen,  
Michael T. Koenig,  
Richard Martin,  
Michelle Seltzer (DC Bar No. 475482),  
Julie Tenney.

Trial Attorneys, U.S. Department of Justice,  
Antitrust Division, Litigation I Section, 1401  
H Street, NW., Suite 4000, Washington, DC  
20530, (202) 353-3106.

Dated: November 14, 2008.

#### The United States District Court for the District of Columbia

United States of America, Plaintiff, v.  
Inbev N.V./S.A., Inbev USA LLC, and  
Anheuser-Busch Companies, Inc.,  
Defendants. Case: 08-cv-Filed: Deck  
Type: Antitrust Date Stamp: \_\_\_\_\_.

#### [Proposed] Final Judgment

Whereas, Plaintiff, United States of America, filed its Complaint on November 14, 2008, and the United States of America and defendants InBev N.V./S.A., InBev USA LLC d/b/a Labatt USA, and Anheuser-Busch Companies, Inc. (collectively, "Defendants"), by their respective attorneys, have consented to the entry of this Final Judgment without trial or adjudication of any issue of fact or law, and without this Final Judgment constituting any evidence against or admission by any party regarding any issue of fact or law; And whereas, Defendants agree to be bound by the provisions of this Final Judgment pending its approval by the Court;

And whereas, the essence of this Final Judgment is the prompt and certain divestiture of certain rights or assets by the Defendants to assure that competition is not substantially lessened;

And whereas, the United States requires Defendants to make certain divestitures for the purpose of remedying the loss of competition alleged in the Complaint;

And whereas, Defendants have represented to the United States that the divestitures required herein can and will be made and that Defendants will later raise no claim of hardship or difficulty as grounds for asking the Court to modify any of the divestiture provisions contained below;

Now therefore, before any testimony is taken, without trial or adjudication of any issue of fact or law, and upon consent of the parties, it is ordered, adjudged, and decreed:

### I. Jurisdiction

This Court has jurisdiction over the subject matter of and each of the parties to this action. The Complaint states a claim upon which relief may be granted against Defendants under section 7 of the Clayton Act, as amended, 15 U.S.C. 18.

### II. Definitions

As used in this Final Judgment:

A. "Acquirer" means the entity or entities to whom Defendants divest the Divestiture Assets.

B. "Advertising" means all existing advertising and promotional materials owned or Licensed by LBCL, including without limitation all copyrights therein, bearing the Licensed Marks for use in the marketing, sale, and distribution of Labatt Brand Beer in the United States.

C. "Anheuser-Busch" means defendant Anheuser-Busch Companies, Inc., a Delaware corporation, with its headquarters in St. Louis, Missouri, its successors and assigns, and its subsidiaries, divisions, groups, affiliates, partnerships, and joint ventures, and their directors, officers, managers, agents, and employees.

D. "Beer" means any fermented alcoholic beverage that (1) is composed in part of water, a type of starch, yeast, and a flavoring and (2) has undergone the process of brewing.

E. "Defendants" means InBev N.V./S.A., InBev USA LLC d/b/a Labatt USA, and Anheuser-Busch Companies, Inc.

F. "Divestiture Assets" means:

(i) An exclusive, perpetual, assignable, transferable, and fully-paid-up license that grants the Acquirer the right:

(A) To brew Labatt Brand Beer in Canada and/or the United States for sale for consumption in the United States;

(B) To promote, market, distribute, and sell Labatt Brand Beer for sale for consumption in the United States; and

(C) To use all intellectual property rights associated with the brewing, marketing, sale, and distribution of Labatt Brand Beer for sale for consumption in the United States, including, without limitation, the Trade Dress, the Advertising, the Licensed Marks, the Recipes, and such molds and designs as are used in the manufacturing process of bottles for the Labatt Brand Beer;

(ii) All production know-how for Labatt Brand Beer, including, without

limitation, all Recipes and packaging, marketing, and distribution know-how and documentation; and

(iii) All of the tangible and intangible assets of IUSA, including, without limitation, (A) all real property (owned or leased), office equipment, office furniture, fixtures, materials, supplies, and other tangible property of IUSA; (B) all contracts and agreements of IUSA except the Existing Import Agreement, including, without limitation, wholesaler and distributor agreements into which InBev or IUSA have entered for the sale or distribution of Labatt Brand Beer within the United States, sponsorship agreements with sports teams and other entities, agreements relating to the placement of advertising, agreements with public relations firms, and agreements with co-packers; (C) all existing inventories of Labatt Brand Beer owned by IUSA; (D) all customer lists, customer accounts, and credit records; (E) all licenses, permits, and authorizations issued by any governmental organization relating to the marketing, sales, and distribution of Labatt Brand Beer in the United States, including, without limitation, brand registrations; and (F) copies of all business, financial and operational books, records and data, both current and historical, that relate to Labatt Brand Beer sold and distributed in the United States; provided, however, that, for books, records, or data that relate to Labatt Brand Beer, but not solely to Labatt Brand Beer sold in the United States, LBCL shall provide only the excerpts of those books, records, or data that relate to the Labatt Brand Beer sold and distributed in the United States;

(iv) Provided, however, that the Acquirer shall have no right to use, and shall not use, the term "InBev" or any derivative of the term "InBev," and provided, further, that the Acquirer shall have no rights to market or sell any brands of Beer owned by InBev other than Labatt Brand Beer.

G. "Existing Import Agreement" means the Exclusive Distributor Agreement dated as of December 1, 1994, among LBCL, Labatt Importers Inc., Labatt's USA Inc., and John Labatt Limited.

H. "InBev" means defendant InBev N.V./S.A., a public company organized under the laws of Belgium, with its headquarters in Leuven, Belgium, its successors and assigns, and its subsidiaries, divisions, groups, affiliates, partnerships, joint ventures, and their respective directors, officers, managers, agents, and employees.

I. "IUSA" means defendant InBev USA LLC d/b/a Labatt USA, a Delaware limited liability company and wholly-

owned, indirect subsidiary of InBev, with its headquarters in Buffalo, New York.

J. "Labatt Brand Beer" means the following brands of Beer: Labatt Blue, Labatt Blue Light, Labatt's 50, Labatt ICE, Labatt Double Blue, Labatt Nordic, Labatt Select, Labatt Non-Alcoholic, Labatt Holiday, and Max ICE, and any extensions of any one or more of such brands for use in connection with brewing, distributing, promoting, marketing, or selling Beer as may be developed from time to time by the Acquirer.

K. "LBCL" means Labatt Brewing Company Limited, a Canadian corporation and wholly-owned, indirect subsidiary of Companhia de Bebidas das Américas—AmBev, a Brazilian corporation and majority-owned subsidiary of InBev.

L. "Licensed Marks" means all trademarks, service marks, or trade names for the Labatt Brand Beer belonging or licensed to LBCL and/or its subsidiaries, divisions, groups, affiliates, partnerships, and joint ventures (whether registered or unregistered, or whether the subject of a pending application) used to brew, distribute, market, and sell Labatt Brand Beer in the United States.

M. "Recipes" means all LBCL's formulae, recipes, processes, and specifications specified by LBCL for use in connection with the production and packaging of Labatt Brand Beer in the United States, including, without limitation, LBCL's yeast, brewing processes, equipment and material specifications, trade and manufacturing secrets, know-how, and scientific and technical information for the Labatt Brand Beer.

N. "Supply Agreement" means an agreement pursuant to which InBev shall supply to the Acquirer Labatt Brand Beer in quantities and units and at prices agreed to between InBev and the Acquirer subject to the approval of the United States in its sole discretion.

O. "Trade Dress" means the print, style, color, labels, and other elements of trade dress currently used by LBCL and/or its subsidiaries, divisions, groups, affiliates, partnerships, and joint ventures in connection with the marketing, sale, and distribution of Labatt Brand Beer in the United States.

### III. Applicability

A. This Final Judgment applies to the Defendants, as defined above, and all other persons in active concert or participation with the Defendants who receive actual notice of this Final Judgment by personal service or otherwise.

B. If, prior to complying with sections IV and V of this Final Judgment, Defendants sell, license, or otherwise dispose of all or substantially all of their assets or lesser business units that include the Divestiture Assets, Defendants shall require the purchaser to be bound by the provisions of this Final Judgment. Defendants need not obtain such an agreement from the Acquirer of the assets divested pursuant to this Final Judgment.

#### IV. Divestiture

A. Defendants are ordered and directed, within ninety (90) calendar days after the filing of the Complaint in this matter, or five (5) calendar days after notice of the entry of this Final Judgment by the Court, whichever is later, to divest the Divestiture Assets in a manner consistent with this Final Judgment to an Acquirer approved by the United States in its sole discretion. The United States, in its sole discretion, may agree to one or more extensions of this time-period, such extensions not to exceed ninety (90) calendar days in total, and shall notify the Court in such circumstances. Defendants agree to use their best efforts to divest the Divestiture Assets as expeditiously as possible.

B. In accomplishing the divestiture ordered by this Final Judgment, Defendants promptly shall make known, by usual and customary means, the availability of the Divestiture Assets. Defendants shall inform any person making inquiry regarding a possible purchase of the Divestiture Assets that they are being divested pursuant to this Final Judgment and provide that person with a copy of this Final Judgment. Defendants shall offer to furnish to all prospective Acquirers, subject to customary confidentiality assurances, all information and documents relating to the Divestiture Assets customarily provided in a due diligence process except such information or documents subject to the attorney-client privilege or work-product doctrine. Defendants shall make available such information to the United States at the same time that such information is made available to any other person.

C. Defendants shall not take any action that will impede in any way the permitting, operation, or divestiture of the Divestiture Assets.

D. Defendants shall warrant to the Acquirer that each asset will be operational on the date of sale.

E. Defendants shall not manufacture, market, distribute, introduce, or sell in the United States any Beer under any brand name or trade name that contains the word "Labatt" after the date of the

execution of the divestiture agreement with the Acquirer, except (i) pursuant to the terms of the Supply Agreement, and (ii) as necessary to satisfy a legal requirement to identify the brewer for and origin of other brands of beer brewed by LBCL and sold in the United States where the corporate identity of the brewer includes the word "Labatt"; provided, however, that Defendants shall not be in violation of this consent decree if an independent party ships Labatt Brand Beer from Canada to the United States without Defendants' permission or knowledge.

F. Defendants shall provide the Acquirer and the United States information relating to IUSA's personnel involved in the management, operations, or sales activities in the United States relating to the Divestiture Assets to enable the Acquirer to make offers of employment. Defendants will not interfere with any efforts by the Acquirer to employ any personnel employed by IUSA having management, operations, or sales responsibilities relating to the Divestiture Assets.

G. Unless the United States otherwise consents in writing, Defendants shall permit prospective Acquirers of the Divestiture Assets to have reasonable access to personnel and to make reasonable inspections of the physical facilities; access to any and all environmental, zoning, and other permit documents and information; and access to any and all financial, operational, or other documents and information customarily provided as part of a due diligence process.

H. Notwithstanding anything to the contrary in this Final Judgment, at the option of the Acquirer, Defendants shall enter into a transition services agreement for a limited period with respect to information technology support, information technology licensing, computer operations, data processing, logistics support, and such other services as are reasonably necessary to operate the Divestiture Assets, with the scope, terms, and conditions of such agreement being subject to the approval of the United States in its sole discretion. Such an agreement may not exceed twelve (12) months from the date of divestiture.

I. Unless the United States otherwise consents in writing, the divestiture pursuant to section IV, or by trustee appointed pursuant to Section V, of this Final Judgment, shall include the entire Divestiture Assets and shall be accomplished in such a way as to satisfy the United States, in its sole discretion, that the Divestiture Assets can and will be used by the Acquirer as part of a viable, ongoing business engaged in the

sale of Beer; provided that it is demonstrated to the sole satisfaction of the United States that the Divestiture Assets will remain viable and the divestiture of such assets will remedy the competitive harm alleged in the Complaint. The divestiture, whether pursuant to section IV or section V of this Final Judgment,

(1) Shall be made to an Acquirer that, in the United States's sole judgment, has the intent and capability (including the necessary managerial, operational, technical, and financial capability) of competing effectively in the sale of Beer; and

(2) Shall be accomplished so as to satisfy the United States, in its sole discretion; that none of the terms of any agreement between the Acquirer and Defendants give Defendants the ability unreasonably to raise the Acquirer's costs, to lower the Acquirer's efficiency, or otherwise to interfere in the ability of the Acquirer to compete effectively.

J. As part of a divestiture, and at the option of the Acquirer, Defendants shall negotiate and consummate a Supply Agreement to supply Labatt Brand Beer in quantities and units and at prices agreed to between InBev and the Acquirer with the approval of the United States. The Supply Agreement shall be no more than three (3) years in length. The terms and conditions of any such Supply Agreement shall be subject to the approval of the United States in its sole discretion. During the term of the Supply Agreement, Defendants shall establish, implement, and maintain procedures and take such other steps that are reasonably necessary to prevent the disclosure of the quantities and units of Labatt Brand Beer ordered or purchased from the Defendants by the Acquirer, the prices paid by the Acquirer, and any other competitively sensitive information regarding the Defendants' or the Acquirer's performance under the Supply Agreement, to any employee of the Defendants that has direct responsibilities for marketing, distributing, or selling Beer in competition with the Acquirer in the United States.

#### V. Appointment of Trustee

A. If Defendants have not divested the Divestiture Assets within the time period specified in section IV(A), Defendants shall notify the United States of that fact in writing. Upon application of the United States, the Court shall appoint a trustee selected by the United States and approved by the Court to effect the divestiture of the Divestiture Assets.



B. After the appointment of a trustee becomes effective, only the trustee shall have the right to sell the Divestiture Assets. The trustee shall have the power and authority to accomplish the divestiture to an Acquirer acceptable to the United States at such price and on such terms as are then obtainable upon reasonable effort by the trustee, subject to the provisions of sections IV, V, and VI of this Final Judgment, and shall have such other powers as this Court deems appropriate. Subject to section V(D) of this Final Judgment, the trustee may hire at the cost and expense of Defendants any investment bankers, attorneys, or other agents, who shall be solely accountable to the trustee, reasonably necessary in the trustee's judgment to assist in the divestiture.

C. Defendants shall not object to a sale by the trustee on any ground other than the trustee's malfeasance. Any such objection by Defendants must be conveyed in writing to the United States and the trustee within ten (10) calendar days after the trustee has provided the notice required under section VI.

D. The trustee shall serve at the cost and expense of Defendants, on such terms and conditions as the United States approves, and shall account for all monies derived from the sale of the assets sold by the trustee and all costs and expenses so incurred. After approval by the Court of the trustee's accounting, including fees for its services and those of any professionals and agents retained by the trustee, all remaining money shall be paid to Defendants and the trust shall then be terminated. The compensation of the trustee and any professionals and agents retained by the trustee shall be reasonable in light of the value of the Divestiture Assets and based on a fee arrangement providing the trustee with an incentive based on the price and terms of the divestiture and the speed with which it is accomplished, but timeliness is paramount.

E. Defendants shall use their best efforts to assist the trustee in accomplishing the required divestiture. The trustee and any consultants, accountants, attorneys, and other persons retained by the trustee shall have full and complete access to the personnel, books, records, and facilities of the business to be divested, and Defendants shall develop financial and other information relevant to such business as the trustee may reasonably request, subject to reasonable protection for trade secrets or other confidential research, development, or commercial information. Defendants shall take no action to interfere with or to impede the

trustee's accomplishment of the divestiture.

F. After its appointment, the trustee shall file monthly reports with the United States and the Court setting forth the trustee's efforts to accomplish the divestiture ordered under this Final Judgment. To the extent such reports contain information that the trustee deems confidential, such reports shall not be filed in the public docket of the Court. Such reports shall include the name, address, and telephone number of each person who, during the preceding month, made an offer to acquire, expressed an interest in acquiring, entered into negotiations to acquire, or was contacted or made an inquiry about acquiring any interest in the Divestiture Assets, and shall describe in detail each contact with any such person. The trustee shall maintain full records of all efforts made to divest the Divestiture Assets.

G. If the trustee has not accomplished the divestiture ordered under this Final Judgment within six (6) months after its appointment, the trustee shall promptly file with the Court a report setting forth (1) the trustee's efforts to accomplish the required divestiture; (2) the reasons, in the trustee's judgment, why the required divestiture has not been accomplished; and (3) the trustee's recommendations. To the extent such reports contain information that the trustee deems confidential, such reports shall not be filed in the public docket of the Court. The trustee shall at the same time furnish such report to the United States, which shall have the right to make additional recommendations consistent with the purpose of the trust. The Court thereafter shall enter such orders as it shall deem appropriate to carry out the purpose of this Final Judgment, which may, if necessary, include extending the trust and the term of the trustee's appointment by a period requested by the United States.

#### VI. Notice of Proposed Divestiture

A. Within two (2) business days following execution of a definitive divestiture agreement, Defendants or the trustee, whichever is then responsible for effecting the divestiture required herein, shall notify the United States of any proposed divestiture required by section IV or V of this Final Judgment. If the trustee is responsible, it shall similarly notify Defendants. The notice shall set forth the details of the proposed divestiture and list the name, address, and telephone number of each person not previously identified who offered or expressed an interest in or desire to acquire any ownership interest

in the Divestiture Assets, together with full details of the same.

B. Within fifteen (15) calendar days of receipt by the United States of such notice, the United States may request from Defendants, the proposed Acquirer, any other third party, or the trustee, if applicable, additional information concerning the proposed divestiture, the proposed Acquirer, and any other potential Acquirer. Defendants and the trustee shall furnish any additional information requested within fifteen (15) calendar days of the receipt of the request, unless the parties shall otherwise agree.

C. Within thirty (30) calendar days after receipt of the notice, or within twenty (20) calendar days after the United States has been provided the additional information requested from Defendants, the proposed Acquirer, any third party, and the trustee, whichever is later, the United States shall provide written notice to Defendants and the trustee, if there is one, stating whether or not it objects to the proposed divestiture. If the United States provides written notice that it does not object, the divestiture may be consummated, subject only to Defendants' limited right to object to the sale under section V(C) of this Final Judgment. Absent written notice that the United States does not object to the proposed Acquirer or upon objection by the United States, a divestiture proposed under section IV or Section V shall not be consummated. Upon objection by Defendants under section V(C), a divestiture proposed under section V shall not be consummated unless approved by the Court.

#### VII. Financing

Defendants shall not finance all or any part of any purchase made pursuant to section IV or V of this Final Judgment.

#### VIII. Hold Separate

Until the divestiture required by this Final Judgment has been accomplished, Defendants shall take all steps necessary to comply with the Hold Separate Stipulation and Order entered by this Court. Defendants shall take no action that would jeopardize the divestiture ordered by this Court.

#### IX. Affidavits

A. Within twenty (20) calendar days of the filing of the Complaint in this matter, and every thirty (30) calendar days thereafter until the divestiture has been completed under section IV or V, Defendants shall deliver to the United States an affidavit as to the fact and manner of its compliance with section

IV or V of this Final Judgment. Each such affidavit shall include the name, address, and telephone number of each person who, during the preceding thirty (30) calendar days, made an offer to acquire, expressed an interest in acquiring, entered into negotiations to acquire, or was contacted or made an inquiry about acquiring, any interest in the Divestiture Assets, and shall describe in detail each contact with any such person during that period. Each such affidavit shall also include a description of the efforts Defendants have taken to solicit buyers for the Divestiture Assets, and to provide required information to a prospective Acquirer, including the limitations, if any, on such information. Assuming the information set forth in the affidavit is true and complete, any objection by the United States to information provided by Defendants, including limitation on information, shall be made within fourteen (14) calendar days of receipt of such affidavit.

B. Within twenty (20) calendar days of the filing of the Complaint in this matter, Defendants shall deliver to the United States an affidavit that describes in reasonable detail all actions Defendants have taken and all steps Defendants have implemented on an ongoing basis to comply with section VIII of this Final Judgment. Defendants shall deliver to the United States an affidavit describing any changes to the efforts and actions outlined in Defendants' earlier affidavits filed pursuant to this section within fifteen (15) calendar days after the change is implemented.

C. Defendants shall keep all records of all efforts made to preserve and divest the Divestiture Assets until one year after such divestiture has been completed.

#### X. Compliance Inspection

A. For the purposes of determining or securing compliance with this Final Judgment, or of determining whether this Final Judgment should be modified or vacated, and subject to any legally recognized privilege, from time to time authorized representatives of the United States Department of Justice Antitrust Division ("DOJ") including consultants and other persons retained by the United States, shall, upon written request of an authorized representative of the Assistant Attorney General in charge of the Antitrust Division, and on reasonable notice to Defendants, be permitted:

(1) Access during Defendants' office hours to inspect and copy, or at the option of the United States, to require Defendants to provide hard copy or

electronic copies of, all books, ledgers, accounts, records, data, and documents in the possession, custody, or control of Defendants, relating to any matters contained in this Final Judgment; and

(2) To interview, either informally or on the record, Defendants' officers, employees, or agents, who may have their individual counsel present, regarding such matters. The interviews shall be subject to the reasonable convenience of the interviewee and without restraint or interference by Defendants.

B. Upon the written request of an authorized representative of the Assistant Attorney General in charge of the Antitrust Division, Defendants shall submit written reports or respond to written interrogatories, under oath if requested, relating to any of the matters contained in this Final Judgment as may be requested.

C. No information or documents obtained by the means provided in this section shall be divulged by the United States to any person other than an authorized representative of the executive branch of the United States, except in the course of legal proceedings to which the United States is a party (including grand jury proceedings), or for the purpose of securing compliance with this Final Judgment, or as otherwise required by law.

D. If, at the time information or documents are furnished by Defendants to the United States, Defendants represent and identify in writing the material in any such information or documents to which a claim of protection may be asserted under Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure, and Defendants mark each pertinent page of such material, "Subject to claim of protection under Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure," then the United States shall give Defendants ten (10) calendar days' notice prior to divulging such material in any legal proceeding (other than a grand jury proceeding).

#### XI. No Reacquisition

Defendants may not reacquire any part of the Divestiture Assets during the term of this Final Judgment.

#### XII. Retention of Jurisdiction

This Court retains jurisdiction to enable any party to this Final Judgment to apply to this Court at any time for further orders and directions as may be necessary or appropriate to carry out or construe this Final Judgment, to modify any of its provisions, to enforce compliance, and to punish violations of its provisions.

#### XIII. Expiration of Final Judgment

Unless this Court grants an extension, this Final Judgment shall expire ten (10) years from the date of its entry.

#### XIV. Public Interest Determination

Entry of this Final Judgment is in the public interest. The parties have complied with the requirements of the Antitrust Procedures and Penalties Act, 15 U.S.C. 16, including making copies available to the public of this Final Judgment, the Competitive Impact Statement, and any comments thereon and the United States's responses to comments. Based upon the record before the Court, which includes the Competitive Impact Statement and any comments and responses to comments filed with the Court, entry of this Final Judgment is in the public interest.

Date:

Court approval subject to procedures of Antitrust Procedures and Penalties Act, 15 U.S.C. 16.

United States District Judge

#### The United States District Court for the District of Columbia

United States of America, Plaintiff. v. InBev N.V./S.A., InBev USA LLC, and Anheuser-Busch Companies, Inc., Defendants. Case: 1:08-cv-01965 Assigned To: Robertson, James Assign. Date: 11/14/2008 Description: Antitrust

#### Competitive Impact Statement

Plaintiff United States of America ("United States"), pursuant to section 2(b) of the Antitrust Procedures and Penalties Act ("APPA" or "Tunney Act"), 15 U.S.C. 16(b)-(h), files this Competitive Impact Statement relating to the proposed Final Judgment submitted for entry in this civil antitrust proceeding.

#### I. Nature and Purpose of the Proceeding

On November 14, 2008, the United States filed a civil antitrust Complaint seeking to enjoin the proposed acquisition of Anheuser-Busch Companies, Inc. ("Anheuser-Busch") by InBev N.V./S.A. ("InBev"). The Complaint alleges that the likely effect of the merger would be to lessen competition substantially in the market for beer in the metropolitan areas of Buffalo, Rochester, and Syracuse, New York, in violation of section 7 of the Clayton Act, 15 U.S.C. 18. In each of these metropolitan areas, the transaction would combine two of the three major manufacturers of beer, creating a highly concentrated market. The transaction would also eliminate substantial head-to-head competition between InBev and

Anheuser-Busch in these regions. This loss of competition likely would result in higher beer prices to consumers in those areas. At the same time that the Complaint was filed, the United States also filed a Hold Separate Stipulation and Order ("Stipulation") and a proposed Final Judgment, which are designed to eliminate the anticompetitive effects of the merger.

Under the proposed Final Judgment, which is explained more fully in section III, Defendants are required to divest InBev USA d/b/a Labatt USA ("IUSA"), a Delaware limited liability company and wholly-owned subsidiary of InBev with its headquarters in Buffalo, New York, and a perpetual, assignable, transferable, and fully-paid-up license and the other rights needed to brew, promote, market, distribute, and sell Labatt brand beer for consumption in the United States (hereafter the "Divestiture Assets"). Under the terms of the Stipulation, Defendants will take certain steps to ensure that the Divestiture Assets are operated as an ongoing, economically viable, and independent competitive business in the brewing, promotion, marketing, distribution, and sale of Labatt brand beer for consumption in the United States.

The United States and Defendants have stipulated that the proposed Final Judgment may be entered after compliance with the APPA. Entry of the proposed Final Judgment would terminate this action, except that the Court would retain jurisdiction to construe, modify, or enforce the provisions of the proposed Final Judgment and to punish violations thereof.

## II. Events Giving Rise to the Alleged Violation

### A. Defendants and the Proposed Transaction

On July 13, 2008, Anheuser-Busch and InBev entered into an Agreement and Plan of Merger pursuant to which InBev intends to acquire 100 percent of the voting securities of Anheuser-Busch in a transaction valued at approximately \$52 billion. The proposed acquisition of Anheuser-Busch by InBev would create the world's largest brewing company with annual revenues of over \$36 billion.

Anheuser-Busch, a Delaware corporation headquartered in St. Louis, Missouri, is the largest brewing company in the United States, accounting for approximately 50 percent of beer sales in the country. Anheuser-Busch's best-selling brands are Budweiser and Bud Light. In the Buffalo

and Rochester metropolitan areas, Anheuser-Busch accounts for approximately 24 percent of beer sales.<sup>1</sup> In the Syracuse metropolitan area, Anheuser-Busch accounts for approximately 28 percent of beer sales.

Belgium-based InBev is the second-largest brewer in the world. InBev's best-selling brands in the United States are Labatt, Stella Artois, Bass, and Becks. Although InBev's share of beer sales nationwide is small, in the Buffalo, Rochester, and Syracuse metropolitan areas, it is substantial. In Buffalo and Rochester, InBev's wholly-owned subsidiary, IUSA, accounts for at least 21 percent of beer sales. In Syracuse, IUSA accounts for approximately 13 percent of beer sales. Combined, IUSA and Anheuser-Busch control at least 45 percent of beer sales in Buffalo and Rochester and approximately 41 percent of beer sales in Syracuse. MillerCoors, the third significant competitor, accounts for approximately 26 percent of sales in Buffalo and Rochester and 28 percent of sales in Syracuse. No other competitor sells more than 5 percent of the beer sold in these areas.

### B. Competitive Effects of the Proposed Merger

#### 1. Beer Is the Relevant Product Market

The Complaint alleges that beer is a line of commerce and a relevant product market within the meaning of section 7 of the Clayton Act. Beer is an alcoholic beverage that is substantially differentiated from other alcoholic beverages by taste, quality, alcohol content, image and price. Neither the price of wine nor the price of spirits significantly influences or constrains the price of beer. Purchasers of beer are unlikely to reduce their purchases of beer in response to a small but significant and non-transitory increase in the price of beer to an extent that would make such a price increase unprofitable. The manufacture and sale of beer is the relevant product market.

<sup>1</sup> The market shares for the Buffalo, Rochester, and Syracuse metropolitan areas are calculated from weekly AC Nielsen grocery store scanner data. This data is not available separately for Buffalo and Rochester, and so the market share calculations are based on a combined Buffalo/Rochester area. Information Resources, Inc. ("IRI") compiles drug store scanner data separately for Buffalo and Rochester, and the IRI data indicates that the AC Nielsen data may underestimate the Defendants' shares of beer sales in Buffalo and Rochester. Based on IRI drug store data, in Buffalo, Anheuser-Busch accounts for 32 percent of beer sales and InBev accounts for 23 percent of beer sales. The IRI drug store data shows that, in Rochester, Anheuser-Busch accounts for 33 percent of beer sales and InBev accounts for 19 percent of beer sales.

#### 2. The Metropolitan Areas of Buffalo, Rochester, and Syracuse, New York, Are Relevant Geographic Markets

As alleged in the Complaint, the metropolitan areas of Buffalo, Rochester, and Syracuse, New York, constitute three separate, relevant geographic markets for the sale of beer within the meaning of the Clayton Act. Beer is sold to consumers in local geographic markets through a three-tier distribution system in New York and throughout the United States. Brewers such as InBev and Anheuser-Busch sell beer to wholesalers (often known as "distributors"), which, in turn, sell to retailers. In New York and throughout the United States, distributors' contracts with brewers contain territorial limits and prohibit distributors from selling beer outside their respective territories.

Because distributors cannot sell a brewer's products outside their territories without violating their contracts with the brewer, brewers can charge different prices in different locales for the same package and brand of beer, and individual distributors (and retailers) cannot defeat such price differences through arbitrage. Consequently, brewers develop beer pricing and promotion strategies on a "local" market basis, based on an assessment of local competitive conditions, local demand for the brewers' beer, and local brand strength. Brewers selling beer in a metropolitan area would be able to increase the price of beer by a small but significant and non-transitory amount without losing sufficient sales to make such a price increase unprofitable.

#### 3. Anticompetitive Effects of the Proposed Merger

As alleged in the Complaint, the Buffalo, Rochester, and Syracuse beer markets are highly concentrated. The top three brewers—Anheuser-Busch, MillerCoors, and IUSA—respectively possess approximately 24 percent, 26 percent, and 21 percent of the Buffalo and Rochester beer markets. In the Syracuse geographic market, the same three brewers respectively possess approximately 28 percent, 28 percent, and 13 percent of the beer market.

If the proposed acquisition is permitted to occur, the beer markets in the Buffalo, Rochester, and Syracuse geographic markets would become substantially more concentrated. Combined, Defendants would account for at least 45 percent of beer sales in Buffalo and Rochester and 41 percent in Syracuse, and the top two brewers—Defendants and MillerCoors—would control about 70 percent of sales in each

market. No other competitor would account for more than 5 percent of sales in these markets. Using a concentration measure called the Herfindahl-Herschman Index (or "HHI", defined and explained in Appendix A), the proposed acquisition would produce an HHI increase of approximately 1,020 and a post-acquisition HHI of approximately 2,790 in the Buffalo and Rochester markets. In Syracuse, the proposed acquisition would produce an HHI increase of approximately 750 and a post-acquisition HHI of approximately 2,580.

The transaction would also eliminate significant head-to-head pricing and promotion competition between InBev's Labatt brands and Anheuser-Busch's Budweiser brands in each of the three geographic markets. The significant increase in market concentration that the transaction would produce in the three geographic markets, combined with the loss of head-to-head competition, is likely to substantially lessen competition, in violation of section 7 of the Clayton Act, resulting in higher prices for beer.

#### 4. Neither Supply Responses Nor Entry Would Prevent the Likely Anticompetitive Effects of the Proposed Merger

The Complaint alleges that supply responses from competitors or potential competitors would not likely prevent the anticompetitive effects of the proposed acquisition of Anheuser-Busch by InBev. Competition from other competitors is insufficient to prevent a small but significant and non-transitory price increase implemented by the Defendants in those markets from being profitable. Entry of a significant new competitor into the marketplace is particularly unlikely because a new entrant would not possess the highly-important brand acceptance necessary to succeed.

### III. Explanation of the Proposed Final Judgment

The proposed Final Judgment is designed to eliminate the anticompetitive effects identified in the Complaint by requiring the Defendants to divest IUSA and all of the real and intellectual property rights required to brew, promote, market, distribute, and sell Labatt brand beer for consumption in the United States. These rights include an exclusive, perpetual, assignable, transferable, and fully-paid-up license that grants the Acquirer the rights to (a) brew Labatt brand beer in Canada and/or the United States, (b) promote, market, distribute, and sell Labatt brand beer for consumption in

the United States, and (c) use all of the intellectual property rights associated with the marketing, sale, and distribution of Labatt brand beer for consumption in the United States, including the trade dress, the advertising, the licensed marks, and such molds and designs as are used in the manufacturing process of bottles for the Labatt brand beer. Final Judgment II(F) and IV(A).

Further, to ensure that the Acquirer can brew Labatt beer without any loss of quality or consistency, the proposed Final Judgment requires Defendants to sell to the Acquirer all production know-how for Labatt brand beer, including recipes, packaging and marketing and distribution know-how and documentation. Final Judgment III(F) and IV(A). The recipes required to be divested include all formulae, recipes, processes and specifications specified \* \* \* for use in connection with the production and packaging of Labatt Brand Beer in the United States, including \* \* \* yeast, brewing processes, equipment and material specifications, trade and manufacturing secrets, know-how and scientific and technical information \* \* \*. Final Judgment II(M).

The proposed Final Judgment ensures the uninterrupted sale of Labatt brand beer in the United States by requiring Defendants to divest all rights pursuant to distributor contracts and, at the option of the Acquirer, to negotiate a transition services agreement of up to one year in length, and to enter into a supply contract for Labatt brand beer sufficient to meet all or part of the Acquirer's needs for a period of up to three years. Final Judgment III(F)(iv) and IV(H). If the Defendants and the Acquirer enter into such a supply contract, the proposed Final Judgment will prevent the exchange of competitively sensitive information between them; the Defendants are required to implement procedures that will prevent the disclosure of the quantities and units of Labatt brand beer ordered or purchased from the Defendants by the Acquirer, the prices paid by the Acquirer, and any other competitively sensitive information regarding the Defendants' or the Acquirer's performance under the Supply Agreement, to any employee of the Defendants who has direct responsibilities for marketing, distributing, or selling beer in competition with the Acquirer in the United States. Final Judgment IV(J).

To ensure that the Acquirer can continue to develop, grow, and improve the Labatt brand, the proposed Final Judgment requires Defendants to grant

to the Acquirer a perpetual license that will allow the Acquirer to brew, distribute, market, and sell "extensions" of Labatt brand beer (e.g., a "Light" or "Ice" version). The extension of beer brands has constituted a significant form of competition among beer brewers in recent years.

The divestiture remedies the anticompetitive effects of the merger by requiring InBev to divest the Divestiture Assets to an independent, viable acquirer that can compete with the merged Anheuser-Busch/InBev. Defendants are required to satisfy the United States in its sole discretion that the Divestiture Assets will be operated as a viable, ongoing business that will compete effectively in the relevant markets, and that the divestiture will successfully remedy the otherwise anticipated anticompetitive effects of the proposed merger. Defendants must take all reasonable steps necessary to accomplish the divestiture quickly and shall cooperate with prospective acquirers.

The proposed Final Judgment requires Defendants, within ninety (90) days after the filing of the Complaint or five (5) calendar days after notice of the entry of this Final Judgment by the Court, whichever is later, to divest the Divestiture Assets, which will be used by the acquirer as part of a viable, ongoing business of brewing, promoting, marketing, distributing and selling Labatt brand beer for consumption in the United States.

In the event that Defendants do not accomplish the divestiture within the periods prescribed in the proposed Final Judgment, the Final Judgment provides that the Court will appoint a trustee selected by the United States to effect the divestiture. If a trustee is appointed, the proposed Final Judgment provides that Defendants will pay all costs and expenses of the trustee. The trustee's commission will be structured so as to provide an incentive for the trustee based on the speed with which the divestiture is accomplished and the price and terms obtained. After his or her appointment becomes effective, the trustee will file monthly reports with the Court and the United States setting forth his or her efforts to accomplish the divestiture. If the requisite divestiture has not been accomplished at the end of the trustee's term, the trustee and the United States will make recommendations to the Court, which shall enter such orders as appropriate in order to carry out the purpose of the trust, including extending the trust or the term of the trustee's appointment.

Until the divestiture under the proposed Final Judgment has been

accomplished, Defendants are required to comply with a Hold Separate Stipulation and Order. Pursuant to this Stipulation and Order, the Defendants are required to preserve, maintain, and operate the Divestiture Assets as an ongoing business, and prohibited from taking any action that would jeopardize the divestiture required by the proposed Final Judgment.

#### IV. Remedies Available to Potential Private Litigants

Section 4 of the Clayton Act, 15 U.S.C. 15, provides that any person who has been injured as a result of conduct prohibited by the antitrust laws may bring suit in federal court to recover three times the damages the person has suffered, as well as costs and reasonable attorneys' fees. Entry of the proposed Final Judgment will neither impair nor assist the bringing of any private antitrust damage action. Under the provisions of section 5(a) of the Clayton Act, 15 U.S.C. 16(a), the proposed Final Judgment has no *prima facie* effect in any subsequent private lawsuit that may be brought against the Defendants.

#### V. Procedures Available for Modification of the Proposed Final Judgment

The United States and Defendants have stipulated that the proposed Final Judgment may be entered by the Court after compliance with the provisions of the APPA, provided that the United States has not withdrawn its consent. The APPA conditions entry upon the Court's determination that the proposed Final Judgment is in the public interest.

The APPA provides a period of at least sixty (60) days preceding the effective date of the proposed Final Judgment within which any person may submit to the United States written comments regarding the proposed Final Judgment. Any person who wishes to comment should do so within sixty (60) days of the date of publication of this Competitive Impact Statement in the **Federal Register**, or the last date of publication in a newspaper of the summary of this Competitive Impact Statement, whichever is later. All comments received during this period will be considered by the United States Department of Justice, which remains free to withdraw its consent to the proposed Final Judgment at any time prior to the Court's entry of judgment. The comments and the response of the United States will be filed with the Court and published in the **Federal Register**. Written comments should be submitted to: Joshua H. Soven, Chief, Litigation I Section, 1401 H Street, NW., Suite 4000, Antitrust Division, U.S.

Department of Justice, Washington, DC 20530.

The proposed Final Judgment provides that the Court retains jurisdiction over this action, and the parties may apply to the Court for any order necessary or appropriate for the modification, interpretation, or enforcement of the Final Judgment.

#### VI. Alternatives to the Proposed Final Judgment

The United States considered, as an alternative to the proposed Final Judgment, a full trial on the merits against Defendants. The United States could have sought preliminary and permanent injunctions against the proposed merger. The United States is satisfied, however, that the divestiture of assets described in the proposed Final Judgment will preserve competition for the provision of beer in the relevant markets identified by the United States. Thus the proposed Final Judgment would achieve all or substantially all of the relief the United States would have obtained through litigation, but avoids the time, expense and uncertainty of a full trial on the merits of the Complaint.

#### VII. Standard of Review Under the APPA for the Proposed Final Judgment

The Clayton Act, as amended by the APPA, requires that proposed consent judgments in antitrust cases brought by the United States be subject to a sixty-day comment period, after which the court shall determine whether entry of the proposed Final Judgment "is in the public interest." 15 U.S.C. 16(e)(1). In making that determination, the court, in accordance with the statute as amended in 2004, is required to consider:

(A) The competitive impact of such judgment, including termination of alleged violations, provisions for enforcement and modification, duration of relief sought, anticipated effects of alternative remedies actually considered, whether its terms are ambiguous, and any other competitive considerations bearing upon the adequacy of such judgment that the court deems necessary to a determination of whether the consent judgment is in the public interest; and

(B) The impact of entry of such judgment upon competition in the relevant market or markets, upon the public generally and individuals alleging specific injury from the violations set forth in the complaint including consideration of the public benefit, if any, to be derived from a determination of the issues at trial. 15 U.S.C. 16(e)(1)(A) & (B). In considering these statutory factors, the

court's inquiry is necessarily a limited one as the government is entitled to "broad discretion to settle with the defendant within the reaches of the public interest." *United States v. Microsoft Corp.*, 56 F.3d 1448, 1461 (D.C. Cir. 1995); see generally *United States v. SBC Commc'ns, Inc.*, 489 F. Supp. 2d 1 (D.D.C. 2007) (assessing public interest standard under the Tunney Act).<sup>2</sup>

As the United States Court of Appeals for the District of Columbia Circuit has held, under the APPA a court considers, among other things, the relationship between the remedy secured and the specific allegations set forth in the government's complaint, whether the decree is sufficiently clear, whether enforcement mechanisms are sufficient, and whether the decree may positively harm third parties. See *Microsoft*, 56 F.3d at 1458-62. With respect to the adequacy of the relief secured by the decree, a court may not "engage in an unrestricted evaluation of what relief would best serve the public." *United States v. BNS, Inc.*, 858 F.2d 456, 462 (9th Cir. 1988) (citing *United States v. Bechtel Corp.*, 648 F.2d 660, 666 (9th Cir. 1981)); see also *Microsoft*, 56 F.3d at 1460-62; *United States v. Alcoa, Inc.*,<sup>3</sup> 152 F. Supp. 2d 37, 40 (D.D.C. 2001). Courts have held that:

[t]he balancing of competing social and political interests affected by a proposed antitrust consent decree must be left, in the first instance, to the discretion of the Attorney General. The court's role in protecting the public interest is one of insuring that the government has not breached its duty to the public in consenting to the decree. The court is required to determine not whether a particular decree is the one that will best serve society, but whether the settlement is "within the reaches of the public interest." More elaborate requirements might undermine the effectiveness of antitrust enforcement by consent decree.

*Bechtel*, 648 F.2d at 666 (emphasis added) (citations omitted).<sup>3</sup>

<sup>2</sup> The 2004 amendments substituted "shall" for "may" in directing relevant factors for court to consider and amended the list of factors to focus on competitive considerations and to address potentially ambiguous judgment terms. Compare 15 U.S.C. 16(e) (2004), with 15 U.S.C. 16(e)(1) (2006); see also *SBC Commc'ns*, 489 F. Supp. 2d at 11 (concluding that the 2004 amendments "effected minimal changes" to Tunney Act review).

<sup>3</sup> Cf. *BNS*, 858 F.2d at 464 (holding that the court's "ultimate authority under the [APPA] is limited to approving or disapproving the consent decree"); *United States v. Gillette Co.*, 406 F. Supp. 713, 716 (D. Mass. 1975) (noting that, in this way, the court is constrained to "look at the overall picture not hypercritically, nor with a microscope, but with an artist's reducing glass"). See generally *Microsoft*, 56 F.3d at 1461 (discussing whether "the remedies [obtained in the decree] are so

In determining whether a proposed settlement is in the public interest, a district court "must accord deference to the government's predictions about the efficacy of its remedies, and may not require that the remedies perfectly match the alleged violations." *SBC Commc'ns*, 489 F. Supp. 2d at 17; see also *Microsoft*, 56 F.3d at 1461 (noting the need for courts to be "deferential to the government's predictions as to the effect of the proposed remedies"); *United States v. Archer-Daniels-Midland Co.*, 272 F. Supp. 2d 1, 6 (D.D.C. 2003) (noting that the court should grant due respect to the United States' prediction as to the effect of proposed remedies, its perception of the market structure, and its views of the nature of the case).

Courts have greater flexibility in approving proposed consent decrees than in crafting their own decrees following a finding of liability in a litigated matter. "[A] proposed decree must be approved even if it falls short of the remedy the court would impose on its own, as long as it falls within the range of acceptability or is "within the reaches of public interest." *United States v. Am. Tel. & Tel. Co.*, 552 F. Supp. 131, 151 (D.D.C. 1982) (citations omitted) (quoting *United States v. Gillette Co.*, 406 F. Supp. 713, 716 (D. Mass. 1975)), *aff'd sub nom. Maryland v. United States*, 460 U.S. 1001 (1983); see also *United States v. Alcan Aluminum Ltd.*, 605 F. Supp. 619, 622 (W.D. Ky. 1985) (approving the consent decree even though the court would have imposed a greater remedy). To meet this standard, the United States "need only provide a factual basis for concluding that the settlements are reasonably adequate remedies for the alleged harms." *SBC Commc'ns*, 489 F. Supp. 2d at 17.

Moreover, the court's role under the APPA is limited to reviewing the remedy in relationship to the violations that the United States has alleged in its Complaint, and does not authorize the court to "construct [its] own hypothetical case and then evaluate the decree against that case." *Microsoft*, 56 F.3d at 1459. Because the "court's authority to review the decree depends entirely on the government's exercising its prosecutorial discretion by bringing a case in the first place," it follows that "the court is only authorized to review the decree itself," and not to "effectively redraft the complaint" to inquire into other matters that the United States did not pursue. *Id.* at 1459-60. As this Court recently confirmed in *SBC*

*Communications*, courts "cannot look beyond the complaint in making the public interest determination unless the complaint is drafted so narrowly as to make a mockery of judicial power." *SBC Commc'ns*, 489 F. Supp. 2d at 15.

In its 2004 amendments, Congress made clear its intent to preserve the practical benefits of utilizing consent decrees in antitrust enforcement, adding the unambiguous instruction that "[n]othing in this section shall be construed to require the court to conduct an evidentiary hearing or to require the court to permit anyone to intervene." 15 U.S.C. 16(e)(2). The language wrote into the statute what Congress intended when it enacted the Tunney Act in 1974, as Senator Tunney explained: "[t]he court is nowhere compelled to go to trial or to engage in extended proceedings which might have the effect of vitiating the benefits of prompt and less costly settlement through the consent decree process." 119 Cong. Rec. 24,598 (1973) (statement of Senator Tunney). Rather, the procedure for the public interest determination is left to the discretion of the court, with the recognition that the court's "scope of review remains sharply proscribed by precedent and the nature of Tunney Act proceedings." *SBC Commc'ns*, 489 F. Supp. 2d at 11.4

#### VIII. Determinative Documents

There are no determinative materials or documents within the meaning of the APPA that were considered by the United States in formulating the proposed Final Judgment.

Dated: November 14, 2008.

**Mitchell H. Glende, Esq.**

*U.S. Department of Justice, Antitrust Division, Litigation I Section, 1401 H Street, NW., Suite 4000, Washington, DC 20530, (202) 353-3106.*

#### Appendix A

##### Definition of Herfindahl-Hirschman Index ("HHI")

"HHI" means the Herfindahl-Hirschman Index, a commonly accepted

<sup>4</sup> See *United States v. Enova Corp.*, 107 F. Supp. 2d 10, 17 (D.D.C. 2000) (noting that the "Tunney Act expressly allows the court to make its public interest determination on the basis of the competitive impact statement and response to comments alone"); *United States v. Mid-Am. Dairyman, Inc.*, 1977-1 Trade Cas. (CCH) 61,508, at 71,980 (W.D. Mo. 1977) ("Absent a showing of corrupt failure of the government to discharge its duty, the Court, in making its public interest finding, should \* \* \* carefully consider the explanations of the government in the competitive impact statement and its responses to comments in order to determine whether those explanations are reasonable under the circumstances."); S. Rep. No. 93-298, 93d Cong., 1st Sess., at 6 (1973) ("Where the public interest can be meaningfully evaluated simply on the basis of briefs and oral arguments, that is the approach that should be utilized.");

measure of market concentration. It is calculated by squaring the market share of each firm competing in the market and then summing the resulting numbers. For example, for a market consisting of four firms with shares of 30 percent, 30 percent, 20 percent, and 20 percent, the HHI is 2600 (30<sup>2</sup> + 30<sup>2</sup> + 20<sup>2</sup> + 20<sup>2</sup> = 2600). The HHI takes into account the relative size distribution of the firms in a market and approaches zero when a market consists of a large number of small firms. The HHI increases both as the number of firms in the market decreases and as the disparity in size between those firms increases.

Markets in which the HHI is between 1000 and 1800 points are considered to be moderately concentrated, and those in which the HHI is in excess of 1800 points are considered to be highly concentrated. See *Horizontal Merger Guidelines* 1.51 (revised Apr. 8, 1997). Transactions that increase the HHI by more than 100 points in concentrated markets presumptively raise antitrust concerns under the guidelines issued by the U.S. Department of Justice and Federal Trade Commission. See *id.*

[FR Doc. E8-27970 Filed 11-24-08; 8:45 am]  
BILLING CODE 4410-11-P

#### DEPARTMENT OF LABOR

##### Office of the Secretary

##### Submission for OMB Review: Comment Request

November 21, 2008.

The Department of Labor (DOL) hereby announces the submission of the following public information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104-13, 44 U.S.C. chapter 35). A copy of this ICR, with applicable supporting documentation; including among other things a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained from the RegInfo.gov Web site at <http://www.reginfo.gov/public/do/PRAMain> or by contacting Darrin King on 202-693-4129 (this is not a toll-free number)/e-mail: [DOL\\_PRA\\_PUBLIC@dol.gov](mailto:DOL_PRA_PUBLIC@dol.gov).

Interested parties are encouraged to send comments to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the Occupational Safety and Health Administration (OSHA), Office of Management and Budget, Room 10235, Washington, DC 20503, Telephone:

inconsonant with the allegations charged as to fall outside of the "reaches of the public interest").

202-395-7316/Fax: 202-395-6974 (these are not toll-free numbers), E-mail: [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov) within 30 days from the date of this publication in the **Federal Register**. In order to ensure the appropriate consideration, comments should reference the OMB Control Number (see below).

The OMB is particularly interested in comments which:

- 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:* Occupational Safety and Health Administration.

*Type of Review:* Extension without change of a previously approved collection.

*Title of Collection:* Inorganic Arsenic (29 CFR 1910.1018).

*OMB Control Number:* 1218-0104.

*Affected Public:* Business or other for-profits.

*Estimated Number of Respondents:* 3.

*Estimated Total Annual Burden*

*Hours:* 385.

*Estimated Total Annual Costs Burden:* \$31,165.

*Description:* The purpose of the Department's Inorganic Arsenic Standard at 29 CFR 1910.1018 and the information collection requirements contained therein is to provide protection for employees from the adverse health effects associated with occupational exposure to inorganic arsenic. For additional information, see the related 60-day preclearance notice published in the **Federal Register** at 73 FR 55871 on September 26, 2008. PRA documentation prepared in association with the preclearance notice is available on <http://www.regulations.gov> under docket number OSHA 2008-0036.

**Darrin A. King,**

*Departmental Clearance Officer.*

[FR Doc. E8-27936 Filed 11-24-08; 8:45 am]

BILLING CODE 4510-26-P

## DEPARTMENT OF LABOR

### Employment and Training Administration

[TA-W-63,924; TA-W-63,924A]

#### **Boise Cascade, LLC, Wood Products Division, La Grande Lumber Mill, La Grande, OR; Boise Cascade, LLC, Wood Products Division, La Grande Particleboard, La Grande, OR; Notice of Affirmative Determination Regarding Application for Reconsideration**

By application postmarked October 24, 2008, the Oregon AFL-CIO Labor Liaison and the Carpenter's Industrial Council requested administrative reconsideration of the negative determination regarding workers' eligibility to apply for Trade Adjustment Assistance (TAA) and Alternative Trade Adjustment Assistance (ATAA) applicable to workers and former workers of the subject firm. The determination was issued on October 1, 2008. The Notice of Determination was published in the **Federal Register** on October 20, 2008 (73 FR 62323).

The initial investigation resulted in a negative determination based on the finding that imports of softwood lumber and particleboard did not contribute importantly to worker separations at the subject firm and no shift of production to a foreign source occurred.

In the request for reconsideration, the petitioner provided additional information pertaining to imports of softwood lumber and particleboard and requested further investigation concerning the import impact on production at the subject firm.

The Department has carefully reviewed the request for reconsideration and the existing record and has determined that the Department will conduct further investigation to determine if the workers meet the eligibility requirements of the Trade Act of 1974.

#### **Conclusion**

After careful review of the application, I conclude that the claim is of sufficient weight to justify reconsideration of the U.S. Department of Labor's prior decision. The application is, therefore, granted.

Signed at Washington, DC, this 14th day of November 2008.

**Elliott S. Kushner,**

*Certifying Officer, Division of Trade Adjustment Assistance.*

[FR Doc. E8-27933 Filed 11-24-08; 8:45 am]

BILLING CODE 4510-FN-P

## DEPARTMENT OF LABOR

### Employment and Training Administration

[TA-W-64,088]

#### **Rexam Closure Systems, Inc., Bowling Green, OH; Notice of Affirmative Determination Regarding Application for Reconsideration**

By application dated October 22, 2008, the International Union, United Automobile, Aerospace and Agricultural Implement Workers of America, Region 2-B, requested administrative reconsideration of the negative determination regarding workers' eligibility to apply for Trade Adjustment Assistance (TAA) and Alternative Trade Adjustment Assistance (ATAA) applicable to workers and former workers of the subject firm. The determination was issued on October 3, 2008. The Notice of Determination was published in the **Federal Register** on October 20, 2008 (73 FR 62323).

The initial investigation resulted in a negative determination based on the finding that imports of plastic closures for plastic food industry packaging did not contribute importantly to worker separations at the subject firm and no shift of production to a foreign source occurred.

In the request for reconsideration, the petitioner provided additional information pertaining to a shift in subject plant production of plastic closures for plastic food industry packaging to China and requested further investigation of import impact as it relates to declining subject plant production of plastic closures for plastic food industry packaging.

The Department has carefully reviewed the request for reconsideration and the existing record and has determined that the Department will conduct further investigation to determine if the workers meet the eligibility requirements of the Trade Act of 1974.

#### **Conclusion**

After careful review of the application, I conclude that the claim is of sufficient weight to justify reconsideration of the U.S. Department of Labor's prior decision. The application is, therefore, granted.

Signed at Washington, DC, this 13th day of November 2008.

**Elliott S. Kushner,**

*Certifying Officer, Division of Trade Adjustment Assistance.*

[FR Doc. E8-27935 Filed 11-24-08; 8:45 am]

BILLING CODE 4510-FN-P

## DEPARTMENT OF LABOR

Employment and Training  
Administration

[TA-W-62,076]

**Ametek, Inc., National Controls Corporation, Instrumentation and Specialty Controls Division, Including On-Site Leased Workers From Manpower, Select Remedy, Clear Staff, Staff Force, Hipp, Staffing Network and Westaff West Chicago, IL; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance**

In accordance with section 223 of the Trade Act of 1974 (19 U.S.C. 2273), and section 246 of the Trade Act of 1974 (26 U.S.C. 2813), as amended, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance on September 18, 2007, applicable to workers of Ametek, Inc., instrumentation and Specialty Controls Division, including on-site leased workers from Manpower, Select Remedy, and Clear Staff, West Chicago, Illinois. The notice was published in the **Federal Register** on October 3, 2007 (72 FR 56384).

At the request of the petitioner, the Department reviewed the certification for workers of the subject firm. The workers are engaged in the production of electronic controls for food service equipment.

New information shows that workers leased workers from Staff Force, HIPP, Staffing Network and Westaff were employed on-site at the West Chicago, Illinois location of Ametek, Inc., National Controls Corporation, Instrumentation and Specialty Controls Division. The Department has determined that these workers were sufficiently under the control of Ametek, Inc., National Controls Corporation, Instrumentation and Specialty Controls Division to be considered leased workers.

Based on these findings, the Department is amending this certification to include workers leased from the above mentioned firms working on-site at the West Chicago, Illinois location of the subject firm and to include the name of the subject firm in its' entirety.

The intent of the Department's certification is to include all workers employed at Ametek, Inc., National Controls Corporation, Instrumentation & Specialty Controls Division, West Chicago, Illinois who were adversely

affected by a shift in production of electronic controls for food service equipment to Mexico.

The amended notice applicable to TA-W-62,076 is hereby issued as follows:

All workers of Ametek, Inc., National Controls Corporation, Instrumentation and Specialty Controls Division, including on-site leased workers of Manpower, Select Remedy, Clear Staff, Staff Force, HIPP, Staffing Network and Westaff, West Chicago, Illinois, who became totally or partially separated from employment on or after April 14, 2007, through September 18, 2009, are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974, and are also eligible to apply for alternative trade adjustment assistance under Section 246 of the Trade Act of 1974.

Signed at Washington, DC this 14th day of November 2008.

**Linda G. Poole,**  
*Certifying Officer, Division of Trade Adjustment Assistance.*

[FR Doc. E8-27931 Filed 11-24-08; 8:45 am]

BILLING CODE 4510-FN-P

## DEPARTMENT OF LABOR

Employment and Training  
Administration

[TA-W-63,927]

**Delfingen US, Inc., El Paso North Division, Formerly Known as M&Q Plastics Products, Also Known as Sofanou, Inc., El Paso, TX; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance**

In accordance with Section 223 of the Trade Act of 1974 (19 U.S.C. 2273), and Section 246 of the Trade Act of 1974 (26 U.S.C. 2813), as amended, the Department of Labor issued a Certification Regarding Eligibility to Apply for Worker Adjustment Assistance and a Negative Determination Regarding Eligibility to Apply for Alternative Trade Adjustment Assistance on September 4, 2008, applicable to workers of Delfingen US, Inc., El Paso North Division, El Paso, Texas. The notice was published in the **Federal Register** on September 18, 2008 (73 FR 54173).

At the request of the State agency, the Department reviewed the certification for workers of the subject firm. The workers were engaged in employment related to the production of plastic tubing.

New information shows that in March 2008, Delfingen US, Inc. purchased M&Q Plastic Products. Currently some of the workers wages at the subject firm

are being reported under several Unemployment Insurance (UI) tax accounts for Delfingen US, Inc., formerly known as M&Q Plastic Products, also known as Safanou, Inc.

Accordingly, the Department is amending this certification to properly reflect this matter.

The intent of the Department's certification is to include all workers of Delfingen US, Inc., El Paso North Division, formerly known as M&Q Plastic Products, also known as Safanou, Inc., El Paso, Texas who were adversely affected by a shift in production of plastic tubing to Mexico and the Philippines.

The amended notice applicable to TA-W-63,927 is hereby issued as follows:

All workers of Delfingen US, Inc., El Paso North Division, formerly known as M&Q Plastic Products, also known as Safanou, Inc., El Paso, Texas, who became totally or partially separated from employment on or after August 22, 2007, through September 4, 2010, are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974 and are also eligible to apply for alternative trade adjustment assistance under Section 246 of the Trade Act of 1974.

Signed at Washington, DC, this 13th day of November 2008.

**Elliott S. Kushner,**  
*Certifying Officer, Division of Trade Adjustment Assistance.*

[FR Doc. E8-27934 Filed 11-24-08; 8:45 am]

BILLING CODE 4510-FN-P

## DEPARTMENT OF LABOR

Employment and Training  
Administration

[TA-W-63,139; TA-W-63,139E]

**Valspar-Furniture Sales Group & International Color Design Center, a Subsidiary of Valspar Global Wood Coatings D/B/A Engineered Polymer Solutions High Point, NC; Including Employees of Valspar-Furniture Sales Group & International Color Design Center, a Subsidiary of Valspar Global Wood Coatings D/B/A Engineered Polymer Solutions High Point, NC Working On-Site at American of Martinsville, Martinsville, VA; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance**

In accordance with section 223 of the Trade Act of 1974 (19 U.S.C. 2273), and section 246 of the Trade Act of 1974 (26 U.S.C. 2813), as amended, the Department of Labor issued a Certification of Eligibility to Apply for



Worker Adjustment Assistance and Alternative Trade Adjustment Assistance on June 20, 2008, applicable to workers of Valspar-Furniture Sales Group & International Color Design Center, a subsidiary of Valspar Global Wood Coatings, d/b/a/ Engineered Polymer Solutions, High Point, North Carolina. The notice was published in the **Federal Register** on July 14, 2008 (73 FR 40388). The certification was amended on October 21, 2008 to include an employee of the subject firm and location working out of Lafayette, Indiana. The notice was published in the **Federal Register** on November 3, 2008 (73 FR 65406).

At the request of the State agency, the Department reviewed the certification for workers of the subject firm. The workers are engaged in the production of wood coatings (paints, lacquers, and stains).

New information shows that worker separations have occurred involving employees (Mr. Michael Cline, Mr. Mark Arrington and Mr. William B. Hampton) working on-site at American of Martinsville, Martinsville, Virginia, a customer of the subject firm. These workers are in support of and under the control of the High Pont, North Carolina location of Valspar-Furniture Sales Group & International Color Design Center, a subsidiary of Valspar Global Wood Coatings, d/b/a/ Engineered Polymer Solutions.

Based on these findings, the Department is amending this certification to include employees in support of the High Point, North Carolina facility of the subject firm working on-site at American of Martinsville, Martinsville, Virginia.

The intent of the Department's certification is to include all workers of Valspar-Furniture Sales Group & International Color Design Center, a subsidiary of Valspar Global Wood Coatings, d/b/a Engineered Polymer Solutions, High Point, North Carolina who qualify as secondarily affected by increased imports of wood coatings (paints, lacquers, and stains).

The amended notice applicable to TA-W-63,139 is hereby issued as follows:

All workers of Valspar-Furniture Sales Group & International Color Design Center, a subsidiary of Valspar Global Wood Coatings, High Point, North Carolina, (TA-W-63,139), including employees in support of Valspar-Furniture Sales Group & International Color Design Center, a subsidiary of Valspar Global Wood Coatings, High Point, North Carolina working on-site at American of Martinsville, Martinsville, Virginia (TA-W-63,139E), who became totally or partially separated from employment on or after May 6, 2007, through June 20, 2010, are eligible to apply for adjustment assistance under Section 223 of

the Trade Act of 1974, and are also eligible to apply for alternative trade adjustment assistance under Section 246 of the Trade Act of 1974.

Signed at Washington, DC this 14th day of November 2008.

**Elliott S. Kushner,**

*Certifying Officer, Division of Trade Adjustment Assistance.*

[FR Doc. E8-27932 Filed 11-24-08; 8:45 am]

BILLING CODE 4510-FN-P

## DEPARTMENT OF LABOR

### Employment and Training Administration

#### Notice of Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, as amended (19 U.S.C. 2273) the Department of Labor herein presents summaries of determinations regarding eligibility to apply for trade adjustment assistance for workers (TA-W) number and alternative trade adjustment assistance (ATAA) by (TA-W) number issued during the period of *November 3 through November 7, 2008*.

In order for an affirmative determination to be made for workers of a primary firm and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of section 222(a) of the Act must be met.

I. Section (a)(2)(A) all of the following must be satisfied:

A. A significant number or proportion of the workers in such workers' firm, or an appropriate subdivision of the firm, have become totally or partially separated, or are threatened to become totally or partially separated;

B. The sales or production, or both, of such firm or subdivision have decreased absolutely; and

C. Increased imports of articles like or directly competitive with articles produced by such firm or subdivision have contributed importantly to such workers' separation or threat of separation and to the decline in sales or production of such firm or subdivision; or

II. Section (a)(2)(B) both of the following must be satisfied:

A. A significant number or proportion of the workers in such workers' firm, or an appropriate subdivision of the firm, have become totally or partially separated, or are threatened to become totally or partially separated;

B. There has been a shift in production by such workers' firm or

subdivision to a foreign country of articles like or directly competitive with articles which are produced by such firm or subdivision; and

C. One of the following must be satisfied:

1. The country to which the workers' firm has shifted production of the articles is a party to a free trade agreement with the United States;

2. The country to which the workers' firm has shifted production of the articles to a beneficiary country under the Andean Trade Preference Act, African Growth and Opportunity Act, or the Caribbean Basin Economic Recovery Act; or

3. There has been or is likely to be an increase in imports of articles that are like or directly competitive with articles which are or were produced by such firm or subdivision.

Also, in order for an affirmative determination to be made for secondarily affected workers of a firm and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of section 222(b) of the Act must be met.

(1) Significant number or proportion of the workers in the workers' firm or an appropriate subdivision of the firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) The workers' firm (or subdivision) is a supplier or downstream producer to a firm (or subdivision) that employed a group of workers who received a certification of eligibility to apply for trade adjustment assistance benefits and such supply or production is related to the article that was the basis for such certification; and

(3) Either—

(A) The workers' firm is a supplier and the component parts it supplied for the firm (or subdivision) described in paragraph (2) accounted for at least 20 percent of the production or sales of the workers' firm; or

(B) A loss or business by the workers' firm with the firm (or subdivision) described in paragraph (2) Contributed importantly to the workers' separation or threat of separation.

In order for the Division of Trade Adjustment Assistance to issue a certification of eligibility to apply for Alternative Trade Adjustment Assistance (ATAA) for older workers, the group eligibility requirements of Section 246(a)(3)(A)(ii) of the Trade Act must be met.

1. Whether a significant number of workers in the workers' firm are 50 years of age or older.

2. Whether the workers in the workers' firm possess skills that are not easily transferable.

3. The competitive conditions within the workers' industry (i.e., conditions within the industry are adverse).

#### Affirmative Determinations for Worker Adjustment Assistance

The following certifications have been issued. The date following the company name and location of each determination references the impact date for all workers of such determination.

The following certifications have been issued. The requirements of section 222(a)(2)(A) (increased imports) of the Trade Act have been met.

NONE

The following certifications have been issued. The requirements of Section 222(a)(2)(B) (shift in production) of the Trade Act have been met.

TA-W-64,115; *Alcoa, Inc., Payroll Operations, Pittsburgh, PA; September 19, 2007.*

The following certifications have been issued. The requirements of section 222(b) (supplier to a firm whose workers are certified eligible to apply for TAA) of the Trade Act have been met.

NONE

The following certifications have been issued. The requirements of section 222(b) (downstream producer for a firm whose workers are certified eligible to apply for TAA based on increased imports from or a shift in production to Mexico or Canada) of the Trade Act have been met.

NONE

#### Affirmative Determinations for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

The following certifications have been issued. The date following the company name and location of each determination references the impact date for all workers of such determination.

The following certifications have been issued. The requirements of Section 222(a)(2)(A) (increased imports) and Section 246(a)(3)(A)(ii) of the Trade Act have been met.

TA-W-64,096; *Hickory Hardware, Caster Assembly, Including Accountemps, Adecon, Kelly, etc, Nashville, TN; September 22, 2007.*  
TA-W-64,241; *The Baxter Corporation, Franklin Lakes, NJ; October 16, 2007.*

TA-W-63,852; *J. J. Digh Machine Co., Inc., Dallas, NC; August 11, 2007.*

TA-W-63,932; *Irving Forest Products, Pinkham Sawmill, Fort Kent, ME; August 21, 2007.*

TA-W-63,961; *Saginaw Machine Systems, Inc., Think Resources and Aerotech, Saginaw, MI; August 27, 2007.*

TA-W-64,070; *Perfection Mold and Machine Company, Akron, OH; September 16, 2007.*

TA-W-64,106; *Wabash Magnetics, South Boston, VA; September 23, 2007.*

TA-W-64,259; *Kimro Manufacturing, Inc., Apparel Div., Trezevant, TN; October 17, 2007.*

TA-W-64,193; *A. Wimpfheimer & Bro., Inc., d/b/a/ American Velvet Co., Stonington, CT; October 8, 2007.*

TA-W-64,355; *VEM Trading, Inc., New York, NY; November 3, 2007.*

The following certifications have been issued. The requirements of Section 222(a)(2)(B) (shift in production) and Section 246(a)(3)(A)(ii) of the Trade Act have been met.

TA-W-63,943; *Dana Holding Corporation, Sealing Products Group, Paris, TN; August 27, 2007.*

TA-W-64,012; *Metropolitan Furniture Corporation, A Subsidiary of Steelcase, Oakland, CA; September 9, 2007.*

TA-W-64,122; *Imation Corporation, Camarillo, CA; September 19, 2007.*

TA-W-64,144; *B & S Hosiery, Sylvania, AL; September 29, 2007.*

TA-W-64,202; *Barco, Inc., Presentation and Simulation Division, Xenia, OH; October 9, 2007.*

TA-W-64,284; *Morse Automotive, Chicago, IL; October 22, 2007.*

TA-W-64,296; *Johnson Controls Interiors Manufacturing, Johnson Controls, Crosswell, MI; October 27, 2007.*

TA-W-64,030; *Fairchild Semiconductor, Wafer Fab Operations, South Portland, ME; September 10, 2007.*

TA-W-64,117; *Clariant Corporation, Pigments & Additives Division, Coventry, RI; November 25, 2008.*

TA-W-64,243; *Super Brands LLC, Henderson, NV; October 14, 2007.*

TA-W-64,290; *Hoya Lens of America, Inc, Maria Nugent and Viking Resource Group, Bethel, CT; October 27, 2007.*

The following certifications have been issued. The requirements of section 222(b) (supplier to a firm whose workers are certified eligible to apply for TAA) and section 246(a)(3)(A)(ii) of the Trade Act have been met.

TA-W-63,859; *Henkel Corporation, Olean, NY; July 15, 2007.*

NONE

The following certifications have been issued. The requirements of section 222(b) (downstream producer for a firm

whose workers are certified eligible to apply for TAA based on increased imports from or a shift in production to Mexico or Canada) and section 246(a)(3)(A)(ii) of the Trade Act have been met.

NONE

#### Negative Determinations for Alternative Trade Adjustment Assistance

In the following cases, it has been determined that the requirements of 246(a)(3)(A)(ii) have not been met for the reasons specified.

The Department has determined that criterion (1) of Section 246 has not been met. The firm does not have a significant number of workers 50 years of age or older.

TA-W-64,115; *Alcoa, Inc., Payroll Operations, Pittsburgh, PA.*

The Department has determined that criterion (2) of section 246 has not been met. Workers at the firm possess skills that are easily transferable.

NONE

The Department has determined that criterion (3) of section 246 has not been met. Competition conditions within the workers' industry are not adverse.

NONE

#### Negative Determinations for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

In the following cases, the investigation revealed that the eligibility criteria for worker adjustment assistance have not been met for the reasons specified.

Because the workers of the firm are not eligible to apply for TAA, the workers cannot be certified eligible for ATAA.

The investigation revealed that criteria (a)(2)(A)(I.A.) and (a)(2)(B)(II.A.) (employment decline) have not been met.

NONE

The investigation revealed that criteria (a)(2)(A)(I.B.) (Sales or production, or both, did not decline) and (a)(2)(B)(II.B.) (shift in production to a foreign country) have not been met.  
TA-W-64,260; *P.H. Glatfelter Co., d/b/a Glatfelter Ohio Operation, Chillicothe, OH.*

The investigation revealed that criteria (a)(2)(A)(I.C.) (increased imports) and (a)(2)(B)(II.B.) (shift in production to a foreign country) have not been met.

TA-W-63,812; *Progressive Molded Products, Inc., St. Joseph, MO.*  
TA-W-63,976; *Stauble Machine and Tool Co., Louisville, KY.*  
TA-W-64,094; *ASMO North Carolina, Inc., Statesville, NC.*

The workers' firm does not produce an article as required for certification under Section 222 of the Trade Act of 1974.

TA-W-64,055; GMGO, Division of The Gorman Group, Shreveport, LA.  
TA-W-64,128; EBI Holdings, LLC, d/b/a Biomet Spine, Trauma, Osteobiologics, Parsippany, NJ.

The investigation revealed that criteria of Section 222(b)(2) has not been met. The workers' firm (or subdivision) is not a supplier to or a downstream producer for a firm whose workers were certified eligible to apply for TAA.  
**NONE**

I hereby certify that the aforementioned determinations were issued during the period of November 3 through November 7, 2008. Copies of these determinations are available for inspection in Room C-5311, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210 during normal business hours or will be mailed to persons who write to the above address.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E8-27930 Filed 11-24-08; 8:45 am]

BILLING CODE 4510-FN-P

## DEPARTMENT OF LABOR

### Employment and Training Administration

#### Investigations Regarding Certifications of Eligibility To Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

Petitions have been filed with the Secretary of Labor under Section 221(a) of the Trade Act of 1974 ("the Act") and are identified in the Appendix to this notice. Upon receipt of these petitions, the Director of the Division of Trade Adjustment Assistance, Employment and Training Administration, has instituted investigations pursuant to Section 221(a) of the Act.

The purpose of each of the investigations is to determine whether the workers are eligible to apply for adjustment assistance under Title II, Chapter 2, of the Act. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

The petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the Director, Division of Trade Adjustment Assistance, at the address shown below, not later than December 5, 2008.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Director, Division of Trade Adjustment Assistance, at the address shown below, not later than December 5, 2008.

The petitions filed in this case are available for inspection at the Office of the Director, Division of Trade Adjustment Assistance, Employment and Training Administration, U.S. Department of Labor, Room C-5311, 200 Constitution Avenue, NW., Washington, DC 20210.

Signed at Washington, DC, this 12th day of November 2008.

Erin Fitzgerald,

Director, Division of Trade Adjustment Assistance.

#### Appendix

#### TAA PETITIONS INSTITUTED BETWEEN 10/27/08 AND 10/31/08

TA-W	Subject firm (petitioners)	Location	Date of institution	Date of petition
64279	Tekni-Plex, Inc. dba Dolco Packaging (Comp)	Troy, OH	10/27/08	10/24/08
64280	Phoenix Leather, Inc. (State)	Brockton, MA	10/27/08	10/01/08
64281	International Paper (State)	Warren, MI	10/27/08	10/27/08
64282	Allied Systems (Union)	Moraine, OH	10/27/08	10/15/08
64283	STEC, Inc. (Comp)	Santa Ana, CA	10/27/08	10/22/08
64284	Morse Automotive (Wkrs)	Chicago, IL	10/27/08	10/22/08
64285	ITT Corporation—Interconnect Solutions and Flow Control (Comp).	Santa Ana, CA	10/27/08	10/24/08
64286	MTD Acquisition, Inc. (Comp)	Chisholm, MN	10/27/08	10/24/08
64287	Logistics Services (UAW)	Fenton, MO	10/27/08	10/23/08
64288	Wabash Magnetics/Rurz Rasch (Wkrs)	Wabash, IN	10/27/08	10/24/08
64289	Hendricks Furniture Group LLC (Comp)	Conover, NC	10/28/08	10/13/08
64290	Hoya Lens of America, Inc. (State)	Bethel, CT	10/28/08	10/27/08
64291	Rosti (State)	Shreveport, LA	10/28/08	10/27/08
64292	PHB, Inc. (USW)	Fairview, PA	10/28/08	10/27/08
64293	Statton Furniture Manufacturing Company, Inc. (Comp)	Hagerstown, MD	10/28/08	10/27/08
64294	Global Tech Building Services Corporation (Wkrs)	Eugene, OR	10/28/08	10/27/08
64295	Coupled Products, LLC (UAW)	Upper Sandusky, OH	10/28/08	10/23/08
64296	Johnson Controls Interiors Manufacturing (Comp)	Croswell, MI	10/28/08	10/27/08
64297	Hewlett-Packard, Graphic Solutions Business (Comp)	Minnetonka, MN	10/28/08	10/22/08
64298	Steel Technologies (Wkrs)	Flint, MI	10/28/08	10/27/08
64299	Hofmann Industries (USW)	Sinking Spring, PA	10/29/08	10/27/08
64300	US Marine Bayliner (State)	Pipestone, MN	10/29/08	10/28/08
64301	Window Fashions, Inc. (Comp)	National Heights, PA	10/29/08	10/22/08
64302	International Paper, Cincinnati Division (USW)	Mason, OH	10/29/08	10/23/08
64303	ITG Automotive Safety (Wkrs)	South Hill, VA	10/29/08	10/22/08
64304	American Die Corporation (Comp)	Chesterfield, MI	10/30/08	10/10/08
64305	Summit Polymers, Inc. (Comp)	Shelbyville, TN	10/30/08	10/29/08
64306	Ainsworth Engineered (State)	Bemidji, MN	10/30/08	10/29/08
64307	Wallace Technologies/King Controls (State)	Bloomington, MN	10/30/08	10/29/08
64308	DLJ Production (Wkrs)	Brooklyn, NY	10/30/08	10/27/08
64309	General Motors (UAW)	Janesville, WI	10/30/08	10/29/08
64310	Dana Corp (State)	Longview, TX	10/30/08	10/29/08
64311	Chrysler Corp (UAW)	Toledo, OH	10/30/08	10/29/08
64312	Acme-McCrary Corp (Comp)	Asheboro, NC	10/30/08	10/29/08
64313	GE Consumer and Industrial Luclox Plant (Comp)	Willoughby, OH	10/31/08	10/29/08

## TAA PETITIONS INSTITUTED BETWEEN 10/27/08 AND 10/31/08—Continued

TA-W	Subject firm (petitioners)	Location	Date of institution	Date of petition
64314	Town of Forest City (Comp)	Forest City, NC	10/31/08	10/30/08
64315	Volunteer Circuits, Inc. (State)	Bells, TN	10/31/08	10/30/08
64316	Modern Plastics Corporation (Wkrs)	Coloma, MI	10/31/08	10/24/08
64317	Callaway Golf Company (Comp)	Carlsbad, CA	10/31/08	10/30/08
64318	Clarion Technologies (State)	Greenville, MI	10/31/08	10/30/08
64319	Allied Hosiery Mill (Comp)	Englewood, TN	10/31/08	10/28/08
64320	Wearbest Sil-Tex Mills, Ltd. (Comp)	Garfield, NJ	10/31/08	10/30/08
64321	Olympic Panel Products LLC (IAMAW)	Shelton, WA	10/31/08	10/22/08
64322	Woodbridge Corporation (Comp)	St Peters, MO	10/31/08	10/30/08
64323	Hoover Universal (Comp)	Jefferson City, MO	10/31/08	10/29/08
64324	Mack Avenue Engine #2 Plant (UAW)	Detroit, MI	10/31/08	10/30/08

[FR Doc. E8-27928 Filed 11-24-08; 8:45 am]

BILLING CODE 4510-FN-P

## DEPARTMENT OF LABOR

Employment and Training  
AdministrationInvestigations Regarding Certifications  
of Eligibility To Apply for Worker  
Adjustment Assistance and Alternative  
Trade Adjustment Assistance

Petitions have been filed with the Secretary of Labor under section 221 (a) of the Trade Act of 1974 ("the Act") and are identified in the Appendix to this notice. Upon receipt of these petitions, the Director of the Division of Trade Adjustment Assistance, Employment and Training Administration, has

instituted investigations pursuant to section 221 (a) of the Act.

The purpose of each of the investigations is to determine whether the workers are eligible to apply for adjustment assistance under Title II, Chapter 2, of the Act. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

The petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the Director, Division of Trade Adjustment Assistance, at the address shown below, not later than December 5, 2008.

Interested persons are invited to submit written comments regarding the

subject matter of the investigations to the Director, Division of Trade Adjustment Assistance, at the address shown below, not later than December 5, 2008.

The petitions filed in this case are available for inspection at the Office of the Director, Division of Trade Adjustment Assistance, Employment and Training Administration, U.S. Department of Labor, Room C-5311, 200 Constitution Avenue, NW., Washington, DC 20210.

Signed at Washington, DC, this 13th day of November 2008.

Linda G. Poole,

Certifying Officer, Division of Trade  
Adjustment Assistance.

## Appendix

## TAA PETITIONS INSTITUTED BETWEEN 11/3/08 AND 11/6/08

TA-W	Subject firm (petitioners)	Location	Date of institution	Date of petition
64325	Yorozu Automotive Mississippi, Inc. (Comp)	Vicksburg, MS	11/03/08	10/31/08
64326	Archway Cookies, LLC (Wkrs)	Ashland, OH	11/03/08	10/27/08
64327	Jatco USA, Inc. (Comp)	Wixom, MI	11/03/08	10/30/08
64328	E. Toman and Company (Comp)	Lyons, IL	11/03/08	10/27/08
64329	Kronos (State)	Chelmsford, MA	11/03/08	10/31/08
64330	Triangle Springs (Wkrs)	DuBois, PA	11/03/08	10/23/08
64331	SUEZ Energy BioPower (Wkrs)	Forest City, NC	11/03/08	10/30/08
64332	Barnes Aerospace (State)	Windsor, CT	11/03/08	10/31/08
64333	TrimQuest (Comp)	Walker, MI	11/03/08	10/31/08
64334	Eaton Powerware (Wkrs)	Raleigh, NC	11/03/08	10/31/08
64335	Indiana Handle Co., Inc. (Comp)	Paoli, IN	11/03/08	10/26/08
64336	Husco International, Inc. (Union)	Waukesha, WI	11/03/08	10/31/08
64337	Moline Machinery, LLC (State)	Duluth, MN	11/03/08	10/29/08
64338	Pine Island Shortswear, Ltd. (Wkrs)	Monroe, NC	11/03/08	10/29/08
64339	Tenneco (UAW)	Napoleon, OH	11/03/08	10/31/08
64340	A B Carter, Inc. (Comp)	Gastonia, NC	11/03/08	10/31/08
64341	Brake Parts, Inc. (Comp)	Litchfield, IL	11/03/08	10/31/08
64342	Hyosung (America), Inc. (Comp)	Scottsburg, IN	11/04/08	11/03/08
64343	Lear Corporation (State)	Southfield, MI	11/04/08	11/03/08
64344	UCO Fabrics, Inc. (Comp)	Rockingham, NC	11/04/08	11/03/08
64345	Sunspring America (Wkrs)	Henderson, KY	11/04/08	10/25/08
64346	Casey Tool and Machine (State)	Charleston, IL	11/04/08	11/03/08
64347	Freudenberg Nonwovens (Wkrs)	Hopkinsville, KY	11/04/08	10/27/08
64348	Tetra Pak Gable Top Systems, Inc. (Comp)	Minneapolis, MN	11/04/08	10/31/08
64349	Wee Ones, Inc. (Wkrs)	Paris, MO	11/05/08	10/30/08
64350	Omega Motion (Comp)	Saltito, MS	11/05/08	11/03/08
64351	Dura Automotive Systems, Inc. (Comp)	Hannibal, MO	11/05/08	11/04/08
64352	Maury City Plastics (Wkrs)	Maury City, IN	11/05/08	10/16/08

TA-W	Subject firm (petitioners)	Location	Date of institution	Date of petition
64353	Woodmark (Comp)	High Point, NC	11/05/08	10/31/08
64354	elInstruction/Maryland Manufacturing (Comp)	Columbia, MD	11/05/08	11/04/08
64355	VEM Trading, Inc. (Wkrs)	New York, NY	11/05/08	11/03/08
64356	Union Apparel, Inc. (Wkrs)	Norvelt, PA	11/05/08	11/04/08
64357	LeRocato Manufacturing, Inc. (State)	Plainfield, CT	11/05/08	11/03/08
64358	First American Title Insurance Company (State)	Roseville, CA	11/05/08	11/04/08
64359	Alcatel/Lucent (Rep)	Plano, TX	11/05/08	11/03/08
64360	MeadWestVaco Corporation (State)	Enfield, CT	11/06/08	11/05/08
64361	Hiley Poly Co., LLC (Wkrs)	Mount Olive, NC	11/06/08	11/05/08
64362	Lear Corporation (Wkrs)	Zanesville, OH	11/06/08	10/30/08
64363	Chrysler, LLC (Wkrs)	Kokomo, IN	11/06/08	10/31/08
64364	Glabman Himes, Inc. (Wkrs)	High Point, NC	11/06/08	10/29/08
64365	ElectroCraft New Hampshire (IUECWA)	Dover, NH	11/06/08	11/05/08
64366	Hewlett Packard (Wkrs)	San Diego, CA	11/06/08	11/03/08
64367	Suntex Industries, Inc. (Wkrs)	Glasgow, KY	11/06/08	11/03/08
64368	Newport Corporation (State)	Irvine, CA	11/06/08	11/05/08
64369	ABX Air (Wkrs)	Wilmington, OH	11/06/08	10/24/08
64370	Wausau Paper Specialty Products, LLC (USW)	Jay, ME	11/06/08	11/04/08
64371	SMI Bell Manufacturing (Wkrs)	Lewiston, ME	11/06/08	11/03/08

[FR Doc. E8-27929 Filed 11-24-08; 8:45 am]

BILLING CODE 4510-FN-P

## DEPARTMENT OF LABOR

### Employment and Training Administration

[TA-W-64,294]

#### Global Tech Building Services, Corp., Employed On-Site at Hynix Semiconductor Manufacturing America, Inc., Eugene, OR; Notice of Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, as amended, an investigation was initiated on October 28, 2008, in response to a petition filed on behalf of workers of Global Tech Building Services Corp., employed on-site at Hynix Semiconductor Manufacturing America, Inc., Eugene, Oregon.

The petitioning group of workers is covered by an active certification (TA-W-63,747, amended), which expires on August 20, 2010. Consequently, further investigation in this case would serve no purpose, and the investigation has been terminated.

Signed at Washington, DC, this 12th day of November 2008.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E8-27927 Filed 11-24-08; 8:45 am]

BILLING CODE 4510-FN-P

## DEPARTMENT OF LABOR

### Bureau of Labor Statistics

#### Federal Economic Statistics Advisory Committee; Notice of Open Meeting and Agenda

The fourteenth meeting of the Federal Economic Statistics Advisory Committee will be held on December 12, 2008, in the Postal Square Building, 2 Massachusetts Avenue, NE., Washington, DC.

The Federal Economic Statistics Advisory Committee is a technical committee composed of economists, statisticians, and behavioral scientists who are recognized for their attainments and objectivity in their respective fields. Committee members are called upon to analyze issues involved in producing Federal economic statistics and recommend practices that will lead to optimum efficiency, effectiveness, and cooperation among the Department of Labor, Bureau of Labor Statistics and the Department of Commerce, Bureau of Economic Analysis and Bureau of the Census.

The meeting will be held in Meeting Rooms 1 and 2 of the Postal Square Building Conference Center. The schedule and agenda for the meeting are as follows:

9 a.m. Opening remarks and introductions; agency updates.

9:30 a.m. Discussion on data synchronization legislation.

10:15 a.m. Discussion of future priorities.

11 a.m. Business list comparison project.

1 p.m. Issues in measuring output, inputs, and productivity by industry.

3 p.m. Business dynamics.

4:45 p.m. Conclude (approximate time).

The meeting is open to the public. Any questions concerning the meeting should be directed to Margaret Hayden, Federal Economic Statistics Advisory Committee, at Area Code (202) 691-5600. Individuals with disabilities, who need special accommodations, should contact Ms. Hayden at least two days prior to the meeting date.

Signed at Washington, DC, the 18th day of November 2008.

Philip L. Rones,

Deputy Commissioner, Bureau of Labor Statistics.

[FR Doc. E8-27975 Filed 11-24-08; 8:45 am]

BILLING CODE 4510-24-P

## NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

### Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: National Archives and Records Administration (NARA).

ACTION: Notice.

SUMMARY: NARA is giving public notice that the agency has submitted to OMB for approval the information collection described in this notice. The public is invited to comment on the proposed information collection pursuant to the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted to OMB at the address below on or before December 26, 2008 to be assured of consideration.

ADDRESSES: Send comments to Mr. Nicholas A. Fraser, Desk Officer for

NARA, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax: 202-395-5167; or electronically mailed to [Nicholas\\_A\\_Fraser@omb.eop.gov](mailto:Nicholas_A_Fraser@omb.eop.gov).

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information or copies of the proposed information collection and supporting statement should be directed to Tamee Fechhelm at telephone number 301-837-1694 or fax number 301-713-7409.

**SUPPLEMENTARY INFORMATION:** Pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104-13), NARA invites the general public and other Federal agencies to comment on proposed information collections. NARA published a notice of proposed collection for this information collection on September 17, 2008 (73 FR 53904). No comments were received. NARA has submitted the described information collection to OMB for approval.

In response to this notice, comments and suggestions should address one or more of the following points: (a) Whether the proposed information collection is necessary for the proper performance of the functions of NARA; (b) the accuracy of NARA's estimate of the burden of the proposed information collection; (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 the use of information technology; and (e) whether small businesses are affected by this collection. In this notice, NARA is soliciting comments concerning the following information collection:

**Title:** Order Forms for U.S. Court Records in the National Archives.

**OMB Number:** 3095-0063.

**Agency Form Number:** NATF Forms 90, 91, 92, and 93.

**Type of Review:** Regular.

**Affected Public:** Individuals or households.

**Estimated Number of Respondents:** 74,513.

**Estimated Time per Response:** 10 minutes.

**Frequency of Response:** On occasion.

**Estimated Total Annual Burden**

**Hours:** 12,419 hours.

**Abstract:** Submission of requests on a form is necessary to handle in a timely fashion the volume of requests received for these records (approximately 69,447 per year for the NATF 90, approximately 1,600 per year for the NATF 91, approximately 3,247 per year for the NATF 92, approximately 219 per year for the NATF 93) and the need to obtain specific information from the

researcher to search for the records sought. As a convenience, the form will allow researchers to provide credit card information to authorize billing and expedited mailing of the copies. Researchers can also use Order Online! (<https://eservices.archives.gov/orderonline/>) to complete the forms and order the copies.

Dated: November 19, 2008.

**Martha Morphy,**

*Assistant Archivist for Information Services.*

[FR Doc. E8-28092 Filed 11-24-08; 8:45 am]

**BILLING CODE 7515-01-P**

## NATIONAL SCIENCE FOUNDATION

### National Science Board; Task Force on Cost Sharing; Committee on Strategy and Budget; Sunshine Act Meetings; Notice

The National Science Board's Task Force on Cost Sharing of the Committee on Strategy and Budget pursuant to NSF regulations (45 CFR Part 614), the National Science Foundation Act, as amended (42 U.S.C. 1862n-5), and the Government in the Sunshine Act (5 U.S.C. 552b), hereby gives notice in regard to the scheduling of meetings for the transaction of National Science Board business and other matters specified, as follows:

**DATE AND TIME:** December 3, 2008 from 4 p.m. to 5 p.m.

**SUBJECT MATTER:** Discussion of Draft Report.

**STATUS:** Open.

**PLACE:** This meeting will be held by teleconference originating at the National Science Board Office, National Science Foundation, 4201 Wilson Blvd., Arlington, VA 22230. Room 130 will be available to the public to listen to this teleconference meeting.

Please refer to the National Science Board Web site (<http://www.nsf.gov/nsb>) for information or schedule updates, or contact: Jennifer Richards, National Science Board Office, 4201 Wilson Blvd., Arlington, VA 22230. Telephone: (703) 292-7000.

**Ann Ferrante,**  
*Writer-Editor.*

[FR Doc. E8-28086 Filed 11-24-08; 8:45 am]

**BILLING CODE 7555-01-P**

## NATIONAL TRANSPORTATION SAFETY BOARD

### SES Performance Review Board

**AGENCY:** National Transportation Safety Board.

**ACTION:** Notice.

**SUMMARY:** Notice is hereby given of the appointment of members of the National Transportation Safety Board Performance Review Board (PRB).

**FOR FURTHER INFORMATION CONTACT:** Anh Bolles, Chief, Human Resources Division, Office of Administration, National Transportation Safety Board, 490 L'Enfant Plaza, SW., Washington, DC 20594-0001, (202)314-6355.

**SUPPLEMENTARY INFORMATION:** Section 4314(c) (1) through (5) of Title 5, United States Code requires each agency to establish, in accordance with regulations prescribed by the Office of Personnel Management, one or more SES Performance Review Boards. The board reviews and evaluates the initial appraisal of a senior executive's performance by the supervisor, and considers recommendations to the appointing authority regarding the performance of the senior executive.

The following have been designated as members of the Performance Review Board of the National Transportation Safety Board.

The Honorable Robert L. Sumwalt, Member, National Transportation Safety Board; PRB Chair.

The Honorable Steven Chealander, Member, National Transportation Safety Board.

Steven Goldberg, Chief Financial Officer, National Transportation Safety Board.

Jack Fox, General Manager, Office of Pipeline Security, Transportation Security Administration, Department of Homeland Security.

Anthony P. Scardino, Assistant Chief Financial Officer, Office of the Chief Financial Officer, U.S. Department of Housing and Urban Development.

Walker Smith, Director, Office of Global Affairs and Policy, Office of International Affairs, Environmental Protection Agency (Alternate).

Thomas G. Motta, Section Chief, Operational Technology Division, Federal Bureau of Investigation (Alternate).

Joseph G. Osterman, Managing Director, National Transportation Safety Board.

Dated: November 19, 2008.

**Vicky D'Onofrio,**

*Federal Register Coordinator.*

[FR Doc. E8-27907 Filed 11-24-08; 8:45 am]

**BILLING CODE 7533-01-M**

**NUCLEAR REGULATORY COMMISSION**

[Docket Nos. 50-317 And 50-318; Docket No. 72-8]

**Calvert Cliffs Nuclear Power Plant, Unit Nos. 1 And 2; Calvert Cliffs Independent Spent Fuel Storage Installation; Notice of Consideration of Approval of 10 CFR 50.80 and 10 CFR 72.50 Indirect Transfers of Control of Licenses and Opportunity for a Hearing**

The U.S. Nuclear Regulatory Commission (NRC, the Commission) is considering the issuance of an Order under 10 CFR 50.80 and 10 CFR 72.50 approving the indirect transfer of Facility Operating License Nos. DPR-53 and DPR-69 for the Calvert Cliffs Nuclear Power Plant, Unit Nos. 1 and 2, respectively, and Material License No. SNM-2505 for the Calvert Cliffs Independent Spent Fuel Storage Installation, currently held by Calvert Cliffs Nuclear Power Plant, Inc. as owner and licensed operator. Calvert Cliffs Nuclear Power Plant, Inc. is owned by Constellation Energy Nuclear Group, LLC (CENG).

According to an application for approval dated October 3, 2008, filed by CENG and MidAmerican Energy Holdings Company (MEHC), the indirect transfers of control would result from the proposed acquisition by merger of CENG's parent corporation, Constellation Energy Group, Inc. (CEG) by MEHC. MEHC will indirectly own 100 percent of CEG through its direct wholly owned subsidiary Constellation Energy Holdings, LLC, a holding company.

CEG will remain as the parent company of CENG and CENG will remain as the parent company of the licensee. There will be no direct transfer of the licenses. Calvert Cliffs Nuclear Power Plant, Inc. will continue to own and operate the facilities. No physical changes to the facilities or operational changes are being proposed in the application.

Pursuant to 10 CFR 50.80, no license, or any right thereunder, shall be transferred, directly or indirectly, through transfer of control of the license, unless the Commission shall give its consent in writing. The Commission will approve an application for the indirect transfer of a license, if the Commission determines that the proposed transfer will not affect the qualifications of the licensee to hold the license, and that the transfer is otherwise consistent with applicable provisions of law, regulations, and

Orders issued by the Commission pursuant thereto.

The filing of requests for hearing and petitions for leave to intervene, and written comments with regard to the license transfer application, are discussed below.

Within 20 days from the date of publication of this notice, any person(s) whose interest may be affected by the Commission's action on the application may request a hearing and intervention via electronic submission through the NRC E-filing system. Requests for a hearing and petitions for leave to intervene should be filed in accordance with the Commission's rules of practice set forth in Subpart C "Rules of General Applicability: Hearing Requests, Petitions to Intervene, Availability of Documents, Selection of Specific Hearing Procedures, Presiding Officer Powers, and General Hearing Management for NRC Adjudicatory Hearings," of 10 CFR Part 2. In particular, such requests and petitions must comply with the requirements set forth in 10 CFR 2.309. Untimely requests and petitions may be denied, as provided in 10 CFR 2.309(c)(1), unless good cause for failure to file on time is established. In addition, an untimely request or petition should address the factors that the Commission will also consider, in reviewing untimely requests or petitions, set forth in 10 CFR 2.309(c)(1)(i)-(viii).

All documents filed in NRC adjudicatory proceedings, including a request for hearing, a petition for leave to intervene, any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities participating under 10 CFR 2.315(c), must be filed in accordance with the NRC E-Filing rule, which the NRC promulgated in August 2007, 72 FR 49139 (Aug. 28, 2007). The E-Filing process requires participants to submit and serve documents over the internet or in some cases to mail copies on electronic storage media. Participants may not submit paper copies of their filings unless they seek a waiver in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least ten (10) days prior to the filing deadline, the petitioner/ requestor must contact the Office of the Secretary by e-mail at [HEARINGDOCKET@NRC.GOV](mailto:HEARINGDOCKET@NRC.GOV), or by calling (301) 415-1677, to request (1) a digital ID certificate, which allows the participant (or its counsel or representative) to digitally sign documents and access the E-Submittal

server for any proceeding in which it is participating; and/or (2) creation of an electronic docket for the proceeding (even in instances in which the petitioner/requestor (or its counsel or representative) already holds an NRC-issued digital ID certificate). Each petitioner/requestor will need to download the Workplace Forms Viewer™ to access the Electronic Information Exchange (EIE), a component of the E-Filing system. The Workplace Forms Viewer™ is free and is available at <http://www.nrc.gov/site-help/e-submittals/install-viewer.html>. Information about applying for a digital ID certificate is available on NRC's public Web site at <http://www.nrc.gov/site-help/e-submittals/apply-certificates.html>.

Once a petitioner/requestor has obtained a digital ID certificate, had a docket created, and downloaded the EIE viewer, it can then submit a request for hearing or petition for leave to intervene. Submissions should be in Portable Document Format (PDF) in accordance with NRC guidance available on the NRC public Web site at <http://www.nrc.gov/site-help/e-submittals.html>. A filing is considered complete at the time the filer submits its documents through EIE. To be timely, an electronic filing must be submitted to the EIE system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an e-mail notice confirming receipt of the document. The EIE system also distributes an e-mail notice that provides access to the document to the NRC Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the documents on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before a hearing request/petition to intervene is filed so that they can obtain access to the document via the E-Filing system.

A person filing electronically may seek assistance through the "Contact Us" link located on the NRC Web site at <http://www.nrc.gov/site-help/e-submittals.html> or by calling the NRC technical help line, which is available between 8:30 a.m. and 4:15 p.m., Eastern Time, Monday through Friday. The help line number is (800) 397-4209 or locally, (301) 415-4737. Participants who believe that they have a good cause for not submitting documents electronically must file a motion, in

accordance with 10 CFR 2.302(g), with their initial paper filing requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, Maryland, 20852. Attention: Rulemaking and Adjudications Staff. Participants filing a document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service.

Documents submitted in adjudicatory proceedings will appear in NRC's electronic hearing docket which is available to the public at [http://ehd.nrc.gov/EHD\\_Proceeding/home.asp](http://ehd.nrc.gov/EHD_Proceeding/home.asp), unless excluded pursuant to an order of the Commission, an Atomic Safety and Licensing Board, or a Presiding Officer. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or home phone numbers in their filings. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submissions.

The Commission will issue a notice or order granting or denying a hearing request or intervention petition, designating the issues for any hearing that will be held and designating the Presiding Officer. A notice granting a hearing will be published in the **Federal Register** and served on the parties to the hearing.

As an alternative to petitions to intervene and requests for hearing, within 30 days from the date of publication of this notice, persons may submit written comments regarding the indirect license transfer application, as provided for in 10 CFR 2.1305. The Commission will consider and, if appropriate, respond to these comments, but such comments will not otherwise constitute part of the decisional record. Comments should be submitted to the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Rulemaking and Adjudications Staff, and should cite

the publication date and page number of this **Federal Register** notice.

For further details with respect to this indirect license transfer application, see the application dated October 3, 2008, available for public inspection at the Commission's Public Document Room (PDR), located at One White Flint North, Public File Area O1 F21, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible electronically from the Agency wide Documents Access and Management System's (ADAMS) Public Electronic Reading Room on the Internet at the NRC Web site, <http://www.nrc.gov/reading-rm/adams.html>. Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS should contact the NRC PDR Reference staff by telephone at 1-800-397-4209, or 301-415-4737, or by e-mail to [pdr.resource@nrc.gov](mailto:pdr.resource@nrc.gov).

*Attorneys for applicants:* Daniel F. Stenger, Hogan & Hartson LLP, 555 Thirteenth Street, NW., Washington, DC 20004, tel: 202-637-5691, e-mail: [DFStenger@hhlaw.com](mailto:DFStenger@hhlaw.com) (counsel for CENG); and John O'Neill, Pillsbury Winthrop Shaw Pittman LLP, 2300 N Street, NW., Washington, DC 20037, telephone 202-663-8148, e-mail: [john.o'neil@pillsburylaw.com](mailto:john.o'neil@pillsburylaw.com) (counsel for MEHC).

Dated at Rockville, Maryland, this, 19th day of November 2008.

For The Nuclear Regulatory Commission.  
**Douglas V. Pickett**,  
*Senior Project Manager, Plant Licensing Branch I-1, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.*

[FR Doc. E8-27944 Filed 11-24-08; 8:45 am]  
BILLING CODE 7590-01-P

## NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50-220 AND 50-410]

### **Nine Mile Point Nuclear Station, LLC; Nine Mile Point Nuclear Station, Unit Nos. 1 and 2; Notice of Consideration of Approval of 10 CFR 50.80 Indirect Transfers of Control of Licenses and Opportunity for a Hearing**

The U.S. Nuclear Regulatory Commission (NRC, the Commission) is considering the issuance of an Order under 10 CFR 50.80 approving the indirect transfer of Facility Operating License Nos. DPR-63 and NPF-69 for the Nine Mile Point Nuclear Station, Unit Nos. 1 and 2, respectively, currently held by Nine Mile Point Nuclear Station, LLC, as owner and

licensed operator. Nine Mile Point Nuclear Station, LLC is currently owned by Constellation Nuclear Power Plants, Inc., which is owned by Constellation Energy Nuclear Group, LLC (CENG).

According to an application for approval dated October 3, 2008, filed by CENG and MidAmerican Energy Holdings Company (MEHC), the indirect transfers of control would result from the proposed acquisition by merger of CENG's parent corporation, Constellation Energy Group, Inc. (CEG) by MEHC. MEHC will indirectly own 100 percent of CEG through its direct wholly owned subsidiary Constellation Energy Holdings, LLC, a holding company.

CEG will remain as the parent company of CENG and CENG will remain as the parent company of the licensee. There will be no direct transfer of the licenses. Nine Mile Point Nuclear Station, LLC, will continue to own and operate the facilities. No physical changes to the facilities or operational changes are being proposed in the application.

Pursuant to 10 CFR 50.80, no license, or any right thereunder, shall be transferred, directly or indirectly, through transfer of control of the license, unless the Commission shall give its consent in writing. The Commission will approve an application for the indirect transfer of a license, if the Commission determines that the proposed transfer will not affect the qualifications of the licensee to hold the license, and that the transfer is otherwise consistent with applicable provisions of law, regulations, and Orders issued by the Commission pursuant thereto.

The filing of requests for hearing and petitions for leave to intervene, and written comments with regard to the license transfer application, are discussed below.

Within 20 days from the date of publication of this notice, any person(s) whose interest may be affected by the Commission's action on the application may request a hearing and intervention via electronic submission through the NRC E-filing system. Requests for a hearing and petitions for leave to intervene should be filed in accordance with the Commission's rules of practice set forth in Subpart C "Rules of General Applicability: Hearing Requests, Petitions to Intervene, Availability of Documents, Selection of Specific Hearing Procedures, Presiding Officer Powers, and General Hearing Management for NRC Adjudicatory Hearings," of 10 CFR Part 2. In particular, such requests and petitions must comply with the requirements set



forth in 10 CFR 2.309. Untimely requests and petitions may be denied, as provided in 10 CFR 2.309(c)(1), unless good cause for failure to file on time is established. In addition, an untimely request or petition should address the factors that the Commission will also consider, in reviewing untimely requests or petitions, set forth in 10 CFR 2.309(c)(1)(i)-(viii).

All documents filed in NRC adjudicatory proceedings, including a request for hearing, a petition for leave to intervene, any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities participating under 10 CFR 2.315(c), must be filed in accordance with the NRC E-Filing rule, which the NRC promulgated in August 2007, 72 FR 49139 (Aug. 28, 2007). The E-Filing process requires participants to submit and serve documents over the internet or in some cases to mail copies on electronic storage media. Participants may not submit paper copies of their filings unless they seek a waiver in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least ten (10) days prior to the filing deadline, the petitioner/requestor must contact the Office of the Secretary by e-mail at [HEARINGDOCKET@NRC.GOV](mailto:HEARINGDOCKET@NRC.GOV), or by calling (301) 415-1677, to request (1) a digital ID certificate, which allows the participant (or its counsel or representative) to digitally sign documents and access the E-Submittal server for any proceeding in which it is participating; and/or (2) creation of an electronic docket for the proceeding (even in instances in which the petitioner/requestor (or its counsel or representative) already holds an NRC-issued digital ID certificate). Each petitioner/requestor will need to download the Workplace Forms Viewer™ to access the Electronic Information Exchange (EIE), a component of the E-Filing system. The Workplace Forms Viewer™ is free and is available at <http://www.nrc.gov/site-help/e-submittals/install-viewer.html>. Information about applying for a digital ID certificate is available on NRC's public Web site at <http://www.nrc.gov/site-help/e-submittals/apply-certificates.html>.

Once a petitioner/requestor has obtained a digital ID certificate, had a docket created, and downloaded the EIE viewer, it can then submit a request for hearing or petition for leave to intervene. Submissions should be in Portable Document Format (PDF) in

accordance with NRC guidance available on the NRC public Web site at <http://www.nrc.gov/site-help/e-submittals.html>. A filing is considered complete at the time the filer submits its documents through EIE. To be timely, an electronic filing must be submitted to the EIE system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an e-mail notice confirming receipt of the document. The EIE system also distributes an e-mail notice that provides access to the document to the NRC Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the documents on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before a hearing request/petition to intervene is filed so that they can obtain access to the document via the E-Filing system.

A person filing electronically may seek assistance through the "Contact Us" link located on the NRC Web site at <http://www.nrc.gov/site-help/e-submittals.html> or by calling the NRC technical help line, which is available between 8:30 a.m. and 4:15 p.m., Eastern Time, Monday through Friday. The help line number is (800) 397-4209 or locally, (301) 415-4737. Participants who believe that they have a good cause for not submitting documents electronically must file a motion, in accordance with 10 CFR 2.302(g), with their initial paper filing requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, Maryland, 20852, Attention: Rulemaking and Adjudications Staff. Participants filing a document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service.

Documents submitted in adjudicatory proceedings will appear in NRC's

electronic hearing docket which is available to the public at [http://ehd.nrc.gov/EHD\\_Proceeding/home.asp](http://ehd.nrc.gov/EHD_Proceeding/home.asp), unless excluded pursuant to an order of the Commission, an Atomic Safety and Licensing Board, or a Presiding Officer. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or home phone numbers in their filings. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submissions.

The Commission will issue a notice or order granting or denying a hearing request or intervention petition, designating the issues for any hearing that will be held and designating the Presiding Officer. A notice granting a hearing will be published in the **Federal Register** and served on the parties to the hearing.

As an alternative to petitions to intervene and requests for hearing, within 30 days from the date of publication of this notice, persons may submit written comments regarding the indirect license transfer application, as provided for in 10 CFR 2.1305. The Commission will consider and, if appropriate, respond to these comments, but such comments will not otherwise constitute part of the decisional record. Comments should be submitted to the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Rulemakings and Adjudications Staff, and should cite the publication date and page number of this **Federal Register** notice.

For further details with respect to this indirect license transfer application, see the application dated October 3, 2008, available for public inspection at the Commission's Public Document Room (PDR), located at One White Flint North, Public File Area O1 F21, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible electronically from the Agency wide Documents Access and Management System's (ADAMS) Public Electronic Reading Room on the Internet at the NRC Web site, <http://www.nrc.gov/reading-rm/adams.html>. Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS should contact the NRC PDR Reference staff by telephone at 1-800-397-4209, or 301-415-4737 or by e-mail to [pdr.resource@nrc.gov](mailto:pdr.resource@nrc.gov).

Attorneys for applicants: Daniel F. Stenger, Hogan & Hartson LLP, 555 Thirteenth Street, NW., Washington, DC

20004, tel: 202.637.5691, e-mail: [DFStenger@hhlaw.com](mailto:DFStenger@hhlaw.com) (counsel for CENG); and John O'Neill, Pillsbury Winthrop Shaw Pittman LLP, 2300 N Street, NW., Washington, DC 20037, tel. 202.663.8148, e-mail: [john.o'neill@pillsburylaw.com](mailto:john.o'neill@pillsburylaw.com) (counsel for MEHC).

Dated at Rockville, Maryland this 19th day of November 2008.

For The Nuclear Regulatory Commission  
**Richard V. Guzman,**

Senior Project Manager, Plant Licensing  
Branch L-1, Division of Operating Reactor  
Licensing, Office of Nuclear Reactor  
Regulation.

[FR Doc. E8-27941 Filed 11-24-08; 8:45 am]

BILLING CODE 7590-01-P

## NUCLEAR REGULATORY COMMISSION

[Docket No. 50-244]

### R.E. Ginna Nuclear Power Plant, LLC; R.E. Ginna Nuclear Power Plant; Notice of Consideration of Approval of 10 CFR 50.80 Indirect Transfer of Control of License and Opportunity for a Hearing

The U.S. Nuclear Regulatory Commission (NRC, the Commission) is considering the issuance of an Order under 10 CFR 50.80 approving the indirect transfer of Facility Operating License No. DPR-18 for the R.E. Ginna Nuclear Power Plant, currently held by R.E. Ginna Nuclear Power Plant, LLC, as owner and licensed operator. R.E. Ginna Nuclear Power Plant, LLC is owned by Constellation Nuclear Power Plants, Inc., which is owned by Constellation Energy Nuclear Group, LLC (CENG).

According to an application for approval dated October 3, 2008, filed by CENG and MidAmerican Energy Holdings Company (MEHC), the indirect transfer of control would result from the proposed acquisition by merger of CENG's parent corporation, Constellation Energy Group, Inc. (CEG) by MEHC. MEHC will indirectly own 100 percent of CEG through its direct wholly owned subsidiary Constellation Energy Holdings, LLC, a holding company.

CEG will remain as the parent company of CENG and CENG will remain as the parent company of the licensee. There will be no direct transfer of the license. R.E. Ginna Nuclear Power Plant, LLC, will continue to own and operate the facility. No physical changes to the facility or operational changes are being proposed in the application.

Pursuant to 10 CFR 50.80, no license, or any right thereunder, shall be

transferred, directly or indirectly, through transfer of control of the license, unless the Commission shall give its consent in writing. The Commission will approve an application for the indirect transfer of a license, if the Commission determines that the proposed transfer will not affect the qualifications of the licensee to hold the license, and that the transfer is otherwise consistent with applicable provisions of law, regulations, and Orders issued by the Commission pursuant thereto.

The filing of requests for hearing and petitions for leave to intervene, and written comments with regard to the license transfer application, are discussed below.

Within 20 days from the date of publication of this notice, any person(s) whose interest may be affected by the Commission's action on the application may request a hearing and intervention via electronic submission through the NRC E-filing system. Requests for a hearing and petitions for leave to intervene should be filed in accordance with the Commission's rules of practice set forth in Subpart C "Rules of General Applicability: Hearing Requests, Petitions to Intervene, Availability of Documents, Selection of Specific Hearing Procedures, Presiding Officer Powers, and General Hearing Management for NRC Adjudicatory Hearings," of 10 CFR Part 2. In particular, such requests and petitions must comply with the requirements set forth in 10 CFR 2.309. Untimely requests and petitions may be denied, as provided in 10 CFR 2.309(c)(1), unless good cause for failure to file on time is established. In addition, an untimely request or petition should address the factors that the Commission will also consider, in reviewing untimely requests or petitions, set forth in 10 CFR 2.309(c)(1)(i)-(viii).

All documents filed in NRC adjudicatory proceedings, including a request for hearing, a petition for leave to intervene, any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities participating under 10 CFR 2.315(c), must be filed in accordance with the NRC E-Filing rule, which the NRC promulgated in August 2007, 72 FR 49139 (Aug. 28, 2007). The E-Filing process requires participants to submit and serve documents over the internet or in some cases to mail copies on electronic storage media. Participants may not submit paper copies of their filings unless they seek a waiver in

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Documents submitted in adjudicatory proceedings will appear in NRC's electronic hearing docket which is available to the public at [http://ehd.nrc.gov/EHD\\_Proceeding/home.asp](http://ehd.nrc.gov/EHD_Proceeding/home.asp), unless excluded pursuant to an order of the Commission, an Atomic Safety and Licensing Board, or a Presiding Officer.

Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or home phone numbers in their filings. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submissions.

The Commission will issue a notice or order granting or denying a hearing request or intervention petition, designating the issues for any hearing that will be held and designating the Presiding Officer. A notice granting a hearing will be published in the *Federal Register* and served on the parties to the hearing.

As an alternative to petitions to intervene and requests for hearing, within 30 days from the date of

publication of this notice, persons may submit written comments regarding the indirect license transfer application, as provided for in 10 CFR 2.1305. The Commission will consider and, if appropriate, respond to these comments, but such comments will not otherwise constitute part of the decisional record. Comments should be submitted to the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Rulemakings and Adjudications Staff, and should cite the publication date and page number of this *Federal Register* notice.

For further details with respect to this indirect license transfer application, see the application dated October 3, 2008, available for public inspection at the Commission's Public Document Room (PDR), located at One White Flint North, Public File Area O1 F21, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible electronically from the Agency wide Documents Access and Management System's (ADAMS) Public Electronic Reading Room on the Internet at the NRC Web site, <http://www.nrc.gov/reading-rm/adams.html>. Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS should contact the NRC PDR Reference staff by telephone at 1-800-397-4209, or 301-415-4737 or by e-mail to [pdr.resource@nrc.gov](mailto:pdr.resource@nrc.gov).

Attorneys for applicants: Daniel F. Stenger, Hogan & Hartson LLP, 555 Thirteenth Street, NW., Washington, DC 20004, tel: 202-637-5691, e-mail: [DFStenger@hhlaw.com](mailto:DFStenger@hhlaw.com) (counsel for CENG); and John O'Neill, Pillsbury Winthrop Shaw Pittman LLP, 2300 N Street, NW., Washington, DC 20037, tel: 202-663-8148, e-mail: [john.o'neill@pillsburylaw.com](mailto:john.o'neill@pillsburylaw.com) (counsel for MEHC).

Dated at Rockville, Maryland this 19th day of November 2008.

For The Nuclear Regulatory Commission.

**Douglas V. Pickett,**

Senior Project Manager, Plant Licensing Branch I-1, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. E8-27950 Filed 11-24-08; 8:45 am]

BILLING CODE 7590-01-P

## NUCLEAR REGULATORY COMMISSION

### Notice of Issuance of Regulatory Guide

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Notice of Issuance and Availability of Regulatory Guide 1.212.

**FOR FURTHER INFORMATION CONTACT:** Mekonen Bayssie, Regulatory Guide Development Branch, Division of Engineering, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-0703 or e-mail to [Mekonen.Bayssie@nrc.gov](mailto:Mekonen.Bayssie@nrc.gov).

### SUPPLEMENTARY INFORMATION:

#### I. Introduction

The U.S. Nuclear Regulatory Commission (NRC) is issuing a new guide in the agency's "Regulatory Guide" series. This series was developed to describe and make available to the public information such as methods that are acceptable to the NRC staff for implementing specific parts of the agency's regulations, techniques that the staff uses in evaluating specific problems or postulated accidents, and data that the staff needs in its review of applications for permits and licenses.

Regulatory Guide 1.212, "Sizing of Large Lead-Acid Storage Batteries," was issued with a temporary identification as Draft Regulatory Guide, DG-1183. This guide describes a method that the staff of the NRC considers acceptable for use in complying with requirements and regulations on the criteria for the sizing of large lead-acid storage batteries for use in nuclear power plants. Specifically, the method described in this regulatory guide relates to requirements set forth in Title 10, Section 50.55a, "Codes and Standards," of the *Code of Federal Regulations* (10 CFR 50.55a) (as amended by the *Federal Register* notice of April 13, 1999) and General Design Criteria (GDC) 1 and 17, as set forth in Appendix A, "General Design Criteria for Nuclear Power Plants," to 10 CFR part 50, "Domestic Licensing of Production and Utilization Facilities".

- 10 CFR 50.55a(a)(1) requires that structures, systems, and components be designed, fabricated, erected, constructed, tested, and inspected to quality standards commensurate with the importance of the safety function to be performed.

- GDC 1, "Quality Standards and Records," requires that structures, systems, and components important to safety shall be designed, fabricated, erected, and tested to quality standards commensurate with the importance of the safety functions to be performed.

- GDC 17, "Electric Power Systems," requires that an onsite electric power

system and an offsite electric power system shall be provided to permit functioning of structures, systems, and components important to safety.

## II. Further Information

In July 2008, DG-1183 was published with a public comment period of 60 days from the issuance of the guide. The public comment period closed on September 5, 2008. There were no public comments received. Electronic copies of Regulatory Guide 1.212 are available through the NRC's public Web site under "Regulatory Guides" at <http://www.nrc.gov/reading-rm/doc-collections/>.

In addition, regulatory guides are available for inspection at the NRC's Public Document Room (PDR), which is located at Room O-1F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852-2738. The PDR's mailing address is USNRC PDR, Washington, DC 20555-0001. The PDR can also be reached by telephone at (301) 415-4737 or (800) 397-4209, by fax at (301) 415-3548, and by e-mail to [pdr.resource@nrc.gov](mailto:pdr.resource@nrc.gov).

Regulatory guides are not copyrighted, and NRC approval is not required to reproduce them.

Dated at Rockville, Maryland, this 19th day of November 2008.

For the Nuclear Regulatory Commission.  
**Andrea D. Valentin,**  
*Chief, Regulatory Guide Development Branch,  
 Division of Engineering, Office of Nuclear  
 Regulatory Research.*  
 [FR Doc. E8-27956 Filed 11-24-08; 8:45 am]  
**BILLING CODE 7590-01-P**

## NUCLEAR REGULATORY COMMISSION

### Sunshine Federal Register Notice

**AGENCY HOLDING THE MEETINGS:** Nuclear Regulatory Commission.

**DATES:** Weeks of November 24, December 1, 8, 15, 22, 29, 2008.

**PLACE:** Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

**STATUS:** Public and Closed.

#### Week of November 24, 2008

There are no meetings scheduled for the week of November 24, 2008.

#### Week of December 1, 2008—Tentative

*Monday, December 1, 2008*

12:55 p.m.

Affirmation Session (Public Meeting) (Tentative).

a. Final Rulemaking—Power Reactor Security Requirements (RIN 3150-

AG63) (Tentative).

#### Week of December 8, 2008—Tentative

*Tuesday, December 9, 2008*

9:30 a.m.

Briefing on Equal Employment Opportunity (EEO) and Small Business Programs (Public Meeting) (Contact: Sandy Talley, 301-415-8059).

This meeting will be Webcast live at the Web address—<http://www.nrc.gov>.

*Thursday, December 11, 2008*

9:30 a.m.

Briefing on Uranium Recovery—Part 1 (Public Meeting).

1:30 p.m.

Briefing on Uranium Recovery—Part 2 (Public Meeting)

(Contact for both parts: Dominick Orlando, 301-415-6749).

Both parts of this meeting will be Webcast live at the Web address—<http://www.nrc.gov>.

*Friday, December 12, 2008*

9:30 a.m.

Discussion of Management Issues (Closed—Ex. 2).

#### Week of December 15, 2008—Tentative

*Monday, December 15, 2008*

1 p.m.

Discussion of Management Issues (Closed—Ex. 2).

*Wednesday, December 17, 2008*

2 p.m.

Briefing on Threat Environment Assessment (Closed—Ex. 1).

#### Week of December 22, 2008—Tentative

There are no meetings scheduled for the week of December 22, 2008.

#### Week of December 29, 2008—Tentative

There are no meetings scheduled for the week of December 29, 2008.

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: Michelle Schroll, (301) 415-1662.

The NRC Commission Meeting Schedule can be found on the Internet at: <http://www.nrc.gov/about-nrc/policy-making/schedule.html>.

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 the

NRC's Disability Program Coordinator, Rohn Brown, at 301-492-2279, TDD: 301-415-2100, or by e-mail at [rohn.brown@nrc.gov](mailto:rohn.brown@nrc.gov). Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

This notice is distributed by mail to several hundred subscribers; if you no longer wish to receive it, or would like to be added to the distribution, please contact the Office of the Secretary, Washington, DC 20555 (301-415-1969). In addition, distribution of this meeting notice over the Internet system is available. If you are interested in receiving this Commission meeting schedule electronically, please send an electronic message to [darlene.wright@nrc.gov](mailto:darlene.wright@nrc.gov).

Dated: November 20, 2008.

**Rochelle C. Baval,**

*Office of the Secretary.*

[FR Doc. E8-28102 Filed 11-21-08; 11:15 am]

**BILLING CODE 7590-01-P**

## OFFICE OF MANAGEMENT AND BUDGET

### FY 2008 Cost of Outpatient Medical, Dental, and Cosmetic Surgery Services Furnished by Department of Defense Medical Treatment Facilities; Certain Rates Regarding Recovery From Tortiously Liable Third Persons

**AGENCY:** Office of Management and Budget, Executive Office of the President.

**ACTION:** Notice.

**SUMMARY:** By virtue of the authority vested in the President by section 2(a) of Public Law 87-603 (76 Stat. 593; 42 U.S.C. 2652), and delegated to the Director of the Office of Management and Budget (OMB) by the President through Executive Order No. 11541 of July 1, 1970, the rates referenced below are hereby established. These rates are for use in connection with the recovery from tortiously liable third persons for the cost of outpatient medical, dental and cosmetic surgery services furnished by military treatment facilities through the Department of Defense (DoD). The rates were established in accordance with the requirements of OMB Circular A-25, requiring reimbursement of the full cost of all services provided. The outpatient medical and dental rates referenced are effective upon publication of this notice in the **Federal Register** and will remain in effect until further notice. Pharmacy rates are updated periodically. The inpatient rates, published on March 6, 2008, remain in effect until further notice.

A full analysis of the rates is posted at the DoD's Uniform Business Office Web Site: <http://www.tricare.mil/ocfo/docs/SIGNED%20Med%20Den%20Reimburse%20Rates%20and%20Cosmetic%20Surgery%205%2030%2008.pdf>. The rates can be found at: [http://www.tricare.mil/ocfo/mcfs/ubo/mhs\\_rates.cfm](http://www.tricare.mil/ocfo/mcfs/ubo/mhs_rates.cfm).

Jim Nussle,  
Director.

[FR Doc. E8-27905 Filed 11-24-08; 8:45 am]  
BILLING CODE 3110-01-P

## OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

### Request for Comments Concerning Compliance With Telecommunications Trade Agreements

**AGENCY:** Office of the United States Trade Representative.

**ACTION:** Notice of request for public comment and reply comment.

**SUMMARY:** Pursuant to section 1377 of the Omnibus Trade and Competitiveness Act of 1988 (19 U.S.C. 3106) ("section 1377"), the Office of the United States Trade Representative ("USTR") is reviewing and requests comments on: The operation, effectiveness, and implementation of and compliance with the following agreements regarding telecommunications products and services of the United States: the World Trade Organization ("WTO") General Agreement on Trade in Services; the North American Free Trade Agreement ("NAFTA"); U.S. free trade agreements ("FTAs") with Australia, Bahrain, Chile, Morocco, and Singapore; the Dominican Republic-Central America-United States Free Trade Agreement ("CAFTA-DR"); and any other FTA or telecommunications trade agreement coming into force on or before January 1, 2009. The USTR will conclude the review by March 31, 2009.

**DATES:** Comments are due by noon on December 12, 2008 and reply comments by noon on January 16, 2009.

**ADDRESSES:** Gloria Blue, Executive Secretary, Trade Policy Staff Committee, ATTN: Section 1377 Comments, Office of the United States Trade Representative, 1724 F Street, NW., Washington, DC 20508.

**FOR FURTHER INFORMATION CONTACT:** Catherine Hinckley, Office of Services and Investment (202) 395-9539; or Amy Karpel, Office of the General Counsel (202) 395-3150.

**SUPPLEMENTARY INFORMATION:** Section 1377 requires the USTR to review

annually the operations and effectiveness of all U.S. trade agreements regarding telecommunications products and services of the United States that are in force with respect to the United States. The purpose of the review is to determine whether any act, policy, or practice of a country that has entered into an FTA or other telecommunications trade agreement with the United States is inconsistent with the terms of such agreement or otherwise denies U.S. firms, within the context of the terms of such agreements, mutually advantageous market opportunities for telecommunications products and services. For the current review, the USTR seeks comments on:

(1) Whether any WTO member is acting in a manner that is inconsistent with its obligations under WTO agreements affecting market opportunities for telecommunications products or services, e.g., the WTO General Agreement on Trade in Services ("GATS"), including the Basic Telecommunications Agreement, the Annex on Telecommunications, and any scheduled commitments including the Reference Paper on Pro-Competitive Regulatory Principles;

(2) Whether Canada or Mexico has failed to comply with its telecommunications obligations under the NAFTA;

(3) Whether El Salvador, the Dominican Republic, Guatemala, Honduras or Nicaragua has failed to comply with its telecommunications obligations under the CAFTA-DR;

(4) Whether Australia, Bahrain, Chile, Morocco, Singapore, or any other country for which an FTA with the United States will be in force on or before January 1, 2009, has failed to comply with its telecommunications obligations under the respective FTA between the United States and that country (see [http://www.ustr.gov/Trade\\_Agreements/Section\\_Index.html](http://www.ustr.gov/Trade_Agreements/Section_Index.html) for U.S. FTAs);

(5) Whether any country has failed to comply with its obligations under telecommunications trade agreements with the United States other than FTAs, e.g., Mutual Recognition Agreements (MRAs) for Conformity Assessment of Telecommunications Equipment (see <http://www.tcc.mac.doc.gov> for a collection of trade agreements related, *inter alia*, to telecommunications);

(6) In regard to issues listed in items (1) to (5) or item (7), also consider whether a country employs a legal standard for granting injunctions with respect to regulatory decisions that is so lenient that it undermines the country's ability to ensure compliance with its

specific obligations under telecom trade agreements;

(7) Whether any act, policy, or practice of a country cited in a previous section 1377 review remains unresolved (see [http://www.ustr.gov/Trade\\_Sectors/Telecom-E-commerce/Section\\_1377/Section\\_Index.html](http://www.ustr.gov/Trade_Sectors/Telecom-E-commerce/Section_1377/Section_Index.html) for the 2008 review); and

(8) Whether any measures or practices impede access to telecommunications markets or otherwise deny telecommunications products and services of the United States market opportunities with respect to any country that is a WTO member or for which an FTA or telecommunications trade agreement has entered into force between such country and the United States. Measures or practices of interest include, for example, prohibitions on voice over Internet protocol (VOIP) services; requirements for access or use of networks that limit the products or services U.S. suppliers can offer in specific markets; the imposition of excessively high licensing fees, and the imposition of unnecessary or discriminatory technical regulations or standards in the telecom product or services sectors.

### Public Comment and Reply Comment: Requirements for Submission

All comments must be in English, must identify (on the first page of the comments) the telecommunications trade agreement(s) discussed therein, and must be submitted by noon on December 12, 2008. Reply comments must also be in English and must be submitted by noon on January 16, 2009. Reply comments should only address issues raised by the comments.

In order to ensure the most timely and expeditious receipt and consideration of comments and reply comments, USTR has arranged to accept on-line submissions via [www.regulations.gov](http://www.regulations.gov). To submit comments enter docket number USTR-2008-0039 on the home page and click "go". The site will provide a search-results page listing all documents associated with this docket. Find a reference to this notice by selecting "Notice" under "Document Type" on the left side of the search-results page, and click on the link entitled "Send a Comment or Submission." (For further information on using the <http://www.regulations.gov>/ Web site, please consult the resources provided on the Web site by clicking on "How to Use This Site" on the left side of the home page. We expect that most comments will be provided in an attached document. If a document is attached, it is sufficient to type "see attached" in

the general comments field. Submissions in Microsoft Word (.doc) or Adobe Acrobat (.pdf) are preferred. If an application other than those two is used, please identify in your submission the specific application used. For any comments submitted electronically containing business confidential information, the file name of the business confidential version should begin with the characters "BC". Any page containing business confidential information must be clearly marked "BUSINESS CONFIDENTIAL" on the top of that page. Filers of submissions containing business confidential information should also attach a public version of their comments. The file name of the public version should begin with the character "P". The "BC" and "P" should be followed by the name of the person or entity submitting the comments or reply comments. Filers submitting comments containing no business confidential information should name their file using the character "P", followed by the name of the person or entity submitting the comments or reply comments. Electronic submissions should not contain separate cover letters; rather, information that might appear in a cover letter should be included in the submission itself. Similarly, to the extent possible, any attachments to a submission should be included in the same file as the submission itself and not as separate files. All non-confidential comments and reply comments may be viewed at <http://www.regulations.gov> by entering Docket # USTR-2008-0039 in the search field.

We strongly urge submitters to avail themselves of the electronic filing, if at all possible. If an electronic submission is impossible, alternative arrangements must be made with Ms. Blue prior to delivery of such submissions. Ms. Blue should be contacted at (202) 395-3475.

**Carmen Suro-Bredie,**

*Chair, Trade Policy Staff Committee.*

[FR Doc. E8-27909 Filed 11-24-08; 8:45 am]

BILLING CODE 3190-W9-P

## SECURITIES AND EXCHANGE COMMISSION

### Proposed Collection; Comment Request

Upon Written Request, Copies Available From: U.S. Securities and Exchange Commission, Office of Investor Education and Advocacy, Washington, DC 20549-0213

*Extension:*

Rule 15c1-5, OMB Control No. 3235-0471, SEC File No. 270-422.

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) the Securities and Exchange Commission ("Commission") has submitted to the Office of Management and Budget a request for approval of extension of the existing collection of information provided for in the following rule: Rule 15c1-5 (17 CFR 240.15c1-5) under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*) ("Exchange Act").

Rule 15c1-5 states that any broker-dealer controlled by, controlling, or under common control with the issuer of a security that the broker-dealer is trying to sell to or buy from a customer must give the customer written notification disclosing the control relationship at or before completion of the transaction. The Commission estimates that 278 respondents collect information annually under Rule 15c1-5 and that approximately each respondent would spend 10 hours per year collecting this information (2,780 hours in aggregate). There is no retention period requirement under Rule 15c1-5. This Rule does not involve the collection of confidential information.

Written comments are invited on: (a) 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; (b) the accuracy of the Commission's estimates of the burden of the proposed collection of information; (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. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

Comments should be directed to Lewis W. Walker, Acting Director/Chief Information Officer, Securities and Exchange Commission, c/o Shirley Martinson, 6432 General Green Way, Alexandria, VA 22312 or send an e-mail to: [PRA\\_Mailbox@sec.gov](mailto:PRA_Mailbox@sec.gov).

Dated: November 19, 2008.

**Florence E. Harmon,**

*Acting Secretary.*

[FR Doc. E8-27986 Filed 11-24-08; 8:45 am]

BILLING CODE 8011-01-P

## SECURITIES AND EXCHANGE COMMISSION

### Proposed Collection; Comment Request

Upon Written Request, Copies Available From: U.S. Securities and Exchange Commission, Office of Investor Education and Advocacy, Washington, DC 20549-0213.

*Extension:*

Rule 15c1-6, OMB Control No. 3235-0472, SEC File No. 270-423.

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) the Securities and Exchange Commission ("Commission") has submitted to the Office of Management and Budget a request for approval of extension of the existing collection of information provided for in the following rule: Rule 15c1-6 (17 CFR 240.15c1-6) under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*) ("Exchange Act").

Rule 15c1-6 states that any broker-dealer trying to sell to or buy from a customer a security in a primary or secondary distribution in which the broker-dealer is participating or is otherwise financially interested must give the customer written notification of the broker-dealer's participation or interest at or before completion of the transaction. The Commission estimates that 556 respondents collect information annually under Rule 15c1-6 and that each respondent would spend approximately 10 hours annually complying with the collection of information requirement (approximately 5,560 hours in aggregate).

Written comments are invited on: (a) 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; (b) the accuracy of the Commission's estimates of the burden of the proposed collection of information; (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. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

Comments should be directed to Lewis W. Walker, Acting Director/Chief Information Officer, Securities and Exchange Commission, c/o Shirley Martinson, 6432 General Green Way,

Alexandria, VA 22312 or send an e-mail to: [PRA\\_Mailbox@sec.gov](mailto:PRA_Mailbox@sec.gov).

Dated: November 19, 2008.

Florence E. Harmon,  
Acting Secretary.

[FR Doc. E8-27987 Filed 11-24-08; 8:45 am]

BILLING CODE 8011-01-P

## SECURITIES AND EXCHANGE COMMISSION

### Proposed Collection; Comment Request

Upon Written Request, Copies Available

From: U.S. Securities and Exchange Commission, Office of Investor Education and Advocacy, Washington, DC 20549-0213.

#### Extension:

Rule 15c1-7; OMB Control No. 3235-0134; SEC File No. 270-146.

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) the Securities and Exchange Commission ("Commission") has submitted to the Office of Management and Budget a request for approval of extension of the existing collection of information provided for in the following rule: Rule 15c1-7 (17 CFR 240.15c1-7) under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*) ("Exchange Act").

Rule 15c1-7 states that any act of a broker-dealer designed to effect securities transactions with or for a customer account over which the broker-dealer (directly or through an agent or employee) has discretion will be considered a fraudulent, manipulative, or deceptive practice under the federal securities laws, unless a record is made of the transaction immediately by the broker-dealer. The record must include (a) the name of the customer, (b) the name, amount, and price of the security, and (c) the date and time when such transaction took place. The Commission estimates that 556 respondents collect information related to approximately 400,000 transactions annually under Rule 15c1-7 and that each respondent would spend approximately 5 minutes on the collection of information for each transaction, for approximately 33,333 aggregate hours per year (approximately 60 hours per respondent).

Written comments are invited on: (a) 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; (b) the accuracy of the Commission's estimates of the burden of the proposed

collection of information; (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. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

Comments should be directed to Lewis W. Walker, Acting Director/Chief Information Officer, Securities and Exchange Commission, c/o Shirley Martinson, 6432 General Green Way, Alexandria, VA 22312 or send an e-mail to: [PRA\\_Mailbox@sec.gov](mailto:PRA_Mailbox@sec.gov).

Dated: November 19, 2008.

Florence E. Harmon,  
Acting Secretary.

[FR Doc. E8-27988 Filed 11-24-08; 8:45 am]

BILLING CODE 8011-01-P

## SECURITIES AND EXCHANGE COMMISSION

### Sunshine Act Meeting

Federal Register Citation of Previous Announcement [73 FR 68464, November 18, 2008].

STATUS: Closed Meeting.

PLACE: 100 F Street, NW., Washington, DC.

DATE AND TIME OF PREVIOUSLY ANNOUNCED MEETING: November 20, 2008 at 2 p.m.

CHANGE IN THE MEETING: Deletion of an Item.

The following item will not be considered during the Closed Meeting on Thursday, November 20, 2008:

Consideration of amicus participation.

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: November 20, 2008.

Florence E. Harmon,  
Acting Secretary.

[FR Doc. E8-28046 Filed 11-24-08; 8:45 am]

BILLING CODE 8011-01-P

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-58949; File No. SR-Phlx-2008-79]

### Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change by NASDAQ OMX PHLX, Inc. Relating to Reducing the Exposure Time for Option Limit Orders to One Second

November 14, 2008.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")<sup>1</sup>, and Rule 19b-4<sup>2</sup>, thereunder, notice is hereby given that on November 10, 2008, NASDAQ OMX PHLX, Inc. ("Phlx" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I, II, and III, 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, pursuant to Section 19(b)(1) of the Act<sup>3</sup> and Rule 19b-4 thereunder,<sup>4</sup> proposes to amend Exchange Rule 1080(c) to provide that: (i) Order Entry Firms<sup>5</sup> may not execute as principal against orders on the limit order book they represent as agent unless such agency orders are first exposed on the limit order book for at least one (1) second, or the Order Entry Firm has been bidding or offering on the Exchange for at least one (1) second prior to receiving an agency order that is executable against such order, and (ii) Order Entry Firms must expose orders they represent as agent for at least one (1) second before such orders may be automatically executed, in whole or in part, against orders solicited from members and non-member broker-dealers to transact with such orders.

The text of the proposed rule change is available on the Exchange's Website at [http://www.phlx.com/regulatory/reg\\_rulefilings.aspx](http://www.phlx.com/regulatory/reg_rulefilings.aspx).

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

<sup>3</sup> 15 U.S.C. 78s(b)(1).

<sup>4</sup> 17 CFR 240.19b-4.

<sup>5</sup> The term "Order Entry Firm" means a member organization of the Exchange that is able to route orders to the Exchange's AUTOM system. See Exchange Rule 1080(c)(ii)(A)(1).

## 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 reduce the exposure time during which Order Entry Firms may not execute as principal against orders they represent as agent while continuing to afford the opportunity for other market participants to execute at or better than the limit order price during such exposure period.

Rules 1080(c)(ii)(C)(1) and (2) currently provide that an Order Entry Firm may not execute as principal against orders on the limit order book they represent as agent unless: (a) Agency orders are first exposed on the limit order book for at least three seconds, (b) the Order Entry Firm has been bidding or offering on the Exchange for at least three (3) seconds prior to receiving an agency order that is executable against such order, or (c) the Order Entry Firm proceeds in accordance with the crossing rules contained in Rule 1064.<sup>6</sup>

In addition, Order Entry Firms must expose orders they represent as agent for at least three (3) seconds before such orders may be automatically executed, in whole or in part, against orders solicited from members and non-

member broker-dealers to transact with such orders. Under the proposal, these exposure periods would be reduced to one second.

The Exchange adopted the 3-second exposure period in August, 2006, in response to similar functionality already in existence on other options exchanges.<sup>7</sup> The Exchange notes that in adopting the three-second order handling and exposure period, it recognized that three seconds would not be long enough to allow human interaction with the orders. Rather, market participants had become sufficiently automated that they could react to these orders electronically. In this context, the Exchange believes it would be in all market participants' best interest to minimize the exposure period to a time frame that continues to allow adequate time for market participants to respond electronically, as both the order being exposed and the participants responding are subject to market risk during the exposure period. In this respect, the Exchange states that its experience with the three-second exposure time period indicates that one second would provide an adequate response time. The Exchange does not believe it is necessary or beneficial to the orders being exposed to continue to subject them to market risk for a full three seconds.

The Exchange has numerous market participants that have the capability and do opt to respond within a one-second exposure period on the Exchange's fully automated trading platform for options, Phlx XL.<sup>8</sup> Recently, the Exchange distributed a survey to members that regularly participate in orders executed on Phlx XL that would be affected by the proposal. To substantiate that its members could receive, process, and communicate a response back to the Exchange within one second, the survey asked members to identify how many milliseconds it took for (i) a broadcast from the Exchange to reach their systems; (ii) their systems to generate responses; and (iii) their responses to reach the Exchange. The survey results indicate that the time it takes a message to travel between the Exchange and its members is not more than 100 milliseconds each way. The survey also indicated that it typically takes not more than 50 milliseconds for member systems to process the information and generate a response. Thus, the survey indicated that it typically takes not more

than 250 milliseconds for members to receive, process, and respond to broadcast messages related to the various Mechanisms. Additionally, all 8 members that responded to the survey indicated that reducing the exposure period to one second would not impair their ability to participate in orders affected by the proposal. The Exchange believes that this information provides additional support for its assertion that reducing the exposure periods from three seconds to one second will continue to provide members with sufficient time to ensure effective interaction with orders.

The Exchange is submitting the instant proposal in order to remain competitive with other exchanges that have reduced the exposure period from 3 seconds to 1 second.<sup>9</sup> The Exchange believes that reducing its order handling and exposure periods from three seconds to one second will benefit market participants. The Exchange further believes that reducing the time periods to one second will allow it to provide investors and other market participants with more timely executions, thereby reducing market risk.<sup>10</sup>

#### 2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act<sup>11</sup> in general, and furthers the objectives of Section 6(b)(5) of the Act<sup>12</sup> in particular, in that it is designed to promote just and equitable principles of trade, 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, by providing investors with more timely execution of their options orders, while ensuring that there is an adequate exposure of limit orders in the Exchange's marketplace.

### 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

<sup>6</sup> Exchange Rule 1064 states, in relevant part: "An Options Floor Broker who holds orders to buy and sell the same option series may cross such orders, provided that he proceeds in the following manner: (i) In accordance with his responsibilities for due diligence, pursuant to Rule 155, an Options Floor Broker shall request bids and offers for such options series and make all persons in the trading crowd aware of his request. (ii) After providing an opportunity for such bids and offers to be made, he must bid and offer at prices differing by the minimum increment and must improve the market by bidding above the highest bid or offering below the lowest offer. (iii) If such higher bid or lower offer is not taken, he may cross the orders at such higher bid or lower offer by announcing by public outcry that he is crossing and giving the quantity and price."

<sup>7</sup> See Securities Exchange Act Release No. 54298 (August 9, 2006), 71 FR 47282 (August 16, 2006) (SR-Phlx-2006-41).

<sup>8</sup> See Securities Exchange Act Release No. 50100 (July 27, 2004), 69 FR 44612 (August 3, 2004) (SR-Phlx-2003-59).

<sup>9</sup> See Securities Exchange Act Release Nos. 57849 (May 22, 2008), 73 FR 31167 (May 30, 2008) (SR-CBOE-2008-16); and 58224 (July 25, 2008), 73 FR 44303 (July 30, 2008) (SR-ISE-2007-94).

<sup>10</sup> The Exchange believes that the proposed timeframe would give market participants sufficient time to respond, compete, and provide price improvement for orders. The Exchange also notes that electronic systems are readily available to, if not already in place for, Exchange members that allow them to respond in a meaningful way within the proposed timeframe.

<sup>11</sup> 15 U.S.C. 78f(b).

<sup>12</sup> 15 U.S.C. 78f(b)(5).



necessary or appropriate in furtherance of the purposes of the Act.

*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**

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding, or (ii) as to which the Phlx consents, the Commission will:

(A) By order approve such proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

The Exchange has requested accelerated approval of this proposed rule change prior to the 30th day after the date of publication of the notice in the **Federal Register**. The Commission is considering granting accelerated approval of the proposed rule change at the end of a 15-day comment period.

**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 e-mail to [rule-comments@sec.gov](mailto:rule-comments@sec.gov). Please include File Number SR-Phlx-2008-79 on the subject line.

*Paper Comments*

- Send paper comments in triplicate to Florence E. Harmon, Acting Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549-1090. All submissions should refer to File Number SR-Phlx-2008-79. This file number should be included on the subject line if e-mail 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 inspection and copying in the Commission's Public Reference Room. 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-2008-79 and should be submitted on or before December 10, 2008.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>13</sup>

Florence E. Harmon,  
Acting Secretary.

[FR Doc. E8-27897 Filed 11-24-08; 8:45 am]  
BILLING CODE 8011-01-P

**SECURITIES AND EXCHANGE COMMISSION.**

[Release No. 34-58975; File No. SR-NYSE-2008-121]

**Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Establish Fees for Transactions in Stocks With a Price of Less than \$1.00 per Share**

November 19, 2008.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"),<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> notice is hereby given that on November 14, 2008, New York Stock Exchange LLC ("NYSE" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule changes as described in Items I, II and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule changes from interested persons.

<sup>13</sup> 17 CFR 200.30-3(a)(12).

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

**I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change**

The Exchange is proposing to establish a fee for all transactions in stocks that have a trading price below \$1.00 equal to the lesser of (i) .3% of the aggregate transaction value and (ii) the fee that would have applied if the stock did not have a trading price below \$1.00. Transactions subject to this fee limitation will include orders routed to other markets, but not transactions that would not otherwise be subject to a transaction fee. With respect to transactions in stocks with a trading price below \$1.00, Designated Market Makers ("DMMs") will receive a rebate of \$0.0004 per share for all transactions when adding liquidity in round lots in both Less Active Securities and More Active Securities. This filing also deletes the Exchange Traded Funds ("ETFs") pricing from the Exchange's 2008 Price List, as ETFs are no longer traded on the Exchange. The text of the proposed rule change is available on the Exchange's Web site (<http://www.nyse.com>), at the Exchange's Office of the Secretary, 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 these statements may be examined at the places specified in Item IV below. The NYSE 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 Exchange is proposing to establish a fee for all transactions in stocks that have a trading price below \$1.00 equal to the lesser of (i) .3% of the aggregate transaction value and (ii) the fee that would have applied if the stock did not have a trading price below \$1.00. Transactions subject to this fee limitation will include orders routed to other markets, but not transactions that would not otherwise be subject to a transaction fee. With respect to transactions in stocks with a trading price below \$1.00, DMMs will receive a

rebate of \$0.0004 per share for all transactions when adding liquidity in round lots in both Less Active Securities and More Active Securities.

Regulation NMS, adopted by the Securities and Exchange Commission ("SEC"),<sup>3</sup> provides that each trading center intending to qualify for trade-through protection under Regulation NMS Rule 611<sup>4</sup> is required to have a Regulation NMS-compliant trading system fully operational by March 5, 2007 (the "Trading Phase Date").<sup>5</sup>

For stocks priced below \$1.00 per share, Regulation NMS Rule 612<sup>6</sup> permits markets to accept bids, offers, orders and indications of interest in increments smaller than a \$0.01, but not less than \$0.0001, and to quote and trade such stocks in sub-pennies. Markets may choose not to accept such bids, offers, orders or indications of interest and the NYSE has done so, maintaining a minimum trading and quoting variation of \$0.01 for all securities trading below \$100,000.00. See NYSE Rule 62.

The SEC's interpretation of Rule 612 requires a market that routes an order to another market in compliance with Rule 611 and receives a sub-penny execution, to accept the sub-penny execution, report that execution to the customer, and compare, clear and settle that trade. The SEC, however, provided a limited exemption to Rule 611's proscription against trade-throughs to protected quotes that include a sub-penny component to such quotes that are better-priced by a minimum of \$0.01.<sup>7</sup>

In March, 2007, the Exchange amended Rule 123D to provide for a "Sub-penny trading" condition because the Exchange's trading systems did not then accommodate sub-penny executions on orders routed to better-priced protected quotations, nor could it recognize a quote disseminated by another market center if such quote had a sub-penny component and, therefore, could have inadvertently traded through

better protected quotations. The amended rule allowed the Exchange to halt trading in a security whose price was about to fall below \$1.00, without delisting the security, so that the security could continue to trade on other markets that deal in bids, offers, orders or indications of interest in sub-penny prices, until the price of the security had recovered sufficiently to permit the Exchange to resume trading in minimum increments of no less than one penny or the issuer is delisted for failing to correct the price condition within the time provided under NYSE rules.<sup>8</sup> A subsequent amendment established that any orders received by the NYSE in a security subject to a "Sub-penny trading" condition would be routed to NYSE Arca, Inc. and handled in accordance with the rules governing that market.<sup>9</sup>

The NYSE now has the technical capability to recognize protected quotations with a sub-penny component in its round-lot market and accommodate away market executions in sub-pennies, in compliance with SEC Rules 611 and 612. Accordingly, the Exchange has filed an immediately effective rule filing to eliminate the "Sub-penny trading" condition in its entirety.<sup>10</sup>

Rule 610(c) of Regulation NMS imposes a limit of .3% of the aggregate dollar value on transaction fees charged by the executing market with respect to transactions in stocks that have trading prices below \$1.00. As the Exchange will now be trading stocks with trading prices below \$1.00, it proposes to adopt this .3% transaction fee limit with respect to all transactions in equities whether executed on the Exchange or routed to another market. This limit will apply to all customers, including Designated Market Makers. However, the Exchange will not be imposing this fee on any transaction that would otherwise be free of charge or qualify for a credit. As, in certain cases, .3% of the transaction value may exceed the fee that would otherwise be charged, in such cases the Exchange will charge the lesser of (i) .3% of the aggregate transaction value and (ii) the fee that would have applied if the stock did not have a trading price below \$1.00.

DMMs currently receive (i) a rebate of \$0.0030 per share when adding liquidity in round lots in active securities (*i.e.*, securities with a consolidated average

daily trading volume ("ADV") of greater than or equal to one million shares) ("More Active Securities); and (ii) a rebate of \$0.0035 per share when they add liquidity in round lots in securities with a consolidated ADV of less than one million shares ("Less Active Securities"). Because of the very low price per share of stocks trading below a dollar, DMMs will receive a rebate of \$0.0004 per share for all transactions when adding liquidity in round lots in both Less Active Securities and More Active Securities that have a trading price below \$1.00.

The Exchange is eliminating all references to ETFs from its Price List as the Exchange no longer lists ETFs or trades them on an unlisted trading privilege basis. As a consequence, these references no longer have any relevance.

## 2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6<sup>11</sup> of the Act in general and Section 6(b)(4) of the Act<sup>12</sup> in particular, in that it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its members and other persons using its facilities. The Exchange believes that the proposal does not constitute an inequitable allocation of dues, fees and other charges as it conforms the Exchange's pricing policies to the requirements of Rule 610(c) of Regulation NMS and the lower rebates to DMMs are consistent with the very low trading price per share of the affected securities.

### 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 that is not necessary or appropriate in furtherance of the purpose of the Act.

### 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

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A)<sup>13</sup> of the Act and Rule 19b-4(f)(2)<sup>14</sup> thereunder.

<sup>11</sup> 15 U.S.C. 78f.

<sup>12</sup> 15 U.S.C. 78f(b)(4).

<sup>13</sup> 15 U.S.C. 78s(b)(3)(A).

<sup>14</sup> 17 CFR 240.19b-4(f)(2).

<sup>3</sup> 17 CFR 242.600 to 242.612. See Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496 (June 29, 2005) ("Regulation NMS Adopting Release").

<sup>4</sup> See 17 CFR 242.611.

<sup>5</sup> See Securities Exchange Act Release No. 55160 (January 24, 2007), 72 FR 4202 (January 30, 2007) (S7-10-04).

<sup>6</sup> 17 CFR 242.612. Rule 612 originally was to become effective on August 29, 2005, but the date was later extended to January 31, 2006. See Securities Exchange Act Release No. 52196 (Aug. 2, 2005), 70 FR 45529 (Aug. 8, 2005) (S7-10-04).

<sup>7</sup> See Securities Exchange Act Release No. 54714 (November 6, 2006), 71 FR 66352 (November 14, 2006). (Order Granting National Securities Exchanges a Limited Exemption from Rule 612 of Regulation NMS under the Securities Exchange Act of 1934 to Permit Acceptance by Exchanges of Certain Sub-Penny Orders.)

<sup>8</sup> See Securities Exchange Act Release No. 55398, 72 FR 11072 (March 12, 2007) (SR-NYSE-2007-25).

<sup>9</sup> See Securities Exchange Act Release No. 55537 (Mar. 27, 2007), 72 FR 15749 (April 2, 2007) (SR-NYSE-2007-30).

<sup>10</sup> See SR-NYSE-2008-111 [sic] (November 6, 2008).

At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate 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:

##### Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an e-mail to [rule-comments@sec.gov](mailto:rule-comments@sec.gov). Please include File Number SR-NYSE-2008-121 on the subject line.

##### Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549-1090.
- All submissions should refer to File Number SR-NYSE-2008-121. This file number should be included on the subject line if e-mail 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 inspection and copying in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing will also be available for inspection and copying at the principal office of the self-regulatory organization. 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-NYSE-2008-121 and should be submitted on or before December 16, 2008.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>15</sup>

**Florence E. Harmon,**  
*Acting Secretary.*

[FR Doc. E8-27989 Filed 11-24-08; 8:45 am]

BILLING CODE 8011-01-P

## DEPARTMENT OF STATE

### [Public Notice 6431]

#### U.S. Department of State Advisory Committee on Private International Law: Working Group on Conflicts of Law

A Working Group on Conflicts of Law has been established under the Department of State Advisory Committee on Private International Law to consider issues relating to choice of law, applicable law and dispute resolution.

In the context of the Seventh Inter-American Specialized Conference on Private International Law (CIDIP-VII), the Committee on Juridical and Political Affairs of the Permanent Council of the Organization of American States (OAS) is carrying out work on consumer rights as part of its program on private law. Three proposals have been put forward: a Brazilian draft convention on applicable law, a Canadian draft model law on jurisdiction and applicable law, and a United States proposal in the form of legislative guidelines and model laws/rules to promote consumer redress mechanisms such as small claims tribunals, collective procedures, on-line dispute resolution, and government actions.

The United States is also considering whether to pursue ratification of the Inter-American Convention on the Law Applicable to International Contracts (known as the Mexico City Convention), which was adopted at the Fifth Inter-American Specialized Conference on Private International Law (CIDIP-V), and whether a possible protocol to that Convention on choice of law concerning consumer protection would be desirable. Other developments which may be relevant to work at the OAS include proposals at UNCITRAL for future work on on-line dispute resolution, proposals at the Hague Conference on Private International Law for work on a non-binding instrument on choice of law in business to business transactions, and the recently concluded

Hague Convention on Choice of Court Agreements.

Accordingly, the Advisory Committee's Working Group on Conflicts of Law will hold a public meeting to obtain views on the three consumer protection proposals identified above and the Mexico City Convention.

*Time and Place:* The public meeting will take place at the Federal Trade Commission, 600 Pennsylvania Ave., NW., Room H-294, Washington, DC on December 10, 2008, from 10 a.m. EST to 4 p.m. EST. If you are unable to attend the public meeting and would like to participate from a remote location, teleconferencing will be available.

*Public Participation:* Advisory Committee Study Group meetings are open to the public. Persons wishing to attend must contact Trisha Smeltzer at [smeltzertk@state.gov](mailto:smeltzertk@state.gov) or 202-776-8423 and provide their name, e-mail address, and affiliation(s). Please contact Ms. Smeltzer for additional meeting information, any of the documents referenced above, or dial-in information on the conference call. Persons who cannot attend or participate by conference call but who wish to comment on any of the topics referred to above are welcome to do so by e-mail to Michael Dennis at [DennisMJ@state.gov](mailto:DennisMJ@state.gov).

Dated: November 10, 2008.

**Keith Loken,**

*Assistant Legal Adviser, Office of Private International Law, Office of the Legal Adviser, Department of State.*

[FR Doc. E8-27979 Filed 11-24-08; 8:45 am]

BILLING CODE 4710-08-P

## DEPARTMENT OF STATE

### [Public Notice 6433]

#### Culturally Significant Objects Imported for Exhibition Determinations: "Pierre Bonnard: The Late Interiors"

**SUMMARY:** Notice is hereby given of the following determinations: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.*; 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236 of October 19, 1999, as amended, and Delegation of Authority No. 257 of April 15, 2003 [68 FR 19875], I hereby determine that the objects to be included in the exhibition "Pierre Bonnard: The Late Interiors," imported from abroad for temporary exhibition

<sup>15</sup> 17 CFR 200.30-3(a)(12).

within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at the Metropolitan Museum of Art, New York, NY, from on or about January 27, 2009, until on or about April 19, 2009, and at possible additional exhibitions or venues yet to be determined, is in the national interest. Public Notice of these Determinations is ordered to be published in the **Federal Register**.

**FOR FURTHER INFORMATION CONTACT:** For further information, including a list of the exhibit objects, contact Carol B. Epstein, Attorney-Adviser, Office of the Legal Adviser, U.S. Department of State (telephone: 202/453-8048). The address is U.S. Department of State, SA-44, 301 4th Street, SW., Room 700, Washington, DC 20547-0001.

Dated: November 14, 2008.

**C. Miller Crouch,**

*Principal Deputy Assistant Secretary for Educational and Cultural Affairs, Department of State.*

[FR Doc. E8-27976 Filed 11-24-08; 8:45 am]

**BILLING CODE 4710-05-P**

## DEPARTMENT OF STATE

[PUBLIC NOTICE 6432]

### Culturally Significant Objects Imported for Exhibition Determinations: "The Birth of Christianity: A Jewish Story"

**SUMMARY:** Notice is hereby given of the following determinations: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.*; 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236 of October 19, 1999, as amended, and Delegation of Authority No. 257 of April 15, 2003 [68 FR 19875], I hereby determine that the objects in the exhibition: "The Birth of Christianity: A Jewish Story," imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at the Houston Museum of Natural Science, Houston, TX, from on or about December 12, 2008, until on or about April 12, 2009, and at possible additional exhibitions or venues yet to be determined, is in the national interest. Public Notice of these

Determinations is ordered to be published in the **Federal Register**.

**FOR FURTHER INFORMATION CONTACT:** For further information, including a list of the exhibit objects, contact Julie Simpson, Attorney-Adviser, Office of the Legal Adviser, U.S. Department of State (telephone: (202-453-8050). The address is U.S. Department of State, SA-44, 301 4th Street, SW., Room 700, Washington, DC 20547-0001.

Dated: November 18, 2008.

**C. Miller Crouch,**

*Principal Deputy Assistant Secretary for Educational and Cultural Affairs, Department of State.*

[FR Doc. E8-27974 Filed 11-24-08; 8:45 am]

**BILLING CODE 4710-05-P**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### Sixth Meeting, Special Committee 214: Standards for Air Traffic Data Communication Services, Working Group 78 (WG-78)

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice of RTCA Special Committee 214, Standards for Air Traffic Data Communication Services Working Group 78 (WG-78).

**SUMMARY:** The FAA is issuing this notice to advise the public of a sixth meeting of RTCA Special Committee 214, Standards for Air Traffic Data Communication Services.

**DATES:** The meeting will be held December 8-12, 2008, from 9 a.m.-5 p.m.

**ADDRESSES:** The meeting will be held at ALTRAN Sud-Ouest, Toulouse, France.

**SUPPLEMENTARY INFORMATION:** Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (P.L. 92-463, 5 U.S.C., Appendix 2), notice is hereby given for a Special Committee 214 meeting. The agenda will include:

#### Meeting Objectives

- Agree the Review Criteria to be used for the Plenary Consultation of the draft standards;
- Complete the Draft Integrated SPR for Plenary Consultation;
- Complete the ATN and FANS-1/A Draft Interop Standards for Plenary Consultation;
- Complete the draft 4DTRAD OSED Standards for Plenary Consultation.
- Review the scope and timescales for the work remaining.

**Note:** The term "Agree" in the objectives above means that the document is on track

with no major changes expected. It does not mean formal approval by the Plenary.

#### Day 1

*Morning:* Review of Status and Needs.

- Welcome/Introductions/Administrative Remarks.
- Approval of the Agenda.
- Review of the work so far, Work Plan and TORs.
- SC-206/WG-76 Coordination.
- WG-51/SC-186 Coordination.
- Approval of the Summary of Plenary #5, RTCA Paper No. 256-08/SC214-016.
- Review of the proposed SC-214/WG-78 Terms of Reference.
- Presentation of the Review Criteria for the Plenary Consultation.

*Afternoon:* SC-214/WG78 Plenary Session.

- Subgroup Reports and Action Item Responses.
- SG-1, SG-2 and SG-3.

*Day 2: Subgroup Working Sessions*

*Morning & Afternoon:*

- Subgroups Activity: subgroups General, SG1, SG2 and SG3.

*Day 3: Subgroup Working Sessions*

*Morning & Afternoon:*

- Subgroups Activity: subgroups General, SG1, SG2 and SG3.

*Day 4: SC-214/WG78 Plenary*

*Morning:*

- Subgroup Reports General, SG-1, SG-2, SG-3.

*Afternoon:*

- Approval of the Review Criteria for the Plenary Consultation.
- Approval of the Draft documents to be submitted to Plenary Consultation.
- Review Committee Plan—Master Schedule.
- Review Dates, Location and Agenda for Next Meeting.
- Any Other Business.

*Day 5: Subgroup Working Sessions (Implementation of Plenary Decisions)*

*Morning & Afternoon:*

- Subgroups Activity: subgroups General, SG1, SG2 and SG3.

Attendance is open to the interested public but limited to space availability. With the approval of the chairmen, members of the public may present oral statements at the meeting. Persons wishing to present statements or obtain information should contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Members of the public may present a written statement to the committee at any time.

Issued in Washington, DC, on November 18, 2008.

Francisco Estrada C.,  
RTCA Advisory Committee.

[FR Doc. E8-28049 Filed 11-24-08; 8:45 am]

BILLING CODE 4910-13-P

## DEPARTMENT OF TRANSPORTATION

### Federal Highway Administration

#### Environmental Impact Statement; Knox County, City of Vincennes, IN and Lawrence County, IL

**AGENCY:** Federal Highway Administration (FHWA), DOT.

**ACTION:** Revised notice of intent.

**SUMMARY:** The Federal Highway Administration (FHWA) is issuing this revised notice to advise the public that FHWA will not be preparing an Environmental Impact Statement (EIS) for the proposed relocation of railroad lines in Knox County, Indiana and Lawrence County, Illinois. A "Notice of Intent" to prepare an EIS was published in the *Federal Register* on March 16, 2007.

**FOR FURTHER INFORMATION CONTACT:** Janice Osadczuk, Planning and Environmental Specialist, Federal Highway Administration, Telephone: (317) 226-7486; or Frank Litherland, INDOT Project Manager, Telephone 812-882-8364.

**SUPPLEMENTARY INFORMATION:** The FHWA, in cooperation with the Indiana Department of Transportation (INDOT) and the Illinois Department of Transportation (IDOT), will not prepare an EIS as previously intended on a proposal to evaluate alternative alignments for the relocation of the two CSXT railroad mainline tracks, the north-south mainline and the east-west mainline that traverses through the City of Vincennes and portions of Knox County, Indiana and Lawrence County, Illinois. Based on further review of the project and related impacts it was determined that the scope of the project would be reduced in scope from a railroad relocation project requiring the preparation of an environmental impact statement to a series of spot improvements where the roadway bridges over the existing railroad. For these improvements either an environmental assessment or categorical exclusions will be prepared.

(Catalog of Federal Domestic Assistance Program No. 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal

programs and activities apply to the program).

**Authority:** 23 U.S.C. 315; 23 CFR 771.123; 49 CFR 1.48.

**Robert F. Tally,**

*Division Administrator, Indianapolis, Indiana.*

[FR Doc. E8-27914 Filed 11-24-08; 8:45 am]

BILLING CODE 4910-22-P

## DEPARTMENT OF TRANSPORTATION

### Federal Highway Administration

#### Environmental Impact Statement: Proposed Improvements to State Route 126 (Memorial Boulevard) From East Center Street in Kingsport, to Interstate 81, Sullivan County, TN

**AGENCY:** Federal Highway Administration (FHWA), DOT.

**ACTION:** Notice of intent.

**SUMMARY:** The Federal Highway Administration (FHWA) is issuing this notice to advise the public that an Environmental Impact Statement (EIS) will be prepared for a proposed highway project in Sullivan County, Tennessee.

**FOR FURTHER INFORMATION CONTACT:** Mr. Charles J. O'Neill, Planning and Program Management Team Leader, Federal Highway Administration—Tennessee Division Office, 640 Grassmere Park Road, Suite 112, Nashville, TN 37211. 615-781-5772.

**SUPPLEMENTARY INFORMATION:** The FHWA in cooperation with the Tennessee Department of Transportation will prepare an Environmental Impact Statement (EIS) on a proposal to improve State Route 126, also known as Memorial Boulevard, from East Center Street in Kingsport to Interstate 81, for a distance of approximately 8.4 miles.

Alternatives to be considered include: (1) No-build; (2) a Transportation System Management (TSM) alternative (3) one or more build alternatives that could include constructing portions of the roadway on new location, upgrading existing SR 126, or a combination of both, and (4) other alternatives that might arise from public input. Public scoping meetings have been conducted for the project corridor. As part of the scoping process, federal, state, and local agencies and officials; private organizations; citizens; and interest groups met to identify issues of concern and provide input on the purpose and need for the project, range of alternatives, methodology, and the development of the Environmental Impact Statement. A Coordination Plan will be developed to include the public

in the project development process. The plan will utilize the following outreach efforts to provide information and solicit input: newsletters, an internet Web site, e-mail and direct mail, informational meetings and briefings, public hearings, and other efforts as necessary and appropriate. A public hearing will be held upon completion of the Draft Environmental Impact Statement, and public notice will be given of the time and place of the hearing. The Draft EIS will be available for public and agency review and comment prior to the public hearing.

To ensure that the full range of issues related to this proposed action are identified and taken into account, comments and suggestions are invited from all interested parties. Comments and questions concerning the proposed action should be directed to the FHWA contact person identified above at the address provided above.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this proposed program).

**Charles J. O'Neill,**

*Planning and Program Mgmt. Team Leader Nashville, TN.*

[FR Doc. E8-27920 Filed 11-24-08; 8:45 am]

BILLING CODE 4910-22-P

## DEPARTMENT OF TRANSPORTATION

### Federal Railroad Administration

#### Proposed Agency Information Collection Activities; Comment Request

**AGENCY:** Federal Railroad Administration, DOT.

**ACTION:** Notice.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995 and its implementing regulations, the Federal Railroad Administration (FRA) hereby announces that it is seeking an extension of the following currently approved information collection activities. These information collection activities received a six-month emergency approval from OMB. FRA seeks this extension while it works on developing a proposed rule related to the same topic of inappropriate cell phone use and other electronic/electrical devices by railroad employees while on-duty. Before submitting these information collection requirements for clearance by the Office of Management and Budget (OMB), FRA is soliciting

public comment on specific aspects of the activities identified below.

**DATES:** Comments must be received no later than January 26, 2009.

**ADDRESSES:** Submit written comments on any or all of the following proposed activities by mail to either: Mr. Robert Brogan, Office of Safety, Planning and Evaluation Division, RRS-21, Federal Railroad Administration, 1200 New Jersey Ave., SE., Mail Stop 17, Washington, DC 20590, or Ms. Nakia Jackson, Office of Information Technology, RAD-20, Federal Railroad Administration, 1200 New Jersey Ave., SE., Mail Stop 35, Washington, DC 20590. Commenters requesting FRA to acknowledge receipt of their respective comments must include a self-addressed stamped postcard stating, "Comments on OMB control number 2130-0579." Alternatively, comments may be transmitted via facsimile to (202) 493-6216 or (202) 493-6170, or via e-mail to Mr. Brogan at [robert.brogan@dot.gov](mailto:robert.brogan@dot.gov), or to Ms. Jackson at [nakia.jackson@dot.gov](mailto:nakia.jackson@dot.gov). Please refer to the assigned OMB control number in any correspondence submitted. FRA will summarize comments received in response to this notice in a subsequent notice and include them in its information collection submission to OMB for approval.

**FOR FURTHER INFORMATION CONTACT:** Mr. Robert Brogan, Office of Safety, Planning and Evaluation Division, RRS-21, Federal Railroad Administration, 1200 New Jersey Ave., SE., Mail Stop 17, Washington, DC 20590 (telephone: (202) 493-6292) or Ms. Nakia Jackson, Office of Information Technology, RAD-20, Federal Railroad Administration, 1200 New Jersey Ave., SE., Mail Stop 35, Washington, DC 20590 (telephone: (202) 493-6073). (These telephone numbers are not toll-free.)

**SUPPLEMENTARY INFORMATION:** The Paperwork Reduction Act of 1995 (PRA), Public Law 104-13, section 2, 109 Stat. 163 (1995) (codified as revised

at 44 U.S.C. 3501-3520), and its implementing regulations, 5 CFR Part 1320, require Federal agencies to provide 60-days notice to the public for comment on information collection activities before seeking approval for reinstatement or renewal by OMB. 44 U.S.C. 3506(c)(2)(A); 5 CFR 1320.8(d)(1), 1320.10(e)(1), 1320.12(a). Specifically, FRA invites interested respondents to comment on the following summary of proposed information collection activities regarding (i) whether the information collection activities are necessary for FRA to properly execute its functions, including whether the activities will have practical utility; (ii) the accuracy of FRA's estimates of the burden of the information collection activities, including the validity of the methodology and assumptions used to determine the estimates; (iii) ways for FRA to enhance the quality, utility, and clarity of the information being collected; and (iv) ways for FRA to minimize the burden of information collection activities on the public by automated, electronic, mechanical, or other technological collection techniques or other forms of information technology (e.g., permitting electronic submission of responses). See 44 U.S.C. 3506(c)(2)(A)(i)-(iv); 5 CFR 1320.8(d)(1)(i)-(iv). FRA believes that soliciting public comment will promote its efforts to reduce the administrative and paperwork burdens associated with the collection of information mandated by Federal regulations. In summary, FRA reasons that comments received will advance three objectives: (i) Reduce reporting burdens; (ii) ensure that it organizes information collection requirements in a "user friendly" format to improve the use of such information; and (iii) accurately assess the resources expended to retrieve and produce information requested. See 44 U.S.C. 3501.

Below is a brief summary of currently approved information collection

activities that FRA will submit for clearance by OMB as required under the PRA:

**OMB Control Number:** 2130-0579.  
**Title:** FRA Emergency Order No. 26, Notice No. 1.

**Abstract:** Emergency Order No. 26—and its associated collection of information—is FRA's direct and proactive response to the September 12, 2008, Chatsworth, California, collision of a Union Pacific (UP) freight train and a Metrolink commuter train, which resulted in the deaths of 25 people and numerous injuries to train occupants, as well as to other train accidents/incidents involving cell phone use and use of electronic/electrical devices that have occurred throughout the country recently. The collection of information under Emergency Order No. 26 is aimed at ensuring that railroads revise their programs of operational tests and inspections, as necessary, to include the requirements of E.O. 26 and specifically include a minimum number of operational tests and inspections; and at ensuring railroads instruct each of their operating employees and supervisors of railroad operating employees concerning the requirements of E.O. 26 and implementing railroad rules and instructions. The collection of information under E.O. 26 also contains a provision that allows railroads to petition for relief from this Order by adopting other means of ensuring that railroad operating employees are not distracted from their duties by use of electronic or electrical devices or by implementing technology that will prevent inappropriate acts and omissions from resulting in injury to persons.

**Form Number(s):** N/A.  
**Affected Public:** Businesses.  
**Respondent Universe:** 718 railroads; 130,000 Railroad Employees.  
**Frequency of Submission:** One-time; on occasion.  
**Reporting Burden:**

Emergency order item No. 26	Respondent universe	Total annual responses	Average time per response	Total annual burden hours
(1)—Revision of Railroad's Program of Operational Tests and Inspections Under 49 CFR 217 to Include Requirements of E.O. 26.	718 Railroads	718 amended programs. 20 amended programs	1 hour ..... 1 hour .....	718 20
(2) Employee Training in Requirements of E.O. 26 and Implementing Railroad Rules and Instructions.	130,000 RR Employees.	130,000 Trained Employees.	15 minutes .....	32,500
(3) Petitions of Relief from E.O. 26 .....	718 Railroads .....	Zero (0) Petitions .....	Zero (0) minutes/ hours.	Zero (0)

**Total Responses:** 130,738.  
**Total Annual Estimated Burden:** 33,238 hours.

**Status:** Regular review.  
Pursuant to 44 U.S.C. 3507(a) and 5 CFR 1320.5(b), 1320.8(b)(3)(vi), FRA

informs all interested parties that it may not conduct or sponsor, and a respondent is not required to respond

to, a collection of information unless it displays a currently valid OMB control number.

**Authority:** 44 U.S.C. 3501-3520.

Issued in Washington, DC, on November 19, 2008.

**Kimberly Orben,**

*Director, Office of Financial Management,  
Federal Railroad Administration.*

[FR Doc. E8-27908 Filed 11-24-08; 8:45 am]

BILLING CODE 4910-06-P

## DEPARTMENT OF TRANSPORTATION

### Federal Railroad Administration

#### Petition for Waiver of Compliance

In accordance with Part 211 of Title 49 Code of Federal Regulations (CFR), notice is hereby given that the Federal Railroad Administration (FRA) received a request for a waiver of compliance with certain requirements of its safety standards. The individual petition is described below, including the party seeking relief, the regulatory provisions involved, the nature of the relief being requested, and the petitioner's arguments in favor of relief.

#### **Union Pacific Railroad Company (Waiver Petition Docket Number FRA-2007-28454)**

The Union Pacific Railroad Company (UP) seeks a waiver of compliance from certain provisions of 49 CFR Part 232, *Brake System Safety Standards for Freight and Other Non-Passenger Trains and Equipment*. Specifically, UP seeks relief from the requirement in § 232.305(b)(2) to perform a single car air brake test (SCABT) when a "car is on a shop or repair track, as defined in § 232.303(a), for any reason and has not received a single car air brake test within the previous 12-month period."

UP submitted a similar request in 2007, which was assigned Docket Number FRA-2007-28454. On September 12, 2008, FRA issued a letter to UP denying the 2007 waiver request because, "[t]he petition was ambiguous regarding the scope of the relief requested" and it lacked sufficient information to support the relief sought.

Subsequently, UP petitioned for reconsideration of FRA's decision to deny its 2007 request. On October 30, 2008, UP withdrew its request that FRA reconsider its denial and at the same time, UP submitted a new waiver petition, requesting similar relief as in 2007, but including new information and data supporting its request. Because this new waiver petition involves the same subject matter as UP's previous request, FRA is utilizing the same

docket number (FRA-2007-28454), and publishing this new public notice of the request. In light of the new data provided by UP, FRA will conduct a new investigation of the facts and the merits of the request. Accordingly, comments submitted to the docket prior to UP's October 30, 2008 petition, will not be considered in FRA's evaluation of this new request.

UP seeks relief from the regulation to the extent necessary to permit the replacement of non FRA-condemnable wheelsets on railcars as part of an in-train wheelset replacement program, without the need to also perform SCABTs required by § 232.305(b)(2). UP seeks relief such that only railcars with FRA-condemnable wheels and cars due for 5-year SCABTs within 6 months would require and receive SCABTs. UP requests that this relief apply to all UP unit trains.

In its petition, UP explains that it implemented the in-train wheelset replacement program beginning in August 2006, as a means to aggressively identify and replace wheelsets with irregularities, thereby reducing the number of derailments due to broken rails, joint bars, defective wheels and bearings. In-train wheelset replacements can be done by UP mechanical forces in as little as 15 minutes with no need to remove the cars from trains. This in turn reduces the number of switching events that would otherwise be required to affect the repairs, further reducing the risk of injury and derailment. In North Platte, UP estimates that switching moves have been reduced by at least 20,000 annually (conservative estimate). Further, UP notes that this in-train wheelset replacement program permits UP to replace approximately 25 percent more wheelsets than it did using traditional wheelset placement techniques.

UP explains that cars with defective wheelsets are identified by wayside defect detectors at various locations before the trains reach the terminal. These wayside detectors identify the following conditions requiring wheelset replacements: (1) Wheels causing excessive impacts, which are measured in kips, or units of 1,000 pounds (currently, AAR allows carriers to replace wheels exerting impacts of 90 kips or more); (2) wheels with high flanges, thin flanges, or other geometrical irregularities; and (3) defective bearings. If left unchecked, any of these conditions can develop into more advanced defects posing higher risks of wheel or axle failures, along with undue forces on track structures leading to rail breaks.

UP states that since the program has been in effect, wheelset related derailments have decreased. Bearing-related derailments have also decreased. UP concludes from their data that if the in-train wheelset program were to stop, there would be four to five additional wheelset related derailments annually. Moreover, UP believes that most SCABTs do not reveal any defects. According to UP, a sample of 2008 data indicated that only 12.08 percent of all railcars undergoing SCABTs on UP's rail network were found to have brake-related defects. UP notes that for coal cars, the defect was lower yet, at 3.05 percent. Accordingly, UP asserts that given the low number of defects revealed by SCABTs and the high safety benefits of in-train wheelset replacements, there is no justification for requiring SCABTs for the in-train wheelset replacement program.

While UP seeks relief from performing the many SCABTs associated with in-train wheelset replacements, UP understands the importance of complying with the 5-year SCABT requirement. To address this, during recent years UP has upgraded its information systems to automatically flag railcars that are due for a 5-year SCABT within 90 days. On January 1, 2009, the system will flag cars within 6 months of a 5-year SCABT. UP states that if FRA grants this waiver request, UP will perform a SCABT on any railcar undergoing an in-train wheelset replacement that is due for a 5-year SCABT in the following 6 months. However, UP states that if this relief is not granted, it would be forced to reduce the number of wheelset replacements it makes, or even eliminate the in-train wheelset replacement program in some locations. UP asserts that this would negate the derailment prevention and safety gains associated with the in-train wheelset replacement program. UP asserts that the delays and disruption of performing a SCABT on every car that has not received such a test in the previous 12 months (roughly 50 percent) would be intolerable. UP also asserts that many of the mechanical forces that currently perform in-train wheelset replacements could be displaced. Finally, UP asserts that requiring the railroad to perform time-consuming and unnecessary SCABTs on railcars that do not contain FRA-condemnable defects would improperly penalize UP for its innovative and safety-enhancing in-train wheelset replacement program, as well as discourage further investment in emerging technologies including

wayside and onboard monitoring, and ECP braking.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number (Docket No. FRA-2007-28454) and may be submitted by any of the following methods:

- **Web site:** <http://www.regulations.gov>. Follow the online instructions for submitting comments.
- **Fax:** 202-493-2251.
- **Mail:** Docket Operations Facility, U.S. Department of Transportation, 1200 New Jersey Avenue, SE., W12-140, Washington, DC 20590.
- **Hand Delivery:** 1200 New Jersey Avenue, SE., Room W12-140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Communications received within 30 days of the date of this notice will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable. All written communications concerning these proceedings are available for examination during regular business hours (9 a.m.-5 p.m.) At the above facility. All documents in the

public docket are also available for inspection and copying on the Internet at the docket facility's Web site at <http://www.regulations.gov>.

Anyone is able to search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the document (or signing the document, 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).

Issued in Washington, DC, on November 19, 2008.

**Grady C. Cothen, Jr.**,  
Deputy Associate Administrator for Safety Standards and Program Development.  
[FR Doc. E8-27901 Filed 11-24-08; 8:45 am]  
BILLING CODE 4910-06-P

## DEPARTMENT OF TRANSPORTATION

### Federal Transit Administration

#### Over-the-Road Bus Accessibility Program Grant Program: Corrections to Project ID Numbers

**AGENCY:** Federal Transit Administration (FTA), DOT.

**ACTION:** Notice; correction

**SUMMARY:** This notice revises Project Identification Numbers published in the August 22, 2008, Federal Transit Administration (FTA) notice titled "Over-the-Road Bus Accessibility Program Announcement of Project Selections." The notice identifies

corrections to Fiscal Year (FY) 2007 and 2008 Project Identification Numbers; however, award amounts remain unchanged.

**FOR FURTHER INFORMATION CONTACT:** Contact the appropriate FTA Regional Office (Appendix A) or Blenda Younger, Office of Program Management, (202) 366-2053.

### I. Corrections

In the **Federal Register** of August 22, 2008 (73 FR 49737), the Federal Transit Administration (FTA) published a table listing award amounts under the Over-the-Road Bus Accessibility Program. A revised table accompanies this notice which includes the following technical corrections.

1. The Project ID number indicated as D2007-OTRB-061, total award \$151,200, should be deleted and replaced with two rows: D2007-OTRB-061, total, \$8,856 and D2008-OTRB-061, total, \$142,344, as this project will be funded using both FY 2007 and FY 2008 funds.

2. The Project ID numbers indicated as D2007-OTRB-062 through D2007-OTRB-079 should be corrected to read D2008-OTRB-062 through D2008-OTRB-079, as these projects will be funded with FY 2008 funds and not FY 2007 funds. The total monetary awards remain unchanged and the total awarded to each recipient remains unchanged.

Issued in Washington, DC, this 4th day of November, 2008.

**James S. Simpson**,  
Administrator.

BILLING CODE 4910-57-P



AWARD AMOUNT					
Operator	City/State	Intercity Fixed-Route	Other	Total	Project ID
<b>Region I</b>					
Arrow Line	E. Hartford, CT		\$155,550	\$155,550	D2007-OTRB-001
Bonanza Bus Lines	Providence, RI	\$194,830		\$194,830	D2007-OTRB-002
Cavalier Coach Trailways	Boston, MA		\$41,000	\$41,000	D2007-OTRB-003
C&J Trailways	Portsmouth, NH	\$76,600		\$76,600	D2007-OTRB-004
Coach Tours, LTD.	Brookfield, CT		\$26,100	\$26,100	D2007-OTRB-005
Concord Coach Lines	Concord, NH	\$48,400		\$48,400	D2007-OTRB-006
Dattco, Inc.	New Britain, CT		\$30,600	\$30,600	D2007-OTRB-007
Flagship Trailways	Johnston, RI		\$41,000	\$41,000	D2007-OTRB-008
Northeast Charter & Tour Co., Inc.	Lewiston, ME		\$41,901	\$41,901	D2007-OTRB-009
Peter Pan Bus Lines	Springfield, MA	\$378,684		\$378,684	D2007-OTRB-010
Plymouth & Brockton	Plymouth, MA	\$55,620		\$55,620	D2007-OTRB-011
<b>Region II</b>					
Adirondack Trailways	Hurley, NY	\$441,000		\$441,000	D2007-OTRB-012
Classic Coach	Bohemia, NY	\$92,250		\$92,250	D2007-OTRB-013
Hampton Jitney, Inc.	Southampton, NY	\$89,412		\$89,412	D2007-OTRB-014
Paradise Trailways	Hicksville, NY		\$44,158	\$44,158	D2007-OTRB-015
Southern Tier Stages, Inc.	Endicott, NY		\$53,000	\$53,000	D2007-OTRB-016
Swartout Coaches, Inc.	Ithaca, NY		\$31,080	\$31,080	D2007-OTRB-017
<b>Region III</b>					
A P Xpress Bus Company	Capital Heights, MD		\$85,980	\$85,980	D2007-OTRB-018
Butler Motor Transit	Butler, PA		\$89,100	\$89,100	D2007-OTRB-019
Capitol Trailways	Harrisburg, PA	\$110,565		\$110,565	D2007-OTRB-020
Carl R. Bieber, Inc.	Kutztown, PA	\$121,624		\$121,624	D2007-OTRB-021
David Thomas Tours, Inc.	Philadelphia, PA	\$27,200		\$27,200	D2007-OTRB-022
First Priority Tours, Inc.	District Heights, MD		\$89,550	\$89,550	D2007-OTRB-023
Fullington Trailways	Clearfield, PA	\$201,800		\$201,800	D2007-OTRB-024
Keller Transportation, Inc.	Waldorf, MD	\$470,496		\$470,496	D2007-OTRB-025
Lenzer Coach Lines	Sewickley, PA		\$78,686	\$78,686	D2007-OTRB-026
Martz Trailways	Wilkes-Barre, PA	\$379,672		\$379,672	D2007-OTRB-027
R & J Transportation, Inc.	Pottsville, PA		\$29,999	\$29,999	D2007-OTRB-028
Trans-Bridge Lines	Bethlehem, PA	\$93,970		\$93,970	D2007-OTRB-029
<b>Region IV</b>					
American Coach Lines of Miami	Miami, FL	\$156,200		\$156,200	D2007-OTRB-030
Blue Grass Tours, Inc.	Lexington, KY		\$24,680	\$24,680	D2007-OTRB-031
Discovery Charters, Inc.	Longwood, FL		\$27,063	\$27,063	D2007-OTRB-032
Endeavor Bus Lines	Miami, FL		\$116,562	\$116,562	D2007-OTRB-033
First Class Coach Company, Inc.	St. Petersburg, FL	\$120,800		\$120,800	D2007-OTRB-034
Florida Cruise Connection, Inc.	Sarasota, FL	\$104,670		\$104,670	D2007-OTRB-035
Majestic Tours	Rock Hill, SC		\$46,000	\$46,000	D2007-OTRB-036
Midnight Sun Tours, Inc.	Lake Worth, FL		\$78,600	\$78,600	D2007-OTRB-037
Royal Tours & Trailways, Inc.	Randleman, NC		\$40,000	\$40,000	D2007-OTRB-038
<b>Region V</b>					
Able Trek Tours, Inc.	Reedsburg, WI		\$25,159	\$25,159	D2007-OTRB-039
American Heritage Trails, LLC	LaOtto, IN		\$30,070	\$30,070	D2007-OTRB-040
Colonial Coach Lines, Inc.	Mount Prospect, IL	\$403,000		\$403,000	D2007-OTRB-041
Compass Coach	Cedar Springs, MI		\$23,721	\$23,721	D2007-OTRB-042
Dean Charters & Tours, Inc.	Lansing, MI		\$139,000	\$139,000	D2007-OTRB-043
Indian Trails, Inc.	Owosso, MI		\$45,720	\$45,720	D2007-OTRB-044
Jefferson Lines	Minneapolis, MN	\$238,400		\$238,400	D2007-OTRB-045
Keeshin Charter Service	Chicago, IL		\$56,000	\$56,000	D2007-OTRB-046
Kobussen Buses LTD.	Kaukauna, WI		\$28,906	\$28,906	D2007-OTRB-047
Lakefront Lines, Inc.	Brook Park, OH	\$97,353		\$97,353	D2007-OTRB-048
Lamers Bus Lines, Inc.	Green Bay, WI		\$82,991	\$82,991	D2007-OTRB-049
Megabus USA	Chicago, IL	\$420,000		\$420,000	D2007-OTRB-050
Miller Transportation	Indianapolis, IN		\$41,000	\$41,000	D2007-OTRB-051
Pioneer Coach Lines, Inc.	Mount Prospect, IL		\$255,000	\$255,000	D2007-OTRB-052
Riteway Bus Service, Inc.	Richfield, WI	\$86,482		\$86,482	D2007-OTRB-053
Thompson Motor Coach	Indianapolis, IN		\$143,000	\$143,000	D2007-OTRB-054

AWARD AMOUNT					
Operator	City/State	Intercity Fixed-Route	Other	Total	Project ID
Van Galder Bus Company	Janesville, WI	\$297,540		\$297,540	D2007-OTRB-055
Wisconsin Coach Lines	Waukesha, WI		\$108,000	\$108,000	D2007-OTRB-056
<b>Region VI</b>					
ACH Travel & Tours, Inc.	Pharr, TX		\$75,000	\$75,000	D2007-OTRB-057
All Aboard America	Santa Fe, NM		\$212,800	\$212,800	D2007-OTRB-058
Americanos USA, LLC	Dallas, TX		\$264,600	\$264,600	D2007-OTRB-059
Calco Travel, Inc.	Geishmar, LA		\$183,000	\$183,000	D2007-OTRB-060
Crucero USA, LLC	Dallas, TX	\$8,856		\$8,856	D2007-OTRB-061
Crucero USA, LLC	Dallas, TX	\$142,344		\$142,344	D2008-OTRB-061
Del Valle Grand Turismo, Inc.	Pharr, TX		\$74,000	\$74,000	D2008-OTRB-062
Eagle Tours, Inc.	Irving, TX		\$51,050	\$51,050	D2008-OTRB-063
Greyhound Lines, Inc.	Dallas, TX	\$6,361,200		\$6,361,200	D2008-OTRB-064
Kerrville Bus Co.	San Antonio, TX	\$160,650		\$160,650	D2008-OTRB-065
Louisiana Coaches, Inc.	Marrero, LA		\$41,000	\$41,000	D2008-OTRB-066
Sun Travel Trailways	Beaumont, TX		\$42,079	\$42,079	D2008-OTRB-067
<b>Region VII</b>					
Arrow Stage Lines	Norfolk, NE		\$92,250	\$92,250	D2008-OTRB-068
Burlington Trailways	W. Burlington, IA	\$54,300		\$54,300	D2008-OTRB-069
Heartland Trailways	St. Joseph, MO		\$58,500	\$58,500	D2008-OTRB-070
White Knight Limousine	Columbia, MO		\$41,000	\$41,000	D2008-OTRB-071
<b>Region VIII</b>					
Powder River Transportation	Gillette, WY	\$26,700		\$26,700	D2008-OTRB-072
Ramblin Express, Inc.	Colorado Springs, CO		\$183,000	\$183,000	D2008-OTRB-073
<b>Region IX</b>					
Amador Stage Lines	Sacramento, CA		\$70,275	\$70,275	D2008-OTRB-074
Marin Airporter	San Rafael, CA	\$122,000		\$122,000	D2008-OTRB-075
Preferred Charters, LLC	Santa Rosa, CA		\$392,300	\$392,300	D2008-OTRB-076
Silverado Stages, Inc.	San Luis Obispo, CA	\$279,360		\$279,360	D2008-OTRB-077
<b>Region X</b>					
Northwestern Stage Lines	Spokane, WA	\$63,022		\$63,022	D2008-OTRB-078
Premier Alaska Tours, Inc.	Anchorage, AK		\$44,970	\$44,970	D2008-OTRB-079
<b>TOTAL</b>		<b>\$11,925,000</b>	<b>\$3,975,000</b>	<b>\$ 15,900,000</b>	

#### Appendix A—FTA Regional Offices

Richard H. Doyle, Regional Administrator, Region 1—Boston; Kendall Square, 55 Broadway, Suite 920, Cambridge, MA 02142-1093, Tel. 617 494-2055. States served: Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont.	Robert C. Patrick, Regional Administrator, Region 6—Ft. Worth, 819 Taylor Street, Room 8A36, Ft. Worth, TX 76102, Tel. 817 978-0550. States served: Arkansas, Louisiana, Oklahoma, New Mexico and Texas.
Brigid Hynes-Cherin, Regional Administrator, Region 2—New York, One Bowling Green, Room 429, New York, NY 10004-1415, Tel. No. 212 668-2170. States served: New Jersey, New York	Mokhtee Ahmad, Regional Administrator, Region 7—Kansas City, MO, 901 Locust Street, Room 404, Kansas City, MO 64106, Tel. 816 329-3920. States served: Iowa, Kansas, Missouri, and Nebraska.
Letitia Thompson, Regional Administrator, Region 3—Philadelphia, 1760 Market Street, Suite 500, Philadelphia, PA 19103-4124, Tel. 215 656-7100. States served: Delaware, Maryland, Pennsylvania, Virginia, West Virginia, and District of Columbia.	Terry Rosapep, Regional Administrator, Region 8—Denver, 12300 West Dakota Ave., Suite 310, Lakewood, CO 80228-2583, Tel. 720-963-3300. States served: Colorado, Montana, North Dakota, South Dakota, Utah, and Wyoming.
Yvette Taylor, Regional Administrator, Region 4—Atlanta, 230 Peachtree Street, NW, Suite 800, Atlanta, GA 30303, Tel. 404 865-5600. States served: Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, Puerto Rico, South Carolina, Tennessee, and Virgin Islands.	Leslie T. Rogers, Regional Administrator, Region 9—San Francisco, 201 Mission Street, Room 1650, San Francisco, CA 94105-1926, Tel. 415 744-3133. States served: American Samoa, Arizona, California, Guam, Hawaii, Nevada, and the Northern Mariana Islands.
Marisol Simon, Regional Administrator, Region 5—Chicago, 200 West Adams Street, Suite 320, Chicago, IL 60606, Tel. 312 353-2789.	Rick Krochalis, Regional Administrator, Region 10—Seattle, Jackson Federal Building, 915 Second Avenue, Suite 3142, Seattle, WA 98174-1002, Tel. 206 220-7954.

States served: Illinois, Indiana, Michigan, Minnesota, Ohio, and Wisconsin.

States served: Alaska, Idaho, Oregon, and Washington.

[FR Doc. E8-27283 Filed 11-24-08; 8:45 am]  
BILLING CODE 4910-57-C

## DEPARTMENT OF TRANSPORTATION

### National Highway Traffic Safety Administration

#### Petition for Exemption From the Vehicle Theft Prevention Standard; Ford Motor Company

**AGENCY:** National Highway Traffic Safety Administration (NHTSA); Department of Transportation (DOT).

**ACTION:** Grant of petition for exemption.

**SUMMARY:** This document grants in full the petition of Ford Motor Company (Ford) in accordance with § 543.9(c)(2) of 49 CFR Part 543, *Exemption from the Theft Prevention Standard*, for the Ford Mercury Mariner vehicle line beginning with model year (MY) 2010. This petition is granted because the agency has determined that the antitheft device to be placed on the line as standard equipment is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of the Theft Prevention Standard.

**DATES:** The exemption granted by this notice is effective beginning with model year (MY) 2010.

**FOR FURTHER INFORMATION CONTACT:** Ms. Carlita Ballard, Office of International Policy, Fuel Economy and Consumer Programs, NHTSA, 1200 New Jersey Avenue, SE., Washington, DC 20590. Ms. Ballard's telephone number is (202) 366-0846. Her fax number is (202) 493-2290.

**SUPPLEMENTARY INFORMATION:** In a petition dated September 18, 2008, Ford requested an exemption from the parts-marking requirements of the Theft Prevention Standard (49 CFR Part 541) for the Mercury Mariner vehicle line beginning with MY 2010. The petition requested an exemption from parts-marking pursuant to 49 CFR Part 543, *Exemption from Vehicle Theft Prevention Standard*, based on the installation of an antitheft device as standard equipment for an entire vehicle line.

Under § 543.5(a), a manufacturer may petition NHTSA to grant exemptions for one vehicle line per model year. Ford has petitioned the agency to grant an exemption for its Mercury Mariner vehicle line beginning with MY 2010. In its petition, Ford provided a detailed

description and diagram of the identity, design, and location of the components of the antitheft device for the Mercury Mariner vehicle line. Ford will install its passive transponder-based electronic immobilizer antitheft device as standard equipment on the vehicle line. Features of the antitheft device will include an electronic key, ignition lock, and a passive immobilizer. The system does not include an audible or visual alarm as standard equipment. Ford's submission is considered a complete petition as required by 49 CFR 543.7, in that it meets the general requirements contained in § 543.5 and the specific content requirements of § 543.6.

The antitheft device to be installed on the MY 2010 Mercury Mariner is the SecuriLock Passive Antitheft Electronic Engine Immobilizer System (SecuriLock). The Ford SecuriLock is a transponder-based electronic immobilizer system. Ford stated that the integration of the transponder into the normal operation of the ignition key assures activation of the system. When the ignition key is turned to the start position, the transceiver module reads the ignition key code and transmits an encrypted message to the cluster. Validation of the key is determined and start of the engine is authorized once a separate encrypted message is sent to the powertrain's control module (PCM). The powertrain will function only if the key code matches the unique identification key code previously programmed into the PCM. If the codes do not match, the powertrain engine starter, spark and fuel will be disabled. Ford also stated that the SecuriLock electronic engine immobilizer device makes conventional theft methods such as hot-wiring or attacking the ignition lock cylinder ineffective and virtually eliminates drive-away thefts. The cluster and PCM share security data when first installed during vehicle assembly from matched modules. Ford stated that as an additional measure of security, these matched modules will not function in other vehicles if they are separated from each other. Ford also stated that key duplication would virtually be impossible because its key is encrypted with many different codes (1<sup>st</sup> quintillion).

Ford stated that there were only two years of reported theft rates available for the Mercury Mariner, but its Escape vehicle line which is comparable in design, size and equipment to the Mariner is installed with the proposed

device. The Ford Escape vehicle line had an average theft rate using 5 MY's data (2001-2005) of 1.4215 and was granted an exemption from the parts marking standard (Part 541) beginning with the 2009 model year. Ford stated that the exceptionally low theft rate (0.6968) for MY 2006 Mariner vehicles is likely to continue or improve in future years. The theft rate using an average of two MY's data (2005-2006) for Mariner vehicles is 0.7913.

Additionally, Ford noted the reduction in the theft rate for other vehicle lines equipped with the SecuriLock device. Ford's SecuriLock device was first introduced as standard equipment on its MY 1996 Mustang GT and Cobra vehicle lines. The SecuriLock system was installed on the entire Mustang vehicle line as standard equipment in MY 1997. Ford stated that according to National Insurance Crime Bureau (NICB) theft statistics, the 1997 model year Mustang with SecuriLock showed a 70% reduction in theft compared to its MY 1995 Mustang vehicles. Comparatively, Ford stated that there were 149 thefts reported in 1997 and 500 thefts reported in 1995.

In addressing the specific content requirements of 543.6, Ford provided information on the reliability and durability of its proposed device. To ensure reliability and durability of the device, Ford conducted tests based on its own specified standards. Ford provided a detailed list of the tests conducted and believes that the device is reliable and durable since the device complied with its specified requirements for each test.

The agency also notes that the device will provide four of the five types of performance listed in § 543.6(a)(3): promoting activation; preventing defeat or circumvention of the device by unauthorized persons; preventing operation of the vehicle by unauthorized entrants; and ensuring the reliability and durability of the device.

Pursuant to 49 U.S.C. 33106 and 49 CFR 543.7(b), the agency grants a petition for exemption from the parts-marking requirements of Part 541 either in whole or in part, if it determines that, based upon substantial evidence, the standard equipment antitheft device is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of Part 541. The agency finds that Ford has provided adequate reasons for its belief that the antitheft device for the Mercury Mariner vehicle

line is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of the Theft Prevention Standard (49 CFR Part 541). This conclusion is based on the information Ford provided about its device.

For the foregoing reasons, the agency hereby grants in full Ford's petition for exemption from the Mercury Mariner vehicle line from the parts-marking requirements of 49 CFR Part 541. The agency notes that 49 CFR Part 541, Appendix A-1, identifies those lines that are exempted from the Theft Prevention Standard for a given model year. 49 CFR Part 543.7(f) contains publication requirements incident to the disposition of all Part 543 petitions. Advanced listing, including the release of future product nameplates, the beginning model year for which the petition is granted and a general description of the anti-theft device is necessary in order to notify law enforcement agencies of new vehicle lines exempted from the parts-marking requirements of the Theft Prevention Standard.

If Ford decides not to use the exemption for this line, it must formally notify the agency. If such a decision is made, the line must be fully marked according to the requirements under 49 CFR Parts 541.5 and 541.6 (marking of major component parts and replacement parts).

NHTSA notes that if Ford wishes in the future to modify the device on which this exemption is based, the company may have to submit a petition to modify the exemption. Part 543.7(d) states that a Part 543 exemption applies only to vehicles that belong to a line exempted under this part and equipped with the anti-theft device on which the line's exemption is based. Further, Part 543.9(c)(2) provides for the submission of petitions "to modify an exemption to permit the use of an anti-theft device similar to but differing from the one specified in that exemption."

The agency wishes to minimize the administrative burden that Part 543.9(c)(2) could place on exempted vehicle manufacturers and itself. The agency did not intend in drafting Part 543 to require the submission of a modification petition for every change to the components or design of an anti-theft device. The significance of many such changes could be *de minimis*. Therefore, NHTSA suggests that if the manufacturer contemplates making any changes, the effects of which might be characterized as *de minimis*, it should consult the agency

before preparing and submitting a petition to modify.

**Authority:** 49 U.S.C. 33106; delegation of authority at 49 CFR 1.50.

Issued on: November 20, 2008.

**Stephen R. Kratzke,**

*Associate Administrator for Rulemaking.*

[FR Doc. E8-27962 Filed 11-24-08; 8:45 am]

**BILLING CODE 4910-59-P**

## DEPARTMENT OF TRANSPORTATION

### National Highway Traffic Safety Administration

[Docket No. NHTSA-2008-0182, Notice 1]

#### Mercedes-Benz, U.S.A. LLC; Receipt of Application for Extension of a Temporary Exemption From Federal Motor Vehicle Safety Standard No. 108

**AGENCY:** National Highway Traffic Safety Administration (NHTSA), DOT.

**ACTION:** Notice of receipt of application for a temporary exemption.

**SUMMARY:** In accordance with the procedures of 49 CFR 555.6(b), Mercedes-Benz, U.S.A. LLC ("MBUSA"), on behalf of its parent corporation Daimler AG ("Daimler") has applied for a renewal of a temporary exemption from S5.5.10 of Federal Motor Vehicle Safety Standard (FMVSS) No. 108. The basis of the application is to continue the development and field evaluation of new motor vehicle safety feature providing a level of safety at least equal to that of the standard. We are publishing this notice of receipt of the application in accordance with the requirements of 49 CFR 555.7(a), and have made no judgment on the merits of the application.

**DATES:** You should submit your comments not later than December 26, 2008.

**FOR FURTHER INFORMATION CONTACT:** Mr. Ari Scott, Office of the Chief Counsel, NCC-112, National Highway Traffic Safety Administration, 1200 New Jersey Avenue, SE., Washington, DC 20590. Telephone: (202) 366-2992; Fax: (202) 366-3820; E-mail: ari.scott@dot.gov.

#### I. Background

In June of 2005, MBUSA petitioned the agency on behalf of its parent corporation, DaimlerChrysler AG,<sup>1</sup> seeking a temporary exemption from S5.5.10 of Federal Motor Vehicle Safety Standard (FMVSS) No. 108. In short, S5.5.10 specifies that with certain

<sup>1</sup> Due to corporate changes since the previous petition was received, the parent company of MBUSA is now Daimler AG.

exceptions not applicable to this petition, all lamps, including stop lamps must be wired to be steady-burning.<sup>2</sup> In order to develop and evaluate an innovative brake signaling system in the United States, MBUSA sought a temporary exemption from the "steady-burning" requirement as it applies to stop lamps. At the time of the original petition, the system was available in Europe on the S-class, CL-class, and SL-class Mercedes vehicles. MBUSA states that the system enhances the emergency braking signal by flashing three stop lamps required by FMVSS No. 108 during strong deceleration. In addition, after emergency braking, the system automatically activates the hazard warning lights of the stopped vehicle until it starts to move again or the lights are manually switched off. The petitioner states that this signaling system reduces the following drivers' reaction time by attracting their attention, and also enhances visibility of the stopped vehicle, thus helping to reduce the incidence and severity of rear end collisions.

NHTSA granted MBUSA's petition for exemption on January 30, 2006.<sup>3</sup> The exemption was for a two-year period.<sup>4</sup> In granting MBUSA's request in the original grant, NHTSA made several determinations. The agency stated that MBUSA had met the requirements to receive an exemption under 49 CFR Part 555(b), which permits exemptions from the Federal Motor Vehicle Safety Standards on the basis that the exemption would make easier the development or field evaluation of safety equipment. Specifically, the agency stated that based on information provided by MBUSA, it appeared the proposed brake lamp system provided at least an equivalent level of safety to those that comply with FMVSS No. 108. Furthermore, NHTSA decided that granting the requested would be in the public interest, because the new field data obtained through this temporary exemption would enable the agency to make more informed decisions regarding the effect of flashing brake

<sup>2</sup> See S5.5.10 of 49 CFR 571.108. Turn signal lamps, hazard warning signal lamps, school bus warning lamps must be wired to flash. Headlamps and side marker lamps may be wired to flash for signaling purposes. Motorcycle headlamps may be wired to modulate.

<sup>3</sup> 71 FR 4961.

<sup>4</sup> We note that under 49 CFR 555.8(e), "if an application for renewal of temporary exemption that meets the requirements of § 555.5 has been filed not later than 60 days before the termination date of an exemption, the exemption does not terminate until the Administrator grants or denies the application for renewal."

signaling systems on motor vehicle safety.

It should be noted that prior to the original petition for exemption, NHTSA had previously denied petitioner's request to permanently amend FMVSS No. 108 to allow flashing brake signaling systems. Among the reasons for the denial was the need for additional data on safety benefits of flashing brake lamps. The petitioner argues that granting this temporary exemption would allow them to provide the information NHTSA found lacking.

In this petition, MBUSA requests that the exemption be extended for an additional two years. The reason given is that MBUSA needs the renewal to further evaluate whether benefits can be realized through the allowance of emergency brake lights on passenger vehicles in the United States. MBUSA cited data gleaned from its trials in the United States and in Germany that indicates that the emergency braking system may help to prevent some crashes. Although the samples used were very limited, MBUSA states that a renewal of the exemption will allow significantly more data to be collected and analyzed.

Between February 2006 and August 2007, MBUSA sold approximately 2870 vehicles with the modified brake lamps. In accordance with the requirements of 49 CFR 555.6(b)(5), MBUSA will not sell more than 2,500 exempted vehicles in any twelve-month period within the two-year exemption period. For addition details, please see the MBUSA petition at <http://www.regulations.gov>, Docket No. NHTSA-2005-22653. The following (Parts II—VIII) summarizes MBUSA's petition in relevant part.

## II. Question as to Whether the Current Request for a Renewal of the Petition Was Received 60 Days Prior to the Expiration of the Current Exemption

In its request for renewal of the temporary exemption granted in the 2006 notice, the petitioner argued that although the 2006 notice stated that "[t]he exemption from S5.5.10 of FMVSS No. 108 is effective from January 23, 2006 until January 23, 2008," because the notice was not published in the *Federal Register* until January 30, 2006, the term of the exemption should be interpreted to run until January 30, 2008. Therefore, under 49 CFR Part 555.8(e), because this petition for renewal was submitted December 3, 2006,<sup>5</sup> the exemption

<sup>5</sup> As the petitioner states, because the day 60 days prior to January 30 falls on the weekend (Saturday, December 1), the period should be deemed to run from the following Monday, which is December 3, 2006.

should not terminate until the Administrator grants or denies the application for renewal.

Having examined the *Federal Register* notice, we agree that the petition for renewal was submitted within the required time period for the exemption to continue until NHTSA reaches a final decision. In the grant notice, we stated that we were granting the exemption for a period of "twenty-four months." While the notice stated that the period ran from January 23, 2006 through January 23, 2008, we believe that these dates were erroneous. We note that 49 CFR 555.7(f) states that "unless a *later* effective date is specified in the notice of the grant, a temporary exemption is effective upon publication of the notice in the *Federal Register* and exempts vehicles manufactured on and after the effective date." [emphasis added] Because the January 23 date stated in the text of the notice was earlier than the date of publication in the *Federal Register*, pursuant to § 555.7(f), the petition was effective only as of January 30, 2006. Accordingly, the twenty-four month period of the exemption commenced from that date, and given the new petition, will not expire until the Administrator grants or denies this new petition.

## III. Description of the New Motor Vehicle Safety Feature

The petitioner states that its brake signaling system provides two innovative safety-enhancing features.

First, three stop lamps required by FMVSS No. 108 flash at a frequency of 5 Hz in the event of strong deceleration. This occurs if the velocity is >50 km/h (31 mph) and at least one of the following conditions is met:

1. Deceleration is >7 m/s<sup>2</sup>; or
2. The brake assist function is active;

or

3. The Electronic Stability Program (ESP) control unit detects a panic braking operation.

The petitioner states that the activation criteria ensures that the enhanced brake signals are only activated when truly needed. Thus, the brake lights will flash only in severe braking situations, and will flash at a relatively high frequency that allows for fast recognition. Further, using the panic brake signal from the ESP control unit as a trigger would activate the system only when the achievable deceleration is substantially smaller than the demanded one. Thus, the stop lamps would not flash in routine situations.

Second, after emergency braking, the system automatically activates the hazard warning lights of the stopped

vehicle until it starts to move again, or the lights are manually switched off.

## IV. Petitioner's Statement Concerning Benefits of the New Motor Vehicle Safety Feature

The petitioner states that the brake signaling system provides important safety enhancements not found in a vehicle equipped with a traditional brake signaling system. First, the flashing system reduces the following driver's reaction time and encourages maximum deceleration of following vehicles. The petitioner expects especially strong benefits during adverse weather conditions and for inattentive drivers. Second, the activation of hazard warning lamps on the stopped vehicle also enhances vehicle recognition after it came to a complete stop. The petitioner believes that together, these features will help to reduce rear end collisions and improve safety.

The petitioner is aware of the agency's longstanding restriction on flashing stop lamps, in the interest of standardized, instantly recognizable lighting functions. However, MBUSA believes its system will be easily recognizable, and would not interfere with NHTSA's objectives.

## V. The Petitioner's Research and Testing Done Prior to the Current Exemption

In its original petition submitted in 2005, the petitioner offered information on driver behavior studies that would help to determine if the proposed brake light system can significantly reduce driver reaction times. One study that MBUSA used was a driver braking behavior study to understand how often rapid deceleration braking occurs in the United States. The study followed 96 subjects using 15 Mercedes-Benz vehicles equipped with a driver behavior and vehicle dynamics recorder. The study indicated that one emergency braking maneuver occurred for every 2,291 miles driven. The study also suggested that, based on the criteria described in the previous section, only 23 out of 100,000 braking maneuvers would activate the flashing stop lamps. The petitioner concluded that the flashing brake light will occur rarely, which will help to avoid "optical pollution" and enhance the effectiveness of the brake light system.<sup>6</sup>

The petitioner stated that the study showed that flashing brake lights reduce driver reaction time by an average of 0.2 seconds, which is a reduction sufficient

<sup>6</sup> Driver behavior research is described in Attachment A of the petition.

to meaningfully reduce the number and/or severity of rear end collisions. MBUSA argues that even higher reduction in reaction time would occur under real-world driving conditions, where drivers are less focused on the driving task and subject to more sources of distraction. The study also showed positive effects from the flashing brake light signal under adverse weather conditions and in distraction situations. Finally, the test subjects expressed a preference for flashing brake lights when compared to other brake light symbols. In addition, the petitioner also referred to a Japanese study showing that short, flashing intervals are more effective than slower intervals, as well as more effective than enlarging the area of the lamp.

#### VI. Additional Planned Research and Research Done During the Period of the Current Exemption

The petitioner states that the plan for monitoring the experience of these vehicles focused on both dealer inputs and insurance claims. However, to date, the petitioner states that it has only acquired a limited amount of data. Data from one insurance company, representing about 20% of the modified vehicles in the U.S. has been obtained. This information, while based on very limited data, showed some improvement in the crash ratio of the experimental vehicles. Additionally, Daimler has been able to collect data from the German Federal Statistical Office. According to the petition, the data indicate a decrease of rear impacts compared to other Mercedes-Benz passenger cars.

Finally, the petitioner notes a recent Department of Transportation study of rear-end crashes in an effort to help develop improvements in this field.<sup>7</sup> MBUSA states that while the agency is studying the issue on its own, the information the petitioner collects will be a valuable supplement to the agency's efforts.

#### VII. Petitioner's Statement Concerning How a Temporary Exemption Facilitate the Development and Field Evaluation of a New Motor Vehicle Safety Feature

The petitioner states that it intends to monitor the exempted vehicles and study the effectiveness of the brake signaling system. First, MBUSA will gather information about rear-end collisions of vehicles equipped with the system. This information will be combined with the parallel results from

the European fleet and, according to the petitioner, may prove to be valuable in evaluating the anticipated safety benefits of the new brake light system. Second, the test fleet may enable MBUSA to evaluate acceptance of the flashing stop lamps among the American public.

#### VIII. Petitioner's Statement Concerning Why Granting the Petition for Exemption Is in the Public Interest

As indicated above, the petitioner argues that granting the requested exemption from FMVSS 108 would enable it to continue developing and evaluating its innovative brake signaling system, thus contributing substantially to ongoing efforts to consider the effectiveness of enhanced lighting systems in reducing rear-end crashes. MBUSA believes that the system will help to significantly reduce following driver reaction times, thus reducing rear end collisions.

The petitioner also noted that rear end collisions are a significant traffic safety concern, particularly in dense traffic areas, and an important cause of rear end collisions is a following driver's failure to detect that a leading vehicle has performed an emergency braking action. MBUSA believes that an enhanced braking signal that alerts following drivers to urgent braking situations has the potential to significantly enhance safety.

#### IX. How You May Comment on This Petition

We invite you to submit comments on the application described above. You may submit comments identified by docket number at the heading of this notice by any of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Follow the online instructions for submitting comments.

- *Mail:* DOT 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.

- *Hand Delivery or Courier:* U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590, Monday through Friday, except Federal Holidays.

- *Fax:* 1-(202)-493-2251

*Instructions:* All submissions must include the agency name and docket number or Regulatory Identification Number (RIN) for this rulemaking. Note that all comments received will be posted without change to [http://](http://www.regulations.gov)

[www.regulations.gov](http://www.regulations.gov), including any personal information provided.

*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 (Volume 65, Number 70; Pages 19477-78) or you may visit <http://dms.dot.gov>.

*Docket:* For access to the docket in order to read background documents or comments received, go to <http://www.regulations.gov> at any time or to 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.

*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, at the address given under **FOR FURTHER INFORMATION CONTACT**. In addition, you should submit two copies, from which you have deleted the claimed confidential business information, to Docket Management at the address given above. 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).

We shall consider all comments received before the close of business on the comment closing date indicated below. To the extent possible, we shall also consider comments filed after the closing date. We shall publish a notice of final action on the application in the **Federal Register** pursuant to the authority indicated below.

**Authority:** 49 U.S.C. 30113; delegations of authority at 49 CFR 1.50 and 501.8.

Issued on: November 19, 2008.

**Stephen R. Kratzke,**

*Associate Administrator for Rulemaking.*

[FR Doc. E8-27961 Filed 11-24-08; 8:45 am]

**BILLING CODE 4910-59-P**

<sup>7</sup> "Analysis of Rear-End Crashes and Near-Crashes in the 100-Car Naturalistic Driving Study to Support Rear-Signaling Countermeasure Development," DOT HS 810 8145, October 2007.

## DEPARTMENT OF TRANSPORTATION

## National Highway Traffic Safety Administration

[Docket No. NHTSA-2008-0181, Notice 1  
Modena Design SpA]

**Receipt of Application for a Temporary Exemption From Advanced Air Bag Requirements of FMVSS No. 208**

**AGENCY:** National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

**ACTION:** Notice of receipt of petition for temporary exemption from certain provisions of Federal Motor Vehicle Safety Standard (FMVSS) No. 208, Occupant Crash Protection.

**SUMMARY:** In accordance with the procedures in 49 CFR Part 555, Modena Design SpA has petitioned the agency for a temporary exemption from certain advanced air bag requirements of FMVSS No. 208. The basis for the application is that compliance would cause substantial economic hardship to a manufacturer that has tried in good faith to comply with the standard.<sup>1</sup>

This notice of receipt of an application for temporary exemption is published in accordance with statutory provisions. NHTSA has not made any judgment on the merits of the application.

**DATES:** You should submit your comments not later than December 26, 2008.

**FOR FURTHER INFORMATION CONTACT:** Ari Scott, Office of the Chief Counsel, NCC-112, National Highway Traffic Safety Administration, 1200 New Jersey Avenue, SE., West Building 4th Floor, Room W41-326, Washington, DC 20590. Telephone: (202) 366-2992; Fax: (202) 366-3820.

**Comments:** We invite you to submit comments on the application described above. You may submit comments identified by docket number at the heading of this notice by any of the following methods:

- **Web Site:** <http://www.regulations.gov>. Follow the instructions for submitting comments on the electronic docket site by clicking on "Help and Information" or "Help/Info."

- **Fax:** 1-202-493-2251.
- **Mail:** U.S. Department of Transportation, Docket Operations, M-30, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590.

- **Hand Delivery:** 1200 New Jersey Avenue, SE., West Building Ground

Floor, Room W12-140, Washington, DC, between 9 am and 5 pm, Monday through Friday, except Federal Holidays.

- **Federal eRulemaking Portal:** Go to <http://www.regulations.gov>. Follow the online instructions for submitting comments.

**Instructions:** All submissions must include the agency name and docket number. 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 discussion below. We will consider all comments received before the close of business on the comment closing date indicated above. To the extent possible, we will also consider comments filed after the closing date.

**Docket:** For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> at any time or to 1200 New Jersey Avenue, SE., West Building Ground Floor, Room W12-140, Washington, DC 20590, between 9 am and 5 pm, Monday through Friday, except Federal Holidays. Telephone: (202) 366-9826.

**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 (Volume 65, Number 70; Pages 19477-78) or you may visit <http://www.dot.gov/privacy.html>.

**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, at the address given under **FOR FURTHER INFORMATION CONTACT**. In addition, you should submit two copies, from which you have deleted the claimed confidential business information, to Docket Management at the address given above. 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).

**SUPPLEMENTARY INFORMATION:**

**I. Advanced Air Bag Requirements and Small Volume Manufacturers**

In 2000, NHTSA upgraded the requirements for air bags in passenger cars and light trucks, requiring what are commonly known as "advanced air bags."<sup>2</sup> The upgrade was designed to meet the goals of improving protection for occupants of all sizes, belted and unbelted, in moderate-to-high-speed crashes, and of minimizing the risks posed by air bags to infants, children, and other occupants, especially in low-speed crashes.

The advanced air bag requirements were a culmination of a comprehensive plan that the agency announced in 1996 to address the adverse effects of air bags. This plan also included an extensive consumer education program to encourage the placement of children in rear seats. The new requirements were phased in beginning with the 2004 model year.

Small volume manufacturers were not subject to the advanced air bag requirements until September 1, 2006, but their efforts to bring their respective vehicles into compliance with these requirements began several years before that. However, because the new requirements were challenging, major air bag suppliers concentrated their efforts on working with large volume manufacturers, and thus, some small volume manufacturers have had limited access to advanced air bag technology. Because of the nature of the requirements for protecting out-of-position occupants, "off-the-shelf" systems could not be readily adopted. Further complicating matters, because small volume manufacturers build so few vehicles, the costs of developing custom advanced air bag systems compared to potential profits discouraged some air bag suppliers from working with small volume manufacturers.

The agency has carefully tracked occupant fatalities resulting from air bag deployment. Our data indicate that the agency's efforts in the area of consumer education and manufacturers' providing depowered air bags were successful in reducing air bag fatalities even before advanced air bag requirements were implemented.

As always, we are concerned about the potential safety implication of any temporary exemptions granted by this agency. In the present case, we are seeking comments on a petition for a temporary exemption from the advanced air bag requirements submitted by Modena Design SpA

<sup>1</sup>To view the application, go to <http://www.regulations.gov> and enter the docket number set forth in the heading of this document.

<sup>2</sup> See 65 FR 30680 (May 12, 2000).

("Modena Design"), a company operated by Horacio Pagani, regarding a high-performance sports car, the C9 ZONDA (the "C9").

## II. Overview of Petition for Economic Hardship Exemption

In accordance with 49 U.S.C. 30113 and the procedures in 49 CFR Part 555, Modena Design has petitioned the agency for a temporary exemption from certain advanced air bag requirements of FMVSS No. 208. The basis for the application is that compliance would cause substantial economic hardship to a manufacturer that has tried in good faith to comply with the standard. A copy of the petition<sup>3</sup> is available for review and has been placed in the docket for this notice. Specifically, Modena Design has requested an exemption for a period of three years from the date of granting, which the petitioner has estimated to be around December 31, 2011. Modena Design has requested an exemption from the advanced air bag requirements of FMVSS 208, set forth in S14. While Modena Design stated that the C9 will be equipped with standard air bags, and that the company will use its best efforts to comply with the S14 requirements for belted 50th percentile and 5th percentile dummies, it was uncertain as to whether that would be possible, and therefore requested an exemption from the entirety of S14. We note that a number of petitions for exemptions from advanced air bags include not only requests for exemption from S14.5.2, but the rigid barrier test requirement using the 5th percentile adult female test dummy (belted and unbelted, S15), the offset deformable barrier test requirement using the 5th percentile adult female test dummy (S17), the requirements to provide protection for infants and children (S19, S21, and S23) and the requirement using an out-of-position 5th percentile adult female test dummy at the driver position (S25). We also note that several small vehicle manufacturers have provided standard air bags that comply with the provisions of S14 in force before the advanced air bag rules came into effect.

## III. Requirements for Economic Hardship Petitions

### a. General Requirements for Petitions for Exemptions

In order to file a petition for exemption based on substantial economic hardship, a manufacturer must satisfy relevant requirements specified in 49 CFR Part 555, *Temporary Exemption from Motor Vehicle Safety and Bumper Standards*. All petitions for exemption must conform to the requirements in 49 CFR 555.5, "Application for exemption." A petition must, among other requirements, state the number and title, and the text or substance of the standard for which the temporary exemption is sought, and the length of time of the requested exemption. The petitioner must set forth the basis of the petition (the requirements listed under Part 555.6(a) for petitions based on economic hardship). The petition must specify any information withheld from public disclosure under Part 512. Finally, the petitioner must set forth the reasons why the granting of the exemption would be in the public interest, and, as applicable, consistent with the objectives of 49 U.S.C. 301 or 325.

### b. Requirements Specific for Exemptions Based on Substantial Economic Hardship

#### i. Statement on Eligibility

The substantial economic hardship exemption is limited to those manufacturers whose motor vehicle production in its most recent year of production did not exceed 10,000 vehicles, as determined by the NHTSA Administrator (See 49 CFR 555.6(a)(2)(v)). In determining whether a manufacturer of a vehicle meets that criterion, NHTSA considers whether a second vehicle manufacturer also might be deemed the manufacturer of that vehicle. The statutory provisions governing motor vehicle safety (49 U.S.C. Chapter 301) do not include any provision indicating that a manufacturer might have substantial responsibility as a manufacturer of a vehicle simply because it owns or controls a second manufacturer that assembled that vehicle. However, the agency considers the statutory definition of "manufacturer" (49 U.S.C. 30102) to be sufficiently broad to include sponsors, depending on the circumstances. Thus, NHTSA has stated that a manufacturer may be deemed to be a sponsor, and thus a secondary manufacturer of a vehicle assembled by a primary manufacturer, if the secondary manufacturer had a substantial role in

the development and manufacturing process of that vehicle. In the event of such a finding, if either manufacturer has produced over 10,000 vehicles in the previous 12 months, neither manufacturer would be eligible to receive an economic hardship exemption for the vehicle in question.

#### ii. Basis for Application

A petition for exemption based on economic hardship must meet the requirements set forth in Part 555.6, "Basis for Application," specifically those in 49 CFR 555.6(a). One of these requirements, specified at 49 CFR 555.6(a)(1), is for the manufacturer to provide engineering and financial information demonstrating how compliance would cause substantial hardship. More specifically, it is required that a manufacturer: (1) State a list or description of each item that would need to be modified to achieve compliance; (2) state the itemized estimated cost of the modifications if compliance were to be achieved under three different time scenarios; and (3) state the estimated cost increase of compliance on a per-vehicle basis. Additionally, the manufacturer must provide corporate balance sheets and income statements for the fiscal year immediately preceding the application, as well as projected statements for the year following a hypothetical denial of the application for exemption. Finally, a manufacturer must provide a discussion of any other hardships that may result from the denial of an application.

The petition must also contain the information specified in 49 CFR 555.6(a)(2), which relate to a manufacturer's efforts to achieve compliance. This section requires that a petition must contain a description of the manufacturer's efforts to comply with the standard. The required information includes: (1) A chronological analysis of such efforts showing its relationship to the rulemaking history of Standard No. 208; (2) a discussion of alternate means of compliance considered, and rationales for the rejection of those means; (3) a discussion of any other factors that the petitioner desires NHTSA to consider in deciding that it tried in good faith to comply with the standard; and (4) a description of its planned efforts to achieve compliance during the exemption period, and the estimated date by which compliance will be achieved or, alternatively, production ceased. Finally, the petitioner must provide the agency with the total number of vehicles produced by or on behalf of the petitioner during 12-month period prior to filing the petition, in

<sup>3</sup> The company requested confidential treatment under 49 CFR Part 512 for certain business and financial information submitted as part of its petition for temporary exemption. Accordingly, the information placed in the docket does not contain information subject to a claim of confidentiality.



order to establish that the manufacturer is eligible to receive the exemption, as stated above.

#### IV. Petition of Modena Design

The following section briefly summarizes the pertinent portions of the petition related to completeness and eligibility. We note that the full petition can be viewed by accessing the docket via <http://www.regulations.gov>, or by any of the other means listed above in the **COMMENTS** section.

##### a. Requested Exemption

Modena Design has requested an exemption from paragraph S14 of FMVSS No. 208, "Occupant Crash Protection." It has requested that the exemption extend for three years upon the date of publication in the **Federal Register**.

##### b. Petitioner's Statements Relating to Eligibility

Modena Design asserts that current production volume ranges from 15 to 17 vehicles per year, well under the 10,000 vehicle limit. To date, Modena Design has only produced 85 vehicles since 1999, all of them the C8 ZONDA model. Modena Design has provided the following figures with regard to past production:

- 2004: 9 vehicles
- 2005: 8 vehicles
- 2006: 16 vehicles
- 2007 (as of November 8): 17 vehicles

Modena Design states that it is an independent vehicle manufacturer specialized in the design, development, and construction of high performance vehicles. Specifically, Modena Design states that it performs the following tasks:

- Design, Style Interior/Exterior.
- Design of the bodywork.
- Design of the chassis/suspensions/brakes.
- Study of the vehicle dynamics.
- Study of the elasto-kinematics.
- Design of the wiring system.
- Design of the models and moulds for the composite materials.

Modena Design states that due to the small size of the company (it states that it has a work force of 30 employees), it contracts out the other aspects of vehicle development. However, it also states that the company does do all of the assembly of its vehicles, and that no third party company is involved with that process, although Mercedes acts as an arms-length engine supplier. Additionally, Modena Design's sister company, Pagani Automobili SpA, performs the marketing work on Modena Design's vehicles. Both companies are owned and run by the Pagani family.

##### c. Petitioner's Statements Concerning Substantial Economic Hardship

While Modena Design has posted a profit in recent years, it claims that it is still suffering from economic hardship, and needs the requested exemption in order to expand into the U.S. market. According to the documentation that Modena Design provided, the company has posted a profit ranging from \$19,990–81,463 (€13,327–54,309) during the past four years. Comparatively, it estimates that the cost of developing a standard air bag system will be approximately \$3,570,000, and the cost of developing an advanced air bag system an additional \$4 million above that.

Modena Design asserts that because of the overwhelming cost of design for standard and advanced air bags, it requires U.S. exempted-vehicle sales to "bridge the gap," that is, to provide the necessary financing to fund its air bag development efforts. It states that if the company is not able to sell vehicles in the U.S., it will not have the funds to develop FMVSS-compliant successor vehicles.

Financially, Modena Design states that the financial impact of the exemption will be approximately \$12,000,000 (€8,000,000) over the period from 2007–2011. Modena Design states that the full cost of developing the C9 will be approximately \$19,500,000 (€13,000,000). To offset this, Modena Design provides two projections for net income during the exemption period, from 2009 to 2011. The first, assuming the exemption is denied, would mean that there are no U.S. sales during the period, and the net income for the company (excluding development costs) would be \$13,783,500 (€9,189,000). This means that the company would incur a total of \$5,700,000 (€3,800,000) shortfall as a result of its investment in the C9. The second projection assumes that an exemption is granted, and that the company would be able to sell vehicles in the U.S. during the aforementioned period, with the resulting net income being \$25,869,000 (€17,246,000). This figure implies a profit of \$6,375,000 (€4,250,000) with regard to the C9 over the period from 2007–2011.

Additionally, Modena Design asserts that it requires a substantial amount of time to design systems that comply with the FMVSSs. In its petition, the company claims that its system of building test prototypes means that it will take a significant investment of time and resources to design new systems for the C9. It states that it takes six months for Modena Design to build

a test car, and "if the company were to devote all resources to prototype building, then it would have to cease building what few C8 production cars [are currently] being built."

Finally, Modena Design states that there is no possibility of technology transfer that could aid it with its homologation projects. As an independent manufacturer, Modena Design asserts that there is "no possibility of technology transfer from a larger parent company that also manufactures motor vehicles."

##### d. Petitioner's Statements Regarding Efforts To Comply With the Standard

In explaining why it has not been currently able to meet the air bag requirements, Modena Design points to the difficulty that many small vehicle manufacturers have had in obtaining items of specialized vehicle equipment. Nonetheless, according to the petition, Modena has made efforts to achieve compliance with the FMVSS. These efforts involve work with several suppliers to develop compliant air bags for the U.S. market.

To begin, Modena Design asserts in its petition that an air bag project is already underway. This project aims first to create standard, and then advanced air bags, at a total cost of around \$7,500,000. To this end, Modena Design states that it has partnered with Applus+ IDIATA, a Spanish engineering services company that has previously provided advanced air bag development solutions and testing for small volume manufacturers. According to figures presented in the petition, a total of \$3,828,000 (€2,552,000) has been invested in the development of standard air bags, and an additional \$4,288,500 (€2,859,000) has been invested in the development of advanced systems. Modena Design provided fairly detailed specifications of the engineering efforts and the design specifications of its air bag systems in its petition.

##### e. Petitioner's Statements Concerning Intent To Comply or Cease Production Upon Expiration of Requested Temporary Exemption

Modena Design states that it "expects its smart air bag system to be ready in December 2011." We note that Modena Design asserted that due to the long product cycle, it expects the C9 to be in production until 2015.

*f. Petitioner's Statements Concerning Why Granting Exemption Would Be in the Public Interest and Consistent With the Objectives of 49 U.S.C. Chapter 301 or 325*

Modena Design argues that the vehicle comes equipped with numerous features that enhance safety, and that the granting of this exemption would be consistent with the public interest and the objectives of the Safety Act (see 49 U.S.C. 301). The petitioner asserts that the Pagani vehicles incorporate design features that have significant safety benefits. These include the use of carbon-fiber technology, which provides great strength at a low weight. The fuel tank is incorporated into the carbon chassis for maximum protection, and the chassis also incorporates the monocoque protective "cell" design. Enhanced by a metal roll cage and alloy front and rear chassis subframes, the vehicle provides a significant safety benefit in the event of a crash or rollover. The monocoque can stay rigid during repeated impacts, providing an additional source of protection in the event of a potentially penetrating impact. Modena Design implies that these features serve, in part, to mitigate

the diminished crashworthiness caused by the lack of FMVSS-compliant air bags.

Modena Design lists six additional rationales as to why an exemption would be in the public interest. They are repeated below:

- All exempted cars will have standard air bags which comply with the pre-S14 provisions of FMVSS No. 208.
- Exempted vehicles will comply with all Federal safety standards other than the provisions that are subject to the exemption.
- Due to the extremely small number of exempted vehicles (even with an increase in production capability, Modena Design states that it will only produce around 50 vehicles per year), the effect on motor vehicle safety will be de minimus.
- If an exemption is not granted, U.S. consumer choice would be adversely affected.
- Modena Design vehicles will not be used extensively, due to their "second vehicle" nature.
- Because of the nature of the C9 as a high-performance sports car, it is not expected to typically transport children, thereby reducing the importance of

advanced air bags, which are, in part, aimed at protecting children.

**V. NHTSA's Initial Review of Petition as to Completeness/Eligibility**

Upon receiving a petition, NHTSA conducts an initial review of the petition with respect to whether the petition is complete and whether the petitioner appears to be eligible to apply for the requested petition. The agency has tentatively concluded that the petition is complete and the petitioner eligible to apply for the requested petition. The agency has not made any judgment on the merits of the application.

**VI. Issuance of Notice of Final Action**

We are providing a 30-day comment period. After considering public comments and other available information, we will publish a notice of final action on the application in the **Federal Register**.

Issued on: November 19, 2008.

**Stephen R. Kratzke,**

*Associate Administrator for Rulemaking.*

[FR Doc. E8-27963 Filed 11-24-08; 8:45 am]

BILLING CODE 4910-59-P



# Federal Register

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Tuesday,  
November 25, 2008

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Part II

## Department of Homeland Security

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U.S. Customs and Border Protection

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19 CFR Parts 4, 12, 18, et al.  
Importer Security Filing and Additional  
Carrier Requirements; Final Rule

**DEPARTMENT OF HOMELAND SECURITY**

**Bureau of Customs and Border Protection**

**19 CFR Parts 4, 12, 18, 101, 103, 113, 122, 123, 141, 143, 149, 178, and 192**

[Docket Number USCBP-2007-0077; CBP Dec. 08-46]

RIN 1651-AA70

**Importer Security Filing and Additional Carrier Requirements**

**AGENCY:** Customs and Border Protection, Department of Homeland Security.

**ACTION:** Interim final rule, solicitation of comments.

**SUMMARY:** To help prevent terrorist weapons from being transported to the United States, vessel carriers bringing cargo to the United States are required to transmit certain information to Customs and Border Protection (CBP) about the cargo they are transporting prior to lading that cargo at foreign ports of entry. This interim final rule requires both importers and carriers to submit additional information pertaining to cargo to CBP before the cargo is brought into the United States by vessel. This information must be submitted to CBP by way of a CBP-approved electronic data interchange system. The required information is reasonably necessary to improve CBP's ability to identify high-risk shipments so as to prevent smuggling and ensure cargo safety and security. These regulations specifically fulfill the requirements of section 203 of the Security and Accountability for Every (SAFE) Port Act of 2006 and section 343(a) of the Trade Act of 2002, as amended by the Maritime Transportation Security Act of 2002.

**DATES:** *Effective Date:* This rule is effective on January 26, 2009.

*Compliance Dates:* The compliance dates for these regulations are set forth in § 4.7c(d), 4.7d(f), and 149.2(g).

*Comment Date:* As provided in the "Public Participation" section of this document, comments are requested on certain aspects of the rule. Comments must be received on or before June 1, 2009.

**ADDRESSES:** You may submit comments, identified by *docket number*, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments via docket number USCBP-2007-0077.

- *Mail:* Border Security Regulations Branch, Office of International Trade, U.S. Customs and Border Protection,

799 9th Street, NW., Washington, DC 20001.

*Instructions:* All submissions received must include the agency name and document number for this rulemaking. All comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the "Public Participation" 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>. Submitted comments may also be inspected on regular business days between the hours of 9 a.m. and 4:30 p.m. at the Office of International Trade, Customs and Border Protection, 799 9th Street, NW., 5th Floor, Washington, DC. Arrangements to inspect submitted comments should be made in advance by calling Mr. Joseph Clark at (202) 325-0118.

**FOR FURTHER INFORMATION CONTACT:** Richard Di Nucci, Office of Field Operations, (202) 344-2513.

**SUPPLEMENTARY INFORMATION:**

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**Abbreviations and Terms Used in This Document**

- AAEI—American Association of Exporters and Importers
- AAPA—American Association of Port Authorities
- ABI—Automated Broker Interface
- ACE—Automated Commercial Environment
- AES—Automated Export System
- AMS—Automated Manifest System
- ANSI—American National Standards Institute
- ATDI—Advance Trade Data Initiative
- ATS—Automated Targeting System
- BAPLIE—Bayplan/stowage plan occupied and empty locations message
- CAMIR—Customs Automated Manifest Interface Requirements
- CATAIR—Customs and Trade Automated Interface Requirements
- CBP—Customs and Border Protection
- CFR—Code of Federal Regulations
- COAC—Departmental Advisory Committee on Commercial Operations of Customs and Border Protection and Related Homeland Security Functions
- CSI—Container Security Initiative
- CSM—Container status message
- C-TPAT—Customs-Trade Partnership Against Terrorism
- DDP—Delivered duty paid

DHS—U.S. Department of Homeland Security  
 DNL—Do not load  
 DUNS—Data Universal Numbering System  
 EIN—Employer identification number  
 FAQ—Frequently asked questions  
 FDA—U.S. Food and Drug Administration  
 FIRMS—Facilities Information and Resources Management System  
 FROB—Foreign cargo remaining on board  
 FTZ—Foreign trade zone  
 FR—Federal Register  
 GLN—Global Location Number  
 HTSUS—Harmonized Tariff Schedule of the United States  
 ICPA—International Compliance Professionals Association  
 IE—Immediate exportation  
 IIT—Instrument of international trade  
 IMO—International Maritime Organization  
 IRS—Internal Revenue Service  
 IT—Immediate transportation  
 ISF—Importer Security Filing  
 JIG—Joint Industry Group  
 LCL—Less than Container Load  
 MID—Manufacturer identification  
 MTTA—Maritime Transportation Security Act of 2002  
 NAM—National Association of Manufacturers  
 NCBFAA—National Customs Brokers and Forwarders Association of America  
 NII—Non-Intrusive Inspection  
 NPRM—Notice of Proposed Rule Making  
 NVOCC—Non-vessel operating common carrier  
 OCS—Outer Continental Shelf  
 OPA—Outward Processing Arrangement  
 OMB—Office of Management and Budget  
 PDF—Portable Document Format  
 PGA—Participating Government Agency Pub. L.—Public Law  
 RILA—Retail Industry Leaders Association  
 RFA—Regulatory Flexibility Act of 1980  
 SAFE Port Act—Security and Accountability for Every Port Act of 2006  
 SBREFA—Small Business Regulatory Enforcement Fairness Act of 1996  
 sFTP—Secure File Transfer Protocol  
 SSN—Social Security Number  
 T&E—Transportation and exportation  
 TIB—Temporary Importation Bond  
 TSC—Technology Support Center  
 TSN—Trade Support Network  
 UMRA—Unfunded Mandates Reform Act of 1995  
 UN EDIFACT—United Nations rules for Electronic Data Interchange For Administration, Commerce and Transport  
 U.S.C.—United States Code  
 VIN—Vehicle Identification Number  
 VOCC—Vessel Operating Common Carrier  
 WHTI—Western Hemisphere Travel Initiative  
 WSC—World Shipping Council

## I. Public Participation

Interested persons are invited to submit written comments on only the six data elements for which CBP is providing some type of flexibility (container stuffing location, consolidator (stuffer), manufacturer (or supplier), ship to party, country of origin, and commodity HTSUS number)

and the requirements related to those elements discussed in section 149.2(b) and (f). CBP also invites comments on the revised Regulatory Assessment and Final Regulatory Flexibility Analysis, including compliance costs for various industry segments, the impact of the flexibilities provided in this rule, and the barriers to submitting Importer Security Filing data 24 hours prior to lading. We urge commenters to reference a specific portion of the rule, explain the reason for any recommended change, and include data, information, or authorities that support such recommended change.

## II. Background

Section 203 of the Security and Accountability for Every Port Act of 2006 (Pub. L. 109-347, 120 Stat. 1884 (SAFE Port Act)) provides that the Secretary of Homeland Security (Secretary), acting through the Commissioner of CBP, shall promulgate regulations to “require the electronic transmission to the Department [of Homeland Security] of additional data elements for improved high-risk targeting, including appropriate security elements of entry data, as determined by the Secretary, to be provided as advanced information with respect to cargo destined for importation into the United States prior to loading of such cargo on vessels at foreign seaports.” Pursuant to this Act, and section 343(a) of the Trade Act of 2002 (19 U.S.C. 2071 note), CBP published a Notice of Proposed Rule Making (NPRM) in the *Federal Register* (73 FR 90) on January 2, 2008, proposing to require importers and carriers to submit additional information pertaining to cargo before the cargo is brought into the United States by vessel.

CBP has provided an overview of existing advance cargo information requirements and entry requirements below. For a detailed discussion of the advance cargo information requirements prior to this interim final rule, the statutory and regulatory histories, and the statutory factors governing development of these regulations, please see the NPRM published at 73 FR 90.

The proposed rule was known to the trade as both the “Importer Security Filing proposal” and the “10 + 2 proposal.” The name “10 + 2” is shorthand for the number of advance data elements CBP was proposing to collect. Carriers would be generally required to submit two additional data elements—a vessel stow plan and container status messages regarding certain events relating to containers loaded on vessels destined to the United States—to the elements they are already

required to electronically transmit in advance (the “2” of “10+2”); and importers,<sup>1</sup> as defined in the proposed regulations, would be required to submit 10 data elements—an Importer Security Filing containing 10 data elements (the “10” of “10+2”).

CBP extended the initial 60-day comment period by 15 days, from March 3, 2008 to March 18, 2008. See 73 FR 6061 (Feb. 1, 2008). Approximately 200 commenters responded in a timely manner to the NPRM. As certain comments pertained to the proposed carrier requirements and others pertained to the proposed importer requirements, this interim final rule addresses separately the issues presented in the comments regarding the proposed carrier requirements and the proposed importer requirements.

## III. Carrier and Importer Requirements

### A. Existing Requirements

Carriers are currently required to submit advance cargo information for vessels, including a vessel's Cargo Declaration, to CBP no later than 24 hours before the cargo is laden aboard a vessel at a foreign port. See 19 CFR 4.7 and 4.7a. This is generally referred to as the “24 Hour Rule.” This information must be submitted to CBP via the Vessel Automated Manifest System (AMS). Carriers are currently not required to submit vessel stow plans or container status messages to CBP. In addition, importers of record are generally required to file entry information, including CBP Form 3461, with CBP within fifteen calendar days of the date of arrival of a shipment at a United States port of entry and entry summary information, including CBP Form 7501, within 10 working days of the entry of the merchandise. Entry and entry summary information is submitted to CBP via the Automated Broker Interface (ABI) or via paper forms. Importers are not currently required to submit advance cargo information to CBP.

### B. New Carrier Requirements Under This Interim Final Rule

#### 1. Vessel Stow Plan

In addition to the existing carrier requirements pursuant to the 24 Hour Rule, this interim final rule requires

<sup>1</sup> For purposes of the proposed regulations, importer means the party causing goods to arrive within the limits of a port in the United States. For foreign cargo remaining on board (FROB), the importer was proposed to be construed as the carrier. For immediate exportation (IE) and transportation and exportation (T&E) in-bond shipments, and goods to be delivered to a foreign trade zone (FTZ), the importer was proposed to be construed as the party filing the IE, T&E, or FTZ documentation with CBP.

carriers to submit a vessel stow plan for vessels destined to the United States. Carriers must transmit the stow plan for vessels transporting containers so that CBP receives the stow plan no later than 48 hours after the carrier's departure from the last foreign port. For voyages less than 48 hours in duration, CBP must receive the stow plan prior to the vessel's arrival at the first port in the United States. Bulk and break bulk carriers are exempt from this requirement for vessels exclusively carrying bulk and break bulk cargo. Carriers must submit the vessel stow plan via the CBP-approved electronic data interchange system, which currently includes AMS, secure file transfer protocol (sFTP), or e-mail. If CBP approves of different or additional electronic data interchange systems, CBP will publish a notice in the **Federal Register**.

The vessel stow plan must include standard information relating to the vessel and each container laden on the vessel, including the following standard information:

With regard to the vessel,

- (1) Vessel name (including international maritime organization (IMO) number);
- (2) Vessel operator; and
- (3) Voyage number.

With regard to each container,

- (1) Container operator;
- (2) Equipment number;
- (3) Equipment size and type;
- (4) Stow position;
- (5) Hazmat code (if applicable);
- (6) Port of lading; and
- (7) Port of discharge.

2. Container Status Messages

In addition to the existing carrier requirements pursuant to the 24 Hour Rule, this interim final rule also requires carriers to submit container status messages (CSMs)<sup>2</sup> to CBP daily for certain events relating to all containers laden with cargo destined to arrive within the limits of a port in the United States by vessel. CSMs created under either the American National Standards Institute (ANSI) X.12 standard or the United Nations rules for Electronic Data Interchange For Administration,

Commerce and Transport (UN EDIFACT) standard are acceptable.

Carriers must submit a CSM when any of the required events occurs if the carrier creates or collects a CSM in its equipment tracking system reporting that event. Carriers are not required to create or collect any CSM data other than those which the carrier already creates or collects on its own and maintains in its electronic equipment tracking system. Carriers must submit CSMs no later than 24 hours after the message is entered into the carrier's equipment tracking system.

The events for which CSMs are required are:

(1) When the booking relating to a container which is destined to arrive within the limits of a port in the United States by vessel is confirmed;

(2) When a container destined to arrive within the limits of a port in the United States by vessel undergoes a terminal gate inspection;

(3) When a container, which is destined to arrive within the limits of a port in the United States by vessel, arrives or departs a facility (These events take place when a container enters or exits a port, container yard, or other facility. Generally, these CSMs are referred to as "gate-in" and "gate-out" messages.);

(4) When a container, which is destined to arrive within the limits of a port in the United States by vessel, is loaded on or unloaded from a conveyance (This includes vessel, feeder vessel, barge, rail and truck movements. Generally, these CSMs are referred to as "loaded on" and "unloaded from" messages.);

(5) When a vessel transporting a container, which is destined to arrive within the limits of a port in the United States by vessel, departs from or arrives at a port (These events are commonly referred to as "vessel departure" and "vessel arrival" notices.);

(6) When a container which is destined to arrive within the limits of a port in the United States by vessel undergoes an intra-terminal movement;

(7) When a container which is destined to arrive within the limits of a port in the United States by vessel is ordered stuffed or stripped;

(8) When a container which is destined to arrive within the limits of a port in the United States by vessel is confirmed stuffed or stripped; and

(9) When a container which is destined to arrive within the limits of a port in the United States by vessel is shipped for heavy repair.<sup>3</sup>

CBP is aware that it might be cost beneficial for some carriers to transmit all CSMs, rather than filter out CSMs relating to containers destined to the United States or relating only to the required events. Therefore, carriers may transmit their "global" CSM messages, including CSMs relating to containers that do not contain cargo destined for importation into the United States and CSMs relating to events other than the required events. By transmitting CSMs in addition to those required by this interim final rule, a carrier authorizes CBP to access and use those data.

For each CSM submitted to CBP by the carrier, the following information must be included:

(1) Event code being reported, as defined in the ANSI X.12 or UN EDIFACT standards;

(2) Container number;

(3) Date and time of the event being reported;

(4) Status of the container (empty or full);

(5) Location where the event took place; and

(6) Vessel identification associated with the message if the container is associated with a specific vessel.

Carriers are exempt from the CSM requirement for bulk and break bulk cargo. Carriers must submit CSMs via the CBP-approved electronic data interchange system. The current electronic data interchange system for CSMs approved by CBP is sFTP. If CBP approves of a different or additional electronic data interchange system, CBP will publish a notice in the **Federal Register**.

The following chart illustrates the existing carrier data requirements pursuant to the 24 Hour Rule and the new carrier data requirements required pursuant to this interim final rule.

EXISTING CARRIER REQUIREMENTS VERSUS NEW CARRIER REQUIREMENTS

	Existing requirements		New requirements
Requirement .....	Advance Cargo Information (i.e., Trade Act Requirements or 24 Hour Rule)	Stow Plan	Container Status Messages

<sup>2</sup> CSMs are used to report terminal container movements (e.g., loading and discharging the

vessel) and to report the change in status of containers (e.g., empty or full).

<sup>3</sup> A container is shipped for heavy repair when it is delivered to a facility for the purpose of being repaired.

EXISTING CARRIER REQUIREMENTS VERSUS NEW CARRIER REQUIREMENTS—Continued

	Existing requirements		New requirements
Timing .....	24 hours prior to lading	48 hours after departure; prior to arrival for voyages less than 48 hrs	24 hours after the message is entered into the carrier's equipment tracking system
Submission Method Elements .....	vessel AMS —Bill of Lading Number —Foreign Port before vessel departs for U.S. —Carrier SCAC [Standard Carrier Alpha Code] —Carrier Assigned Voyage Number —Date of Arrival at First U.S. Port —Quantity —Unit of measure of Quantity —First Foreign Place of Receipt —Commodity Description (or six-digit HTSUS Number) —Commodity Weight —Shipper Name and Address —Consignee Name and Address or ID Number —Vessel Name —Vessel Country —Vessel Number —Foreign Port of Lading —Hazmat Code —Container numbers —Seal Numbers —Date of Departure from Foreign Port —Time of Departure from Foreign Port	vessel AMS, sFTP, or email With regard to the vessel, —Vessel name (including international maritime organization (IMO) number); —Vessel operator; and —Voyage number With regard to each container, —Container operator; —Equipment number; —Equipment size and type; —Stow position; —Hazmat code (if applicable); —Port of lading; and —Port of discharge.	sFTP —Event code being reported, as defined in the ANSI X.12 or UN EDIFACT standards; —Container number; —Date and time of the event being reported; —Status of the container (empty or full); —Location where the event took place; and —Vessel identification associated with the message if the container is associated with a specific vessel.

C. New Importer Requirements Under This Interim Final Rule

This interim final rule requires Importer Security Filing (ISF) Importers, as defined in these regulations, or their agents, to transmit an Importer Security Filing to CBP, for cargo other than foreign cargo remaining on board (FROB), no later than 24 hours before cargo is laden aboard a vessel destined to the United States. See the "Structured Review and Flexible Enforcement Period" section of this document for flexibilities related to timing for certain Importer Security Filing elements. Because FROB is frequently laden based on a last-minute decision by the carrier, the Importer Security Filing for FROB is required any time prior to lading. An Importer Security Filing is required for each shipment, at the lowest bill of lading level (i.e., at the house bill of lading level, if applicable). The party required to submit the Importer Security Filing is the party causing the goods to enter the limits of a port in the United States. This party is the carrier for FROB and the party filing for the immediate exportation (IE), transportation and exportation (T&E), or foreign trade zone (FTZ) documentation for those types of shipments. The ISF Importer, as a business decision, may designate an authorized agent to file the Importer Security Filing on the ISF Importer's behalf. A party can act as an authorized

agent for purposes of filing the Importer Security Filing if that party obtains access to ABI or AMS.

ISF Importers, or their agents, must transmit the Importer Security Filing via a CBP-approved electronic data interchange system. The current approved electronic data interchange systems for the Importer Security Filing is ABI and vessel AMS. If CBP approves a different or additional electronic data interchange system in the future, CBP will publish a notice in the **Federal Register**.

The party who filed the Importer Security Filing must update the Importer Security Filing if, after the filing and before the goods arrive within the limits of a port in the United States, there are changes to the information filed or more accurate information becomes available.

ISF Importers, or their agents, must submit 10 elements to CBP for shipments consisting of goods intended to be entered into the United States and goods intended to be delivered to an FTZ. ISF Importers, or their agents, must submit five elements to CBP for shipments consisting entirely of FROB and shipments consisting entirely of goods intended to be "transported" as IE or T&E in-bond shipments.

For shipments other than those consisting entirely of FROB and goods intended to be "transported" in-bond as

an IE or T&E, the Importer Security Filing must consist of 10 elements, unless an element is specifically exempted. The manufacturer (or supplier), country of origin, and commodity Harmonized Tariff Schedule of the United States (HTSUS) number must be linked to one another at the line item level. The 10 elements are as follows: (1) Seller; (2) Buyer; (3) Importer of record number/Foreign trade zone applicant identification number; (4) Consignee number(s); (5) Manufacturer (or supplier); (6) Ship to party; (7) Country of origin; (8) Commodity HTSUS number; (9) Container stuffing location; and (10) Consolidator (stuffer).

For shipments consisting entirely of FROB and shipments consisting entirely of goods intended to be "transported" in-bond as an IE or T&E, the Importer Security Filing must consist of five elements, unless an element is specifically exempted. The five elements are as follows: (1) Booking party; (2) Foreign port of unloading; (3) Place of delivery; (4) Ship to party; and (5) Commodity HTSUS number.

Four of the Importer Security Filing elements are identical to elements submitted for entry (CBP Form 3461) and entry summary (CBP Form 7501) purposes. These elements are the importer of record number, consignee number, country of origin, and

commodity HTSUS number when provided at the 10-digit level. An importer may submit these elements once to be used for both Importer Security Filing and entry/entry summary purposes. If an importer chooses to have these elements used for entry/entry summary purposes, the Importer Security Filing and entry/entry summary must be self-filed by the importer or filed by a licensed customs broker in a single transmission to CBP no later than 24 hours prior to lading.

In addition, the HTSUS number must be provided at the 10-digit level.

Two of the Importer Security Filing elements are identical to elements submitted for application to admit goods to an FTZ (CBP Form 214). These elements are the country of origin and commodity HTSUS number when provided at the 10-digit level. The filer may submit the Importer Security Filing and CBP Form 214 in the same electronic transmission to CBP and may submit the country of origin and

commodity HTSUS number once to be used for both Importer Security Filing and FTZ admission purposes. If the party submitting the Importer Security Filing chooses to have this element used for FTZ admission purposes, the HTSUS number must be provided at the 10-digit level.

The following chart illustrates the existing importer data requirements for entry and entry summary purposes and the new importer data requirements pursuant to this interim final rule.

EXISTING IMPORTER REQUIREMENTS VERSUS NEW IMPORTER REQUIREMENTS

	Existing Requirements	New Requirements
Requirement Timing .....	Entry and Entry Summary* Entry within 15 calendar days of date of arrival; Entry summary within 10 working days of entry	Importer Security Filing 24 hours prior to lading for 8 of the elements; as early as possible, in no event later than 24 hours prior to arrival, for 2 of the elements
Submission Method. Elements .....	ABI or paper  —Bill of Lading Number —Importer of Record Number*  —Foreign Port before vessel departs for U.S. —Carrier SCAC  —Carrier Assigned Voyage Number —Date of Arrival at First U.S. Port —Quantity —Unit of measure of Quantity —First Foreign Place of Receipt —Commodity Description —Commodity HTSUS Number* —Commodity Weight —Shipper Name and Address —Consignee Name and Address and Number* —Country of Origin* —Vessel Name —Vessel Country —Vessel Number —Foreign Port of Lading —Hazmat Code —Container numbers —Seal Numbers —Date of Departure from Foreign Port —Time of Departure from Foreign Port	ABI or vessel AMS  Shipments Other Than FROB, IE Shipments and T&E Shipments: —Seller —Buyer —Importer of record number/FTZ applicant identification number* —Consignee number(s)* —Manufacturer (or supplier) —Ship to party —Country of origin* —Commodity HTSUS number* —Container stuffing location —Consolidator (stuffer)  FROB, IE Shipments and T&E Shipments: —Booking party —Foreign port of unloading —Place of delivery —Ship to party —Commodity HTSUS number

\* These elements are provided for Importer Security Filing and entry/entry summary or FTZ admission purposes.

**D. Structured Review and Flexible Enforcement Period**

In order to provide the trade sufficient time to adjust to the new requirements and in consideration of the business process changes that may be necessary to achieve full compliance, CBP will show restraint in enforcing the rule, taking into account difficulties that importers may face in complying with the rule, so long as importers are making satisfactory progress toward compliance and are making a good faith effort to comply with the rule to the extent of their current ability. This policy will

last for twelve months after the effective date and will apply to all aspects of the filing rule.

In addition, this rule provides flexibility with respect to certain elements of the Importer Security Filings. This flexibility falls into two categories:

- Two elements of the Importer Security Filings will be subject to flexibility as to timing. These elements are the Container stuffing location and Consolidator (stuffer). The ISF Importer must submit these elements as early as possible, and in any event no later than 24 hours prior to arrival in a U.S. port (or upon lading at the foreign port if that

is later than 24 hours prior to arrival in a U.S. port).

- Four elements will be subject to flexibility as to interpretation. These elements are the Manufacturer (or supplier), Ship to party, Country of origin, and Commodity HTSUS number. There is no special timing flexibility for these elements; they must be filed 24 hours prior to lading. However, CBP has added flexibility by allowing ISF Importers, in their initial filing, to provide a range of acceptable responses based on facts available to the importer at the time, in lieu of a single specific response (which may become known to the importer only at a later time). ISF Importers will be required to update

\* Importers are not currently required to submit any information to CBP prior to foreign lading for targeting purposes.



their filings with respect to these elements as soon as more precise or more accurate information is available, in no event later than 24 hours prior to arrival at a U.S. port (or upon lading at the foreign port if that is later than 24 hours prior to arrival in a U.S. port). For example, 24 hours prior to lading:

- The ISF Importer could identify the manufacturer as being one of three typically used manufacturers, with more precision to be provided in subsequent ISF updates.
- The ISF Importer could submit the identity of the importer, consignee, or the facility where the goods will be unladen in the event that the ship to party is unavailable (e.g., "to order" shipments).
- If the ISF Importer is, in good faith, unable to determine whether the country where the final stage of production of an article took place is the country of origin, the ISF Importer may provide the country where the final stage of production of the article took place in lieu of the country of origin, and update the ISF submission as soon as more accurate data are available.

The purpose of these flexibilities is to allow CBP to conduct a structured review of the elements, including an evaluation of any specific compliance difficulties that the trade may be encountering with respect to these elements. CBP may gather information by conducting reviews of particular importers to determine whether submission of all 10 data elements 24 hours prior to lading was in fact feasible

and, if not, what barriers the importer encountered. The structured review will cover a range of enterprises, from small to large, and will include both integrated and nonintegrated supply chains.

The structured review will further be enhanced by comments filed in response to this publication. Although the rule is now final, CBP invites comments on the 6 data elements for which CBP is providing some type of flexibility (Container stuffing location, Consolidator (stuffer), Manufacturer (or supplier), Ship to party, Country of origin, and Commodity HTSUS number). These comments are due by June 1, 2009.

The structured review will also be enhanced by feedback provided in CBP's formal outreach program, described below. The information gathering phase of the structured review will end on June 1, 2009. All comments must be submitted to CBP by that date. We note, again, that CBP is not reopening the proposed rule in this action for comment; rather CBP is seeking comment on the requirements discussed in section 149.2(b) and (f) of this rule and the revised Regulatory Impact Assessment.

On the basis of information obtained during the structured review and public comments, DHS will undertake an analysis of the elements subject to flexibilities discussed in this section. The analysis will examine compliance costs for various industry segments, the impact of the flexibilities, the barriers to

submitting these data 24 hours prior to lading, and the benefits of collecting these data. Based on that analysis, DHS, in coordination with other parts of the Executive Branch, will determine whether to eliminate, modify, or leave unchanged these requirements.

CBP is committed to fully supporting the trade community in its efforts to successfully implement the requirements of this rule. During the first months of implementation—(1) CBP will conduct an extended round of structured outreach activities to engage with the trade on all aspects of the rule with a series of regional seminars and trade round table discussions at all of CBP's major seaports of entry and other ports as needed or requested by the trade. (2) CBP will identify trade community operators who have established processes (or who have successfully re-engineered processes) to deliver the data timely to CBP to provide their colleagues in the community with business advice on how to comply with the regulatory requirements. (3) CBP's seminars will focus on all topics related to this rule, technical, operational, and process components, such as documentation adjustments (e.g., modifying the terms of letters of credit to require receipt of data to effect final payment) and developing automated solutions to track supply chain partners and commodity orders (e.g. creating vendor/supplier databases).

A proposed schedule for these outreach activities is as follows:

Regions	Proposed dates
North East Coast:	
• Ports of Newark/New York and Boston .....	30 days after publication.
South East Coast:	
• Ports of Baltimore, Philadelphia, and Norfolk .....	45 days after publication.
• Ports of Charleston, Savannah, and Jacksonville .....	60 days after publication.
• Ports of Miami, Port Everglades, and San Juan .....	75 days after publication.
Gulf Coast:	
• Ports of Houston and New Orleans .....	90 days after publication.
Northwest Pacific Coast:	
• Ports of Seattle/Tacoma and Portland .....	105 days after publication.
• Ports of Oakland/San Francisco .....	120 days after publication.
Pacific Coast:	
• Ports of Los Angeles/Long Beach .....	135 days after publication.

Additional sessions will be scheduled based on trade community needs and feedback. All material discussed and presented at the seminars will be published on the CBP Web site along with Frequently Asked Questions (FAQs) and a general "How to Guide." CBP will consider an entity's progress in the implementation of the rule during the delayed enforcement period as a mitigating factor in any enforcement

action following the delayed enforcement period.

#### E. Summary of Changes From NPRM

As referenced below, CBP is making several significant changes from the proposed rule. These changes consist of the following:

- (1) A compliance date of one year from the effective date of this final rule

is established (in new §§ 4.7c(d), 4.7d(f), and 149.2(g)).

(2) CBP has added flexibility for four Importer Security Filing elements (Manufacturer (or supplier), Ship to party, Country of origin, and Commodity HTSUS number). Specifically, CBP is allowing importers, in their initial filing, to provide a range of acceptable responses based on facts available to the importer at the time, in

lieu of a single specific response (which may become known to the importer only at a later time). Importers will be required to update their filings with respect to these elements as soon as more precise or more accurate information is available, in no event less than 24 hours prior to arrival at a U.S. port (or upon lading at the foreign port if that is later than 24 hours prior to arrival in a U.S. port).

(3) CBP has added flexibility for two Importer Security Filing elements (Container stuffing location and Consolidator (stuffer)) by requiring submission as early as possible, and in any event no later than 24 hours prior to arrival in a U.S. port (or upon lading at the foreign port if that is later than 24 hours prior to arrival in a U.S. port).

(4) The requirement that break bulk cargo be included on vessel stow plans is removed from § 4.7c.

(5) The liquidated damages amount for violations of the Importer Security Filing requirements are changed from the value of the merchandise, as proposed, to \$5,000 for each violation in proposed §§ 113.62(j), 113.64(e), and 113.73(c) and new § 113.63(g) and Appendix D to part 113.

CBP is also making the following additional changes from the proposed rule:

(1) Proposed § 4.7(c)(5) required carriers to provide the "Hazmat-UN code." This section is changed to allow the carrier to provide any Hazmat code, if applicable.

(2) Proposed § 4.7d(a) is changed to clarify that CSMs are required for empty containers.

(3) The label for the party required to submit the Importer Security Filing is changed from the "importer" to the "ISF Importer" in part 149 and proposed § 149.1(a) is changed to clarify that the ISF Importer is construed as the owner, purchaser, consignee, or agent such as a licensed customs broker.

(4) Proposed § 149.3(a)(5) is changed to clarify that the supplier must be the "party supplying" the finished goods in the country from which the goods are leaving and that this party does not necessarily need to be in the country from which the goods are leaving.

(5) The definition for the "Booking party" element in proposed § 149.3(b)(1) is changed to require the identity of the "party who initiates the reservation of the cargo space for the shipment."

(6) Proposed § 149.3(a)(1), (2), (5), (6), (9), and (10) and (b)(1) and (b)(4) are changed to allow the ISF Importer to provide widely recognized commercially accepted identification numbers.

(7) The section heading for proposed § 149.5 is changed to clarify that the eligibility and bond requirements therein apply to an ISF Importer who submits an Importer Security Filing on his own behalf as well as agents submitting an Importer Security Filing on behalf of another party.

(8) An importer security filing bond is added in a new Appendix D of part 113 and provisions for the Importer Security Filing are added to § 113.63 in a new paragraph (g).

(9) The new importer security filing bond and basic custodial bond are added to the list of bonds in proposed § 149.5(b) that may be posted for Importer Security Filing purposes.

(10) Proposed § 149.5(b) is changed to require the ISF Importer to possess one of the required bonds or to have an agent post the agent's bond when submitting an Importer Security Filing on behalf of the ISF Importer.

(11) Proposed § 149.5(c) is changed to clarify that powers of attorney must be in English and that powers of attorney and letters of revocation must be retained for five years from revocation.

(12) Proposed new 113.64(c) provides that liquidated damages for violations of advance cargo information requirements are capped at \$100,000 for vessel carriers. Proposed redesignated paragraph (d) of § 113.64 is changed to include a \$100,000 cap on all other conveyance arrivals as well.

(13) Sections 4.7c, 4.7d, and 149.2 are added to the list of approved information collections in § 178.2.

#### IV. Discussion of Comments Regarding This Rulemaking Generally

##### Comment

CBP should postpone implementation until the regulations can be implemented through the Automated Commercial Environment (ACE), a vigorous outreach to the public sector and other agencies of the government is undertaken and CBP is able to further study the costs, benefits, and alternatives. CBP should then issue a new Strawman<sup>5</sup> or initially publish the rule as an interim final rule providing details of the bonding, liquidated damages, penalty, collection proposal, and data requirements, so that companies can develop or adapt their information technology systems and software to properly transmit the filing. When CBP does proceed, the rule should include a delayed effective date of 90 days to 14 months to provide ample time for the trade to prepare their

systems and processes. Following the delayed effective date, CBP should phase-in enforcement over a 12-month period during which CBP should accept less than the full complement of data elements, accept data at some point less than 24 hours prior to lading, phase in individual elements, phase in trade participants, and/or not impose any punitive measures.

##### CBP Response

Section 203 of the SAFE Port Act of 2006 provides that the Secretary of Homeland Security shall promulgate regulations requiring additional data elements for improved high-risk targeting. CBP has engaged the trade through the rulemaking process and through consultation as required by section 203 of the SAFE Port Act (incorporating the requirements of section 343(a) of the Trade Act of 2002). CBP has met with groups representing the trade while developing the proposal, including: The Departmental Advisory Committee on Commercial Operations of Customs and Border Protection and Related Homeland Security Functions (COAC), the American Association of Exporters and Importers (AAEI), the American Association of Port Authorities (AAPA), the Joint Industry Group (JIG), the National Association of Manufacturers (NAM), the National Customs Brokers and Forwarders Association of America (NCBFAA), the International Compliance Professionals Association (ICPA), the Retail Industry Leaders Association (RILA), the Trade Support Network (TSN), the U.S. Chamber of Commerce, and the World Shipping Council (WSC). Prior to publishing the NPRM, CBP also posted a "strawman" proposal on the CBP Web site along with a request for comments from the trade. CBP has also considered the costs, benefits, and alternatives and has prepared a cost, benefit, and feasibility analysis. An updated cost, benefit, and feasibility analysis has been prepared for this interim final rule and is available in the public docket and on Regulations.gov.

After careful consideration, DHS has determined that issuance of this interim final rule is necessary at this time to fulfill the SAFE Port Act's statutory mandate and increase the security of cargo entering the United States by vessel by improving CBP's risk assessment capabilities. The information collected pursuant to this interim final rule will greatly enhance CBP's enforcement decision making process. The sooner that CBP can obtain these data, the sooner CBP can use these data to perform better risk analysis and identification of high-risk shipments.

<sup>5</sup> Prior to publishing the NPRM, CBP posted a "strawman" proposal on the CBP website along with a request for comments from the trade.

CBP understands that the trade may need time to adjust business practices to comply with this interim final rule and that large and complex parties may respond to these requirements differently than small and less sophisticated importers. Therefore, in order to provide the trade sufficient time to adjust to the new requirements and in consideration of the business process changes that may be necessary to achieve full compliance, CBP will show restraint in enforcing the rule, taking into account difficulties that importers may face in complying with the rule, so long as importers are making satisfactory progress toward compliance and are making a good faith effort to comply with the rule to the extent of their current ability. This policy will last for twelve months after the effective date and will apply to all aspects of the filing rule.

During this period, CBP will also work with the trade to assist them in achieving compliance and will continue to update the trade on issues associated with the regulations in the form of FAQs, postings on the CBP Web site, other outreach to the trade, and consultation with foreign countries. This rule also provides flexibilities with respect to certain elements of Importer Security Filings. CBP has also committed to a structured review of the elements, including an evaluation of any specific compliance difficulties that the trade may be encountering with respect to these elements. See the "Structured Review and Flexible Enforcement Period" section of this document for further discussion regarding the delayed compliance period, flexibilities, and CBP's structured review.

#### *Comment*

Prior to finalizing the regulations, CBP should undertake a pilot test using the required timeframes for data submission and employing the actual targeting, validation, and electronic processes that are intended to be employed upon implementation.

#### *Comment Response*

As part of CBP's pre-existing Advance Trade Data Initiative (ATDI), CBP worked with a wide variety of volunteers from the world trade community to test the trade's ability to provide data, including some elements of the Importer Security Filing, to CBP. ATDI has proven that the industry has access to the required data and can get the data to CBP. CBP also has proven the ability to incorporate the ATDI data into the Automated Targeting System (ATS). Regarding timing requirements,

some ATDI participants are hitting the 24 hours prior to lading deadline today. However, CBP understands that some business practices may need to change in order for the ISF Importer to obtain the required information 24 hours prior to lading. Therefore, in order to provide the trade sufficient time to comply with these requirements, CBP has taken several steps, including adoption of a 12-month delayed compliance date. This rule also provides flexibilities with respect to certain elements of Importer Security Filings. In addition, CBP has committed to a structured review of the elements, including an evaluation of any specific compliance difficulties that the trade may be encountering with respect to these elements. See the "Structured Review and Flexible Enforcement Period" section of this document for further discussion regarding the delayed compliance period, flexibilities, and CBP's structured review.

#### *Comment*

CBP should extend the comment period for the NPRM.

#### *Comment Response*

CBP published a document in the **Federal Register** (73 FR 6061) on February 1, 2008, extending the comment period an additional 15 days until March 18, 2008.

#### *Comment*

When the technical information has been developed, CBP should publish proposed data specifications in the Customs and Trade Automated Interface Requirements (CATAIR) and Customs Automated Manifest Interface Requirements (CAMIR) without requiring that a confidentiality agreement be signed and should re-issue the NPRM with a 90-day comment period.

#### *Comment Response*

CBP disagrees that re-issuing the NPRM is necessary. CBP has amended the CATAIR, CAMIR, and American National Standards Institute (ANSI) X.12 transaction messages, providing the technical requirements necessary to comply with these regulations. CBP has posted these documents to the CBP Web site. While this interim final rule becomes effective 60 days from the date of publication in the **Federal Register**—thus codifying the specific requirements—CBP is extending the compliance date to one year from the effective date and is providing flexibilities with respect to certain elements of Importer Security Filings. See the "Structured Review and

Flexible Enforcement Period" section of this document for further discussion regarding the delayed compliance period and flexibilities. CBP believes that, especially with the flexibilities that CBP is providing, this is sufficient time for the trade to prepare for and comply with the new requirements.

#### *Comment*

The proposed regulation runs afoul of section 343(a)(3)(I) of the Trade Act of 2002 which requires that, where practicable, the regulations shall avoid redundant requirements because the requirement for line item information for each shipment will result in redundant Importer Security Filing submissions and CBP has announced that it intends to target upon receipt of the Importer Security Filing as well as upon entry.

#### *Comment Response*

CBP is aware that four of the Importer Security Filing elements, while collected at a different time, are identical to elements submitted for entry (CBP Form 3461) and entry summary (CBP Form 7501) purposes and two of the Importer Security Filing elements, while collected at a different time, are identical to elements submitted for application to admit goods to an FTZ (CBP Form 214). In an effort to minimize the redundancy of data transmitted to CBP, after further consideration and in response to public comments, CBP is allowing an importer to submit these elements once via the same electronic transmission to be used for both Importer Security Filing and entry/entry summary or FTZ admission purposes. With regard to redundancy of multiple Importer Security Filings, CBP understands that for some Importer Security Filing filings the 10 data elements will not change for multiple bills of lading. Therefore, CBP will accept one Importer Security Filing for multiple bills of lading in the same shipment.

#### *Comment*

This rule has become superfluous with the statutory requirement for the foreign port image scanning of all containerized maritime cargoes prior to their being placed on vessels for shipment to the United States. In addition, there has been no demonstration that the Importer Security Filing will contribute to the effectiveness of the ATS.

#### *Comment Response*

CBP disagrees. Advance cargo information provides transparency into the transaction, including the parties

and goods involved, which is part of the overall risk analysis. The information required by this rule will allow CBP to conduct data analysis to more effectively identify high-risk containers for increased scrutiny, and screen out shipments for increased scrutiny. Additional scrutiny could include additional non-intrusive inspection (NII) and physical examination. The value of NII, including radiation detection capabilities, is increased when the targeter has a frame of reference which is provided by accompanying transaction data such as the data required pursuant to these regulations.

*Comment*

CBP should scan 100% of cargo in lieu of requiring an Importer Security Filing, vessel stow plans and container status messages (CSMs).

*CBP Response*

CBP disagrees. The physical cargo is only one piece of the puzzle. Information, such as the information collected as a result of this rulemaking will allow CBP to put the image produced by a scan into context. The scan and Importer Security Filing together will provide additional transparency and validate the shipment and parties involved.

*Comment*

It is unclear how the proposed requirements will enhance the security of the United States. This rule could result in increased transit time, which could actually increase security risks.

*CBP Response*

Pursuant to section 203 of the SAFE Port Act (6 U.S.C. 943), the Secretary of Homeland Security, acting through the Commissioner of CBP, must promulgate regulations to require the electronic transmission of additional data elements for improved high-risk targeting, including appropriate security elements of entry data for cargo destined to the United States by vessel prior to loading of such cargo on vessels at foreign seaports. The Importer Security Filing elements, vessel stow plans, and CSMs will enhance CBP's targeting and risk analysis capabilities by increasing the transparency of key supply chain participants, cargo, and events. CBP does not agree that increased transit time (dwell time at a foreign port terminal), if incurred due to this rulemaking, will result in an increased security risk. The risk reduction provided by the collection of additional information that will result from these regulations is significantly greater than any risk increase resulting from any

increased dwell times. Furthermore, CBP is addressing global port security through other initiatives.

*Comment*

The Importer Security Filing should be expanded to prevent dangerous merchandise, including narcotics and other illegal consignments, from being shipped to the United States.

*CBP Response*

This rule is one part of CBP's layered approach to cargo security. CBP has implemented a comprehensive strategy designed to enhance national security while protecting the economic vitality of the United States. The Container Security Initiative (CSI), the 24 Hour Rule, and the Customs-Trade Partnership Against Terrorism (C-TPAT) are cornerstone approaches implemented to further this goal. Additionally, CBP has developed cargo risk assessment capabilities in its Automated Targeting System (ATS) to screen all maritime containers before they are loaded aboard vessels in foreign ports. Each of these initiatives is dependent upon data supplied by trade entities, including carriers, non-vessel operating common carriers (NVOCCs), brokers, importers or their agents. Internal and external government reviews have concluded that the more complete advance shipment data required pursuant to this interim final rule will produce even more effective and more vigorous cargo risk assessments. Accordingly, CBP will use these data to ensure cargo safety and security and to prevent smuggling.

*Comment*

Limiting the proposed requirements to the vessel environment will encourage circumvention by transshipment through Canada and Mexico. Does CBP plan to apply these requirements to other modes in the future? Significant adjustment will be necessary if these rules are applied to other modes.

*CBP Response*

CBP disagrees that this rule encourages circumvention, as the United States has a strong working relationship with both Canadian and Mexican border enforcement agencies. CBP will monitor any unexplained increases in land border traffic and will take appropriate security measures if warranted. This interim final rule is focused on vessel cargo pursuant to the requirements under the SAFE Port Act 2006 and the Trade Act of 2002. As such, this rule is an incremental step toward meeting the goal of securing

shipments to the United States. CBP will continue to evaluate the effectiveness of this rule. However, at this time, CBP is not considering expanding the advance data requirements for other modes.

*Comment*

CBP should conduct outreach with the trade, including presentation of a white paper, PowerPoint presentation, and FAQs, prior to implementation and during the implementation phase, including a regular and recurring collaborative process with COAC and the TSN. CBP should also produce a "best practices" document, including detailed process flows, for industry and CBP officers to ensure that all trade participants understand how to comply with the new requirements. Importers will need to implement new processes regardless of whether enforcement is phased in.

*CBP Response*

CBP agrees that business practices and processes will need to be adjusted and that is reflected in our delayed compliance period and outreach efforts. See the "Structured Review and Flexible Enforcement Period" section of this document for further discussion regarding the delayed compliance period. CBP has amended the CATAIR, CAMIR, and X.12 transaction messages, providing the technical requirements necessary for submitting Importer Security Filings. These documents have been posted to the "Automated Systems" section of the CBP Web site. CBP will continue to conduct outreach with the trade, in fulfillment of its regulatory and statutory obligations, both during the delayed compliance period and thereafter, via FAQs, postings on the CBP Web site, and other outreach.

*Comment*

CBP should provide a Help Desk to assist in the resolution of problems associated with the Importer Security Filing requirements.

*CBP Response*

CBP will utilize existing resources to resolve problems associated with the Importer Security Filing requirements. In order to get access to the Automated Broker Interface (ABI) or the Vessel Automated Manifest System (vessel AMS), members of the trade should contact a CBP Client Representative or the CBP Technology Support Center (TSC), formerly known as the CBP Help Desk, for resolution of technical problems associated with Importer Security Filings. In addition, CBP has

established a dedicated email account for Importer Security Filing-related issues. Members of the public are directed to the CBP Web site at <http://www.cbp.gov> for the latest information regarding these contacts. CBP will also continue to update the trade in the form of FAQs, postings on the CBP Web site, and other outreach to the trade.

#### Comment

The information that CBP has requested is the same information that thousands of shippers, importers and manufacturers have at their fingertips every day. It has long been understood that importing into the United States is a privilege, not a right. Thus, it is completely proper for CBP to require those who would take advantage of our nation's prosperity to help to protect that prosperity. Importers will have an added incentive to investigate and identify the identity of their suppliers due to the penalties associated with improper Importer Security Filings. CBP should also be commended for its open, consultative approach in developing this initiative and these regulations.

#### CBP Response

CBP appreciates the support and cooperation offered by the trade.

### V. Discussion of Comments Regarding Proposed Carrier Requirements Relating to Vessel Cargo Destined to the United States

#### A. Overview; Vessel Stow Plan

CBP proposed to require carriers to submit a vessel stow plan for vessels destined to the United States. Under the proposed regulations, carriers were required to transmit the stow plan for vessels transporting containers and/or break bulk cargo so that CBP received it no later than 48 hours after the carrier's departure from the last foreign port. For voyages less than 48 hours in duration, CBP was to receive the stow plan prior to the vessel's arrival at the first port in the United States. Bulk carriers were to be exempt from this requirement for vessels exclusively carrying bulk cargo. The proposal required carriers to submit the vessel stow plan via the CBP-approved electronic data interchange system. The current approved electronic data interchange system for the vessel stow plan is vessel AMS. The proposal stated that if CBP approves of different or additional electronic data interchange systems, CBP would publish a notice in the **Federal Register**.

Under the proposed regulations, the vessel stow plan was required to include standard information relating to the vessel and each container and unit

of break bulk cargo laden on the vessel. The vessel stow plan was to include the following standard information:

- With regard to the vessel,
- (1) Vessel name (including international maritime organization (IMO) number);
  - (2) Vessel operator; and
  - (3) Voyage number.
- With regard to each container or unit of break bulk cargo,
- (1) Container operator, if containerized;
  - (2) Equipment number, if containerized;
  - (3) Equipment size and type, if containerized;
  - (4) Stow position;
  - (5) Hazmat-UN code;
  - (6) Port of lading; and
  - (7) Port of discharge.

#### B. Public Comments; Vessel Stow Plan

##### Comments Regarding Responsibilities

The vessel operating carrier, rather than the non-vessel operating common carrier (NVOCC), should be responsible for filing the stow plan. The NVOCC may not have the vessel stow plan because they do not operate the vessel and have no knowledge of the physical location of cargo as loaded on the vessel. Stow plans are not created to meet regulatory requirements, and therefore a vessel operating carrier should not be responsible for inaccuracies or incompleteness. In addition, carriers should not be responsible for errors in information carriers are unable to verify.

##### CBP Response

CBP agrees that the vessel operating carrier (i.e., vessel operator) is responsible for filing the stow plan. While, prior to this interim final rule, stow plans were not created to meet regulatory requirements, CBP is requiring, through this rulemaking, that vessel carriers submit accurate and timely stow plans for containerized cargo. CBP will use stow plan data to compare the containers listed on the stow plan with containers listed on the vessel's manifest in an effort to identify potentially unmanifested containers. CBP may take enforcement action against a carrier that fails to comply with the requirement to submit stow plans in a timely or accurate manner. CBP enforcement actions may include, but are not limited to, claims for liquidated damages pursuant to 19 CFR 113.64(f). However, CBP has set a compliance date of one year from the effective date of this interim final rule. During that one-year delayed compliance period, CBP will work with

the trade to assist them in achieving compliance. CBP will also work with the trade on ongoing issues and will keep updating and posting new FAQs to the CBP Web site, while conducting additional outreach to the trade and various foreign government entities. See the "Structured Review and Flexible Enforcement Period" section of this document for further discussion regarding the delayed compliance period and CBP's planned outreach efforts.

##### Comments Regarding Procedures

Commenters questioned whether a stow plan is required for every U.S. arrival from a foreign port. Some also stated that CBP should provide the vessel stow plan filer an electronic acknowledgment, containing time and date of receipt and unique identification number, as evidence that the vessel stow plan was successfully received. Others questioned which formats can be used for submission of vessel stow plans and whether CBP will accept vessel stow plans in Adobe Portable Document Format (.pdf). Some also stated that CBP should also accept the U.S. hazardous material (hazmat) codes or Hazmat class in addition to the proposed Hazmat-UN code and that CBP should not use the stow plan for securing detailed and complete hazmat information. Where reference is made to the equipment number, commenters questioned whether CBP wanted carriers to report the unique Vehicle Identification Number (VIN) for vehicles or if a simple vehicle count is sufficient.

##### CBP Response

CBP must receive a stow plan after the vessel departs from the last foreign port. CBP agrees that the vessel stow plan filer should receive a status notification message acknowledging that the vessel stow plan was accepted by CBP's system. As to formats, CBP will accept vessel stow plans in the United Nations rules for Electronic Data Interchange For Administration, Commerce and Transport (UN EDIFACT) Bayplan/stowage plan occupied and empty locations message (BAPLIE) SMDG format, which is the industry-wide standard for carriers who currently use electronic stow plans. CBP will also work with carriers to accept the ANSI X.12 "324" format on a case-by-case basis. Other formats, such as the Adobe.pdf format, are not specifically designed for stow plans and, therefore, would be difficult for CBP systems to interpret. Therefore, CBP cannot justify the costs associated with supporting these additional formats at this time. CBP will continue to consider

additional formats in the future. Regarding hazardous materials reporting on vessel stow plans, the commenter did not provide information regarding what was intended by reference to U.S. Hazmat codes. The U.S. Department of Transportation Hazardous Materials Table lists Hazmat-UN identification numbers and hazard classes. See 49 CFR part 172.101. In order to minimize the cost to carriers, CBP will accept any widely recognized commercially acceptable hazardous materials identification numbers and classifications that the carrier uses in the normal course of business, such as those listed on the U.S. Department of Transportation Hazardous Materials Table. Regarding VINs, a VIN is not required as part of a stow plan. Also, since stow plans are not required for break bulk merchandise, they will not be required for vehicles unless they are containerized.

#### Comments Regarding Scope of Requirements for Stow Plan

CBP should not require stow plans for vessels transporting fewer than a threshold number of containers or for vessels traveling solely within the U.S. Outer Continental Shelf (OCS). CBP should not require stow plans for break bulk cargo (including roll-on/roll-off vessels) because break bulk is obvious as to what it is and where it is in the cargo hold and, therefore, of limited security value. CBP should also not require stow plans for bulk ships carrying either containers or break bulk cargoes on deck. Some questioned whether a carrier will need to include cargo that is not bound for the United States on a stow plan.

#### CBP Response

A stow plan must be filed for each vessel carrying containerized cargo that is required to transmit an advance cargo declaration pursuant to section 343(a) of the Trade Act of 2002. CBP will use stow plan data to compare the containers listed on the stow plan with containers listed on the vessel's manifest in an effort to identify potentially unmanifested containers. Unmanifested containers are considered to be of the highest risk to our nation's security since there is little information available about the contents or intended destination of these containers. Even a single unmanifested container poses a possible threat to the security of the United States. For this reason, CBP does not intend to establish an exemption from the stow plan requirement based on the number of containers carried on a vessel or for vessels traveling solely within the U.S. OCS. After further

consideration and in response to comments, CBP has determined to not require break bulk cargo on stow plans. However, regardless of the type of vessel (including break bulk and bulk vessels), a vessel stow plan accounting for all containers onboard a vessel must be submitted to CBP. Finally, carriers will be required to submit stow plans for all containerized cargo that will enter the limits of a port in the United States.

#### Comments Regarding the Timing for Submission of the Stow Plan

Commenters questioned the timing for stow plans for trips of very short duration (e.g., Vancouver to Seattle). It was suggested that the stow plan not be required earlier than the required United States Coast Guard Notice of Arrival, which is 96 hours prior to arrival. It was also suggested that CBP should amend the regulations, as proposed, to require submission of the stow plan 48 hours after the vessel departs from the last foreign port where goods are laden on the vessel rather than the last foreign port. Others questioned when a vessel "arrives" for vessel stow plan timing purposes. Finally, commenters questioned whether carriers need to amend stow plans. If so, carriers should only be required to amend stow plans when they find that a container has been stowed aboard that was not on the stow plan as submitted to CBP and not when a container is on a stow plan but was not loaded aboard the vessel.

#### CBP Response

Stow plans are required for vessels carrying containers destined to the United States. For voyages less than 48 hours in duration (including very short voyages), CBP must receive the stow plan prior to the vessel's arrival at the first port in the United States. CBP disagrees with the remaining comments. Under the interim final rule, stow plans are required no later than 48 hours after the vessel departs from the last foreign port so that CBP has an accurate representation of the cargo laden on the vessel as it arrives in the United States. Except for voyages less than 48 hours in duration, a vessel stow plan must be submitted 48 hours after the vessel departs from the last foreign port, whether goods are laden and/or unladen at that port, so that the vessel stow plan will accurately depict the cargo onboard when the vessel arrives within the limits of a port in the United States. Vessel arrival for vessel stow plan purposes is the same as vessel arrival for vessel entry purposes. Arrival of a vessel is defined in 19 CFR 4.0. See also 19 CFR 4.2 regarding reports of arrival

of vessels. Finally, inasmuch as CBP requires that an accurate and complete stow plan be submitted, a carrier must submit a new accurate stow plan immediately upon discovery of any inaccuracies. However, the carrier will still be liable for enforcement actions resulting from the inaccurate vessel stow plan.

#### C. Overview; Container Status Messages

Pursuant to section 343(a) of the Trade Act of 2002, CBP proposed to require carriers to submit CSMs daily for certain events relating to all containers laden with cargo destined to arrive within the limits of a port in the United States by vessel.

Under the proposed regulations, CSMs created under either the ANSI X.12 standard or the UN EDIFACT standard were to be acceptable.

Under the proposed regulations, carriers were required to submit a CSM when any of the required events occurs if the carrier creates or collects a CSM in its equipment tracking system reporting that event. The proposed regulations would not require a carrier to create or collect any CSM data other than that which the carrier already creates or collects on its own and maintains in its electronic equipment tracking system. CSMs were to be submitted no later than 24 hours after the message is entered into the carrier's equipment tracking system.

The events for which CSMs would be required are:

- (1) When the booking relating to a container which is destined to arrive within the limits of a port in the United States by vessel is confirmed;
- (2) When a container which is destined to arrive within the limits of a port in the United States by vessel undergoes a terminal gate inspection;
- (3) When a container, which is destined to arrive within the limits of a port in the United States by vessel, arrives or departs a facility (These events take place when a container enters or exits a port, container yard, or other facility. Generally, these CSMs are referred to as "gate-in" and "gate-out" messages.);
- (4) When a container, which is destined to arrive within the limits of a port in the United States by vessel, is loaded on or unloaded from a conveyance (This includes vessel, feeder vessel, barge, rail and truck movements. Generally, these CSMs are referred to as "loaded on" and "unloaded from" messages);
- (5) When a vessel transporting a container, which is destined to arrive within the limits of a port in the United States by vessel, departs from or arrives

at a port (These events are commonly referred to as "vessel departure" and "vessel arrival" notices);

(6) When a container which is destined to arrive within the limits of a port in the United States by vessel undergoes an intra-terminal movement;

(7) When a container which is destined to arrive within the limits of a port in the United States by vessel is ordered stuffed or stripped;

(8) When a container which is destined to arrive within the limits of a port in the United States by vessel is confirmed stuffed or stripped; and

(9) When a container which is destined to arrive within the limits of a port in the United States by vessel is shopped for heavy repair.

CBP is aware that it might be cost beneficial for some carriers to transmit all CSMs, rather than filter out CSMs relating to containers destined to the United States or relating only to the required events. Therefore, CBP proposed to allow carriers to transmit their "global" CSM messages, including CSMs relating to containers that do not contain cargo destined for importation into the United States and CSMs relating to events other than the required events. CBP stated in the proposal that by transmitting CSMs in addition to those required by the proposed regulations, a carrier would authorize CBP to access and use those data.

For each CSM submitted, the following information was proposed to be included:

- (1) Event code being reported, as defined in the ANSI X.12 or UN EDIFACT standards;
- (2) Container number;
- (3) Date and time of the event being reported;
- (4) Status of the container (empty or full);
- (5) Location where the event took place; and
- (6) Vessel identification associated with the message.

Carriers would be exempt from the CSM requirement for bulk and break bulk cargo. Under the proposed regulations, carriers would be required to submit CSMs via the CBP-approved electronic data interchange system. The current approved electronic data interchange system for CSMs is vessel AMS. The proposal stated that if CBP approves of a different or additional electronic data interchange system, CBP will publish notice in the **Federal Register**.

#### *D. Public Comments; Container Status Messages*

##### Comments Regarding Responsibilities

Some commenters questioned whether the vessel operating carrier or NVOCC, when applicable, is required to submit CSMs. Others asked whether a carrier that has no electronic equipment tracking system needs to report any CSMs and when a carrier may stop sending event messages. Some noted that CBP should require all carriers, not just those who currently create or collect CSMs, to submit CSMs.

##### CBP Response

Vessel operating carriers are required to submit CSMs. If a carrier currently does not create or collect CSMs in an equipment tracking system, the carrier is not required to submit CSMs to CBP. If a carrier does create or collect CSMs, the carrier's obligation to transmit CSMs ends upon discharge of the cargo in the United States. However, a carrier may transmit other CSMs in addition to those required by these regulations. By transmitting additional CSMs, the carrier authorizes CBP to access and use those data. In order to minimize the cost to carriers whose volume of business does not justify the creation of CSMs, CBP is declining to impose an obligation upon carriers to create or collect any CSM data pursuant to this rule.

##### Comments Regarding Scope of Requirements for CSMs

Some questioned whether CSMs are required for empty containers since as proposed, 19 CFR 4.7d would require CSMs for containers laden with cargo destined to arrive within the limits of a port in the United States from a foreign port by vessel. For each CSM, however, it seems that the "status of the container (empty or full)" must be reported. Others observed that some of the events for which CSMs are required are not reported via CSMs in all instances. For example, carriers may not create or collect CSMs when bookings are confirmed, when a container enters or exits a facility, when a vessel departs or arrives, when a container undergoes an intra-terminal movement, or when a container is ordered stuffed or stripped or confirmed stuffed or stripped. In addition, loaded containers are not "shopped for heavy repairs." Others noted that since CSMs are not created to meet regulatory requirements a vessel operating carrier should not be responsible for inaccuracies or incompleteness. In addition, there should not be an obligation to ensure that each of the six data elements is in each CSM since there is "no

requirement that a carrier create or collect any CSM data."

##### CBP Response

CSMs are required for all containers, including empty containers, destined to arrive within the limits of a port in the United States from foreign by vessel (if the carrier creates or collects a CSM in its equipment tracking system). As commenters pointed out, each CSM must include the status of the container as either empty or full. The reference in the NPRM to containers "laden with cargo destined to arrive within the port limits in the United States" was intended to differentiate those containers that are destined for the United States from containers that are not destined to arrive within the limits of a port in the United States. Section 4.7d has been amended to clarify that CSMs are required for all containers destined to arrive within the limits of a port in the United States. It remains CBP's position at this time to minimize the cost to carriers whose volume of business does not justify the creation of CSMs by only requiring a carrier to submit CSMs if the carrier creates or collects a CSM in its equipment tracking system. Nevertheless, CBP believes that every CSM for containers laden with cargo destined to arrive within the limits of a port in the United States from foreign by vessel, by their very nature, must contain the six required elements. Accordingly, while there is no requirement that carriers create or collect any CSMs pursuant to this rule, every CSM submitted to CBP must contain the six required elements with the exception of the "Vessel identification associated with the message." This element is not required when a container has not yet been associated with a specific vessel.

##### Comments Regarding Procedures

When the NPRM refers to "loaded on" and "unloaded from" messages, is CBP referring to CSMs generated when a container is loaded or unloaded to or from a vessel or to or from a rail carrier? CBP should also clarify whether the "date and time of the event being reported" refers to the date and time when the event occurred in real-time and not when it was entered into a carrier's equipment tracking system and whether CBP will accept the carrier's definition of location where the event took place as currently reported in their equipment system. CBP should clarify what type of identification should be transmitted for the "vessel identification associated with the message"—i.e., should this be a vessel name, number, IMO, vessel operator, or other

identification? In addition, some CSMs will be created before there is a vessel associated with the message. Commenters also stated that CBP should clarify when a container is considered to have been "confirmed stuffed or stripped,"—i.e., will it be left up to the carrier's discretion to define when they deem a booking has reached a "confirmed" status? A date should be optional for this CSM since stuffing and stripping of containers is generally not performed by the carrier. Finally, commenters questioned whether a do not load (DNL) should be issued; whether an importer's cargo would be subject to increased scrutiny if the carrier fails to submit a vessel stow plan or container status messages; whether the Importer Security Filing will be notified if a DNL is issued in this instance; and whether the importer be liable for vessel stow plan and CSM related errors (e.g., when a carrier "rolls over" a container to another vessel and fails to report this to CBP).

#### CBP Response

CSM events include messages about movements such as when a container, which is destined to arrive within the limits of a port in the United States by vessel, is loaded on or unloaded from any conveyance. This includes vessel, feeder vessel, barge, rail, and truck movements. The date and time when the event actually occurred should be reported. The location as recorded in the carrier's equipment tracking system should be reported. For purposes of the vessel identification, CBP will accept whatever unique identifier is used within the carrier's tracking system. CBP has changed the proposal in these interim final regulations to require the vessel identification associated with the message only if a container has been associated with a specific vessel. With regard to confirmation of stuffing, a booking is "confirmed" by a carrier's own booking system. Similarly, a container is confirmed stuffed or stripped by a carrier's own booking system. Accordingly, it is left up to the carrier's discretion to define when a booking is deemed confirmed and a container is confirmed stuffed or stripped. Finally, if a carrier fails to submit a vessel stow plan or container status messages, when a carrier is required to do so, CBP may take appropriate enforcement actions, including but not limited to, issuance of a DNL, a prelude to a denial of a permit to unlade the container(s) upon arrival in the United States. However, CBP will not notify the party who filed the Importer Security Filing regarding DNL messages not related to their Importer

Security Filing. If parties wish to share these data, they will need to do so privately. Regarding vessel stow plan and CSM-related errors, the importer is not responsible for submitting stow plans and CSMs to CBP and is therefore not liable for inaccuracies or errors.

#### E. Public Comments; Carrier Requirements Generally

##### Comment

CBP should require the terminal operator to submit vessel stow plans and container status messages. The vessel operator should be responsible for filing CSMs and vessel stow plans when there is a vessel sharing or space charter agreement. In the alternative, carriers should be able to designate a third party to submit CSMs and the vessel stow plan on the carrier's behalf.

##### CBP Response

CBP disagrees that terminal operators should be required to submit vessel stow plans and container status messages. The vessel operator is responsible for the submission of the vessel stow plan because it is the party operating the vessel and transporting the cargo to the United States. All vessel operating carriers who create or collect CSMs for cargo that is destined to enter the limits of a port in the United States, including slot and other vessel sharing partners, are responsible for the submission of CSMs. In response to requests from the trade, CBP will allow the responsible carrier to designate a third party agent to transmit stow plans and CSMs. However, the obligation and liability for those requirements remains with the carrier.

#### VI. Discussion of Comments Regarding Proposed Importer Requirements for Vessel Cargo Destined to the United States

##### A. Overview; Proposed Importer Requirements

Pursuant to the authority of section 343(a) of the Trade Act of 2002, as amended by MTTSA, and section 203 of the SAFE Port Act, in order to enhance the security of the maritime environment, CBP proposed to require importers, as defined in the proposal, or their agents, to transmit an Importer Security Filing to CBP, for cargo other than FROB, no later than 24 hours before cargo is laden aboard a vessel destined to the United States. Because FROB is frequently laden based on a last-minute decision by the carrier, the Importer Security Filing for FROB was

to be required any time prior to lading.<sup>6</sup> Under the proposed regulations, an Importer Security Filing was required for each shipment, at the lowest bill of lading level (i.e., at the house bill of lading level, if applicable). It is information from the relevant house bill that CBP proposed to collect.

Under the proposal, the party required to submit the Importer Security Filing was the party causing the goods to enter the limits of a port in the United States. The proposal stated that this party would be construed as the carrier for FROB and as the party filing IE, T&E, or FTZ documentation for those types of shipments. CBP proposed to allow an importer, as defined in the proposal, as a business decision, to designate an authorized agent to file the Importer Security Filing on the importer's behalf. Under the proposed regulations, a party could act as an authorized agent for purposes of filing the Importer Security Filing if that party obtains access to ABI or AMS and obtains a bond.

Under the proposed regulations, importers, as defined in the proposal, or their agents, would be required to transmit the Importer Security Filing via a CBP-approved electronic data interchange system. The proposal stated that the current approved electronic data interchange systems for the Importer Security Filing was ABI and vessel AMS and that, if CBP approves a different or additional electronic data interchange system in the future, CBP would publish notice in the **Federal Register**.

Under the proposed regulations, the party who filed the Importer Security Filing would be required to update the Importer Security Filing if, after the filing and before the goods arrive within the limits of a port in the United States, there were changes to the information filed or more accurate information becomes available.

Under the NPRM, CBP proposed to require ISF Importers to submit 10 elements for shipments consisting of goods intended to be entered into the United States and goods intended to be delivered to an FTZ. For goods to be delivered to an FTZ, CBP considered the importer to be the party filing the FTZ documentation with CBP. CBP proposed to require that the importer or the importer's agent must transmit these 10 elements to CBP. Under the proposal, five elements were required for shipments consisting entirely of FROB and shipments consisting entirely of

<sup>6</sup> CBP did not propose to amend the timing requirements in 19 CFR part 4 requiring submission of advance manifest information 24 hours prior to lading.



goods intended to be "transported" as IE or T&E in-bond shipments.

Under the proposal, for FROB, the importer would be construed as the international carrier of the vessel arriving in the United States. For IE and T&E in-bond shipments, the importer was construed as the party filing the IE or T&E documentation with CBP.

#### 1. Shipments Other Than FROB, IE Shipments, and T&E Shipments

Under the proposed regulations, for the Importer Security Filing for shipments other than those consisting entirely of FROB and goods intended to be "transported" in-bond as an IE or T&E, 10 elements were required, unless specifically exempted. The manufacturer (or supplier) name and address, country of origin, and commodity Harmonized Tariff Schedule of the United States (HTSUS) number were to be linked to one another at the line item level.

The 10 proposed required elements were:

(1) *Manufacturer (or supplier) name and address.* Name and address of the entity that last manufactures, assembles, produces, or grows the commodity or name and address of the supplier of the finished goods in the country from which the goods are leaving. In the alternative, the name and address of the manufacturer (or supplier) that is currently required by the import laws, rules and regulations of the United States (i.e., entry procedures) may be provided (this is the information that is used to create the existing manufacturer identification (MID) number for entry purposes).

(2) *Seller name and address.* Name and address of the last known entity by whom the goods are sold or agreed to be sold. If the goods are to be imported otherwise than in pursuance of a purchase, the name and address of the owner of the goods must be provided.<sup>7</sup>

(3) *Buyer name and address.* Name and address of the last known entity to whom the goods are sold or agreed to be sold. If the goods are to be imported otherwise than in pursuance of a purchase, the name and address of the owner of the goods must be provided.<sup>8</sup>

(4) *Ship to name and address.* Name and address of the first deliver-to party scheduled to physically receive the goods after the goods have been released from customs custody.

(5) *Container stuffing location.* Name and address(es) of the physical location(s) where the goods were stuffed into the container. For break bulk shipments, the name and address(es) of the physical location(s) where the goods were made "ship ready" must be provided.

(6) *Consolidator (stuffer) name and address.* Name and address of the party who stuffed the container or arranged for the stuffing of the container. For break bulk shipments, the name and address of the party who made the goods "ship ready" or the party who arranged for the goods to be made "ship ready" must be provided.

(7) *Importer of record number/FTZ applicant identification number.* Internal Revenue Service (IRS) number, Employer Identification Number (EIN), Social Security Number (SSN), or CBP assigned number of the entity liable for payment of all duties and regulatory requirements, incurred as a result of importation. For goods intended to be delivered to an FTZ, the IRS number, EIN, SSN, or CBP assigned number of the party filing the FTZ documentation with CBP must be provided. The importer of record number for Importer Security Filing purposes is the same as "importer number" on CBP Form 3461.

(8) *Consignee number(s).* Internal Revenue Service (IRS) number, Employer Identification Number (EIN), Social Security Number (SSN), or CBP assigned number of the individual(s) or firm(s) in the United States on whose account the merchandise is shipped. This element is the same as the "consignee number" on CBP Form 3461.

(9) *Country of origin.* Country of manufacture, production, or growth of the article, based upon the import laws, rules and regulations of the United States. This element is the same as the "country of origin" on CBP Form 3461.

(10) *Commodity HTSUS number.* Duty/statistical reporting number under which the article is classified in the Harmonized Tariff Schedule of the United States (HTSUS). The HTSUS number is required to be provided to the six-digit level. The HTSUS number may be provided up to the 10-digit level. This element is the same as the "H.S. number" on CBP Form 3461 and can only be used for entry purposes, if it is provided at the 10-digit level or greater.

#### 2. FROB, IE Shipments, and T&E Shipments

Under the proposed regulations, for the Importer Security Filing for shipments consisting entirely of FROB and shipments consisting entirely of goods intended to be "transported" in-

bond as an IE or T&E, five elements were to be provided in order to enhance the security of the maritime environment.

The five proposed required elements were:

(1) *Booking party name and address.* Name and address of the party who is paying for the transportation of the goods.

(2) *Foreign port of unloading.* Port code for the foreign port of unloading at the intended final destination.

(3) *Place of delivery.* City code for the place of delivery.

(4) *Ship to name and address.* Name and address of the first deliver-to party scheduled to physically receive the goods after the goods have been released from customs custody.

(5) *Commodity HTSUS number.* Duty/statistical reporting number under which the article is classified in the Harmonized Tariff Schedule of the United States (HTSUS). The HTSUS number must be provided to the six-digit level. The HTSUS number may be provided up to the 10-digit level.

Four of the proposed Importer Security Filing elements are identical to elements submitted for entry (CBP Form 3461) and entry summary (CBP Form 7501) purposes. These elements are the importer of record number, consignee number, country of origin, and commodity HTSUS number when provided at the 10-digit level. CBP proposed to allow an importer to submit these elements once to be used for both Importer Security Filing and entry/entry summary purposes. Under the proposed regulations, if an importer chooses to have these elements used for entry/entry summary purposes, the Importer Security Filing and entry/entry summary must be self-filed by the importer or filed by a licensed customs broker in a single transmission to CBP. In addition, the HTSUS number would be required at the 10-digit level.

As proposed, two of the Importer Security Filing elements are identical to elements submitted for application to admit goods to an FTZ (CBP Form 214). These elements are the country of origin and commodity HTSUS number when provided at the 10-digit level. CBP proposed to allow a filer to submit the Importer Security Filing and CBP Form 214 in the same electronic transmission to CBP and to submit the country of origin and commodity HTSUS number once to be used for both Importer Security Filing and FTZ admission purposes. If the party submitting the Importer Security Filing chose to have this element used for FTZ admission purposes, the HTSUS number would be required at the 10-digit level.

<sup>7</sup> The party required for this element is consistent with the information required on the invoice of imported merchandise. See 19 CFR 141.86(a)(2).

<sup>8</sup> The party required for this element is consistent with the information required on the invoice of imported merchandise. See 19 CFR 141.86(a)(2).

*B. Public Comments; Responsible Party Comment*

Under section 343(a) of the Trade Act of 2002, as amended, the requirement to provide information to CBP is generally to be imposed upon the party likely to have direct knowledge of the required information. Although CBP has identified the importer (as defined in the NPRM) as the party to send the data, it has not demonstrated that the importer is in fact that party. The supplier, freight forwarder, and/or carrier actually may have the most direct knowledge of the required information. For example, some suppliers arrange their own carriage and, therefore, the importer will not have the information necessary to submit the Importer Security Filing. Similarly, the importer may not even be aware that the merchandise has been shipped until it arrives in the United States. CBP should require the party with the best knowledge of the shipment to submit the Importer Security Filing. Commenters suggested that CBP not create a new definition of "importer" for Importer Security Filing purposes only, but rather adopt an alternate term. This party should be defined to include the "importer" (as defined in 19 CFR 101.1) or the duly authorized agent of that party, and should include the traditional importer of record as listed on the CBP Form 7501. In the alternative, the definition of "importer" should be the "principal party of interest" as that term is used for the Shipper's Export Declaration or parties as defined for Incoterms.

*CBP Response*

Based on CBP's experience in the movement of goods in international trade, there is one party that is ultimately interested in and responsible for causing goods to arrive in the United States. CBP has determined that the party most likely to have direct knowledge of the required information, and therefore, the party considered to be the ISF Importer, is the party causing the goods to enter the limits of a port in the United States. CBP also has determined that such party must be the owner, purchaser, consignee or their agent (such as a licensed broker) who as a result of this rulemaking will now have an obligation to ascertain and report the data elements that CBP is requiring under this rule to enhance its ability to target high risk cargo destined for the United States. However, in recognition that there may be circumstances where the ISF Importer may not reasonably be able to verify the information, these regulations allow this

party to submit the information on the basis of what it reasonably believes to be true. For FROB cargo, the ISF Importer is construed as the carrier. For IE and T&E in-bond shipments, and goods to be delivered to an FTZ, the ISF Importer is construed as the party filing the IE, T&E, or FTZ documentation. For other types of shipments, this party will usually be the importer of record. However, the party causing the goods to enter the limits of a port in the United States may be different parties to a transaction depending on the terms of the transaction and the parties involved, and this party may be a party other than the importer of record (e.g., for "to order" shipments). Therefore, requiring the importer of record to submit the Importer Security Filing in all instances would be inappropriate.

*Comment*

An international carrier may not have house bill of lading level information for Importer Security Filings for FROB shipments because NVOCCs may not provide the information to the vessel operating carriers. Therefore, CBP should make the NVOCC responsible for Importer Security Filings in these situations. In addition, NVOCCs do not generate unique sub-house bills and, therefore, in order to comply with the Importer Security Filing requirements, NVOCCs will need six months to convert their systems. If the sub-house bill of lading number is required for the Importer Security Filing, this should also be required for AMS.

*CBP Response*

CBP disagrees that NVOCCs should be required to submit Importer Security Filings. The obligation for the Importer Security Filing for FROB remains with the vessel operating carrier because this is the party choosing to transport the cargo to the United States. CBP understands the house bill of lading level information may belong to the NVOCCs. Therefore, CBP clarifies that the NVOCC can submit the Importer Security Filing directly to CBP, if it does so as the vessel operating carrier's agent. CBP is requiring an Importer Security Filing at the lowest level to the house bill of lading level, if applicable. CBP is not requiring Importer Security Filings for sub-house bills.

*Comment*

For FTZ goods, CBP should require the "applicant on the FTZ documentation filed with CBP" to file the Importer Security Filing rather than the "party filing the FTZ documentation with CBP." For IE and T&E shipments, commenters questioned whether the

party required to submit the Importer Security Filing is the party named on the CBP Form 7512 or the party that submits the CBP Form 7512. Who is responsible for filing the Importer Security Filing for personal/household goods and military/government shipments? Who is the responsible party for delivered duty paid (DDP) shipments where the Importer Security Filing "importer" can be the overseas shipper? Commenters asked how NVOCCs will comply with the Importer Security Filing requirements.

*CBP Response*

For IE and T&E in-bond shipments and goods to be delivered to an FTZ, the ISF Importer is the party filing the documentation with CBP and not merely a party delivering the form to CBP. For shipments, including personal/household goods, military/government shipments, and DDP shipments that are intended to be entered into the United States, the ISF Importer would be the owner, purchaser, consignee, or agent such as a licensed customs broker, as the party causing the goods to enter the limits of the United States. If an NVOCC is the party required to submit an Importer Security Filing on its own behalf, or as an agent for another party, the NVOCC will need to submit the Importer Security Filing pursuant to these regulations.

*Comment*

CBP should expand the manifest filing to include elements such as the container stuffing location and consolidator (stuffer) rather than require a separate Importer Security Filing submission. CBP should require entry, with additional elements, be made prior to lading in lieu of requiring a separate Importer Security Filing.

*CBP Response*

CBP disagrees that the advance cargo declaration filing should be expanded. The data elements for the advance cargo declaration and the Importer Security Filing are required pursuant to two distinct statutory obligations, each with its own enforcement mechanism. With regard to the container stuffing location and consolidator (stuffer), CBP believes that the "importer," as the party that ultimately has an interest in the goods and the responsibility for causing the goods to be placed on a vessel for delivery to the United States, has the most control over the underlying transaction so the importer can require this information be received by it more than 24 hours prior to lading as part of terms and conditions of purchase

contracts. However, in response to requests from the trade, CBP will allow carriers to submit an Importer Security Filing for IE, T&E, or FROB cargo and the advance cargo declaration via the same electronic transmission. CBP also disagrees that entry should be required, with additional elements, prior to lading. CBP is not requiring that entry be made 24 hours prior to lading. There are only four data elements on the current entry (CBP Form 3461) and entry summary (CBP Form 7512) that are among the 10 additional data elements CBP deems necessary for high risk targeting enhancement under this rule. However, in response to requests from the trade, CBP will allow an importer to submit the entry or entry/entry summary data via the same electronic transmission as the Importer Security Filing. If an importer chooses to do so, transmission must be made by the party entitled to make entry pursuant to 19 U.S.C. 1484 on its own behalf or a licensed customs broker.

#### Comment

In the NPRM, CBP stated that "one party must aggregate and submit all required elements." Does one party need to aggregate and submit all elements per bill of lading, for each origin port, or for each importer at all origin ports? CBP should aggregate portions of a single Importer Security Filing, linked by the bill of lading, from multiple parties (similar to the Automated Export System (AES)).

#### CBP Response

One party must aggregate and submit all required elements for each individual Importer Security Filing. CBP will not aggregate portions of a single Importer Security Filing because it would be overly burdensome and costly for CBP to administer such a system. However, in response to requests from the trade, CBP will allow ISF Importers to designate an agent to submit the filing on behalf of the importer. While CBP understands that some business practices may need to be altered (e.g., amendment of shipping documents) to obtain the required information at an earlier point, CBP does not anticipate that these changes will be unduly burdensome, especially given the one-year delayed compliance period and other flexibilities that CBP is providing. See the "Structured Review and Flexible Enforcement Period" section of this document for further discussion regarding the delayed compliance period and flexibilities. CBP's ATDI testing has demonstrated that, in many cases, importers were able to collect this information from

manufacturers, suppliers, and shippers at an earlier point by requiring the container stuffing location and consolidator name and address be provided as part of the regular commercial documentation.

#### C. Public Comments; Agents

##### Comment

Commenters stated that CBP should only allow U.S.-based entities or Customs-Trade Partnership Against Terrorism (C-TPAT) members to act as an agent for Importer Security Filing purposes. CBP should require authorized agents, including foreign parties, to meet the standards required of customs brokers when filing the Importer Security Filing, including standards relating to security. Commenters also stated that importers should be able to designate filers with CBP and Importer Security Filings submitted by undesignated parties should be rejected. Commenters asked what the liability would be for a party who misrepresents that they are sending data on behalf of an importer.

##### CBP Response

CBP will not create functionality whereby an ISF Importer can authorize alternate parties with CBP to file on their behalf. Nor will CBP create functionality to document unauthorized parties. CBP does not do this in its systems for other purposes and believes that it is best for private parties to manage these types of business relationships to allow for maximum flexibility. In order to provide this functionality, CBP would need to create and maintain a system cross-referencing millions of relationships between importers and their agents. This type of functionality would be extremely costly to set up and maintain and the potential advantages of such a system do not outweigh these costs.

In response to requests from the trade, an ISF Importer may, as a business decision, designate an agent to file the Importer Security Filing on the ISF Importer's behalf. CBP is not requiring the use of an agent and the ISF Importer is ultimately responsible for the timely, accurate, and complete submission of the Importer Security Filing. In order to act as an agent for purposes of filing the Importer Security Filing, a party must obtain access to ABI or AMS. CBP disagrees that agents should be limited to U.S.-based entities or C-TPAT members. Doing so would greatly limit the flexibility of ISF Importers in selecting agents for Importer Security Filing purposes. The accuracy and timeliness of Importer Security Filings

is secured by a bond. An agent can file the Importer Security Filing under the ISF Importer's bond or, if the ISF Importer does not possess a required bond, the ISF Importer may choose to designate a bonded agent to file the Importer Security Filing under the agent's bond if the agent agrees to do so in writing.

##### Comment

CBP should require the Importer Security Filing filer, when the filer is an agent, to furnish the importer with a copy of the Importer Security Filing submitted on the importer's behalf.

##### CBP Response

CBP disagrees. CBP believes that this is a matter between private parties and, therefore, is not requiring the Importer Security Filing to be shared among private parties.

##### Comment

Commenters asked whether an importer will be held liable if an agent experiences problems with its systems resulting in a late, incomplete, or inaccurate Importer Security Filing. Commenters also stated that agents should not be liable for any lack of compliance with vessel stow plans, container status messages, or Importer Security Filings that are submitted on behalf of another party.

##### CBP Response

The ISF Importer is ultimately responsible for the timely, accurate, and complete submission of the Importer Security Filing, regardless of the cause for a late, inaccurate, or incomplete filing. After analyzing the results of tests performed through ATDI and in response to requests from the trade, CBP will allow ISF Importers and carriers to use agents to submit Importer Security Filings, vessel stow plans, and container status messages. However, the ISF Importer is ultimately liable for the timely, accurate, and complete submission of the Importer Security Filing and the carrier is ultimately responsible for the timely, accurate, and complete submission of the vessel stow plan and container status messages.

##### Comment

Because AMS users must be licensed by the Federal Maritime Commission, this will severely limit the choices for filers, driving self filers and brokers to utilize the Automated Broker Interface.

##### CBP Response

CBP disagrees that AMS users must be licensed by the Federal Maritime Commission. Any party will be able to

obtain access to ABI or AMS, with CBP approval, for purposes of filing an Importer Security Filing.

#### Comment

CBP has proposed to require a power of attorney to file an Importer Security Filing on another's behalf, but did not specify a particular form, the required language, the length of time, or the manner in which powers of attorney must be stored. Under what authority will CBP require production of power of attorney records? Is there a penalty for not having a power of attorney on file? Will CBP allow an exemption to the power of attorney requirement for goods consigned to the military, the government, or for household/personal goods?

#### CBP Response

CBP is not requiring a particular form for a power of attorney for Importer Security Filing purposes. However, 19 CFR 141.32 contains an example of an acceptable general power of attorney with unlimited authority. CBP has revised the regulations under this interim final rule to require that powers of attorney must be in English. Pursuant to 19 U.S.C. 1508(a), CBP has also clarified in the regulations that powers of attorney must be retained until revoked, and revoked powers of attorney and letters of revocation must be retained for five years after the date of revocation. Finally, CBP will not allow an exemption to the power of attorney requirement for goods consigned to the military, the government, or for personal/household goods. An exemption is not merited as there is no less of a security risk associated with these shipments. CBP still requires the certainty that powers of attorney provide when parties are interacting with CBP.

#### D. Public Comments; Customs Business

##### Comment

Commenters stated that the Importer Security Filing, including providing the HTSUS number (even at the six-digit level), importer of record number, and consignee number, is "customs business." Therefore, the Importer Security Filing should be restricted to licensed Customs brokers. Other commenters stated that classification at the 10-digit level is "customs business" and, therefore, when the Importer Security Filing and entry are filed via the same electronic transmission (unified filing), this submission constitutes "customs business." Non-brokers should be limited to the filing of the Importer Security Filing alone.

#### CBP Response

"Customs business" does not involve the mere electronic transmission of data received for transmission to CBP, but does involve classification for entry purposes. See 19 CFR 111.1. The six-digit HTSUS number is intended exclusively for ensuring cargo safety and security, and not for determining merchandise entry procedures that fall within the scope of customs business. However, a 10-digit HTSUS number is needed and is used for merchandise entry purposes and, therefore, classification at the 10-digit level is considered customs business. CBP disagrees that providing the importer of record number and consignee number falls within the definition of customs business in 19 CFR 111.1. Pursuant to this interim final rule, if the Importer Security Filing and entry or entry summary are provided via a single electronic transmission to CBP, the party making the transmission must be an importer acting on its own behalf or a licensed customs broker.

#### E. Public Comments; Bills of Lading

##### Comment

Commenters asked CBP to clarify whether the bill of lading number (house and/or master) is a required data field, and whether the house or master bill number is required. If the bill of lading number is required, CBP should only require the house bill of lading number and it should be added as an additional required data element for the Importer Security Filing. Other commenters stated that carriers may not generate bill of lading numbers early enough for an importer to submit this information for Importer Security Filing purposes. Therefore, CBP should require the bill of lading number prior to arrival in the United States rather than 24 hours prior to lading. In the alternative, CBP should require carriers to make the bill of lading number available no later than 48 hours prior to lading the vessel or CBP should allow the use of booking number in lieu of the bill of lading number. In any event, the importer should not be penalized for a late Importer Security Filing when a carrier fails to provide the bill of lading number early enough. Commenters asked whether multiple Importer Security Filings will be required when one bill of lading covers multiple shipments. Commenters also stated that CBP should allow an importer to file one Importer Security Filing for all bills of lading in a shipment where the manufacturer, country of origin, and HTSUS numbers are the same. Lastly, commenters asked how the Importer Security Filing will be

handled if the goods are divided and sold in transit to at least two separate parties, resulting in two new bills of lading.

#### CBP Response

A bill of lading number is integral to the Importer Security Filing and therefore, must be provided with the Importer Security Filing. The bill of lading number is not a data field, but an identifier which will be provided in the header information. However, after further consideration, CBP is requiring only the number for the bill of lading at the lowest level (*i.e.*, the regular straight/simple bill of lading or house bill of lading) and not the master bill of lading number. Under existing 24 Hour Rule requirements, the bill of lading number is required for containerized cargo 24 hours prior to lading. For bulk cargo and exempted break bulk cargo, the carrier must submit the bill of lading number 24 hours prior to arrival. Under this interim final rule, for containerized cargo, the Importer Security Filing is also required 24 hours prior to lading. For break bulk cargo that is exempted for 24 Hour Rule purposes, the Importer Security Filing is required 24 hours prior to arrival. For bulk cargo, an Importer Security Filing is not required. Accordingly, the bill of lading number will be available for Importer Security Filing purposes, and has always been a part of the transaction identification. CBP understands that business processes may need to be changed to ensure that the importer, as defined for these regulations, has the bill of lading number in a timely fashion. Regarding bills of lading covering multiple shipments, CBP has the capability to accept multiple Importer Security Filings per bill of lading. CBP will issue a unique identification number for each separate, not unified, Importer Security Filing as part of the acceptance/rejection acknowledgment response. Modification of a particular Importer Security Filing will be possible using the unique identification number. Under this interim final rule, one Importer Security Filing can satisfy multiple bills of lading. However, the manufacturer (or supplier), country of origin, and commodity HTSUS number elements must be linked to one another at the line item level. Lastly, when a shipment is divided into a new or multiple new shipments, each with its own house bill of lading number, the original Importer Security Filing will need to be amended. In addition, a new Importer Security Filing will be required for each new bill of lading number.

*F. Public Comments; Required Elements*

## 1. Manufacturer (or Supplier)

## Comment

Commenters stated that, in some cases, there may be no manufacturer or the manufacturer may not be known. This may be the case for personal effects entered on a CBP Form 3299, for antiques, or when the importer purchases goods from a party who is not willing to provide the identity of their supplier due to business confidentiality concerns. Commenters also stated that the MID should be accepted for the manufacturer (or supplier). If the MID is not accepted, CBP should set up a registration system like the U.S. Food and Drug Administration (FDA) did for bioterrorism purposes. Commenters asked which law, rule, or regulation CBP was referring to in the NPRM which states that the name and address of the manufacturer (or supplier) that is currently required by the import laws, rules, and regulations of the United States may be provided. Commenters stated that the supplier of the goods may not be located in the "country from which the goods are leaving" and, therefore, this element should be changed accordingly. Commenters stated that the manufacturer (or supplier) requirements are inconsistent with merchandise produced under Outward Processing Arrangements (OPAs), for which importers must construct the MID based on the origin conferring manufacturer. Commenters asked which address should be used when a manufacturer has more than one address, including a corporate address.

## CBP Response

CBP recognizes that, in some cases, the manufacturer's identity may be unavailable to the party responsible for filing the Importer Security Filing. Accordingly, CBP is requiring the identity of the manufacturer *or the supplier of the finished goods* if the actual manufacturer is unknown. CBP disagrees that the MID should be accepted for the manufacturer (or supplier). In general, the MID does not include the complete address of the manufacturer. CBP believes that the complete manufacturer's (or supplier's) name and address is a critical piece of information to effectively target high risk cargo. Since the current MID has limited targeting utility, CBP will not accept the current MID as an alternative to the complete name and address of the manufacturer. However, CBP will allow the trade to provide widely recognized commercially accepted identification numbers such as Dun and Bradstreet

Data Universal Numbering System (DUNS) numbers as an alternative. When referring to previously existing laws and regulations, CBP is referring to title 19 of the United States Code Annotated and title 19 of the Code of Federal Regulations. CBP agrees that the supplier may not be located in the same country where the goods are leaving. In this interim final rule, CBP clarifies that this is the party supplying the finished goods in the country from which the goods are leaving. In many instances, this party will be located in the country from which the goods are leaving. In instances where the MID for the origin conferring manufacturer is currently supplied for entry purposes, the identity for this party should be provided in the Importer Security Filing. When a manufacturer has more than one address, CBP would like the address where the goods were actually manufactured. CBP understands that, in certain cases, this address may not be known to the ISF Importer and, therefore, will accept the corporate address for the manufacturer or supplier.

## 2. Buyer

## Comment

The buyer's identity may not be available at the time of shipment and, when available, may not be applicable to each individual carton in a shipment. This data element, as well as the ship to party, should not be required prior to shipment, but at the time of the filing of the entry. What party's identity should be provided for multi-tier transactions, "sold in shipments," and shipments involving a buying agent? What if merchandise is sold in transit?

## CBP Response

The Importer Security Filing elements must be reported at the lowest bill of lading level. At this level, the buyer's identity should be applicable to the entire shipment. If the buyer's name and address is not available at the time of shipment, the identity of the owner, consignee, or the buyer's agent should be provided instead on the Importer Security Filing. For "buying agent" transactions, the buying agent should be provided for the buyer element and the party who sold the goods to the buying agent should be provided for the seller element. If, after the filing is submitted and before the goods enter the limits of a port in the United States, any of the information submitted in an Importer Security Filing changes or more accurate information becomes available, including changes to the buyer's

identity, the ISF Importer must update the filing.

## 3. Ship to Party

## Comment

Commenters stated that the ship to party should not be required because this party will be the importer of record. In addition, the physical location where the container will arrive does not pose a security risk as much as who is the party that caused the importation to the United States. If the ship to party is required, CBP should accept the identity of the importer or consignee as indicated on the bill of lading when the ship to party is unknown when the Importer Security Filing is submitted. Commenters also stated that the ship to party should be kept confidential because it could be used by competitors. Commenters also asked whether the "ship to name" needs to be the name of a legal business entity. Can the importer transmit the name of its distribution center, even though the distribution center is not a separate legal entity in its own right? Will CBP accept Facilities Information and Resources Management System (FIRMS) codes in lieu of the name and address for the ship to party? Lastly, commenters asked which address should be used when a ship to party has more than one address, including a corporate address. Does a container freight station constitute the first ship to party?

## CBP Response

CBP has determined, as the result of internal and external analysis, including analysis of ATDI testing, that the ship to party's identity and address will allow CBP to more effectively assess the risk of cargo destined for the United States. In some instances, the ship to party may also be the importer of record or consignee. However, this is not always the case. In addition, the importer of record's and consignee's corporate offices usually differ from the actual delivery address which is required for this element. Therefore, both parties' identities are necessary for effective risk assessment. If the party scheduled to physically receive the goods after the goods will be released from CBP custody is unknown 24 hours prior to lading (e.g., "to order" shipments), the filer must provide the identity of the facility where the goods will be unladen. The filer must update this element if, after the filing is submitted and before the goods enter the limits of a port in the United States, the party scheduled to physically receive the goods becomes known. All elements of the Importer Security Filing, including

the ship to party information, will be kept confidential as per the statutory requirements within the SAFE Port Act of 2006 and section 343(a) of the Trade Act of 2002. The ISF Importer must identify the ship to party, regardless of whether that party is a separate legal entity. However, CBP will accept a widely recognized commercially accepted identification number such as the DUNS number or FIRMS code, when applicable, for the ship to party. The first deliver-to party scheduled to physically receive the goods after the goods have been released from customs custody must be provided. A container freight station can be the ship to party if it meets the parameters of the definition in this rule that it is the first place of delivery after the goods have been released from customs custody.

#### 4. Container Stuffing Location

##### Comment

Commenters stated that importers do not know the container stuffing location, except in the case of repetitive movements. Commenters also stated that providing the container stuffing location would be redundant in cases where shipments are stuffed by the manufacturer. Commenters asked which location should be reported when multiple containers are included on one bill of lading, and thus one Importer Security Filing contains multiple containers stuffed in multiple locations. Also, in some cases, there may be multiple stuffing locations, such as for "Less than Container Load" (LCL) shipments. Commenters also stated that CBP should accept the "scheduled" stuffing location in lieu of the actual stuffing location because the actual stuffing location cannot be confirmed until stuffing is completed, particularly in cases involving the use of a container freight station. The container stuffing location may change at the last minute for legitimate reasons. Lastly, commenters asked CBP to define "ship ready" with regard to container stuffing location and consolidator (stuffer) for break bulk cargo.

##### CBP Response

If an ISF Importer does not know an element, including container stuffing location, this party must take steps necessary to obtain the information. Where the ISF Importer receives any of the required information, including container stuffing location, from another party, CBP will take into consideration how, in accordance with ordinary commercial practices, that party acquired the information, and whether and how the importer is able to verify

the information. If the container is sealed at the manufacturer or factory facility, as is the case for a factory load, this location should be provided for the container stuffing location. CBP is aware that the same entity may be provided for more than one element. In cases where the consolidator has subcontracted out, or arranged a third party to do the actual stuffing, the name and address of the party at whose location the container was stuffed should be provided. When a container is stuffed at more than one location and/or more than one container is on a single bill of lading, all of the stuffing locations for the goods listed on the bill of lading must be provided. However, an ISF Importer is not required to submit container numbers and, when container numbers are reported, an ISF Importer is not required to report which container was stuffed at which location. CBP agrees that the "scheduled" stuffing location should be accepted. The ISF Importer is required to report the container stuffing location 24 hours prior to lading based on the ISF Importer's knowledge at that time. However, the ISF Importer must update the filing if, after the filing is submitted and before the goods enter the limits of a port in the United States, any of the information submitted changes or more accurate information, including container stuffing location, becomes available. Regarding break bulk cargo, break bulk cargo is made "ship ready" when the cargo is palletized, lashed, wrapped, or otherwise prepared to be laden on a vessel.

#### 5. Consolidator (Stuffer)

##### Comment

The consolidator (stuffer) element should only be required when a container is stuffed by a consolidator because the container stuffing location already spells out the location where the physical container will be stuffed.

##### CBP Response

CBP disagrees with the comment that the consolidator (stuffer) element should be conditional. CBP is aware that the same entity may be provided for more than one element. If an element is not provided, CBP would have no way of knowing whether the element is not provided because the same information is provided for another element or because the ISF Importer merely failed to provide the information. In addition, when the same information is provided for more than one element, the additional burden on the trade should be minimal.

##### Comment

The "last known" consolidator should be required for the consolidator (stuffer) element.

##### CBP Response

Even if there are multiple stuffing locations, there should only be one party per bill of lading who stuffed the container or arranged for the stuffing of the container.

#### 6. Importer of Record Number/FTZ Applicant Identification Number

##### Comment

The importer of record number is not always known. For example, what number should be provided for household goods and personal effects where a foreign party without one of the required unique identification numbers is importing their own goods?

##### CBP Response

The ISF Importer must submit the IRS number, EIN, SSN, or CBP assigned number of the entity liable for payment of all duties and responsible for meeting all statutory and regulatory requirements incurred as a result of importation. For goods intended to be delivered to an FTZ, the IRS number, EIN, SSN, or CBP assigned number of the party filing the FTZ documentation with CBP must be provided. If this party does not have an IRS number, EIN, SSN, or CBP assigned number when the Importer Security Filing is submitted, this party must obtain one. For household goods and personal effects where a foreign party without one of the required unique identification numbers is importing their own goods, the ISF Importer may provide the importer of record's passport number, country of issuance, and date of birth.

##### Comment

The importer of record number should not be required prior to shipment, but at the time of the filing of the entry.

##### CBP Response

CBP disagrees. In order for CBP to effectively target cargo before it is loaded, the Importer Security Filing, including the importer of record number or FTZ applicant identification number, must be received by CBP 24 hours prior to lading (any time prior to lading for FROB). CBP notes that section 203 of the SAFE Port Act requires that this information be provided prior to lading of cargo at foreign seaports.

##### Comment

The importer of record may not always be the party responsible for

filing the Importer Security Filing and, therefore, CBP should clarify that penalties and other liabilities will be applicable to the party required to file the Importer Security Filing pursuant to proposed 19 CFR 149.1.

#### CBP Response

CBP recognizes that the importer of record may not always be the party responsible for filing the Importer Security Filing. The ISF Importer is required to post their bond to secure the timely, accurate, and complete Importer Security Filing. When necessary, CBP will issue penalties and claims for liquidated damages against that party.

#### 7. Consignee Number(s)

##### Comment

The consignee number(s) may not be known prior to shipment from overseas. What should be submitted for the consignee number(s) when a shipment cannot be consigned to the importer at the time of filing? For example, some shipments are consigned to a factory or a vendor's negotiating bank. What number should be provided for household goods and personal effects where a foreign party without one of the required unique identification numbers is importing their own goods?

##### CBP Response

CBP understands that business practices may need to change in order for the ISF Importer to determine who the consignee in the United States is for a shipment 24 hours prior to lading. For example, for shipments that are consigned to the importer, a factory, or vendor's negotiating bank, where those parties will not be the actual consignee if the goods are not consigned before arrival in the United States, the ISF Importer may need to designate a warehouse in the United States to receive the goods and, therefore, to be listed as the consignee. For household goods and personal effects where a foreign party without one of the required unique identification numbers is importing their own goods, the ISF Importer may provide the importer of record's passport number, country of issuance, and date of birth.

##### Comment

Can the unique identification number for a nominal consignee be provided for the consignee number element?

##### CBP Response

Yes, the unique identification number for a nominal consignee may be provided for the consignee number(s) element.

##### Comment

CBP should accept the name and address of the consignee in lieu of the consignee number because of the sensitive nature of the consignee number.

##### CBP Response

CBP disagrees. Based on external and internal analysis, CBP has determined that the consignee number will provide more visibility into the parties involved in a transaction than the name and address.

##### Comment

CBP should allow the use of the ACE ID or other universal participating government agency (PGA) identifiers.

##### CBP Response

CBP disagrees because these identifiers do not currently exist in the CBP systems. CBP will continue to explore the potential use of the ACE ID and PGA identifiers in the future and as ACE is developed.

##### Comment

The consignee number(s) element should be consistent with the party submitted to CBP on the CBP Form 3461 pursuant to 19 CFR 142.3(a)(6).

##### CBP Response

The party required for the consignee number(s) element is the same party provided on the CBP Form 3461.

#### 8. Country of Origin

##### Comment

The importer may not have direct knowledge of the country of origin.

##### CBP Response

Where the ISF Importer receives any of the information from another party, CBP will take into consideration how, in accordance with ordinary commercial practices, the ISF Importer acquired such information, and whether and how that party is able to verify this information. Where that party is not reasonably able to verify such information, CBP will permit the party to electronically present the information on the basis of what the party reasonably believes to be true.

#### 9. Commodity HTSUS Number

##### Comment

The precise manifest description should be accepted in lieu of the HTSUS number. The ISF Importer may lack the expertise to classify merchandise and/or the ISF Importer may not know the HTSUS number prior to lading. If CBP does require the

HTSUS number, the HTSUS number should be limited to the four-digit level because the four-digit number provides sufficient information to properly assess risk factors.

##### CBP Response

CBP disagrees. Based on external and internal analysis, CBP has determined that the six-digit HTSUS number will provide more visibility into cargo imported into the United States than the four-digit HTSUS number or a textual description because the six-digit number provides a more specific classification of the cargo. Furthermore, the tariff schedule is harmonized internationally to the six-digit level. If an ISF Importer does not know an element that is required pursuant to the regulations, including the HTSUS number at the six-digit level, the ISF Importer must take steps necessary to obtain the information. CBP recognizes that, for most importers, this information is known well before the placement of the order for their goods because of the need to determine duty cost and admissibility status prior to finalizing the purchase contract or shipment contract.

##### Comment

CBP should allow the submission of the 10-digit HTSUS code regardless of whether the Importer Security Filing is combined with the entry. The HTSUS number is subject to change (e.g., based on the quota fill status at the date of entry).

##### CBP Response

CBP agrees. While CBP is not requiring the HTSUS number at the 10-digit level unless the Importer Security Filing is submitted via the same electronic transmission as entry or entry/entry summary, CBP will accept the HTSUS number at the 10-digit level if the Importer Security Filing is submitted in a separate transmission. The ISF Importer must update the filing if, after the filing is submitted and before the goods enter the limits of a port in the United States, any of the information submitted changes or more accurate information, including HTSUS number, becomes available.

##### Comment

Will CBP compare the HTSUS data submitted in the Importer Security Filing with the HTSUS data used at entry?

##### CBP Response

Yes. CBP will use the information available, including entry data, to

analyze and assess risk and to validate Importer Security Filing data.

Comment

The HTSUS and country of origin do not have any security value to CBP. In addition, this information is already required under the 24 Hour Rule.

CBP Response

CBP is requiring this information pursuant to Section 203 of the SAFE Port Act, which requires the electronic transmission prior to lading of additional data elements, including appropriate security elements of entry data, as determined by the Secretary of Homeland Security. Based on external and internal analysis, CBP has determined that the HTSUS and country of origin will allow CBP to more accurately assess risk. CBP is aware that some information is also provided at other times and by other parties, such as for entry purposes on CBP Forms 3461 and 7501. However, this information is often submitted after the cargo departs on a vessel destined for the United States and, in many cases, after the cargo arrives in the United States. By collecting this information at an earlier point, CBP will be able to more effectively target cargo prior to it being laden on a vessel at a foreign port and prior to its arrival in the United States. In addition, CBP is collecting supply chain information from more than one party in order to more effectively validate the information.

Comment

Can an importer provide a single HTSUS number for multiple parts when the number is the same at the six-digit level (i.e., as reported on the CBP Form 7501)?

CBP Response

The HTSUS number is required to be provided to the six-digit level and, therefore, a single HTSUS number may be provided for multiple parts when the numbers are the same at the six-digit level.

Comment

Carriers are unable to provide the HTSUS number because they do not see the invoice details. The six-digit HTSUS number should be an optional element when a carrier submits an Importer Security Filing for FROB, IE, and T&E cargo as it is for manifest filings for U.S. import cargo. The precise cargo description should be accepted in lieu of the HTSUS number.

CBP Response

CBP disagrees. The six-digit HTSUS number is sometimes provided by members of the trade community on T&E and IE in-bond movements. CBP understands that, in some cases, business practices may have to be altered to obtain the required information in a timely fashion (e.g., requiring the information on commercial documents).

10. Booking Party

Comment

The definition of the booking party does not meet commercial practices because the carrier may not know the party "paying for the transportation of the goods" at the time of filing and there may be more than one party that is paying for the transportation. CBP should amend the definition of this element to be "the party who initiates the reservation of the cargo space for the shipment." In addition, the booking party should only be required when it is available to the carrier.

CBP Response

In response to comments and in an effort to align this element with commercial practices, CBP has changed the definition for booking party to be "the party who initiates the reservation of the cargo space for the shipment."

11. Foreign Port of Unlading

Comment

CBP should accept Bureau of Census Schedule K port codes for the foreign port of unlading element. When designating a source for port codes, CBP should consider that the foreign port of unlading could be an air or land port for cargo that is transferred to another mode.

CBP Response

CBP agrees. CBP will accept Bureau of Census Schedule K port codes for the foreign port of unlading element.

12. Place of Delivery

Comment

Is the "place of delivery" the place of delivery under the terms of the carrier's contract of carriage? CBP should accept port codes in lieu of city codes for this element.

CBP Response

The place of delivery is the foreign location where the carrier's responsibility for the transport of the goods terminates. CBP will allow the use of UN Locodes or Schedule K codes, when applicable, for this element.

G. Public Comments; Technical Issues

Comment

CBP should include the actual data fields that will need to be submitted in the interim final rule. CBP should establish a guide for developers that will include sample record sets for different business scenarios. A test system and a technical FAQ should be made available to developers.

CBP Response

CBP has amended the guides for developers, including the CATAIR, CAMIR, and X.12 transaction messages, providing the technical requirements necessary for submitting Importer Security Filings. These documents include the actual data fields, and have been posted to the "Automated Systems" section of the CBP Web site. An electronic FAQ will also be posted to the CBP Web site. In addition, the ability to submit data to a test system and receive responses will be provided.

Comments

CBP should work with the trade to identify the mechanisms that are needed for all parties to manage the Importer Security Filing. Importers should receive a timely confirmation message, including a unique identification number, indicating that the Importer Security Filing has been received and accepted by CBP (or rejected listing errors). Unique identifiers should also be created for amendments and deletions.

CBP Response

CBP will send a response message to the Importer Security Filing filer indicating whether an Importer Security Filing has been accepted or rejected by CBP's systems. The response message will contain a unique number generated by CBP. The ISF Importer may choose to share this Importer Security Filing number with other parties. However, CBP will not issue a new unique identifier when an Importer Security Filing is amended or deleted.

Comment

How will a carrier validate that an Importer Security Filing has been filed? Carriers should be notified through AMS. The filer should also be able to identify additional parties to be notified of the acknowledgement message.

CBP Response

AMS creates notifications of the status of the bill that go back to the filer and any other parties nominated on the bill to receive such notification. CBP will notify the filer of the bill of lading that



an Importer Security Filing has been received for the bill of lading through this process.

**Comment**

How long will carrier submissions remain in the CBP data system without being reconciled with Importer Security Filing submissions?

**CBP Response**

The carrier's advance cargo declaration is submitted pursuant to a different regulatory requirement and is not dependent upon the submission of Importer Security Filings.

**Comment**

How must the Importer Security Filings, vessel stow plans, and container status messages be transmitted to CBP? The CAMIR should be modified accordingly.

**CBP Response**

Importer Security Filings, stow plans, and container status messages (CSMs) must be submitted via a CBP-approved electronic interchange system. The current approved electronic interchange systems for Importer Security Filings are the vessel AMS and ABI. CBP has re-evaluated the electronic interchange systems that will best allow the trade to submit vessel stow plans and container status messages and has determined that stow plans must be submitted through vessel AMS, secure file transfer protocol (sFTP), or email, and CSMs may be submitted through sFTP. CBP will publish a notice in the *Federal Register* if different or additional electronic data interchange systems are approved in the future. CBP has amended the CATAIR, CAMIR, and X.12 transaction messages, providing the technical requirements necessary for submitting Importer Security Filings. These documents have been posted to the "Automated Systems" section of the CBP Web site.

**Comment**

The Importer Security Filing should be deemed to have taken place upon submission, not CBP receipt.

**CBP Response**

CBP agrees. This provision of the regulatory text has been changed accordingly. In the absence of specific evidence to the contrary, however, the time of CBP's receipt of the Importer Security Filing will be evidence of the time of submission by the filer. In response to requests from the trade, CBP will transmit an acknowledgement to the filer to confirm that CBP has received an Importer Security Filing. CBP will publish FAQs regarding

protocols for when an approved electronic interchange system is experiencing technical difficulties (e.g., for scheduled maintenance).

**Comment**

Importers may not possess the technology to transmit these data directly to CBP.

**CBP Response**

If an ISF Importer does not possess the technology to transmit the Importer Security Filing data to CBP, the importer can either obtain the necessary technology or use an agent to submit the Importer Security Filing on the ISF Importer's behalf.

**Comment**

CBP should allow a filer to initially submit a "shell record" of partial Importer Security Filing data that can be subsequently amended by multiple parties.

**CBP Response**

CBP disagrees. A shell record would not serve any targeting or risk assessment purposes. Records of this type that could subsequently be amended by multiple parties would create numerous problems, including a lack of finality (CBP would not know when the final Importer Security Filing information has been submitted and/or amended), security and privacy issues (who will determine which parties can amend which information), and cost (such a system would be expensive to develop and maintain). The ISF Importer is ultimately responsible for the timely, accurate, and complete submission of the Importer Security Filing. In response to requests from the trade, an ISF Importer can designate an agent to submit the filing on behalf of the ISF Importer. While CBP understands that some business practices may need to be altered to obtain the required information at an earlier point, CBP does not anticipate that these changes will be unduly burdensome.

**Comment**

Importers should be allowed a review period before the Importer Security Filing must be filed if it is filed by an agent.

**CBP Response**

The Importer Security Filing must be filed no later than 24 hours prior to lading (any time prior to lading for FROB). However, see the "Structured Review and Flexible Enforcement Period" section of this document for flexibilities related to timing for certain

Importer Security Filing elements. If an ISF Importer chooses to use an agent, the ISF Importer may choose to include a "review period" as part of their contract with their agent.

**Comment**

CBP should transmit an electronic acknowledgement to the filer after an Importer Security Filing is received. This acknowledgement should include a unique number which can be used by other parties to verify that an Importer Security Filing has been filed. The importer should be able to designate multiple parties to receive the acknowledgement. Parties should also be able to query previously submitted Importer Security Filings.

**CBP Response**

CBP will transmit an electronic acknowledgement to the filer only when CBP receives an Importer Security Filing. The acknowledgement will include a unique identification number. This number cannot be used to perform a query in ABI or AMS. However, the party who submits the advance manifest information and any notify party on the bill of lading in AMS will receive all status notifications posted to that bill, including the notification that an Importer Security Filing was accepted for the bill of lading.

**Comment**

What will the procedures be when the Importer Security Filing system is down? Will CBP's systems be able to handle the exponential increase in data that will result from this rule?

**CBP Response**

CBP has planned for the expected increase of data that will result from this rule. However, CBP will publish FAQs regarding protocols for when an approved electronic interchange system is experiencing technical difficulties (e.g., for scheduled maintenance).

**Comment**

The technical detail of the construct of the Importer Security Filing should be developed consistent with CATAIR and CAMIR standards. CBP should immediately release, and accept additional comments on, the data formats for the new requirements, including templates and instructions relating to the following: data type for each element (alphanumeric, numeric, etc.), length for each element, address information format, element definitions, hierarchy of message, and what validations for existing data will be performed for these filings.

**CBP Response**

CBP has amended the CATAIR, CAMIR, and X.12 transaction messages, providing the technical requirements necessary for submitting Importer Security Filings. These documents have been posted to the "Automated Systems" section of the CBP Web site. CBP disagrees that any further notice and comment is necessary for technical changes.

**Comment**

CBP should codify all elements that require a name and address and assign a unique identification number to each entity, or CBP should accept widely recognized commercially acceptable identification numbers such as DUNS numbers in lieu of the name and address.

**CBP Response**

CBP disagrees that a unique identifier number should be assigned to each party listed in the Importer Security Filing because, at this time, CBP is not technologically prepared to create such a system and such a system would be unduly burdensome and expensive. However, CBP will continue to explore the potential development and use of the ACE ID in the future as ACE is developed. In response to requests from the trade, CBP has changed the proposal in this interim final rule so that widely recognized commercially accepted identification numbers (such as DUNS numbers) will be accepted in lieu of the name and address.

**Comment**

CBP should provide a source, such as United Nations Location Codes (UN Locodes), for city codes that are required for the "place of delivery" element. An ABI query would be helpful to maintain the list as updates are made to add or delete items on the list.

**CBP Response**

CBP agrees and, where applicable, such as "place of delivery," CBP has adopted the use of UN Locodes and Schedule K codes. However, CBP will not provide a table of codes in ABI or AMS that the trade can query because these are available from other sources.<sup>9</sup>

**Comment**

CBP should adopt standards for address information, such as the use of

<sup>9</sup>UN Locodes are available on the United Nations Web site at [http://www.unece.org/cefact/codesfortrade/codes\\_index.htm](http://www.unece.org/cefact/codesfortrade/codes_index.htm). Schedule K codes are available on the U.S. Army Corps of Engineers Web site at <http://www.iwr.usoce.army.mil/NDC/wcs/scheduleK/schedulek.htm>.

Global Location Number (GLN) standards. Such standards should be harmonized on a global basis.

**CBP Response**

In response to requests from the trade, CBP has changed the regulations, as proposed, so that widely recognized commercially accepted identification numbers (such as DUNS numbers) will be accepted in lieu of the name and address. At this time, however, CBP will not accept the GLN because it is unclear whether the GLN is a widely recognized and commercially accepted number. However, CBP will continue to work with the trade to evaluate existing identification numbers such as the GLN to determine which of these are appropriate for Importer Security Filing purposes. CBP will also continue to explore the potential development and use of the ACE ID in the future as ACE is developed. CBP will continue to update the trade regarding acceptable numbers in the form of FAQs, postings on the CBP Web site, and other outreach to the trade. The technical requirements necessary for submitting Importer Security Filings, including guidance relating to the submission of address information, has been added to the CATAIR, CAMIR, and X.12 transaction messages. These documents have been posted to the "Automated Systems" section of the CBP Web site.

**H. Public Comments; Update and Withdrawal of Importer Security Filing****Comment**

The requirement that the party who initially filed the Importer Security Filing must update the filing does not take into consideration the dynamic nature of international trade. For example, goods may be sold in transit. In addition, the SAFE Port Act and the Trade Act of 2002 do not contemplate an ongoing duty to update information on a post loading basis. Any authorized party should be able to update the filing.

**CBP Response**

The ISF Importer, as the party who causes the goods to enter the limits of a port in the United States, submits (or uses an agent to submit) the Importer Security Filing, and posts their bond. Therefore, it is ultimately responsible for updating the Importer Security Filing if, after the filing is submitted and before the goods enter the limits of a port in the United States, any of the information submitted changes or more accurate information becomes available. However, that party may use an agent to update the Importer Security Filing. If goods are sold in transit, the original

Importer Security Filing filer must notify CBP that the goods have been sold, including the party to whom the goods have been sold.

**Comment**

The final importer should be able to see and update the Importer Security Filing.

**CBP Response**

CBP disagrees. Importers will not be able to access specific Importer Security Filing elements in CBP systems. Such functionality would be too costly and raises security concerns. If an ISF Importer wants to access Importer Security Filings that are submitted on their behalf by an agent, the ISF Importer should obtain the information from their agent.

**Comment**

How will a filer designate an update so that it is applied to the correct Importer Security Filing, particularly in the case where there are multiple filings for a single bill of lading?

**CBP Response**

CBP will issue a CBP-generated unique identifier for each Importer Security Filing it receives. That unique number can be used by the Importer Security Filing filer to amend an Importer Security Filing.

**Comment**

What if cargo is diverted while in transit, due to shifting inventory/distribution needs? Will an Importer Security Filing need to be updated if a shipment is split after the initial Importer Security Filing has been filed?

**CBP Response**

Pursuant to this interim final rule, the Importer Security Filing must be updated if, after the filing and before the goods enter the limits of a port in the United States, there are changes to the information filed, including when cargo is diverted into a shipment for which a different number of elements is required (5 elements to 10 elements or 10 elements to 5 elements). In addition, when a shipment is split resulting in (a) new bill of lading number(s), a new Importer Security Filing must be filed for each new bill of lading because each Importer Security Filing is associated with a bill of lading.

**Comment**

Does an Importer Security Filing need to be updated if a shipment is rolled to a different vessel?

## CBP Response

If the bill of lading number remains the same, a new Importer Security Filing is not required, nor is an amendment required. However, if a new bill of lading is issued or the bill number changes, a new Importer Security Filing must be filed.

## Comment

If a party reported on an Importer Security Filing remains the same, but the address for that party changes, is an amendment required?

## CBP Response

The Importer Security Filing must be amended if any of the information submitted, including the address of a party, changes or more accurate information becomes available.

## Comment

The NPRM states that an Importer Security Filing must be amended if there is a change "before the goods enter the limits of a port in the United States." Does "port" refer to the first port of arrival or the port of discharge or the port of destination on the ocean bill of lading?

## CBP Response

The Importer Security Filing must be amended if there is a change before the goods enter the limits of a port in the United States. For goods that will be unladen in the United States, the Importer Security Filing must be updated if there is a change before the goods enter the port of discharge.

## Comment

When an Importer Security Filing is submitted in the same electronic transmission as entry, will both need to be amended independently?

## CBP Response

When an Importer Security Filing is initially submitted in the same electronic transmission as entry, both can be amended via the same electronic transmission. CBP has amended the CATAIR, CAMIR, and X.12 transaction messages, providing the technical requirements necessary for amending Importer Security Filings. These documents have been posted to the "Automated Systems" section of the CBP Web site. CBP will continue to conduct outreach with the trade, fulfilling its regulatory and statutory obligations, both during the delayed compliance period and thereafter, via FAQs, postings on the CBP Web site, and other outreach.

## Comment

CBP should accept the entry information submitted on CBP Forms 3461, 7501, and 214 as an update of the Importer Security Filing.

## CBP Response

CBP disagrees. Entry information will not be accepted in lieu of an Importer Security Filing update. Entry is governed by a different statutory provision, 19 U.S.C. 1484, and serves a much different function. It is a well settled area of law that has distinct limitations as to who may make entry, and what constitutes the act of making entry on another's behalf, with its own discrete regulations and limitations. Furthermore, most of the Importer Security Filing elements are not current entry data elements nor is the totality of what constitutes an entry necessarily compatible with what constitutes an Importer Security Filing.

*I. Public Comments; In-Bond Shipments*

## Comment

For shipments consisting entirely of FROB and shipments intended to be transported in-bond as an IE or a T&E, does the IE or T&E in-bond need to be created before an Importer Security Filing is submitted?

## CBP Response

No. Parties are not required to file an in-bond document prior to submission of an Importer Security Filing.

## Comment

The submission of an Importer Security Filing consisting of 10 elements should serve as the request for permission to convert a shipment from an IE or T&E shipment into a shipment that will be entered into the United States. If CBP declines to accept the full Importer Security Filing as the request for permission, permission should be required from the port director of the original port of entry or the port of entry filing. How will CBP indicate that permission has been granted?

## CBP Response

The ISF Importer must submit the complete Importer Security Filing to CBP consisting of 10 elements as soon as a decision is made to change the disposition of the cargo. However, CBP disagrees that this submission should serve as the request for permission to convert an IE or T&E shipment into a shipment that will be entered into the United States. Instead, the party wishing to divert the cargo, must present the request to CBP in writing at the original

port of unloading and CBP will indicate permission on the documentation.

## Comment

CBP should clarify the application of proposed 19 CFR 18.5, which would require permission to "divert" in-bond shipments regarding IE in-bond shipment since IE shipments are retained within the port of unloading. Will affirmative permission be required for such changes and, if so, what is the purpose of such permission and on what basis would CBP refuse permission?

## CBP Response

For in-bond shipments which, at the time of transmission of the Importer Security Filing are intended to be entered as an IE or T&E shipment, permission to divert the in-bond movement to a port other than the listed port of destination or export or to change the in-bond entry into a consumption entry must be obtained from the port director of the port of origin. Since IE shipments cannot be diverted, an ISF Importer will need permission to change an IE entry to a consumption entry or other type of entry.

## Comment

Will an importer who submitted an Importer Security Filing consisting of 10 elements, because the importer intended to enter the shipment into the United States or deliver the goods to an FTZ, need to file an Importer Security Filing consisting of five elements if the shipment is changed to an IE, T&E, or FROB?

## CBP Response

If an Importer Security Filing consisting of 10 elements pursuant to new 19 CFR 149.3(a) was initially submitted for a shipment and the shipment is changed to an IE, T&E, or FROB, the Importer Security Filing must be updated pursuant to new § 149.2(d). This update must be performed by submission of an Importer Security Filing consisting of five elements as listed in section 149.3(b) because these elements are necessary to better assess the security risk of IE, T&E, and FROB shipments.

## Comment

CBP should ensure the regulations and AMS permit filing of an in-bond request and issuance of an immediate transportation (IT) number prior to loading at the foreign port.

## CBP Response

CBP disagrees. CBP is not changing the protocols for filing in-bond requests and issuing IT numbers because an IT number is not a required data element of the Importer Security Filing and, therefore, amending the in-bond system is unnecessary.

## Comment

How will an importer request permission to divert an IE or T&E shipment to a port other than the listed port of destination or export?

## CBP Response

Pursuant to existing regulations, IE shipments may not be diverted.<sup>10</sup> The shipper must submit a request to divert a T&E shipment to a port other than the listed port of destination or export to the port director of the port of origin either in writing or, when the function is available, electronically.

## Comment

The importer's (or, truck/rail carrier's) failure to obtain permission should not subject an ocean carrier's bond to liability.

## CBP Response

The ISF Importer must provide a bond (or use an agent's bond) when the original Importer Security Filing is submitted. This party is liable for the accuracy of that Importer Security Filing, including any failure to obtain permission for diversion of the cargo as required by § 18.5, as amended by this interim final rule. The party requesting permission must submit a new Importer Security Filing consisting of 10 elements and must provide a bond at that time. The party submitting the new Importer Security Filing consisting of 10 elements will be liable for the accuracy of that Importer Security Filing.

## Comment

Will CBP create special provisions for IT shipments which will be cleared at an inland destination? If not, brokers located at inland ports will be placed at a disadvantage.

## CBP Response

CBP will not create special provisions for IT shipments that are cleared at an inland destination.

<sup>10</sup> See 19 CFR 18.25. See also Policy and Procedures Manual Supplement 3285-02 (February 22, 1982), Customs Directive 3280-01 (November 25, 1983), and HQ Ruling 113946 (July 7, 1997).

*J. Public Comments; Importer Security Filing, Entry, and Application for FTZ Admission*

## Comment

CBP should finish its targeting and pre-clear shipments prior to the shipment's arrival in port when entry or an application for admission to an FTZ are filed at an earlier point (i.e., when entry, entry summary, or FTZ application documentation are submitted via a single electronic transmission as the Importer Security Filing).

## CBP Response

CBP disagrees. CBP is not amending, at this time, the procedures generally governing entry release and FTZ admission of imported goods. The laws governing entry release and FTZ admission are governed by different statutory authorities and were enacted for a variety of purposes, such as commercial enforcement and preventing fraud, that are distinct from assessing security risk. However, CBP will carefully consider the merits of completing targeting and pre-clearance at an earlier point in the vessel mode in the near future.

## Comment

The Importer Security Filing is duplicative because it is basically collecting entry data at an earlier point in time.

## CBP Response

Pursuant to section 203 of the SAFE Port Act, the Secretary of Homeland Security, acting through the Commissioner of CBP, must promulgate regulations to require the electronic transmission of additional data elements for improved high-risk targeting, including appropriate security elements of entry data. While CBP recognizes that several of the data elements are repeated in both the Importer Security Filing and the entry documents, each of these submissions has a different purpose. Pursuant to section 343(a) of the Trade Act of 2002, "the use of the additional information collected pursuant to these regulations is to be only for ensuring cargo safety and security and preventing smuggling and not for determining merchandise entry or for any other commercial enforcement purposes." However, in response to requests from the trade, CBP will allow an importer to submit the entry or entry/entry summary data via the same electronic transmission as the Importer Security Filing, in which case an importer is only required to provide the four common elements (importer of record number,

consignee number, country of origin, and HTSUS number if provided at the 10-digit level) one time to be used for Importer Security Filing, entry, or entry/entry summary purposes. If an importer chooses to submit the Importer Security Filing and entry or entry/entry summary via the same electronic transmission, CBP may use these four elements for commercial enforcement purposes.

## Comment

It would be commercially unfeasible to accomplish both entry and the Importer Security Filing via the same electronic transmission in many instances since brokers may not submit entry from outside of the United States.

## CBP Response

In response to requests from the trade, CBP will allow an importer to submit the entry or entry/entry summary data via the same electronic transmission as the Importer Security Filing. CBP is not requiring this unified filing. If an importer chooses to do so, the consolidated submission of both the Importer Security Filing and entry must be filed by the party entitled to make entry pursuant to 19 U.S.C. 1484 on its own behalf or a licensed customs broker. All existing requirements regarding entry must still be met. CBP is not amending, at this time, the regulations generally governing entry of imported goods.

## Comment

Will a modification to the Importer Security Filing affect the entry summary and impact the examination of the merchandise?

## CBP Response

Whether filed as an initial submission or as a modification in a unified filing, the Importer Security Filing or the entry/entry summary will be accepted or rejected individually as separate and distinct filings. The Importer Security Filing information, including updates, will be used exclusively for ensuring cargo safety and security and preventing smuggling and will not be used for determining merchandise entry or for any other commercial enforcement purposes.

## Comment

The importer should be able to submit the CBP Form 7501 along with the Importer Security Filing 24 hours prior to lading.

## CBP Response

Pursuant to this interim final rule, the Importer Security Filing must be submitted 24 hours prior to lading (any

time prior to lading for FROB). Entry summary can also be submitted 24 hours prior to lading, either individually or via the same electronic transmission as the Importer Security Filing.

#### Comment

In addition to the country of origin and the HTSUS number, the manufacturer, ship to party, and consignee number elements for FTZ goods are also duplicative with the information collected on CBP Form 214. The filer should only be required to submit these five elements one time.

#### CBP Response

In an effort to minimize the redundancy of data transmitted to CBP, this interim final rule allows a filer to submit the Importer Security Filing and CBP Form 214 in the same electronic transmission to CBP and to submit the country of origin and commodity HTSUS number once to be used for both Importer Security Filing and FTZ admission purposes. If the party submitting the Importer Security Filing chooses to have these elements used for FTZ admission purposes, the HTSUS number must be provided at the 10-digit level. CBP disagrees that the manufacturer, ship to party, and consignee number are collected on CBP Form 214.

#### K. Public Comments; Requests for Special Treatment

##### Comment

How does CBP plan to address holds and DNLs on agricultural products, where delay could result in irreparable damage to an importer's relationship with its buyer(s)?

##### CBP Response

CBP will not institute special procedures for agricultural products. DNLs are placed for security reasons and the status of a shipment as "perishable" or "non-perishable" does not necessarily indicate increased or decreased security risk. In all instances, CBP will work with the trade to communicate holds and DNLs as quickly as possible. It is the responsibility of the ISF Importer to resolve Importer Security Filing issues that result in a hold or DNL.

##### Comment

CBP should exempt from the Importer Security Filing requirements cargo that is refused admission or for another reason is returned from a foreign country after having been exported from the United States.

##### CBP Response

CBP disagrees. Cargo refused admission at a foreign port is not exempt from these regulations if that cargo will enter the limits of a port in the United States via vessel. This cargo has been out of the control of the exporter and CBP and, therefore, poses a possible security risk.

##### Comment

CBP should exempt carnets from the Importer Security Filing requirements because they are covered by an international convention. If carnets are not exempted, CBP must gain acceptance from the international convention that governs carnets prior to enforcement. At a minimum, the HTSUS number should not be required for carnet shipments.

##### CBP Response

CBP disagrees. Carnet shipments are not exempt from these regulations if the cargo will enter the limits of a port in the United States via vessel. These shipments are not inherently less of a risk than other shipments.

##### Comment

CBP should exempt temporary importation bond (TIB) shipments from the Importer Security Filing requirements.

##### CBP Response

CBP disagrees. An Importer Security Filing is required for TIB shipments that will enter the limits of a port in the United States via vessel. These shipments are not inherently less of a risk than other shipments.

##### Comment

CBP has already vetted the supply chains of C-TPAT members and, therefore, the Importer Security Filing requirements are duplicative for C-TPAT members. Therefore, C-TPAT members, specifically tier three members, should be exempt from the Importer Security Filing requirements, especially when shipments have been subject to pre-export scanning at a CSI port. C-TPAT members, including tier two and three members, should be permitted to file on an account basis rather than on a per-shipment basis (e.g., annual blanket filings). In the alternative, C-TPAT members should be subject to a phase-in period, permitted to submit fewer than all of the required Importer Security Filing elements, permitted to submit the Importer Security Filing 12 hours prior to lading, and/or subject to reduced penalties.

##### CBP Response

CBP disagrees. CBP will use the Importer Security Filing to assess the risk of individual shipments. For purposes of this rule, all cargo arriving to the United States by vessel, regardless of the parties involved, will be subject to the Importer Security Filing requirements. CBP is not allowing exemption from, or alteration of, the requirement that C-TPAT partners submit Importer Security Filing information in advance of arrival. CBP believes that compliance with these regulations complements supply chain security and efficiency procedures being implemented by C-TPAT partners. Furthermore, it is emphasized that C-TPAT membership will continue to be viewed in a positive light for targeting purposes. It is more likely that shipments made by C-TPAT members will be readily and expeditiously cleared, and not be delayed for greater scrutiny. Other related advantages of C-TPAT partnership may include essential security benefits for suppliers, employees, and customers, such as a reduction in the number and extent of border inspections and eligibility for account-based processes.

##### Comment

Shipments that transit through CSI ports should be exempt from the Importer Security Filing requirements.

##### CBP Response

CBP disagrees. This rule is one part of CBP's layered approach to cargo security. CBP's comprehensive strategy includes CSI, the 24 Hour Rule, C-TPAT, and the Importer Security Filing. Importer Security Filing data are particularly useful for cargo that transits through a CSI port because CSI ports provide CBP the opportunity to review cargo before it is laden on a vessel destined for the United States.

##### Comment

Shipments intended for a duty-free warehouse should be exempt from the Importer Security Filing requirements. For duty-free stores, vendors may ship directly to the manufacturer's site, yet later issue the invoice from the United States or other location. In these circumstances, the shipper only has a packing list or no invoice and there is no way to determine the HTSUS number and country of origin at the time of shipping.

##### CBP Response

CBP disagrees that an exemption is warranted. An Importer Security Filing is required for merchandise destined for a duty-free warehouse. These shipments

are not inherently less of a risk than other shipments. CBP is aware that business practices may need to change (e.g., amendment of shipping documents) to obtain this information 24 hours prior to lading. Where the party is not reasonably able to verify the information 24 hours prior to lading, the regulations allow the party to submit the information on the basis of what it reasonably believes to be true. If any of the information changes or more accurate information becomes available before the goods enter the limits of a port in the United States, the Importer Security Filing must be updated.

#### Comment

CBP should allow an exemption for shipments originally destined for a foreign port (with the intent to remain foreign) that are diverted to the United States because of an emergency. CBP should also allow an exemption for shipments diverted to the United States that were originally destined for a foreign sea port to be loaded on a rail car or truck destined for the United States, in cases where the vessel is diverted because of emergency.

#### CBP Response

CBP disagrees that a regulatory exemption is warranted. If an emergency arises regarding cargo that was never intended to enter the limits of a port in the United States for which an Importer Security Filing was not filed, the ISF Importer is required to file an Importer Security Filing. If an event occurs, including an emergency, affecting cargo for which an Importer Security Filing was submitted, and the event results in changes to any of the elements for that filing, the ISF Importer is required to immediately amend the Importer Security Filing. The ISF Importer will still be liable for enforcement actions resulting from the late Importer Security Filing submission. However, CBP will consider the totality of the circumstances surrounding the event before any further CBP actions are taken.

#### Comment

CBP should allow an exemption for ferries or barges, especially when merchandise is diverted to a ferry or barge when the land border crossing is down.

#### CBP Response

An Importer Security Filing is not required if the movement of the cargo by ferry or barge is considered to have crossed a "land border" crossing for CBP purposes. However, an Importer

Security Filing is required for cargo that is transported on a vessel that is required to make formal vessel entry pursuant to 19 U.S.C. 1434 (see also 19 U.S.C. 1441 for vessels exempted from vessel entry).

#### Comment

FROB should be exempted from these requirements because, at the time of loading, whether a cargo is destined to be FROB may not be known or may be subject to change due to changes in port destinations or due to last minute cargo being loaded which is destined for the United States after cargo for other countries has been loaded.

#### CBP Response

CBP disagrees. If the cargo is known to be FROB prior to lading, the ISF Importer must submit an Importer Security Filing consisting of five elements. If the cargo is not known to be FROB (or an IE or T&E shipment) and the cargo is intended to enter the limits of a port in the United States 24 hours prior to lading, the importer must submit an Importer Security Filing consisting of 10 elements. If an event occurs (e.g., an emergency) affecting cargo for which an Importer Security Filing was submitted, and the event results in changes to any of the elements for that filing, the ISF Importer is required to immediately amend the Importer Security Filing. If an Importer Security Filing was not filed because the cargo was not intended to enter the limits of a port in the United States by vessel, and the cargo will enter the limits of a port in the United States, the importer must immediately file an Importer Security Filing. In this case, the ISF Importer will still be liable for enforcement actions resulting from the late Importer Security Filing submission.

#### Comment

CBP should clarify that FROB cargo does not include U.S. export cargo or foreign-to-foreign cargo.

#### CBP Response

U.S. export cargo that was not laden at a foreign port is outside of the scope of this rule.

#### Comment

Will an Importer Security Filing be required for goods that are discharged in a foreign port and transhipped via truck/rail into the United States?

#### CBP Response

No. This rule only applies to cargo arriving in the limits of a port in the United States by vessel.

#### Comment

Cargo that is imported by the Department of Defense should be exempt from the Importer Security Filing requirements.

#### CBP Response

CBP agrees. If cargo arrives on a vessel for which vessel entry and a manifest is required, an Importer Security Filing must be submitted. However, if Department of Defense cargo arrives on a government vessel as per 19 CFR 4.5 for which vessel entry and a manifest is not required, an Importer Security Filing is not required.

#### Comment

The HTSUS number, manufacturer (or supplier), and seller should not be required for personal effects.

#### CBP Response

CBP disagrees. The ISF Importer must submit an Importer Security Filing for shipments consisting of personal effects. These shipments are not inherently less of a risk than other shipments. All data elements are required regardless of whether the parties identified in the data elements are private or commercial.

#### Comment

Ship's equipment and carrier's inter-company moves should be exempt from the Importer Security Filing requirements.

#### CBP Response

An Importer Security Filing is not required for ship's equipment.<sup>11</sup> However, unless otherwise exempted, the ISF Importer must submit an Importer Security Filing for inter-company moves.

#### Comment

Why is CBP exempting instruments of international trade (IITs) from the Importer Security Filing requirements?

#### CBP Response

CBP is requiring that IITs be reported via vessel stow plans and container status messages. However, many of the Importer Security Filing elements are not applicable to IIT shipments and CBP has determined that the additional information would be of limited targeting value.

#### Comment

CBP should not require Importer Security Filings for shipments arriving in the United States via inland waterways, such as the Great Lakes.

<sup>11</sup> CBP is not amending existing advance manifest information requirements in 19 CFR Part 4.

#### CBP Response

CBP disagrees. The SAFE Port Act of 2006 requires data elements for cargo destined to the United States by vessel prior to loading of such cargo on vessels at foreign seaports. Accordingly, the ISF Importer must submit an Importer Security Filing for cargo arriving in the United States via inland waterways.

#### Comment

CBP should clarify that these rules are not applicable to cargo being returned to the United States from any vessel or outer continental shelf (OCS) facility positioned over the U.S. OCS for the purposes of engaging in OCS activities, as defined in 33 CFR 140.10. CBP should carefully consider the fundamental difference between cargoes returned to the United States from offshore locations and cargoes imported to the United States from foreign countries in the application of this rule. The cargoes shipped (returned) from offshore locations to the United States have never made what CBP has in the past referred to as "a meaningful departure" from the United States. In the NPRM, CBP uses the term "foreign port" to determine the applicability of reporting. The use of the term is significant and correct so long as it is clearly defined as meaning the foreign port of lading of a cargo container for transport to the United States. The term "foreign port" has at times been used to include operations involving the carriage of cargo to/from "Hovering Vessels." However, vessels positioned over the OCS to conduct OCS activities are clearly not "Hovering Vessels." In addition, the information required by these regulations is, in some instance inapplicable to the OCS (e.g., port codes) and would provide no tangible benefit to CBP. The same logic used for the Western Hemisphere Travel Initiative whereby persons traveling to/from mobile offshore drilling units located on the OCS are not required to present a passport to enter/re-enter the U.S. should be applied to cargo for these requirements and the regulations should exempt cargoes transported to/from the OCS. CBP should exempt equipment brought into the United States from an OCS facility, whether the equipment is new, unused, or damaged. CBP should exempt such equipment as merchandise pursuant to 49 U.S.C. 55102, or as bulk cargo. CBP should clarify whether foreign merchandise arriving at an OCS facility within the coastwise waters of the United States is subject to the Importer Security Filing requirement. CBP should clarify whether equipment transported from the customs territory

of the United States to an OCS facility to be used for repair or emergency work, having already been entered or is otherwise domestic, is subject to the Importer Security Filing.

#### CBP Response

Domestic cargo (whether of U.S. origin, or of foreign origin and having been formally entered), including cargo intended for repair or emergency work, that is transported between CBP ports, or other places within the customs territory of the United States, including an OCS facility, is not subject to Importer Security Filing requirements. Whether any piece of equipment, new, unused, or damaged, is either considered an OCS facility or device attached to an OCS facility, or is subject to the provisions of 46 U.S.C. 55102, is decided on a case-by-case basis. We note here, however, that a vessel that is positioned over the OCS and is either anchored or moored to the seabed is considered an OCS facility. Conversely, the party causing foreign cargo, including cargo intended for repair or emergency work, to be brought into the customs territory of the United States, whether it is a CBP port or any other point within the customs territory of United States, including an OCS facility, from a foreign port or place must comply with Importer Security Filing requirements. The party causing foreign cargo to arrive at an OCS facility must comply with Importer Security Filing requirements using the port code of the nearest CBP service port. CBP will consider the exigent circumstances surrounding such transportation in the assessment of any liquidated damages claim or other enforcement action.

#### Comment

Low risk repetitive shipments should be exempt from the Importer Security Filing requirements. In the alternative, CBP should consider an alternative data submission procedure which would take into account repetitive shipments in which the content varies little from shipment to shipment.

#### CBP Response

CBP disagrees. Repetitive shipments are not inherently of less risk than other shipments. CBP will use the Importer Security Filing to assess the risk of individual shipments and, therefore, no exemptions to the Importer Security Filing requirements will be given for repetitive shipments.

#### Comment

Roll on/roll off cargo should be exempt from the Importer Security Filing requirements.

#### CBP Response

CBP disagrees. Roll on/roll off cargo is not inherently less of a risk than other shipments. Therefore, an Importer Security Filing is required for all cargo other than bulk cargo destined to enter the limits of a port in the United States, including roll on/roll off cargo.

#### Comment

Samples and trade show displays should be exempt from the Importer Security Filing requirements. In the alternative, manufacturer (or supplier) and country of origin should not be required for these shipments.

#### CBP Response

CBP disagrees. Samples and trade show displays are not inherently less of a risk than other shipments. Therefore, a complete Importer Security Filing is required for samples and trade show displays.

#### Comment

Goods being imported into the U.S. Virgin Islands should be exempt from the Importer Security Filing, stow plan, and CSM requirements.

#### CBP Response

The U.S. Virgin Islands are not part of the customs territory of the United States and are, therefore, outside of the scope of this rule.

#### Comment

CBP should maintain a list of break bulk cargo for which an Importer Security Filing is required 24 hours prior to arrival. Specifically, new and used vehicles and ISO tanks should be considered break bulk.

#### CBP Response

For purposes of this interim final rule, break bulk cargo is defined in new § 149.1(d) as "cargo that is not containerized, but which is otherwise packaged or bundled." CBP does not maintain a list of break bulk cargo. Rather, CBP considers applications for exemption from the timing requirement under the 24 Hour Rule and the Importer Security Filing requirements on a case-by-case basis. Regarding vehicles, if vehicles are non-containerized, they are considered break bulk for purposes of this rule. Bulk cargo is defined in new § 149.1(c) as "homogeneous cargo that is stowed loose in the hold and is not enclosed in any container such as a box, bale, bag, cask, or the like. \* \* \* Specifically, bulk cargo is composed of either: (1) Free flowing articles such as oil, grain, coal, ore, and the like, which can be pumped or run through a chute or

handled by dumping; or (2) Articles that require mechanical handling such as bricks, pig iron, lumber, steel beams, and the like." Regarding ISO tanks, a container that carries liquids is still a container for purposes of this rule.

*L. Public Comments; Importer Security Filing, Other Comments*

**Comment**

Providing essentially the same information on a shipment-by-shipment basis, albeit in different combinations and permutations will not increase security. Instead, importers should be allowed and/or required to provide a profile of suppliers, ship-to locations, etc.

**CBP Response**

It is unlikely that every element will be one hundred percent identical in different shipments. CBP will use the Importer Security Filing to assess the risk of individual shipments and, therefore, an Importer Security Filing is required for each shipment. For purposes of this rule, all cargo arriving to the United States by vessel, unless specifically exempt, is subject to the Importer Security Filing requirements.

**Comment**

The Importer Security Filing requirements are duplicative with FDA submissions. DHS and the FDA should collect this information through one submission.

**CBP Response**

CBP disagrees. These submissions are authorized by different laws with different responsible parties and enforcement actions for failure to comply. However, CBP will continue to evaluate all submissions and ways to reduce the burden on the trade through eliminating redundant submissions.

**Comment**

If CBP proceeds before ACE is fully functional, CBP should wait until ACE is available before requiring linking of the manufacturer name and address, country of origin, and HTSUS number. CBP should also fulfill its commitment to integrating this data submission process with the future ongoing development work and implementation of ACE. The record formats should be compatible with those that will be required in ACE without further changes in order to avoid additional programming requirements for the trade.

**CBP Response**

CBP disagrees that the linking requirement should be postponed until ACE is fully functional. The linking of

the required data is required at the entry level and not necessarily at the bill of lading or invoice level. This is a process that is already required upon cargo arrival for entry purposes on CBP Form 3461. The linking of the required data will allow CBP to more effectively target high risk shipments. Absent the linking of the data, CBP would need to consider every possible permutation of the data and would, therefore, be forced to designate cargo as high risk when it may not, in fact, be high risk. As stated previously, CBP will take into account systems changes made by the trade to comply with this rule as ACE is developed.

**Comment**

CBP will need to allow the filer the ability to designate an Importer Security Filing as relating to either a consumption entry or FTZ shipment; or an IE, T&E, or FROB shipment.

**CBP Response**

CBP agrees. The Importer Security Filing submission must indicate whether the submission is for: (1) A shipment intended to be entered into the United States or a shipment intended to be delivered to a foreign trade zone, requiring an Importer Security Filing consisting of 10 elements; or (2) an IE, T&E, or FROB shipment, requiring an Importer Security Filing consisting of five elements.

**Comment**

The NPRM did not propose to require container number as part of the Importer Security Filing. How will CBP target containers for examination when there are multiple containers on one bill of lading?

**CBP Response**

An ISF Importer will be given the option to provide container numbers as part of the Importer Security Filing. If the ISF Importer chooses to have one bill of lading cover multiple containers, all of those containers will be subject to the same risk assessment.

**Comment**

Each Importer Security Filing filer should be issued a unique "filer" number.

**CBP Response**

Any party not already an ABI or AMS participant intending to transmit Importer Security Filings through ABI or AMS will be issued a filer code when they obtain ABI or AMS access to uniquely identify them as the filer of the transmission.

**Comment**

Importers, and other designated parties, should be able to access past Importer Security Filings.

**CBP Response**

CBP disagrees. Importers and other designated parties will not be able to access past Importer Security Filings in CBP systems. As discussed in response to another comment, such functionality would be too costly and raises security and privacy concerns. However, CBP will continue to evaluate this possibility as ACE is developed.

**Comment**

The requirement to request a ruling when an element does not exist will jeopardize supply chain efficiency. When an element is unknown, the importer should be allowed to leave a field blank or provide a code indicating lack of knowledge without penalty. In the alternative, CBP should provide for an expedited ruling procedure when an importer believes that a required data element does not exist for a non-exempt transaction type.

**CBP Response**

First, CBP is not requiring that the ISF Importer seek a ruling when a data element is unknown. If an ISF Importer does not know an element that is required pursuant to this interim final rule, the ISF Importer must take steps necessary to obtain the information. If the ISF Importer believes that a required data element does not exist for a non-exempt transaction type, the ISF Importer should request a ruling prior to the time required for the Importer Security Filing. The advance rulings procedures found in 19 CFR part 177 remain available to the public for this purpose. CBP disagrees that separate special ruling procedures for Importer Security Filing are necessary because the part 177 procedures are sufficient to handle all questions that may arise.

**Comment**

CBP should not require importers to provide data of which they do not have direct knowledge or cannot reasonably be expected to obtain. CBP should have flexibility to identify appropriate alternatives to elements that are unknown at the time of filing.

**CBP Response**

CBP believes that, in most cases, the Importer Security Filing information is available to the party causing the goods to enter the limits of a port in the United States. However, CBP is aware that business practices may need to change (e.g., amendment of shipping



documents) to obtain this information 24 hours prior to lading. Where the ISF Importer is not reasonably able to verify the information, the regulations allow the party to submit the information on the basis of what it reasonably believes to be true. In addition, as discussed in the "Structured Review and Flexible Enforcement Period" section of this document, this rule provides flexibilities with respect to certain elements of Importer Security Filings such as the ability to provide a range of possible responses based on the best data available in lieu of a single specific response.

#### Comment

The importer should not be required to link the manufacturer (or supplier), country of origin, and commodity HTSUS number. This requirement is not included in the SAFE Port Act. Instead, CBP should manipulate the data through the use of an improved algorithm, as required by the SAFE Port Act, to best achieve effective security screening.

#### CBP Response

Pursuant to section 203 of the SAFE Port Act, this interim final rule requires the submission of additional data elements for improved high-risk targeting, including appropriate security elements of *entry data*. Importers are already required to link data in this way for entry purposes and CBP currently uses these data to target. The line-item linking will provide CBP with specific information about the origin of the goods, the manufacturer/supplier of the goods and an accurate description of the goods. For example, manhole covers, in and of themselves are relatively benign. Goods with a specific country of origin may not merit any special consideration. But manhole covers coming from a specific manufacturer in a specific country of origin have been found to be contaminated with radioactive waste.

#### Comment

Do the manufacturer (or supplier), country of origin, and commodity HTSUS number need to be linked to one another at the invoice line item level or the entry line item level?

#### CBP Response

The manufacturer (or supplier), country of origin, and commodity HTSUS number must be linked to one another at the entry line level and not at the invoice line item level. This is consistent with what the trade provides to CBP for entry purposes and will

allow CBP to better assess the risk of cargo destined for the United States.

#### Comment

How will items with multiple HTSUS numbers be linked (e.g., a suit could have up to four different 10-digit HTSUS numbers)?

#### CBP Response

Multiple HTSUS numbers will be linked at the line item level with country of origin, and manufacturer. This will be similar to the current CBP Form 3461 entry procedures.

#### Comment

CBP should wait until ACE is available before requiring linking of data.

#### CBP Response

CBP disagrees. After careful consideration, DHS has determined that immediate action is necessary to increase the security of cargo entering the United States by vessel by improving CBP's risk assessment capabilities. Existing CBP systems are prepared to receive the manufacturer (or supplier), country of origin, and commodity HTSUS number linked to one another. CBP will take into account systems changes made by the trade to comply with this rule as ACE is developed.

#### Comment

CBP should require the same 10 elements that are required for shipments intended to be entered into the United States for FROB cargo.

#### CBP Response

CBP disagrees. Several of the elements (e.g., importer of record and consignee number) are not applicable to FROB shipments. Therefore, CBP is requiring five elements which are applicable to FROB shipments.

#### Comment

CBP should require that an Importer Security Filing be filed 24 hours prior to lading for all cargo, including FROB.

#### CBP Response

Because FROB cargo is frequently laden based on a last-minute decision by the carrier, the Importer Security Filing for FROB is not required 24 hours prior to lading. Rather, the Importer Security Filing for FROB is required *any time* prior to lading. Therefore, a carrier may submit the Importer Security Filing for FROB cargo 24 hours prior to lading if the carrier chooses to do so.

#### Comment

Carriers would be in the position of non-compliance when cargo is transformed into FROB while en route, when cargo that was originally intended to remain onboard the vessel (i.e., FROB) will be unladen in the United States, or when additional cargo is booked at the last minute.

#### CBP Response

An Importer Security Filing must be submitted to CBP no later than 24 hours before cargo that is intended to enter the limits of a port in the United States is laden. See the "Structured Review and Flexible Enforcement Period" section of this document for flexibilities related to timing for certain Importer Security Filing elements. For FROB, the Importer Security Filing must be submitted prior to lading. The ISF Importer must update the filing if, before the goods enter the limits of a port in the United States, any of the information submitted changes or more accurate information becomes available, including when cargo is transformed into FROB. CBP acknowledges the wide range of logistical issues that carriers face that may change vessel patterns and ultimately cargo status. The change in status of cargo needs to be communicated to CBP as soon as that decision is made and Importer Security Filing filings must be submitted immediately. However, the ISF Importer will still be liable for enforcement actions resulting from late Importer Security Filing submissions.

#### VII. Discussion of Comments Regarding Proposed Amendments to Bond Requirements and Enforcement

In order to provide a clear enforcement mechanism for the proposed requirements, CBP proposed to amend the regulations covering certain bond conditions to include agreements to pay liquidated damages for violations of the new proposed regulations. CBP also proposed to amend the bond conditions for violations of the advance cargo information requirements under the Trade Act regulations in order to make the liquidated damages amounts for those violations consistent with the liquidated damages amounts for violations of the proposed requirements.

##### A. Overview; Bond Conditions and Enforcement Related to the Proposed Importer Security Filing, Vessel Stow Plan, and Container Status Message Requirements

CBP will enforce the Importer Security Filing, vessel stow plan, and container status message requirements

through the assessment of liquidated damages, in addition to penalties applicable under other provisions of law.

CBP proposed to add a new condition to those provisions in 19 CFR 113.62 required to be included in a basic importation and entry bond. Specifically, CBP proposed to amend 19 CFR 113.62 to include a condition whereby the principal agrees to comply with the proposed Importer Security Filing requirements. Under the proposed condition, if the principal fails to comply with the proposed Importer Security Filing requirements, the principal and surety (jointly and severally) would pay liquidated damages equal to the value of the merchandise involved in the default.

CBP also proposed to amend those provisions in 19 CFR 113.64 required to be included in an international carrier bond. Specifically, CBP proposed to amend 19 CFR 113.64 to include three new conditions. First, a new condition would be added whereby the principal agrees to comply with the proposed Importer Security Filing requirements if the principal elects to provide the Importer Security Filing on behalf of an importer, as defined in the proposal. If the principal fails to comply with the proposed Importer Security Filing requirements, the principal and surety (jointly and severally) would agree to pay liquidated damages equal to the value of the merchandise involved in the default. Second, a new condition would be added whereby the principal agrees to comply with the proposed vessel stow plan requirements. If the principal fails to comply with the proposed vessel stow plan requirements, the principal and surety (jointly and severally) would agree to pay liquidated damages of \$50,000 for each vessel arrival. Third, a new condition would be added whereby the principal agrees to comply with the proposed container status message requirements. If the principal fails to timely provide CSMs for all events that occur relating to a container, for which the carrier creates or collects CSMs in its equipment tracking system, the principal and surety (jointly and severally) would pay liquidated damages of \$5,000 for each violation, to a maximum of \$100,000 per vessel arrival.

Lastly, CBP proposed to amend those provisions in 19 CFR 113.73 required to be included in a foreign trade zone operator bond. Specifically, CBP proposed to amend 19 CFR 113.73 to include a condition whereby the principal agrees to comply with the Importer Security Filing requirements.

Under the proposed condition, if the principal fails to comply with the proposed Importer Security Filing requirements, the principal and surety (jointly and severally) would pay liquidated damages equal to the value of the merchandise involved in the default.

*B. Public Comments; Bond Conditions and Enforcement Related to the Proposed Importer Security Filing, Vessel Stow Plan, and Container Status Message Requirements*

**Comment**

When an agent submits an Importer Security Filing on behalf of an importer, both parties should not be required to obtain bonds. If both parties are required to have a bond, CBP should clarify who will be responsible for liquidated damages. Will both parties be responsible? Will an additional bond (or a separate bond rider) be required for the Importer Security Filing and, if so, which type of bond (or rider)?

**CBP Response**

CBP agrees. The regulations have been changed to remove the requirement that the filer have a separate bond. The ISF Importer, as defined for purposes of these regulations, is ultimately liable for the timely, accurate, and complete submission of the Importer Security Filing. The regulations have also been changed to include a new importer security filing bond and to allow the ISF Importer to use a basic custodial bond or new importer security filing bond in addition to the bond types included in the proposal. Therefore, the ISF Importer must possess a basic importation and entry bond containing all the necessary provisions of 19 CFR 113.62, a basic custodial bond containing all the necessary provisions of 19 CFR 113.63, an international carrier bond containing all the necessary provisions of 19 CFR 113.64, a foreign trade zone operator bond containing all the necessary provisions of 19 CFR 113.73, or an importer security filing bond as provided in Appendix D to part 113 of 19 CFR. If the ISF Importer does not have one of these bonds, the party must obtain a bond or designate a bonded agent to file under the agent's bond if the agent agrees in writing.

**Comment**

Licensed customs brokers should be exempt from bond requirements with regard to the Importer Security Filing.

**CBP Response**

A customs broker who submits an Importer Security Filing on behalf of another party must do one of the following: (1) Submit the filing under its

own bond; or (2) at an ISF Importer's direction, submit the filing under that party's bond.

**Comment**

The requirement that the Importer Security Filing filer have a bond will ensure a high degree of diligence and perfection, especially when the filer is a foreign entity.

**CBP Response**

CBP will enforce the Importer Security Filing, vessel stow plan, and container status message requirements through the assessment of liquidated damages, in addition to penalties applicable under other provisions of law. CBP agrees that the requirement that a bond be posted for the Importer Security Filing will ensure a high degree of diligence. However, under this interim final rule, if the ISF Importer does not have one of the required bonds, the importer may designate a bonded agent to file under the agent's bond if the agent agrees in writing.

**Comment**

Will a continuous or single transaction bond be required?

**CBP Response**

Generally, continuous bonds will be accepted for the Importer Security Filing. Continuous bonds are verifiable electronically and will give CBP more transparency into the party and bond's existence. Requests to file single transaction bonds for Importer Security Filings will be evaluated by CBP on a case-by-case basis consistent with current practices.

**Comment**

How can an importer use an importation and entry bond for the Importer Security Filing because an importer's liability under an importation and entry bond attaches at the time of entry? Moreover, liability attaches based on conditions that are beyond the importer's control.

**CBP Response**

An ISF Importer will obligate its bond for purposes of submission of the importer security filing. Not all basic importation bond obligations attach at entry (for example, the obligation to comply with airport security requirements.) An ISF Importer must possess a basic importation and entry bond containing all the provisions of 19 CFR 113.62, a basic custodial bond containing all the provisions of 19 CFR 113.63, an international carrier bond containing all the provisions of 19 CFR 113.64, a foreign trade zone operator

bond containing all the provisions of 19 CFR 113.73, or an importer security filing bond as provided in Appendix D of part 113 of 19 CFR in order to submit an importer security filing. CBP has amended the relevant bond provisions to provide that the principle agrees to comply with Importer Security Filing requirements. CBP has also amended the international carrier bond provisions to provide that the principle agrees to comply with vessel stow plan and container status message requirements.

#### Comment

If NVOCCs are excluded from the vessel stow plan and CSM requirements, will CBP differentiate between International Carrier Bonds required for vessel operating common carriers (VOCCs) and NVOCCs.

#### CBP Response

NVOCCs are not required to submit vessel stow plans and CSMs. The responsible party's bond will be subject to liquidated damages. Therefore, an NVOCC should not be subject to liquidated damages for violations of the vessel stow plan and CSM requirements unless the NVOCC posts its bond for this purpose (e.g., if the NVOCC submits a vessel stow plan or CSMs on behalf of a vessel operating carrier).

#### Comment

Will CBP change the required bond amounts? If so, how will the bond amount be calculated? The ability to obtain bonds for Importer Security Filings would be undermined by an inability to quantify and underwrite risks, which would limit importer and broker access to viable customs bond providers. Furthermore, the ability to underwrite a foreign company is very limited. In addition, some importers and carriers may no longer qualify for the required bond because sureties may increase their thresholds as a result of these new requirements. In any event, the inclusion of liquidated damages provisions will result in a significant increase in customs bonds costs. This increased cost has not been quantified.

#### CBP Response

CBP is not increasing bond amounts through this rulemaking. If CBP does increase bond amounts in the future, it will do so through established procedures.

#### Comment

CBP should clarify that a bond must be in place at the time of submission of the Importer Security Filing.

#### CBP Response

Pursuant to new 19 CFR 149.5, to be qualified to file Importer Security Filing information, an ISF Importer must possess a bond or, if an ISF Importer does not have a required bond, the ISF Importer can have the agent submitting the Importer Security Filing post the agent's bond.

#### Comment

Liquidated damages are inappropriate because they are not related to the security goals of this rule and because the Importer Security Filing is not "customs business." In addition, CBP did not consult with the trade regarding the proposed liquidated damages and bond provisions and CBP has not offered a rational basis for the use of liquidated damages in lieu of other deterrents, including the following: Rejection of the Importer Security Filing, do not load messages at the port of export, examination of the cargo, and detention of the cargo at the port of entry for examination. CBP should only use monetary penalties for Importer Security Filing violations.

#### CBP Response

The provisions of 19 U.S.C. 1623 authorize CBP to require such bonds as deemed necessary to assure compliance with any provision of law the CBP may be authorized to enforce. See 19 CFR 113.1. The fact that the Importer Security Filing is not "customs business" is not relevant to this statutory authorization. Liquidated damages for breaches of bond conditions are appropriate for violations of the Importer Security Filing.

Other enforcement actions, such as DNL messages and general cargo examination authorities, may also be applicable and within the discretion of CBP. Liquidated damages will allow for appropriate enforcement in lieu of monetary penalties.

#### Comment

The proposed inclusion of provisions relating to the Importer Security Filing requirements is contrary to the entry (commercial) purposes of the basic importation and entry bond.

#### CBP Response

In an effort to minimize the burden on the trade, CBP is allowing the use of the basic importation and entry bond, as modified by this rulemaking, for Importer Security Filing purposes. The ISF Importer may also obtain a basic custodial bond, an international carrier bond, a foreign trade zone operator bond, or an importer security filing bond. CBP disagrees that the inclusion

of provisions relating to the Importer Security Filing in the basic importation and entry bond is inappropriate because, inasmuch as the obligation to provide this information vests with the importer, it is reasonable to establish a condition in the importer's bond to guarantee performance of that obligation.

#### Comment

Can a carrier be indemnified for liquidated damages for loading a container if the carrier can provide a valid Importer Security Filing number and the bond ID of the filer?

#### CBP Response

ISF Importers are required to submit Importer Security Filings. A carrier's ability to seek indemnification for liquidated damages from another party for loading a container with an Importer Security Filing-related problem is a private matter best handled by private parties (i.e., through contractual instruments).

#### Comment

There does not appear to be any risk assessment associated with the proposed liquidated damage amounts. Liquidated damages should be a set amount per container rather than the value of the merchandise as proposed.

#### CBP Response

After review of the comments and further consideration, CBP has changed the liquidated damage amount for failure to timely, accurately, and completely file an Importer Security Filing. If a party who is responsible for filing the Importer Security Filing fails to timely, accurately, and completely submit the Importer Security Filing, that party will be subject to a claim for liquidated damages in the amount of \$5,000 per Importer Security Filing. Any demand for liquidated damages will be subject to mitigation on a case-by-case basis. However, mitigation will be the exception and not the rule for violations of these requirements.

#### Comment

Why are liquidated damages amounts different for importers and carriers under the proposed regulations?

#### CBP Response

In determining liquidated damages amounts, CBP considered the nature of the obligation that vests for the bond principal. The obligation to submit a vessel stow plan, which is submitted once per vessel voyage, versus the obligation to submit Importer Security Filings, which are submitted once per

bill of lading, and container status messages, which may be submitted numerous times per container, provide different risk levels to CBP that are treated differently when a breach of the obligation occurs. CBP does not consider the identity of the bond principal when calculating those risks and determining liquidated damages amounts.

#### Comment

The proposed liquidated damages provisions do not adhere to section 343(a)(3)(F) of the Trade Act of 2002 which states that "[t]he information collected pursuant to the regulations shall be used exclusively for ensuring cargo safety and security and preventing smuggling and shall not be used for determining merchandise entry or for any other commercial enforcement purposes" because the enforcement provisions are consistent in scope with 19 U.S.C. 1592, which is for commercial enforcement.

#### CBP Response

CBP will not use the information collected pursuant to these regulations for determining entry or for any other commercial enforcement purposes, such as for assessment of a penalty pursuant to 19 U.S.C. 1592. The liquidated damages provisions are completely separate authorities granted to CBP to provide a contractual remedy for any actions taken in violation of the customs laws for which a customs bond is required to be in place, including Importer Security Filing provisions. See 19 U.S.C. 1623 and the implementing regulations contained in 19 CFR part 113. The mere similarity in enforcement provisions will not affect CBP's ability to enforce provisions relating to bonds.

#### Comment

CBP fails to link the nature of the violation with the party responsible for the breach.

#### CBP Response

The party who posts their bond does so for the purpose of securing the Importer Security Filing. Obligations that vest under the terms and conditions of the bond are the responsibility of the bond principal. When those obligations are breached, the bond principal and surety are liable, jointly and severally, for any resultant liquidated damages. It is, therefore, appropriate for CBP to hold these parties liable for any breach of the bond conditions.

#### Comment

The proposed penalties are unreasonable and should be reduced,

or eliminated. Penalties are unnecessary if other avenues such as "no load" messages are utilized. DNLs are sufficient and the imposition of fines of any sort is administratively burdensome and actually less effective than other means. If CBP does utilize penalties or liquidated damages, CBP should publish revised mitigation guidelines governing the failure to comply with the Importer Security Filing requirements and should only issue penalties in cases of willful or repeat serious violations.

#### CBP Response

CBP disagrees. DNL holds are issued by CBP to alleviate risk. Penalties and liquidated damages are appropriate responses for breaches of the bond conditions or obligations imposed by law or regulation. If the Importer Security Filing requirements are not met, CBP reserves the right to use any enforcement remedy available in this rule, including, but not limited to, the assessment of liquidated damages and penalties. CBP will be issuing mitigation guidelines for these claims.

#### Comment

The proposed enforcement provisions should require a finding of culpability. CBP should consider the party's intent and severity of the violation when issuing penalties, and determining the penalty amounts, for violations of these regulations. In addition, CBP should issue one penalty if multiple violations result from the same fundamental error. Importers should not be held accountable for the accuracy of a data element they do not own or control. Fines should only be issued when false data are knowingly reported, not for failure to file.

#### CBP Response

CBP may issue claims if an Importer Security Filing is not filed in a timely, accurate, and complete manner. Failing to file is a serious violation in that it deprives CBP of the ability to analyze and assess the risk with regard to loading the cargo for transport to the United States. If an ISF Importer does not know an element that is required pursuant to the regulations, the importer must take steps necessary to obtain the information. While CBP will not consider levels of culpability in claim assessment, the agency will issue mitigation guidelines for violations of these regulations.

#### Comment

Pursuant to the proposed regulations, "where the presenting party is not reasonably able to verify the [Importer

Security Filing] information, CBP will permit the party to electronically present the information on the basis of what the party reasonably believes to be true." Clarification is needed on what constitutes that the filer is "reasonably able to verify" and which situations will result in a penalty.

#### CBP Response

CBP will issue penalties for violations of these regulations in accordance with established penalty guidelines. However, where the party electronically presenting to CBP the Importer Security Filing receives any of this information from another party, CBP will take into consideration how, in accordance with ordinary commercial practices, the presenting party acquired such information, and whether and how the presenting party is able to verify this information. Where the presenting party is not reasonably able to verify such information, CBP will permit the party to electronically present the information on the basis of what the party reasonably believes to be true. CBP will make this determination on a case-by-case basis.

#### Comment

The proposed amendment to 19 CFR 113.62 whereby the principle agrees to "comply with all Importer Security Filing requirements" is inappropriate.

#### CBP Response

CBP disagrees. The amendment to 19 CFR 113.62 is not intended to recite the specific obligations, but merely enable CBP to enforce the new requirements by allowing CBP to assess liquidated damages for failure to comply with the bond provisions. Therefore, CBP believes that changing the bond to reflect new obligations in this manner is appropriate and allows for existing bonds to be used, thereby reducing redundancy and burden for CBP and the trade.

#### Comment

Who will receive DNL messages resulting from Importer Security Filing problems? CBP should add a mandatory field to the existing 24 Hour Rule for an Importer Security Filing confirmation number and should timely issue a DNL to the carrier against the AMS manifest filing when a number is not present or when there are problems with the Importer Security Filing. CBP should also transmit DNLs to the importer so that Importer Security Filing-related DNLs can be resolved.

**CBP Response**

Consistent with current practice, DNL messages will be sent to the AMS filer of the associated bill of lading and any "secondary notify party" associated with the bill of lading. CBP will also communicate electronically to the filer of the Importer Security Filing when there are Importer Security Filing-related inaccuracies. In addition, CBP will send a status notification message to the AMS filer and any "secondary notify party" when an Importer Security Filing has been submitted and matched by CBP with a bill of lading. CBP has not added a field to the 24 Hour Rule manifest filing for an Importer Security Filing confirmation number because the ISF Filer is not required to submit the Importer Security Filing before the carrier submits the 24 Hour Rule advance cargo information.

**Comment**

Will CBP issue "no load" directives to carriers and terminal operators in the case of failure to file timely and/or complete Importer Security Filings?

**CBP Response**

CBP has issued internal directives for port personnel in order to harmonize actions within CBP. However, CBP will not issue separate "no load" directives to carriers and terminal operators for Importer Security Filing-related DNLs. CBP has adopted a delayed compliance period following the effective date of this rule, during which CBP will work with the trade to assist them in achieving full compliance, thereby minimizing the issuance of DNLs. See the "Structured Review and Flexible Enforcement Period" section of this document for further discussion regarding the delayed compliance period.

**Comment**

CBP should issue a DNL for any bill of lading that does not have the Importer Security Filing on file at the time the carrier files the 24 Hour advance manifest data.

**CBP Response**

It would be inappropriate and premature for CBP to issue an Importer Security Filing-related DNL when the carrier files the 24 Hour Rule advance manifest data because the Importer Security Filing is required 24 hours prior to lading (any time prior to lading for FROB). Therefore, CBP will not issue DNL messages for missing Importer Security Filings until the Importer Security Filing time period has passed (i.e., 24 hours prior to lading for cargo

other than FROB and any time prior to lading for FROB).

**Comment**

An importer's goods that are part of a consolidated shipment may be delayed if the Importer Security Filing by one of the other parties in the consolidated shipment is not timely filed, resulting in a DNL for the container. CBP should permit the portion of a consolidated shipment for which an Importer Security Filing has been received to split from the shipment.

**CBP Response**

CBP will follow existing DNL procedures for Importer Security Filing-related DNLs.

**Comment**

CBP should provide an affirmative message that specific cargo is approved to be laden.

**CBP Response**

CBP disagrees. CBP will continue to follow existing DNL procedures and will not issue affirmative load messages.

**Comment**

What are the carrier's responsibilities with regard to the Importer Security Filing and loading of containers onboard a vessel? Carriers should not be impacted in any way, including liability under the carrier bond, if there are shipments onboard where a filing was not done.

**CBP Response**

The ISF Importer is required to submit the Importer Security Filing. For FROB, the ISF Importer is construed as the carrier because there is no importer of record and the carrier is the party causing the goods to enter the limits of a port in the United States by transporting the goods to the United States. For IE and T&E in bond shipments, and goods to be delivered to an FTZ, the ISF Importer is construed as the party filing the IE, T&E, or FTZ documentation because there is no importer of record and this is the party principally causing the goods to enter the limits of a port in the United States. CBP will issue a DNL to instruct a carrier not to load specific cargo, including cargo for which a complete and accurate Importer Security Filing has not been filed. Vessel operating carriers are prohibited from loading such cargo. If a carrier is the party required to submit the Importer Security Filing (i.e., FROB cargo), the carrier will be liable for the timeliness and accuracy of the Importer Security Filing.

**C. Overview; Bond Conditions Related to the Trade Act Regulations**

CBP proposed to amend the liquidated damages amounts for violations of the advance cargo information requirements under 19 CFR 4.7 and 4.7a to be \$5,000 for each violation of the advance cargo information requirements, to a maximum of \$100,000 per conveyance arrival.

**D. Public Comments; Bond Conditions Related to the Trade Act Regulations****Comment**

CBP's proposal to amend 19 CFR 4.7, 4.7a, and 113.64 to assess liquidated damages in the amount of \$5,000 for each violation of the advance cargo information requirements, to a maximum of \$100,000 per conveyance arrival, would have a significant impact on other modes of transportation besides vessel.

**CBP Response**

CBP agrees that there will be an unintended impact on other modes through this regulatory amendment in that there will be a \$100,000 damage cap on vessel conveyance arrivals which does not exist for arrivals in other transportation modes. Accordingly, to make assessment consistent, CBP is amending the provisions of newly redesignated 19 CFR 113.64(d) to provide for the \$100,000 cap on all other conveyance arrivals.

**VIII. Discussion of Comments Regarding the Cost, Benefit, and Feasibility Study****Comment**

Commenters stated that the Regulatory Assessment underestimates costs because it did not account for delay to coordinate data collection among relevant parties nor did it account for increased infrastructure costs to house delayed goods. Commenters cited an economic study (See David Hummels, *Time as a Trade Barrier* (July 2001) (unpublished paper, Purdue University) (on file with author).) which estimated that a day of delay is approximately equivalent to a one percent tariff on imported goods and that this rule will result in a reduced demand for imports.

**CBP Response**

Based on the public comments, CBP has revised its cost and benefit analysis, a summary of which is presented below. The revised analysis includes a new methodology for estimating the costs due to potential delays in the supply chain by estimating the economic

welfare losses to U.S. importers. These estimated losses sufficiently account for costs associated with these delays, including additional inventory carrying costs, the costs to hold larger buffer-stock inventories to accommodate variation in arrival time, depreciation in shipment value, and storage and security costs. The analysis relies on the economic study that estimated the value of a one-day delay to be equivalent to approximately a one percent tariff, however we apply more precise percentages obtained directly from the study's author for each relevant category of imported goods. Furthermore, our revised analysis appropriately includes only consumer surplus lost to U.S. importers, whereas the commenters' estimate results in an overestimate of the total loss that is greater than the sum of both consumer surplus lost to U.S. importers and producer surplus lost to foreign manufacturers, suppliers, and distributors.

#### *Comment*

Commenters stated that costs of delay should be applied to all shipments, not just consolidated shipments.

#### *CBP Response*

CBP's revised cost and benefit analysis, a summary of which is presented below, includes unconsolidated or full container shipments in the estimation of welfare losses to U.S. importers arising from potential delays in the supply chain.

#### *Comment*

Commenters stated that a risk assessment was not conducted and that this rule will not reduce risk. Commenters also asked how the filing of the Importer Security Filing would deter terrorist attacks. Lastly, commenters stated that CBP did not provide any evidence of a benefit from the rule if promulgated.

#### *CBP Response*

The purpose of the rule is to improve CBP's ability to prevent smuggling and ensure cargo safety and security. The additional cargo information will assist CBP in focusing its security resources on those shipments that pose the highest risk. In the "break-even" analysis presented in the Regulatory Assessment, CBP described several terrorist attack scenarios that could potentially be affected by the rule. The break-even analysis is not intended to measure the risk of attack that will occur with implementation of the rule; rather, the break-even analysis is intended to inform the reader of the absolute reduction in baseline risk that

would have to occur in order for the annualized costs of the rule to equal the benefits. CBP cannot determine if this risk reduction will occur or if this level of risk reduction is achievable through implementation of this rule.

#### *Comment*

Commenters stated that increased bond costs, liquidated damages, and penalty costs were not accounted for in the Regulatory Assessment.

#### *CBP Response*

CBP agrees. The economic analysis assumes that parties subject to the requirements of the rule will comply with those requirements. During the one-year delayed enforcement period, CBP will work with the trade to assist them in achieving compliance with this rule.

#### *Comment*

The Regulatory Assessment did not estimate the costs and benefits of requiring data elements to be linked at the line-item level.

#### *CBP Response*

CBP agrees. CBP is not able to isolate estimates of costs or benefits at this very specific level of detail. The cost estimated for a security filing is intended to cover the range of potential activities involved with collecting and compiling the data for an Importer Security Filing, including the costs of linking data.

#### *Comment*

The Regulatory Assessment did not account for all of the elements of an importer's supply chain and the economic analysis did not account for start-up costs.

#### *CBP Response*

CBP agrees. However, CBP could not realistically account for the tens of thousands of possible supply chain relationships that include importers. In addition, many of the supply chain entities are based overseas (foreign), and therefore their compliance costs do not represent the incremental costs borne by U.S. entities. Instead, through conversations with trade representatives, CBP developed a range of costs in the form of an Importer Security Filing transaction fee that is intended to include any costs incurred by the various parties within the supply chain that are then ultimately passed on to the importers. CBP's revised cost and benefit analysis, a summary of which is presented below, includes an estimate of the start-up or initial costs incurred by importers or their designated filing

agents to implement the rule's requirements.

#### *Comment*

The Regulatory Assessment should account for two days of delay in the supply chain as a result of this rule.

#### *CBP Response*

CBP agrees. CBP has revised the cost and benefit analysis, a summary of which is presented below, by assuming two or three days of delay during the first year of implementation. For subsequent years, however, the analysis assumes a decrease in delay to one day, based on conversations with trade representatives who were drawing on their experience with the 24 Hour Rule. Generally, representatives were in agreement that initial implementation of the 24 Hour Rule's requirements caused some delays in the supply chain, which decreased noticeably in subsequent years as they adapted to the new requirements. CBP expects a similar situation upon implementation of this rule, and notes that CBP has adopted a delayed compliance period following the effective date of this rule. See the "Structured Review and Flexible Enforcement Period" section of this document for further discussion regarding the delayed compliance period.

#### *Comment*

The Regulatory Assessment understated recurring costs for large importing operations.

#### *CBP Response*

CBP acknowledges that the recurring costs for a particular importer to comply with this rule will be driven largely by factors such as the number of Importer Security Filings the importer has to complete, the complexity of the importer's supply chain and business style, and the level of the importer's sophistication. However, we do not have the data or information to characterize each of the estimated 200,000 to 750,000 unique importers by these factors or to quantify the extent to which the recurring costs would reliably change with these factors. Due to limitations in the available data, we varied the recurrent, transaction costs for Importer Security Filings based on importer transaction volume (e.g., highest volume importers have the lowest recurrent transaction costs). The trade representatives most commonly cited transaction volume as a factor in determining the transaction costs. From their experience with entry filing or manifest fees charged by brokers or carriers, brokers and carriers are likely

to charge lower security filing fees to their customers importing a large number of shipments on an annual basis. The transaction costs applied in the Regulatory Assessment are consistent with quantified per transaction cost estimates provided by other commenters.

#### Comment

The annual recordkeeping burden estimated was too low.

#### CBP Response

CBP disagrees. The annual recordkeeping burden of 52.3 hours per importer is intended to represent the average burden for all importers, ranging from those that have very few shipments per year to those that have more than a thousand shipments per year. The Regulatory Assessment finds that most importers are small; specifically, in 2005, more than 70 to 85 percent of all importers imported fewer than 12 shipments. We believe that most of these smaller importers will have a burden lower than the 52.3 hours we estimated.

#### Comment

The trade representatives interviewed in conjunction with the Regulatory Assessment were not a representative sample.

#### CBP Response

CBP disagrees. CBP interviewed more than 20 representatives from a broad range of the parties likely to be affected by the interim final rule, including small and large importers, vessel and non-vessel operating common carriers, freight forwarders, brokers, trade groups and consultants, and trade software providers. In addition, CBP considered the additional input expressed by the trade in their public comments to the proposed rule during its revision of the cost and benefit analysis, a summary of which is presented below.

#### Comment

Commenters stated that the Regulatory Assessment was "unreliable" and "flawed." The costs of the rule cannot be known until CBP releases the data formats that will be required for the Importer Security Filing.

#### CBP Response

While these commenters were dissatisfied with the economic analysis, they did not submit specific information that would enhance the current analysis. These commenters did not submit alternative analyses that more robustly considered the impacts on

affected entities. CBP is required to prepare an economic analysis to be considered as part of the NPRM. The analysis prepared for the NPRM was reviewed by the Office of Management and Budget (OMB) in accordance with Executive Order 12866 and OMB Circular A-4. According to OMB Circular A-4, a good regulatory analysis should include: (1) A statement of the need for the proposed action, (2) an examination of alternative approaches, and (3) an evaluation of the benefits and costs—quantitative and qualitative—of the proposed action and the main alternatives identified by the analysis.

#### Comment

Customs brokers would incur additional costs as a result of this rule and these costs would be passed on to the importer.

#### CBP Response

CBP agrees with this comment, and the cost and benefit analysis does assume that any costs, both initial and recurring, incurred by brokers to comply with the rule's requirements would be passed on to the importers in the form of an Importer Security Filing transaction fee.

### IX. Adoption of Proposal

In view of the foregoing, and following careful consideration of the comments received and further review of the matter, CBP has concluded that the proposed regulations with the modifications discussed above should be adopted as follows:

- The requirements in section 149.2(b) regarding the timing of transmission for 6 of the 10 Importer Security Filing elements (Container stuffing location, Consolidator (stuffer), Manufacturer (or supplier), Ship to party, Country of origin, and Commodity HTSUS number) and section 149.2(f) regarding the flexible requirements for 4 of the elements (Manufacturer (or supplier), Ship to party, Country of origin, and Commodity HTSUS number) are adopted as an interim final rule. CBP invites comments on these requirements.
- All other requirements in this rule are adopted as a final rule. CBP is not inviting comments on these requirements.

### X. Regulatory Analyses

#### A. Executive Order 12866

This rule is considered to be an economically significant regulatory action under Executive Order 12866 because it may result in the expenditure of over \$100 million in any one year.

Accordingly, this rule has been reviewed by the Office of Management and Budget (OMB). The following summary presents the costs and benefits of the rule plus a range of alternatives considered. (The "Regulatory Assessment" can be found in the docket for this rulemaking: <http://www.regulations.gov>; see also <http://www.cbp.gov>).

In the analysis that follows, CBP has estimated the costs of the rule assuming that all affected entities are compliant upon the effective date of the rule, which likely overstates costs. Additionally, our analysis presents a low and high cost estimate. The costs for the high scenario incorporate potential supply chain delay impacts of 1 to 3 days. We analyzed the potential for supply chain delays based on our interviews with trade representatives and comments to the NPRM. As stated previously, CBP is committed to ensuring that its trade partners are positioned to successfully implement the requirements of this rule and will work with the trade during the delayed compliance period and thereafter. Based on the magnitude of the impact of potential delay in the high-cost scenario, estimated at billions of dollars annually, CBP has determined that a 12-month delayed compliance period for the rule and flexible requirements for 6 of the 10 Importer Security Filing elements are prudent and necessary steps to minimize the delay costs that could result from the rule and to ensure that these high costs are not, in fact, realized. See the "Structured Review and Flexible Enforcement Period" section of this document for further discussion regarding the delayed compliance period and flexibilities. CBP believes that the direct result of these modifications and the extensive outreach initiative will be a positive downward pressure on supply chain delay costs, and the true impacts of this rule are much more likely to be reflected in the low-cost scenario presented, where no supply chain delays are assumed.

In this analysis, we first estimate current and future baseline conditions in the absence of the rule using 2005 shipping data. In this baseline analysis, we characterize and estimate the number of unique shipments, carriers, and vessel-trips potentially affected by the rule. We then identify the incremental measures that importers and carriers will take to meet the requirements of the rule and estimate the costs of these activities, as well as the cost to CBP of implementing the rule. Next, relying on published literature, we identify hypothetical

scenarios describing representative terrorist attacks potentially prevented by this regulation and estimate the economic costs (i.e., the consequences) of these events. We compare these consequences to the costs of the regulation and estimate the reduction in the probability of a successful terrorist attack resulting from the regulation that would be required for the benefits of the regulation to equal the costs of the regulation.

As of the projected effective date of the regulation, we estimate that approximately 11 million import shipments conveyed by 1,000 different carrier companies operating 37,000 unique voyages or vessel-trips for delivery to between 200,000 and 750,000 ISF Importers in the United States will be subject to the rule. Table

1 summarizes the results of the regulatory analysis. We consider and evaluate the following four alternatives:

*Alternative 1 (the chosen alternative):* Importer Security Filings and Additional Carrier Requirements are required. Bulk cargo is exempt from the Importer Security Filing requirements;<sup>12</sup>

*Alternative 2:* Importer Security Filings and Additional Carrier Requirements are required. Bulk cargo is not exempt from the Importer Security Filing requirements;

*Alternative 3:* Only Importer Security Filings are required. Bulk cargo is exempt from the Importer Security Filing requirements; and,

*Alternative 4:* Only the Additional Carrier Requirements are required.

We estimate costs separately for the Importer Security Filing requirements

(up to 10 importer data elements) and the Additional Carrier Requirements (Vessel Stow Plans and CSMs). The estimated costs for the Importer Security Filing requirements are developed on a per-importer and per-shipment basis and applied to the estimated number of importers and shipments annually for a period of 10 years (2009 through 2018). In addition, we estimate the welfare losses to U.S. importers arising from potential delays in the supply chain that may result from having to meet the required filing deadline of 24 hours prior to lading at the foreign port. The estimated costs for the Additional Carrier Requirements are developed on a per-carrier and per-vessel trip basis and applied to the estimated number of carriers and vessel trips in each year of the 10-year analysis period.

TABLE 1—SUMMARY OF FINDINGS

Discount rate	Annualized costs (2009–2018, \$200B)	Terrorist attack scenario	Percent reductions in baseline risk that must be achieved for benefits to equal costs		Comments
			Absolute reduction in baseline risk required	Number of these events that must be avoided for benefits to equal costs	
<b>Alternative 1 (chosen alternative): Importer Security Filings and Additional Carrier Requirements, bulk cargo exempt</b>					
3% .....	\$890 million to \$6.6 billion.	Actual West Coast Port Shutdown (12-days).	0.59 to 4.38 .....	One event in 3 months to 2 years.	Preferred Alternative: Most favorable combination of cost and stringency.
		Hypothetical Nuclear Attack.	< 0.01 to 0.02 .....	One event in 60 to 500 years.	
		Hypothetical Biological Attack.	0.02 to 0.15 .....	One event in 7 to 50 years.	
7% .....	\$990 million to \$7.0 billion.	Actual West Coast Port Shutdown (12-days).	0.66 to 4.64 .....	One event in 3 months to 2 years.	
		Hypothetical Nuclear Attack.	< 0.01 to 0.02 .....	One event in 60 to 400 years.	
		Hypothetical Biological Attack.	0.02 to 0.16 .....	One event in 6 to 50 years.	
<b>Alternative 2: Importer Security Filings and Additional Carrier Requirements, bulk cargo not exempt</b>					
3% .....	\$890 million to \$6.6 billion.	Actual West Coast Port Shutdown (12-days).	0.59 to 4.39 .....	One event in 3 months to 2 years.	More stringent than Alternative 1, but limited expected additional benefit for increased cost.
		Hypothetical Nuclear Attack.	< 0.01 to 0.02 .....	One event in 60 to 500 years.	
		Hypothetical Biological Attack.	0.02 to 0.15 .....	One event in 7 to 50 years.	
7% .....	\$990 million to \$7.0 billion.	Actual West Coast Port Shutdown (12-days).	0.66 to 4.65 .....	One event in 3 months to 2 years.	
		Hypothetical Nuclear Attack.	< 0.01 to 0.02 .....	One event in 60 to 400 years.	
		Hypothetical Biological Attack.	0.02 to 0.16 .....	One event in 6 to 50 years.	

<sup>12</sup> For each alternative, the Additional Carrier Requirements apply only to containerized cargo.



TABLE 1—SUMMARY OF FINDINGS—Continued

Discount rate	Annualized costs (2009–2018, \$2008)	Terrorist attack scenario	Percent reductions in baseline risk that must be achieved for benefits to equal costs		Comments
			Absolute reduction in baseline risk required	Number of these events that must be avoided for benefits to equal costs	
<b>Alternative 3: Importer Security Filings only, bulk cargo exempt</b>					
3% .....	\$890 million to \$6.6 billion.	Actual West Coast Port Shutdown (12-days).	0.59 to 4.37 .....	One event in 3 months to 2 years.	Similar cost to Alternative 1 with decreased effectiveness. Importer Security Filings and Additional Carrier Requirements are not working in tandem.
		Hypothetical Nuclear Attack.	< 0.01 to 0.02 .....	One event in 60 to 500 years.	
		Hypothetical Biological Attack.	0.02 to 0.15 .....	One event in 7 to 50 years.	
7% .....	\$990 million to \$7.0 billion.	Actual West Coast Port Shutdown (12-days).	0.66 to 4.63 .....	One event in 3 months to 2 years.	
		Hypothetical Nuclear Attack.	< 0.01 to 0.02 .....	One event in 60 to 400 years.	
		Hypothetical Biological Attack.	0.02 to 0.16 .....	One event in 6 to 50 years.	
<b>Alternative 4: Additional Carrier Requirements only</b>					
3% .....	\$2 million to \$11 million.	Actual West Coast Port Shutdown (12-days).	< 0.01 to 0.01 .....	One event in 100 to 700 years.	Least cost, but also least effective alternative. Does not meet the statutory requirements of Section 203 of the SAFE Port Act nor provide data on shipment history. Importer Security Filings and Additional Carrier Requirements are not working in tandem.
		Hypothetical Nuclear Attack.	< 0.01 .....	One event in 40,000 to 200,000 years.	
		Hypothetical Biological Attack.	< 0.01 .....	One event in 4,000 to 20,000 years.	
7% .....	\$2 million to \$12 million.	Actual West Coast Port Shutdown (12-days).	< 0.01 to 0.01 .....	One event in 100 to 600 years.	
		Hypothetical Nuclear Attack.	< 0.01 .....	One event in 30,000 to 200,000 years.	
		Hypothetical Biological Attack.	< 0.01 .....	One event in 4,000 to 20,000 years.	

The annualized cost range presented in each cell results from varying assumptions about the estimated initial and transaction costs for Importer Security Filings, the potential for supply chain delays, and the estimated costs to transmit Vessel Stow Plans and CSMs to CBP.

To estimate the full range of the total costs for complying with the rule, for the four alternatives we develop a high cost scenario and a low cost scenario by assuming certain values for the key cost factors. Annualized costs for Alternatives 1 through 3 range from \$890 million to \$7.0 billion, depending on the discount rate applied, the cost scenario, whether or not bulk shipments are exempt, and whether or not the

Additional Carrier Requirements are required. The annualized costs for Alternative 4 are substantially lower, ranging from \$2 million to \$12 million. However, this alternative is the least stringent and effective option because it only collects data on the conveyance of the shipment.

Ideally, the quantification and monetization of the benefits of this regulation would involve estimating the current level of risk of a successful terrorist attack, absent this regulation, and the incremental reduction in risk resulting from implementation of the rule. We would then multiply the change by an estimate of the value individuals place on such a risk reduction to produce a monetary

estimate of direct benefits. However, existing data limitations and a lack of complete understanding of the true risks posed by terrorists prevent us from establishing the incremental risk reduction attributable to this rule. As a result, we undertake a break-even analysis to inform decision-makers of the necessary incremental change in the probability of such an event occurring that would result in direct benefits equal to the costs of the rule.

In the break-even analysis, we identify three types of terrorist attack scenarios that may be prevented by the regulation and obtain cost estimates of the consequences of these events from publicly available literature. The analysis compares the annualized costs

of the regulation to the avoided costs of each event to estimate the reduction in the probability of such events (also presented in terms of "odds," e.g., a 0.25 reduction in the probability of an event occurring in a single year implies that one additional event must be avoided in a four-year period) that must be achieved for the benefits of the regulation to equal the costs. The reduction in the odds of terrorist events are rough estimates that do not take into account changes in risk through time or factors that may affect willingness to pay to avoid the consequences of these events, such as changes in income.

For each attack scenario, Table 1 indicates what would need to occur for the costs of each alternative to equal its benefits, assuming the alternative only reduces the risk of a single event of that type of attack. As summarized in Table 1, the break-even risk reductions for Alternative 4 are significantly lower than the other three alternatives, reflecting the significantly lower costs associated with requiring only the Additional Carrier Requirements. The breakeven results for the remaining three alternatives are similar because the costs of these options are not very different. For the most severe attack scenario (a hypothetical nuclear attack in a major city), the rule must result in the avoidance of one such event in a time period of 60 to 500 years for the benefits of the regulation to equal the

costs. For the least severe of the three hypothetical attack scenarios (costs of the actual 12-day West Coast port shutdown), the estimated costs of a single incident are closer in value to the annualized costs of the rule. As a result, if the rule only reduced the risk of a single attack on a port, a shutdown would need to be avoided at a rate of once in three months to two years for the benefits of the rule to equal costs. The results expressed as absolute reductions in baseline risk also show higher reductions needed if port attacks only are mitigated (about 0.59 to 4.65) and lesser reductions associated with prevention of the more catastrophic events. We note that this analysis is highly sensitive to the chosen incident scenarios.

Total present value costs of the rule are presented in Table 2, based on the cost projections we estimate for the 10-year analysis period, 2009 through 2018. Applying a discount rate of three percent, the total costs of Alternatives 1, 2, and 3 are projected to range from \$7.6 billion to \$56 billion over 10 years depending on the cost scenario, whether or not bulk shipments are exempt, and whether or not Additional Carrier Requirements are required. If a discount rate of seven percent is applied instead, total costs range from \$7.0 billion to \$49 billion. Under Alternative 2, which requires Importer Security Filings for both non-bulk cargo and bulk cargo,

costs are not significantly higher because the number of bulk shipments is relatively small compared to the number of non-bulk shipments. Under Alternative 3, costs are not significantly lower because the estimated costs for the Additional Carrier Requirements are relatively small compared to the estimated costs for the Importer Security Filings. The present value costs for Alternative 4 are significantly lower than the other three alternatives, ranging from \$16 million to \$95 million.

As a result, the relatively large difference in values between the lower end (e.g., present value cost of \$7.6 billion at a discount rate of three percent) and higher end (\$56 billion) of the estimated total cost range for Alternatives 1, 2, and 3 is attributable primarily to the cost scenario and not on whether or not Importer Security Filings for bulk shipments or the Additional Carrier Requirements are required. The higher end of the estimated total cost range reflects the variations made for the high cost scenario, and more specifically, the assumption that delays in the supply chain would occur as a result of this rule. For the high cost scenario, our present value estimate of the welfare loss to U.S. importers arising from delays in the supply chain is approximately \$43 billion (at a discount rate of three percent).

TABLE 2—TOTAL PRESENT VALUE COSTS, 2009–2018 \$2008

Discount rate	Present value costs
<b>Alternative 1 (chosen alternative): Importer Security Filings and Additional Carrier Requirements, bulk cargo exempt</b>	
3% .....	\$7.6 billion to \$56 billion.
7% .....	\$7.0 billion to \$49 billion.
<b>Alternative 2: Importer Security Filings and Additional Carrier Requirements, bulk cargo not exempt</b>	
3% .....	\$7.6 billion to \$56 billion.
7% .....	\$7.0 billion to \$49 billion.
<b>Alternative 3: Importer Security Filings only, bulk cargo exempt</b>	
3% .....	\$7.6 billion to \$56 billion.
7% .....	\$7.0 billion to \$49 billion.
<b>Alternative 4: Additional Carrier Requirements only</b>	
3% .....	\$0.02 billion to \$0.1 billion.
7% .....	\$0.02 billion to \$0.09 billion.

Again, the range presented in each cell results from varying assumptions about the estimated initial and transaction costs for Importer Security

Filings, the potential for supply chain delays, and the estimated costs to transmit Vessel Stow Plans and CSMs to CBP.

Annual undiscounted costs of the regulation are presented in Table 3.

TABLE 3—ANNUAL UNDISCOUNTED COSTS BY YEAR, 2009–2018 (\$2008, IN MILLIONS)

Year	Alternative 1 (chosen alternative): importer security filings and additional carrier requirements, bulk cargo exempt	Alternative 2: importer security filings and additional carrier requirements, bulk cargo not exempt	Alternative 3: importer security filings only, bulk cargo exempt	Alternative 4: additional carrier requirements only
2009	\$1,900 to \$11,000	\$1,900 to \$11,000	\$1,900 to \$11,000	\$0.4 to \$14.
2010	1,900 to 7,100	1,900 to 7,100	1,900 to 7,100	0.4 to 14.
2011	1,900 to 7,300	1,900 to 7,300	1,900 to 7,300	0.4 to 14.
2012	290 to 4,600	290 to 4,600	290 to 4,600	0.3 to 7.
2013	310 to 4,800	310 to 4,800	310 to 4,800	0.3 to 7.
2014	320 to 5,100	330 to 5,100	320 to 5,100	0.3 to 7.
2015	340 to 5,300	340 to 5,300	340 to 5,300	0.3 to 7.
2016	360 to 5,600	360 to 5,600	360 to 5,600	0.3 to 7.
2017	380 to 5,900	380 to 5,900	380 to 5,900	0.3 to 7.
2018	400 to 6,200	400 to 6,300	400 to 6,200	0.4 to 7.

As shown in Table 3, annual discounted costs are highest in the first years of implementation, then decrease notably, then steadily increase for the remainder of the 10-year period of analysis. Costs are highest in the first year as the potential for supply chain delays are greatest during initial implementation of the rule. Also in the first years of implementation, we account for software costs incurred by those importers who import frequently to the United States. These software costs are amortized over the first three years (until 2011), not for the full 10 years of the analysis. Steady increases from 2012 to the end of the analysis period reflect our projected annual increases in the number of shipments, the value of shipments, and the vessel-trips into the United States.

The results indicate that Alternative 1 provides the most favorable combination of cost and stringency. While Alternative 2 might be considered more stringent because it does not exempt bulk cargo from the Importer Security Filing requirements, the impact of this is expected to be slight, because the number of bulk shipments is relatively small compared to the number of non-bulk shipments. Alternative 3 is expected to have costs similar to Alternative 1, but will be less stringent because it only requires Importer Security Filings and does not include data that verify the information on the cargo manifest and identify and track the movement, location, and status of

cargo (and in particular, containerized cargo) from the time its transport is booked until its arrival in the United States. Without the Additional Carrier Requirements, CBP will not be able to assess the specific risks associated with the many individual movements and transfers involved in shipping cargo to the United States. Thus, an important element of CBP's layered, risk-based approach to cargo security would, consequently, be omitted.

Alternatives 3 and 4 are not chosen, in part, because it is CBP's judgment that neither of these options will be as effective as the selected option. Specifically, the Importer Security Filing requirements and the Additional Carrier Requirements work in tandem. The Additional Carrier Requirements focus on the conveyance of the goods and are distinct from the Importer Security Filing elements, which are focused on the merchandise and the parties involved in the acquisition process. Specifically, Vessel Stow Plans will assist CBP in validating other advanced cargo information submissions by allowing CBP to, among other things, better detect unmanifested containers without relying on physical verification methods that are manpower intensive and costly. CSMS will provide CBP with additional transparency into the custodial environment through which inter-modal containers are handled and transported before arrival in the United States. Because CSMS are created independently of the manifest,

CBP can utilize them to corroborate other advanced data elements, including Importer Security Filings and those elements related to container and conveyance origin. This corroboration with other advanced data messages, including Importer Security Filings, and an enhanced view into the international supply chain will contribute to the security of the United States and the international supply chain through which containers and imported cargo are shipped to U.S. ports.

Based on this analysis of alternatives, CBP has determined that Alternative 1 provides the most favorable balance between security outcomes and impacts to maritime transportation. As summarized in Table 4, the incremental costs of this regulation, on a per-shipment basis, is a small fraction of the value of a shipment. The relatively high cost of the rule over 10 years is driven by the large volume of shipments rather than high per-transaction costs. Shipment data indicate that the median value of a shipment of goods imported into the United States is approximately \$38,000. As shown in Table 4, the increase in costs of imported shipments will range from \$48 to \$390 per shipment, depending on the discount rate applied, the cost scenario, and whether or not bulk shipments are exempt. The added costs of this regulation are estimated to be only 0.13 percent to 1.03 percent of the median value of \$38,000 per shipment.

TABLE 4—COSTS PER SHIPMENT, MEDIAN VALUE OF SHIPMENT, VESSEL-TRIP, AND CARRIER (\$2008)

	3% discount rate	7% discount rate
<b>Importer Security Filing Costs: Alternatives 1 and 3 (bulk cargo exempt)</b>		
Total Present Value Cost	\$7.5 billion to \$56 billion	\$6.9 billion to \$49 billion.
Number of shipments (10-year total)	144 million	144 million.
Equivalent per shipment cost	\$52 to \$390	\$48 to \$341.

TABLE 4—COSTS PER SHIPMENT, MEDIAN VALUE OF SHIPMENT, VESSEL-TRIP, AND CARRIER—Continued  
[\$2008]

	3% discount rate	7% discount rate
Median value per shipment .....	\$37,900 .....	\$37,900.
Cost per median value .....	0.14 to 1.03 percent .....	0.13 to 0.90 percent.
<b>Importer Security Filing Costs: Alternative 2 (bulk cargo not exempt)</b>		
Total Present Value Cost .....	\$7.6 billion to \$56 billion .....	\$7.0 billion to \$49 billion.
Number of shipments (10-year total) .....	145 million .....	145 million.
Equivalent per shipment cost .....	\$52 to \$388 .....	\$48 to \$339.
Median value per shipment .....	\$38,200 .....	\$38,200.
Cost per median value .....	0.14 to 1.02 percent .....	0.13 to 0.89 percent.
<b>Vessel Stow Plan Costs: Alternatives 1, 2, and 4</b>		
Total present value cost .....	\$3 million to \$27 million .....	\$2 million to \$33 million.
Number of non-bulk vessel-trips, small and large carriers (10-year total) .....	294,000 .....	294,000.
Equivalent per vessel-trip cost .....	\$9 to \$90 .....	\$8 to \$78.
<b>Container Status Message Costs: Alternatives 1, 2, and 4</b>		
Total present value cost .....	\$0.3 million to \$54 million .....	\$0.3 million to \$48 million.
Number of container carriers, large .....	74 .....	74.
Equivalent per carrier cost .....	\$3,900 to \$730,000 .....	\$3,700 to \$650,000.

The rule may increase the time shipments are in transit, particularly for shipments conveyed in containers. Especially for shipments consolidated in containers, the supply chain is generally more complex and the importer has less control of the flow of goods and exchange of associated security filing information. Foreign cargo consolidators may be consolidating multiple shipments from one or more shippers in a container destined for one or more buyers or consignees. In order to ensure that the security filing data are provided by the shippers to the ISF Importers (or their designated agents) and is then transmitted to and accepted by CBP in advance of the 24 hour deadline, carriers and consolidators may advance their cut-off times for receipt of shipments and associated Importer Security Filing data.

These advanced cut-off times would help prevent a carrier or consolidator from having to unpack or unload a container in the event the security filing for one of the shipments contained in the container is inadequate or not accepted by CBP. For example, carriers or consolidators may require shippers to submit, transmit, or obtain CBP acceptance of their security filing data before their shipments are stuffed in the container, before the container is sealed, or before the container is delivered to the port for lading. In such cases, importers may experience additional delays in their supply chain to accommodate these advanced cut-off

times imposed by their carriers or consolidators. The costs associated with these delays include: (1) Higher inventory carrying costs; (2) the need to hold larger buffer-stock inventories to accommodate variation in arrival time; (3) depreciation in shipment value; (4) costs of storage at the manufacturer, freight forwarder, consolidator, or port; and (5) costs for additional security to protect the freight from tampering. To capture all of these costs in our estimate of the impact of time delays, we estimate the welfare loss to U.S. importers by relying on estimates of the willingness to pay for reducing transit time. The high end of the cost ranges presented in Table 4 assumes an initial supply chain delay of three days (consolidated container shipments) or two days (unconsolidated or full container shipments) for the first year of implementation (2009) and a delay of one day for years 2 through 10 (2010–2018).

#### B. Regulatory Flexibility Act

In response to the requirements of the Regulatory Flexibility Act (RFA) of 1980, as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) and Executive Order 13272, entitled "Proper Consideration of Small Entities in Agency Rulemaking," federal agencies must consider the potential distributional impact of rules on small businesses, small governmental jurisdictions, and small organizations during the development of their rules.

The types of entities subject to the rule's requirements include all importers receiving shipments via vessel and all vessel operating common carriers (VOCCs) transporting containerized shipments via vessel to the United States. One, the other, or both of the types of entities will be affected depending on the alternative under consideration. The results of our screening analysis indicated that the proposed rule may significantly impact a substantial number of small importers or carriers, and CBP conducted an Initial Regulatory Flexibility Analysis (IRFA) to further assess these impacts. The IRFA provided a detailed analysis of the potential impact of the proposed rule on small entities and was made available for public comment at the same time as the proposed rule on January 2, 2008.

At the publication of the interim final rule, if CBP still determines that it cannot certify the rule, then it must prepare and make available a Final Regulatory Flexibility Analysis (FRFA). As discussed below, CBP cannot certify that the rule will not have a significant impact on a substantial number of small importers. It can certify the rule relative to the impact on small carriers; however, for the purpose of simplicity, the FRFA presented here includes both importers and carriers. The following is a summary of the FRFA. For full details on the complete analysis, please refer to the Final Regulatory Flexibility Act analysis contained in the "Regulatory Assessment," which can be found in the

docket for this rulemaking: <http://www.regulations.gov>; see also <http://www.cbp.gov>. CBP invites comments on this FRFA and will update it with the final rule.

*A succinct statement of the objectives of, and legal basis for, the rule:* Section 203(b) of the Security and Accountability for Every Port Act (SAFE Port Act) of 2006 states that the Secretary of Homeland Security "shall require the electronic transmission to the Department of additional data elements for improved high-risk targeting, including appropriate elements of entry data \* \* \* to be provided as advanced information with respect to cargo destined for importation into the United States prior to loading of such cargo on vessels at foreign ports." The information required is that which is reasonably necessary to enable high-risk shipments to be identified so as to prevent smuggling and ensure cargo safety and security pursuant to the laws enforced and administered by CBP. In addition, section 343(a) of the Trade Act of 2002 states that the Secretary of Homeland Security "shall promulgate regulations providing for the transmission \* \* \* of information pertaining to cargo destined for importation into the United States.\* \* \*"

*A summary of the significant issues raised by the public comments in response to the IRFA, a summary of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments:* CBP received several comments specifically addressing impacts to small entities.

Comments suggested that CBP should consider an exemption of small business from some requirements of the rule. CBP believes that the language of the SAFE Port Act does not allow it to exempt small entities from the regulation. Furthermore, although we do not have explicit information regarding the portion of importers who are small entities, the information provided in the screening analysis suggests that the majority of affected entities are likely to be small businesses. Exempting most importers would significantly diminish the effectiveness of the rule.

Comments suggested that CBP attempt to calculate the number of entities that will cease operations as a result of the requirements of the rule. Data are not readily-available that would allow us to segregate all the importers in the PIERS dataset, which was the primary dataset used in the primary analysis (summarized in the previous section), the IRFA, and the FRFA by North American Industry Classification System (NAICS) code. This step is necessary to identify the proportion of small entities affected by the rule. Furthermore, we are unable to estimate a distribution of the number of shipments by industry and size category. As a result, given the currently available data, we are unable to estimate the magnitude of the impact to small entities in each industry and the number of businesses that may be forced to cease operations as a result of the rule.

Comments reported that the costs associated with software purchase were underestimated for small entities. In response to these comments, we revised the primary analysis and the FRFA to include initial, one-time costs of \$25,000 to address this perceived understatement of costs in the Regulatory Assessment that accompanied the proposed rule. Note that we assume importers transporting only one shipment annually do not incur this cost.

Commenters suggested that CBP conduct a prototype test with small entity volunteers to better understand the potential impact to these businesses. CBP is adopting a delayed compliance period whereby CBP will work with the trade following the effective date of the interim final rule to assist them in achieving full compliance with minimal disruption. See the "Structured Review and Flexible Enforcement Period" section of this document for further discussion regarding the delayed compliance period. The interim final rule also provides flexibility with respect to certain elements of the Importer Security Filings. Additionally, as part of CBP's pre-existing Advance Trade Data Initiative (ATDI), CBP has worked with a wide variety of volunteers from the world trade

community to test the trade's ability to provide data, including some elements of the Importer Security Filing, to CBP. ATDI has proven that the industry has access to the required data and can get the data to CBP.

*A description of, and, where feasible, an estimate of the number of small entities to which the rule will apply:* As discussed earlier, the interim final rule applies to all entities importing containerized, break-bulk, or Ro-Ro shipments into the United States. The regulation also applies to VOCCs transporting shipments via vessel to the United States. The majority of the affected entities are likely to be small. In the summary of impacts presented here, we focus on Alternative 1, the chosen alternative and the interim final rule. For the complete results for all alternatives, please refer to the detailed Final Regulatory Flexibility Act analysis, which is contained in the "Regulatory Assessment," which can be found in the docket for this rulemaking: <http://www.regulations.gov>; see also <http://www.cbp.gov>.

The regulation will affect importers in the form of initial, one-time costs and transaction fees for collecting and transmitting the security filing as well as consumer surplus losses if the rule delays the supply chain. For the purposes of our screening analysis, importers are not an industry as defined by SBA. Rather, many industries import goods subject to the rule. We must determine the number of importers that belong to each of these industries, and then determine the appropriate industry-specific measure of a "small entity."

Our PIERS dataset includes information on over 200,000 unique importers. We took a random sample of importers from the dataset and collected market data on the entities from Dun & Bradstreet until we had information describing 400 entities (a statistically significant sample, 5 percent margin of error). Table 5 details the top industries importing containerized cargo, identified by NAICS code, in our sample and ranks them by number of occurrences.

TABLE 5—TOP INDUSTRIES FROM IMPORTERS SAMPLE (CONTAINERIZED CARGO)

NAICS code	Number of occurrences	Percent of sample	Industry description
424900 .....	20	5.00	Miscellaneous Nondurable Goods Merchant Wholesalers.
999990 .....	19	.....	UNKNOWN INDUSTRY.
423830 .....	13	3.25	Industrial Machinery and Equipment Merchant Wholesalers.
442110 .....	11	2.75	Furniture Stores.
488510 .....	10	2.50	Freight Transportation Arrangement.
423220 .....	8	2.00	Home Furnishing Merchant Wholesalers.

TABLE 5—TOP INDUSTRIES FROM IMPORTERS SAMPLE (CONTAINERIZED CARGO)—Continued

NAICS code	Number of occurrences	Percent of sample	Industry description
423120 .....	7	1.75	Motor Vehicle Supplies and New Parts Merchant Wholesalers.
423710 .....	7	1.75	Hardware Merchant Wholesalers.
424320 .....	7	1.75	Men's and Boys' Clothing and Furnishings Merchant Wholesalers.
424330 .....	7	1.75	Women's, Children's, and Infants' Clothing and Accessories Merchant Wholesalers.
424490 .....	7	1.75	Other Grocery and Related Products Merchant Wholesalers.
423910 .....	6	1.50	Sporting and Recreational Goods and Supplies Merchant Wholesalers.
326199 .....	5	1.25	All Other Plastics Product Manufacturing.
423690 .....	5	1.25	Other Electronic Parts and Equipment Merchant Wholesalers.
423990 .....	5	1.25	Other Miscellaneous Durable Goods Merchant Wholesalers.
424310 .....	5	1.25	Piece Goods, Notions, and Other Dry Goods Merchant Wholesalers.
561499 .....	5	1.25	All Other Business Support Services.
423210 .....	4	1.00	Furniture Merchant Wholesalers.
423430 .....	4	1.00	Computer and Computer Peripheral Equipment and Software Merchant Wholesalers.
423440 .....	4	1.00	Other Commercial Equipment Merchant Wholesalers.
423450 .....	4	1.00	Medical, Dental, and Hospital Equipment and Supplies Merchant Wholesalers.
424460 .....	4	1.00	Fish and Seafood Merchant Wholesalers.
424480 .....	4	1.00	Fresh Fruit and Vegetable Merchant Wholesalers.
442299 .....	4	1.00	All Other Home Furnishings Stores.
453220 .....	4	1.00	Gift, Novelty, and Souvenir Stores.
236115 .....	3	0.75	New Single-Family Housing Construction (except Operative Builders).
315191 .....	3	0.75	Outerwear Knitting Mills.
325620 .....	3	0.75	Toilet Preparation Manufacturing.
332510 .....	3	0.75	Hardware Manufacturing.
333911 .....	3	0.75	Pump and Pumping Equipment Manufacturing.
423320 .....	3	0.75	Brick, Stone, and Related Construction Material Merchant Wholesalers.
423390 .....	3	0.75	Other Construction Material Merchant Wholesalers.
423940 .....	3	0.75	Jewelry, Watch, Precious Stone, and Precious Metal Merchant Wholesalers.
424130 .....	3	0.75	Industrial and Personal Service Paper Merchant Wholesalers.
424340 .....	3	0.75	Footwear Merchant Wholesalers.
441310 .....	3	0.75	Automotive Parts and Accessories Stores.
	207	51.75	ALL OTHER INDUSTRIES RECORDED IN SAMPLE.

In most industries, information on revenues or number of employees is used to define whether an entity is "small" for the purpose of RFA/SBREFAs analyses. For the top ten

industries appearing in our sample, Table 6 reports SBA's thresholds used to define "small" entities in each industry and the share of entities in the United States that meet that definition. For each

industry, the share of entities considered small is at least 50 percent. For most industries, the share of entities considered small is at least 75 percent.

TABLE 6—SHARE OF SMALL ENTITIES IN EACH OF THE TOP 10 INDUSTRIES (CONTAINERIZED CARGO)

NAICS code	Industry description	Percent of sample	"Small" threshold	Share of small entities in U.S. (percent)
424900 .....	Miscellaneous Nondurable Goods Merchant Wholesalers .....	5.00	100 employees .....	93
423830 .....	Industrial Machinery and Equipment Merchant Wholesalers	3.25	100 employees .....	92
442110 .....	Furniture Stores .....	2.75	\$6.5 million .....	50
488510 .....	Freight Transportation Arrangement .....	2.50	\$6.5 million .....	75
423220 .....	Home Furnishing Merchant Wholesalers .....	2.00	100 employees .....	75
423120 .....	Motor Vehicle Supplies and New Parts Merchant Wholesalers.	1.75	100 employees .....	71
423710 .....	Hardware Merchant Wholesalers .....	1.75	100 employees .....	86
424320 .....	Men's and Boys' Clothing and Furnishings Merchant Wholesalers.	1.75	100 employees .....	83
424330 .....	Women's, Children's, and Infants' Clothing and Accessories Merchant Wholesalers.	1.75	100 employees .....	100
424490 .....	Other Grocery and Related Products Merchant Wholesalers	1.75	100 employees .....	86

Table 7 reports summary statistics on our sample of 400 importers. For example, it shows that four industries appeared more than ten times in the

sample, accounting for 54 individual firms. Within the United States, there are 81,923 entities in those four industries, and 96.4 percent of those

businesses meet SBA's definition of a small entity.

TABLE 7—CONTAINERIZED CARGO IMPORTERS, SUMMARY STATISTICS

Number of appearances in sample	Number of industries in sample	Number of firms in sample	Total number of entities in U.S.	Number of small entities in U.S.	Share small (percent)
10+ .....	4	54	81,923	78,977	96.4
6-9 .....	7	49	1,371,759	1,341,422	97.8
5 .....	5	25	33,931	32,558	96.0
4 .....	8	32	72,596	70,829	97.6
3 .....	11	33	44,448	42,977	96.7
2 .....	27	54	467,998	461,318	98.6
1 .....	152	153	834,709	812,717	97.4
Total .....	214	400	2,907,364	2,840,798	97.7

Based on these summary statistics, we conclude that the majority of firms in industries conducting importing activities are likely to be small entities. Therefore, a *substantial* number of small entities are likely to be affected by the rule. Next, we estimate whether the costs to these importers of implementing the regulation are likely to be significant.

Typically, Federal agencies compare per-business compliance costs to annual revenues of small entities in various size classes to determine the impact of the regulation on small entities. For this rule, such a comparison requires a significant amount of data given that the rule potentially affects hundreds of industries. Annual compliance costs are driven by the number of shipments an importer makes security filings on each year. To estimate the number of shipments per small entity, we ideally would: (1) Take our PIERS dataset of shipments and group the shipments by business; (2) group the businesses by NAICS code; (3) determine the number of businesses in each NAICS code that meet the definition of a small entity; (4) and examine the number and value of shipments by those entities.

We have completed the first step: Identifying approximately 200,000 importers in our sample dataset. As

discussed previously, we were able to use Dun and Bradstreet data to identify the appropriate NAICS code for 400 of these 200,000 importers. Next, we conservatively assume that the majority of importers in each NAICS code are small entities. However, estimating the typical number of shipments in each industry is problematic. In 75 percent of the industries identified in our sample of 400 importers, the number of entities affected is less than five. Although we have shipment data for these businesses, these data are unlikely to provide a meaningful sample of shipment volume or value on an industry by industry basis.

Alternatively, when we extrapolate our PIERS dataset to estimate shipments for the entire year, we are able to calculate lower and upper bound estimates of the number of importers and stratify these importers by shipping volume. However, we cannot reliably translate this stratification on a per-industry basis. More importantly, we do not believe that shipment volume is necessarily a good predictor of whether an entity is considered to be a small business in its industry. For example, a small entity with a business model that is heavily dependent on overseas manufacturers may import many

shipments a month, while a large entity relying primarily on domestic suppliers may import only one shipment a year.

For these reasons, we are unable to estimate average shipment volume for small entities, preventing us from comparing compliance costs to importers' revenues. Instead, we compare per-shipment compliance costs to the average value of all affected shipments. This comparison may over- or understate small entities' per-shipment compliance costs if their shipment value is higher or lower than the average. In addition, the ratio of compliance costs to shipment value may under- or overstate the significance of the costs depending on the purpose of those shipments and their resale value in the United States.

We calculate information on the mean value of shipments from the PIERS database for all industries identified in our sample. We include all shipments associated with an entity identified within a certain industry. Table 8 presents the mean shipment value and the number of shipments for each of the top 10 industries. These mean values are provided simply for illustration of our data limitations and to provide a sense of the range of mean shipment values.

TABLE 8—MEAN VALUE PER SHIPMENT IN THE TOP 10 INDUSTRIES (CONTAINERIZED CARGO)

NAICS code	Number of importers	Total number of shipments	Mean value per shipment (\$)
424900 .....	20	114	\$173,683
423830 .....	13	51	47,250
442110 .....	11	27	22,081
488510 .....	10	175	107,828
423220 .....	8	76	45,342
423120 .....	7	60	72,895
424330 .....	7	25	181,893
424320 .....	7	121	130,213
423710 .....	7	49	36,614
424490 .....	7	10	18,354

Table 9 reports the initial, one-time costs (reported on a per-shipment basis) and the security filing fee for importer frequency classes. In addition, the table reports the percentage share that the cost of the security filing requirements plays as a part of the mean value per

shipment. In each case presented below, the security filing cost represents an increase of less than 4.7 percent of the value of the shipment. We recognize that small entities' mean value per shipment may be higher or lower than \$103,164; therefore, the impact to small

entities may be greater than the percentages reported in the table. The results suggest that costs of complying with the rule may be *significant* relative to the value of an affected shipment.

TABLE 9—RELATIVE COST OF SECURITY FILING REQUIREMENTS (CONTAINERIZED CARGO)

NAICS code	Number of entities	Number of shipments	Security filing fee	Initial, one-time fee (per entity per shipment)	Total cost as share of mean value (percent)
<b>Lower Bound Estimate:</b>					
Once per year .....	0	0	\$75.00	.....	0.07
Twice yearly to less than monthly .....	134,000	697,000	60.00	\$4,817	4.73
Monthly to less than weekly .....	44,100	1,230,000	45.00	900	0.92
Weekly to less than daily .....	9,900	2,190,000	30.00	113	0.14
Daily or greater .....	615	2,360,000	15.00	7	0.02
Anonymous .....	38,000	1,300,000	22.50	730	0.73
<b>Upper Bound Estimate:</b>					
Once per year .....	370,000	456,000	75.00	.....	0.07
Twice yearly to less than monthly .....	262,000	1,380,000	60.00	4,740	4.65
Monthly to less than weekly .....	66,900	1,640,000	45.00	1,017	1.03
Weekly to less than daily .....	18,100	1,810,000	30.00	250	0.27
Daily or greater .....	1,480	1,180,000	15.00	31	0.04
Anonymous .....	144,000	1,300,000	22.50	2,776	2.71

In our upper-bound impact estimate, importers of containerized shipments may also experience a loss in consumer surplus associated with delays. While these losses represent lost value, they do not represent actual expenditures. The

impact of these losses on small entities is unknown.

The PIERS dataset includes information on over 4,600 unique break-bulk importers. We took a random sample from that dataset and collected

financial information on the entities from Dun & Bradstreet until we had data on 75 entities. Table 10 details the top industries in our sample ranked by number of occurrences.

TABLE 10—TOP INDUSTRIES FROM IMPORTERS SAMPLE (BREAK-BULK CARGO)

NAICS code	Number of occurrences	Percentage	Industry description
423510 .....	8	10.67	Metal Service Centers and Other Metal Merchant Wholesalers.
423310 .....	6	8.00	Lumber, Plywood, Millwork, and Wood Panel Merchant Wholesalers.
336611 .....	4	5.33	Ship Building and Repairing.
999990 .....	4	.....	UNKNOWN INDUSTRY.
424480 .....	3	4.00	Fresh Fruit and Vegetable Merchant Wholesalers.
488510 .....	3	4.00	Freight Transportation Arrangement.
423830 .....	2	2.67	Industrial Machinery and Equipment Merchant Wholesalers.
424410 .....	2	2.67	General Line Grocery Merchant Wholesalers.
424470 .....	2	2.67	Meat and Meat Product Merchant Wholesalers.
424490 .....	2	2.67	Other Grocery and Related Products Merchant Wholesalers.
424690 .....	2	2.67	Other Chemical and Allied Products Merchant Wholesalers.
511110 .....	2	2.67	Newspaper Publishers.
.....	39	52.00	ALL OTHER INDUSTRIES RECORDED IN SAMPLE.

We present the share of entities considered small in each of the top ten industries from our PIERS sample. Table 11 reports those definitions of "small"

from the SBA and the share of entities that are small. For most industries, the share of entities considered small is at least 75 percent. Therefore, we assume

that a *substantial* number of small break-bulk importers will be affected by the rule.



TABLE 11—SHARE OF SMALL ENTITIES IN THE TOP 10 INDUSTRIES (BREAK-BULK CARGO)

NAICS code	Industry description	Percent of sample	"Small" threshold	Share of small entities (percent)
423510	Metal Service Centers and Other Metal Merchant Wholesalers.	10.67	100 employees	63
423310	Lumber, Plywood, Millwork, and Wood Panel Merchant Wholesalers.	8.00	100 employees	100
336611	Ship Building and Repairing	5.33	1,000 employees	75
424480	Fresh Fruit and Vegetable Merchant Wholesalers	4.00	100 employees	33
488510	Freight Transportation Arrangement	4.00	\$6.5 million	0
423830	Industrial Machinery and Equipment Merchant Wholesalers	2.67	100 employees	100
424410	General Line Grocery Merchant Wholesalers	2.67	100 employees	100
424470	Meat and Meat Product Merchant Wholesalers	2.67	100 employees	100
424490	Other Grocery and Related Products Merchant Wholesalers	2.67	100 employees	100
424690	Other Chemical and Allied Products Merchant Wholesalers	2.67	100 employees	50

Table 12 reports summary statistics on our sample of 75 break-bulk importers. Only two industries appeared in the sample more than five times, accounting for 14 firms. For all industries importing break-bulk shipments, over 93 percent of the firms in that industry are small entities.

TABLE 12—BREAK-BULK IMPORTERS, SUMMARY STATISTICS

Number of appearances in sample	Number of industries in sample	Number of firms in sample	Total number of entities in U.S.	Number of small entities in U.S.	Share small (percent)
6+	2	14	13,771	12,883	93.6
5	0	0			(1)
4	1	4	1,670	1,642	98.3
3	2	6	16,228	15,552	95.8
2	6	12	49,028	46,938	95.7
1	34	39	196,116	186,854	95.3
Total	45	75	276,813	263,869	95.3

<sup>1</sup> Not applicable.

Table 13 details the mean shipment value and the number of shipments for each of the top 10 industries. These mean values are provided simply for illustration of our data limitations and to provide a sense of the range of mean shipment values.

TABLE 13—MEAN VALUE PER SHIPMENT IN THE TOP TEN INDUSTRIES (BREAK-BULK CARGO)

NAICS code	Number of importers	Total number of shipments	Mean value per shipment (\$)
423510	8	922	\$145,731
423310	6	28	303,095
336611	4	10	509,161
424480	3	238	77,106
488510	3	31	520,999
423830	2	2	743,823
424410	2	10	140,086
424470	2	16	40,493
424490	2	13	76,597
424690	2	68	56,595

Table 14 reports the initial, one-time costs (reported on a per-shipment basis) and the security filing fee for importer frequency classes. In addition, the table reports the percentage share that the cost of the security filing requirements plays as a part of the mean value per shipment. In each case presented below, the security filing cost represents an increase of less than 2 percent of the value of the shipment. In most cases, the security filing cost represents an increase of less than 0.4 percent of the value of the shipment. We recognize that small entities' mean value per shipment may be higher or lower than \$309,174; therefore, the filing costs may represent a smaller or larger percentage of the total value.

TABLE 14—RELATIVE COST OF SECURITY FILING REQUIREMENTS (BREAK-BULK CARGO)

NAICS code	Number of entities	Number of shipments	Security filing fee	Initial, one-time fee (per entity per shipment)	Total cost as share of mean value (percent)
Lower Bound Estimate:					
Once per year .....	0	0	\$75.00	.....	0.02
Twice yearly to less than monthly .....	2,740	11,400	60.00	6,013	1.96
Monthly to less than weekly .....	693	15,700	45.00	1,104	0.37
Weekly to less than daily .....	216	42,400	30.00	127	0.05
Daily or greater .....	14	60,000	15.00	6	0.01
Anonymous .....	272	9,630	22.50	707	0.24
Upper Bound Estimate:					
Once per year .....	7,870	7,870	75.00	.....	0.02
Twice yearly to less than monthly .....	4,470	18,200	60.00	6,157	2.01
Monthly to less than weekly .....	1,050	25,400	45.00	1,032	0.35
Weekly to less than daily .....	490	56,100	30.00	218	0.08
Daily or greater .....	30	21,900	15.00	35	0.02
Anonymous .....	1,040	9,630	22.50	2,686	0.88

The security filing cost as a share of the mean value of shipments made by other industries (outside of the top 10) is in many instances higher than 1 percent. Therefore, we would ideally compare each entity's total annual compliance costs to annual revenues. However, based on our 96-day PIERS data sample set, we are not able to predict the number of break-bulk shipments made each year by these entities. Therefore, we cannot predict annual compliance costs and are unable to make a determination as to whether the effects of the rule are *significant* for a substantial number of small break-bulk importers.

We do not complete the same analysis for roll-on/roll-off (Ro-Ro) cargo importers. We referenced Dun & Bradstreet for information on approximately 100 importers and found that information was only available for six entities. A closer examination of the 100 importers suggested that the majority are private individuals, which are not considered small entities.

According to the SBA-defined small business size standards for Vessel Operating Common Carriers (VOCCs), which fall under NAICS 483111 (Deep Sea Freight Transportation), firms with fewer than 500 employees are

considered to be small entities. Dun and Bradstreet's Market Identifiers report 492 entities operating within NAICS 483111. Of these 492 entities, 477 are firms that report fewer than 500 employees.

We have concerns about the reliability of the Dun & Bradstreet data in the case of this particular business area. First, CBP's Vessel Automated Manifest System (Vessel AMS) database identifies 1,179 carriers importing shipments to the United States in 2005. This is more than double the number of entities identified in the Dun & Bradstreet list or the 487 entities identified by the U.S. Census Bureau. It would appear that a considerable number of VOCCs do not have deep sea cargo transportation as their primary area of business and that this NAICS classification is missing a significant number of entities. Second, we understand the focus of the RFA/SBREFEA analysis to be on U.S., and not foreign, small businesses. There is no expeditious and economical method of assessing the corporate nationality of either the Vessel AMS or Dun & Bradstreet list of shipping companies. We are aware, however, that the majority of the shipping lines carrying containers into the United States,

regardless of size, operate under foreign ownership.

In the absence of alternative data sources, we proceed to conduct the screening analysis relying on descriptive financial information about NAICS 483111 entities found in the Dun & Bradstreet database and the number of VOCCs identified in Vessel AMS. We also conclude that a *substantial* number of small entities are likely to be directly affected by the regulation under the rule.

For data on revenues and employees, we use the Dun & Bradstreet data for the 477 entities with fewer than 500 employees. Table 15 summarizes the total annual average revenues (2004) for firms within NAICS 483111, organized by ranges of employee-size classes. Specifically, we organize the Dun & Bradstreet company data by the employee-size classes and then calculate the average revenue of companies within that size class. Businesses with zero to 100 employees have average annual revenues of \$6 million, those with 101 to 250 employees have average annual revenues of \$59 million, and those with 251 to 500 employees have average annual revenues of \$105 million.

TABLE 15—AVERAGE ANNUAL REVENUE ESTIMATES (CARRIERS)

Carrier size	Number of business entities	Average annual revenues
0–100 employees .....	456	\$6,000,000
101–250 employees .....	13	59,000,000
251–500 employees .....	8	105,000,000
501–5,000 employees .....	15	450,000,000

The first of the two Additional Carrier Requirements is the Vessel Stow Plan, which will be required of carriers carrying containerized cargo. Our calculations assume that the cost to a small entity of submitting a Vessel Stow Plan will depend on the number of vessel trips completed. Carriers that complete between one and 100 vessel trips per year are assigned a cost of \$50 per trip. Larger carriers (those that complete at least 101 vessel trips per year) are assigned a one-time fixed cost

of \$50,000 and a variable cost of \$100 per trip. Because we do not know the number of vessel trips undertaken by carriers in the various size classes, we conservatively assume that for every trip volume, some of the carriers may be small entities.

We estimate that the average annual revenue of small carriers is \$9.1 million, which represents the average of the average annual revenues of small business entities identified in Table 15, weighted by the number of business

entities. In Table 16, we present each category of carrier (based on the annual number of vessel trips) with their corresponding annual worst-case cost of submitting Vessel Stow Plans. We then divide these costs by the average annual revenue of \$9.1 million, and as shown in Table 16, we estimate that the average share of revenue of submitting Vessel Stow Plans for small carriers is 0.25 percent, which does not rise to the level of a *significant* cost to carriers.

TABLE 16—VESSEL STOW PLAN COSTS

Vessel trips	Container carriers	Worst-case annual costs	Costs as share of revenue (percent)
1 .....	51	\$50	0.00
2-10 .....	116	500	0.01
11-100 .....	183	5,000	0.05
101-1,000 .....	70	116,667	1.28
1,001+ .....	4	136,667	1.50
Total .....	424	22,851	0.25

The second of the two Additional Carrier Requirements is the Container Status Message (CSM), which will be required of carriers carrying containerized cargo, provided they already collect and maintain CSM data in their electronic equipment tracking systems. Our calculations assume that the cost to a small entity associated with submitting CSMs will depend on the number of vessel trips completed.

Carriers that complete between one and 100 vessel trips per year will experience no cost associated with submitting CSMs. Larger carriers (those that complete at least 101 vessel trips per year) are assigned a one-time fixed cost of \$250,000 and a variable cost of \$55,000 per year. In Table 17, we present each category of carrier (based on the annual number of vessel trips) with their corresponding annual worst-

case cost of submitting CSMs. We then divide these costs by the average annual small carrier revenue of \$9.1 million, as calculated previously for Vessel Stow Plans. As shown in Table 17, we estimate that the average share of revenue of submitting CSMs for small carriers is 0.16 percent, which again does not rise to the level of a *significant* cost to carriers.

TABLE 17—CONTAINER STATUS MESSAGE COSTS

Vessel trips	Container carriers	Worst-case annual costs	Costs as share of revenue (percent)
1 .....	58	\$0	0.00
2-10 .....	162	0	0.00
11-100 .....	175	0	0.00
101-1,000 .....	45	138,333	1.52
1,001+ .....	2	138,333	1.52
Total .....	442	14,710	0.16

The two costs for two additional carrier elements are additive for containerized cargo, so the average cost share would be 0.41 percent (0.25 percent plus 0.16 percent). Therefore, we conclude that the additional data elements required for the VOCCs are unlikely to result in a *significant* cost to small entities.

*A description of the projected reporting, recordkeeping and other compliance requirements of the rule, including an estimate of the classes of small entities that will be subject to the requirement and the type of professional*

*skills necessary for preparation of the report or record:* The requirements of the rule are expected to be submitted electronically by importers or VOCCs (or an agent representing either). Professional skills necessary for preparation of the report or record include basic administrative and recordkeeping skills used to manage data transaction, shipment, manifest, security, and other data used in the commercial supply chain environment, along with a working knowledge of import shipment arrangements, brokerage, conveyance/shipping, and

consolidation customs procedures and regulation.

*A description of the steps the agency has taken to minimize the significant adverse economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the rule and why each of the other significant alternatives to the rule considered by the agency was rejected:* We have previously described the alternatives and why Alternative 1 was ultimately

selected as the interim final rule. Given the prevalence of small entities conducting importing activities and the need for all entities to participate for the rule to be effective, CBP is not exempting small entities from the regulation.

**Conclusion:** In summary, because the interim final rule affects all importers and carriers bringing goods to the United States, it likely affects a *substantial* number of small entities in each industry conducting these activities. Based on the data limitations discussed above, we are uncertain whether these effects will be *significant* on a per-entity basis for importers. Therefore, based on the results of this analysis, CBP cannot certify that the rule will not have a significant impact on a substantial number of small importing entities. As a result, we have conducted a FRFA. Based on the analysis presented above, we believe that a substantial number of small VOCCs are not likely to be significantly affected.

#### C. Unfunded Mandates Reform Act

Title II of the Unfunded Mandate Reform Act of 1995 (UMRA) requires agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. The regulation is exempt from these requirements under 2 U.S.C. 1503 (Exclusions) which states that UMRA "shall not apply to any provision in a bill, joint resolution, amendment, motion, or conference report before Congress and any provision in a proposed or final federal regulation that is necessary for the national security or the ratification or implementation of international treaty obligations."

#### D. Paperwork Reduction Act

The collections of information encompassed within this interim final rule have been submitted to OMB for review in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507) under OMB control number 1651-0001. An agency may not conduct, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number assigned by OMB.

There are three collections of information in this document. The collections are contained in 19 CFR 4.7c, 4.7d, and 149.2. This information will be used by CBP to further improve the ability of CBP to identify high-risk shipments so as to prevent smuggling and ensure cargo safety and security. The likely respondents and/or

recordkeepers are individuals and businesses.

Under § 4.7c, a vessel stow plan is required from a carrier when that carrier causes a vessel to arrive in the United States. Vessel stow plans are used to transmit information about cargo loaded aboard a vessel. The estimated average annual burden associated with the information collection in § 4.7c is 102.6 hours per carrier.

Under § 4.7d, container status messages are required from an incoming carrier for all containers destined to be transported by that carrier and to arrive within the limits of a port in the United States by vessel. Container status messages serve to facilitate the intermodal handling of containers by streamlining the information exchange between trading partners involved in administration, commerce, and transport of containerized shipments. The messages can also be used to report terminal container movements (e.g., loading and discharging the vessel) and to report the change in status of containers (e.g., empty or full). Container status messages will provide CBP with additional transparency into the custodial environment through which inter-modal containers are handled and transported before arrival and after unloading in the United States. This enhanced view (in corroboration with other advance data messages) into the international supply chain would contribute to the security of the United States and in the international supply chain through which containers and import cargos reach ports in the United States. The estimated average annual burden associated with the information collection in § 4.7d is 91.3 hours per carrier.

Under § 149.2, an Importer Security Filing, consisting of security elements of entry data for cargo destined to the United States, is required from the ISF Importer, as defined in these regulations. For shipments other than FROB cargo, IE and T&E in-bond shipments, and goods to be delivered to an FTZ, the ISF Importer will be the owner, purchaser, consignee, or agent such as a licensed customs broker. For FROB, the ISF Importer will be the carrier. For IE and T&E in-bond shipments, and goods to be delivered to an FTZ, the ISF Importer will be the party filing the IE, T&E, or FTZ documentation. The estimated average annual burden associated with the information collection in § 149.2 is 52.3 hours per respondent or recordkeeper.

Comments on the accuracy of these burden estimates and suggestions for reducing this burden should be sent to the Border Security Regulations Branch,

Office of International Trade, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue, NW., (Mint Annex), Washington, DC 20229.

The list of approved information collections, contained in 19 CFR Part 178, is being amended as appropriate to reflect the approved information collections covered by this interim final rule.

#### XI. Signing Authority

The signing authority for these amendments falls under 19 CFR 0.1(b). Accordingly, this document is signed by the Secretary of Homeland Security (or his delegate).

#### XII. Coordination of Interim Final Rule With Congress

Pursuant to section 343(a)(3)(L) (19 U.S.C. 2071 note, section (a)(3)(L)), the required report regarding this interim final rule document has been timely made to the Committees on Finance and Commerce, Science, and Transportation of the Senate and the Committees on Ways and Means and Transportation and Infrastructure of the House of Representatives.

#### XIII. Regulatory Amendments

##### List of Subjects

##### 19 CFR part 4

Customs duties and inspection, Freight, Maritime carriers, Reporting and recordkeeping requirements, Vessels.

##### 19 CFR part 12

Customs duties and inspection, Reporting and recordkeeping requirements.

##### 19 CFR part 18

Common carriers, Customs duties and inspection, Freight, Penalties, Reporting and recordkeeping requirements, Surety bonds.

##### 19 CFR part 101

Customs duties and inspection, Vessels.

##### 19 CFR part 103

Administrative practice and procedure, Confidential business information, Courts, Freedom of information, Law enforcement, Privacy, Reporting and recordkeeping requirements.

##### 19 CFR part 113

Common carriers, Customs duties and inspection, Freight, Reporting and recordkeeping requirements, Surety bonds.

**19 CFR part 122**

Administrative practice and procedure, Customs duties and inspection, Penalties, Reporting and recordkeeping requirements.

**19 CFR part 123**

Customs duties and inspection, Freight, Reporting and recordkeeping requirements, Vessels.

**19 CFR part 141**

Customs duties and inspection, Reporting and recordkeeping requirements.

**19 CFR part 143**

Customs duties and inspection, Reporting and recordkeeping requirements.

**19 CFR part 149**

Arrival, Declarations, Customs duties and inspection, Freight, Importers, Imports, Merchandise, Reporting and recordkeeping requirements, Shipping, Vessels.

**19 CFR part 178**

Reporting and recordkeeping requirements.

**19 CFR part 192**

Penalties, Reporting and recordkeeping requirements, Vessels.

**Amendments to the Regulations**

■ Parts 4, 12, 18, 101, 103, 113, 122, 123, 141, 143, 149, and 192 of title 19, Code of Federal Regulations (19 CFR parts 4, 12, 18, 101, 103, 113, 122, 123, 141, 143, 149, 178, and 192), are amended as set forth below.

**PART 4—VESSELS IN FOREIGN AND DOMESTIC TRADES**

■ 1. The general authority citation for part 4 is revised, the relevant specific authority citations are revised, and the specific authority citation for sections 4.7c and 4.7d is added to read as follows:

**Authority:** 5 U.S.C. 301; 19 U.S.C. 66, 1431, 1433, 1434, 1624, 2071 note; 46 U.S.C. 60105;

\* \* \* \* \*

Section 4.7 also issued under 19 U.S.C. 1581(a);

Section 4.7a also issued under 19 U.S.C. 1498, 1584;

\* \* \* \* \*

Sections 4.7c and 4.7d also issued under 6 U.S.C. 943.

\* \* \* \* \*

■ 2. Amend § 4.7 by revising paragraph (b)(2); and

■ a. In paragraph (e), by removing the phrase “in addition to penalties

applicable under other provisions of law” at the end of the first sentence and adding in its place the phrase “in addition to damages under the international carrier bond of \$5,000 for each violation discovered”; and

■ b. In paragraph (e), by removing the phrase “, in addition to any other penalties applicable under other provisions of law” at the end of the paragraph and adding in its place “of \$5,000 for each violation discovered”.

The revised paragraph (b)(2) reads as follows:

**§ 4.7 Inward foreign manifest; production on demand; contents and form; advance filing of cargo declaration.**

\* \* \* \* \*

(b) \* \* \*

(2) In addition to the vessel stow plan requirements pursuant to § 4.7c of this part and the container status message requirements pursuant to § 4.7d of this part, subject to the effective date provided in paragraph (b)(5) of this section, and with the exception of any bulk or authorized break bulk cargo as prescribed in paragraph (b)(4) of this section, Customs and Border Protection (CBP) must receive from the incoming carrier, for any vessel covered under paragraph (a) of this section, the CBP-approved electronic equivalent of the vessel's Cargo Declaration (Customs Form 1302), 24 hours before the cargo is laden aboard the vessel at the foreign port (see § 4.30(n)(1)). The current approved system for presenting electronic cargo declaration information to CBP is the Vessel Automated Manifest System (AMS).

\* \* \* \* \*

**§ 4.7a [Amended]**

■ 3. Amend § 4.7a(f) by:

■ a. Removing the phrase “in addition to penalties applicable under other provisions of law” at the end of the first sentence and adding in its place “in addition to damages under the international carrier bond of \$5,000 for each violation discovered”; and

■ b. Removing the phrase “, in addition to other penalties applicable under other provisions of law” at the end of the paragraph and adding in its place “of \$5,000 for each violation discovered”.

■ 4. Add a new § 4.7c to read as follows:

**§ 4.7c Vessel stow plan.**

*Vessel stow plan required.* In addition to the advance filing requirements pursuant to §§ 4.7 and 4.7a of this part and the container status message requirements pursuant to § 4.7d of this part, for all vessels subject to § 4.7(a) of this part, except for any vessel

exclusively carrying break bulk cargo or bulk cargo as prescribed in § 4.7(b)(4) of this part, the incoming carrier must submit a vessel stow plan consisting of vessel and container information as specified in paragraphs (b) and (c) of this section within the time prescribed in paragraph (a) of this section via the CBP-approved electronic data interchange system.

(a) *Time of transmission.* Customs and Border Protection (CBP) must receive the stow plan no later than 48 hours after the vessel departs from the last foreign port. For voyages less than 48 hours in duration, CBP must receive the stow plan prior to arrival at the first U.S. port.

(b) *Vessel information required to be reported.* The following information must be reported for each vessel:

- (1) Vessel name (including international maritime organization (IMO) number);
- (2) Vessel operator; and
- (3) Voyage number.

(c) *Container information required to be reported.* The following information must be reported for each container carried on each vessel:

- (1) Container operator;
- (2) Equipment number;
- (3) Equipment size and type;
- (4) Stow position;
- (5) Hazmat code (if applicable);
- (6) Port of lading; and
- (7) Port of discharge.

(d) *Compliance date of this section.*

(1) *General.* Subject to paragraph (d)(2) of this section, all affected ocean carriers must comply with the requirements of this section on and after January 26, 2010.

(2) *Delay in compliance date of section.* CBP may, at its sole discretion, delay the general compliance date set forth in paragraph (d)(1) of this section in the event that any necessary modifications to the approved electronic data interchange system are not yet in place or for any other reason. Notice of any such delay will be provided in the **Federal Register**.

■ 5. Add a new section 4.7d to read as follows:

**§ 4.7d Container status messages.**

(a) *Container status messages required.* In addition to the advance filing requirements pursuant to §§ 4.7 and 4.7a of this part and the vessel stow plan requirements pursuant to § 4.7c of this part, for all containers destined to arrive within the limits of a port in the United States from a foreign port by vessel, the incoming carrier must submit messages regarding the status of the events as specified in paragraph (b) of this section if the carrier creates or

collects a container status message (CSM) in its equipment tracking system reporting that event. CSMs must be transmitted to Customs and Border Protection (CBP) within the time prescribed in paragraph (c) of this section via a CBP-approved electronic data interchange system. There is no requirement that a carrier create or collect any CSMs under this paragraph that the carrier does not otherwise create or collect on its own and maintain in its electronic equipment tracking system.

(b) *Events required to be reported.* The following events must be reported if the carrier creates or collects a container status message in its equipment tracking system reporting that event:

(1) When the booking relating to a container which is destined to arrive within the limits of a port in the United States by vessel is confirmed;

(2) When a container which is destined to arrive within the limits of a port in the United States by vessel undergoes a terminal gate inspection;

(3) When a container, which is destined to arrive within the limits of a port in the United States by vessel, arrives or departs a facility (These events take place when a container enters or exits a port, container yard, or other facility. Generally, these CSMs are referred to as "gate-in" and "gate-out" messages.);

(4) When a container, which is destined to arrive within the limits of a port in the United States by vessel, is loaded on or unloaded from a conveyance (This includes vessel, feeder vessel, barge, rail and truck movements. Generally, these CSMs are referred to as "loaded on" and "unloaded from" messages);

(5) When a vessel transporting a container, which is destined to arrive within the limits of a port in the United States by vessel, departs from or arrives at a port (These events are commonly referred to as "vessel departure" and "vessel arrival" notices);

(6) When a container which is destined to arrive within the limits of a port in the United States by vessel undergoes an intra-terminal movement;

(7) When a container which is destined to arrive within the limits of a port in the United States by vessel is ordered stuffed or stripped;

(8) When a container which is destined to arrive within the limits of a port in the United States by vessel is confirmed stuffed or stripped; and

(9) When a container which is destined to arrive within the limits of a port in the United States by vessel is stopped for heavy repair.

(c) *Time of transmission.* For each event specified in paragraph (b) of this section that has occurred, and for which the carrier creates or collects a container status message (CSM) in its equipment tracking system reporting that event, the carrier must transmit the CSM to CBP no later than 24 hours after the CSM is entered into the equipment tracking system.

(d) *Contents of report.* The report of each event must include the following:

(1) Event code being reported, as defined in the ANSI X.12 or UN EDIFACT standards;

(2) Container number;

(3) Date and time of the event being reported;

(4) Status of the container (empty or full);

(5) Location where the event took place; and

(6) Vessel identification associated with the message if the container is associated with a specific vessel.

(e) A carrier may transmit other container status messages in addition to those required pursuant to paragraph (b) of this section. By transmitting additional container status messages, the carrier authorizes Customs and Border Protection (CBP) to access and use those data.

(f) *Compliance date of this section.* (1) *General.* Subject to paragraph (f)(2) of this section, all affected ocean carriers must comply with the requirements of this section on and after January 26, 2010.

(2) *Delay in compliance date of section.* CBP may, at its sole discretion, delay the general compliance date set forth in paragraph (f)(1) of this section in the event that any necessary modifications to the approved electronic data interchange system are not yet in place or for any other reason. Notice of any such delay will be provided in the *Federal Register*.

**PART 12—SPECIAL CLASSES OF MERCHANDISE**

■ 6. The general authority citation for part 12 and specific authority citation for § 12.3 continue to read as follows:

*Authority:* 5 U.S.C. 301; 19 U.S.C. 66, 1202 (General Note 3(i), Harmonized Tariff Schedule of the United States (HTSUS)), 1624;

\* \* \* \* \*

Section 12.3 also issued under 7 U.S.C. 135h, 21 U.S.C. 381;

\* \* \* \* \*

**§ 12.3 [Amended]**

■ 7. Amend § 12.3(b)(2) and (c) by removing references to "\$ 113.62(l)(1)"

and adding in their place "\$ 113.62(m)(1)".

**PART 18—VESSELS IN FOREIGN AND DOMESTIC TRADES**

■ 8. The general authority citation for part 18 continues to read as follows:

*Authority:* 5 U.S.C. 301; 19 U.S.C. 66, 1202 (General Note 3(i), Harmonized Tariff Schedule of the United States), 1551, 1552, 1553, 1623, 1624;

\* \* \* \* \*

■ 9. Amend § 18.5 by:

■ a. In paragraph (a), removing the reference to "paragraphs (c), (d), (e) and (f)" and adding in its place "paragraphs (c), (d), (e), (f), and (g)"; and

■ b. Adding a new paragraph (g).

The new paragraph (g) reads as follows:

**§ 18.5 Diversion.**

\* \* \* \* \*

(g) For in-bond shipments which, at the time of transmission of the Importer Security Filing as required by § 149.2 of this chapter, are intended to be entered as an immediate exportation (IE) or transportation and exportation (T&E) shipment, permission to divert the in-bond movement to a port other than the listed port of destination or export or to change the in-bond entry into a consumption entry must be obtained from the port director of the port of origin. Such permission would only be granted upon receipt by Customs and Border Protection (CBP) of a complete Importer Security Filing as required by part 149 of this chapter.

**PART 103—AVAILABILITY OF INFORMATION**

■ 10. The general authority citation for part 103 continues, and the specific authority citation for § 103.31a is revised to read as follows:

*Authority:* 5 U.S.C. 301, 552, 552a; 19 U.S.C. 66, 1624; 31 U.S.C. 9701.

\* \* \* \* \*

Section 103.31a also issued under 19 U.S.C. 2071 note and 6 U.S.C. 943;

\* \* \* \* \*

■ 11. Revise § 103.31a to read as follows:

**§ 103.31a Advance electronic information for air, truck, and rail cargo; Importer Security Filing information for vessel cargo.**

The following types of advance electronic information are per se exempt from disclosure under § 103.12(d), unless CBP receives a specific request for such records pursuant to § 103.5, and the owner of the information expressly agrees in writing to its release:

(a) Advance cargo information that is electronically presented to Customs and Border Protection (CBP) for inbound or outbound air, rail, or truck cargo in accordance with § 122.48a, 123.91, 123.92, or 192.14 of this chapter;

(b) Importer Security Filing information that is electronically presented to CBP for inbound vessel cargo in accordance with § 149.2 of this chapter;

(c) Vessel stow plan information that is electronically presented to CBP for inbound vessels in accordance with § 4.7c of this chapter; and

(d) Container status message information that is electronically presented for inbound containers in accordance with § 4.7d of this chapter.

#### PART 113—CUSTOMS BONDS

■ 12. The general authority citation for part 113 continues to read as follows:

Authority: 19 U.S.C. 66, 1623, 1624.

\* \* \* \* \*

■ 13. Amend § 113.62 by:

■ a. Redesignating paragraphs (j) through (l) as paragraphs (k) through (m);

■ b. Adding new paragraph (j);

■ c. In newly redesignated paragraph (k), removing the phrase "\$5,000 for each regulation violated" and adding in its place "\$5,000 for each violation";

■ d. In newly redesignated paragraph (m)(1), removing the reference to "paragraphs (a), (g), (i), (j)(2), or (k)" and adding in its place "paragraphs (a), (g), (i), (j), (k)(2), or (l)";

■ e. In newly redesignated paragraph (m)(4), replacing the reference to "paragraph (l)(1)" and adding in its place "paragraph (m)(1)"; and

■ f. In newly redesignated paragraph (m)(5), removing the reference to "paragraph (k)" and adding in its place "paragraph (l)".

The new paragraph (j) reads as follows:

##### § 113.62 Basic importation and entry bond conditions.

\* \* \* \* \*

(j) The principal agrees to comply with all Importer Security Filing requirements set forth in part 149 of this chapter including but not limited to providing security filing information to Customs and Border Protection in the manner and in the time period prescribed by regulation. If the principal defaults with regard to any obligation, the principal and surety (jointly and severally) agree to pay liquidated damages of \$5,000 for each violation.

\* \* \* \* \*

■ 14. Amend § 113.63 by:

■ a. Redesignating paragraphs (g) and (h) as paragraphs (h) and (i); and  
 ■ b. Adding new paragraph (g);

The new paragraph (g) reads as follows:

##### § 113.63 Basic custodial bond conditions.

\* \* \* \* \*

(g) The principal agrees to comply with all Importer Security Filing requirements set forth in part 149 of this chapter including but not limited to providing security filing information to Customs and Border Protection in the manner and in the time period prescribed by regulation. If the principal defaults with regard to any obligation, the principal and surety (jointly and severally) agree to pay liquidated damages of \$5,000 per violation.

\* \* \* \* \*

■ 15. Amend § 113.64 by:

■ a. Redesignating paragraphs (d) through (g) as paragraphs (h) through (k);

■ b. Redesignating paragraph (c) as paragraph (d);

■ c. Adding new paragraphs (c), (e), (f), and (g); and

■ d. In newly redesignated paragraph (d), removing the phrase "\$5,000 for each regulation violated" and adding in its place "\$5,000 for each violation, to a maximum of \$100,000 per conveyance arrival";

New paragraphs (c), (e), (f), and (g) read as follows:

##### § 113.64 International carrier bond conditions.

\* \* \* \* \*

(c) *Agreement to provide advance cargo information.* The incoming carrier agrees to provide advance cargo information to CBP in the manner and in the time period required under §§ 4.7 and 4.7a of this chapter. If the incoming carrier, as principal, defaults with regard to these obligations, the principal and surety (jointly and severally) agree to pay liquidated damages of \$5,000 for each violation, to a maximum of \$100,000 per conveyance arrival.

\* \* \* \* \*

(e) *Agreement to comply with Importer Security Filing requirements.* If the principal elects to provide the Importer Security Filing information to Customs and Border Protection (CBP), the principal agrees to comply with all Importer Security Filing requirements set forth in part 149 of this chapter including but not limited to providing security filing information to CBP in the manner and in the time period prescribed by regulation. If the principal defaults with regard to any obligation, the principal and surety (jointly and

severally) agree to pay liquidated damages of \$5,000 for each violation.

(f) *Agreement to comply with vessel stow plan requirements.* If the principal causes a vessel to arrive within the limits of a port in the United States, the principal agrees to submit a stow plan in the manner and in the time period required pursuant to part 4.7c of this chapter. If the principal defaults with regard to this obligation, the principal and surety (jointly and severally) agree to pay liquidated damages of \$50,000 for each vessel arrival.

(g) *Agreement to comply with container status message requirements.* If the principal causes a vessel to arrive within the limits of a port in the United States, the principal agrees to submit container status messages in the manner and in the time period required pursuant to part 4.7d of this chapter. If the principal defaults with regard to these obligations, the principal and surety (jointly and severally) agree to pay liquidated damages of \$5,000 for each violation, to a maximum of \$100,000 per vessel arrival.

\* \* \* \* \*

■ 16. Amend § 113.73 by:

■ a. Redesignating paragraphs (c) and (d) as paragraphs (d) and (e); and  
 ■ b. Adding a new paragraph (c).

The new paragraph (c) reads as follows:

##### § 113.73 Foreign trade zone operator bond conditions.

\* \* \* \* \*

(c) *Agreement to comply with Importer Security Filing requirements.* The principal agrees to comply with all Importer Security Filing requirements set forth in part 149 of this chapter including but not limited to providing security filing information to Customs and Border Protection (CBP) in the manner and in the time period prescribed by regulation. If the principal defaults with regard to any obligation, the principal and surety (jointly and severally) agree to pay liquidated damages of \$5,000 for each violation.

\* \* \* \* \*

■ 17. Add a new Appendix D to part 113 to read as follows:

#### Appendix D to Part 113—Importer Security Filing Bond

##### Importer Security Filing Bond

KNOW ALL MEN BY THESE PRESENTS, that \_\_\_\_\_ of \_\_\_\_\_, as principal having Customs and Border Protection (CBP) Identification Number \_\_\_\_\_ and \_\_\_\_\_, as surety are held and firmly bound unto the United States of America up to the sum of \_\_\_\_\_ dollars (\$ \_\_\_\_\_) for the payment of which we bind ourselves, our heirs, executors, administrators, successors, and

assigns, jointly and severally, firmly by these presents.

Whereas, the named principal (including the named principal's employees, agents and contractors) agrees to comply with all Importer Security Filing requirements set forth in 19 CFR part 149, including but not limited to providing security filing information to CBP in the manner and in the time period prescribed by regulation.

Whereas, if the named principal incurs any claim that relates to any of the requirements set forth in 19 CFR part 149, the obligors (principal and surety, jointly and severally) agree to pay any amount prescribed by law or regulation upon demand by CBP.

This bond is effective \_\_\_\_\_, 20\_\_\_\_, and remains in force for one year beginning with the effective date and for each succeeding annual period, or until terminated. This bond constitutes a separate bond for each period in the amount listed above for liabilities that accrue in each period. The intention to terminate this bond must be conveyed within the period and manner prescribed in the CBP Regulations.

SIGNED, SEALED AND DELIVERED IN THE PRESENCE OF:

(Name) \_\_\_\_\_

(Address) \_\_\_\_\_

(Name) \_\_\_\_\_

(Address) \_\_\_\_\_

(Principal Name) (Seal) \_\_\_\_\_

(Principal Address) \_\_\_\_\_

(Surety Name) (Seal)  
Surety No. \_\_\_\_\_

(Surety Mailing Address)  
Surety Agent Name  
Surety Agent ID Number \_\_\_\_\_

**PART 122—AIR COMMERCE REGULATIONS**

■ 18. The general authority citation for part 122 continues to read as follows:

**Authority:** 5 U.S.C. 301; 19 U.S.C. 58b, 66, 1431, 1433, 1436, 1448, 1459, 1590, 1594, 1623, 1624, 1644, 1644a, 2071 note.

\* \* \* \* \*

**§ 122.48a [Amended]**

■ 19. Amend § 122.48a(c)(2) by removing the reference to “§ 113.62(j)(2)” and adding in its place “§ 113.62(k)(2)”.

**PART 123—CUSTOMS RELATIONS WITH CANADA AND MEXICO**

■ 20. The general authority citation for part 123 continues to read as follows:

**Authority:** 19 U.S.C. 66, 1202 (General Note 3(i), Harmonized Tariff Schedule of the

United States (HTSUS)), 1431, 1433, 1436, 1448, 1624, 2071 note.

\* \* \* \* \*

**§ 123.92 [Amended]**

■ 21. Amend § 123.92(c)(2) by removing the reference to “§ 113.62(j)(2)” and adding in its place “§ 113.62(k)(2)”.

**PART 141—ENTRY OF MERCHANDISE**

■ 22. The general authority citation for part 141 and specific authority citation for § 141.113 continue to read as follows:

**Authority:** 19 U.S.C. 66, 1448, 1484, 1498, 1624.

Section 141.113 also issued under 19 U.S.C. 1499, 1623.

**§ 141.113 [Amended]**

■ 23. Amend § 141.113(b) by removing the reference to “§ 113.62(l)(1)” and adding in its place “§ 113.62(m)(1)”.

**PART 143—SPECIAL ENTRY PROCEDURES**

■ 24. The general authority citation for part 143 continues to read as follows:

**Authority:** 19 U.S.C. 66, 1481, 1484, 1498, 1624.

■ 25. Revise § 143.1 to read as follows:

**§ 143.1 Eligibility.**

The Automated Broker Interface (ABI) is a module of the Customs Automated Commercial System (ACS) which allows participants to transmit data electronically to CBP through ABI and to receive transmissions through ACS. Its purposes are to improve administrative efficiency, enhance enforcement of customs and related laws, lower costs and expedite the release of cargo.

(a) *Participants for entry and entry summary purposes.* Participants in ABI for the purposes of transmitting data relating to entry and entry summary may be:

- (1) Customs brokers as defined in § 111.1 of this chapter;
- (2) Importers as defined in § 101.1 of this chapter; and
- (3) ABI service bureaus, that is, an individual, partnership, association or corporation which provides communications facilities and data processing services for brokers and importers, but which does not engage in the conduct of customs business as defined in § 111.1 of this chapter.

(b) *Participants for Importer Security Filing purposes.* Any party may participate in ABI solely for the purposes of filing the Importer Security Filing pursuant to § 149.2 of this chapter if that party fulfills the eligibility

requirements contained in § 149.5 of this chapter. If a party other than a customs broker as defined in § 111.1 of this chapter or an importer as defined in 19 U.S.C. 1484 submits the Importer Security Filing, no portion of the Importer Security Filing can be used for entry or entry summary purposes pursuant to § 149.5 of this chapter.

(c) *Participants for other purposes.* Upon approval by CBP, any party may participate in ABI for other purposes, including transmission of protests, forms relating to in-bond movements (CBP Form 7512), and applications for FTZ admission (CBP Form 214).

**PART 146—FOREIGN TRADE ZONES**

■ 26. The general authority citation for part 146 continues to read as follows:

**Authority:** 19 U.S.C. 66, 81a–81u, 1202 (General Note 3(i), Harmonized Tariff Schedule of the United States), 1623, 1624.

■ 27. Amend § 146.32 by:

- a. Removing all references to “Customs Form 214” and adding in their place “CBP Form 214” wherever they appear;
- b. Redesignating paragraph (a) as paragraph (a)(1); and
- c. Adding a new paragraph (a)(2).  
The new paragraph (a)(2) reads as follows:

**§ 146.32 Application and permit for admission of merchandise.**

(a)(1) \* \* \*

(2) *CBP Form 214 and Importer Security Filing submitted via a single electronic transmission.* If an Importer Security Filing is filed pursuant to part 149 of this chapter via the same electronic transmission as CBP Form 214, the filer is only required to provide the following fields once to be used for Importer Security Filing and CBP Form 214 purposes:

- (i) Country of origin; and
- (ii) Commodity HTSUS number if this number is provided at the 10-digit level.

\* \* \* \* \*

■ 28. Add part 149 to chapter I to read as follows:

**PART 149—IMPORTER SECURITY FILING**

Sec.

- 149.1 Definitions.
- 149.2 Importer security filing—requirement, time of transmission, verification of information, update, withdrawal, compliance date.
- 149.3 Data elements.
- 149.4 Bulk and break bulk cargo.
- 149.5 Eligibility to file an Importer Security Filing, authorized agents.
- 149.6 Entry and entry summary documentation and Importer Security



Filing submitted via a single electronic transmission.

**Authority:** 5 U.S.C. 301; 6 U.S.C. 943; 19 U.S.C. 66, 1624, 2071 note.

#### § 149.1 Definitions.

(a) *Importer Security Filing Importer.* For purposes of this part, "Importer Security Filing (ISF) Importer" means the party causing goods to arrive within the limits of a port in the United States by vessel. For shipments other than foreign cargo remaining on board (FROB), immediate exportation (IE) and transportation and exportation (T&E) in-bond shipments, and goods to be delivered to a foreign trade zone (FTZ), the ISF Importer will be the goods' owner, purchaser, consignee, or agent such as a licensed customs broker. For FROB cargo, the ISF Importer will be the carrier. For IE and T&E in-bond shipments, and goods to be delivered to an FTZ, the ISF Importer will be the party filing the IE, T&E, or FTZ documentation.

(b) *Importation.* For purposes of this part, "importation" means the point at which cargo arrives within the limits of a port in the United States.

(c) *Bulk cargo.* For purposes of this part, "bulk cargo" is defined as homogeneous cargo that is stowed loose in the hold and is not enclosed in any container such as a box, bale, bag, cask, or the like. Such cargo is also described as bulk freight. Specifically, bulk cargo is composed of either:

(1) Free flowing articles such as oil, grain, coal, ore, and the like, which can be pumped or run through a chute or handled by dumping; or

(2) Articles that require mechanical handling such as bricks, pig iron, lumber, steel beams, and the like.

(d) *Break bulk cargo.* For purposes of this part, "break bulk cargo" is defined as cargo that is not containerized, but which is otherwise packaged or bundled.

#### § 149.2 Importer security filing—requirement, time of transmission, verification of information, update, withdrawal, compliance date.

(a) *Importer security filing required.* For cargo arriving by vessel, with the exception of any bulk cargo pursuant to § 149.4(a) of this part, the ISF Importer, as defined in § 149.1 of this part, or authorized agent (see § 149.5 of this part) must submit in English the Importer Security Filing elements prescribed in § 149.3 of this part within the time specified in paragraph (b) of this section via a CBP-approved electronic interchange system.

(b) *Time of transmission.* With the exception of any break bulk cargo

pursuant to § 149.4(b) of this part, ISF Importers must submit:

(1) Seller, buyer, importer of record number / foreign trade zone applicant identification number, and consignee number(s) (as defined in § 149.3(a)(1) through (4) of this part) no later than 24 hours before the cargo is laden aboard the vessel at the foreign port.

(2) Manufacturer (or supplier), ship to party, country of origin, and commodity HTSUS number (as defined in § 149.3(a)(5) through (8) of this part) no later than 24 hours before the cargo is laden aboard the vessel at the foreign port.

(3) Container stuffing location and consolidator (stuffer) (as defined in § 149.3(a)(9) and (10) of this part) as early as possible, in no event later than 24 hours prior to arrival in a United States port (or upon lading at a foreign port that is less than a 24 hour voyage to the closest United States port).

(4) The data elements required under § 149.3(b) of this part for FROB, prior to lading aboard the vessel at the foreign port.

(c) *Verification of information.* Where the party electronically presenting to CBP the Importer Security Filing required in paragraph (a) of this section receives any of this information from another party, CBP will take into consideration how, in accordance with ordinary commercial practices, the presenting party acquired such information, and whether and how the presenting party is able to verify this information. Where the presenting party is not reasonably able to verify such information, CBP will permit the party to electronically present the information on the basis of what the party reasonably believes to be true.

(d) *Update of Importer Security Filing.* The party who submitted the Importer Security Filing pursuant to paragraph (a) of this section must update the filing if, after the filing is submitted and before the goods enter the limits of a port in the United States, any of the information submitted changes or more accurate information becomes available.

(e) *Withdrawal of Importer Security Filing.* If, after an Importer Security Filing is submitted pursuant to paragraph (a) of this section, the goods associated with the Importer Security Filing are no longer intended to be imported to the United States, the party who submitted the Importer Security Filing must withdraw the Importer Security Filing and transmit to CBP the reason for such withdrawal.

(f) *Flexible Requirements.* For each of the four data elements required under paragraph (b)(2) of this section ISF Importers will be permitted to submit an

initial response or responses based on the best available data available at the time that, in accordance with paragraph (d) of this section, ISF Importers will be required to update as soon as more precise or more accurate information is available, in no event less than 24 hours prior to arrival at a U.S. port (or upon lading at a foreign port that is less than a 24 hour voyage to the closest U.S. port).

(g) *Compliance date of this section.*

(1) *General.* Subject to paragraph (g)(2) of this section, ISF Importers must comply with the requirements of this section on and after January 26, 2010.

(2) *Delay in compliance date of section.* CBP may, at its sole discretion, delay the general compliance date set forth in paragraph (g)(1) of this section in the event that any necessary modifications to the approved electronic data interchange system are not yet in place or for any other reason. Notice of any such delay will be provided in the **Federal Register**.

#### § 149.3 Data elements.

(a) *Shipments intended to be entered into the United States and shipments intended to be delivered to a foreign trade zone.* Except as otherwise provided for in paragraph (b) of this section, the following elements must be provided for each good listed at the six-digit HTSUS number at the lowest bill of lading level (i.e., at the house bill of lading level, if applicable). The manufacturer (or supplier), country of origin, and commodity HTSUS number must be linked to one another at the line item level.

(1) *Seller.* Name and address of the last known entity *by whom* the goods are sold or agreed to be sold. If the goods are to be imported otherwise than in pursuance of a purchase, the name and address of the owner of the goods must be provided. A widely recognized commercially accepted identification number for this party may be provided in lieu of the name and address.

(2) *Buyer.* Name and address of the last known entity *to whom* the goods are sold or agreed to be sold. If the goods are to be imported otherwise than in pursuance of a purchase, the name and address of the owner of the goods must be provided. A widely recognized commercially accepted identification number for this party may be provided in lieu of the name and address.

(3) *Importer of record number/Foreign trade zone applicant identification number.* Internal Revenue Service (IRS) number, Employer Identification Number (EIN), Social Security Number (SSN), or CBP assigned number of the entity liable for payment of all duties

and responsible for meeting all statutory and regulatory requirements incurred as a result of importation. For goods intended to be delivered to a foreign trade zone (FTZ), the IRS number, EIN, SSN, or CBP assigned number of the party filing the FTZ documentation with CBP must be provided.

(4) *Consignee number(s)*. Internal Revenue Service (IRS) number, Employer Identification Number (EIN), Social Security Number (SSN), or CBP assigned number of the individual(s) or firm(s) in the United States on whose account the merchandise is shipped.

(5) *Manufacturer (or supplier)*. Name and address of the entity that last manufactures, assembles, produces, or grows the commodity or name and address of the party supplying the finished goods in the country from which the goods are leaving. In the alternative the name and address of the manufacturer (or supplier) that is currently required by the import laws, rules and regulations of the United States (i.e., entry procedures) may be provided (this is the information that is used to create the existing manufacturer identification (MID) number for entry purposes). A widely recognized commercially accepted identification number for this party may be provided in lieu of the name and address.

(6) *Ship to party*. Name and address of the first deliver-to party scheduled to physically receive the goods after the goods have been released from customs custody. A widely recognized commercially accepted identification number for this party may be provided in lieu of the name and address.

(7) *Country of origin*. Country of manufacture, production, or growth of the article, based upon the import laws, rules and regulations of the United States.

(8) *Commodity HTSUS number*. Duty/statistical reporting number under which the article is classified in the Harmonized Tariff Schedule of the United States (HTSUS). The HTSUS number must be provided to the six-digit level. The HTSUS number may be provided up to the 10-digit level. This element can only be used for entry purposes if it is provided at the 10-digit level or greater by the importer of record or its licensed customs broker.

(9) *Container stuffing location*. Name and address(es) of the physical location(s) where the goods were stuffed into the container. For break bulk shipments, as defined in § 149.1 of this part, the name and address(es) of the physical location(s) where the goods were made "ship ready" must be provided. A widely recognized commercially accepted identification

number for this element may be provided in lieu of the name and address.

(10) *Consolidator (stuffer)*. Name and address of the party who stuffed the container or arranged for the stuffing of the container. For break bulk shipments, as defined in § 149.1 of this part, the name and address of the party who made the goods "ship ready" or the party who arranged for the goods to be made "ship ready" must be provided. A widely recognized commercially accepted identification number for this party may be provided in lieu of the name and address.

(b) *FROB, IE shipments, and T&E shipments*. For shipments consisting entirely of foreign cargo remaining on board (FROB) and shipments intended to be transported in-bond as an immediate exportation (IE) or transportation and exportation (T&E), the following elements must be provided for each good listed at the six-digit HTSUS number at the lowest bill of lading level (i.e., at the house bill of lading level, if applicable).

(1) *Booking party*. Name and address of the party who initiates the reservation of the cargo space for the shipment. A widely recognized commercially accepted identification number for this party may be provided in lieu of the name and address.

(2) *Foreign port of unloading*. Port code for the foreign port of unloading at the intended final destination.

(3) *Place of delivery*. City code for the place of delivery.

(4) *Ship to party*. Name and address of the first deliver-to party scheduled to physically receive the goods after the goods have been released from customs custody. A widely recognized commercially accepted identification number for this party may be provided in lieu of the name and address.

(5) *Commodity HTSUS number*. Duty/statistical reporting number under which the article is classified in the Harmonized Tariff Schedule of the United States (HTSUS). The HTSUS number must be provided to the six-digit level. The HTSUS number may be provided to the 10-digit level.

#### § 149.4 Bulk and break bulk cargo.

(a) *Bulk cargo exempted from filing requirement*. For bulk cargo that is exempt from the requirement set forth in § 4.7(b)(2) of this chapter that a cargo declaration be filed with Customs and Border Protection (CBP) 24 hours before such cargo is laden aboard the vessel at the foreign port, ISF Importers, as defined in § 149.1 of this part, of bulk cargo are also exempt from filing an

Importer Security Filing with respect to that cargo.

(b) *Break bulk cargo exempted from time requirement*. For break bulk cargo that is exempt from the requirement set forth in § 4.7(b)(2) of this chapter for carriers to file a cargo declaration with Customs and Border Protection (CBP) 24 hours before such cargo is laden aboard the vessel at the foreign port, ISF Importers, as defined in § 149.1 of this part, of break bulk cargo are also exempt with respect to that cargo from the requirement set forth in § 149.2 of this part to file an Importer Security Filing with CBP 24 hours before such cargo is laden aboard the vessel at the foreign port. Any importers of break bulk cargo that are exempted from the filing requirement of § 149.2 of this part must present the Importer Security Filing to CBP 24 hours prior to the cargo's arrival in the United States. These ISF Importers must still report 24 hours in advance of loading any containerized or non-qualifying break bulk cargo they will be importing.

#### § 149.5 Eligibility to file an Importer Security Filing, authorized agents.

(a) *Eligibility*. To be qualified to file Importer Security Filing information electronically, a party must establish the communication protocol required by Customs and Border Protection for properly presenting the Importer Security Filing through the approved data interchange system. If the Importer Security Filing and entry or entry summary are provided via a single electronic transmission to CBP pursuant to § 149.6(b) of this part, the party making the transmission must be an importer acting on its own behalf or a licensed customs broker.

(b) *Bond required*. The ISF Importer must possess a basic importation and entry bond containing all the necessary provisions of § 113.62 of this chapter, a basic custodial bond containing all the necessary provisions of § 113.63 of this chapter, an international carrier bond containing all the necessary provisions of § 113.64 of this chapter, a foreign trade zone operator bond containing all the necessary provisions of § 113.73 of this chapter, or an importer security filing bond as provided in Appendix D to part 113 of this chapter. If an ISF Importer does not have a required bond, the agent submitting the Importer Security Filing on behalf of the ISF Importer may post the agent's bond.

(c) *Powers of attorney*. Authorized agents must retain powers of attorney in English until revoked. Revoked powers of attorney and letters of revocation must be retained for five years after the date of revocation. Authorized agents

must make powers of attorney and letters of revocation available to representatives of Customs and Border Protection upon request.

**§ 149.6 Entry and entry summary documentation and Importer Security Filing submitted via a single electronic transmission.**

If the Importer Security Filing is filed pursuant to § 149.2 of this part via the same electronic transmission as entry or entry/entry summary documentation pursuant to § 142.3 of this chapter, the importer is only required to provide the

following fields once to be used for Importer Security Filing, entry, or entry/entry summary purposes, as applicable:

- (a) Importer of record number;
- (b) Consignee number;
- (c) Country of origin; and
- (d) Commodity HTSUS number if this number is provided at the 10-digit level.

**PART 178—APPROVAL OF INFORMATION COLLECTION REQUIREMENTS**

■ 29. The general authority citation for part 178 continues to read as follows:

**Authority:** 5 U.S.C. 301; 19 U.S.C. 1624; 44 U.S.C. 3501 *et seq.*

■ 30. Amend § 178.2 by adding new listings for §§ 4.7c, 4.7d, and 149.2 in appropriate numerical sequence according to the section number under the columns indicated, to read as follows:

**§ 178.2 Listing of OMB control numbers.**

19 CFR section	Description	OMB Control No.
§ 4.7c	Vessel stow plan.	
§ 4.7d	Container status messages.	
§ 149.2	Importer Security Filing.	

**PART 192—EXPORT CONTROL**

■ 31. The general authority citation for part 192 continues to read as follows:

**Authority:** 19 U.S.C. 66, 1624, 1646c. Subpart A also issued under 19 U.S.C. 1627a,

1646a, 1646b; subpart B also issued under 13 U.S.C. 303; 19 U.S.C. 2071 note; 46 U.S.C. 91.

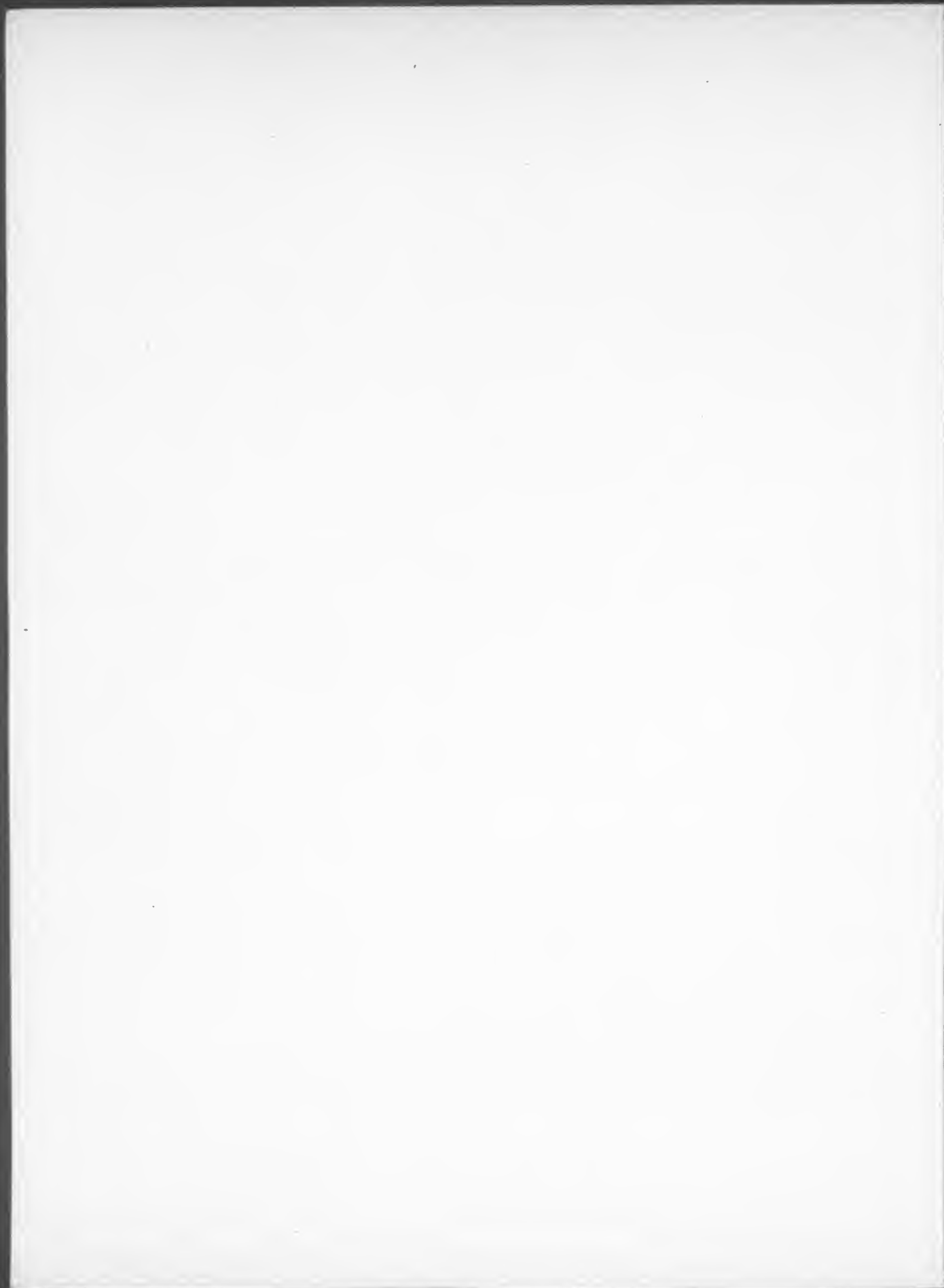
**§ 192.14 [Amended]**

■ 32. Amend § 192.14(c)(4)(ii) by removing the reference to “§ 113.64(g)(2)” and adding in its place “§ 113.64(k)(2)”.

Dated: November 7, 2008.

**Michael Chertoff,**  
*Secretary.*

[FR Doc. E8-27048 Filed 11-24-08; 8:45 am]  
BILLING CODE 9111-14-P





# Federal Register

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Tuesday,  
November 25, 2008

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## Part III

## Department of the Interior

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Fish and Wildlife Service

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50 CFR 17

Endangered and Threatened Wildlife and  
Plants; 12-Month Finding on a Petition  
To List the Northern Mexican  
Gartersnake (*Thamnophis eques*  
*megalops*) as Threatened or Endangered  
With Critical Habitat; Proposed Rule

## DEPARTMENT OF THE INTERIOR

## Fish and Wildlife Service

## 50 CFR Part 17

[FWS-R2-ES-2008-0065; MO 9221050083-B2]

**Endangered and Threatened Wildlife and Plants; 12-Month Finding on a Petition To List the Northern Mexican Gartersnake (*Thamnophis eques megalops*) as Threatened or Endangered with Critical Habitat**

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Notice of 12-month petition finding.

**SUMMARY:** We, the U.S. Fish and Wildlife Service (Service), announce a 12-month finding on a petition to list the northern Mexican gartersnake (*Thamnophis eques megalops*) as threatened or endangered with critical habitat under the Endangered Species Act of 1973, as amended (Act). The petitioners provided three listing options for consideration by the Service: (1) Listing the U.S. population as a Distinct Population Segment (DPS); (2) listing *Thamnophis eques megalops* throughout its range in the United States and Mexico based on its rangewide status; or (3) listing *Thamnophis eques megalops* throughout its range in the United States and Mexico based on its status in the United States. On the basis of the best scientific and commercial information available, we find that listing the northern Mexican gartersnake as threatened or endangered throughout its range in the United States and Mexico, based on its rangewide status, is warranted under the Act, due to the present or threatened destruction, modification or curtailment of its habitat; predation; and the inadequacy of existing regulatory mechanisms. Currently, listing is precluded by higher priority actions to amend the Lists of Endangered and Threatened Wildlife and Plants. Upon publication of this 12-month petition finding, the northern Mexican gartersnake will be added to our candidate species list. We will develop a proposed rule to list the northern Mexican gartersnake as our priorities allow. Any determination on critical habitat will be made during development of the proposed rule.

**DATES:** The finding announced in this document was made on November 25, 2008.

**ADDRESSES:** This finding is available on the Internet at <http://www.regulations.gov> at Docket Number

FWS-R2-ES-2008-0065. Supporting documentation we used in preparing this finding is available for public inspection, by appointment, during normal business hours at the U.S. Fish and Wildlife Service, Arizona Ecological Services Office, 2321 West Royal Palm Road, Suite 103, Phoenix, AZ 85021-4951. Please submit any new information, materials, comments, or questions concerning this finding to the above address.

**FOR FURTHER INFORMATION CONTACT:** Steve Spangle, Field Supervisor, Arizona Ecological Services Office (see **ADDRESSES**), telephone 602-242-0210. If you use a telecommunications device for the deaf (TDD), please call the Federal Information Relay Service (FIRS) at 800-877-8339.

**SUPPLEMENTARY INFORMATION:****Background**

Section 4(b)(3)(B) of the Act (16 U.S.C. 1531 *et seq.*), requires that, for any petition containing substantial scientific and commercial information indicating that listing may be warranted, we make a finding within 12 months of the date of receipt of the petition on whether the petitioned action is: (a) Not warranted, (b) warranted, or (c) warranted, but immediate proposal of a regulation implementing the petitioned action is precluded by other pending proposals to determine whether species are threatened or endangered, and expeditious progress is being made to add or remove qualified species from the Lists of Endangered and Threatened Wildlife and Plants. Section 4(b)(3)(C) of the Act requires that we treat a petition for which the requested action is found to be warranted but precluded as though resubmitted on the date of such finding; that is, requiring a subsequent finding to be made within 12 months. We must publish these 12-month findings in the **Federal Register**.

On December 19, 2003, we received a petition dated December 15, 2003, requesting that we list the northern Mexican gartersnake as threatened or endangered, and that we designate critical habitat concurrently with the listing. The petition, submitted by the Center for Biological Diversity, was clearly identified as a petition for a listing rule and contained the names, signatures, and addresses of the requesting parties. Included in the petition was supporting information regarding the species' taxonomy and ecology, historical and current distribution, present status, and actual and potential causes of decline. We acknowledged the receipt of the petition in a letter to Mr. Noah Greenwald, dated

March 1, 2004. In that letter, we also advised the petitioners that, due to funding constraints in fiscal year (FY) 2004, we would not be able to begin processing the petition at that time.

**Previous Federal Actions**

The Mexican gartersnake (*Thamnophis eques*) (which included the subspecies *megalops*) was placed on the list of candidate species as a Category 2 species in 1985 (50 FR 37958). Category 2 species were those for which existing information indicated that listing was possibly appropriate, but for which substantial supporting biological data to prepare a proposed rule were lacking. In the 1996 Candidate Notice of Review (February 28, 1996; 61 FR 7596), the use of Category 2 candidates was discontinued, and the northern Mexican gartersnake was no longer recognized as a candidate.

On May 17, 2005, the petitioners filed a complaint for declaratory and injunctive relief, challenging our failure to issue a 90-day finding in response to the petition as required by 16 U.S.C. 1533(b)(3)(A) and (B). In a stipulated settlement agreement, we agreed to submit a 90-day finding to the **Federal Register** by December 16, 2005, and if substantial, submit a 12-month finding to the **Federal Register** by September 15, 2006 (*Center for Biological Diversity v. Norton*, CV-05-341-TUC-CK) (D. Az.). The settlement agreement was signed and adopted by the District Court of Arizona on August 2, 2005.

On December 13, 2005, we made our 90-day finding that the petition presented substantial scientific information indicating that listing the northern Mexican gartersnake (*Thamnophis eques megalops*) may be warranted, but we did not discuss the applicability of any of the three listing scenarios that were provided in the petition. The finding and our initiation of a status review was published in the **Federal Register** on January 4, 2006 (71 FR 315).

On September 26, 2006, we published a 12-month finding that listing of the northern Mexican gartersnake was not warranted because we determined that not enough information on the subspecies' status and threats in Mexico was known at that time (71 FR 56227). On November 17, 2007, the petitioners filed a complaint for declaratory and injunctive relief pursuant to section 11 of the Act (16 U.S.C. 1540), seeking to set aside the 12-month finding. Additionally, a formal opinion was issued by the Solicitor of the Department of the Interior, "The Meaning of In Danger of Extinction Throughout All or a Significant Portion

of Its Range" (U.S. DOI 2007), which provides further guidance on how to conduct a detailed analysis of whether a species is in danger of extinction throughout a significant portion of its range. In December 2007, the Service withdrew the September 26, 2006, 12-month finding to consider the new "Significant Portion of the Range" policy. In a stipulated settlement agreement with the petitioners, we agreed to submit a new 12-month finding to the **Federal Register** by November 17, 2008 (*Center for Biological Diversity v. Kempthorne*, CV-07-596-TUC-RCCJ (D. Az)). The settlement agreement was signed and adopted by the District Court of Arizona on June 18, 2008.

This notice constitutes a new 12-month finding for the petition to list the northern Mexican gartersnake as threatened or endangered. The petitioners described three potentially listable entities of gartersnake for consideration by the Service: (1) Listing the U.S. population as a Distinct Population Segment (DPS); (2) listing *Thamnophis eques megalops* throughout its range in the United States and Mexico based on its rangewide status; or (3) listing *Thamnophis eques megalops* throughout its range in the United States and Mexico based on its status in the United States. Because we found that listing the northern Mexican gartersnake rangewide was warranted, there was no need to conduct any further analysis of the remaining two options, which are smaller geographic entities and are subsumed by the rangewide listing.

### Biology

**Species Description.** The northern Mexican gartersnake ranges in color from olive to olive-brown or olive-gray with three stripes that run the length of the body, the middle of which darkens towards the tail. It may occur with other native gartersnake species and can be difficult for people without herpetological expertise to identify. The snake may reach a maximum known length of 44 inches (in) [(112 centimeters (cm))]. The pale yellow to light-tan lateral stripes distinguish the northern Mexican gartersnake from other sympatric (co-occurring) gartersnake species because a portion of the lateral stripe is found on the fourth scale row, while it is confined to lower scale rows for other species. Paired black spots extend along the olive dorsolateral fields (region adjacent to the top of the snake's back) and the olive-gray ventrolateral fields (region adjacent to the area of the snake's body in contact with the ground). A more

detailed species description can be found in our 2006 12-month finding for this species (71 FR 56227), or by reviewing Rosen and Schwalbe (1988, p.4), Rossman *et al.* (1996, pp. 171-172), or Manjarrez and Garcia (1993, pp. 1-5).

**Taxonomy.** The northern Mexican gartersnake is a member of the family Colubridae and subfamily Natricinae (harmless live-bearing snakes) (Lawson *et al.* 2005, p. 596). The taxonomy of the genus *Thamnophis* has a complex history, partly because many of the species are similar in appearance and scutellation (arrangement of scales), but also because many of the early museum specimens were in such poor and faded condition that it was difficult to study them (Conant 2003, p. 6).

In recent history and prior to 2003, *Thamnophis eques* was considered to have three subspecies, *T. e. eques*, *T. e. megalops*, and *T. e. virgatenus* (Rossman *et al.* 1996, p. 175). In 2003, an additional seven new subspecies were identified under *T. eques*: (1) *T. e. cuitzeoensis*; (2) *T. e. patzcuaroensis*; (3) *T. e. inspiratus*; (4) *T. e. obscurus*; (5) *T. e. diluvialis*; (6) *T. e. carmenensis*; and (7) *T. e. scotti* (Conant 2003, p. 3). Common names were not provided, so in this finding, we use the scientific name for all subspecies of Mexican gartersnake other than the northern Mexican gartersnake. These seven new subspecies were described based on morphological differences in coloration and pattern; have highly restricted distributions; and occur in isolated wetland habitats within the mountainous Transvolcanic Belt region of southern Mexico, which contains the highest elevations in the country (Conant 2003, pp. 7-8). There are no known challenges within the scientific literature of the validity of current taxonomy of any of the 10 subspecies of *T. eques*. A more detailed description of the taxonomy of the northern Mexican gartersnake is found in our September 26, 2006 12-month finding for this species (71 FR 56227). Additional information regarding this species' taxonomy can be found in De Queiroz *et al.* (2002, p. 323), De Queiroz and Lawson (1994, p. 217), Rossman *et al.* (1996, pp. xvii-xviii, pp. 171-175), Rosen and Schwalbe (1988, pp. 2-3), Limer (1994, p. 107), and Crother (2008, p. 63).

On many occasions throughout this finding, we discuss the status of and threats to several prey species of the northern Mexican gartersnake, including anuran (frog and toad) species of the genera historically known as *Rana* and *Bufo* (true frogs and true toads, respectively). Frost *et al.* (2006, pp. 9-11) proposed several taxonomic

name changes, including many species under the genus *Rana* to *Lithobates*, and many species under the genus *Bufo* to *Anaxyrus*. Crother (2008, pp. 2-12), Committee Chair for the Standard English and Scientific Names Committee, adopted these scientific name changes. However, these taxonomic revisions have not escaped significant scrutiny in the scientific literature. Weins (2007, pp. 55-56) criticized the methodologies and analysis of Frost *et al.* (2006, pp. 9-11). Subsequently, Frost *et al.* (2008, pp. 385-395) rebutted these criticisms. Throughout this finding, we continue to use the genera *Rana* and *Bufo* to maintain taxonomic familiarity among the interested parties, retain consistency in the **Federal Register** with respect to notices regarding the northern Mexican gartersnake, and allow ample opportunity for peer review and deliberation in the scientific community with respect to the findings of Frost *et al.* (2006, pp. 9-11).

**Habitat.** Throughout its rangewide distribution, the northern Mexican gartersnake occurs at elevations from 130 to 8,497 feet (ft) (40 to 2,590 meters (m)) (Rossman *et al.* 1996, p. 172). The northern Mexican gartersnake is a riparian obligate (restricted to riparian areas when not engaged in dispersal behavior) and occurs chiefly in the following general habitat types: (1) Source-area wetlands (e.g., cienegas (mid-elevation wetlands with highly organic, reducing (basic or alkaline) soils), stock tanks (small earthen impoundment), etc.); (2) large-river riparian woodlands and forests; and (3) streamside gallery forests (as defined by well-developed broadleaf deciduous riparian forests with limited, if any, herbaceous ground cover or dense grass) (Hendrickson and Minckley 1984, p. 131; Rosen and Schwalbe 1988, pp. 14-16; Arizona Game and Fish Department 2001). Additional information on the habitat requirements of the northern Mexican gartersnake within the United States and Mexico can be found in our 2006 12-month finding for this species (71 FR 56227) and in Rosen and Schwalbe (1988, pp. 14-16), Rossman *et al.* (1996, p. 176), McCranie and Wilson (1987, pp. 11-17), and Cirett-Galan (1996, p. 156).

**Behavior, Prey Base, and Reproduction.** The northern Mexican gartersnake is surface active at ambient temperatures ranging from 71 degrees Fahrenheit (°F) to 91 °F (22 degrees Celsius (°C) to 33 °C) and forages along the banks of waterbodies. Rosen (1991, pp. 308-309) found that northern Mexican gartersnakes spent approximately 60 percent of their time

moving, 13 percent of their time basking on vegetation, 18 percent of their time basking on the ground, and 9 percent of their time under surface cover; body temperatures ranged from 24–33 °C (75–91 °F) and averaged 28 °C (82 °F), which is lower than other, similar species with comparable habitat and prey preferences. Rosen (1991, p. 310) suggested that lower preferred body temperatures exhibited by northern Mexican gartersnakes may be due to both (1) their tendency to occupy cienega-like habitat where warm ambient temperatures are relatively unavailable; and, (2) their tendency to remain in dense cover.

The northern Mexican gartersnake is an active predator and is believed to heavily depend upon a native prey base (Rosen and Schwalbe 1988, pp. 18, 20). Northern Mexican gartersnakes forage generally along vegetated banklines, searching for prey in water and on land, using different strategies (Alfaro 2002, p. 209). Generally, its diet consists predominantly of amphibians and fishes, such as adult and larval native leopard frogs (e.g., lowland leopard frog (*Rana yavapaiensis*) and Chiricahua leopard frog (*Rana chiricahuensis*)), as well as juvenile and adult native fish species (e.g., Gila topminnow (*Poeciliopsis occidentalis occidentalis*), desert pupfish (*Cyprinodon macularius*), Gila chub (*Gila intermedia*), and roundtail chub (*Gila robusta*)) (Rosen and Schwalbe 1988, p. 18). Auxiliary prey items may also include young Woodhouse's toads (*Bufo woodhousei*), treefrogs (Family Hylidae), earthworms, deer mice (*Peromyscus* spp.), lizards of the genera *Aspidoscelis* and *Sceloporus*, larval tiger salamanders (*Ambystoma tigrinum*), and leeches (Gregory *et al.* 1980, pp. 87, 90–92; Rosen and Schwalbe 1988, p. 20; Holm and Lowe 1995, pp. 30–31; Degenhardt *et al.* 1996, p. 318; Rossman *et al.* 1996, p. 176; Manjarrez 1998). To a much lesser extent, this snake's diet may include nonnative species, including larval and juvenile bullfrogs, and mosquitofish (*Gambusia affinis*) (Holycross *et al.* 2006, p. 23). Venegas-Barrera and Manjarrez (2001, p. 187) reported the first observation of a snake in the natural diet of any species of *Thamnophis* after documenting the consumption by a Mexican gartersnake of a Mexican alpine blotched gartersnake (*Thamnophis scalaris*).

Marcías-García and Drummond (1988, pp. 129–134) sampled the stomach contents of Mexican gartersnakes and the prey populations at (ephemeral) Lake Tecocomulco, Hidalgo, Mexico. Field observations indicated with high statistical significance that larger snakes

fed primarily upon aquatic vertebrates (fishes, frogs, and larval salamanders) and leeches, whereas smaller snakes fed primarily upon earthworms and leeches (Marcías-García and Drummond 1988, p. 131). Marcías-García and Drummond (1988, p. 130) also found that parturition (birth) of neonatal *T. eques* tended to coincide with the annual peak density of annelids (earthworms and leeches). Positive correlations were also made with respect to capture rates (which are correlated with population size) of *T. eques* to lake levels and to prey scarcity; that is, when lake levels were low and/or prey species scarce, Mexican gartersnake capture rates declined (Marcías-García and Drummond 1988, p. 132). This indicates the importance of available water and an adequate prey base to maintaining viable populations of Mexican gartersnakes. Marcías-García and Drummond (1988, p. 133) found that while certain prey items were positively associated with size classes of snakes, the largest of specimens consume any prey available.

Sexual maturity in northern Mexican gartersnakes occurs at 2 years of age in males and at 2 to 3 years of age in females (Rosen and Schwalbe 1988, pp. 16–17). Northern Mexican gartersnakes are ovoviviparous (eggs develop and hatch within the oviduct of the female). Mating occurs in April and May followed by the live birth of between 7 and 26 newborns (newly born individuals) (average is 13.6) in July and August (Rosen and Schwalbe 1988, p. 16). Unlike other gartersnake species, which typically breed annually, approximately half of the sexually mature females within a population of northern Mexican gartersnake reproduce in any one season (Rosen and Schwalbe 1988, p. 17). This may have negative implications for the species' ability to rebound in isolated populations facing threats such as nonnative species, habitat modification or destruction, and other perturbations. Low birth rates will impede recovery of such populations by accentuating the effects of these threats.

#### Distribution

**Historical Distribution.** Within the United States, the northern Mexican gartersnake historically occurred predominantly in Arizona at elevations ranging from 130 to 6,150 ft (40 to 1,875 m) in elevation. It was generally found where water was relatively permanent and supported suitable habitat. The northern Mexican gartersnake historically occurred in every county within Arizona, within several perennial or intermittent drainages and disassociated wetlands (Woodin 1950,

p. 40; Nickerson and Mays 1970, p. 503; Bradley 1986, p. 67; Rosen and Schwalbe 1988, Appendix I; 1995, p. 452; 1997, pp. 16–17; Holm and Lowe 1995, pp. 27–35; Sredl *et al.* 1995b, p. 2; 2000, p. 9; Rosen *et al.* 2001, Appendix I; Holycross *et al.* 2006, pp. 1–2, 15–51; Brennan and Holycross 2006, p. 123; Radke 2006; Rosen 2006; Holycross 2006).

Historically, the northern Mexican gartersnake had a limited distribution in New Mexico that consisted of scattered locations throughout the Gila and San Francisco headwater drainages in Grant and western Hidalgo Counties (Price 1980, p. 39; Fitzgerald 1986, Table 2; Degenhardt *et al.* 1996, p. 317; Holycross *et al.* 2006, pp. 1–2).

One record for the northern Mexican gartersnake exists for the State of Nevada, opposite Fort Mohave, in Clark County along the shore of the Colorado River (De Queiroz and Smith 1996, p. 155). The species may have occurred historically in the lower Colorado River region of California, although we were unable to verify any museum records for California. Any populations of northern Mexican gartersnakes that may have historically occurred in either Nevada or California likely pertained directly to the Colorado River and are extirpated.

Within Mexico, northern Mexican gartersnakes historically occurred within the Sierra Madre Occidental and the Mexican Plateau in the Mexican states of Sonora, Chihuahua, Durango, Coahuila, Zacatecas, Guanajuato, Nayarit, Hidalgo, Jalisco, San Luis Potosí, Aguascalientes, Tlaxacala, Puebla, México, Veracruz, and Querétaro, comprising approximately 85 percent of the total rangewide distribution of the species (Conant 1963, p. 473; 1974, pp. 469–470; Van Devender and Lowe 1977, p. 47; McCranie and Wilson 1987, p. 15; Rossman *et al.* 1996, p. 173; Lemos-Espinal *et al.* 2004, p. 83).

#### Status in the United States.

Variability in survey design and effort makes it difficult to compare population trends among sites and between sampling periods. Thus, for each of the sites considered in our analysis, we have attempted to translate and quantify search and capture efforts into comparable units (i.e., person-search hours and trap-hours) and have cautiously interpreted those results. Given the data provided, it is not possible to determine population densities at the sites.

A detailed status of the northern Mexican gartersnake in the United States and Mexico can be found in our 2006 12-month finding (71 FR 56227) and in Holycross *et al.* (2006, p. 12); Rosen and Schwalbe (1988, Appendix 1); Rosen *et*



*al.* (2001, pp. 21–22, Appendix 1); d'Orgeix (2008); Holm and Lowe (1995, pp. 27–35). Subsequent to our 2006 12-month finding, we have obtained and analyzed additional information pertinent to the status of the northern Mexico gartersnake and present it below.

Scotia Canyon was the last area intensively resurveyed by Rosen *et al.* (2001, pp. 15–16). In comparing capture rates from Holm and Lowe (1995, pp. 27–35), northern Mexican gartersnake populations in this area appear to have declined from 1980–1982, to low capture rates in 1993, and even lower capture rates in 2000 (Boyarski 2008c, p. 1). In 2008, a multi-party effort was initiated within Scotia Canyon, including the Peterson Ranch Pond and vicinity, to eradicate bullfrogs as well as record observations of Chiricahua leopard frogs or northern Mexican gartersnakes (Frederick 2008, 2008b). These efforts occurred in the same area investigated by Holm and Lowe (1995, pp. 27–35) and Rosen *et al.* (2001, pp. 15–16). After many surveys of herpetofauna (reptiles and amphibians) in this area to identify the presence of bullfrogs for eradication, a single, large adult northern Mexican gartersnake was observed, the first in over 8 years of informal surveys at this site (Frederick 2008b), which is frequently visited by biologists. This observation suggests that the species continues to occur in the upper Scotia Canyon area, but, given the extensive survey effort, it occurs in exceptionally low densities and no longer represents a stable population because of problems with reproduction and survivorship that exist with populations comprised of very low numbers of individuals.

A significant amount of survey effort for northern Mexican gartersnakes was conducted at the Las Cienegas National Conservation Area (Cienega Creek and Empire Cienega) from 2002–2008. During the 2002 and 2003 field seasons, Rosen and Caldwell (2004, pp. 1–52) conducted an in-depth assessment of the riparian herpetofaunal community of this area and in 11,784 trap-hours captured by hand and trap, 29 northern Mexican gartersnakes that were marked and released. Twenty-one northern Mexican gartersnakes were trapped, which equates to 561 trap-hours per snake. In 2004, Rosen and Caldwell (2004, p. 21) considered the species to be “widely distributed, though perhaps reduced in abundance” in this area.

In 2007 and 2008, significant effort to collect northern Mexican gartersnakes was given to this same area using similar techniques as Rosen and Caldwell (2004) (Gartersnake

Conservation Working Group (GCWG) 2008, pp. 1–10). Servoss *et al.* (2007, p. 4) captured one juvenile northern Mexican gartersnake by hand after 27 person search-hours and 1,000 trap-hours of effort.

Due to limited success in collecting the species in 2007, in 2008, the Arizona Game and Fish Department contracted with a recognized reptile and amphibian researcher familiar with the area to collect specimens for captive propagation (GCWG 2008, pp. 1–10). The herpetologist trapped a single juvenile northern Mexican gartersnake in 3,612 trap-hours and 104 person search-hours of effort (Caldwell 2008a, 2008b).

The wildlife biologist for the Bureau of Land Management (BLM) Tucson Field Office (who has conducted fish sampling at the Las Cienegas National Conservation Area since 1998) expressed concerns for the apparent population decline of northern Mexican gartersnakes in this area. Several fish sampling techniques he employs are also used specifically to sample aquatic snake species such as the northern Mexican gartersnake. Simms (2008) stated that seining and hoop netting at 40 locations, as well as visual surveys of this area performed in 2008, have yielded no observations of Mexican gartersnakes.

The data from 2007 and 2008 confirm that this formerly stable population at the Las Cienegas National Conservation Area is experiencing significant declines, may no longer be viable, and could become extirpated in the near-term. In 2007 and 2008, more than 2,300 trap-hours were required per snake captured (Caldwell 2008a, 2008b; Servoss *et al.* 2007, p. 1–12), compared with Rosen and Caldwell's (2004, p. 21 Table 2) capture rates of 561 trap-hours per snake in 2002 and 2003. This is a more than four-fold increase in the effort needed to capture northern Mexican gartersnakes.

The recently documented population of northern Mexican gartersnakes within Tonto Creek is the only known population that remains from the Salt River Basin (the status of the species in the basin on the White Mountain Apache and San Carlos Apache reservations remains unknown). Wallace *et al.* (2008, pp. 243–244) documented the first record of northern Mexican gartersnakes from the Tonto Creek watershed in Gila County, from a specimen that was observed in the road (killed by a vehicle) on State Route 188 in 1995. Seventeen individual northern Mexican gartersnakes were subsequently captured in Tonto Creek with 20,444 trap-hours of effort (1,202

trap-hours per snake) in 2004 and 2005 (Holycross *et al.* 2006, pp. 41–44; Wallace *et al.* 2008, pp. 243–244). Wallace *et al.* (2008, pp. 243–244) suggest northern Mexican gartersnakes in Tonto Creek persist in low densities and raise the possibility that recruitment (the process by which individuals within a population achieve reproductive maturity) may be in decline because only adult and newborn specimens were captured, with no intermediate age classes observed.

The population of northern Mexican gartersnakes along the Verde River within the Verde Valley of Yavapai County is presumed to remain as a low-density population. Approximately 15 individuals, including agency personnel and private citizens, surveyed the Verde River within the Verde Valley (including Dead Horse Ranch State Park) for the purpose of collecting 5 Mexican gartersnakes for captive propagation in 2007 (GCWG 2007, p. 2). Approximately 120 person-search hours resulted in no observations of northern Mexican gartersnakes (GCWG 2007, p. 2). Haney *et al.* (2008, p. 61) declared the northern Mexican gartersnake nearly lost from the Verde River.

A population of northern Mexican gartersnakes that remains at the Arizona Game and Fish Department's Page Springs and Bubbling Ponds fish hatcheries (hatcheries), located adjacent to Oak Creek, upstream of its confluence with the Verde River, represents the highest density population in Arizona and potentially the last remaining viable population in the United States. Boyarski (2008b, pp. 1–10) summarizes the first (2007) field season of a northern Mexican gartersnake monitoring project at the hatcheries, which had the objective of establishing the baseline population demographics from which to launch future investigations (Boyarski 2008b, p. 4). Although several capture techniques were employed, trapping was the most effective by far. In total, 52 individual northern Mexican gartersnakes were captured in 2007; 42 from Bubbling Ponds, 8 from Page Springs, and 2 from the adjacent Oak Creek (Boyarski 2008b, p. 5). In total, 19,457 trap-hours captured 56 northern Mexican gartersnakes (including 7 recaptures), which equates to 347 trap-hours per capture (Boyarski 2008b, p. 6). As this was the first year to acquire population data for northern Mexican gartersnakes within the hatcheries, population trends at these sites cannot be determined. However, hatchery personnel stated that northern Mexican gartersnakes are not observed as frequently and do not appear to be as common as they once were at these sites

(Boyarski 2008b, p. 8). While not associated with a scientific study, this statement by hatchery personnel, who spend most of their time in the immediate vicinity of occupied habitat, is of special concern because it illustrates the potential that long-term declines may have been occurring at the hatchery although potential declines can not be quantified.

Sonoita Creek in Santa Cruz County in southern Arizona was a historical location for northern Mexican gartersnakes. Turner (2006, pp. 1–21) found no northern Mexican gartersnakes in a herpetological inventory conducted from April through September 2006, in the Sonoita Creek State Natural Area. The last record of a northern Mexican gartersnake in this area was in 1974 and the subspecies was not found during Turner's 204-person-search-hour, 5,472-trap-hour survey effort (Turner 2006, pp. 3, 9). Crayfish, bullfrogs, and nonnative fish were observed by Turner (2006, p. 10) throughout the riparian area of the study area, as was evidence of improper livestock grazing.

In our 2006 12-month finding for this species, we specified that the last known observation of the northern Mexican gartersnake in New Mexico occurred in 1994 on private land (Painter 2000, p. 36, Painter 2005). In 2007, we became aware of a single photo-vouchered record of a northern Mexican gartersnake in New Mexico. The specimen was discovered and photo-vouchered in August 2002, observed in a debris pile along the Gila River off Highway 180 in Grant County, New Mexico (Hill 2007). Subsequent searches for northern Mexican gartersnakes were conducted in the same vicinity in 2006 and 2007, but no individuals were observed (Hill 2007). In our 2006 finding (71 FR 56227), we considered the northern Mexican gartersnake as extirpated from New Mexico. In consideration of: (1) A single observation of the species in New Mexico within the last 14 years that occurred in 2002; (2) 2 years of survey effort in 2006 and 2007 within the Gila River in the area of the 2002 observation by Hill (2007); and (3) additional survey effort of historical habitat for the species in New Mexico in 2007, we consider the status of the northern Mexican gartersnake in the Gila River at the Highway 180 crossing in New Mexico as unknown at this time (Painter 2008; Cotton 2008; Kindscher *In Prep.*, pp. 1–26). All other historical locations of the northern Mexican gartersnake in New Mexico are considered extirpated (Painter 2005).

General concerns within the scientific community exist for age class structure

within northern Mexican gartersnake populations that have been affected by nonnative species. It is widely believed that recruitment of northern Mexican gartersnakes may be significantly impeded by nonnative predation on the neonate and juvenile age classes. Individuals that survive past these age classes are likely to have increased survivorship, in part by foraging on the nonnative species that preyed upon them during their younger age classes. These population-level observations have been made in several populations including Scotia Canyon (Holm and Lowe 1995, p. 34), Tonto Creek (Wallace *et al.* 2008, pp. 243–244), and the San Bernardino National Wildlife Refuge (Rosen and Schwalbe 1988, p. 18).

Our analysis of the best available data on the status of the northern Mexican gartersnake distribution in the United States indicates that its distribution has been significantly reduced, and it is likely extirpated from a large portion of its historical distribution within the United States. We define a population as "likely extirpated" when there have been no northern Mexican gartersnakes reported for a decade or longer at a site within the historical distribution of the species, despite survey efforts, and there is no expectation of natural recovery at the site due to the presence of known or strongly suspected causes of extirpation. The perennial or intermittent stream reaches and disassociated wetlands (i.e., stock tanks, ponds, cienegas, etc.) where the northern Mexican gartersnake has likely been extirpated in Arizona include: (1) The Gila River; (2) the Lower Colorado River from Davis Dam to the International Border; (3) the San Pedro River; (4) the Santa Cruz River downstream from the International Border at Nogales; (5) the Salt River; (6) the Rio San Bernardino from International Border to headwaters at Astin Spring (San Bernardino National Wildlife Refuge); (7) the Agua Fria River; (8) the Verde River upstream of Clarkdale; (9) the Verde River from the confluence with Fossil Creek downstream to its confluence with the Salt River; (10) Tanque Verde Creek in Tucson; (11) Rillito Creek in Tucson; (12) Agua Caliente Spring in Tucson; (13) Potrero Canyon/Springs; (14) Babocamari Cienega; (15) Barchas Ranch, Huachuca Mountain bajada; (16) Parker Canyon Lake and tributaries in the Canelo Hills; and (17) Oak Creek at Midgley Bridge (Rosen and Schwalbe 1988, pp. 25–26, Appendix I; 1997, pp. 16–17; Rosen *et al.* 2001, Appendix I; Brennan and Holycross 2006, p. 123; Holycross 2006; Holycross *et al.* 2006, pp. 15–51, 66; Radke 2006; Rosen 2006).

In New Mexico, the following historical populations are considered extirpated: (1) Mule Creek; (2) the Gila River, 5 miles (mi) (8 kilometers (km)) east of Virden; (3) Spring Canyon; (4) the West Fork Gila River at Cliff Dwellings National Monument; (5) the Tularosa River at its confluence with the San Francisco River; (6) the San Francisco River at Tub Spring Canyon; (7) Little Creek at Highway 15; (8) the Middle Box of Gila River at Ira Ridge; (9) Turkey Creek; (10) Negrito Creek; and (11) the Rio Mimbres (Fitzgerald 1986, Table 2; Painter 2005, 2006; 2008; Cotton 2008; Kindscher *In Prep.*, pp. 1–26).

Conversely, our review of the best available information indicates the northern Mexican gartersnake likely occurs in a fraction of its former range in Arizona. We define populations as "likely occurring" when the species is expected to reliably occur in appropriate habitat as supported by recent museum records and/or recent (i.e., less than 10 years) reliable observations. The perennial or intermittent stream reaches and disassociated wetlands where we conclude northern Mexican gartersnakes remain include: (1) The Santa Cruz River/Lower San Rafael Valley (headwaters downstream to the International Border); (2) the Verde River from the confluence with Fossil Creek upstream to Clarkdale; (3) Oak Creek at Page Springs; (4) Tonto Creek from the mouth of Houston Creek downstream to Roosevelt Lake; (5) Cienega Creek from the headwaters downstream to the "Narrows" just downstream of Apache Canyon; (6) Pantano Wash (Cienega Creek) from Pantano downstream to Vail; (7) Appleton-Whittell Research Ranch and vicinity near Elgin; and (8) Red Rock Canyon east of Patagonia (Rosen *et al.* 2001, Appendix I; Caldwell 2005; Brennan and Holycross 2006, p. 123; Holycross 2006; Holycross *et al.* 2006, pp. 15–51, 66; Rosen 2006; Jones 2008a).

The current status of the northern Mexican gartersnake is unknown in several areas within Arizona and New Mexico where the species is known to have historically occurred. We base this determination primarily on historical museum records for locations where survey access is restricted, survey data are unavailable or insufficient, and/or current threats could preclude occupancy. The perennial or intermittent stream reaches and disassociated wetlands where the status of the northern Mexican gartersnake remains uncertain include: (1) The downstream portion of the Black River drainage from the Paddy Creek

confluence; (2) the downstream portion of the White River drainage from the confluence of the East and North forks; (3) Big Bonito Creek; (4) Lake O'Woods near Lakeside; (5) Spring Creek above the confluence with Oak Creek; (6) Bog Hole Wildlife Area; (7) Upper 13 Tank, Patagonia Mountain bajada; (8) Babocamari River; (9) Upper Scotia Canyon in the Huachuca Mountains; (10) Arivaca Cienega; and, (11) Gila River at Highway 180 (in New Mexico) (Rosen and Schwalbe 1988, Appendix I; Rosen *et al.* 2001, Appendix I; Brennan and Holycross 2006, p. 123; Holycross 2006; Holycross *et al.* 2006, pp. 15–51; Rosen 2006).

In summary, based upon our analysis of the best available scientific and commercial data, we conclude that the northern Mexican gartersnake has been extirpated from approximately 90 percent of its historical distribution in the United States.

**Status in Mexico.** Determining the status and current distribution of the northern Mexican gartersnake in Mexico is difficult because of the lack of large-scale surveys, research, and other pertinent information. We can determine that there have been important large-scale losses of northern Mexican gartersnake habitat, and that, at least locally, northern Mexican gartersnake populations have been extirpated or are declining. We relied, in part, on information that addresses the status of both riparian and aquatic biological communities that are habitat for the northern Mexican gartersnake and the status of native freshwater fish species that are documented prey species for the northern Mexican gartersnake from areas within its historical distribution in Mexico. From the status of those communities or fish species, we inferred a similar status for the northern Mexican gartersnake as we have no reason to conclude these particular predator-prey relationships respond any differently to biological community-level perturbations in Mexico as has been observed reliably in the United States. See Factors A and C for analysis of threats to the habitat and prey base.

A large number of springs have dried up in several Mexican states within the distribution of the northern Mexican gartersnake, particularly from the years 1974–1994 in states including Chihuahua, Durango, Coahila, and San Luis Potosí (Contreras Balderas and Lozano 1994, p. 381). Because this has eliminated the habitat and aquatic prey base of the snake, we conclude that the

northern Mexican gartersnake has also been lost from these sites. Contreras Balderas and Lozano (1994, p. 381) stated that several streams and rivers throughout Mexico and within the distribution of the northern Mexican gartersnake have also dried up or become intermittent due to overuse of surface and groundwater supplies. Ramirez Bautista and Arizmendi (2004, p. 3) stated that the principal threats to northern Mexican gartersnake habitat in Mexico include the drying of wetlands. Because this has decreased the amount of habitat and the aquatic prey base of the snake, we conclude that the northern Mexican gartersnake has likely declined at these sites.

Burger (2008) provides a preliminary data set of survey effort for Mexican gartersnakes (*Thamnophis eques*), southern Durango spotted gartersnakes (*T. nigronuchalis*), and narrow-headed gartersnakes (*T. rufipunctatus*) from the United States and Mexico through 2007 (*T. nigronuchalis* only occurs in Mexico). The Burger (2008) data set provides information from surveys of 17 stream systems in the Mexican states of Durango and southern Chihuahua along the Sierra Madre Occidental during June 2007. Mexican gartersnakes were observed at 5 of the 17 sites visited; however, specimens were not identified to subspecies, and some sites visited may not have been within the historical distribution of the northern Mexican gartersnake. Individuals observed from locations in southern Durango were likely *T. e. virgatenuis*, rather than the northern Mexican gartersnake. This sampling effort in Mexico geographically constitutes a small portion of the range of the northern Mexican gartersnake in that country, but it provides limited regional insight into the species' status. Population trends at locations visited cannot be assessed because these sites have only been visited once.

A research biologist with the Universidad Autonoma del Estado de México, who has been doing field research on Mexican gartersnakes in central Mexico (within the distribution of northern Mexican gartersnakes) for approximately two decades, has documented the decline or disappearance of populations from drying of water bodies, water contamination, and other human impacts where, 20 years ago, the species was abundant (Manjarrez 2008).

Determining the status of the northern Mexican gartersnake in Mexico is hampered by the lack of large-scale

surveys, research, and other pertinent information for that country. We can determine that there have been important large-scale losses of northern Mexican gartersnake habitat, including surface waters such as rivers, streams, wetlands, and springs, that certainly have affected gartersnake populations. We can also determine that, where local surveys have been conducted, northern Mexican gartersnakes have been extirpated or are declining (Manjarrez 2008).

#### Summary of Factors Affecting the Northern Mexican Gartersnake

Section 4 of the Act (16 U.S.C. 1533), and implementing regulations at 50 CFR 424, set forth procedures for adding species to the Federal Lists of Endangered and Threatened Wildlife and Plants. Under section 4(a)(1) of the Act, we may list a species on the basis of any of five factors, as follows: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence. In making this finding, information regarding the status of, and threats to, the northern Mexican gartersnake in relation to the five factors provided in section 4(a)(1) of the Act is discussed below and summarized in Table 1 below.

Table 1—Summary of northern Mexican gartersnake status and threats by population in the United States. (Note: “Extirpated” means that there have been no northern Mexican gartersnakes reported for a decade or longer at a site within the historical distribution of the species, despite survey efforts, and there is no expectation of natural recovery at the site due to the presence of known or strongly suspected causes of extirpation. “Extant” means areas where the species is expected to reliably occur in appropriate habitat as supported by museum records or recent, reliable observations. “Unknown” means areas where the species is known to have occurred based on museum records (mostly historical) but access is restricted, or survey data is unavailable or insufficient, or where threats could preclude occupancy.)

Population locality	Current status	Regional historical or current threats
Gila River (outside of Highway 180 crossing) (Arizona, New Mexico).	Extirpated .....	<i>Factor A:</i> Improper grazing, recreation, development, groundwater pumping, water diversions, channelization, dewatering, road construction/use, wildfire, intentional harm, dams. <i>Factor C:</i> Nonnative species, prey base reduction.
Gila and San Francisco Headwaters (New Mexico).	Extirpated .....	<i>Factor A:</i> Improper grazing, recreation.  <i>Factor C:</i> Nonnative species, prey base reduction.
Lower Colorado River from Davis Dam to International Border (Arizona).	Extirpated .....	<i>Factor A:</i> Recreation, development, road construction and use, borderland security and undocumented immigration, intentional harm, dams. <i>Factor C:</i> Nonnative species, prey base reduction.
San Pedro River in United States (Arizona).	Extirpated .....	<i>Factor A:</i> Improper grazing, groundwater pumping, road construction and use, borderland security and undocumented immigration, intentional harm. <i>Factor C:</i> Nonnative species, prey base reduction.
Santa Cruz River downstream of the Nogales area of the International Border (Arizona).	Extirpated .....	<i>Factor A:</i> Improper grazing, development, groundwater pumping, water diversions, channelization, road construction and use, borderland security and undocumented immigration, intentional harm, contaminants. <i>Factor C:</i> Nonnative species, prey base reduction.
Salt River (Arizona) .....	Extirpated .....	<i>Factor A:</i> Improper grazing, recreation, development, water diversions, wildfire, channelization, road construction/use, intentional harm, dams. <i>Factor C:</i> Nonnative species, prey base reduction.
Rio San Bernardino from International Border to headwaters at Astin Spring (San Bernardino National Wildlife Refuge, Arizona).	Extirpated .....	<i>Factor A:</i> Borderland security and undocumented immigration, intentional harm. <i>Factor C:</i> Nonnative species, prey base reduction.
Agua Fria River (Arizona) .....	Extirpated .....	<i>Factor E:</i> Competition with Marcy's checkered gartersnake. <i>Factor A:</i> Improper grazing, development, recreation, dams, road construction and use, wildfire, intentional harm. <i>Factor C:</i> Nonnative species, prey base reduction.
Verde River upstream of Clarkdale (Arizona).	Extirpated .....	<i>Factor A:</i> Improper grazing, recreation, development, groundwater pumping, water diversions, channelization, road construction and use, intentional harm. <i>Factor C:</i> Nonnative species, prey base reduction.
Verde River from the confluence with the Salt upstream to Fossil Creek (Arizona).	Extirpated .....	<i>Factor A:</i> Improper grazing, recreation, groundwater pumping, water diversions, channelization, road construction and use, wildfire, development, intentional harm, dams. <i>Factor C:</i> Nonnative species, prey base reduction.
Potrero Canyon/Springs (Arizona) .....	Extirpated .....	<i>Factor A:</i> Improper grazing. <i>Factor C:</i> Nonnative species, prey base reduction.
Tanque Verde Creek in Tucson (Arizona)	Extirpated .....	<i>Factor A:</i> Improper grazing, recreation, development, groundwater pumping, road construction and use, intentional harm. <i>Factor C:</i> Nonnative species, prey base reduction.
Rillito Creek in Tucson (Arizona) .....	Extirpated .....	<i>Factor A:</i> Improper grazing, recreation, development, groundwater pumping, road construction and use, intentional harm. <i>Factor C:</i> Nonnative species, prey base reduction.
Agua Caliente Spring in Tucson (Arizona).	Extirpated .....	<i>Factor A:</i> Improper grazing, recreation, development, groundwater pumping, road construction and use, intentional harm. <i>Factor C:</i> Nonnative species, prey base reduction.
Babocamari Cienega (Arizona) .....	Extirpated .....	<i>Factor A:</i> Improper grazing. <i>Factor C:</i> Nonnative species, prey base reduction.
Barchas Ranch, Huachuca Mountain bajada (Arizona).	Extirpated .....	<i>Factor A:</i> Improper grazing, borderland security and undocumented immigration, intentional harm. <i>Factor C:</i> Nonnative species, prey base reduction.
Parker Canyon Lake and tributaries in the Canelo Hills (Arizona).	Extirpated .....	<i>Factor A:</i> Improper grazing, recreation, road construction and use, borderland security and undocumented immigration, intentional harm, dams. <i>Factor C:</i> Nonnative species, prey base reduction.
Oak Creek at Midgley Bridge (Arizona) ...	Extirpated .....	<i>Factor A:</i> Improper grazing, recreation, development, intentional harm. <i>Factor C:</i> Nonnative species, prey base reduction.
Santa Cruz River/Lower San Rafael Valley (headwaters downstream to International Border) (Arizona).	Extant .....	<i>Factor A:</i> Improper grazing, borderland security and undocumented immigration, intentional harm. <i>Factor C:</i> Nonnative species, prey base reduction.
Verde River from the confluence with Fossil Creek upstream to Clarkdale (Arizona).	Extant .....	<i>Factor A:</i> Improper grazing, recreation, development, groundwater pumping, water diversions, channelization, road construction and use, intentional harm, dams. <i>Factor C:</i> Nonnative species, prey base reduction.
Oak Creek at Page Springs (Arizona) ....	Extant .....	<i>Factor A:</i> Development, construction, vehicle mortality. <i>Factor C:</i> Nonnative species, prey base reduction, domestic cat predation, parasites.
Tonto Creek from mouth of Houston Creek downstream to Roosevelt Lake (Arizona).	Extant .....	<i>Factor A:</i> Improper grazing, recreation, development, water diversions, channelization, road construction and use, wildfire, intentional harm, dams, flood control. <i>Factor C:</i> Nonnative species, prey base reduction.
Cienega Creek from headwaters downstream to the "Narrows" just downstream of Apache Canyon (Arizona).	Extant .....	<i>Factor A:</i> Improper grazing. <i>Factor C:</i> Nonnative species, prey base reduction.

Population locality	Current status	Regional historical or current threats
Pantano Wash (Cienega Creek) from Pantano downstream to Vail (Arizona).	Extant .....	<i>Factor A:</i> Improper grazing, development, wildfire.
Appleton-Whittell Research Ranch and vicinity near Elgin (Arizona).	Extant .....	<i>Factor C:</i> Nonnative species, prey base reduction.
Upper Scotia Canyon in the Huachuca Mountains (Arizona).	Unknown .....	<i>Factor A:</i> Improper grazing. <i>Factor C:</i> Nonnative species, prey base reduction.
Downstream portion of the Black River drainage from the Paddy Creek confluence (Arizona).	Unknown .....	<i>Factor A:</i> Wildfire.
Downstream portion of the White River drainage from the confluence of the East/North (Arizona).	Unknown .....	<i>Factor C:</i> Nonnative species, prey base reduction.
Big Bonito Creek (Arizona) .....	Unknown .....	<i>Factor A:</i> Improper grazing, recreation, intentional harm. <i>Factor C:</i> Nonnative species, prey base reduction.
Lake O' Woods (Lakeside, Arizona) .....	Unknown .....	<i>Factor A:</i> Improper grazing, recreation, road construction and use, intentional harm. <i>Factor C:</i> Nonnative species, prey base reduction.
Spring Creek above confluence with Oak Creek (Arizona).	Unknown .....	<i>Factor A:</i> recreation, development, road construction/use, intentional harm. <i>Factor C:</i> Nonnative species, prey base reduction.
Bog Hole Wildlife Area (Arizona) .....	Unknown .....	<i>Factor A:</i> Development.
Upper 13 Tank, Patagonia Mountains bajada (Arizona).	Unknown .....	<i>Factor C:</i> Nonnative species, prey base reduction.
Babocamari River (Arizona) .....	Unknown .....	<i>Factor A:</i> Improper grazing.
Arivaca Cienega (Arizona) .....	Unknown .....	<i>Factor C:</i> Nonnative species, prey base reduction.
Gila River at Highway 180 (New Mexico)	Unknown .....	<i>Factor A:</i> Improper grazing, borderland security and undocumented immigration, intentional harm. <i>Factor C:</i> Nonnative species, prey base reduction.
		<i>Factor A:</i> Improper grazing, recreation, development, groundwater pumping, water diversions, channelization, dewatering, road construction/use, wildfire, intentional harm, dams. <i>Factor C:</i> Nonnative species, prey base reduction.

**References:** For each of the population localities discussed in Table 1, a detailed textual discussion of the identified threats, including applicable reference citations, is found in subsequent sections of this finding related to each of the five listing factors. Site-specific information from locations in Mexico is limited and, therefore, locations in Mexico are not included in this table. Where available, the information from Mexico is presented and cited in our discussion of the five listing factors below.

In the discussions of Factors A through E below, we describe the known factors that have contributed to the current status of the northern Mexican gartersnake. For populations within the United States, our analysis benefitted from the availability of specific research, monitoring, and other studies. The discussion of these factors that pertain to the status and threats to the northern Mexican gartersnake in Mexico are mainly regional, or statewide, in scope because, in many cases, there was limited specific information available. In some instances, we do include discussion on more refined geographic areas of Mexico when supported by the literature. It is important to understand, however, that many of the threats that affect the

northern Mexican gartersnake in the United States are also likely present in Mexico, as further discussed below, despite the lack of formal documentation. Thus, we expect impacts to the habitat and the species to be similar in the United States and Mexico.

#### A. The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range

Various threats that have affected and continue to affect riparian and aquatic communities that provide habitat for the northern Mexican garter snake include dams, water diversions, groundwater pumping, introduction of nonnative species (vertebrates, plants, and crayfish), woodcutting, recreation, mining, contaminants, urban and agricultural development, road construction, improper livestock grazing, wildfires, and undocumented immigration (Hendrickson and Minckley 1984, p. 161; Ohmart *et al.* 1988, p. 150; Bahre 1995, pp. 240–252; Medina 1990, p. 351; Sullivan and Richardson 1993, pp. 35–42; Fleischner 1994, pp. 630–631; Hadley and Sheridan 1995; Hale *et al.* 1995, pp. 138–140; DeBano and Neary 1996, pp. 73–75; Rinne and Neary 1996, p. 135; Stromberg *et al.* 1996, p. 124–127;

Girmendock and Young 1997, pp. 45–52; Rinne *et al.* 1998, pp. 7–11; Belsky *et al.* 1999, pp. 8–12; Esque and Schwalbe 2002, pp. 165, 190; Hancock 2002, p. 765; Voeltz 2002, pp. 87–88; Webb and Leake 2005, pp. 305–308; Holycross *et al.* 2006, pp. 52–61; McKinnon 2006a, 2006b, 2006c, 2006d, 2006e; Paradzick *et al.* 2006, pp. 88–93; Segee and Neeley 1996, Executive Summary, pp. 10–12, 21–23; Burger 2008, USFS 2008; USFWS 2007, pp. 25, 35–39; Gila County Board of Supervisors 2008, pp. 1–2; Kimmel 2008; Trammell 2008; Sanchez 2008; Lyons and Navarro-Perez 1990, p. 37; Minckley *et al.* 2002, pp. 696; Nijhuis 2007, pp. 1–7; Ouren *et al.* 2007, pp. 16–22; Rorabaugh 2008, pp. 25–26). Threats to northern Mexican gartersnake habitat in Mexico include the intentional and unintentional introductions of nonnative species, improper livestock grazing, urbanization and development, water diversions and groundwater pumping, loss of vegetation cover and deforestation, erosion, and pollution, as well as impoundments and dams that have modified or destroyed riparian and aquatic communities within Mexico in areas where the species occurred historically (Conant 1974, p. 471; Lyons and Navarro-Perez 1990, p. 37; Contreras Balderas and Lozano 1994, p.

384; va Landa *et al.* 1997, p. 316; Jiménez-Ruiz *et al.* 2002, p. 458; Minckley *et al.* 2002, pp. 696; Miller *et al.* 2005, pp. 60–61; Abarca 2006; Burger 2008; Luja and Rodríguez-Estrella 2008, pp. 17–22; Rorabaugh 2008, pp. 25–26; Manjarrez 2008).

Rorabaugh (2008, pp. 25–26) noted threats to northern Mexican gartersnakes and their native amphibian prey base in Sonora, which included disease, pollution, improper livestock grazing, conversion of land for agriculture, nonnative plant invasions, and logging. Ramirez Bautista and Arizmendi (2004, p. 3) stated that the principal threats to northern Mexican gartersnake habitat in Mexico include the drying of wetlands, improper livestock grazing, deforestation, wildfires, and urbanization. In addition, nonnative species, such as bullfrogs and sport and bait fish, have been introduced throughout Mexico and continue to disperse naturally, broadening their distributions (Conant 1974, pp. 487–489; Miller *et al.* 2005, pp. 60–61; Luja and Rodríguez-Estrella 2008, pp. 17–22).

The activities outlined above for both the United States and Mexico and their effects on the northern Mexican gartersnake are discussed in further detail below. It is important to recognize that in most areas where northern Mexican gartersnakes historically or currently occur, two or more threats may be acting in combination in their influence on the suitability of those habitats or on the northern Mexican gartersnake itself. In our assessment of the status of these habitats, discussion of the role that nonnative species introductions have had on habitat suitability is critical. However, we provide that discussion under “Factor C. Disease and Predation” due to the intricate and complex relationship nonnative species have with respect to direct and indirect pressures applied to the northern Mexican gartersnake and to its native prey base.

#### Destruction and Modification of Riparian and Aquatic Biological Communities

The modification and destruction of aquatic and riparian communities in the post-settlement arid southwestern United States is well documented (Medina 1990, p. 351; Sullivan and Richardson 1993, pp. 35–42; Fleischner 1994, pp. 630–631; Stromberg *et al.* 1996, pp. 113, 123–128; Girmendock and Young 1997, pp. 45–52; Belsky *et al.* 1999, pp. 8–12; Webb and Leake 2005, pp. 305–310; Holycross *et al.* 2006, pp. 52–61; Nijhuis 2007, pp. 1–7; Ouren *et al.* 2007, pp. 16–22). Several

threats have been identified in the decline of many native riparian flora and fauna species through habitat modification and destruction, as well as nonnative species introductions. Researchers agree that the period from 1850 to 1940 marked the greatest loss and degradation of riparian and aquatic communities in Arizona, which were caused by anthropogenic (human-caused) land uses and the primary and secondary effects of those uses (Stromberg *et al.* 1996, p. 114; Webb and Leake 2005, pp. 305–310). Many of these land activities continue today and are discussed in detail below. An estimated one-third of Arizona’s pre-settlement wetlands have dried or have been rendered ecologically dysfunctional (Yuhás 1996).

*Modification and Loss of Cienegas.* Cienegas are particularly important habitat for the northern Mexican gartersnake and are considered ideal for the species (Rosen and Schwalbe 1988, p. 14). Hendrickson and Minckley (1984, p. 131) defined cienegas as “mid-elevation (3,281–6,562 ft (1,000–2,000 m)) wetlands characterized by permanently saturated, highly organic, reducing [lowering of oxygen level] soils.” Many of these unique communities of the southwestern United States, Arizona in particular, and Mexico have been lost in the past century to streambed modification, improper livestock grazing, woodcutting, artificial drainage structures, stream flow stabilization by upstream dams, channelization, and stream flow reduction from groundwater pumping and water diversions. (Hendrickson and Minckley 1984, p. 161). Stromberg *et al.* (1996, p. 114) state that cienegas were formerly extensive along streams of the Southwest; however, most were destroyed during the late 1800s, when groundwater tables declined several meters and stream channels became incised.

Nonnative shrub species in the genus *Tamarix*, such as salt cedar, have been widely introduced throughout the western States and appear to thrive in regulated river systems (Stromberg and Chew 2002, pp. 210–213). *Tamarix* invasions may result in habitat alteration from potential effects to water tables, changes to canopy and ground vegetation structures, and increased fire risk, which hasten the loss of native cottonwood and willow communities and affect the suitability of the vegetation component to northern Mexican gartersnake habitat (Stromberg and Chew 2002, pp. 211–212; USFWS 2002b, p. H–9).

Many sub-basins, where cienegas have been severely modified or lost entirely, wholly or partially overlap the historical distribution of the northern Mexican gartersnake, including the San Simon, Sulphur Springs, San Pedro, and Santa Cruz valleys of southeastern and south-central Arizona. The San Simon Valley in Arizona possessed several natural cienegas with luxuriant vegetation prior to 1885, and was used as a watering stop for pioneers, military, and surveying expeditions (Hendrickson and Minckley 1984, pp. 139–140). In the subsequent decades, the disappearance of grasses and commencement of severe erosion were the result of heavy grazing pressure by large herds of cattle, as well as the effects from wagon trails that paralleled arroyos, occasionally crossed them, and often required stream bank modification (Hendrickson and Minckley 1984, p. 140). Today, only the artificially maintained San Simon Cienega exists in this valley. Similar accounts of past conditions, adverse effects from historical anthropogenic activities, and subsequent reduction in the extent and quality of cienega habitats in the remaining valleys are also provided in Hendrickson and Minckley (1984, pp. 138–160).

*Urban and Rural Development.* Development within and adjacent to riparian areas has proven to be a significant threat to riparian biological communities and their suitability for native species (Medina 1990, p. 351). Riparian communities are sensitive to even low levels (less than 10 percent) of urban development within a watershed (Wheeler *et al.* 2005, p. 142). Development along or within proximity to riparian zones can alter the nature of stream flow dramatically, changing once-perennial streams into ephemeral streams, which has direct consequences on the riparian community (Medina 1990, pp. 358–359) and, within occupied habitat, the northern Mexican gartersnake. Medina (1990, pp. 358–359) concluded that perennial streams had greater tree densities in all diameter size classes of *Alnus oblongifolius* (Arizona alder) and *Acer negundo* (box elder) as compared to ephemeral reaches where small-diameter trees were absent. Small-diameter trees assist the northern Mexican gartersnake by providing additional habitat complexity and cover needed to reduce predation risk and enhance the usefulness of areas for maintaining optimal body temperature.

Obvious examples of the influence of urbanization and development can be observed within the areas of greater Tucson and Phoenix, Arizona, where impacts have modified riparian vegetation, structurally altered stream

channels, facilitated nonnative species introductions, and dewatered large reaches of formerly perennial rivers where the northern Mexican gartersnake historically occurred (Santa Cruz, Gila, and Salt rivers, respectively). Urbanization and development of these areas, along with the introduction of nonnative species, are largely responsible for the likely extirpation of the northern Mexican gartersnake from these areas.

Urbanization on smaller scales can also impact habitat suitability and the prey base for the northern Mexican gartersnake. Regional development and subsequent land use changes, spurred by increasing populations, along lower Tonto Creek and within the Verde Valley where northern Mexican gartersnakes occur, continue to threaten this snake's habitat and affect the habitat's suitability for the northern Mexican gartersnake and its prey species (Girmendock and Young 1997, pp. 45–52; Voeltz 2002, pp. 58–59, 69–71; Paradzick *et al.* 2006, pp. 89–90). Holycross *et al.* (2006, pp. 53, 56) recently documented the damage and removal of northern Mexican gartersnake streamside habitat from development in the vicinity of Rock Springs along the Agua Fria River and also within the Verde Valley along the Verde River.

Ongoing small-scale development projects within the Page Springs and Bubbling Ponds fish hatcheries along Oak Creek, upstream of its confluence with the Verde River, occur within potentially the most robust remaining population of northern Mexican gartersnakes in the United States (AGFD 1997a, pp. 1–13; 1997b, pp. 1–12). The Page Springs trout hatchery is an 82-acre (ac) (33-hectare (ha)) facility located within a semi-desert grassland vegetative community (AGFD 1997a, p. 3). It is the largest State-run hatchery and was renovated in 1993, resulting in construction-related impacts such as the removal of riparian vegetation and other earth-moving activities to occupied snake habitat (AGFD 1997a, p.1). Current and future management and maintenance of Page Springs include a variety of activities that would potentially affect occupied snake habitat, such as the maintenance of roads, buildings, fences, equipment, as well as development (residences, storage facilities, asphalt, resurfacing, etc.) and both human- and habitat-based enhancement projects (AGFD 1997a, p. 8). Implementation of such projects is expected to result in the damage or removal of habitat or potentially the contamination of habitat from the use of industrial products and chemicals.

These projects may adversely affect the northern Mexican gartersnake directly through physical harm or injury or indirectly from effects to its habitat or prey base.

The Bubbling Ponds hatchery, which raises nonnative and native fish (largemouth bass, smallmouth bass, and bluegill, Colorado River pikeminnow, razorback sucker), is located on Oak Creek, just north of the Page Springs hatchery, and comprises 2 parcels approximately 117 ac (47 ha) in size (AGFD 1997b, p. 2). The hatchery consists of 11 earthen ponds and 6 lined ponds totaling 10 surface acres (4 surface hectares), 3 residential structures, and the hatchery building (AGFD 1997b, p. 2). Hatchery operations are confined to 17 of the 117 ac (7 of 47 ha) and have been modified extensively (AGFD 1997b, p. 4). The remaining 100 ac (40 ha) support riparian woodland and forest along Oak Creek (AGFD 1997b, p. 4). Northern Mexican gartersnakes are presumed to occur throughout this property; using the earthen ponds for foraging on young bullfrogs, their tadpoles, and fish, and using areas near or adjacent to structures on the property. Current and future management and maintenance of Bubbling Ponds include a variety of activities that would potentially affect snake habitat, such as the maintenance of roads, buildings, fences, equipment, as well as development (residences, storage facilities, asphalt, resurfacing, etc.) and both human- and habitat-based enhancement projects (AGFD 1997b, pp. 8–9; Wilson and Company 1991, pp. 1–40; 1992, pp. 1–99). Implementation of such projects is expected to result in the damage or removal of habitat or potentially the contamination of habitat from the use of industrial products and chemicals. The small-scale development projects at these hatcheries may injure or kill northern Mexican gartersnakes or their prey base, and may also temporarily damage or remove occupied habitat. The Arizona Game and Fish Department is a long-standing partner in research and survey efforts related to the northern Mexican gartersnake, and there is an ongoing population study at the hatcheries. Adaptive management in relation to activities at the hatcheries, as informed by the population study, will help reduce the overall effects to gartersnakes and their habitat at the hatcheries.

The effects of urban and rural development are expected to increase as human populations increase. Consumer interest in second home and/or retirement real estate investments has increased significantly in recent times within the southwestern United States.

Medina (1990, p. 351) points out that many real estate investors are looking for aesthetically scenic, mild climates to enjoy seasonally or year-round and hence choose to develop pre- or post-retirement properties that are within or adjacent to riparian areas due to their aesthetic appeal and available water, especially in the southwestern United States. Arizona increased its population by 394 percent from 1960 to 2000, and is second only to Nevada as the fastest growing State in terms of human population (Social Science Data Analysis Network (SSDAR) 2000, p.1). Over the same time period, population growth rates in Arizona counties where the northern Mexican gartersnake historically occurred or may still occur have varied by county but are no less remarkable, and all are increasing: Maricopa (463 percent); Pima (318 percent); Santa Cruz (355 percent); Cochise (214 percent); Yavapai (579 percent); Gila (199 percent); Graham (238 percent); Apache (228 percent); Navajo (257 percent); Yuma (346 percent); LaPaz (142 percent); and Mohave (2004 percent) (SSDAR 2000).

Population growth trends in Arizona, Maricopa County in particular, are expected to continue into the future. The Phoenix metropolitan area, founded in part due to its location at the junction of the Salt and Gila rivers, is a population center of 3.63 million people. The Phoenix metropolitan area is the sixth largest in the United States and resides in the fastest growing county in the United States since the 2000 census (Arizona Republic 2006). Given the large amount of perennial habitat at the confluence of two large, flowing rivers that was historically present in this area prior to settlement, northern Mexican gartersnakes likely maintained dense populations in this region of Arizona. However, with the burgeoning population growth and associated urbanization and development that have occurred since, any remaining habitat for the northern Mexican gartersnake has been rendered unsuitable and the subspecies is now likely extirpated from this area and its recovery is unlikely.

Massive growth predictions have been made for traditionally rural portions of Arizona. The populations of developing cities and towns of the Verde watershed are expected to more than double in the next 50 years, which may pose exceptional threats to riparian and aquatic communities of the Verde Valley where northern Mexican gartersnakes occur (Girmendock and Young 1993, p. 47; American Rivers 2006; Paradzick *et al.* 2006, p. 89). Communities in Yavapai and Gila

counties such as the Prescott-Chino Valley, Strawberry, Pine, and Payson have all seen rapid population growth in recent years. For example, the population in the town of Chino Valley, at the headwaters of the Verde River, has grown by 22 percent between 2000 and 2004; Gila County, which includes reaches of the Salt, White, and Black rivers and Tonto Creek, grew by 20 percent between 2000 and 2003 (<http://www.census.gov>). The upper San Pedro River is also the location of rapid population growth in the Sierra Vista-Huachuca City-Tombstone-Benson area (<http://www.census.gov>). All of these communities are near or within the vicinity of historical or current northern Mexican gartersnake populations.

In Mexico, the magnitude and significance of adverse effects to riparian communities related to development lags somewhat behind that experienced in the United States due to slower population and economic growth, but it is reported that threats to riparian and aquatic communities that have been observed in Arizona are currently occurring with increasing significance in Mexico (Conant 1974, pp. 471, 487–489; Contreras Balderas and Lozano 1994, pp. 379–381; va Landavet *et al.* 1997, p. 316; Miller *et al.* 2005, p. 60–61; Abarca 2006; Rosen 2006).

Ortega-Huerta and Kral (2007, p. 1) found that land legislation within Mexico has changed considerably over recent years to integrate free market policies into local agricultural production methods that may result in the loss of land management practices that protect the natural environment. Community-based lands generally presented higher instance of habitat conservation in terms of natural vegetation, higher species aggregations, more evenly distributed cover types, and greater species richness (Ortega-Huerta and Kral 2007, p. 1). These correlations between land ownership and bird and mammal species richness can be generally extrapolated to other aspects of biotic communities, including the aquatic and semi-aquatic communities within areas. A shift away from traditional land management in Mexico presents threats to riparian and aquatic habitats occupied by the northern Mexican gartersnake.

Collectively, development impacts of all types in Mexico are expected to continue as a result of Mexico's expanding role as an economical labor force for international manufacturing under the North American Free Trade Agreement (NAFTA) and the subsequent increase in population size, economic growth and development, and

infrastructure. The threats to northern Mexican gartersnake habitat in riparian and aquatic communities in Mexico vary in their significance, based on geographical distribution of land management activities and urban centers, but are expected to continue into the future.

Mexico's human population grew 700 percent from 1910 to 2000 (Miller *et al.* 2005, p. 60). Mexico's population increased by 245 percent from 1950 to 2002, and is projected to grow by another 28 percent by 2025 (EarthTrends 2005). As of 1992, Mexico had the second highest gross domestic product in Latin America at 5.8 percent, following Brazil (DeGregorio 1992, p. 60). As a result of NAFTA, the number of maquiladoras (export assembly plants) is expected to increase by as many as 3,000 to 4,000 (Contreras Balderas and Lozano 1994, p. 384). To accommodate Mexico's increasing human population, rural areas are largely devoted to food production based on traditional methods, which has led to serious losses in vegetative cover and soil erosion (va Landa *et al.* 1997, p. 316).

*Road Construction, Use, and Maintenance.* Roads cover approximately 1 percent of the land area in the United States, but negatively affect 20 percent of the habitat and biota in the United States (Angermeier *et al.* 2004, p. 19). Roads pose unique threats to herpetofauna and specifically to species like the northern Mexican gartersnake, its prey base, and the habitat where it occurs through: (1) Fragmentation, modification, and destruction of habitat; (2) increase in genetic isolation; (3) alteration of movement patterns and behaviors; (4) facilitation of the spread of nonnative species via human vectors; (5) an increase in recreational access and the likelihood of subsequent, decentralized urbanization; (6) interference with or inhibition of reproduction; (7) contributions of pollutants to riparian and aquatic communities; and (8) population sinks (a factor resulting in unnaturally high death rates that exceed birth rates within a population) through direct mortality (Rosen and Lowe 1994, pp. 146–148; Waters 1995, p. 42; Carr and Fahrig 2001, pp. 1074–1076; Hels and Buchwald 2001, p. 331; Smith and Dodd 2003, pp. 134–138; Angermeier *et al.* 2004, pp. 19–24; Shine *et al.* 2004, pp. 9, 17–19; Andrews and Gibbons 2005, pp. 777–781; Wheeler *et al.* 2005, pp. 145, 148–149; Roe *et al.* 2006, p. 161).

Construction and maintenance of roads and highways near riparian areas can be a source of sediment and

pollutants (Waters 1995, p. 42; Wheeler *et al.* 2005, pp. 145, 148–149). Sediment can adversely affect fish populations used as prey by the northern Mexican gartersnake by (1) interfering with respiration; (2) reducing the effectiveness of fish's visually-based hunting behaviors; and (3) filling in interstitial spaces of the substrate, which reduces reproduction and foraging success of fish (Wheeler *et al.* 2005, p. 145). Excessive sediment also fills in intermittent pools required for amphibian prey reproduction and foraging. Fine sediment pollution in streams impacted by highway construction without the use of sediment control structures was 5 to 12 times greater than control streams (Wheeler *et al.* 2005, p. 144). As stated above, sediment can lead to several effects in resident fish species used by northern Mexican gartersnakes as prey, which can ultimately cause increased direct mortality, reduced reproductive success, lower overall abundance of the northern Mexican gartersnake, lower species diversity of prey, and reductions in food base as documented by Wheeler *et al.* (2005, p. 145). The underwater foraging ability of northern Mexican gartersnakes is also directly compromised by excessive turbidity caused by sedimentation of water bodies, because this snake locates its prey visually.

Metal contaminants, including iron, zinc, lead, cadmium, nickel, copper, and chromium, are associated with highway construction and use (Foreman and Alexander 1998, p. 220; Hopkins *et al.* 1999, p. 1260; Campbell *et al.* 2005, p. 241; Wheeler *et al.* 2005, pp. 146–149) and are bioaccumulative. A bioaccumulative substance increases in concentration in an organism or in the food chain over time. A mid- to higher-order predator, such as a gartersnake, may therefore accumulate these types of contaminants over time in their fatty tissues, which may lead to adverse health effects. Several studies have addressed the effects of bioaccumulative substances on watersnakes. We find these studies relevant because watersnakes and gartersnakes have very similar life histories and prey bases and, therefore, the effects from contamination of their habitat from bioaccumulative agents are expected to be similar. Campbell *et al.* (2005, pp. 241–243) found that metal concentrations accumulated in the northern watersnake (*Nerodia sipedon*) at levels six times that of their primary food item, the central stoneroller (fish) (*Camptostoma anomalum*). Metals, in trace amounts, affect the structure and



function of the liver and kidneys of vertebrates and may also act as neurotoxins, affecting nervous system function (Rainwater *et al.* 2005, p. 670). Metals may also be sequestered in the skin of reptiles, but this effect is tempered somewhat by ecdysis (the regular shedding or molting of the skin) (Burger 1999, p. 212). Hopkins *et al.* (1999, p. 1261) found that metals may even interfere with metabolic rates of banded watersnakes (*Nerodia fasciata*), altering the allocation of energy between maintenance and reproduction, reducing the efficiency of energy stores, and forcing individuals to forage more often, which increases activity costs (the energy expended in hunting, which affects the net nutritional intake of an organism) and predation risk.

Snakes of all species are particularly vulnerable to mortality when they attempt to cross roads. Snakes are animals that derive heat from warm surfaces, which often compels them to slow down or even stop and rest on road surfaces that have been warmed by the sun as they attempt to cross (Rosen and Lowe 1994, p. 143). Gartersnakes are generally diurnal (active during daylight hours) and are often active when traffic densities are greatest (Rosen and Lowe 1994, p. 147). Mortality data have been collected at the Bubbling Ponds Hatchery since 2006. Of the eight dead specimens, half were struck by vehicles on roads adjacent to the hatchery ponds that are crossed by northern Mexican gartersnakes in traveling between ponds to forage (Boyarski 2008a). Van Devender and Lowe (1977, p. 47), however, observed several northern Mexican gartersnakes crossing the road at night after the commencement of the summer monsoon (rainy season), which highlights the seasonal variability in surface activity of this snake. Perhaps the most common factor in road mortality of snakes is the propensity for drivers to intentionally run over snakes, which generally make easy targets because they usually cross roads at a perpendicular angle (Klauber 1956, p. 1026; Langley *et al.* 1989, p. 47; Shine *et al.* 2004, p. 11). This driving behavior is exacerbated by the general animosity that humans have toward snakes (Ernst and Zug 1996, p. 75; Green 1997 pp. 285–286). In fact, Langley *et al.* (1989, p. 47) conducted an experiment on the propensity for drivers to hit reptiles on the road using turtle and snake models and found that many people have a greater desire to hit a snake on the road than any other animal; several drivers actually stopped and backed-over the snake mimic to ensure it was dead. Roe *et al.* (2006, p. 161) conclude that

mortality rates due to roads are higher in vagile (mobile) species, such as gartersnakes (active hunters), than those of more sedentary species, which more commonly employ sit-and-wait foraging strategies. Roads that bisect wetland communities also act as mortality sinks in the dispersal or migratory movements of snakes (Roe *et al.* 2006, p. 161). The effect of road mortality of snakes becomes most significant in the case of small, highly fragmented populations where the chance removal of mature females from the population may appreciably degrade the viability of a population.

Even lightly used roads may also lead to mortality of northern Mexican gartersnakes. For example, gravel roads that surround the hatchery ponds that are traveled by hatchery, research lab, and resident vehicles at the Bubbling Ponds fish hatchery have resulted in four documented northern Mexican gartersnake mortalities since mortality data began being collected in 2006 (Boyarski 2008a, pp. 1–4). These vehicle mortalities represent 50 percent of the mortalities documented at the hatcheries. Of note is the fact that these vehicles are likely traveling at slow speeds, which indicates that even slow-moving vehicles pose a hazard to crossing and basking snakes. Wallace *et al.* (2008, pp. 243–244) documented a vehicle-related mortality of a northern Mexican gartersnake on Arizona State Route 188 near Tonto Creek that occurred in 1995. As shown in the above examples, vehicle-related mortalities of northern Mexican gartersnakes likely occur routinely along roads or trails adjacent to occupied habitat throughout the range of the subspecies but are generally difficult to document.

Off-highway vehicle (OHV) use has grown considerably in Arizona. For example, as of 2007, 385,000 OHVs were registered in Arizona (a 350 percent increase since 1998) and 1.7 million people (29 percent of the Arizona's public) engaged in off-road activity from 2005–2007 (Sacco 2007). Over half of OHV users reported that merely driving off-road was their primary activity, versus using the OHV for the purpose of hunting, fishing, or hiking (Sacco 2007). Given the pervasive use of OHV's on the landscape, OHV-related mortalities are likely a threat to northern Mexican gartersnakes. Ouren *et al.* (2007, pp. 16–22) provide additional data on the effects of OHV use on wildlife. Specifically, OHV use may cause mortality or injury to species, such as northern Mexican gartersnakes, that attempt to cross trails created through

occupied habitat and may even lead to depressed populations of snakes depending on the rate of use and number of trails within a given area (Ouren *et al.* 2007, pp. 20–21). This threat may be even more extensive from OHVs than from conventional vehicles because OHV trails often travel through undeveloped habitat and often cross directly through waterbodies. OHV use may also affect northern Mexican gartersnake habitat by reducing vegetation cover and plant species diversity, reducing infiltration rates, increasing erosion, and reducing habitat connectivity (Ouren *et al.* 2007, pp. 6–7, 11, 16).

Roads create access to areas that were previously visited only infrequently or were inaccessible to humans, increasing the frequency and significance of anthropogenic threats to riparian areas and fragmenting the landscape, which in addition to direct effects to snakes and habitat, may genetically isolate herpetofaunal populations (Rosen and Lowe 1994, pp. 146–148; Andrews and Gibbons 2005, p. 772).

McCranie and Wilson (1987, p. 2) discuss threats to the pine-oak communities of higher elevation habitats within the distribution of the northern Mexican gartersnake in the Sierra Madre Occidental in Mexico, specifically noting that “\* \* \* the relative pristine character of the pine-oak woodlands is threatened \* \* \* every time a new road is bulldozed up the slopes in search of new maderal or pasturage. Once the road is built, further development follows; pueblos begin to pop up along its length \* \* \*.” Several drainages that possess suitable habitat for the species occur in the area referenced above by McCranie and Wilson (1987, p. 2) including the Rio de la Cuidad, Rio Quebrada El Salto, Rio Chico, Rio Las Bayas, Rio El Cigarrero, Rio Galindo, Rio Santa Barbara, and the Rio Chavaria.

While snakes of all species may suffer direct mortality as a result of attempting to cross roads, Andrews and Gibbons (2005, pp. 777–779) found that many individuals of small, diurnal snake species avoid open areas (e.g., roads) instinctively in order to lower predation rates, which represents a different type of threat from roads. Shine *et al.* (2004, p. 9) found that the common gartersnake typically changed direction when encountering a road. These avoidance behaviors by individuals averse to crossing roads affect movement patterns and may ultimately affect reproductive output within populations (Shine *et al.* 2004, pp. 9, 17–19). Not crossing roads can reduce the amount of habitat available for individual snakes to find

prey, mates, etc. This avoidance behavior has been observed in the common gartersnake (*Thamnophis sirtalis*), a sister taxon to the Mexican gartersnake with similar life histories and behavior (Shine *et al.* 2004, p. 9). In our discussion and as evidenced by the literature we reviewed on the effect of roads on snake movements, we acknowledge the individuality of snakes in their behaviors towards road crossings.

In addition to altering the movement patterns of some snakes, roads interfere with the male gartersnake's olfactory-driven ability to follow the pheromone trails left by receptive females (Shine *et al.* 2004, pp. 17–18). This effect to the male's ability to efficiently trail females may exacerbate the effects of low population density and fragmentation that affect several species of snakes, including the northern Mexican gartersnake. Because the male gartersnake's ability to trail females is hampered by roads, the extra time and distance traveled by male snakes seeking receptive females increases exposure to predation and subsequently increases mortality rates (Shine *et al.* 2004, pp. 18–19). Although the northern Mexican gartersnake was not the subject of the 2004 Shine *et al.* study, similar responses can be expected in the northern Mexican gartersnake because its life history is similar to the study's subject species (i.e., the common gartersnake).

Roads also affect prey availability for northern Mexican garter snakes. Roads tend to adversely affect aquatic breeding anuran populations more so than other species due to their activity patterns (mass movements of individuals), population structures (large cohorts of similarly aged individuals within a population), and preferred habitats which are often adjacent to roads and usually constrained to aquatic or semiaquatic areas (Hels and Buchwald 2001, p. 331). Carr and Fahrig (2001, pp. 1074–1076) found that populations of highly mobile anuran species such as leopard frogs (*Rana pipiens*) were run over more frequently than more sedentary species and that population persistence can be at risk depending on traffic densities, which may adversely affect the prey base for northern Mexican gartersnakes because leopard frogs are a primary prey species.

**Recreation.** As discussed above, population growth trends are expected to continue into the future. Expanding population growth leads to higher recreational use of riparian areas, as evidenced along reaches of the Salt and Verde rivers in proximity to the Phoenix metropolitan area. Riparian areas

located near urban areas are vulnerable to the effects of increased recreation with predictable changes in the type and intensity of land use following residential development. An example of such an area within the existing distribution of the northern Mexican gartersnake is the Verde Valley. The reach of the Verde River that winds through the Verde Valley receives a high amount of recreational use from people living in central Arizona (Paradzick *et al.* 2006, pp. 107–108). Increased human use results in the trampling of near-shore vegetation, which reduces cover for gartersnakes, especially newborns. Increased human visitation in occupied habitat also increases the potential for human-gartersnake interactions, which frequently leads to the capture, injury, or death of the snake (Rosen and Schwalbe 1988, p. 43; Ernst and Zug 1996, p. 75; Green 1997, pp. 285–286; Nowak and Santana-Bendix 2002, p. 39). Recreational activities in the Southwest are often tied to water bodies and riparian areas. Increased recreational impacts on the quantity and quality of water, as well as the adjacent vegetation, are threats to local populations of the northern Mexican gartersnake.

**Groundwater Pumping, Surface Water Diversions, and Flood Control.**

Increased urbanization and population growth results in an increase in the demand for water and, therefore, water development projects. Collier *et al.* (1996, p. 16) mention that water development projects are one of two main causes of decline of native fish in the Salt and Gila rivers of Arizona. Municipal water use in central Arizona has increased by 39 percent in the last 8 years (American Rivers 2006). Water for development and urbanization is often supplied by groundwater pumping and surface water diversions from sources that include reservoirs and Central Arizona Project's allocations from the Colorado River. The hydrologic connection between groundwater and surface flow of intermittent and perennial streams is becoming better understood. Groundwater pumping creates a cone of depression within the affected aquifer that slowly radiates outward from the well site. When the cone of depression intersects the hyporheic zone of a stream (the active transition zone between two adjacent ecological communities under or beside a stream channel or floodplain between the surface water and groundwater that contributes water to the stream itself), the surface water flow may decrease, and the subsequent drying of riparian and wetland vegetative communities

can follow. This situation has been created by groundwater use by the community of Sierra Vista in Cochise County, which continues to threaten the riparian community along the upper San Pedro River where the northern Mexican gartersnake historically occurred. Continued groundwater pumping at such levels draws down the aquifer sufficiently to create a water-level gradient away from the stream and floodplain (Webb and Leake 2005, p. 309). Finally, complete disconnection of the aquifer and the stream results in strong negative effects to riparian vegetation (Webb and Leake 2005, p. 309). If complete disconnection occurs, the hyporheic zone could be adversely affected. The hyporheic zone can promote "hot spots" of productivity where groundwater upwelling produces nitrates that can enhance the growth of vegetation, but its significance is contingent upon its activity and extent of connection with the groundwater (Boulton *et al.* 1998, p. 67; Boulton and Hancock 2006, pp. 135, 138). Such "hot spots" can enhance the quality of northern Mexican gartersnake habitat. Conversely, changes to the duration and timing of upwelling can potentially lead to localized extinctions in biota (Boulton and Hancock 2006, p. 139), reducing gartersnake habitat suitability.

The effects of groundwater pumping on surface water flow and riparian communities have been observed in the Santa Cruz, San Pedro, and Verde rivers as a result of groundwater demands of Tucson, Sierra Vista, and the rapidly growing Prescott Valley, respectively (Stromberg *et al.* 1996, pp. 113, 124–128; Rinne *et al.* 1998, p. 9; Voeltz 2002, pp. 45–47, 69–71). Along the upper San Pedro River, Stromberg *et al.* (1996, pp. 124–127) found that wetland herbaceous species, important as cover for northern Mexican gartersnakes, are the most sensitive to the effects of a declining groundwater level. Webb and Leake (2005, pp. 302, 318–320) described a correlative trend regarding vegetation along southwestern streams from historically being dominated by marshy grasslands preferable to northern Mexican gartersnakes, to currently being dominated by woody species more tolerant of declining water tables due to their associated deeper rooting depths.

The full effects of large-scale groundwater pumping associated with the proposed Big Chino Water Ranch Project and its associated 30-mile (48-km), 36-in (91-cm) diameter pipeline have yet to be realized in the Verde River (McKinnon 2006c). This groundwater pumping and inter-basin transfer project is projected to deliver

2.8 billion gallons of groundwater annually from the Big Chino sub-basin aquifer to the rapidly growing area of Prescott Valley for municipal use (McKinnon 2006c). The Big Chino sub-basin provides 86 percent of the baseflow to the upper Verde River (American Rivers 2006; McKinnon 2006a). The potential for this project to obtain funding and approval for implementation has placed the Verde River on American River's 2006 "Ten Most Endangered Rivers List" (American Rivers 2006). This potential reduction or loss of baseflow in the Verde River could seasonally dry up large reaches or adversely affect the riparian community and the suitability of the habitat for remaining populations of the northern Mexican gartersnake and its prey species in that area.

Within the Verde River watershed, and particularly within the Verde Valley where the northern Mexican gartersnake is believed to currently remain, several other activities continue to threaten surface flows (Rinne *et al.* 1998, p. 9; Paradzick *et al.* 2006, pp. 104–110). The demands for surface water allocations from rapidly growing communities and agricultural and mining interests have altered flows or dewatered significant reaches during the spring and summer months in some of the Verde River's larger, formerly perennial tributaries such as Wet Beaver Creek, West Clear Creek, and the East Verde River, which may have supported the northern Mexican gartersnake (Girmendock and Young 1993, pp. 45–47; Sullivan and Richardson 1993, pp. 38–39; Paradzick *et al.* 2006, pp. 104–110). Groundwater pumping in the Tonto Creek drainage regularly eliminates surface flows during parts of the year (Abarca and Weedman 1993, p. 2). The upper Gila River is also threatened by water diversions and water allocations. In New Mexico, a proposed water project that resulted from a landmark Gila River water settlement in 2004 allows New Mexico the right to withhold 4.5 billion gallons of surface water every year (McKinnon 2006d). If this proposed water diversion project is implemented, in dry years, currently perennial reaches of the upper Gila River will dry completely, which removes all suitability of this habitat for the northern Mexican gartersnakes and a host of other riparian and aquatic species (McKinnon 2006d).

The Arizona Department of Water Resources (ADWR) manages water supplies in Arizona and has established five Active Management Areas (AMA) across the State (ADWR 2006). An AMA is established by ADWR when an area's water demand has exceeded the

groundwater supply and an overdraft has occurred. In these areas, groundwater use has exceeded the rate that precipitation can recharge the aquifer, which leads to conditions described above. Geographically, all five AMAs overlap the historical distribution of the northern Mexican gartersnake in Arizona. The declaration of these AMAs further illustrates the condition and future threats to riparian habitat in these areas and are a cause of concern for the long-term maintenance of historical and occupied northern Mexican gartersnake habitat. Such overdrafts reduce surface water flow of streams that are hydrologically connected to the aquifer under stress, which can be further exacerbated by the surface water diversions.

To accommodate the needs of rapidly growing rural and urban populations, surface water is commonly diverted to serve many industrial and municipal uses. These water diversions have dewatered large reaches of once perennial or intermittent streams, adversely affecting northern Mexican gartersnake habitat throughout its range in Arizona and New Mexico. Many tributaries of the Verde River are permanently or seasonally dewatered by water diversions for agriculture (Paradzick *et al.* 2006, pp. 104–110).

Effects from flood control projects threaten riparian and aquatic habitat, as well as threaten the northern Mexican gartersnake directly. Kimmell (2008), Gila County Board of Supervisors (2008), Trammell (2008), and Sanchez (2008) all discuss a growing concern of residents that live within or adjacent to the floodplain of Tonto Creek in Gila County, Arizona, both upstream and downstream of the town of Gisela, Arizona. Specifically, there is growing concern to address threats to private property and associated infrastructure posed by flooding of Tonto Creek (Sanchez 2008). The only known remaining population of northern Mexican gartersnakes within the large Salt River watershed occurs on Tonto Creek. The status of the northern Mexican gartersnake on tribal lands within the Salt River watershed remains unknown. In Resolution No. 08–06–02, the Gila County Board of Supervisors has proactively declared a state of emergency within Gila County as a result of the expectation for heavy rain and snowfall causing repetitive flooding conditions (Gila County Board of Supervisors 2008). In response, the Arizona Division of Emergency Management called meetings and initiated discussions among stakeholders in an attempt to mitigate these flooding concerns (Kimmell 2008,

Trammell 2008). Mitigation measures that have been discussed include removal of riparian vegetation, removal of debris piles, potential channelization of Tonto Creek, improvements to existing flood control structures or addition of new structures, and the construction of new bridges. Adverse effects of these types of activities to aquatic and riparian habitat and to the northern Mexican gartersnake or its prey species will result from the physical alteration or destruction of habitat, significant increases to flow velocity, and removal of key foraging habitat and areas to hibernate, such as debris jams. Specifically, flood control projects permanently alter stream flow characteristics and have the potential to make the stream unsuitable as habitat for the northern Mexican gartersnake by reducing or eliminating stream sinuosity and associated pool and backwater habitats that are critical to northern Mexican gartersnakes and their prey species. Threats presented by these flood control planning efforts are considered imminent.

In Mexico, Conant (2003, p. 4) noted human-caused threats to seven fragmented, highly localized subspecies of Mexican gartersnake in the Transvolcanic Belt Region of southern Mexico, which extends from southern Jalisco eastward through the State of Mexico to central Veracruz. Although this is a relatively small area, rural land uses are widespread in the region and these threats can be extrapolated to other areas of that region within the distribution of the northern Mexican gartersnake in Mexico. Some of these threats included water diversions, pollution (e.g., discharge of raw sewage), sedimentation of aquatic habitats, and increased dissolved nutrients, resulting in decreased dissolved oxygen, in still-water habitats. Conant (2003, p. 4) stated that many of these threats were evident during his field work in the 1960s, but that they are "continuing with increased velocity."

Water pollution, dams, groundwater pumping, and impoundments were identified by Miller *et al.* (2005, pp. 60–61) as significant threats to aquatic biota in Mexico. Miller *et al.* (2005, p. 60) stated that "During the time we have collectively studied fishes in México and southwestern United States, the entire biotas of long reaches of major streams where the northern Mexican gartersnake is distributed, such as the Río Grande de Santiago below Guadalajara (Jalisco) and Río Colorado (lower Colorado River in Mexico) downstream of Hoover (Boulder) Dam (in the United States), have simply been destroyed by pollution and river

alteration." Near Torreón, Coahuila, where the northern Mexican gartersnake occurs, groundwater pumping has resulted in flow reversal, which has dried up many local springs, drawn arsenic-laden water to the surface, and resulted in adverse human health effects in that area. Severe water pollution from untreated domestic waste is evident downstream of large Mexican cities, such as Mexico City, and inorganic pollution from nearby industrialized areas and agricultural irrigation return flow has dramatically affected aquatic communities through contamination (Miller *et al.* 2005, p. 60). Miller *et al.* (2005, p. 61) provides an excerpt from Soto Galera *et al.* (1999) addressing the threats to the Río Lerma, Mexico's longest river, and which is occupied by the northern Mexican gartersnake: "The basin has experienced a staggering amount of degradation during the 20th Century. By 1985–1993, over half of our study sites had disappeared or become so polluted that they could no longer support fishes. Only 15 percent of the sites were still capable of supporting sensitive species. Forty percent (17 different species) of the native fishes of the basin had suffered major declines in distribution, and three species may be extinct. The extent and magnitude of degradation in the Río Lerma basin matches or exceeds the worst cases reported for comparably sized basins elsewhere in the world."

Several rivers within the historical range of the northern Mexican gartersnake have been impounded and dammed throughout Mexico, resulting in habitat modification and the dispersal and establishment of nonnative species. The damming and modification of the lower Colorado River in Mexico, where the northern Mexican gartersnake occurred, has facilitated the replacement of the entire native fishery with nonnative species (Miller *et al.* 2005, p. 61). Nonnative species continue to pose significant threats in the decline of native, often highly localized, prey species of the northern Mexican gartersnake, as discussed further in Factor C below (Miller *et al.* 2005, p. 60).

Miller *et al.* (2005) provide information on threats to freshwater fishes, and riparian and aquatic communities in specific waterbodies throughout Mexico that are within the historical range of the northern Mexican gartersnake: The Río Grande (dam construction, p. 78 and extirpations of freshwater fish species, pp. 82, 112); headwaters of the Río Lerma (extirpation of freshwater fish species, nonnative species, pollution, dewatering, pp. 60, 105, 197); Lago de

Chapala and its outlet to the Río Grande de Santiago (major declines in freshwater fish species, p. 106); medium-sized streams throughout the Sierra Madre Occidental (localized extirpations, logging, dewatering, pp. 109, 177, 247); the Río Conchos (extirpations of freshwater fish species, p. 112); the ríos Casas Grandes, Santa María, del Carmen, and Laguna Bustillos (water diversions, groundwater pumping, channelization, flood control practices, pollution, and introduction of nonnative species, pp. 124, 197); the Río Santa Cruz (extirpations, p. 140); the Río Yaqui (nonnative species, pp. 148, Plate 61); the Río Colorado (nonnative species, p. 153); the ríos Fuerte and Culiacán (logging, p. 177); canals, ponds, lakes in the Valle de México (nonnative species, extirpations, pollution, pp. 197, 281); the Río Verde Basin (dewatering, nonnative species, extirpations, Plate 88); the Río Mayo (dewatering, nonnative species, p. 247); the Río Papaloapan (pollution, p. 252); lagos de Zacapu and Yuriria (habitat destruction, p. 282); and the Río Pánuco Basin (nonnative species, p. 295).

Conant (1974, pp. 486–489) described significant threats to northern Mexican gartersnake habitat within its distribution in western Chihuahua, Mexico, and within the Río Concho system where it occurs. These threats included impoundments, water diversions, and purposeful introductions of largemouth bass, common carp, and bullfrogs. We discuss the threats from nonnative species introductions below in our discussion of Factor C.

Clearly, water quality and quantity are being affected by ongoing activities in the United States and Mexico. Due to the reliance of the northern Mexican gartersnake on ecosystems and communities supported by permanent water sources, these threats are significant to the survival and viability of existing and future northern Mexican gartersnake populations.

*Improper Livestock Grazing and Agricultural Uses.* In a number of ways described below, poorly managed livestock grazing has damaged approximately 80 percent of stream, cienega, and riparian ecosystems in the western United States (Kauffman and Krueger 1984, pp. 433–435; Weltz and Wood 1986, pp. 367–368; Waters 1995, pp. 22–24; Pearce *et al.* 1998, p. 307; Belsky *et al.* 1999, p. 1). Fleischner (1994, p. 629) found that "Because livestock congregate in riparian ecosystems, which are among the most biologically rich habitats in arid and semiarid regions, the ecological costs of grazing are magnified at these sites."

Stromberg and Chew (2002, p. 198) and Trimble and Mendel (1995, p. 243) also discussed the propensity for poorly managed cattle to remain within or adjacent to riparian communities. Trimble and Mendel (1995, p. 243) stated that "Cows, unlike sheep, appear to love water and spend an inordinate amount of time together lounging in streams and ponds, especially in summer (surface-active season for reptiles and amphibians), sometimes going in and coming out several times in the course of a day." Expectedly, this behavior is more pronounced in more arid regions (Trimble and Mendel 1995, p. 243). In one rangeland study, it was concluded that 81 percent of the vegetation that was consumed, trampled, or otherwise removed was from a riparian area, which amounted to only 2 percent of the total grazing space (Trimble and Mendel 1995, p. 243). Another study reported that grazing rates were 5 to 30 times higher in riparian areas than on the uplands, which may be due in part to several factors: (1) Higher forage volume and palatability of species in riparian areas; (2) water availability; (3) the close proximity of riparian areas to the best upland grazing sites; and (4) microclimatic features such as cooler temperatures and shade (Trimble and Mendel 1995, p. 244).

Effects of improper livestock management on riparian and aquatic communities have spanned from early settlement to modern day. Some historical accounts of riparian area conditions in Arizona clarify early effects of poor livestock management. Cheney *et al.* (1990, pp. 5, 10) provide historical accounts of the early adverse effects of improper livestock management in the riparian zones and adjacent uplands of the Tonto National Forest and in south-central Arizona. These accounts describe the removal of riparian trees for preparation of livestock use and substantial changes to flow regimes accentuated by observed increases in runoff and erosion rates. Such accounts of riparian conditions within the historical distribution of the northern Mexican gartersnake in Arizona contribute to the understanding of when declines in abundance and distribution may have occurred and the contributions of this factor to the subsequent fragmentation of populations and widespread extirpations.

Poor livestock management causes a decline in diversity, abundance, and species composition of riparian herpetofauna communities from direct or indirect threats to the prey base, the habitat, or to the northern Mexican

gartersnake. These effects include: (1) Declines in the structural richness of the vegetative community; (2) losses or reductions of the prey base; (3) increased aridity of habitat; (4) loss of thermal cover and protection from predators; and (5) a rise in water temperatures to levels lethal to larval stages of amphibian and fish development (Szaro *et al.* 1985, p. 362; Schulz and Leininger 1990, p. 295; Belsky *et al.* 1999, pp. 8–11). Improper livestock grazing may also lead to desertification (the process of becoming arid land or desert as a result of land mismanagement or climate change) due to a loss in soil fertility from erosion and gaseous emissions spurred by a reduction in vegetative ground cover (Schlesinger *et al.* 1990, p. 1043).

Szaro *et al.* (1985, p. 360) assessed the effects of improper livestock management on a sister taxon. They found that western (terrestrial) gartersnake (*Thamnophis elegans vagrans*) populations were significantly higher (versus controls) in terms of abundance and biomass in areas that were excluded from grazing, where the streamside vegetation remained lush, than where uncontrolled access to grazing was permitted. This effect was complemented by higher amounts of cover from organic debris from ungrazed shrubs that accumulate as the debris moves downstream during flood events. Specifically, results indicated that snake abundance and biomass were significantly higher in ungrazed habitat, with a five-fold difference in number of snakes captured, despite the difficulty of making observations in areas of increased habitat complexity (Szaro *et al.* 1985, p. 360). Szaro *et al.* (1985, p. 362) also noted the importance of riparian vegetation for the maintenance of an adequate prey base and as cover in thermoregulation and predation avoidance behaviors, as well as for foraging success.

Watersheds where improper grazing has been documented as a contributing factor of northern Mexican gartersnake declines include the Verde, Salt, Agua Fria, San Pedro, Gila, and Santa Cruz (Hendrickson and Minckley 1984, pp. 140, 152, 160–162; Rosen and Schwalbe 1988, pp. 32–33; Girmendock and Young 1997, p. 47; Voeltz 2002, pp. 45–81; Krueper *et al.* 2003, pp. 607, 613–614; Holycross *et al.* 2006, pp. 52–61; McKinnon 2006d, 2006e; Paradzick *et al.* 2006, pp. 90–92; USFS 2008). Holycross *et al.* (2006, pp. 53–55, 58) recently documented adverse effects from improper livestock grazing on northern Mexican gartersnake habitat along the Agua Fria from EZ Ranch to Bloody Basin Road, along Dry Creek

from Dugas Road to Little Ash Creek, along Little Ash Creek from Brown Spring to Dry Creek, along Sycamore Creek in the vicinity of its confluence with the Verde River, and on potential northern Mexican gartersnake habitat along Pinto Creek at the confluence with the West Fork of Pinto Creek. In southeastern Arizona, there have been observations of effects to the vegetative community suggesting that livestock grazing activities continue to adversely affect remaining populations of northern Mexican gartersnakes by reducing or eliminating cover required by the northern Mexican gartersnake for thermoregulation, protection from predation, and foraging (Hale 2001, pp. 32–34, 50, 56).

To increase forage and stocking rates for livestock production in the arid lowlands of northern Mexico, African buffelgrass was widely introduced in Mexico and has subsequently spread via its own natural means of dispersal (Búrquez-Montijo *et al.* 2002, p. 131; Nijhuis 2007, pp. 1–7). Buffelgrass invasions pose a serious threat to native arid ecosystems because buffelgrass prevents germination of native plant species, competes for water, crowds out native vegetation, and creates fine fuels in vegetation communities not adapted to fire. In such native arid ecosystems, buffelgrass has caused many changes, including severe soil erosion resulting from an increase in the number and severity of fires (Búrquez-Montijo *et al.* 2002, pp. 135, 138). Erosion affects the suitability of habitat for northern Mexican gartersnakes and their prey species by increasing the turbidity of streams and filling in important pool habitat, which increases the water temperature of pools, lowers the dissolved oxygen content of the water, and reduces their permanency. Recent estimates indicate that 80 percent of Mexico is affected by soil erosion caused by vegetation removal related to grazing, fires, agriculture, deforestation, etc. The most serious erosion is occurring in the States of Guanajuato (43 percent of the State's land area), Jalisco (25 percent of the State's land area), and México (25 percent of the State's land area) (va Landa *et al.* 1997, p. 317), the states in which the northern Mexican gartersnake occurs.

The effects of stock tanks associated with livestock grazing on northern Mexican gartersnakes depend on how they are managed. Dense bank and aquatic vegetation is an important habitat characteristic for the northern Mexican gartersnake that can be affected if the impoundment is poorly managed, which may lead to trampling or overgrazing of the bankside vegetation.

Alternatively, well-managed stock tanks can provide habitat suitable for northern Mexican gartersnakes both structurally and in terms of prey base, especially when the tank remains devoid of nonnative species while supporting native prey species; provides adequate vegetation cover; and provides reliable water sources in periods of prolonged drought. Given these benefits of well-managed stock tanks, we believe well-managed stock tanks may be an important component to northern Mexican gartersnake conservation.

Direct mortality of amphibian species, in all life stages, from being trampled by livestock has been documented in the literature (Bartelt 1998, p. 96; Ross *et al.* 1999, p. 163). The resultant extirpation risk of amphibian populations as a prey base for northern Mexican gartersnakes by direct mortality is governed by the relative isolation of the amphibian population, the viability of that population, and the propensity for stochastic events such as wildfires. Livestock grazing within habitat occupied by northern Mexican gartersnakes can result in direct mortality of individual gartersnakes as observed in a closely related taxon on the Apache-Sitgreaves National Forest. In that instance, a black-necked gartersnake (*Thamnophis cyrtopsis cyrtopsis*) had apparently been killed by trampling by cattle along the shore of a stock tank within an actively grazed allotment (Chapman 2005). This event was not observed first-hand, but was supported by postmortem photographic documentation of the physical injuries to the specimen and the location of the carcass among a dense cluster of hoof tracks along the shoreline of the stock tank. It is also unlikely that a predator would kill the snake and leave it uneaten. While this type of direct mortality of gartersnakes has long been suspected by agency biologists and academia, this may be the first recorded observation of direct mortality of a gartersnake due to livestock trampling. We expect this type of direct mortality to be uncommon but significant in the instance of a fragmented population with a skewed age-class distribution (large adults), without a neighboring source population to assist with recolonization, and low to no recruitment as currently observed in many northern Mexican gartersnake populations in the United States. In these circumstances, the loss of one or more adults, most notably reproductive females, may lead directly to extirpation of the species from a given site with no expectation of recolonization.

Poor forestry and agricultural practices were cited as the largest and

most widespread threats to the native fisheries of the Jalisco and Colima area in Mexico investigated by Lyons and Navarro-Perez (1990, p. 37), affecting prey availability for northern Mexican gartersnakes in areas where they occur. Lyons and Navarro-Perez (1990, p. 37) indicated that in high-elevation areas, clear-cutting of trees and unrestricted livestock grazing have increased erosion and sedimentation. They suspected impacts on fish and invertebrate populations had occurred. In lowland areas, Lyons and Navarro-Perez (1990, p. 37) cited diversion of water for irrigation, runoff from cultivated fields, and runoff from small towns and villages as causing additional environmental degradation. Lyons and Navarro-Perez (1990, p. 37) found that the tolerance of several fish species to degradation depended on the form of degradation.

Minckley *et al.* (2002, pp. 687–705) described three new species of pupfish and provided a summary of threats (p. 696) to these species and their habitat in Chihuahua, Mexico, within the distribution of the northern Mexican gartersnake. Initial settlement and agricultural development of the area resulted in significant channel cutting through soil layers protecting the alluvial plain above them, which resulted in reductions in the base level of each basin in succession (Minckley *et al.* 2002, p. 696). Related to these activities, the building of dams and diversion structures dried entire reaches of some regional streams and altered flow patterns of others (Minckley *et al.* 2002, p. 696). This was followed by groundwater pumping (enhanced by the invention of the electric pump) which lowered groundwater levels and dried-up springs and small channels and reduced the reliability of baseflow in “essentially all systems” (Minckley *et al.* 2002, p. 696). Subsequently, the introduction and expansion of nonnative species in the area successfully displaced or extirpated many native species (Minckley *et al.* 2002, p. 696).

Our analysis of the best available scientific and commercial information available indicates that adverse effects from improper livestock management on the northern Mexican gartersnake, its habitat, and its prey base can be significant, especially when combined with other threats, most notably nonnative species (discussed below under Factor C). Preliminary gartersnake survey data from Burger (2008) from the States of Durango and southern Chihuahua, Mexico, indicate that the northern Mexican gartersnake is less susceptible to population impacts

associated with physical disturbances to its habitat, such as livestock grazing, when the biotic community is comprised of wholly native species. However, even modest alterations in the physical habitat of the northern Mexican gartersnake may lead to population declines, or even extirpations, when these adverse effects act in combination with the adverse effects of nonnative species. In Mexico, livestock grazing, often in association with deforestation and crop cultivation, are also having adverse effects on the northern Mexican gartersnake. We recognize that well-managed grazing can occur with limited effects to this species when the presence or absence of nonnative species is considered, and management emphasis is directed towards limiting some access to riparian and aquatic habitats within occupied habitat. These actions, combined with management that disperses livestock away from riparian areas, reduce the threats of livestock grazing on northern Mexican gartersnakes and their habitats. As previously stated, we also recognize well-managed stock tanks as a valuable tool in the conservation of northern Mexican gartersnakes.

Additional information on the effects of improper livestock grazing to the northern Mexican gartersnake and its habitat can be found in our 2006, 12-month finding for this species (71 FR 56227) and in Sartz and Tolsted (1974, p. 354); Szaro *et al.* (1985, pp. 360, 362, 364); Weltz and Wood (1986, pp. 367–368); Rosen and Schwalbe (1988, pp. 32–33, 47); Clary and Webster (1989, p. 1); Clary and Medin (1990, p. 1); Schulz and Leininger (1990, p. 295); Schlesinger *et al.* (1990, p. 1043); Orodho *et al.* (1990, p. 9); Fleischner (1994, pp. 629, 631–632); Trimble and Mendel (1995, pp. 235–236, 243–244); Pearce *et al.* (1998, p. 302); Belsky *et al.* (1999, pp. 8–11); Stromberg and Chew (2002, p. 198); and Krueper *et al.* (2003, pp. 607, 613–614).

**High-Intensity Wildfires.** Low-intensity fire has been a natural disturbance factor in forested landscapes for centuries, and low-intensity fires were common in southwestern forests prior to European settlement (Rinne and Neary 1996, pp. 135–136). Rinne and Neary (1996, p. 143) discuss the current effects of fire management policies on aquatic communities in Madreaan Oak Woodland biotic communities in the southwestern United States. They concluded that existing wildfire suppression policies intended to protect the expanding number of human structures on forested public lands have altered the fuel loads in these

ecosystems and increased the probability of devastating wildfires. The effects of these catastrophic wildfires include the removal of vegetation, the degradation of watershed condition, altered stream behavior, and increased sedimentation of streams. These effects can harm fish communities, as observed in the 1990 Dude Fire, when corresponding ash flows decimated some fish populations in Dude Creek and the East Verde River (Voeltz 2002, p. 77), which, ultimately, affects habitat suitability for the gartersnake. These effects can significantly reduce the prey base for northern Mexican gartersnakes and could lead to direct mortality in the case of high-intensity fires that are within occupied habitat. The Chiricahua leopard frog recovery plan cites altered fire regimes as a serious threat to Chiricahua leopard frogs, a prey species for northern Mexican gartersnakes (USFWS 2008, pp. 38–39).

Fire has also become an increasingly significant threat in lower elevation communities as well. Esque and Schwalbe (2002, pp. 180–190) discuss the effect of wildfires in the upper and lower subdivisions of Sonoran desertscrub where the northern Mexican gartersnake historically occurred. The widespread invasion of nonnative annual grasses, such as brome species (*Bromus sp.*) and Mediterranean grasses (*Schismus sp.*), appear to be largely responsible for altered fire regimes that have been observed in these communities, which are not adapted to fire (Esque and Schwalbe 2002, p. 165). African buffelgrass (*Pennisetum ciliare*) is recognized as another invading nonnative plant species throughout the lower elevations of northern Mexico and Arizona. Nijhuis (2007, pp. 1–7) discuss the spread of nonnative buffelgrass within the Sonoran Desert of Arizona and adjoining Mexico, citing the grass' ability to out compete native vegetation and present significant risks of fire in an ecosystem that is not adapted to fire. In areas comprised entirely of native species, ground vegetation density is mediated by barren spaces that do not allow fire to carry itself across the landscape. However, in areas where nonnative grasses have become established, the fine fuel load is continuous, and fire is capable of spreading quickly and efficiently (Esque and Schwalbe 2002, p. 175).

After disturbances such as fire, nonnative grasses may exhibit dramatic population explosions, which hasten their effect on native vegetative communities. Additionally, with increased fire frequency, these population explosions ultimately lead to a type-conversion of the vegetative

community from desert scrub to grassland (Esque and Schwalbe 2002, pp. 175–176). Fires carried by the fine fuel loads created by nonnative grasses often burn at unnaturally high temperatures, which may result in soils becoming hydrophobic (water repelling), exacerbate sheet erosion, and contribute large amounts of sediment to receiving water bodies, thereby affecting the health of the riparian community (Esque and Schwalbe 2002, pp. 177–178). The siltation of isolated, remnant pools in intermittent streams significantly affects lower elevation species by increasing the water temperature, reducing dissolved oxygen, and reducing or eliminating the permanency of pools, as observed in pools occupied by lowland leopard frogs and native fish, important prey species for northern Mexican gartersnakes (Esque and Schwalbe 2002, p. 190).

*Undocumented Immigration and International Border Enforcement and Management.* Undocumented immigrants and smugglers attempt to cross the International border from Mexico into the United States in areas historically and currently occupied by the northern Mexican gartersnake. These illegal border crossings and the corresponding efforts to enforce U.S. border laws and policies have been occurring for many decades with increasing intensity and have resulted in unintended adverse effects to biotic communities in the border region. During the warmest months of the year, many attempted border crossings occur in riparian areas that serve to provide shade, water, and cover. Increased U.S. border enforcement efforts that began in the early 1990s in California and Texas have resulted in a shift in crossing patterns and increasingly concentrated levels of attempted illegal border crossings into Arizona (Segee and Neeley 2006, p. 6).

Riparian habitats that historically supported or may currently support northern Mexican gartersnakes in the San Bernardino National Wildlife Refuge, the San Pedro River corridor, the Santa Cruz River corridor, the lower Colorado River corridor, and along many smaller streamside and canyon bottom areas within Cochise, Santa Cruz, and Pima counties have high levels of undocumented immigrant traffic (Segee and Neeley 2006, Executive Summary, pp. 10–12, 21–23).

Traffic on new roads and trails from illegal border crossing and enforcement activities, as well as the construction, use, and maintenance of enforcement infrastructure (*i.e.*, fences, walls, and lighting systems), leads to compaction

of streamside soils, and the destruction and removal of riparian vegetation necessary as cover for the northern Mexican gartersnake. Current border infrastructure projects, including vehicle barriers and pedestrian fences, are located specifically in valley bottoms and have resulted in direct impacts to water courses and altered drainage patterns affecting northern Mexican gartersnake habitat (USFWS 2008, p. 4). These activities also produce sediment in streams, which affects their suitability as habitat for prey species of the northern Mexican gartersnake by reducing their permanency and altering their physical and chemical parameters. Riparian areas along the upper San Pedro River have been impacted by abandoned fires that undocumented immigrants started to keep warm or prepare food (Segee and Neeley 2006, p. 23). There is also the threat of pursuit, capture, and death of northern Mexican gartersnakes when they are encountered by illegal border crossers and border enforcement personnel in high-use areas due to the snake's stigma in society (Rosen and Schwalbe 1988, p. 43; Ernst and Zug 1996, p. 75; Green 1997, pp. 285–286; Nowak and Santana-Bendix 2002, p. 39).

The wetland habitat within the San Bernardino National Wildlife Refuge provides habitat for the northern Mexican gartersnake, where it is now likely extirpated, and has been adversely affected by undocumented immigration. It is estimated that approximately 1,000 undocumented immigrants per month use these important wetlands for bathing, drinking, and other uses during their journey northward (Segee and Neeley 2006, pp. 21–22). These activities occur in other border areas, such as the Santa Cruz River, where the northern Mexican gartersnake occurs, although they have not been quantified (Segee and Neeley 2006, pp. 21–22). They can contaminate the water quality of the wetlands and lead to reductions in the prey base for the northern Mexican gartersnake, as well as increase exposure of the snake to humans, and thereby increase direct mortality rates (Rosen and Schwalbe 1988, p. 43; Ernst and Zug 1996, p. 75; Green 1997, pp. 285–286; Nowak and Santana-Bendix 2002, p. 39; Segee and Neeley 2006, pp. 21–22). In addition, numerous observations of littering and destruction of vegetation and wildlife occur annually throughout the San Bernardino National Wildlife Refuge, which adversely affect the quality and quantity of vegetation as habitat for the northern Mexican gartersnake (USFWS

2006, p. 95). Due to the immediate proximity of the upper Santa Cruz River to the international border and the effect of border control operations that funnel undocumented immigrants into rural environments, we conclude that these adverse effects likely occur in this area, which is occupied by the northern Mexican gartersnake.

Threats from illegal border crossers appear to have increased in recent years within the Coronado National Forest of southern Arizona (USFS 2008). Reports of significant water pollution from bathing activities by undocumented immigrants in habitat occupied by northern Mexican gartersnakes have been received (USFS 2008). Of particular concern to USFS (2008), was the concentrated use of pools by undocumented immigrants during the warmest months before summer rains commence, when the habitat is also critical to the northern Mexican gartersnake and its prey. The amount of surface water is generally considered the lowest during the early summer, pre-monsoon months in Arizona, which compounds the effects of the use of pools for bathing by concentrating water contamination in the limited habitat available to northern Mexican gartersnakes and their prey species. Because of the limited amount of alternative habitat, illegal border crossers and gartersnakes are concentrated in the same areas, increasing encounter rates and the potential threats to northern Mexican gartersnakes.

*Summary of Factor A.* Riparian and aquatic habitats that are essential for the survival of the northern Mexican gartersnake are being negatively impacted throughout the subspecies' range. Threats including water diversions, groundwater pumping, dams, channelization, and erosion-related effects are occurring in both the United States and Mexico that affect the amount of water within occupied northern Mexican gartersnake habitat, directly affecting its suitability for northern Mexican gartersnakes. Threats from development, roads, flood control and water diversion, improper livestock grazing, high-intensity wildfire, and undocumented immigration that alter the vegetation of occupied northern Mexican gartersnake habitat are documented throughout its range and reduce the habitat's suitability as cover for protection from predators, as a foraging area, and as an effective thermoregulatory site. However, Rorabaugh (2008, p. 26) suggests that an increased awareness of the potential for ecotourism to provide rural economic growth is occurring in many areas

within Sonora, Mexico, which may provide enhanced opportunities for conservation of biologically rich ecosystems in the future.

Nonnative plant species, in particular shrubs (genus *Tamarix*) and buffelgrass, are increasing their distribution in both the United States and Mexico and adversely affect habitat suitability and availability for the northern Mexican gartersnake.

*B. Overutilization for Commercial, Recreational, Scientific, or Educational Purposes*

The northern Mexican gartersnake may not be collected in the United States without special authorization by the Arizona Game and Fish Department or the New Mexico Department of Game and Fish. We have found no evidence that current or historical levels of lawful or unlawful field collecting of northern Mexican gartersnakes has played a significant role in the decline of this species. The Arizona Game and Fish Department recently produced identification cards for distribution that provide information to assist with the field identification of each of Arizona's five native gartersnake species, as well as guidance on submitting photographic vouchers for university museum collections. Additionally, Arizona State University and the University of Arizona recently began to accept photographic vouchers, versus physical specimens, in their respective museum collections, which will reduce the amount of collection. We believe these measures reduce the necessity for field biologists to collect physical specimens (unless discovered postmortem) for locality voucher purposes and, therefore, further reduce impacts to vulnerable populations of the northern Mexican gartersnake. We were unable to obtain information about the effect of overutilization for commercial, recreational, scientific, or educational purposes in Mexico. Specific discussion of the regulatory protections for the northern Mexican gartersnake is provided under Factor D "Inadequacy of Existing Regulatory Mechanisms" below.

*C. Disease or Predation*

*Disease.* Disease in northern Mexican gartersnakes has not yet been documented as a specific threat in the United States or Mexico. However, because little is known about disease in wild snakes, it is premature to conclude that there is no disease threat that could directly affect remaining northern Mexican gartersnake populations (Rosen 2006).

Disease and nonnative parasites have been implicated in the decline in the prey base of the northern Mexican gartersnake. Particularly, the outbreak of chytridiomycosis or "Bd," a skin fungus (*Batrachochytrium dendrobatidis*), has been identified as a chief causative agent in the significant declines of many of the native ranid frogs and other amphibian species, and regional concerns exist for the native fish community due to nonnative parasites such as the Asian tapeworm (*Bothriocephalus acheilognathi*) in southeastern Arizona (Rosen and Schwalbe 1997, pp. 14–15; 2002c, pp. 1–19; Morell 1999, pp. 728–732; Sredl and Caldwell 2000, p. 1; Hale 2001, pp. 32–37; Bradley *et al.* 2002, p. 206). Bd has been implicated in both large-scale declines and local extirpations of many amphibians, chiefly anuran species, around the world (Johnson 2006, p. 3011). Lips *et al.* (2006, pp. 3166–3169) suggest that the high virulence and large number of potential hosts make Bd a serious threat to amphibian diversity. In Arizona, Bd infections have been reported in several northern Mexican gartersnake native prey species within the distribution of the snake (Morell 1999, pp. 731–732; Sredl and Caldwell 2000, p. 1; Hale 2001, pp. 32–37; Bradley *et al.* 2002, p. 207; USFWS 2002a, pp. 40802–40804; USFWS 2007, pp. 26, 29–32). Declines of native prey species of the northern Mexican gartersnake from Bd infections have contributed to the decline of this species in the United States and likely in Mexico (Morell 1999, pp. 731–732; Sredl and Caldwell 2000, p. 1; Hale 2001, pp. 32–37; Bradley *et al.* 2002, p. 207; USFWS 2002a, pp. 40802–40804; USFWS 2007, pp. 26, 29–32).

Research shows that, in a pure culture, the fungus *Batrachochytrium* can grow on boiled snakeskin (keratin), which indicates the potential for the fungus to live on gartersnake skin in the wild, if other components of the ecosystem are favorable (Longcore *et al.* 1999, p. 227). Despite the demonstrated potential, no reports of the organism on reptilian hosts in the wild have been documented. We, as well as other researchers, will monitor the incidence of this disease in gartersnakes in the wild for early detection purposes and to determine the status of this potential threat.

Parasites have been observed in northern Mexican gartersnakes. Boyarski (2008b, pp. 5–6) recorded several snakes within the population at the Page Springs and Bubbling Ponds fish hatcheries with interior bumps or bulges along the anterior one-third of the body although the cause of these

bumps was not identified or speculated upon, nor were there any signs of trauma to their body in these areas. Dr. Jim Jarchow, a veterinarian with herpetological expertise, reviewed photographs of affected specimens and suggested the bumps may likely contain plerocercoid larvae of a pseudophyllidean tapeworm (possibly *Spirometra* spp.), which are common in fish- and frog-eating gartersnakes. This may not be detrimental to their health provided the bumps do not grow large enough to impair movement or other bodily functions (Boyarski 2008b, p. 8). However, Gúzman (2008, p. 102) documented the first observation of mortality of a Mexican gartersnake from a larval *Eustrongylides* sp. (endoparasitic nematode) which "raises the possibility that infection of Mexican gartersnakes by *Eustrongylides* sp. larvae might cause mortality in some wild populations," especially in the presence of other threats.

*Nonnative Species Interactions.* A host of native predators prey upon northern Mexican gartersnakes including birds of prey, other snakes [kingsnakes (*Lampropeltis* sp.), whipsnakes (*Masticophis* sp.), etc.], wading birds, raccoons (*Procyon lotor*), skunks (*Mephitis* sp.), and coyotes (*Canis latrans*) (Rosen and Schwalbe 1988, p. 18). Historically, large, highly predatory native fish species such as Colorado pikeminnow may have preyed upon northern Mexican gartersnakes where the two species co-occurred. However, nonnative species represent the most serious threat to the northern Mexican gartersnake through direct predation and predation on northern Mexican gartersnake prey (competition). Nonnative species, such as the bullfrog, the northern (virile) crayfish (*Orconectes virilis*) and red swamp (*Procambarus clarkii*) crayfish, and numerous species of nonnative sport and bait fish species continue to be the most significant threat to the northern Mexican gartersnake and to its prey base from direct predation, competition, and modification of habitat (Meffe 1985, pp. 179–185; Rosen and Schwalbe 1988, pp. 28, 32; 1997, p. 1; Bestgen and Propst 1989, pp. 409–410; Clarkson and Rorabaugh 1989, pp. 531, 535; Marsh and Minckley 1990, p. 265; Stefferud and Stefferud 1994, p. 364; Douglas *et al.* 1994, pp. 9–19; Rosen *et al.* 1995, pp. 257–258; 1996b, pp. 2, 11–13; 2001, p. 2; Degenhardt *et al.* 1996, p. 319; Fernandez and Rosen 1996, pp. 8, 23–27; Richter *et al.* 1997, pp. 1089, 1092; Weedman and Young 1997, p. 1, Appendices B, C; Inman *et al.* 1998, p. 17; Rinne *et al.* 1998, pp. 4–6; Minckley



*et al.* 2002, p. 696; DFT 2003, p. 1; Clarkson *et al.* 2005, p. 20; Fagan *et al.* 2005, pp. 34, 34–41; Olden and Poff 2005, pp. 82–87; Turner 2006, p. 10; Holycross *et al.* 2006, pp. 13–15; Brennan and Holycross 2006, p. 123; USFWS 2007, pp. 22–23; Caldwell 2008a, 2008b; Jones 2008b; d'Orgeix 2008; Haney *et al.* 2008, p. 59; Luja and Rodríguez-Estrella 2008, pp. 17–22; Rorabaugh 2008, p. 25; USFS 2008; Wallace *et al.* 2008, pp. 243–244; Witte *et al.* 2008, p. 1).

Riparian and aquatic communities in both the United States and Mexico have been dramatically impacted by a shift in species' composition, from being historically dominated by native fauna to being increasingly occupied by an expanding assemblage of nonnative animal species that have been intentionally or accidentally introduced, such as crayfish, bullfrogs, sportfish, and domestic pets. For example, in two of eight cases of northern Mexican gartersnake mortality collected at Bubbling Ponds Hatchery since 2006, the cause of death was considered to be from domestic cats (Boyarski 2008a).

The population of northern Mexican gartersnakes at the hatcheries occurs with potential and known nonnative predators including rainbow and brown trout, largemouth and smallmouth bass, bluegill, crayfish (in Oak Creek), and bullfrogs (Boyarski 2008b, pp. 3–4, 8). Seven snakes (11 percent of those captured) were observed as having some level of tail damage, presumably from bullfrog predation attempts and were noted as having a lower body condition index (an indicator of overall health based on a set of pre-determined variables) (Boyarski 2008b, pp. 5, 8). The relatively low occurrence of tail damage, as compared to the 78 percent of snakes with tail damage found by Rosen and Schwalbe (1988, pp. 28–31), may indicate (1) adequate vegetation density was used by gartersnakes to avoid bullfrog predation attempts; (2) a relatively low density population of bullfrogs occurs at the site (bullfrog population density data were not collected); (3) gartersnakes may not need to move significant distances to achieve foraging success, which might have reduced the potential for encounters with bullfrogs; or, (4) that gartersnakes infrequently escape bullfrog predation attempts, were removed from the population, and were consequently not detected by surveys. Additional information on tail damage as an indicator of predation is found in our discussion of Factor C below.

Stock tanks associated with livestock grazing may facilitate the spread of nonnative species when nonnative

species of fish, amphibians, and crayfish are intentionally or unintentionally stocked by anglers and private landowners (Rosen *et al.* 2001, p. 24). The management of stock tanks is an important consideration for northern Mexican gartersnakes. Stock tanks associated with livestock grazing can be intermediary "stepping stones" in the dispersal of nonnative species from larger source populations to new areas (Rosen *et al.* 2001, p. 24).

The northern Mexican gartersnake appears to be particularly vulnerable to a loss in native prey species (Rosen and Schwalbe 1988, p. 20). Rosen *et al.* (2001, pp. 10, 13, 19) examined this issue in detail and proposed two reasons for the decline in northern Mexican gartersnakes following the loss or decline in the native prey base: (1) The species is unlikely to increase foraging efforts at the risk of increased predation; and (2) the species needs substantial food regularly to maintain its weight and health. If forced to forage more often for smaller prey items, a reduction in growth and reproductive rates can result (Rosen *et al.* 2001, pp. 10, 13). Rosen *et al.* (2001, p. 22) concluded that the presence and expansion of nonnative predators (mainly bullfrogs, crayfish, and green sunfish) are the primary causes of decline in northern Mexican gartersnakes and their prey in southeastern Arizona.

The decline of the northern Mexican gartersnake within its historical and currently occurring distribution was subsequent to the declines in its prey base (native amphibian and fish populations) from predation following introductions of nonnative bullfrogs, crayfish, and numerous species of exotic sport and bait fish as documented in an extensive body of literature (Nickerson and Mays 1970, p. 495; Hulse 1973, p. 278; Vitt and Ohmart 1978, p. 44; Meffe 1985, pp. 179–185; Ohmart *et al.* 1988, pp. 143–147; Rosen and Schwalbe 1988, pp. 28–31; 1997, pp. 8–16; Bestgen and Propst 1989, pp. 409–410; Clarkson and Rorabaugh 1989, pp. 531–538; Marsh and Minckley 1990, p. 265; Sublette *et al.* 1990, pp. 112, 243, 246, 304, 313, 318; Stefferud and Stefferud 1994, p. 364; Holm and Lowe 1995, p. 5; Rosen *et al.* 1995, pp. 251, 257–258; 1996a, pp. 2–3; 1996b, p. 2; 2001, p. 2; Sredl *et al.* 1995a, pp. 7–8; 1995b, pp. 8–9; 1995c, pp. 7–8; 2000, p. 10; Degenhardt *et al.* 1996, p. 319; Fernandez and Rosen 1996, pp. 8–27; Drost and Nowak 1997, p. 11; Weedman and Young 1997, p. 1, Appendices B, C; Inman *et al.* 1998, p. 17; Rinne *et al.* 1998, pp. 4–6; Turner *et al.* 1999, p. 11; Nowak and Spille 2001, p. 11; Bonar *et al.* 2004, p. 3; Fagan *et*

*al.* 2005, pp. 34, 34–41; Olden and Poff 2005, pp. 82–87; Holycross *et al.* 2006, pp. 13–15, 52–61; Brennan and Holycross 2006, p. 123; USFWS 2007, pp. 22–23; Caldwell 2008a, 2008b; Jones 2008b; d'Orgeix 2008; Haney *et al.* 2008, p. 59; Luja and Rodríguez-Estrella 2008, pp. 17–22; Rorabaugh 2008, p. 25; USFS 2008; Wallace *et al.* 2008, pp. 243–244; Witte *et al.* 2008, p. 1).

*Declines in the Northern Mexican Gartersnake Anuran Prey Base.* Declines in the native leopard frog populations in Arizona have contributed to declines in the northern Mexican gartersnake as a primary native predator. Native rapid frog species such as lowland leopard frogs, northern leopard frogs, and federally threatened Chiricahua leopard frogs have all experienced significant declines throughout their distribution in the Southwest, partially due to predation and competition with nonnative species (Clarkson and Rorabaugh 1989, pp. 531, 535; Hayes and Jennings 1986, p. 490). Rosen *et al.* (1995, pp. 257–258) found that Chiricahua leopard frog distribution in the Chiricahua Mountain region of Arizona was inversely related to nonnative species distribution and without corrective action, predicted that the Chiricahua leopard frog will be extirpated from this region. Along the Mogollon Rim, Holycross *et al.* (2006, p. 13) found that only 3 sites of 57 surveyed (15 percent) consisted of an entirely native anuran community and that native frog populations in another 19 sites (33 percent) had been completely displaced by invading bullfrogs.

Scotia Canyon in the Huachuca Mountains of southeastern Arizona is a location where corresponding declines of leopard frog and northern Mexican gartersnake populations have been documented through repeated survey efforts over time (Holm and Lowe 1995, p. 33). Surveys of Scotia Canyon occurred during the early 1980s and again during the early 1990s. Leopard frogs in Scotia Canyon were infrequently observed during the early 1980s and were apparently extirpated by the early 1990s (Holm and Lowe 1995, pp. 45–46). Northern Mexican gartersnakes were observed in decline during the early 1980s with low capture rates remaining through the early 1990s (Holm and Lowe 1995, pp. 27–35). Surveys documented further decline in 2000 (Rosen *et al.* 2001, pp. 15–16). A former large, local population of northern Mexican gartersnakes at the San Bernardino National Wildlife Refuge has also experienced a correlative decline of leopard frog and northern Mexican gartersnake

populations, at least in part related to illegal immigration and smuggling activities in riparian and aquatic habitats as discussed in Factor A above (Rosen and Schwalbe 1988, p. 28; 1995, p. 452; 1996, pp. 1-3; 1997, p. 1; 2002b, pp. 223-227; 2002c, pp. 31, 70; Rosen *et al.* 1996b, pp. 8-9; 2001, pp. 6-10). Survey data indicate that declines of leopard frog populations, often correlated with nonnative species introductions, the spread of chytridiomycosis disease, and habitat modification and destruction, have occurred throughout much of the U.S. distribution of the northern Mexican gartersnake (Nickerson and Mays 1970, p. 495; Vitt and Ohmart 1978, p. 44; Ohmart *et al.* 1988, p. 150; Rosen and Schwalbe 1988, Appendix I; 1995, p. 452; 1996, pp. 1-3; 1997, p. 1; 2002b, pp. 232-238; 2002c, pp. 1, 31; Clarkson and Rorabaugh 1989, pp. 531-538; Sredl *et al.* 1995a, pp. 7-8; 1995b, pp. 8-9; 1995c, pp. 7-8; 2000, p. 10; Holm and Lowe 1995, pp. 45-46; Rosen *et al.* 1996b, p. 2; 2001, pp. 2, 22; Degenhardt *et al.* 1996, p. 319; Fernandez and Rosen 1996, pp. 6-20; Drost and Nowak 1997, p. 11; Turner *et al.* 1999, p. 11; Nowak and Spille 2001, p. 32; Holycross *et al.* 2006, pp. 13-14, 52-61). Specifically, Holycross *et al.* (2006, pp. 53-57, 59) recently documented extirpations of the northern Mexican gartersnake's native leopard frog prey base at several currently, historically, or potentially occupied locations including the Agua Fria River in the vicinity of Table Mesa Road and Little Grand Canyon Ranch and at Rock Springs, Dry Creek from Dugas Road to Little Ash Creek, Little Ash Creek from Brown Spring to Dry Creek, Sycamore Creek (Agua Fria watershed) in the vicinity of the Forest Service Cabin, at the Page Springs and Bubbling Ponds fish hatchery along Oak Creek, Sycamore Creek (Verde River watershed) in the vicinity of the confluence with the Verde River north of Clarkdale, along several reaches of the Verde River mainstem, Cherry Creek on the east side of the Sierra Ancha Mountains, and Tonto Creek from Gisela to "the Box," near its confluence with Rye Creek.

Rosen *et al.* (2001, p. 22) identified the expansion of bullfrogs into the Sonoita grasslands, which border occupied northern Mexican gartersnake habitat, and the introduction of crayfish into Lewis Springs as being of particular concern in terms of future recovery efforts for the northern Mexican gartersnake. Rosen *et al.* (1995, pp. 252-253) sampled 103 sites in the Chiricahua Mountains region, which included the Chiricahua, Dragon, and

Peloncillo mountains, and the Sulphur Springs, San Bernardino, and San Simon valleys. They found that 43 percent of all cold-blooded aquatic and semi-aquatic vertebrate species detected were nonnative. The most commonly encountered nonnative species was the bullfrog (Rosen *et al.* 1995, p. 254).

Native ranid frogs (particularly lowland and Chiricahua leopard frogs), which are a primary prey species for northern Mexican gartersnakes, are one of the most imperiled taxa of Sonora, Mexico, due primarily to threats from nonnative species (bullfrogs, crayfish, and sport fish) (Rorabaugh 2008, p. 25).

Witte *et al.* (2008, p. 1) found that the disappearance of ranid frog populations in Arizona were 2.6 times more likely in the presence of crayfish. Witte *et al.* (2008, p. 7) emphasized the significant influence of nonnative species on the disappearance of ranid frogs in Arizona.

*Declines in the Northern Mexican Gartersnake Native Fish Prey Base.* Native fish species such as the federally endangered Gila chub, roundtail chub (a species petitioned for Federal listing), and federally endangered Gila topminnow historically were among the primary prey species for the northern Mexican gartersnake (Rosen and Schwalbe 1988, p. 18). Northern Mexican gartersnakes depend on native fish as a principle part of their prey base, although nonnative mosquitofish may also be taken as prey (Holycross *et al.* 2006, p. 23). Both nonnative sport and bait fish compete with the northern Mexican gartersnake in terms of its native fish and native anuran prey base. Collier *et al.* (1996, p. 16) note that interactions between native and nonnative fish have significantly contributed to the decline of many native fish species from direct predation and indirectly from competition (which has adversely affected the prey base for northern Mexican gartersnakes). Holycross *et al.* (2006, pp. 53-55) recently documented significantly depressed or extirpated native fish prey bases for the northern Mexican gartersnake along the Agua Fria in the vicinity of Table Mesa Road and the Little Grand Canyon Ranch, along Dry Creek from Dugas Road to Little Ash Creek, along Little Ash Creek from Brown Spring to Dry Creek, along Sycamore Creek (Agua Fria watershed) in the vicinity of the Forest Service Cabin, and along Sycamore Creek (Verde River watershed) in the vicinity of its confluence with the Verde River north of Clarkdale. Rosen *et al.* (2001, Appendix I) documented the decline of several native fish species in several locations visited in southeastern Arizona, further affecting the prey base

of northern Mexican gartersnakes in that area.

The widespread decline of native fish species from the arid southwestern United States and Mexico has resulted largely from interactions with nonnative species and has been captured in the listing rules of 13 native species listed under the Act whose historical ranges overlap with the historical distribution of the northern Mexican gartersnake. Native fish species that were likely prey species for the northern Mexican gartersnake, including bonytail chub (*Gila elegans*, 45 FR 27710, April 23, 1980), Yaqui catfish (*Ictalurus pricei*, 49 FR 34490, August 31, 1984), Yaqui chub (*Gila purpurea*, 49 FR 34490, August 31, 1984), Yaqui topminnow (*Poeciliopsis occidentalis sonoriensis*, 32 FR 4001, March 11, 1967), beautiful shiner (*Cyprinella formosa*, 49 FR 34490, August 31, 1984), humpback chub (*Gila cypha*, 32 FR 4001, March 11, 1967), Gila chub (*Gila intermedia*, 70 FR 66663, November 2, 2005), Colorado pikeminnow (*Ptychocheilus lucius*, 32 FR 4001, March 11, 1967), spikedace (*Meda fulgida*, 51 FR 23769, July 1, 1986) loach minnow (*Tiaroga cobitis*, 51 FR 39468, October 28, 1986), razorback sucker (*Xyrauchen texanus*, 56 FR 54957, October 23, 1991), desert pupfish (*Cyprinodon macularius*, 51 FR 10842, March 31, 1986), and Gila topminnow (*Poeciliopsis occidentalis occidentalis*, 32 FR 4001, March 11, 1967). In total within Arizona, 19 of 31 (61 percent) of native fish species are listed under the Act. Arizona ranks the highest of all 50 States in the percentage of native fish species with declining trends (85.7 percent, Stein 2002, p. 21; Warren and Burr 1994, pp. 6-18).

There are significant ongoing threats from nonnative species to the snake in Mexico. Lyons and Navarro-Perez (1990, pp. 32-46) investigated the fish communities of 17 streams in and adjacent to the Sierra de Manantlán Biosphere Reserve in Jalisco and Colima, Mexico. They noted the exceptionally high number of native fish species with small, localized distributions, which makes them more susceptible to threats and subsequent extirpation, stating that degradation of just a few streams could result in the elimination of many species of fish and, thus, prey availability for the northern Mexican gartersnake.

In an evolutionary context, native fishes co-evolved with very few predatory fish species, whereas many of the nonnative species co-evolved with many predatory species (Clarkson *et al.* 2005, p. 21). A contributing factor to the decline of native fish species cited by Clarkson *et al.* (2005, p. 21) is that most

of the nonnative species evolved behaviors, such as nest guarding, to protect their offspring from these many predators, while native species are generally broadcast spawners that provide no parental care. In the presence of nonnative species, the reproductive behaviors of native fish fail to allow them to compete effectively with the nonnative species and, as a result, the viability of native fish populations is reduced.

Olden and Poff (2005, p. 75) stated that environmental degradation and the proliferation of nonnative fish species threaten the highly localized and unique fish faunas of the American Southwest. The fastest expanding nonnative species are red shiner (*Cyprinella lutrensis*), fathead minnow (*Pimephales promelas*), green sunfish (*Lepomis cyanellus*), largemouth bass (*Micropterus salmoides*), western mosquitofish, and channel catfish (*Ictalurus punctatus*). These species are considered to be the most invasive in terms of their negative impacts on native fish communities (Olden and Poff 2005, p. 75). Many nonnative fishes in addition to those listed immediately above, including yellow and black bullheads (*Ameiurus sp.*), flathead catfish (*Pylodictis olivaris*), and smallmouth bass (*Micropterus dolomieu*), have been introduced into formerly and currently occupied northern Mexican gartersnake habitat and are predators on northern Mexican gartersnakes and their prey (Bestgen and Propst 1989, pp. 409–410; Marsh and Minckley 1990, p. 265; Sublette *et al.* 1990, pp. 112, 243, 246, 304, 313, 318; Abarca and Weedman 1993, pp. 6–12; Stefferud and Stefferud 1994, p. 364; Weedman and Young 1997, pp. 1, Appendices B, C; Rinne *et al.* 1998, pp. 3–6; Voeltz 2002, p. 88; Bonar *et al.* 2004, pp. 1–108; Fagan *et al.* 2005, pp. 34, 38–39, 41).

Several authors have identified both the presence of nonnative fish as well as their deleterious effects on native species within Arizona. Abarca and Weedman (1993, pp. 6–12) found that the number of nonnative fish species was twice the number of native fish species in Tonto Creek in the early 1990s, with a stronger nonnative species influence in the lower reaches where the northern Mexican gartersnake is considered to still occur. Surveys in the Salt River above Lake Roosevelt indicate a decline of roundtail chub and other natives with an increase in flathead and channel catfish numbers (Voeltz 2002, p. 49). In New Mexico, nonnative fish have been identified as the main cause for declines observed in roundtail chub populations (Voeltz 2002, p. 40). Douglas *et al.* (1994, pp. 9–19) provide

data indicating that the nonnative red shiner may be competitively displacing spikedeace (a potential prey item of the northern Mexican gartersnake) in Arizona and New Mexico within the historical or current distribution of the northern Mexican gartersnake.

In a comprehensive and thorough assessment of the Verde River, Bonar *et al.* (2004, p. 57) found that in the Verde River mainstem, nonnative fishes were approximately 2.6 times more dense per unit volume of river than native fishes, and their populations were approximately 2.8 times that of native fishes per unit volume of river.

Haney *et al.* (2008, p. 61) declared the northern Mexican gartersnake as nearly lost from the Verde River and suggested that diminished river flow may be an important factor. Differing river flows may provide both advantages and disadvantages to aquatic species. The timing, duration, intensity, and frequency of flood events has been altered to varying degrees by the presence of dams along the Verde River, which has an effect on fish communities. Specifically, Haney *et al.* (2008, p. 61) suggested that flood pulses may help to reduce populations of nonnative species (see discussion below) and efforts to increase the baseflows may assist in sustaining native prey species for the northern Mexican gartersnake. However, the investigators also suggest that, because the northern Mexican gartersnake preys on both fish and frogs, it may be less affected by reductions in baseflow but might incur greater risks from concentrating nonnative predators and higher water-borne disease rates (Haney *et al.* 2008, pp. 82, 93).

The Desert Fishes Team (DFT) is an "independent group of biologists and parties interested in protecting and conserving native fishes of the Colorado River basin" and includes personnel from the U.S. Forest Service, U.S. Bureau of Reclamation, U.S. Bureau of Land Management, University of Arizona, Arizona State University, the Nature Conservancy, and independent experts (DFT 2003, p. 1). DFT (2003, p. 1) declared the native fish fauna of the Gila River basin to be critically imperiled, cite habitat destruction and nonnative species as the primary factors for the declines, and call for the control and removal of nonnative fish as an overriding need to prevent the decline and ultimate extinction of native fish species within the basin.

Northern Mexican gartersnakes can successfully use some nonnative species, such as mosquitofish and red shiner, as prey species. However, all other nonnative species, most notably

the spiny-rayed fish, are not considered prey species for the northern Mexican gartersnake. These nonnative species can be difficult to swallow due to their body shape and spiny dorsal fins. They are predatory on juvenile gartersnakes and reduce the abundance of or completely eliminate native fish populations. This is particularly important in the wake of random, high-intensity events, such as flooding, extreme water temperatures, or excessive turbidity. Native fish are adapted to the dramatic fluctuations in water conditions and flow regimes, and generally persist in the wake of stochastic events and continue to provide a prey base for the northern Mexican gartersnake. Nonnative fish, even species that may be used as prey by the northern Mexican gartersnake, generally are ill-adapted to these conditions and may be removed from the area temporarily or permanently, depending on the hydrologic connectivity to current populations. If an area is solely comprised of nonnative fish, the northern Mexican gartersnake may be faced with nutritional stress or starvation because only a few small-bodied, soft-rayed fish species are taken as prey and significant effort may be required to obtain these species.

Clarkson *et al.* (2005) discuss management conflicts as a primary factor in the decline of native fish species in the southwestern United States and declare the entire native fauna as imperiled. The investigators cite nonnative species as the most consequential factor that has led to rangewide declines that prevents or negates species' recovery efforts from being implemented or being successful (Clarkson *et al.* 2005, p. 20). Clarkson *et al.* (2005, p. 20) note that over 50 nonnative species have been introduced into the Southwest as either sportfish or baitfish and are still being actively stocked, managed for, and promoted by both Federal and State agencies as nonnative recreational fisheries. To help resolve the conflicting management mandates of native fish recovery and the promotion of recreational fisheries, Clarkson *et al.* (2005, pp. 22–25) propose the designation of entire watersheds as having either native or nonnative fisheries and manage for these goals aggressively. While some discussion within Arizona has taken place to designate portions of watersheds as either native or nonnative fisheries, the geographic areas under consideration for native fishery development do not currently coincide with current populations of northern Mexican gartersnakes and no immediate

benefit is provided to the subspecies from their implementation. Clarkson *et al.* (2005, p. 25) suggest that current management of fisheries within the southwestern United States as status quo will have serious adverse effects to native fish species and affect the long-term viability of the northern Mexican gartersnake and to its potential recovery.

We are not aware of any studies that have addressed the direct relationship between prey base diversity and northern Mexican gartersnake recruitment and survivorship. However, Krause and Burghardt (2001, pp. 100–123) discuss the benefits and costs that may be associated with diet variability in the common gartersnake (*Thamnophis sirtalis*), an ecologically similar species to the northern Mexican gartersnake. Foraging for mixed-prey species may impede predator learning, as compared to specialization, on a certain prey species, but may also provide long-term benefits (Krause and Burghardt 2001, p. 101). Krause and Burghardt (2001, p. 112) stated that varied predatory experience played an important role in the feeding abilities of gartersnakes through the first 8 months of age. These data suggest that a varied prey base might also be important for neonatal and juvenile northern Mexican gartersnakes (also a species with a varied diet) and that decreases in the diversity of the prey base during the young age classes might adversely affect the ability of individuals to capture prey throughout their lifespan, in addition to the more obvious effects of reduced prey availability.

The most conclusive evidence for the northern Mexican gartersnake's intolerance for nonnative fish invasions remains the fact that, in most incidences, nonnative fish species generally do not occur in the same locations as the northern Mexican gartersnake and its native prey species. Additional information on the decline of the northern Mexican gartersnake's native fish prey species can be found in Bonar *et al.* (2004, pp. 4, 79–87); DFT (2003, pp. 1–3, 5–6, 19; 2004, pp. 1–2, 4–5, 10, Table 1; 2006, pp. iii, 25); Richter *et al.* (1997, pp. 1081–1093); and Haney *et al.* (2008, pp. 54–61, 82, 93).

#### *Bullfrog Diet and Distribution.*

Bullfrogs are widely considered one of the most serious threats to the northern Mexican gartersnake throughout its range (Conant 1974, pp. 471, 487–489; Rosen and Schwalbe 1988, pp. 28–30; Rosen *et al.* 2001, pp. 21–22). Bullfrogs adversely affect northern Mexican gartersnakes through direct predation of juveniles and sub-adults and from competition with native prey species. Bullfrogs first appeared in Arizona in

1926, as a result of a systematic introduction effort by the State Game Department (now, the Arizona Game and Fish Department) for the purposes of sport hunting and as a food source. (Tellman 2002, p. 43). Bullfrogs are extremely prolific, adept at colonizing new areas, and may disperse to distances of 6.8 miles (10.9 km) and likely further within drainages (Bautista 2002, p. 131; Rosen and Schwalbe 2002a, p. 7; Casper and Hendricks 2005, p. 582). In Arizona, using mark and recapture methods, bullfrogs have been documented to make overland movements of up to 7 miles (11 kilometers) across semi-desert grassland habitat on the Buenos Aires National Wildlife Refuge (BANWR) (Suhre 2008). Investigators on the BANWR also observed two bullfrogs at an overland distance of 10 miles (16 kilometers) from the nearest source population although the origin of the bullfrogs could not be confirmed. Batista (2002, p. 131) confirmed "the strong colonizing skills of the bullfrog and that the introduction of this exotic species can disturb local anuran communities."

Bullfrogs are voracious, opportunistic, even cannibalistic predators that readily attempt to consume any animal smaller than themselves, including other species within the same genus, which can comprise 80 percent of their diet (Casper and Hendricks 2005, p. 543). Bullfrogs have a varied diet, which has been documented to include vegetation, numerous invertebrate and vertebrate species which include numerous species of snakes [eight genera; including six different species of gartersnakes, two species of rattlesnakes, and Sonoran gophersnakes (*Pituophis catenifer affinis*)] (Bury and Whelan 1984, p. 5; Clarkson and DeVos 1986, p. 45; Holm and Lowe 1995, pp. 37–38; Carpenter *et al.* 2002, p. 130; King *et al.* 2002; Hovey and Bergen 2003, pp. 360–361; Casper and Hendricks 2005, p. 544; Combs *et al.* 2005, p. 439; Wilcox 2005, p. 306; DaSilva *et al.* 2007, p. 443; Neils and Bugbee 2007, p. 443).

Bullfrogs have been documented throughout the State of Arizona. Holycross *et al.* (2006, pp. 13–14, 52–61) found bullfrogs at 55 percent of sample sites in the Agua Fria watershed, 62 percent of sites in the Verde River watershed, 25 percent of sites in the Salt River watershed, and 22 percent of sites in the Gila River watershed. In total, bullfrogs were observed at 22 of the 57 sites surveyed (39 percent) across the Mogollon Rim (Holycross *et al.* 2006, p. 13). A number of authors have also documented the presence of bullfrogs through their survey efforts throughout

Arizona in specific regional areas, drainages, and disassociated wetlands within or adjacent to the historical distribution of the northern Mexican gartersnake, including the Kaibab National Forest (Sredl *et al.* 1995a, p. 7); the Coconino National Forest (Sredl *et al.* 1995c, p. 7); the White Mountain Apache Reservation (Hulse 1973, p. 278); Beaver Creek (tributary to the Verde River) (Drost and Nowak 1997, p. 11); the Watson Woods Riparian Preserve near Prescott (Nowak and Spille 2001, p. 11); the Tonto National Forest (Sredl *et al.* 1995b, p. 9); the Lower Colorado River (Vitt and Ohmart 1978, p. 44; Clarkson and DeVos 1986, pp. 42–49; Ohmart *et al.* 1988, p. 143); the Huachuca Mountains (Rosen and Schwalbe 1988, Appendix I; Holm and Lowe 1995, pp. 27–35; Sredl *et al.* 2000, p. 10; Rosen *et al.* 2001, Appendix I); the Pinaleno Mountains region (Nickerson and Mays 1970, p. 495); the San Bernardino National Wildlife Refuge (Rosen and Schwalbe 1988, Appendix I; 1995, p. 452; 1996, pp. 1–3; 1997, p. 1; 2002b, pp. 223–227; 2002c, pp. 31, 70; Rosen *et al.* 1995, p. 254; 1996b, pp. 8–9; 2001, Appendix I); the Buenos Aires National Wildlife Refuge (Rosen and Schwalbe 1988, Appendix I); the Arivaca Area (Rosen and Schwalbe 1988, Appendix I; Rosen *et al.* 2001, Appendix I); Cienega Creek drainage (Rosen *et al.* 2001, Appendix I); Babocamari River drainage (Rosen *et al.* 2001, Appendix I); Turkey Creek drainage (Rosen *et al.* 2001, Appendix I); O'Donnell Creek drainage (Rosen *et al.* 2001, Appendix I); Appleton-Whittell Research Ranch near Elgin (Rosen *et al.* 2001, Appendix I); Santa Cruz River drainage (Rosen and Schwalbe 1988, Appendix I; Rosen *et al.* 2001, Appendix I); San Rafael Valley (Rosen *et al.* 2001, Appendix I); San Pedro River drainage (Rosen and Schwalbe 1988, Appendix I; Rosen *et al.* 2001, Appendix I); Bingham Cienega (Rosen *et al.* 2001, Appendix I); Sulfur Springs Valley (Rosen *et al.* 1996a, pp. 16–17); Whetstone Mountains region (Turner *et al.* 1999, p. 11); Aqua Fria River drainage (Rosen and Schwalbe 1988, Appendix I; Holycross *et al.* 2006, pp. 13, 15–18, 52–53); Verde River drainage (Rosen and Schwalbe 1988, Appendix I; Holycross *et al.* 2006, pp. 13, 26–28, 55–56); greater metropolitan Phoenix area (Rosen and Schwalbe 1988, Appendix I); greater metropolitan Tucson area (Rosen and Schwalbe 1988, Appendix I); Sonoita Creek drainage (Rosen and Schwalbe 1988, Appendix I); Sonoita Grasslands (Rosen and Schwalbe 1988, Appendix I); Canelo Hills (Rosen and Schwalbe 1988,

Appendix I); Pajarito Mountains (pers. observation, J. Servoss, Fish and Wildlife Biologist, U.S. Fish and Wildlife Service); Picacho Reservoir (Rosen and Schwalbe 1988, Appendix I); Dry Creek drainage (Holycross *et al.* 2006, pp. 19, 53); Little Ash Creek drainage (Holycross *et al.* 2006, pp. 19, 54); Oak Creek drainage (Holycross *et al.* 2006, pp. 23, 54); Sycamore Creek drainages (Holycross *et al.* 2006, pp. 20, 25, 54–55); Rye Creek drainage (Holycross *et al.* 2006, pp. 37, 58); Spring Creek drainage (Holycross *et al.* 2006, pp. 25, 59); Tonto Creek drainage (Holycross *et al.* 2006, pp. 40–44, 59); Wallace *et al.* 2008, pp. 243–244); San Francisco River drainage (Holycross *et al.* 2006, pp. 49–50, 61); Sonoita Creek (Tuner 2006, p. 10); and the upper Gila River drainage (Holycross *et al.* 2006, pp. 45–50, 60–61).

Perhaps one of the most serious consequences of bullfrog introductions is their persistence in an area once they have become established, and the subsequent difficulty in eliminating bullfrog populations. Rosen and Schwalbe (1995, p. 452) experimented with bullfrog removal at various sites on the San Bernardino National Wildlife Refuge in addition to a control site with no bullfrog removal in similar habitat on the BANWR. Removal of adult bullfrogs, without removal of eggs and tadpoles, resulted in a substantial increase in younger age-class bullfrogs where removal efforts were the most intensive (Rosen and Schwalbe 1997, p. 6). Contradictory to the goals of bullfrog eradication, evidence from dissection samples from young adult and sub-adult bullfrogs indicated these age-classes readily prey upon juvenile bullfrogs (up to the average adult leopard frog size) as well as juvenile gartersnakes, which suggests that the selective removal of only the large adult bullfrogs (presumed to be the most dangerous size class to leopard frogs and gartersnakes), favoring the young adult and sub-adult age classes, could indirectly lead to increased predation of leopard frogs and juvenile gartersnakes (Rosen and Schwalbe 1997, p. 6). These findings illustrate that in addition to large adults, bullfrogs in the young adult and subadult age classes also negatively impact northern Mexican gartersnakes and their prey species.

*Bullfrog Effects on the Native Anuran Prey Base for the Northern Mexican Gartersnake.* As documented above and in the following studies, bullfrogs significantly reduce native anuran prey availability for the northern Mexican gartersnake (Conant (1974, pp. 471, 487–489); Hayes and Jennings (1986, pp. 491–492); Rosen and Schwalbe (1988,

pp. 28–30; 2002b, pp. 232–238); Rosen *et al.* (1995, pp. 257–258; 2001, pp. 2, Appendix I); Wu *et al.* (2005, p. 668); Pearl *et al.* (2004, p. 18); Kupferberg (1994, p. 95) Kupferberg (1997, pp. 1736–1751); Lawler *et al.* (1999); Bury and Whelan (1986, pp. 9–10); Hayes and Jennings (1986, pp. 500–501); Moyle (1973, pp. 18–22)). Different age classes of bullfrogs within a community can affect native ranid populations via different mechanisms. Juvenile bullfrogs affect native ranids through competition, male bullfrogs affect native ranids through predation, and female bullfrogs affect native ranids through both mechanisms depending on body size and microhabitat (Wu *et al.* 2005, p. 668). Pearl *et al.* (2004, p. 18) also suggested that the effect of bullfrog introductions on native ranids may be different based on specific habitat conditions, but also suggested that an individual ranid frog species' physical ability to escape influences the effect of bullfrogs on each native ranid community.

*Bullfrog Predation on Northern Mexican Gartersnakes.* Sub-adult and adult bullfrogs not only compete with the northern Mexican gartersnake for prey items, but directly prey upon juvenile and occasionally sub-adult northern Mexican gartersnakes (Rosen and Schwalbe 1988, pp. 28–31; 1995, p. 452; 2002b, pp. 223–227; Holm and Lowe 1995, pp. 29–29; Rossman *et al.* 1996, p. 177; AGFD *In Prep.*, p. 12; 2001, p. 3; Rosen *et al.* 2001, pp. 10, 21–22; Carpenter *et al.* 2002, p. 130; Wallace 2002, p. 116). A well-circulated photograph of an adult bullfrog in the process of consuming a northern Mexican gartersnake at Parker Canyon Lake, Cochise County, Arizona, taken by John Carr of the Arizona Game and Fish Department in 1964, provides photographic documentation of bullfrog predation (Rosen and Schwalbe 1988, p. 29; 1995, p. 452). A common observation in northern Mexican gartersnake populations that co-occur with bullfrogs is a preponderance of large, mature adult snakes with conspicuously low numbers of individuals in the newborn and juvenile age size classes due to bullfrogs preying on young small snakes, which ultimately leads to low reproductive rates and survival of young (Rosen and Schwalbe 1988, p. 18; Holm and Lowe 1995, p. 34). Potential recruitment problems for northern Mexican gartersnakes due to effects from nonnative species are also suspected at Tonto Creek (Wallace *et al.* 2008, pp. 243–244).

The tails of gartersnakes broken off through predation attempts may also

lead to infection or compromise an individual's physical ability to escape future predation attempts or successfully forage. Tails of gartersnakes do not regenerate. The incidence of tail breaks in gartersnakes can often be used to assess predation pressures within gartersnake populations. Rosen and Schwalbe (1988, p. 22) found the incidence of tail breaks to be statistically higher in females than in males. Fitch (2003, p. 212) also found that tail breaks in the common gartersnake occurred more frequently in females than males and in adults more than in juveniles. Fitch (2003, p. 212) also commented that, while tail breakage in gartersnakes can save the life of an individual snake, it also leads to permanent handicapping of the snake, resulting in slower swimming and crawling speeds, which could leave the snake more vulnerable to predation or affect its foraging ability. Furthermore, Mushinsky and Miller (1993, pp. 662–664) found that the incidence of tail injury in water snakes in the genera *Nerodia* and *Regina* (which have similar life histories to northern Mexican gartersnakes) was higher in females than in males and in adults more than juveniles. This can be explained by higher basking rates associated with pregnant females that increase their visibility to predators. Additionally, predation on juvenile snakes generally results in complete consumption of the animal, which would limit observations of tail injury in their age class. Rosen and Schwalbe (1988, p. 22) suggested that the indication that female northern Mexican gartersnakes bear more injuries is consistent with the inference that they employ a riskier foraging strategy. Willis *et al.* (1982, p. 98) discussed the incidence of tail injury in three species in the genus *Thamnophis* (common gartersnake, Butler's gartersnake (*T. butleri*), and the eastern ribbon snake (*T. sauritus*)) and concluded that individuals that suffered nonfatal injuries prior to reaching a length of 12 in (30 cm) are not likely to survive and that physiological stress during post-injury hibernation may play an important role in subsequent mortality.

Ecologically significant observations on tail injuries were made by Rosen and Schwalbe (1988, pp. 28–31) on the formerly occurring population of northern Mexican gartersnakes on the San Bernardino National Wildlife Refuge. Seventy-eight percent of specimens had broken tails with a "soft and club-like" terminus, which suggests repeated injury from multiple predation attempts by bullfrogs. While medically

examining pregnant female northern Mexican gartersnakes, Rosen and Schwalbe (1988, p. 28) noted bleeding from the posterior region which, suggested to the investigators the snakes suffered from "squeeze-type" injuries inflicted by adult bullfrogs. While a sub-adult or adult northern Mexican gartersnake may survive an individual predation attempt from a bullfrog while only incurring tail damage, secondary effects from infection of the wound can significantly contribute to mortality of individuals.

Research on the effects of attempted predation performed by Mushinsky and Miller (1993, pp. 661–664) and Willis *et al.* (1982, pp. 100–101) supports the observations made by Holm and Lowe (1995, p. 34) on the northern Mexican gartersnake population age class structure in Scotia Canyon in the Huachuca Mountains of southeastern Arizona in the early 1990s. Specifically, Holm and Lowe (1995, pp. 33–34) observed a conspicuously greater number of adult snakes in that population than sub-adult snakes, as well as a higher incidence of tail injury (89 percent) in all snakes captured. Bullfrogs have been identified as the primary cause for both the collapse of the native leopard frog (prey base for the northern Mexican gartersnake) and northern Mexican gartersnake populations on the San Bernardino National Wildlife Refuge (Rosen and Schwalbe 1988, p. 28; 1995, p. 452; 1996, pp. 1–3; 1997, p. 1; 2002b, pp. 223–227; 2002c, pp. 31, 70; Rosen *et al.* 1996b, pp. 8–9). Rosen and Schwalbe (1988, p. 18) stated that the low survivorship of newborns, and possibly yearlings, due to bullfrog predation is an important proximate cause of population declines of this snake at the San Bernardino National Wildlife Refuge and throughout its distribution in Arizona.

**Crayfish.** Nonnative crayfish are a primary threat to many prey species of the northern Mexican gartersnake and may also prey upon juvenile gartersnakes (Fernandez and Rosen 1996, p. 25; Voeltz 2002, pp. 87–88; USFWS 2007, p. 22). Fernandez and Rosen (1996, p. 3) studied the effects of crayfish introductions on two stream communities in Arizona, a low-elevation semi-desert stream and a high mountain stream, and concluded that crayfish can noticeably reduce species diversity and destabilize food chains in riparian and aquatic ecosystems through their effect on vegetative structure, stream substrate (stream bottom; i.e., silt, sand, cobble, boulder) composition, and predation on eggs, larval, and adult forms of native invertebrate and

vertebrate species. Crayfish fed on embryos, tadpoles, newly metamorphosed frogs, and adult leopard frogs, but they did not feed on egg masses (Fernandez and Rosen 1996, p. 25). However, Gamradt and Kats (1996, p. 1155) found that crayfish readily consumed the egg masses of California newts (*Taricha torosa*). Fernandez and Rosen (1996, pp. 6–19, 52–56) and Rosen (1987, p. 5) discussed observations of inverse relationships between crayfish abundance and native reptile and amphibian populations including narrow-headed gartersnakes, northern leopard frogs, and Chiricahua leopard frogs. Crayfish may also affect native fish populations. Carpenter (2005, pp. 338–340) documented that crayfish may reduce the growth rates of native fish through competition for food and noted that the significance of this impact may vary between species. Crayfish also prey on fish eggs and larvae (Inman *et al.* 1998, p. 17).

Crayfish alter the abundance and structure of aquatic vegetation by grazing on aquatic and semiaquatic vegetation, which reduces the cover needed by frogs and gartersnakes as well as the food supply for prey species such as tadpoles (Fernandez and Rosen 1996, pp. 10–12). Fernandez and Rosen (1996, pp. 10–12) also found that crayfish frequently burrow into stream banks, which leads to increased bank erosion, stream turbidity, and siltation of substrates. Creed (1994, p. 2098) found that filamentous alga (*Cladophora glomerata*) was at least 10-fold greater in aquatic habitat absent crayfish. Filamentous alga is an important component of aquatic vegetation that provides cover for foraging gartersnakes as well as microhabitat for prey species.

Inman *et al.* (1998, p. 3) documented nonnative crayfish as widely distributed and locally abundant in a broad array of natural and artificial free-flowing and still-water habitats throughout Arizona, many of which overlapped the historical and current distribution of the northern Mexican gartersnake. Hyatt (undated, p. 71) concluded that the majority of waters in Arizona contained at least one species of crayfish. In surveying for northern Mexican and narrow-headed gartersnakes, Holycross *et al.* (2006, p. 14) found crayfish in 64 percent of the sample sites in the Agua Fria watershed; in 85 percent of the sites in the Verde River watershed; in 46 percent of the sites in the Salt River watershed; and in 67 percent of the sites in the Gila River watershed. In total, crayfish were observed at 35 (61 percent) of the 57 sites surveyed across the Mogollon Rim (Holycross *et al.* 2006, p. 14), most of which were sites historically occupied

by northern Mexican gartersnakes, or sites the investigators believed possessed suitable habitat and may be occupied based upon the known historical distribution of the subspecies.

Several other authors have specifically documented the presence of crayfish in many areas and drainages throughout Arizona, which is testament to their ubiquitous distribution in Arizona and their strong colonizing abilities. These areas all fall within the range of the northern Mexican gartersnake and include the Kaibab National Forest (Sredl *et al.* 1995a, p. 7); the Coconino National Forest (Sredl *et al.* 1995c, p. 7); the Watson Woods Riparian Preserve near Prescott (Nowak and Spille 2001, p. 33); the Tonto National Forest (Sredl *et al.* 1995b, p. 9); the Lower Colorado River (Ohmart *et al.* 1988, p. 150; Inman *et al.* 1998, Appendix B); the Huachuca Mountains (Sredl *et al.* 2000, p. 10); the Arivaca Area (Rosen *et al.* 2001, Appendix I); Babocamari River drainage (Rosen *et al.* 2001, Appendix I); O'Donnell Creek drainage (Rosen *et al.* 2001, Appendix I); Santa Cruz River drainage (Rosen and Schwalbe 1988, Appendix I; Rosen *et al.* 2001, Appendix I); San Pedro River drainage (Inman *et al.* 1998, Appendix B; Rosen *et al.* 2001, Appendix I); Aqua Fria River drainage (Inman *et al.* 1998, Appendix B; Holycross *et al.* 2006, pp. 14, 15–18, 52–54); Verde River drainage (Inman *et al.* 1998, Appendix B; Holycross *et al.* 2006, pp. 14, 20–28, 54–56); Salt River drainage (Inman *et al.* 1998, Appendix B; Holycross *et al.* 2006, pp. 15, 29–44, 56–60); Black River drainage (Inman *et al.* 1998, Appendix B); San Francisco River drainage (Inman *et al.* 1998, Appendix B; Holycross *et al.* 2006, pp. 14, 49–50, 61); Nutrioso Creek drainage (Inman *et al.* 1998, Appendix B); Little Colorado River drainage (Inman *et al.* 1998, Appendix B); Leonard Canyon Drainage (Inman *et al.* 1998, Appendix B); East Clear Creek drainage (Inman *et al.* 1998, Appendix B); Chevelon Creek drainage (Inman *et al.* 1998, Appendix B); Eagle Creek drainage (Inman *et al.* 1998, Appendix B; Holycross *et al.* 2006, pp. 47–48, 60); Bill Williams drainage (Inman *et al.* 1998, Appendix B); Sabino Canyon drainage (Inman *et al.* 1998, Appendix B); Dry Creek drainage (Holycross *et al.* 2006, pp. 19, 53); Little Ash Creek drainage (Holycross *et al.* 2006, pp. 19, 54); Sycamore Creek drainage (Holycross *et al.* 2006, pp. 25, 54–55); East Verde River drainage (Holycross *et al.* 2006, pp. 21–22, 54); Oak Creek drainage (Holycross *et al.* 2006, pp. 23, 54); Pine Creek drainage (Holycross *et al.* 2006, pp. 24, 55); Spring Creek

drainage (Holycross *et al.* 2006, pp. 25, 55); Big Bonito Creek drainage (Holycross *et al.* 2006, pp. 29, 56); Cherry Creek drainage (Holycross *et al.* 2006, pp. 33, 57); East Fork Black River drainage (Holycross *et al.* 2006, pp. 34, 57); Haigler Creek drainage (Holycross *et al.* 2006, pp. 35, 58); Houston Creek drainage (Holycross *et al.* 2006, pp. 35–36, 58); Rye Creek drainage (Holycross *et al.* 2006, pp. 37, 58); Tonto Creek drainage (Holycross *et al.* 2006, pp. 40–44, 59); Wallace *et al.* 2008; pp. 243–244); Blue River drainage (Holycross *et al.* 2006, pp. 45, 60); Campbell Blue River drainage (Holycross *et al.* 2006, pp. 46, 60); and the Gila River drainage (Inman *et al.* 1998, Appendix B; Holycross *et al.* 2006, pp. 45–50, 61). Like bullfrogs, crayfish can be very difficult, if not impossible, to eradicate once they have become established in an area (Rosen and Schwalbe 1996a, pp. 5–8; 2002a, p. 7; Hyatt undated, pp. 63–71).

**Nonnative Fish Distribution and Community Interactions.** As indicated earlier in this document, nonnative fish are a threat to northern Mexican gartersnakes and their native anuran and fish prey. Similar to bullfrogs, predatory nonnative fish species, such as largemouth bass, also prey upon juvenile northern Mexican gartersnakes. Rosen *et al.* (2001, Appendix I) and Holycross *et al.* (2006, pp. 15–51) conducted large-scale surveys for northern Mexican gartersnakes in southeastern and central Arizona and narrow-headed gartersnakes in central and east-central Arizona and documented the presence of nonnative fish at many locations. Rosen *et al.* (2001, Appendix I) found nonnative fish in the following survey locations: The Arivaca Area; Babocamari River drainage; O'Donnell Creek drainage; Appleton-Whittell Research Ranch (Post Canyon) near Elgin; Santa Cruz River drainage; Agua Caliente Canyon; Santa Catalina Mountains; and the San Pedro River drainage. Holycross *et al.* (2006, pp. 14–15, 52–61) found nonnative fish in the Aqua Fria River drainage; the Verde River drainage; the Dry Creek drainage; the Little Ash Creek drainage; the Sycamore Creek drainage; the East Verde River drainage; the Oak Creek drainage; the Pine Creek drainage; the Big Bonito Creek drainage; the Black River drainage; the Canyon Creek drainage; the Cherry Creek drainage; the Christopher Creek drainage; the East Fork Black River drainage; the Haigler Creek drainage; the Houston Creek drainage; the Rye Creek drainage; the Salt River drainage; the Spring Creek drainage; the Tonto Creek drainage; the

Blue River drainage; the Campbell Blue River drainage; the Eagle Creek drainage; and the San Francisco River drainage. Other authors have documented the presence of nonnative fish through their survey efforts in specific regions that include the Tonto National Forest (Sredl *et al.* 1995b, p. 8) and the Huachuca Mountains (Sredl *et al.* 2000, p. 10).

Holycross *et al.* (2006, pp. 14–15) found nonnative fish species in 64 percent of the sample sites in the Agua Fria watershed, 85 percent of the sample sites in the Verde River watershed, 75 percent of the sample sites in the Salt River watershed, and 56 percent of the sample sites in the Gila River watershed. In total, nonnative fish were observed at 41 of the 57 sites surveyed (72 percent) across the Mogollon Rim (Holycross *et al.* 2006, p. 14). Entirely native fish communities were detected in only 8 of 57 sites surveyed (14 percent) (Holycross *et al.* 2006, p. 14). While the locations and drainages identified above that are known to support populations of nonnative fish do not provide a thorough representation of the status of nonnative fish distribution Statewide in Arizona, it is well documented that nonnative fish have infiltrated the majority of aquatic communities in Arizona.

Nonnative fish can also affect native amphibian populations. Matthews *et al.* (2002, p. 16) examined the relationship of gartersnake distributions, amphibian population declines, and nonnative fish introductions in high-elevation aquatic ecosystems in California. Matthews *et al.* (2002, p. 16) specifically examined the effect of nonnative trout introductions on populations of amphibians and mountain gartersnakes (*Thamnophis elegans elegans*). Their results indicated the probability of observing gartersnakes was 30 times greater in lakes containing amphibians than in lakes where amphibians have been extirpated by nonnative fish. These results supported prediction by Jennings *et al.* (1992, p. 503) that native amphibian declines will lead directly to gartersnake declines. Matthews *et al.* (2002, p. 20) noted that in addition to nonnative fish species adversely impacting amphibian populations that are part of the gartersnake's prey base, direct predation on gartersnakes by nonnative fish also occurs. Inversely, gartersnake predation on nonnative species, such as centrarchids, may physically harm the snake. Choking injuries to northern Mexican gartersnakes may occur from attempting to ingest nonnative spiny-rayed fish species (such as green sunfish and bass) because the spines located in the dorsal

fins of these species can become lodged in, or cut into the gut tissue, of the snake, as observed in narrow-headed gartersnakes (Nowak and Santana-Bendix 2002, p. 25).

Nonnative fish invasions can indirectly affect the health, maintenance, and reproduction of the northern Mexican gartersnake by altering its foraging strategy and foraging success. The more energy expended in foraging, coupled by the reduced number of small to medium-sized prey fish available in lower densities, may lead to deficiencies in nutrition affecting growth and reproduction because energy is instead allocated to maintenance and the increased energy costs of intense foraging activity (Rosen *et al.* 2001, p. 19). In contrast, a northern Mexican gartersnake diet that includes both fish and amphibians such as leopard frogs provides larger prey items which reduce the necessity to forage at a higher frequency allowing metabolic energy gained from larger prey items to be allocated instead to growth and reproductive development. Myer and Kowell (1973, p. 225) experimented with food deprivation in common gartersnakes and found significant reductions in lengths and weights in juvenile snakes that were deprived of regular feedings versus the control group that were fed regularly at natural frequencies. Reduced foraging success means that individuals will become vulnerable to effects from starvation, which may, therefore, increase mortality rates in the juvenile size class and consequently affect recruitment of northern Mexican gartersnakes where their prey base has been compromised by nonnative species.

**Nonnative Species in Mexico.** As in the United States, the native fish prey base for northern Mexican gartersnakes in Mexico has been dramatically affected by the introduction of nonnative species (Conant 1974, pp. 471, 487–489; Miller *et al.* 2005, pp. 60–61; Abarca 2006). In the lower elevations of Mexico where northern Mexican gartersnakes occurred historically or are still found, there are approximately 200 species of native freshwater fish documented with 120 native species under some form of threat and an additional 15 that have become extinct due to human activities, which include the introduction of nonnative species (Contreras Balderas and Lozano 1994, pp. 383–384). In 1979, The American Fisheries Society listed 69 species of native fish in Mexico as threatened or in danger of becoming extinct. Ten years later that number rose to 123 species, an increase of 78 percent

(Contreras Balderas and Lozano 1994, pp. 383–384). Miller *et al.* (2005, p. 60) concludes that some 20 percent of Mexico's native fish are threatened or in danger of becoming extinct. Nonnative species are increasing everywhere throughout Mexico, and this trend will have adverse impacts on native fish, according to Miller *et al.* (2005, p. 61). A number of freshwater fish populations have been adversely affected by nonnative species in many locations, several of which were previously noted in the discussion under Factor A.

At the time of our 2006 12-month finding, we had less information on the status and distribution of bullfrogs within Mexico. However, since that time, Luja and Rodríguez-Estrella (2008, pp. 17–22) examined the invasion of the bullfrog in Mexico. The earliest records of bullfrogs in Mexico were Nuevo Leon (1853), Tamaulipas (1898), Morelos (1968), and Sinaloa (1969) (Luja and Rodríguez-Estrella 2008, p. 20). By 1976, the bullfrog was documented in 7 more States: Aguascalientes, Baja California Sur, Chihuahua, Distrito Federal, Puebla, San Luis Potosí, and Sonora (Luja and Rodríguez-Estrella 2008, p. 20). To date, Luja and Rodríguez-Estrella (2008, p. 20) have recorded bullfrogs in 20 of the 31 Mexican States (65 percent of the states in Mexico) and suspect that they have invaded other States, but were unable to find documentation.

Sponsored by the then Mexican Secretary of Aquaculture Support, bullfrogs have been commercially produced for food in Mexico in Yucatan, Nayarit, Morelos, Estado de Mexico, Michoacán, Guadalajara, San Luis Potosí, Tamaulipas, and Sonora (Luja and Rodríguez-Estrella 2008, p. 20). However, frog legs ultimately never gained popularity in Mexican culinary culture (Conant 1974, pp. 487–489) and Luja and Rodríguez-Estrella (2008, p. 22) point out that only 10 percent of these farms remain in production. Luja and Rodríguez-Estrella (2008, p. 20 and 22) document instances where bullfrogs have escaped production farms and suspect the majority of the frogs that were produced commercially in farms that have since ceased operation have assimilated into surrounding habitat.

Luja and Rodríguez-Estrella (2008, p. 20) also state that Mexican people deliberately introduce bullfrogs for ornamental purposes, or “for the simple pleasure of having them in ponds.” The act of deliberately releasing bullfrogs into the wild in Mexico was cited by Luja and Rodríguez-Estrella (2008, p. 21) as being “more common than we can imagine.” To further compound these introductions, bullfrogs are

available for purchase at Mexican pet stores (Luja and Rodríguez-Estrella 2008, p. 22).

Adverse effects such as predation upon, and competition with, northern Mexican gartersnakes and their prey base from bullfrog invasions in Mexico have been specifically documented with respect to Chiricahua leopard frogs, a primary prey item for northern Mexican gartersnakes (Luja and Rodríguez-Estrella 2008, p. 21). Luja and Rodríguez-Estrella (2008, p. 21) also stated that bullfrog eradication efforts in Mexico are often thwarted by their being favored by local communities. Currently, no regulation exists in Mexico to address the threat of bullfrog invasions (Luja and Rodríguez-Estrella 2008, p. 22).

Rosen and Melendez (2006, p. 54) report bullfrog invasions to be prevalent in northwestern Chihuahua and northwestern Sonora, where the northern Mexican gartersnake is thought to occur. In many areas, native leopard frogs were completely displaced where bullfrogs were observed. Rosen and Melendez (2006, p. 54) also demonstrated the relationship between fish and amphibian communities in Sonora and western Chihuahua. Native leopard frogs, a primary prey item for the northern Mexican gartersnake, only occurred in the absence of nonnative fish and were absent from waters containing nonnative species, which included several major waters. In Sonora, Rorabaugh (2008, p. 25) also considers the bullfrog to be a significant threat to the northern Mexican gartersnake and its prey base.

Unmack and Fagan (2004, p. 233) compared historical museum collections of nonnative fish species from the Gila River basin in Arizona and the Yaqui River basin in Sonora, Mexico, to gain insight into the trends in distribution, diversity, and abundance of nonnative fishes in each basin over time. They found that nonnative species are slowly but steadily increasing in all three parameters in the Yaqui Basin (Unmack and Fagan 2004, p. 233). Unmack and Fagan (2004, p. 233) predicted that, in the absence of aggressive management intervention, significant extirpations or range reductions of native fish species are expected to occur in the Yaqui Basin of Sonora, Mexico, which may have current populations of northern Mexican gartersnake, as did much of the Gila Basin before the introduction of nonnative species. Loss of native fishes will impact prey availability for the northern Mexican gartersnake and threaten its persistence in these areas.

*Summary of Factor C.* While disease is not currently considered a direct

threat to northern Mexican gartersnakes, Bd does have a widespread effect on anuran prey availability for the species. In addition, stress placed on northern Mexican gartersnakes as a result of threats discussed under Factor A may affect the health condition of individuals within populations affected by these threats, which may increase the potential for disease within current populations in the future.

Direct predation by nonnative bullfrogs, crayfish, and fishes on northern Mexican garter snakes is a significant threat rangewide, as is predation on gartersnake prey species (competition) by these same groups of nonnative taxa. Nonnative fish, crayfish, and bullfrogs have reduced native populations of prey species throughout the range.

#### *D. The Inadequacy of Existing Regulatory Mechanisms*

Currently, the northern Mexican gartersnake is considered “State Endangered” in New Mexico. In the State of New Mexico, an “Endangered Species” is defined as “any species of fish or wildlife whose prospects of survival or recruitment within the State are in jeopardy due to any of the following factors: (1) The present or threatened destruction, modification, or curtailment of its habitat; (2) overutilization for scientific, commercial or sporting purposes; (3) the effect of disease or predation; (4) other natural or man-made factors affecting its prospects of survival or recruitment within the state; or (5) any combination of the foregoing factors” as per New Mexico Statutory Authority (NMSA) 17–2–38.D. “Take,” defined as “means to harass, hunt, capture or kill any wildlife or attempt to do so” by NMSA 17–2–38.L., is prohibited without a scientific collecting permit issued by the New Mexico Department of Game and Fish as per NMSA 17–2–41.C and New Mexico Administrative Code (NMAC) 19.33.6. However, while the New Mexico Department of Game and Fish can issue monetary penalties for illegal take of northern Mexican gartersnakes, the same provisions are not in place for actions that result in loss or modification of habitat (NMSA 17–2–41.C and NMAC 19.33.6) (Painter 2005).

The northern Mexican gartersnake is considered a “Candidate Species” in the Arizona Game and Fish Department draft document, *Wildlife of Special Concern (WSCA) (AGFD In Prep., p. 12)*. A “Candidate Species” is one “whose threats are known or suspected but for which substantial population declines from historical levels have not been documented (though they appear to



have occurred)" (AGFD *In Prep.*, p. 12). The purpose of the WSCA list is to provide guidance in habitat management implemented by land-management agencies. Additionally, the northern Mexican gartersnake is considered a "Tier 1b Species of Greatest Conservation Need" in the Arizona Game and Fish Department draft document, Arizona's Comprehensive Wildlife Conservation Strategy (CWCS) (AGFD 2006a, p. 32; 2006b). The purpose for the CWCS is to "provide an essential foundation for the future of wildlife conservation and a stimulus to engage the States, federal agencies, and other conservation partners to strategically think about their individual and coordinated roles in prioritizing conservation efforts" (AGFD 2006a, p. 2). A "Tier 1b Species of Greatest Conservation Need" is one that requires immediate conservation actions aimed at improving conditions through intervention at the population or habitat level (AGFD 2006a, p. 32).

Prior to 2005, the Arizona Game and Fish Department allowed for take of up to four northern Mexican gartersnakes per person per year as specified in Commission Order Number 43. The Arizona Game and Fish Department defines "take" as "pursuing, shooting, hunting, fishing, trapping, killing, capturing, snaring, or netting wildlife or the placing or using any net or other device or trap in a manner that may result in the capturing or killing of wildlife." The Arizona Game and Fish Department subsequently amended Commission Order Number 43, effective January 2005. Take of northern Mexican gartersnakes is no longer permitted in Arizona without issuance of a scientific collecting permit (Ariz. Admin. Code R12-4-401 *et seq.*). While the Arizona Game and Fish Department can seek criminal or civil penalties for illegal take of northern Mexican gartersnakes, the same provisions are not in place for actions that result in destruction or modification of northern Mexican gartersnake habitat.

In addition to making the necessary regulatory changes to promote the conservation of the northern Mexican gartersnake, the Arizona Game and Fish Department continues as a strong partner in research and survey efforts that further our understanding of current populations within Arizona. They continue to assist with future conservation efforts and the establishment of long-term conservation partnerships.

Gartersnakes are active, diurnal (daytime) foragers and humans encounter gartersnake species in riparian areas used for recreational

purposes or for other reasons. These encounters can result in the capture, injury, or death of the gartersnake due to the lay person's fear or dislike of snakes (Rosen and Schwalbe 1988, p. 43; Ernst and Zug 1996, p. 75; Green 1997, pp. 285-286; Nowak and Santana-Bendix 2002, p. 39). It is very difficult for the Arizona Game and Fish Department or the New Mexico Department of Fish and Game to monitor or even be aware of such forms of take. We believe that unregulated take occurs, particularly in areas frequently visited by the public with current populations of northern Mexican gartersnakes, such as at Page Springs and Bubbling Ponds hatcheries and along Tonto Creek near the town of Gisela. We are reasonably certain that the level of illegal field collecting by the hobbyist community is low because gartersnakes are relatively undesirable in amateur herpetological collections.

Neither the New Mexico Department of Game and Fish, nor the Arizona Game and Fish Department have specified or mandated recovery goals for the northern Mexican gartersnake, nor has either State developed a conservation agreement or plan for this species.

Throughout Mexico, the Mexican gartersnake is listed at the species level of its taxonomy as "Amenazadas," or Threatened, by the Secretaria de Medio Ambiente y Recursos Naturales (SEMARNAT) (SEDESOL 2001). Threatened species are "those species, or populations of the same, likely to be in danger of disappearing in a short or medium timeframe, if the factors that negatively impact their viability, cause the deterioration or modification of their habitat or directly diminish the size of their populations continue to operate" (SEDESOL 2001 (NOM-059-ECOL-2001), p. 4). This designation prohibits taking of the species, unless specifically permitted, as well as prohibits any activity that intentionally destroys or adversely modifies its habitat (SEDESOL 2000 (LGVS) and 2001 (NOM-059-ECOL-2001)). Additionally, in 1988, the Mexican Government passed a regulation that is similar to the National Environmental Policy Act of the United States (42 U.S.C. 4321 *et seq.*). This Mexican regulation requires an environmental assessment of private or government actions that may affect wildlife or their habitat (SEDESOL 1988 (LGEEPA)).

The Mexican Federal agency known as the Instituto Nacional de Ecología (INE) is responsible for the analysis of the status and threats that pertain to species that are proposed for listing in the Norma Oficial Mexicana NOM-059

(the Mexican equivalent to a threatened and endangered species list), and if appropriate, the nomination of species to the list. INE is generally considered the Mexican counterpart to the United States' Fish and Wildlife Service. INE developed the Method of Evaluation of the Risk of Extinction of the Wild Species in Mexico (MER), which unifies the criteria of decisions on the categories of risk and permits the use of specific information fundamental to listing decisions. The MER is based on four independent, quantitative criteria: (1) Size of the distribution of the taxon in Mexico; (2) state (quality) of the habitat with respect to natural development of the taxon; (3) intrinsic biological vulnerability of the taxon; and (4) impacts of human activity on the taxon. INE began to use the MER in 2006; therefore, all species previously listed in the NOM-059 were based solely on expert review and opinion in many cases. Specifically, until 2006, the listing process under INE consisted of a panel of scientific experts who convened as necessary for the purpose of defining and assessing the status and threats that affect Mexico's native species that are considered to be at risk and applying those factors to the definitions of the various listing categories. In 1994, when the Mexican gartersnake was placed on the NOM-059 (SEDESOL 1994 (NOM-059-ECOL-1994), p. 46) as a threatened species, the decision was made by a panel of scientific experts.

Although the Mexican gartersnake is considered a federally threatened species in Mexico, no recovery plan or other conservation planning occurs because of this status. Enforcement of the regulation protecting the gartersnake is sporadic, based on available resources and location. Based upon the information on the status of the species and the historic and continuing threats to its habitat in Mexico, our analysis concludes that protections afforded to the northern Mexican gartersnake may not be adequate to preclude the continued decline of this species throughout its range.

Ortega-Huerta and Kral (2007, p. 1) found that land legislation within Mexico has changed considerably over recent years to integrate free market policies into local agricultural production methods. This may result in the loss of land management practices that protect the natural environment. In 1992, the Mexican Government made a constitutional amendment ending the Ejido's special legal status and permitting the sale of collectively controlled lands (Ortega-Huerta and Kral 2007, p. 2). An Ejido is an

amalgamation of various types of ownership of a particular piece of land, e.g., state, cooperative, communal, and private. Ejidos are generally managed in traditional means, which generally have less of an impact to the environment compared to more modern free market uses, resulting in higher levels of biodiversity (Ortega-Huerta and Kral 2007, p. 2; Randall 1996, pp. 218–220; Kiernan 2000, pp. 13–23). The loss of regulation that prevented the division and sale of collectively controlled lands in Mexico is likely to reduce the protection of intact northern Mexican gartersnake habitat.

Existing water laws in Arizona, New Mexico, and Mexico are inadequate to protect wildlife. The presence of water is a primary habitat constituent for the northern Mexican gartersnake. Gelt (2008, pp. 1–12) highlighted the fact that, because the existing water laws are so old, they reflect a legislative interpretation of the resource that is not consistent with what we know today; yet the laws have never been updated or amended to account for this discrepancy. For example, over 100 years ago when Arizona's water laws were written, the important connection between groundwater and surface water was not known (Gelt 2008, pp. 1–12). Gelt (2008, pp. 8–9) suggested that preserving stream flows and riparian areas may be better accomplished by curtailing surface water uses rather than ground water uses, and that the prior appropriation doctrine (appropriation of water rights based upon the water law concept of "first in use, first in rights") may be outdated and impractical for arid areas like Arizona.

The majority of current populations of northern Mexican gartersnake in the United States occur on lands managed by the U.S. Bureau of Land Management and U.S. Forest Service. Although both agencies have riparian protection goals, neither agency has specific management plans for the northern Mexican gartersnake. The U.S. Bureau of Land Management considers the northern Mexican gartersnake as a "Special Status Species," and agency biologists actively attempt to identify gartersnakes observed incidentally during fieldwork for their records (Young 2005). Otherwise, no specific protection or land-management consideration is afforded to the species on Bureau of Land Management lands.

The U.S. Forest Service does not include northern Mexican gartersnake on their Management Indicator Species List, but it is included on the Regional Forester's Sensitive Species List. This means that northern Mexican gartersnakes are considered in land

management decisions. Individual U.S. Forest Service biologists who work within the range of the northern Mexican gartersnake may opportunistically gather data for their records on gartersnakes observed incidentally in the field, although it is not required.

Activities that could adversely affect northern Mexican gartersnakes and their habitat continue to occur throughout their current distribution on National Forest lands. Clary and Webster (1989, p. 1) stated that "\* \* \* most riparian grazing results suggest that the specific grazing system used is not of dominant importance, but good management is—with control of use in the riparian area a key item." Due to ongoing constraints in funding, staff levels, and time and regulatory compliance pertaining to monitoring and reporting duties tied to land management, proactive measures continue to be limited. These factors affect a land manager's ability to employ adaptive management procedures when effects to sensitive species or their habitat could be occurring at levels greater than anticipated in regulatory compliance mechanisms, such as in section 7 consultation under the Act for listed species that may co-occur with the northern Mexican gartersnake in an area. In other words, and due to the existing regulatory framework, some land managers may not have the flexibility required to adopt adaptive management where necessary to adequately account for adverse effects of projects on public lands.

Riparian communities are complex and recognized as unique in the southwestern United States but are highly sensitive to many human-caused land uses, as evidenced by the comparatively high number of federally listed riparian or aquatic species. Four primary prey species for the northern Mexican gartersnake, the Chiricahua leopard frog, Gila topminnow, Gila chub, and roundtail chub, are federally listed or were petitioned for listing. Other listed or proposed riparian species or their proposed or designated critical habitat overlap the current or historical distribution of the northern Mexican gartersnake. Despite secondary protections that may be afforded to the northern Mexican gartersnake from federally listed species or their critical habitat, riparian and aquatic communities continue to be adversely impacted for reasons previously discussed, contributing to the declining status of the northern Mexican gartersnake throughout its range in the United States.

*Summary of Factor D.* Existing regulations within the range of the

northern Mexican gartersnake address the direct take of individuals without a permit, and unpermitted take by recreationists or collectors is not thought to be at levels that impact the subspecies. Arizona and New Mexico statutes do not provide protection of habitat and ecosystems. Legislation in Mexico prohibits intentional destruction or modification of the snake's habitat, but neither that or prohibitions on take appear to be adequate to preclude the continued decline of the subspecies. Currently, there are no regulatory mechanisms in place that specifically target the conservation of northern Mexican gartersnake habitat. Legislation in Mexico has removed regulation of ejidos that promoted intact protection of important riparian and aquatic habitats. Regulations protecting the quantity and quality of water in riparian and aquatic communities are inadequate to protect water resources for the northern Mexican gartersnake, particularly in the face of the significant population growth expected within the historical range of the snake discussed under Factor A.

#### *E. Other Natural or Manmade Factors Affecting Its Continued Existence*

*Competition With Other Species Within the Same Genus.* Marcy's checkered gartersnake (*Thamnophis marcianus marcianus*) may impact the future conservation of the northern Mexican gartersnake in southern Arizona, although supporting data are limited. Marcy's checkered gartersnake is a semi-terrestrial species that is able to co-exist to some degree with riparian and aquatic nonnative predators. This is largely due to its ability to forage in more terrestrial habitats, specifically in the juvenile size classes (Rosen and Schwalbe 1988, p. 31; Rosen *et al.* 2001, pp. 9–10). In every age class, the northern Mexican gartersnake forages in aquatic habitats where bullfrogs, nonnative sportfish, and crayfish also occur, which increases not only the encounter rate between the species but also the juvenile mortality rate of the northern Mexican gartersnake. As northern Mexican gartersnake numbers decline within a population, space becomes available for occupation by checkered gartersnakes. Marcy's checkered gartersnake subsequently affects the maximum number of northern Mexican gartersnakes that an area can maintain based upon available resources and could potentially accelerate the decline of or preclude reoccupancy by the northern Mexican gartersnake (Rosen and Schwalbe 1988, p. 31).

Rosen *et al.* (2001, pp. 9–10) documented the occurrence of Marcy's

checkered gartersnakes out-competing and replacing northern Mexican gartersnakes at the San Bernardino National Refuge and surrounding habitats of the Black Draw. They suspected that the drought from the late 1980s through the late 1990s played a role in the degree of competition for aquatic resources, provided an advantage to the more versatile Marcy's checkered gartersnake, and expedited the decline of the northern Mexican gartersnake. The competition between these two species, in combination with other factors described above that have adversely affected the northern Mexican gartersnake prey base and the suitability of occupied and formerly occupied habitat, may be contributing to the decline of this species.

*Current and Future Effects from Changes in Climatic Patterns and Drought.* Seagar *et al.* (2007, pp. 1181–1184) analyzed 19 different computer models of differing variables to estimate the future climatology of the southwestern United States and northern Mexico in response to predictions of changing climatic patterns. All but 1 of the 19 models predicted a drying trend within the Southwest; one predicted a trend toward a wetter climate (Seager *et al.* 2007, p. 1181). A total of 49 projections were created using the 19 models and all but 3 predicted a shift to increasing aridity (dryness) in the Southwest as early as 2021–2040 (Seager, *et al.* 2007, p. 1181). The northern Mexican gartersnake and its prey base depend on permanent or nearly permanent water for survival. A large percentage of habitat within the current distribution of the northern Mexican gartersnake is predicted to be at risk of becoming more arid (Seager *et al.* 2007, pp. 1183–1184), which has severe implications to the integrity of aquatic and riparian ecosystems and the water that supports them. Potential drought associated with changing climatic patterns may not only adversely affect habitat of the northern Mexican gartersnake, but also its prey. Amphibians may be among the first vertebrates to exhibit broad-scale changes in response to changes in global climatic patterns due to their sensitivity to changes in moisture and temperature (Reaser and Blaustein 2005, p. 61). Changes in temperature and moisture, combined with the ongoing threat to amphibians from the persistence of Bd may cause prey species to experience increased physiological stress and decreased immune system function, possibly leading to disease outbreaks (Carey and Alexander 2003, pp. 111–121; Pounds *et al.* 2006, pp. 161–167).

Changes to climatic patterns are predicted to have implications for the effect of, and management for, nonnative species within the distribution of the northern Mexican gartersnake. Based upon climate change models, nonnative species biology, and ecological observations, Rahel *et al.* (2008, p. 551) conclude that climate change could foster the expansion of nonnative aquatic species into new areas, magnify the effects of existing aquatic nonnative species where they currently occur, increase nonnative predation rates, and heighten the virulence of disease outbreaks in North America. Many of the nonnative species have similar, basic ecological requirements as our native species, such as the need for permanent or nearly permanent water. Therefore, it is likely that effects from changes to climatic patterns (such as a trend towards a more arid environment) that negatively affect nonnative species such as bullfrogs and nonnative fish may also negatively affect native prey species for the northern Mexican gartersnake.

Changes to climatic patterns may warm water temperatures, alter stream flow events, and may increase demand for water storage and conveyance systems (Rahel and Olden 2008, pp. 521–522). Warmer water temperatures across temperate regions are predicted to expand the distribution of existing aquatic nonnative species by providing 31 percent more suitable habitat for aquatic nonnative species, which are often tropical in origin and adaptable to warmer water temperatures. This conclusion is based upon studies that compared the thermal tolerances of 57 fish species with predictions made from climate change temperature models (Mohseni *et al.* 2003, p. 389). Eaton and Scheller (1996, p. 1,111) reported that while several cold-water fish species in North America are expected to have reductions in their distribution from effects of climate change, several warmwater fish species are expected to increase their distribution. In the southwestern United States, this situation may occur where the quantity of water is sufficient to sustain effects of potential prolonged drought conditions but where water temperature may warm to a level found suitable to harmful nonnative species that were previously physiologically precluded from occupation of these areas. Species that are particularly harmful to northern Mexican gartersnake populations such as the green sunfish, channel catfish, largemouth bass, and bluegill are expected to increase their distribution by 7.4 percent, 25.2 percent, 30.4

percent, and 33.3 percent, respectively (Eaton and Scheller 1996, p. 1,111).

Rahel and Olden (2008, p. 526) expect that increases in water temperatures in drier climates such as the southwestern United States will result in periods of prolonged low flows and stream drying. These effects from changing climatic conditions may have profound effects on the amount, permanency, and quality of habitat for the northern Mexican gartersnake and its prey base. Warmwater nonnative species such as red shiner, common carp, mosquitofish, and largemouth bass are expected to benefit from prolonged periods of low flow (Rahel and Olden 2008, p. 527).

Data specific to changing climatic patterns in Mexico, other than the Seager *et al.* (2007) climate change modeling, are limited. However, because the predictive climate models include northern Mexico, we assume that the changes predicted for the southwestern United States will likely be similar.

The effects of the water withdrawals discussed above may be exacerbated by the current, long-term drought facing the arid southwestern United States. Philips and Thomas (2005, pp. 1–4) provided streamflow records that indicate that the drought Arizona experienced between 1999 and 2004 was the worst drought since the early 1940s and possibly earlier. The Arizona Drought Preparedness Plan Monitoring Technical Committee (ADPPMTC) (2008) assessed Arizona's drought status through June 2008 in watersheds where the northern Mexican gartersnake occurs or historically occurred. They found that the Verde, Agua Fria, San Pedro, Santa Cruz, and Whitewater Draw watersheds continue to experience moderate drought (ADPPMTC 2008). Whereas the Salt, Upper Gila, Lower Gila, and Lower Colorado watersheds were abnormally dry (ADPPMTC 2008). Ongoing drought conditions have depleted recharge of aquifers and decreased baseflows in the region. While drought periods have been relatively numerous in the arid Southwest from the mid-1800s to the present, the effects of human-caused impacts on riparian and aquatic communities have compromised the ability of these communities to function under the additional stress of prolonged drought conditions. Holycross *et al.* (2006, pp. 52–53) recently documented the effects of drought on northern Mexican gartersnake habitat in the vicinity of Arcosante along the Agua Fria River and at Big Bug Creek. The streams were completely dry and therefore unsuitable northern Mexican gartersnake habitats.

*Summary of Factor E.* It is unlikely that competition with other gartersnakes will be a significant cause of decline in northern Mexican gartersnake populations in comparison to other threats we have discussed. All but one model evaluating changing climatic patterns for the southwestern United States and northern Mexico predict a drying trend for the region (Seagar *et al.* 2007, pp. 1181–1184). We acknowledge that drought and the loss of surface water in riparian and aquatic communities are related to changing climatic conditions (Seagar *et al.* 2007, pp. 1181–1184). The extent to which changing climate patterns will affect the northern Mexican gartersnake is not known with certainty at this time. However, threats to the northern Mexican gartersnake identified in Factors A and C will likely be exacerbated by changes to climatic patterns in the southwestern United States due to resulting increasing drought and reduction of surface waters if the predicted patterns are realized. Data specific to changes in climatic patterns in Mexico are limited, but because the models for the southwestern United States included northern Mexico, we believe that the effect from the changing climatic patterns will exacerbate threats due to Factors A and C in that country as well.

#### Foreseeable Future

When determining whether a species is in danger of extinction throughout all or a significant portion of its range, or is likely to become in danger of extinction in the foreseeable future, we must identify that foreseeable future for the species. The Act does not specifically define the term “foreseeable future.” In discussing the concept of foreseeable future for the northern Mexican gartersnake, we considered (1) the biological and demographic characteristics of the species (such as generation times, population genetics, trends in age-class distribution within current populations, etc.); (2) our ability to predict or extrapolate the effects of threats facing the species into the future; and (3) the relative permanency or irreversibility of these threats. Of the threats to the northern Mexican gartersnake and its prey base that have been discussed above in our analysis of the threats, we believe the threat of nonnative species presents the most widespread, imminent, and serious threat to the long-term sustainability of this subspecies. Therefore, we concentrate primarily upon this threat to the northern Mexican gartersnake in our analysis of the subspecies’ viability into the foreseeable future. Because our

knowledge of the threats to and status of the northern Mexican gartersnake in Mexico is not as robust as that for the United States, our analysis focuses on the United States and presumes (1) similar human-caused threats occur to the subspecies’ habitat in areas in proximity to human population centers in Mexico, and (2) a time-lagged effect, with respect to nonnative species invasions, within more remote habitat in Mexico as postulated in Unmack and Fagan (2004, pp. 233–243).

Based on museum records found in Holycross *et al.* (2006, Appendix F), we expect the northern Mexican gartersnake retained its entire historic distribution within the United States through the 1920s and likely into the 1930s. Activities such as the construction of dams and water diversions that occurred throughout the early to mid-1900s for agriculture and regional economic development likely eliminated surface flow throughout stream reaches with occupied habitat, which led to subsequent and widespread extirpations of northern Mexican gartersnake populations in areas such as the lower Gila and Salt rivers in Arizona.

After the period of dam construction and the subsequent creation of reservoirs, widespread nonnative fish stocking efforts ensued throughout Arizona beginning during the mid 1900’s. In the Verde River system alone, Rinne *et al.* (1998, p. 3) estimated that over 5,300 independent stocking actions occurred that involved 12 different species of nonnative fish species since the 1930s and 1940s. If we extrapolate that effort over the same timeframe for other historically occupied, larger-order systems known as recreational fisheries such as the Salt, upper Gila, Colorado, Santa Cruz, Agua Fria, and San Pedro rivers, Tonto and Oak creeks, and other tributaries with significant flow throughout central and southern Arizona, in addition to the other private stockings of stock tanks and other isolated habitat, the magnitude of the nonnative species invasion over this timeframe becomes clear. Subsequent to these efforts, but to a lesser extent, the spread of bullfrogs and crayfish, both purposefully and incidentally, commenced during the 1970s and 1980s (Tellman 2002, p. 43). We estimate that near 100 percent of the habitat that historically supported northern Mexican gartersnakes has been invaded over-time, either purposefully or indirectly through dispersal, by nonnative species whether they be nonnative fish, bullfrogs, or crayfish. The effects from this influx of nonnative species throughout the American Southwest

resulted in significant declines in native fish and ranid frog distribution and abundance, and the subsequent listing of 19 of Arizona’s 31 native fish species throughout the last 35 years (see discussion under “Declines in the Northern Mexican Gartersnake Native Fish Prey Base” within Listing Factor C). The decline of native fish species that depend on native riparian and aquatic systems provides evidence of overall impacts to the affected biotic communities. These effects were discussed in detail in Factor A and Factor C above.

In response to the impacts to the northern Mexican gartersnake and its native prey base discussed above and in our analysis of threats, the distribution of northern Mexican gartersnake has been reduced to approximately 10 percent of its historic range within the United States over the last 80 years. However, because of the sensitivity of the northern Mexican gartersnake to community-wide effects from nonnative species, we believe the most significant period of declines and subsequent extirpations of entire populations likely coincided with the proliferation of nonnative species beginning in the 1940s and 1950s, most notably with the widespread introduction and expansion of sportfish such as largemouth bass, green sunfish, and channel and flathead catfish. In addition, further declines and extirpations likely resulted from systematic bullfrog introductions, beginning in the 1970s and early 1980s, caused by the bullfrog’s natural capacity to disperse and its predation behavior on the northern Mexican gartersnake and associated prey base. In several areas where northern Mexican gartersnakes remain in the United States, we have observed skewed age-class distributions within populations that favor large-bodied, older individuals with significantly less newborns and juveniles (Holm and Lowe 1995, pp. 33–34; Holycross *et al.* 2006, pp. 41–44; Wallace *et al.* 2008, pp. 243–244). These trends are particularly apparent in areas where habitat remains structurally intact, but where nonnative species maintain stable populations.

The observed effects of nonnative species on age-class distribution and recruitment are an important influence on the maintenance of current populations to be considered in our evaluation of the foreseeable future for this species. We were not able to locate any quantitative studies on longevity of the northern Mexican gartersnake in the wild, or on gartersnakes in general. However, Bowler (1975) recorded longevity of amphibians and reptiles in captivity that included several species

within the genus *Thamnophis*. Lifespans of six different gartersnake species ranged from 2 to 10 years (Bowler 1975). These data are old, however, and innovations in the captive care of specimens in the subsequent three decades have improved our knowledge of captive husbandry for these species, allowing longer lifespans in captivity. Simply knowing that individuals of a certain species are capable of living a certain number of years under ideal captive conditions means that longevity in the wild might be longer than suspected, although usually shorter than in captivity. Ernst and Zug (1996, p. 39) provide one record on wild longevity in the common gartersnake (*Thamnophis sirtalis*) as nine years. It is reasonable to conclude that the northern Mexican gartersnake, a similarly sized snake of the same genus, may have similar longevity in the wild.

The average age of sexual maturity is 2.5 years for female northern Mexican gartersnakes, and 2 years for males. Females may only breed once every 2 years (Rosen and Schwalbe 1988, pp. 16–17). Considering these timeframes, a female northern Mexican gartersnake might reproduce up to three times during a maximum lifespan in the wild. We are aware of no studies on the survivorship of northern Mexican gartersnakes in the wild. However, Jayne and Bennett (1990, pp. 1209–1221) studied survivorship within a population of common gartersnakes, a similar species, and found that, in two groups of similarly aged snakes within that population, survivorship during the first year following birth was 29 percent and 43 percent in this 2-year study, although we are unaware of the presence, type, or extent of threats that may have influenced survivorship. Only 16 percent of one group survived into their second year, while 50 percent of the second group survived into their second year (Jayne and Bennett 1990, pp. 1209–1221). Jayne and Bennett (1990, pp. 1209–1221) calculated that 15 percent of individuals live to be older than 2 years. Adult survival rates in common gartersnakes appears to be quite variable, however. In Manitoba, adult year-to-year survivorship was calculated at 34 percent and at 67 percent in the Northwest Territories (Larsen and Gregory 1989, pp. 84–85; Larsen *et al.* 1993, pp. 338–342). Based on demographic studies on the common gartersnake and making a conservative estimate on survivorship and fecundity rates without consideration of the presence or degree of threats, it is reasonable to presume that, on average, two individual northern Mexican

gartersnakes from each litter may reach reproductive age. Whether or not these individuals find a mate and successfully reproduce depends upon the population density and the degree of threats that may be acting on a given population.

In Table 4 of Holycross *et al.* (2006, p. 64), capture rates of northern Mexican gartersnakes during surveys in 2004 and 2005 along the Mogollon Rim of Arizona were compared to those from a previous study, Rosen and Schwalbe (1988, Appendix I). In total, capture rates in nine different stream reaches surveyed by both sets of investigators were compared. Rosen and Schwalbe (1988, Appendix I) spent 128 person-search hours to capture a total of 10 individuals at six of the nine (66 percent) stream reaches. Holycross *et al.* (2006, p. 64) spent 142 person-search hours [11 percent more than Rosen and Schwalbe (1988, Appendix I)] and found six total individuals in only two stream reaches of the nine (22 percent) that were comparably surveyed. These data indicate that Holycross *et al.* (2006, p. 64) found northern Mexican gartersnakes at 66 percent fewer locations than did Rosen and Schwalbe (1988, Appendix I) which indicate potential population extirpations in two-thirds of populations during that 17-year time period. The averaged number of person-search hours per capture was 12.8 hours in 1988 (Rosen and Schwalbe 1988, Appendix I), but approximately twice that (23.6 person-search hours) in 2004–2005 (Holycross *et al.* 2006, p. 64).

Today, there remain three areas in the United States where the northern Mexican gartersnake is most reliably found, the Upper Santa Cruz River in the San Rafael Valley of south-central Arizona, Tonto Creek from the vicinity of Gisela downstream to Roosevelt Lake, and the Page Springs/Bubbling Ponds hatchery complex along Oak Creek slightly upstream of its confluence with the Verde River. These populations are geographically disjunct, genetically isolated from one-another, and lack significant, nearby source populations to serve as a natural source of individuals for recolonization should any one of them become extirpated. Therefore, these populations remain highly vulnerable to the effects of the threats discussed in detail in Factors A–E above, and to stochastic events not previously anticipated. If we extrapolate the last 20 years of population trends documented in the previous paragraph, we anticipate that in approximately 15–20 years, these remaining, currently reliable populations may become extirpated should current trends persist into the future. This is not to say that

the northern Mexican gartersnake, in its entirety, will be extirpated from the United States during this time frame because it would remain plausible that extremely low-density populations of a few individuals may persist in other areas past this time frame.

Considering the above discussion on (1) reproduction biology, observed trends in population demographics, and age-class survivorship; (2) the time periods that correlated to the onset of the most significant threats to the species and number of years it has taken for a 90 percent reduction of the distribution of the subspecies in the United States; (3) the relative isolation and disjunct nature of current populations and their inability to serve as a basis for genetic exchange; (4) comparative analysis between comprehensive survey results spread over 17 years over a significant portion of the subspecies' historical distribution in the United States and subsequent extrapolations for remaining populations; and (5) the future potential for threats most detrimental to the long-term viability of the subspecies in the United States (such as the continued proliferation of nonnative species), we anticipate that northern Mexican gartersnake may be predominantly extirpated from the U.S. within 25 years. We base this estimate largely upon our most current observations of population trends and their response to threats posed by nonnative species, as discussed above.

We do not expect that current policies on native fish restoration and recovery will change. These policies now focus activities on replacing fisheries which contain nonnative species with wholly native fisheries in stream types that are generally not suitable for northern Mexican gartersnakes, rather than mainstem rivers of lower gradient which provide preferred habitat for the northern Mexican gartersnake. We have also discussed in Factor C above the widespread influence of crayfish and bullfrogs on riparian and aquatic communities and the significant difficulty of removing them from areas once they have become established. As discussed in Factor E, climate change and subsequent drought will likely exacerbate the threats to the northern Mexican gartersnake related to habitat and prey base. Thus, the foreseeable future for the northern Mexican gartersnake in the U.S. is 25 years to 2033.

With respect to the species' foreseeable future throughout its distribution in Mexico, threats to the northern Mexican gartersnake from human-related activities are most likely

in areas adjacent to human population centers, and these threats affect the subspecies to a similar degree as observed in the United States. We conclude that changes to climatic patterns will affect northern Mexican gartersnake habitat in similar ways in the more northern latitudes of Mexico as has been anticipated for the southwestern United States. Therefore, we estimate the foreseeable future in populated areas of Mexico within the range of the subspecies to be 25 years.

Unmack and Fagan (2004, p. 233) hypothesized that a time-lagged effect is occurring in portions of Mexico with respect to nonnative species invasions, due primarily to the remoteness of some areas. However, there is widespread consensus that it is inevitable that nonnative species will continue to invade new habitats throughout Mexico, leading to further declines and extirpations of the northern Mexican gartersnake and its prey species in Mexico (Conant 1974, pp. 471, 487–489; Contreras Balderas and Lozano 1994, pp. 383–384; Miller *et al.* 2005, pp. 60–61; Abarca 2006; Luja and Rodríguez-Estrella 2008, pp. 17–22). Consequently, for the more remote areas of Mexico, the foreseeable future may be beyond 2033, but we are not confident estimating how far beyond.

#### Significant Portion of the Range Analysis

As required by the Act, we considered the five potential threat factors to assess whether the northern Mexican gartersnake is threatened or endangered throughout all or a significant portion of its range. When considering the listing status of the species, the first step in the analysis is to determine whether the species is in danger of extinction throughout all of its range. If this is the case, then we list the species in its entirety. For instance, if the threats to a species are directly acting on only a portion of its range, but they are at such a large scale that they place the entire species in danger of extinction, we would list the entire species.

We next consider whether any significant portion of the northern Mexican gartersnake range meets the definition of endangered or is likely to become endangered in the foreseeable future (threatened). On March 16, 2007, a formal opinion was issued by the Solicitor of the Department of the Interior, "The Meaning of 'In Danger of Extinction Throughout All or a Significant Portion of Its Range'" (USDO I 2007, pp. 1–36). A portion of a species' range is significant if it is part of the current range of the species and is important to the conservation of the

species because it contributes meaningfully to the representation, resiliency, or redundancy of the species. The contribution must be at a level such that its loss would result in a decrease in the ability of the species to persist.

The first step in determining whether a species is threatened or endangered in a significant portion of its range is to identify any portions of the range of the species that warrant further consideration. The range of a species can theoretically be divided into portions in an infinite number of ways. To identify portions that warrant further consideration, we determine whether there is substantial information indicating that (1) the portions may be significant, and (2) the species may be in danger of extinction there or likely to become so within the foreseeable future. In practice, a key part of this analysis is whether the threats are geographically concentrated in some way. If the threats to the species are essentially uniform throughout its range, no portion is likely to warrant further consideration. Moreover, if any concentration of threats applies only to portions of the range that are unimportant to the conservation of the species, such portions will not warrant further consideration.

If we identify any portions that warrant further consideration, we then determine whether the species is threatened or endangered in any significant portion. If we determine that a portion of the range is not significant, we do not determine whether the species is threatened or endangered there.

The terms "resiliency," "redundancy," and "representation" are intended to be indicators of the conservation value of portions of the range. Resiliency of a species allows it to recover from periodic disturbances. A species will likely be more resilient if large populations exist in high-quality habitat that is distributed throughout its range in a way that captures the environmental variability available. A portion of the range of a species may make a meaningful contribution to the resiliency of the species if the area is relatively large and contains particularly high-quality habitat, or if its location or characteristics make it less susceptible to certain threats than other portions of the range. When evaluating whether or how a portion of the range contributes to resiliency of the species, we evaluate the historical value of the portion and how frequently the portion is used by the species, if possible. The range portion may contribute to resiliency for other reasons; for instance, it may contain an important concentration of

certain types of habitat that are necessary for the species to carry out its life-history functions, such as breeding, feeding, migration, dispersal, or wintering.

Redundancy of populations may be needed to provide a margin of safety for the species to withstand catastrophic events. This concept does not mean that any portion that provides redundancy is per se a significant portion of the range of a species. The idea is to conserve enough areas of the range so that random perturbations in the system only act on a few populations. Therefore, we examine each area based on whether that area provides an increment of redundancy that is important to the conservation of the species.

Adequate representation ensures that the species' adaptive capabilities are conserved. Specifically, we evaluate a range portion to see how it contributes to the genetic diversity of the species. The loss of genetically based diversity may substantially reduce the ability of the species to respond and adapt to future environmental changes. A peripheral population may contribute meaningfully to representation if there is evidence that it provides genetic diversity due to its location on the margin of the species' habitat requirements.

Based upon factors that contribute to our analysis of whether a species or subspecies is "In Danger of Extinction Throughout All or a Significant Portion of Its Range," and in consideration of the status of and threats to the northern Mexican gartersnake discussed previously, we find that significant threats to the continued existence of the northern Mexican gartersnake occur throughout all of its range in the United States and Mexico. Therefore, it is not necessary to conduct further analysis with respect to the significance of any portion of its range at this time.

#### Finding

We have carefully examined the best scientific and commercial information available regarding the past, present, and future threats faced by the northern Mexican gartersnake. We reviewed the petition, information available in our files, other published and unpublished information submitted to us during the public comment periods following our 90-day and previous 12-month petition findings and consulted with recognized northern Mexican gartersnake experts and other Federal, State, Tribal, and Mexican resource agencies. On the basis of the best scientific and commercial information available, we find that listing of the northern Mexican

gartersnake as threatened or endangered throughout its range in the United States and Mexico, based on its rangewide status, is warranted, due to the present or threatened destruction, modification or curtailment of its habitat; predation; and the inadequacy of existing regulatory mechanisms. However, as explained in more detail below, an immediate proposal of a regulation implementing this action is precluded by higher priority listing actions, and progress is being made to add or remove qualified species from the Lists of Endangered and Threatened Wildlife and Plants.

We recognize there have been remarkable declines in the distribution and abundance of the northern Mexican gartersnake within its distribution in the United States, which are primarily attributed to individual and community interactions with nonnative species that occur in every single locality where northern Mexican gartersnakes have been documented. We identified the ecological mechanisms for which nonnative interactions occur to include: (1) Direct predation on northern Mexican gartersnakes by nonnative species; and (2) the effects of a diminished prey base via nonnative species preying upon and competing with native prey species as documented in a large body of scientific research, which is cited and analyzed in our discussion of threats under each of the listing factors.

Throughout the range of the northern Mexican gartersnake, literature documents the cause and effect relationship of modification of the food chains within native riparian and aquatic communities. The substantial decline of primary native prey species, such as leopard frogs and native fish, has contributed significantly to the decline of a primary predator, the northern Mexican gartersnake. In this respect, the northern Mexican gartersnake is considered an indicator species, or a species that can be used to gauge the condition of a particular habitat, community, or ecosystem. The synergistic effect of nonnative species both reducing the prey base of, and directly preying upon, northern Mexican gartersnakes has placed significant pressure upon the viability and sustainability of current northern Mexican gartersnake populations and has led to significant fragmentation and risks to the continued viability of current populations. The evolutionary biology of the northern Mexican gartersnake, much like that of native fish and leopard frogs, has left the species without adaptation to and

defenseless against the effect of nonnative species invasions.

The decline of the northern Mexican gartersnake has been exacerbated by historical and ongoing threats to its habitat in the United States. The threats identified and discussed above in detail under Factor A include: (1) The modification and loss of ecologically valuable riparian and aquatic communities; (2) urban and rural development; (3) road construction, use, and maintenance; (4) human population growth; (5) groundwater pumping, surface water diversions, and flood; (6) improper livestock grazing; (7) catastrophic wildfire and wildfire in non-fire adapted communities; and (8) undocumented immigration and international border enforcement and management. In addition, disease and parasitism, climate change, and drought may pose threats to the northern Mexican gartersnake and its prey base.

As a result of our assessment, we find that certain land use activities, such as road construction and use, improper livestock grazing, undocumented immigration and associated international border enforcement and management activities, and some types of development, pose a more significant risk to highly fragmented, low-density populations of northern Mexican gartersnakes, particularly in the presence of nonnative species. We know of no current population of northern Mexican gartersnakes in the United States that does not occur in the presence of nonnative species.

In this finding, we have emphasized the importance of the protection of the ecosystems upon which the northern Mexican gartersnake depends, and documented the status of riparian and aquatic communities in the southwestern United States and much of Mexico. Evidence of the current precarious status of native riparian and aquatic ecosystems in the southwestern United States is the proportion of riparian or aquatic obligate species that are either federally listed under the Act or candidates for listing. In Arizona, there is a total of 73 species that meet these criteria. Of these 73 species, 38 (52 percent) are riparian or aquatic. Of the 45 vertebrate species that are either federally listed or candidates for listing in Arizona, 30 (67 percent) have riparian or aquatic life histories, and 19 (42 percent) are potential northern Mexican gartersnake prey species in larval, juvenile, or adult forms, based on overlapping historical distributions. These data suggest that the riparian and aquatic ecosystems in Arizona, upon which the northern Mexican gartersnake depends, cannot currently support

many of the species that rely upon them.

In making this finding, we acknowledge that the Mexican Government has found the Mexican gartersnake to be in danger of disappearance in the short-or medium-term future in their country from the destruction and modification of its habitat or from the effects of shrinking population sizes, or both, and has, therefore, listed the species as Threatened, under the listing authority of SEMARNAT (SEDESOL 2001). We have provided an assessment of the status of the northern Mexican gartersnake and its habitat in Mexico, but we also rely on the assessment of the species made by the Mexican Government in listing the entity as Threatened. The available literature supports the assessment of the species made by the Mexican Government, which indicates that nonnative species and habitat modification and loss are adversely affecting the status of northern Mexican gartersnakes in Mexico.

Additionally, land uses, such as urbanization and development, improper livestock grazing, water diversions and groundwater pumping, and impoundments, have resulted in losses of vegetative cover, deforestation, erosion, and pollution that have modified or destroyed historical northern Mexican gartersnake habitat in Mexico. Collectively, the impacts of traditional rural land management practices and growth of the economic sector, infrastructure, and population growth are expected to continue into the future.

We have reviewed the available information to determine if the existing and foreseeable threats pose an emergency. We have determined that an emergency listing is not warranted for this subspecies at this time because, within the current distribution of the subspecies in Mexico, there are at least some populations of the northern Mexican gartersnake that exist in relatively natural conditions that are unlikely to change in the short-term. However, if at any time we determine that emergency listing of the northern Mexican gartersnake is warranted, we will initiate an emergency listing.

The Service adopted guidelines on September 21, 1983 (48 FR 43098) to establish a rational system for allocating available appropriations to the highest priority species when adding species to the Lists of Endangered or Threatened Wildlife and Plants or reclassifying threatened species to endangered status. The system places greatest importance on the immediacy and magnitude of

threats, but also factors in the level of taxonomic distinctiveness by assigning priority in descending order to monotypic genera, full species, and subspecies (or equivalently, distinct population segments of vertebrates). As a result of our analysis of the best available scientific and commercial information, we have assigned the northern Mexican gartersnake a Listing Priority Number of 3, based on high magnitude and immediacy of threats. One or more of the threats discussed above is occurring in each known population in the United States and throughout historically occupied habitats in Mexico. These threats are ongoing and, in some cases (e.g., nonnative species), considered irreversible. While we conclude that listing the northern Mexican gartersnake is warranted, an immediate proposal to list this species is precluded by other higher priority listing, which we address below.

#### Preclusion and Expeditious Progress

Preclusion is a function of the listing priority of a species in relation to the resources that are available and competing demands for those resources. Thus, in any given fiscal year (FY), multiple factors dictate whether it will be possible to undertake work on a proposed listing regulation or whether promulgation of such a proposal is warranted but precluded by higher-priority listing actions.

The resources available for listing actions are determined through the annual Congressional appropriations process. The appropriation for the Listing Program is available to support work involving the following listing actions: proposed and final listing rules; 90-day and 12-month findings on petitions to add species to the Lists of Endangered and Threatened Wildlife and Plants (Lists) or to change the status of a species from threatened to endangered; annual determinations on prior "warranted but precluded" petition findings as required under section 4(b)(3)(C)(i) of the Act; proposed and final rules designating critical habitat; and litigation-related, administrative, and program management functions (including preparing and allocating budgets, responding to Congressional and public inquiries, and conducting public outreach regarding listing and critical habitat). The work involved in preparing various listing documents can be extensive and may include, but is not limited to: Gathering and assessing the best scientific and commercial data available and conducting analyses used as the basis for our decisions; writing

and publishing documents; and obtaining, reviewing, and evaluating public comments and peer review comments on proposed rules and incorporating relevant information into final rules. The number of listing actions that we can undertake in a given year also is influenced by the complexity of those listing actions; that is, more complex actions generally are more costly. For example, during the past several years, the cost (excluding publication costs) for preparing a 12-month finding, without a proposed rule, has ranged from approximately \$11,000 for one species with a restricted range and involving a relatively uncomplicated analysis to \$305,000 for another species that is wide-ranging and involving a complex analysis.

We cannot spend more than is appropriated for the Listing Program without violating the Anti-Deficiency Act (see 31 U.S.C. 1341(a)(1)(A)). In addition, in FY 1998 and for each fiscal year since then, Congress has placed a statutory cap on funds which may be expended for the Listing Program, equal to the amount expressly appropriated for that purpose in that fiscal year. This cap was designed to prevent funds appropriated for other functions under the Act (for example, recovery funds for removing species from the Lists), or for other Service programs, from being used for Listing Program actions (see House Report 105-163, 105th Congress, 1st Session, July 1, 1997).

Recognizing that designation of critical habitat for species already listed would consume most of the overall Listing Program appropriation, Congress also put a critical habitat subcap in place in FY 2002 and has retained it each subsequent year to ensure that some funds are available for other work in the Listing Program: "The critical habitat designation subcap will ensure that some funding is available to address other listing activities" (House Report No. 107-103, 107th Congress, 1st Session, June 19, 2001). In FY 2002 and each year until FY 2006, the Service has had to use virtually the entire critical habitat subcap to address court-mandated designations of critical habitat, and consequently none of the critical habitat subcap funds have been available for other listing activities. In FY 2007, we were able to use some of the critical habitat subcap funds to fund proposed listing determinations for high-priority candidate species; however, in FY 2008 we were unable to do this due to our workload for designating critical habitat.

Thus, through the listing cap, the critical habitat subcap, and the amount of funds needed to address court-

mandated critical habitat designations, Congress and the courts have in effect determined the amount of money available for other listing activities. Therefore, the funds in the listing cap, other than those needed to address court-mandated critical habitat for already listed species, set the limits on our determinations of preclusion and expeditious progress.

Congress also recognized that the availability of resources was the key element in deciding whether, when making a 12-month petition finding, we would prepare and issue a listing proposal or instead make a "warranted but precluded" finding for a given species. The Conference Report accompanying Public Law 97-304, which established the current statutory deadlines and the warranted-but-precluded finding, states (in a discussion on 90-day petition findings that by its own terms also covers 12-month findings) that the deadlines were "not intended to allow the Secretary to delay commencing the rulemaking process for any reason other than that the existence of pending or imminent proposals to list species subject to a greater degree of threat would make allocation of resources to such a petition [that is, for a lower-ranking species] unwise."

In FY 2008, expeditious progress is that amount of work that could be achieved with \$8,206,940, which is the amount of money that Congress appropriated for the Listing Program (that is, the portion of the Listing Program funding not related to critical habitat designations for species that are already listed). Our process is to make our determinations of preclusion on a nationwide basis to ensure that the species most in need of listing will be addressed first and also because we allocate our listing budget on a nationwide basis. The \$8,206,940 was used to fund work in the following categories: Compliance with court orders and court-approved settlement agreements requiring that petition findings or listing determinations be completed by a specific date; section 4 (of the Act) listing actions with absolute statutory deadlines; essential litigation-related, administrative, and listing program management functions; and high-priority listing actions. The allocations for each specific listing action are identified in the Service's FY 2008 Allocation Table (part of our administrative record).

For FY 2009, on September 23, 2008 Congress passed a Continuing Resolution to operate the Federal government at the FY 2008 level of funding through March 6, 2009 (Pub. L.



110–329). Although we are currently developing the allocations for specific listing actions that we will fund during FY 2009, we anticipate funding work to comply with court orders and court-approved settlement agreements, work on statutorily required petition findings, final listing determinations for those species that were proposed for listing with funds from FY 2008, and continued work on proposed listing determinations for high-priority species.

In FY 2007, we had more than 120 species with an LPN of 2, based on our September 21, 1983, guidance for assigning an LPN for each candidate species (48 FR 43098). Using this guidance, we assign each candidate an LPN of 1 to 12, depending on the magnitude of threats, imminence of threats, and taxonomic status; the lower the LPN, the higher the listing priority (that is, a species with an LPN of 1 would have the highest listing priority). Because of the large number of high-priority species, we further ranked the candidate species with an LPN of 2 by using the following extinction-risk type criteria: International Union for the Conservation of Nature and Natural Resources (IUCN) Red list status/rank, Heritage rank (provided by NatureServe), Heritage threat rank (provided by NatureServe), and species currently with fewer than 50 individuals, or 4 or fewer populations. Those species with the highest IUCN rank (critically endangered), the highest Heritage rank (G1), the highest Heritage threat rank (substantial, imminent threats), and currently with fewer than 50 individuals, or fewer than 4 populations, comprised a list of approximately 40 candidate species (“Top 40”). These 40 candidate species

have had the highest priority to receive funding to work on a proposed listing determination. As we work on proposed listing rules for these 40 candidates, we are applying the ranking criteria to the next group of candidates with LPN of 2 and 3 to determine the next set of highest priority candidate species.

To be more efficient in our listing process, as we work on proposed rules for these species in the next several years, we are preparing multi-species proposals when appropriate, and these may include species with lower priority if they overlap geographically or have the same threats as a species with an LPN of 2. In addition, available staff resources are also a factor in determining high-priority species provided with funding. Finally, proposed rules for reclassification of threatened species to endangered are lower priority, since as listed species, they are already afforded the protection of the Act and implementing regulations.

We assigned the northern Mexican gartersnake an LPN of 3, based on our finding that the subspecies faces immediate and high magnitude threats from the present or threatened destruction, modification or curtailment of its habitat; predation; and the inadequacy of existing regulatory mechanisms. One or more of the threats discussed above are occurring in each known population in the United States and throughout historically occupied habitats in Mexico. These threats are ongoing and, in some cases (e.g., nonnative species), considered irreversible. Pursuant to the 1983 Guidelines, a “species” facing imminent high-magnitude threats is assigned an LPN of 1, 2, or 3 depending on its taxonomic status. Because the northern Mexican

gartersnake is a subspecies, we assigned it an LPN of 3 (the highest category available for a subspecies). Therefore, work on a proposed listing determination for the northern Mexican gartersnake was, and will continue to be in the next year, precluded by work on higher priority candidate species (species with LPN of 2); listing actions with absolute statutory, court ordered, or court-approved deadlines; and final listing determinations for those species that were proposed for listing with funds from FY 2008. This work includes all the actions listed in the tables below under expeditious progress.

As explained above, a determination that listing is warranted but precluded must also demonstrate that expeditious progress is being made to add or remove qualified species to and from the Lists of Endangered and Threatened Wildlife and Plants. (We note that we do not discuss specific actions taken on progress towards removing species from the Lists because that work is conducted using appropriations for our Recovery program, a separately budgeted component of the Endangered Species Program. As explained above in our description of the statutory cap on Listing Program funds, the Recovery Program funds and actions supported by them cannot be considered in determining expeditious progress made in the Listing Program.) As with our “precluded” finding, expeditious progress in adding qualified species to the Lists is a function of the resources available and the competing demands for those funds. Our expeditious progress in FY 2008 in the Listing Program included preparing and publishing the following determinations:

#### FY 2008 COMPLETED LISTING ACTIONS

Publication date	Title	Actions	FR pages
10/09/2007	90-Day Finding on a Petition to List the Black-Footed Albatross ( <i>Phoebastria nigripes</i> ) as Threatened or Endangered.	Notice of 90-day Petition Finding, Substantial.	72 FR 57278–57283.
10/09/2007	90-Day Finding on a Petition To List the Giant Palouse Earthworm as Threatened or Endangered.	Notice of 90-day Petition Finding, Not substantial.	72 FR 57273–57276.
10/23/2007	90-Day Finding on a Petition To List the Mountain Whitefish ( <i>Prosopium williamsoni</i> ) in the Big Lost River, ID, as Threatened or Endangered.	Notice of 90-day Petition Finding, Not substantial.	72 FR 59983–59989.
10/23/2007	90-Day Finding on a Petition To List the Summer-Run Kokanee Population in Issaquah Creek, WA, as Threatened or Endangered.	Notice of 90-day Petition Finding, Not substantial.	72 FR 59979–59983.
11/08/2007	Response to Court on Significant Portion of the Range, and Evaluation of Distinct Population Segments, for the Queen Charlotte Goshawk.	Response to Court	72 FR 63123–63140.

## FY 2008 COMPLETED LISTING ACTIONS—Continued

Publication date	Title	Actions	FR pages
12/13/2007	12-Month Finding on a Petition To List the Jollyville Plateau salamander ( <i>Eurycea tonkawae</i> ) as Endangered With Critical Habitat.	Notice of 12-month Petition Finding, Warranted but Precluded.	72 FR 71039-71054.
1/08/2008	90-Day Finding on a Petition To List the Pygmy Rabbit ( <i>Brachylagus idahoensis</i> ) as Threatened or Endangered.	Notice of 90-day Petition Finding, Substantial.	73 FR 1312-1313.
1/10/2008	90-Day Finding on Petition To List the Amargosa River Population of the Mojave Fringe-Toed Lizard ( <i>Uma scoparia</i> ) as Threatened or Endangered With Critical Habitat.	Notice of 90-day Petition Finding, Substantial.	73 FR 1855-1861.
1/24/2008	12-Month Finding on a Petition To List the Siskiyou Mountains Salamander ( <i>Plethodon stormi</i> ) and Scott Bar Salamander ( <i>Plethodon asupak</i> ) as Threatened or Endangered.	Notice of 12-month Petition Finding, Not Warranted.	73 FR 4379-4418.
2/05/2008	12-Month Finding on a Petition To List the Gunnison's Prairie Dog as Threatened or Endangered.	Notice of 12-month Petition Finding, Warranted.	73 FR 6660 6684.
02/07/2008	12-Month Finding on a Petition To List the Bonneville Cutthroat Trout ( <i>Oncorhynchus clarki utah</i> ) as Threatened or Endangered.	Notice of Review	73 FR 7236 7237.
02/19/2008	Listing <i>Phyllostegia hispida</i> (No Common Name) as Endangered Throughout Its Range.	Proposed Listing, Endangered	73 FR 9078 9085.
02/26/2008	Initiation of Status Review for the Greater Sage-Grouse ( <i>Centrocercus urophasianus</i> ) as Threatened or Endangered.	Notice of Status Review	73 FR 10218 10219.
03/11/2008	12-Month Finding on a Petition To List the North American Wolverine as Endangered or Threatened.	Notice 12 month petition finding, Not warranted.	73 FR 12929 12941.
03/20/2008	90-Day Finding on a Petition To List the U.S. Population of Coaster Brook Trout ( <i>Salvelinus fontinalis</i> ) as Endangered.	Notice of 90-day Petition Finding, Substantial.	73 FR 14950 14955.
04/29/2008	90-Day Finding on a Petition to List the Western Sage-Grouse ( <i>Centrocercus urophasianus phaios</i> ) as Threatened or Endangered.	Notice of 90-day Petition Finding, Substantial.	73 FR 23170 23172.
04/29/2008	90-Day Finding on Petitions To List the Mono Basin Area Population of the Greater Sage-Grouse ( <i>Centrocercus urophasianus</i> ) as Threatened or Endangered.	Notice of 90-day Petition Finding, Substantial.	73 FR 23173 23175.
05/06/2008	Petition To List the San Francisco Bay-Delta Population of the Longfin Smelt ( <i>Spirinchus thaleichthys</i> ) as Endangered.	Notice of 90-day Petition Finding, Substantial.	73 FR 24611 24915.
05/06/2008	90-Day Finding on a Petition to List Kokanee ( <i>Oncorhynchus nerka</i> ) in Lake Sammamish, Washington, as Threatened or Endangered.	Notice of 90-day Petition Finding, Substantial.	73 FR 24915 24922.
05/06/2008	12-Month Finding on a Petition to List the White-tailed Prairie Dog ( <i>Cynomys leucurus</i> ) as Threatened or Endangered.	Notice of Status Review	73 FR 24910 24911.
05/15/2008	90-Day Finding on a Petition To List the Ashy Storm-Petrel ( <i>Oceanodroma homochroa</i> ) as Threatened or Endangered.	Notice of 90-day Petition Finding, Substantial.	73 FR 28080 28084.
05/15/2008	Determination of Threatened Status for the Polar Bear ( <i>Ursus maritimus</i> ) Throughout Its Range; Final Rule.	Final Listing, Threatened	73 FR 28211 28303.
05/15/2008	Special Rule for the Polar Bear; Interim Final Rule.	Interim Final Special Rule	73 FR 28305 28318.
05/28/2008	Initiation of Status Review for the Northern Mexican Gartersnake ( <i>Thamnophis eques megalops</i> ).	Notice of Status Review	73 FR 30596 30598.
06/18/2008	90-Day Finding on a Petition To List the Long-Tailed Duck ( <i>Clangula hyemalis</i> ) as Endangered.	Notice of 90-day Petition Finding, Not substantial.	73 FR 34686 34692.

## FY 2008 COMPLETED LISTING ACTIONS—Continued

Publication date	Title	Actions	FR pages
07/10/2008	90-Day Finding on a Petition To Reclassify the Delta Smelt ( <i>Hypomesus transpacificus</i> ) From Threatened to Endangered.	Notice of 90-day Petition Finding, Substantial.	73 FR 39639 39643.
07/29/2008	90-Day Finding on a Petition To List the Tucson Shovel-Nosed Snake ( <i>Chionactis occipitalis klauberi</i> ) as Threatened or Endangered with Critical Habitat.	Notice of 90-day Petition Finding, Substantial.	73 FR 43905 43910.
8/13/2008	Proposed Endangered Status for Reticulated Flatwoods Salamander; Proposed Designation of Critical Habitat for Frosted Flatwoods Salamander and Reticulated Flatwoods Salamander.	Proposed Critical Habitat, Proposed Listing, Endangered.	73 FR 47257 47324.
9/9/2008	12-month Finding on a Petition to List the Bonneville Cutthroat Trout as Threatened or Endangered.	Notice 12 month petition finding, Not warranted.	73 FR 52235 52256.
10/15/2008	90-Day Finding on a Petition To List the Least Chub.	Notice of 90-day Petition Finding, Substantial.	73 FR 61007 61015.
10/21/2008	Listing 48 Species on Kauai as Endangered and Designating Critical Habitat.	Proposed Listing, Endangered; Proposed Critical Habitat.	73 FR 62591 62742.
10/24/2008	90-Day Finding on a Petition to List the Sacramento Valley Tiger Beetle as Endangered.	Notice of 90-day Petition Finding, Not substantial.	73 FR 63421 63424.
10/28/2008	90-Day Finding on a Petition To List the Dusky Tree Vole ( <i>Arborimus longicaudus silvicola</i> ) as Threatened or Endangered.	Notice of 90-day Petition Finding, Substantial.	73 FR 63919 63926.

Our expeditious progress also included work on listing actions, which were funded in FY 2008, but have not yet been completed. These actions are listed below. We have completed all work funded in FY 2008 on all actions under a deadline set by a court. Actions in the middle section of the table are being conducted to meet statutory

timelines, that is, timelines required under the Act. Actions in the bottom section of the table are high priority listing actions. These actions include work primarily on species with an LPN of 2, and selection of these species is partially based on available staff resources, and when appropriate, include species with a lower priority if

they overlap geographically or have the same threats as the species with the high priority. Including these species together in the same proposed rule results in considerable savings in time and funding as compared to preparing separate proposed rules for each of them in the future.

## ACTIONS FUNDED IN FY 2008 BUT NOT COMPLETED

Species	Action
Actions Subject to Court Order/Settlement Agreement	
NONE	NONE.
Actions with Statutory Deadlines	
Phyllostegia hispida	Final listing.
Yellow-billed loon	12-month petition finding.
Black-footed albatross	12-month petition finding.
Mount Charleston blue butterfly	12-month petition finding.
Goose Creek milk-vetch	12-month petition finding.
Mojave fringe-toed lizard	12-month petition finding.
White-tailed prairie dog	12-month petition finding.
Pygmy rabbit (rangewide)	12-month petition finding.
Black-tailed prairie dog	90-day petition finding.
Lynx (include New Mexico in listing)	90-day petition finding.
Wyoming pocket gopher	90-day petition finding.
Llanero coqui	90-day petition finding.
American pika	90-day petition finding.
Sacramento Mts. checkerspot butterfly	90-day petition finding.
206 species	90-day petition finding.
475 Southwestern species	90-day petition finding.
High Priority Listing Actions	
21 Oahu candidate species (16 plants, 5 damselflies) (18 with LPN =2, 3 with LPN = 3, 1 with LPN =9).	Proposed listing.

## ACTIONS FUNDED IN FY 2008 BUT NOT COMPLETED—Continued

Species	Action
3 southeast aquatic species (Georgia pigtoe, interrupted rocksnail, rough hornsnail) <sup>1</sup> (all with LPN = 2).	Proposed listing.
Casey's june beetle (LPN = 2)	Proposed listing.
Sand dune lizard (LPN = 2)	Proposed listing.
2 southwest springsnails ( <i>Pyrgulopsis bernadina</i> (LPN = 2), <i>Pyrgulopsis trivialis</i> (LPN = 2)).	Proposed listing.
3 southwest springsnails ( <i>Pyrgulopsis chupaderae</i> (LPN = 2), <i>Pyrgulopsis gilae</i> (LPN = 11), <i>Pyrgulopsis thermalis</i> (LPN 11)).	Proposed listing.
2 mussels (rayed bean (LPN = 2), snuffbox No LPN)	Proposed listing.
2 mussels (sheepnose (LPN = 2), spectaclecase (LPN = 4).)	Proposed listing.
Ozark hellbender <sup>2</sup> (LPN = 3)	Proposed listing.
Altamaha spiny mussel (LPN = 2)	Proposed listing.
4 southeast fish (rush darter (LPN = 2), chunky madtom (LPN = 2), Cumberland darter (LPN = 5), laurel dace (LPN = 5)).	Proposed listing.
2 Colorado plants (Parchute beardtongue ( <i>Penstemon debilis</i> ) (LPN = 2), Debeque phacelia ( <i>Phacelia submutica</i> ) (LPN = 8)).	Proposed listing.
Pagosa skyrocket ( <i>Ipomopsis polyantha</i> ) (LPN = 2)	Proposed listing.

<sup>1</sup> Funds for listing actions for 3 of these species were also provided in FY 2007.

<sup>2</sup> We funded a proposed rule for this subspecies with an LPN of 3 ahead of other species with LPN of 2, because the threats to the species were so imminent and of a high magnitude that we considered emergency listing if we were unable to fund work on a proposed listing rule in FY 2008.

We have endeavored to make our listing actions as efficient and timely as possible, given the requirements of the relevant law and regulations, and constraints relating to workload and personnel. We are continually considering ways to streamline processes or achieve economies of scale, such as by batching related actions together. Given our limited budget for implementing section 4 of the Act, these actions described above collectively constitute expeditious progress.

The northern Mexican gartersnake will be added to the list of candidate species upon publication of this 12-month finding. We will continue to monitor the status of this species as new information becomes available. This

review will determine if a change in status is warranted, including the need to make prompt use of emergency listing procedures.

We intend that any proposed listing action for the northern Mexican gartersnake will be as accurate as possible. Therefore, we will continue to accept additional information and comments from all concerned governmental agencies, the scientific community, industry, or any other interested party concerning this finding.

#### References Cited

A complete list of all references cited in this document is available upon request from the Field Supervisor at the Arizona Ecological Services Office (see **ADDRESSES** section).

#### Author

The primary author of this notice is the Arizona Ecological Services Office (see **FOR FURTHER INFORMATION CONTACT** section).

#### Authority

The authority for this action is section 4 of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: November 12, 2008.

#### Kenneth Stansell,

Acting Director, U.S. Fish and Wildlife Service.

[FR Doc. E8-27524 Filed 11-24-08; 8:45 am]

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# Federal Register

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Tuesday,  
November 25, 2008

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## Part IV

### Department of Health and Human Services

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Centers for Medicare & Medicaid Services

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42 CFR Parts 447 and 457

Medicaid Program; Premiums and Cost  
Sharing; Final Rule

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

**42 CFR Parts 447 and 457**

[CMS-2244-F]

RIN 0938-A047

**Medicaid Program; Premiums and Cost Sharing**

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Final rule.

**SUMMARY:** This final rule implements and interprets the provisions of sections 6041, 6042, and 6043 of the Deficit Reduction Act of 2005 (DRA), and section 405(a)(1) of the Tax Relief and Health Care Act of 2006 (TRHCA). The DRA was amended by the TRHCA which revised sections 6041, 6042, and 6043 of the DRA including limitations on cost sharing for individuals with family incomes at or below 100 percent of the federal poverty line. These sections amended the Social Security Act (the Act) by adding a new section 1916A to provide State Medicaid agencies with increased flexibility to impose premium and cost sharing requirements on certain Medicaid recipients. This flexibility supplements the existing authority States have to impose premiums and cost sharing under section 1916 of the Act. The DRA provisions also specifically address cost sharing for non-preferred drugs and non-emergency care furnished in a hospital emergency department.

**DATES:** *Effective Date:* These regulations are effective 60 days after the date of publication in the **Federal Register**.

**FOR FURTHER INFORMATION CONTACT:** Donna Schmidt, (410) 786-5532.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

*A. General*

For more than a decade, States have been asking for the tools to modernize their Medicaid programs. With the enactment of the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109-171, enacted on February 8, 2006), States now have new options to create programs that are aligned with today's Medicaid populations and the health care environment. The alternative cost sharing discussed in this issuance is one part of that modernization; other parts include benefit flexibility through benchmark plans, and the health opportunity accounts (HOA)

demonstration projects. Together, these innovations provide the opportunities for States to modernize Medicaid by expanding coverage, making the overall cost of the program and health care more affordable, and providing a bridge to private insurance coverage. States will be able to reconnect families to the larger insurance system that serves most Americans and promote continuity of coverage. The sweeping DRA provisions on Medicaid include six chapters and 39 sections. Through a combination of new options for States and new requirements related to program integrity, the DRA will help to ensure the sustainability of the Medicaid program over time.

*B. Statutory Authority*

Sections 6041, 6042, and 6043 of the DRA established a new section 1916A of the Social Security Act (the Act), which was amended by section 405(a)(1) of the Tax Relief and Health Care Act of 2006 (TRHCA) (Pub. L. No. 109-432, enacted on December 20, 2006). Section 1916A of the Act sets forth options for alternative premiums and cost sharing, including options for higher cost sharing for non-preferred prescription drugs and for non-emergency use of a hospital emergency room.

Section 6041 of the DRA established new subsections 1916A(a) and (b) of the Act, which allow States to amend their State plans to impose alternative premiums and cost sharing on certain groups of individuals, for items and services other than drugs (which are subject to a separate provision discussed below), and to enforce payment of the premiums and cost sharing. Subsections 1916A(a) and (b) of the Act set forth limitations on alternative premiums and cost-sharing that vary based on family income, and exclude some specific services from alternative cost sharing. Section 6041 of the DRA also created a new section 1916(h) of the Act, which requires the Secretary to increase the "nominal" cost sharing amounts under section 1916 of the Act for each year (beginning with 2006) by the annual percentage increase in the medical care component of the consumer price index for all urban consumers (CPI-U) as rounded up in an appropriate manner. Section 405(a)(1) of the TRHCA modified subsections 1916A(a) and (b) of the Act.

Section 6042 of the DRA created section 1916A(c) of the Act, which provides States with additional options for establishing cost sharing requirements for drugs to encourage the use of preferred drugs. Section 405(a)(1) of the TRHCA also modified section 1916A(c) of the Act. Under section

1916A(c) of the Act, States may amend their State plans to require increased cost sharing by certain groups of individuals for non-preferred drugs and to waive or reduce the otherwise applicable cost sharing for preferred drugs. States may also permit pharmacy providers to require the receipt of a cost sharing payment from an individual before filling a prescription.

Section 6043 of the DRA created section 1916A(e) of the Act, which permits States to amend their State plans to allow hospitals, after an appropriate medical screening examination under section 1867 (EMTALA) of the Act, to impose higher cost sharing upon certain groups of individuals for non-emergency care or services furnished in a hospital emergency department. Section 405(a)(1) of the TRHCA modified section 1916A(e) of the Act. Under this option, if the hospital determines that an individual does not have an emergency medical condition, before providing the non-emergency services and imposing cost sharing, it must inform the individual that an available and accessible alternate non-emergency services provider can provide the services without the imposition of the same cost sharing and that the hospital can coordinate a referral to that provider. After notice is given, the hospital may require payment of the cost sharing before providing the non-emergency services to the individual.

**II. Provisions of the Proposed Rule and Analysis of and Response to Public Comments**

We published a proposed rule in the **Federal Register** on February 22, 2008 (73 FR 9727) that proposed to implement sections 6041, 6042, and 6043 of the DRA. In response to the proposed rule, we received approximately 50 timely items of correspondence. Many of the commenters represented State and local advocacy groups, national associations that represent various aspects of beneficiary groups, physician and provider groups, medical associations and hospitals, and State Medicaid agency senior officials. The remaining comments were from individuals and human services agencies.

*A. Public Comment Process*

On February 22, 2008, the date we published the Premiums and Cost Sharing proposed rule, we also published a proposed rule entitled, "State Flexibility for Medicaid Benefit Packages" (73 FR 9714 through 9727) that proposed to implement provisions of the DRA. The comment period for

both proposed rules closed on the same day and commenters submitted comments on both the State Flexibility for Medicaid Benefit Packages proposed rule, and Premiums and Cost Sharing (73 FR 9727 through 9740) proposed rule. To the extent that the comments relate to Premiums and Cost Sharing, we believe that the concerns expressed by commenters are addressed in the comments and responses presented below. We note that we will address comments related to the State Flexibility for Medicaid Benefit Packages proposed rule (73 FR 9714 through 9727) in a subsequent final rule.

In this section, we briefly describe our proposed regulatory changes, followed by a discussion of the comments we received on each proposal. Comments related to the paperwork and other burdens are addressed in the Collection of Information Requirements section in this preamble.

**B. Medicaid Regulations**

**1. Maximum Allowable and Nominal Charges (§ 447.54)**

We proposed to revise § 447.54 to update the existing "nominal" Medicaid cost sharing amounts, specifically the nominal deductible amount described at § 447.54(a)(1) and the nominal copayment amounts described at § 447.54(a)(3). We also proposed to add a new § 447.54(a)(4) to establish a maximum copayment amount for services provided by a managed care organization (MCO).

Section 6041(b)(2) of the DRA requires the Secretary to increase the nominal cost sharing amounts under section 1916 of the Act for each year (beginning with 2006) by the annual percentage increase in the medical care component of the consumer price index for all urban consumers (U.S. city average) as rounded up in an appropriate manner. In accordance with the statute, we proposed to increase the nominal amounts effective as of October 1 of each year, the beginning of the Federal fiscal year (FY), by the percentage increase in the medical care component of the Consumer Price Index for All Urban Consumers (CPI-U) for the period of September to September ending in the preceding calendar year. We use this period to update other amounts, such as the Medicaid spousal impoverishment standards, by inflation. The first adjustment would be for FY 2007, and would be based on the CPI-U increases during the period September 2004 to September 2005. The medical care component of the CPI-U increased by 3.9 percent between September 2004 and September 2005;

therefore, we proposed to update the nominal amounts by that factor. We also proposed to round to the next higher 10-cent increment because it would simplify calculation and collection of the amounts involved. Based on this methodology, we proposed a maximum deductible for \$2.10 per month per family for each period of Medicaid eligibility. In addition, we proposed the following copayment schedule for FY 2007:

State payment for the service	Maximum copayment
\$10 or less .....	\$ .60
\$10.01 to \$25 .....	1.10
\$25.01 to \$50 .....	2.10
\$50.01 or more .....	3.20

We proposed that these amounts would be updated each October 1 by the percentage increase in the medical care component of the CPI-U for the period of September to September ending in the preceding year, rounded to the next higher 10-cent increment.

In addition, we proposed at 447.54(a)(4) to specify a maximum copayment amount for services provided by an MCO. When we published the final Medicaid managed care rules on June 14, 2002 (67 FR 40989), we also required at § 447.60, that contracts with MCOs limit cost sharing charges an MCO may impose on Medicaid enrollees to the amounts that could be imposed if fee-for-service payment rates were applicable.

Specific comments to this section and our responses to those comments are as follows:

*Comment:* One commenter stated that the matrix of cost sharing requirements and exemptions established under the proposed rule is complex and the commenter requested a chart for clarification.

*Response:* We agree with the commenter that the cost sharing matrix established under the proposed rule is complex. We believe it is sufficiently clear to establish a Federal framework defining the State flexibility available. Actual cost sharing will be specified in State plans and may vary based on circumstances. We expect States to clearly communicate applicable cost sharing responsibilities to affected beneficiaries in simple and understandable terms, consistent with the requirement in 42 CFR 435.905. We included in the proposed rule information for FY 2007: A chart of updated maximum levels for cost sharing, the maximum deductible level, and a chart of maximum allowable charges. The amounts for Federal FY 2008 increase by the percentage increase

in the MCPI-U from September 2005 to September 2006 of 4.2 percent, and, as we discuss below, we are including the FY 2008 updated levels in this final rule. Since we are currently in Federal FY 2009, we are also including the FY 2009 updated levels. The amount for Federal FY 2009 increased by the percentage increase in the MCPI-U from September 2006-2007 is 4.6 percent.

Additionally, we set forth in other regulatory provisions the limitations that apply to alternative cost sharing under section 1916A of the Act that apply based on income level. We discuss these limitations in § 447.70 of this final rule—General Cost Sharing Protections.

*Comment:* Several commenters stated that the proposed rule did not give effect to the statutory provisions for lower cost sharing (10 percent of the cost of the service) for those with family incomes above 100 percent of the Federal poverty but below 150 percent of the FPL than for those with family incomes over 150 percent (20 percent of the cost of the service) in fee-for-service plans by varying the maximum copayment by income and setting lower managed care maximum copayments for those with lower incomes. Commenters believe this would be more consistent with Congressional intent.

*Response:* The statute provides for variance of copayments by income level only when alternative copayments are imposed. The provision at § 447.54 in this final rule defines nominal levels under section 1916 of the Act. In section 1916A of the Act, the income related limitations apply to alternative cost sharing in addition to the definition of nominal levels, and are set forth in the regulations that directly apply to alternative cost sharing at §§ 447.62 through 447.82.

*Comment:* Several commenters stated that clarification is needed on whether the "per visit" qualification on the MCO maximum co-payment restricts charging of co-payments by the MCO.

*Response:* We have not defined what constitutes a "visit" in a managed care context because we wish to maintain State flexibility. However, we agree that it would be problematic if an MCO was generating excess "visits" for the purpose of extracting extra co-payments. We believe that States should not permit MCOs to impose more than one copayment for any service or services that could be furnished by a provider during one office visit, even if it actually delivered in multiple office visits.

*Comment:* Some commenters stated that CMS should annually publish a notice in the **Federal Register** of the maximum cost sharing amounts by

March 31 for the upcoming Federal FY. Other commenters stated that there is no statutory basis for imposing this cost sharing.

*Response:* We will publish annually the updated amounts, increased based on the medical care component of the consumer price index for urban consumers. We cannot commit to publication on or by March 31, since publication will be dependent on the availability of data. We may publish before or after that time, but will seek to give sufficient advance notice to facilitate timely adjustment of State cost sharing levels. Since the update methodology is detailed in the published rule and does not involve discretionary elements, the implementation of updated maximum levels should not depend upon CMS publication of specific figures. Nevertheless, we intend to publish updates either in the **Federal Register** or in some other form that ensures general availability. We do not wish to limit publication options in light of the increasing shift toward electronic media.

To respond to the commenters concerning the statutory basis for imposing this cost sharing, as stated earlier, this final rule implements sections 6041 through 6043 of the DRA of 2005, which amended the Social Security Act to add section 1916A. The authority to set nominal levels for cost sharing is contained in sections 1916(a)(3) and (b)(3) of the Social Security Act, and the authority to update those amounts annually is section 6041(b)(2) of the DRA, which added section 1916A(h) to the Social Security Act. We established the MCO nominal cost sharing levels based on these same authorities. The MCO nominal cost sharing levels are consistent with the longstanding levels for fee for service nominal cost sharing, and clarify how nominal levels are applied in a managed care context. The MCO nominal cost sharing levels are updated annually in the same manner as are fee-for-service nominal cost sharing levels.

*Comment:* Several commenters believe that the proposed methodology to update the nominal cost sharing amounts would round up the amounts at a faster rate than Congress intended. Specifically, several individuals asserted that, under the proposed methodology, each year's new maximum co-payment amount would be calculated by applying the annual inflation adjustment to the previous year's cost sharing limit after it was rounded up. The new maximum would be higher than warranted if the inflation

adjustment had been applied without the rounding increase. As a result, this would increase the nominal cost sharing limits at a rate faster than Congress intended.

*Response:* We agree that to calculate each subsequent year's new maximum co-payment amount by applying the annual inflation adjustment to the previous year's cost sharing limit after it was rounded up would increase the nominal cost sharing limits at a rate faster than Congress intended. To round up the nominal Medicaid and SCHIP amounts based on the "rounded" values would provide that the nominal amounts would grow larger over time, thus, making the nominal Medicaid and SCHIP co-payments charged by States increasingly onerous for the poorest beneficiaries.

We clarify that it was always our intent that, for the purpose of increasing the nominal cost sharing for a future FY, we would increase the unrounded values underlying the previous FY's nominal amounts by the percentage increase in the MCPI-U for the 12-month period ending in September of the preceding calendar year.

*Comment:* Commenters stated that the impact is exacerbated by the decision to also round up by a 10-cent increment rather than a 5-cent increment. The commenters noted that the DRA does not specify a rounding methodology, and pointed out that a 5-cent increment is used in the Medicare Part D program. They also questioned whether a 5-cent increment would be harder to collect and calculate, and asserted that consistency with Medicare would be simpler for both providers and for beneficiaries enrolled in both programs.

*Response:* We agree with the commenters, and in this final rule, we provide that in calculating maximum nominal amounts for Medicaid and SCHIP, we will update the amounts by the annual percentage increase in the MCPI-U and round up to the next 5-cent increment. As discussed above, we will calculate the update each year without considering any rounding adjustment made in the previous year. The revised chart for FY 2007 would therefore read as follows:

State payment for the service	Maximum copayment
\$10 or less .....	\$ 0.55
\$10.01 to \$25 .....	1.05
\$25.01 to \$50 .....	2.10
\$50.01 or more .....	3.15

The amounts for Federal FY 2008 reflect an increase in the FY 2007 levels set forth above based on the percentage increase in the MCPI-U from September

2005 to September 2006 of 4.2 percent, rounded up to the next highest 5-cent increment. The chart for Federal FY 2008 reads as follows:

State payment for the service	Maximum copayment
\$10 or less .....	\$ 0.55
\$10.01 to \$25 .....	1.10
\$25.01 to \$50 .....	2.20
\$50.01 or more .....	3.25

In this final rule at 42 CFR 447.54 we are including the chart for FY 2009, since it will provide more immediate useful information for States.

*Comment:* One commenter questioned if the requirement to increase the nominal cost sharing amounts annually also requires the State to adjust its amounts annually.

*Response:* There is no requirement under Medicaid that States impose the maximum level of cost sharing. If the maximum nominal cost sharing levels increase as a result of updating, a State may nevertheless maintain a lower cost sharing level.

*Comment:* Several individuals were concerned about the proposed \$5.20 per visit maximum cost-sharing for Medicaid services provided by a MCO, stating that it could significantly increase the burden on Medicaid beneficiaries because it would permit imposition of the maximum cost sharing level regardless of the cost of the services provided. These commenters stated that beneficiaries with family incomes below the poverty line should not be subject to the new \$5.20 co-payment.

*Response:* In proposing a maximum managed care co-payment under the Medicaid program, we looked to the SCHIP program for guidance. Under SCHIP rules at § 457.555, promulgated in 2001, we established a maximum per visit copayment level for managed care services at the highest level for fee-for-service cost sharing under SCHIP, instead of applying the same copayment limitations applicable to services received on a fee-for-service basis. Based on that precedent, we proposed a similar structure in Medicaid to effectively replace limitations on managed care cost sharing that were tied to the same limitations as fee-for-service copayments. Instead of reflecting the proposed maximum Medicaid fee-for-service co-payment level of \$3.20 (consistent with § 447.54(a)(3)(i)), we proposed a maximum level per visit at the maximum SCHIP fee-for-service level at \$5.20.

Our reasoning in both SCHIP and Medicaid is related to the different way services are delivered under managed



care. We believe that managed care services are typically less fragmented than services furnished on a fee-for-service basis, and, for virtually all services for which managed care entities charge cost sharing (for example, physician visits), the cost sharing would be at the maximum level. We also considered reducing the burden on managed care entities of justifying each individual cost sharing charge based on a comparison to fee-for-service levels when, in many States, there is no comparable fee-for-service program.

After consideration of public comments, we have determined to alter our approach. In this final rule, the maximum MCO per visit rate would apply only when there is no comparable fee-for-service delivery system. When there is a comparable fee-for-service delivery system, managed care copayments must follow the same limitations applicable to fee-for-service. Because it is important to align Medicaid and SCHIP, so that States can provide benefits seamlessly under either program to individuals referenced in the title XXI State child health plan, we include an exception applicable only to such individuals. For these individuals, the maximum MCO copayment level will be the same level permitted under the SCHIP program. The higher nominal levels permitted for individuals referenced in the title XXI State child health plan is consistent with the fact that such individuals would not be Medicaid-eligible except for the SCHIP-related expansion of Medicaid.

Therefore, this final rule provides for a managed care maximum copayment based on the applicable Medicaid fee-for-service maximum rate or, where there is no fee-for-service delivery system, at a per-visit maximum based on the highest fee-for-service level of \$3.15 in FY 2007, \$3.25 in FY 2008, and \$3.40 in FY 2009. In addition, in this final rule, we provide for a specific exception to permit alignment with SCHIP levels for individuals in a Medicaid expansion referenced in the approved State child health plan, so that the maximum copayment level would be the maximum under the SCHIP program, which for FY 2007 is \$5.20, for FY 2008 is \$5.45, and for FY 2009 is \$5.70.

States that impose alternate cost sharing under 1916A of the Act, as implemented by this rule, are still required to comply with the other requirements under 1916A of the Act, such as the limits on cost sharing for populations under 100 percent of the FPL, and the aggregate maximum and the individual service limits.

## 2. Alternative Premiums and Cost Sharing: Basis, Purpose and Scope (§ 447.62)

Section 1916A of the Act allows States to impose alternative premiums and cost sharing that are not subject to the limitations on premiums and cost sharing under section 1916 of the Act. Section 1916A of the Act does not affect the Secretary's existing waiver authority with regard to premiums and cost sharing. Section 447.62 of the regulations as stated in this final rule briefly describes this statutory provision which is the basis for §§ 447.64 through 447.82.

Section 447.62 also makes clear, as specified in section 1916A(b)(6) of the Act, that these regulations do not limit the Secretary's waiver authority, or affect existing waivers, concerning premiums or cost sharing.

Section 405(a)(1) of the TRHCA amended section 1916A of the Act by explicitly providing certain exemptions from certain alternative cost sharing provisions for the population with family incomes at or below 100 percent of the FPL. The statute also includes protections for individuals with family incomes between 100 and 150 percent of the FPL and individuals with family incomes above 150 percent of the FPL. CMS proposed to implement the protections outlined in the TRHCA including the imposition of nominal cost sharing for individuals with family income at or below 100 percent of the FPL.

Specific comments on this section and our responses to those comments are as follows:

*Comment:* Several commenters supported the proposed regulation. They believe that permitting cost sharing under an approved State plan provides States with increased flexibility, provides for States to better meet the health care needs of Medicaid enrollees, and provides States with the ability to contain the growth in the program. The commenters believe that the flexibilities approved in the DRA may lead to cost efficiencies over time; however, they also stated these flexibilities cannot, nor were they intended to, address broader economic downturns.

*Response:* We agree with the commenters that alternative premiums and cost sharing can lead to cost-efficiencies and that these provisions can be used to sustain State Medicaid programs. If States submit State plan amendments to implement the flexibility outlined in the DRA to impose alternative premiums and cost sharing, we anticipate that Federal and

State savings will be generated. The projected savings can be found in the Regulatory Impact Analysis section of this final rule and include savings through 2011. These savings are based on only those States that currently charge co-payments and/or premiums. If additional States choose to implement these flexibilities, these savings could be even more. Although CMS is not in a position to address future economic downturns, we do believe that savings can be generated beyond 2011 and that savings can be generated for more States if additional States choose to implement these provisions. We encourage States to consider these flexibilities and the potential savings that can be generated to help with a State's economic concerns.

*Comment:* Other commenters believe these provisions will have negative consequences for beneficiaries and will cause individuals to delay or forgo needed care. These commenters requested that the regulation be withdrawn.

*Response:* While it is possible that some individuals may choose to delay or forgo care rather than pay their cost sharing obligations, the Medicaid statute has been amended to permit State flexibility to impose cost sharing as outlined in this regulation. Because the rule implements these statutory provisions, withdrawal of the rule is not an option consistent with administration of the statutory Medicaid program. Moreover, we disagree with the commenter's suggestion that the impact of the rule will be wholly negative. States requested maximum flexibility in designing their Medicaid programs in order to expand and maintain health care coverage to our nation's most vulnerable populations and to maintain growth and control costs of Medicaid and SCHIP programs over the long term. This flexibility will help protect the program from cutbacks in a time of tight State budgets, and permit program expansion. Any adverse impact is mitigated by the fact that Congress has protected numerous Medicaid eligibility groups and services from the imposition of alternative premiums and cost sharing.

*Comment:* One commenter believes that States should carefully evaluate their health care resources in order to identify and remedy problems with access to alternative care options for Medicaid recipients before imposing co-payments for non-emergency care furnished by emergency rooms. The commenter believes that CMS should undertake a national initiative to identify creative solutions to the lack of accessible routine medical services for

the poor. CMS should make a commitment by revising the rules of the DRA to protect the lives of some of our most vulnerable citizens.

The commenter states that CMS should carefully monitor and evaluate the impact of the new Medicaid policies being rolled out so that the impact on cost and services can be analyzed and used for future policy-making.

*Response:* We believe that States are in the best position to evaluate their health care resources in order to identify and remedy problems with access to alternative care options for Medicaid recipients before imposing co-payments for non-emergency care furnished by emergency rooms.

As for future policy-making and conducting a national initiative to identify creative solutions to the lack of accessible routine medical services for the poor, Section 6043 of the DRA of 2005 provides for \$50 million in grant funding to States to provide for the establishment of alternative non-emergency service providers or networks of such providers to address primary care access. CMS recently awarded the grant funding to 20 States to help in addressing this issue. State programs include providing education to beneficiaries on the benefits of a medical home, establishment of additional Federally qualified health centers in the State to provide for additional primary care access for beneficiaries, and extending the hours of operation of currently established Federally qualified health centers to include evenings and weekends when Medicaid beneficiaries are more prone to presenting in the emergency room with a non-emergent condition.

We are always interested in working with States on initiatives to improve the delivery of services under the Medicaid program and better provide health care services to our nation's low-income populations. We have approved a number of demonstration projects under the authority of section 1115 of the Social Security Act for this purpose. In addition, we have worked with States to improve access to care through flexibility in payment methods.

*Comment:* One commenter believes that a thorough analysis of the actual impact of cost sharing on Medicaid recipients and State revenues should be conducted before adoption of this rule.

*Response:* This rule incorporates options for States that are contained in statutory provisions currently in effect. There is no basis to unduly delay issuance of this rule which could provide guidance on implementing these statutory provisions. Moreover, while we can make some estimates as to

the impact, those estimates are speculative. We are required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), and Executive Order 13132 on Federalism, and the Congressional Review Act (5 U.S.C. 804(2)) to conduct a regulatory analysis of the impact of any regulatory revision to the Medicare, Medicaid, and/or SCHIP programs before adoption of any rule. We direct the commenter to the Regulatory Impact Analysis included in this rule. Specifically, we estimate that this rule is "economically significant." The Regulatory Impact Analysis presents the estimated costs and benefits of the rulemaking. In the Regulatory Impact Analysis, CMS estimates the anticipated effects of this rule.

*Comment:* Several commenters stated that the specifics of the statutory language have provided fairly narrow opportunities for implementing many of the new provisions. That is, many high cost populations are excluded from the flexible provisions, and the greatest flexibility is often targeted to higher income populations, which do not make up the bulk of Medicaid consumers in most States.

*Response:* We agree. This rule provides some operational guidance in implementing the statutory provisions, but those provisions established a relatively comprehensive framework for State flexibility in premiums and cost sharing.

*Comment:* One commenter indicated the belief that cost sharing, while one of several avenues provided to modernize Medicaid, can be used by the States in conjunction with other alternatives, such as flexibility in benefit packages, to be more cost effective. The commenter also recommended that this rule be revised to ensure that State election of alternative cost sharing would be cost-effective by itself.

*Response:* We wish to clarify that Medicaid modernization options, such as alternative premiums and cost sharing, can be used separately, and do not have to be used jointly with benefit flexibility. States are in the best position to determine whether alternative cost sharing would be cost effective and whether it is appropriate to provide for alternative cost sharing in modernizing their Medicaid and SCHIP programs.

*Comment:* Several commenters stated that imposing premiums and cost sharing on Medicaid services acts as a deterrent to individuals receiving care,

including children. The commenters stated that imposing premiums and cost sharing could lead to higher costs overall, poorer health outcomes for beneficiaries, barriers to access and care, shifts in costs to providers, and higher rates of uninsured.

In addition, commenters stated that individuals with low incomes will be faced with unreasonable financial burdens and are likely to forgo needed treatment. Several commenters stated that our most vulnerable populations, those with chronic medical needs and those below the poverty line, will be required to choose to provide for their basic needs like food and shelter rather than obtain necessary medical health care because of the rigor created by following a private health insurance model of premiums and co-pays.

Commenters also stated that people with very low incomes will be required to pay more for their care. The commenters are concerned that individuals will be unable to pay premiums to enroll in Medicaid coverage, or that providers will deny necessary care to those who cannot afford to pay cost sharing. The commenters stated that this situation will invariably lead to increases in emergency room visits and hospitals, and should not be allowed within a program created to serve our country's neediest residents. The commenters also stated that any cost savings are outweighed because people who go without needed care will eventually present in the emergency room with complicated, costly conditions that could have been prevented with earlier medical attention.

Several commenters also stated that any new premiums and cost sharing imposed on Medicaid recipients would result in negative consequences for the recipients who are the poorest individuals and families in this country, the providers of Medicaid services, and the Medicaid program. Cost sharing results in insurance coverage for fewer needy individuals and families. Further, the failure by Medicaid recipients to access care and prescription drugs in the community due to their inability to afford deductibles and co-payments could result in serious health problems and the need for costlier services (for example, hospitalization). The commenters further stated that, in turn, this could result in eventual higher expenditures by Medicaid and, for dually eligible individuals, by Medicare.

Some commenters stated that other costs, which are more difficult to quantify, for example, school absences for children and missed work for parents when children are sick as well

as the adverse consequences of delayed treatment are also likely.

*Response:* We acknowledge the commenters' concerns that the imposition of premiums and cost sharing can lead to individuals delaying or forgoing care and to higher costs in the long-term if individuals delay care and therefore, become sicker and costlier to treat. We assume that Congress considered these concerns when it passed the statutory provisions for alternative premiums and cost sharing at State option. Indeed, the statute seems to indicate these considerations when it provides protections for certain populations and income groups.

The statutory framework appears to reflect the principle that States are in the best position to weigh the commenters' concerns and determine the appropriate levels and scope of alternative cost sharing. States have the statutory authority and option to impose lower cost sharing than the maximum levels permitted, or to exempt additional classes of individuals or additional items or services from cost sharing.

In section V of this final rule, we recognized, among other possibilities, that increased cost sharing could result in declines in utilization as some enrollees subject to new cost sharing requirements choose to decrease their use of services.

*Comment:* Several commenters stated that the cost sharing proposed rule would have a negative impact on community-based services. These individuals receiving community-based services require a multitude of services, including frequent physician visits, laboratory testing on a regular basis, medical equipment and supplies, and numerous prescription drugs in addition to their home health services. Although cost sharing for services would be limited to 5 percent of total family income, these individuals are disproportionately affected by the cost sharing and have other costs associated with their illness that are not reflected in Medicaid covered services. For example, many are prescribed special diets that carry with them higher food costs. Another example is the additional expenses they must incur for transportation to medical appointments. Elderly and severely disabled individuals with bowel and bladder problems require incontinence products that are not covered by Medicare or many Medicaid programs.

*Response:* As indicated in the last response, the statutory framework appears to reflect the principle that States are in the best position to weigh

the commenters' concerns and determine the appropriate levels and scope of alternative cost sharing. For community-based services, States have the option to impose lower cost sharing than the maximum levels permitted, or to exempt additional classes of individuals or additional items or services from alternative premiums or cost sharing.

*Comment:* Some commenters stated that dual eligible consumers should be exempt from premium and cost sharing requirements. Without excluding dual eligible consumers from the premium protected lists, the commenters indicated that barriers to care would be established.

*Response:* Dual eligible individuals (individuals eligible for both Medicare and Medicaid) are not a group specifically exempted by statute from alternative cost sharing. If States determine that this group should be exempted or protected from alternative premiums or cost sharing, States have the authority and the option to impose lower cost sharing than the maximum levels permitted, or to exempt the class of individuals from alternative premiums or cost sharing.

*Comment:* Many commenters stated that each of these areas of the proposed rule has the potential to become the behavioral healthcare Medicaid Trojan horse: It appears harmless but it will reverse hard-fought progress won over years of struggle that brought about equitable, decent care for Medicaid recipients experiencing mental illness or who have a developmental disability. They fear that these rules will have costlier results—and not the desired economizing—while also negatively impacting peoples' lives, their well-being and care, and our society.

*Response:* These concerns should be raised with States for consideration in designing their programs. If States determine that a group should be exempted or protected from alternative premiums or services exempted from cost sharing requirements, States have the option to impose lower cost sharing than the maximum levels permitted, or to exempt a class of individuals from alternative premiums or cost sharing.

*Comment:* One commenter stated that health centers such as Federally Qualified Health Centers (FQHCs) or other health care centers (that is, title X family planning clinics) are statutorily required to care for patients who visit the health center regardless of their ability to pay. In addition, the commenter stated that any decrease in Medicaid coverage only results in increasing health centers' already growing population of uninsured. The

commenter indicated that cost sharing should not apply to FQHC services or other health care centers (that is, title X family planning clinics) and should not affect health center reimbursements or their ability to provide quality care to their patients.

*Response:* We note that this is a concern that should be raised with States. The Federal statute does not provide for any specific treatment of these health centers or their patients.

*Comment:* One commenter stated that the proposed rule read together with other CMS rules (for example, the citizenship documentation requirement and the State Health Officials of August 17, 2007) create major barriers to access to health care. In addition, the commenter stated that the proposed rule has a devastating impact on the low income population who cannot afford cost sharing.

*Response:* The citizenship and documentation requirements are part of the DRA but are not part of this rule. The August 17 State Health Officials letter is also not part of this rule.

*Comment:* Many commenters stated that providing for new or increased cost sharing was a bad policy. They referred to the Congressional Budget Office analysis indicating that some 13 million people—a third of them children who could face new or increased cost sharing over the first 10 years the provision is in effect—and that 80 percent of the savings expected to result from the new cost sharing would be due to decreased use of services and/or because individuals are unable to pay the new premiums. In that analysis, some who were expected to lose coverage are children.

Several commenters refer to recent experience with section 1115 Medicaid waivers and the finding that premiums and cost sharing can create barriers to obtaining or maintaining coverage, increase the number of uninsured, reduce use of essential services, and increase financial strains on families who already devote a significant share of their incomes to out of pocket medical expenses. Some commenters cited studies that show that health insurance participation steadily declines when premiums are imposed, particularly at low levels of income and providers often faced additional administrative burdens related to attempts to collect co-payments and a reduction in payment levels if they were unable to do so.

*Response:* We assume that Congress considered these concerns when it passed the statutory provisions for alternative premiums and cost sharing at State option. The materials cited by

the commenters were available to Congress at the time. Indeed, the statute appears to reflect such consideration when it provides specific protections for certain populations and income groups.

The statutory framework appears to reflect the principle that States are in the best position to weigh the commenters' concerns and determine the appropriate levels and scope of alternative cost sharing. States have the discretion under the statute and the option to impose lower cost sharing than the maximum levels permitted, or to exempt additional classes of individuals and/or additional items or services from cost sharing.

*Comment:* Several commenters stated that the accelerated pace of this short comment period, given the broad implications, would lead to a short-sighted, onerous rule that has dangerous health impacts for the poor. The commenters stated that this proposed rule was published in the **Federal Register** on February 22, 2008 and the deadline for submission of comments was March 24, 2008. The commenter indicated that other rulemaking has taken a longer period and that given the impact of the discussion in this rule, a longer comment period is warranted.

*Response:* We disagree with the commenters suggesting that 30 days is too short of a time period to respond to the regulation. Neither section 553(c) of the Administrative Procedures Act nor the Social Security Act specify a time period for submission of comments. (While section 1871(b) of the Act requires a 60-day comment period for Medicare proposed rules, there is no specified time period for Medicaid rules.) Thus, for Medicaid rules, we allow 30 days or 60 days based on the complexity and size of the rule, or the need to publish the final rule quickly. Since the statute was fairly prescriptive and the proposed rule contains little policy interpretation, we have chosen a 30-day comment period in the interest of quickly getting guidance to States on the DRA flexibilities contained herein. Moreover, none of the commenters identified any specific inability to effectively comment on the proposed rule in the 30-day time period.

*Comment:* Several comments were provided by organizations that have an interest in how the premiums and cost sharing impact American Indians and Alaskan Natives (AI/ANs). They believe they are like other low-income groups; cost sharing requirements serve as a substantial barrier to AI/AN enrollment in the Medicaid program. Because of the Federal government's trust responsibility to provide health care to AI/ANs, cost sharing requirements have

specific tribal implications that have not been addressed in this rule.

Several commenters believe that the imposition by States of cost sharing requirements on Medicaid beneficiaries would have serious adverse consequences on Indian Health Service and tribally operated health programs in at least three ways: (1) An AI/AN beneficiary who is eligible to enroll in Medicaid may be dissuaded from doing so where a cost is imposed on him or her for such enrollment; (2) the Indian Health Service or tribal operated health program who services an AI/AN patient would lose Medicaid reimbursement for that patient; and (3) even if the eligible AI/AN does enroll in Medicaid, the Indian Health Service or tribally operated health program would have to use scarce IHS-appropriated funds to pay the cost share amount.

*Response:* We recognize that AI/ANs may have special concerns because of their eligibility for services through the Indian Health Service (IHS) or tribal health programs without charge. In addition, IHS and tribal providers may have special concerns. Nevertheless, the statute does not provide for special treatment of this group and these concerns should be raised to States for consideration in designing their programs. We encourage States to consider these issues fully when they design their programs.

*Comment:* Several commenters believe that AI/ANs should be exempt from premiums and cost sharing requirements entirely.

*Response:* We are not aware of any provision in the Medicaid statute that authorizes CMS to adopt a position providing for special treatment of AI/AN individuals. In contrast, section 2103(b)(3)(D) of the SCHIP statute provides for special treatment of such individuals, when it requires procedures to ensure that AI/AN targeted low-income children receive child health assistance. We have interpreted that SCHIP requirement to authorize the position at § 457.535 requiring exemption of AI/AN children from premiums, deductibles, coinsurance, co-payments, or any other cost sharing charges. In light of the absence of a similar statutory authorization, we are unable to adopt a similar policy under Medicaid.

*Comment:* One commenter indicated that according to the DRA, AI/ANs are required to prove both citizenship and identity in order to obtain Medicaid services. The commenter stated that Native Americans have been told that tribal documentation is insufficient to prove eligibility for Medicaid services. The commenters also stated that many

Navajo elders were born at home and do not have birth certificates and it is a substantial burden to obtain birth certificates in this situation. Hence, this new rule limits the Navajo elders ability to access Medicaid. Further, the commenter stated that CMS issued the August 17 State Officials letter that restricts States from requesting health care expansions for SCHIP up to 250 percent limit until the State can prove enrollment of 95 percent of children under the 200 percent of the poverty line. The August 17 directive is unrealistic in obtaining this type of proof of participation. All of these CMS efforts have the collective effect of limiting health care for the poor and AI/AN populations, and present barriers to receiving health care.

*Response:* The citizenship documentation and identity requirements and the August 17 State Health Officials letter are not part of this rule.

*Comment:* Several commenters stated that this rule is contrary to the Department of Health and Human Services Tribal Consultation policy since CMS did not consult with Tribes in the development of these regulations before they were promulgated. The commenters indicated that CMS did not obtain advice and input from the CMS Tribal Technical Advisory Group (TTAG) even though the TTAG meets on a monthly basis via conference calls and holds quarterly face to face meetings. In addition, the commenter stated that CMS did not consult with the CMS TTAG Policy Subcommittee which was specifically established by CMS for the very purpose of obtaining advice and input in the development of policy guidance and regulations.

Furthermore the commenter stated that the proposed rule does not contain a Tribal summary impact statement describing the extent of the tribal consultation or lack thereof; or an explanation of how the concerns of Tribal officials have been met. Several commenters request that these regulations not be made applicable to AI/AN Medicaid beneficiaries until Tribal consultation is conducted.

*Response:* We follow the Department of Health and Human Services' Tribal Consultation Policy. The Departmental guidelines provide for determination of critical events that require special consultation efforts. This action was not considered as a critical event under the Departmental guidelines and thus special consultation efforts were not undertaken. Tribes have had an opportunity to review the proposed rule and submit comments either directly or through the CMS TTAG that has been

established to facilitate consultation. We are currently developing our own consultation guidelines to better serve its tribal stakeholders, consistent with the Departmental guidelines. Even under those draft CMS consultation guidelines, we would not routinely require consultation before notice and comment rulemaking on policies that do not specifically refer to AI/ANs, or tribes. In this instance, it appears that tribes are not directly affected by the provisions of greater flexibility to States, but only by the manner in which individual States choose to exercise that flexibility. We encourage States which decided to implement alternative premiums and cost sharing to consult with tribes and notify them whenever possible on implementation policies that will directly affect the Tribes.

*Comment:* Several commenters indicated that in the event CMS proceeds to make these regulations effective on Indian tribes, the CMS TTAG should strongly encourage that the proposed rule be modified to require State Medicaid programs to consult with Indian Tribes before the development of any policy that would impose any premium or cost sharing requirements on AI/ANs served by Indian Health Service or tribal health programs similar to the way consultation takes place with Indian Tribes in the development of waiver proposals.

*Response:* This rule is not "effective on Indian tribes". The rule will implement a statutory provision that affects federal review of State Medicaid plans. While we recognize that the resulting changes in State Medicaid programs may have an impact on Indian tribes, we believe these concerns should be raised on a State level. The statutory framework appears to reflect the principle that States are in the best position to weigh the commenters' concerns and determine the appropriate levels and scope of alternative cost sharing. States have the option to impose lower cost sharing than the maximum levels permitted, and/or to exempt additional classes of individuals or additional items or services from cost sharing.

*Comment:* One commenter stated that it is laudable that the proposed rule would not affect existing waiver authority with respect to premiums and cost sharing but, in the interest of consistency, using similar methodologies under waivers and the State plan should be allowable. For automated eligibility systems and tracking purposes, having one method of charging and defining co-payments would simplify the process for all providers.

*Response:* We agree that similar methodologies for calculating premiums and cost sharing should be allowable. For example, States can use similar methodologies for determining family income and eligibility. States can use similar methodologies for tracking cost sharing as under approved waivers, or can use the methods that SCHIP programs use to track cost sharing. States can program their automated systems to track and compute recipients' cost sharing.

We note that the DRA provides States with flexibility to choose not to use the same methodologies in determining family income and eligibility. It is up to the States to determine what methodologies work best for them in providing health care coverage to their Medicaid beneficiaries and in imposing alternative premiums and cost sharing. The DRA provisions provide States with unprecedented flexibilities and we have maintained that flexibility in promulgating this rule.

*Comment:* One commenter appreciates and supports making explicit the Secretary's authority to waive the limitations on premiums and cost sharing.

*Response:* The DRA did not expand or contract the Secretary's waiver authority with respect to premiums and cost sharing. We note that States may no longer need waivers from the Secretary for certain programmatic options. This could be particularly advantageous for States since waivers need to be periodically renewed.

*Comment:* One commenter stated that the collection of co-payments and deductibles is especially problematic when health care services (for example, home health) are delivered in the community. The barriers that exist to the collection of fees by clinicians during home visits are the potential negative impact on the clinician/patient relationship and safety concerns for clinicians collecting and transporting cash, despite the fact that the amounts may be small.

Several commenters stated that States would experience increased costs because States would be required to develop new accounting systems in order to reflect cost sharing payments timely, disenroll recipients for failure to pay premiums, identify and transfer individuals in and out of exception groups, and hear and adjudicate exception eligibility decisions. In addition, several commenters stated that cost sharing responsibilities that are shifted to the provider of service may discourage participation, thereby increasing access problems.

*Response:* In response to the burden to develop systems to track premiums and cost sharing, we are not requiring that States develop electronic or new accounting systems to track Medicaid beneficiaries' cost sharing obligations. We only require that States indicate the method they will use in tracking cost sharing. We believe that using electronic systems to comply with the requirement is ideal, however, it is not a requirement under this rule.

We note that this provision is at the State option. States are not required to impose premiums and cost sharing on Medicaid beneficiaries and providers have the statutory authority under 1916A(d)(2) of the Act to waive or reduce cost sharing if they believe imposing cost sharing produces a negative relationship between providers and clients. Safety for providers collecting co-payments should be a consideration by States before choosing to adopt the flexibilities outlined in this rule.

### 3. Alternative Premiums, Enrollment Fees, or Similar Fees: State Plan Requirements (§ 447.64)

Section 1916A(a)(1) of the Act requires that the State plan specify the group or groups of individuals upon which it will impose alternate premiums. In accordance with the statute, at § 447.64(a), we proposed that the State plan describe the group or groups of individuals that may be subject to such premiums, enrollment fees, or similar charges. We further proposed in § 447.64(b) that the State plan must include a schedule of the premiums, enrollment fees, or similar charges and the process for informing recipients, applicants, providers, and the public of the schedule. States may vary the premiums, enrollment fees, or similar charges among the groups of individuals.

Section 1916A(b)(4) of the Act requires that the State plan specify the manner and the period for which the State determines family income. In accordance with the statute, at § 447.64(c), we proposed that the State plan describe the methodology used to determine family income, including the period and periodicity of those determinations. We also proposed in § 447.64(d) that the State plan describe the methodology the State would use to ensure that the aggregate amount of premiums and cost sharing imposed for all individuals in the family does not exceed 5 percent of family income as applied during the monthly or quarterly period specified by the State.

Section 1916A(d)(1) of the Act requires that the State specify the group

or group of individuals for whom payment of premiums is a condition of eligibility. In accordance with the statute, at § 447.64(e), we proposed that the State plan list the group or groups of individuals. We further propose in § 447.64(f) that the State plan describe the premium payment terms for the group or groups.

Specific comments on this section and our responses to those comments are as follows:

*Comment:* One commenter stated that States should be required to notify pharmacists, providers, recipients, and the public no later than 60 days before the effective date of any changes in cost sharing requirements under the State plan.

*Response:* We proposed at § 447.76 to require issuance of a public schedule that includes current cost sharing requirements. We required contemporaneous but not advance notice of any change in that schedule. As we discuss below, we have revised the proposed provision to require at least 1 month before notice of any change in premiums or cost sharing, to permit individuals and providers an opportunity to plan for the increased financial responsibility.

*Comment:* Several commenters stated that States should be required to include in their State plan amendment a schedule of prescription drug cost sharing for the various covered populations and indicate in this schedule whether these cost sharing amounts must be paid by the Medicaid patient in order to receive the prescription. The commenters stated that the schedule should be posted to the State Medicaid program Web site and to the CMS Web site. This information should be distributed to patients and include a statement regarding the expectation that patients would pay the cost sharing amounts. Other commenters stated that the State plans should indicate how the State would communicate to providers that some individuals are exempt from co-payment obligations.

*Response:* We agree that any changes to cost sharing should be made available to pharmacists, providers, recipients, and the general public. Section 447.76 requires that a public schedule be prepared and made available that includes a current listing of cost sharing charges. We also require that the public schedule be made available to recipients, at the time of enrollment and reenrollment, and when charges are revised.

We plan to include an assurance concerning the public schedule requirement in the State plan.

In terms of the commenter's recommendation to post the public schedule to the State Web site and the CMS Web site, we have not prescribed that public schedules or State plans be posted to the State Web site or CMS Web site because we wish to maintain State flexibility in this regard.

*Comment:* Several commenters complained that the proposed rule contained no requirement that the State facilitate pharmacy providers' attempts at point-of-sale to determine whether specific patients are subject to cost sharing for a transaction at hand. Some commenters stated that it is necessary for States to set up systems for tracking and computing recipients' co-payments at point-of-sale and to adopt policies that support electronic identification of non-preferred drugs to minimize confusion for recipients and providers. The commenters stated that the information should include the level of cost sharing imposed, whether the recipient has met his or her aggregate limit for the month or quarter, and whether the co-payment is enforceable.

*Response:* Section 447.68(d) requires that the State plan must specify the method for tracking cost sharing. If the state is tracking cost sharing electronically, cost sharing information regarding the appropriate levels, whether the beneficiary has met his or her 5 percent aggregate cap and whether the co-payment is enforceable could all be available. However, States can use other methods to track cost sharing; thus, information at point-of-sale may not be available in all States.

#### 4. General Alternative Premium Protections (§ 447.66)

Section 1916A(b)(3)(A) of the Act specifies that the State plan may not impose premiums on certain groups. In accordance with § 447.66(a), we proposed that the State exclude these classes of individuals from the imposition of premiums.

Section 1916A(b)(3)(C) of the Act clarifies that a State may exempt additional classes of individuals from premiums. We proposed to implement this provision at § 447.66(b).

Specific comments on this section and our responses to those comments are as follows:

*Comment:* One commenter requests clarification of proposed § 447.66, which States that premiums cannot be imposed on disabled children who are receiving medical assistance because of the Family Opportunity Act. The commenter questioned at what age premiums can be imposed upon these children.

*Response:* We clarify that in § 447.66, we specified that disabled children who are receiving medical assistance because of the Family Opportunity Act (sections 1902(a)(10)(A)(ii)(XIX) and 1902(cc) of the Act) cannot have alternative premiums nor cost sharing imposed upon them under section 1916A of the Act. Neither the Family Opportunity Act nor the DRA specify an age for children. The age for qualification as a child is determined by each State individually, thus it would vary as to when premiums could be imposed under the authority of the Family Opportunity Act.

*Comment:* One commenter indicated that women who choose to delay or prevent pregnancy should be exempt from premiums, regardless of their ability to pay a premium, just like pregnant women are exempt. Additionally, the commenter stated that CMS should exempt individuals eligible for family planning services pursuant to a section 1115 family planning waiver from the imposition of premiums.

*Response:* Section 1916A(b)(3)(A)(ii) of the Act provides that pregnant women are exempt from premiums, but there is no statutory exemption for women who choose to receive family planning supplies to prevent unintended pregnancies, nor individuals who receive family planning services pursuant to a section 1115 demonstration explicitly exempt from premiums. While States may elect to exempt such groups in designing alternative cost sharing, the regulations do not require States to do so, which is consistent with the DRA statutory language.

#### 5. Alternative Copayments, Coinsurance, Deductibles, or Similar Cost Sharing Charges: State Plan Requirements (§ 447.68)

Section 1916A(a)(1) of the Act requires that the State plan specify the group or groups of individuals upon which it opts to impose cost sharing. In accordance with the statute, at § 447.68(a), we proposed that the State plan describe the group or groups of individuals that may be subject to cost sharing. We further proposed that the State plan must include a schedule of the copayments, coinsurance, deductibles, or similar cost sharing charges, the items or services for which the charges apply, and the process for informing recipients, applicants, providers, and the public of the schedule. We note that States may vary cost sharing among the types of items and services.

Section 1916A(b)(4) of the Act requires that the State plan specify the

manner and the period for which the State determines family income. In accordance with the statute, at § 447.68(b), we proposed that the State plan describe the methodology used to determine family income, including the period and periodicity of these determinations.

We also proposed that the State plan describe the methodology the State would use to ensure that the aggregate amount of premiums and cost sharing imposed for all individuals in the family does not exceed 5 percent of family income as applied during the monthly or quarterly period specified by the State. We further proposed that the State plan describe the State's methods for tracking cost sharing charges, informing recipients and providers of their liability, and notifying recipients and providers when individual recipients have reached their aggregate limit on premiums and cost sharing. States can use the same methods that SCHIP programs use to track cost sharing. For example, States can program their automated systems to track and compute recipients' cost sharing.

Finally, we proposed that the State plan specify whether the State permits a provider participating under the State plan, to require payment of authorized cost sharing as a condition for the provision of covered care, items, or services.

Specific comments on this section and our responses to those comments are as follows:

*Comment:* One commenter expressed concern that States would be unable to identify transition Medicaid recipients who develop a terminal illness in a timely manner to ensure that they are exempted from premiums and co-payments when they access hospice services.

The commenter also stated that States should be required to institute expedited processes for transition of recipients that have been diagnosed as having a terminal illness to the exclusion group.

*Response:* We agree with the commenter's suggestion that it is important that individuals who have been diagnosed with a terminal illness should not have to worry about premiums and co-payments and States should promptly identify these individuals as exempt from these obligations. Congress clearly identified in section 1916A(b)(3) of the Act individuals with a terminal illness receiving hospice care as individuals exempt from premiums and cost sharing. We included these exemptions in § 447.66—General Premium

Protections and § 447.70—General Cost Sharing Protections.

Beyond the State plan requirements required by this section, we believe it is important to provide flexibility to States and therefore, have not prescribed methods for States to follow to ensure that exempted individuals are not charged premiums and/or cost sharing. If an individual is part of a population for which no premiums and/or cost sharing can be imposed, it is incumbent upon the State to ensure that procedures are in place so that there is no routine reliance on a refund for overpayments. If premiums or co-payments are imposed in error on these individuals, the State should take prompt corrective action to ensure full and continuing compliance with applicable requirements.

*Comment:* One commenter stated that co-payments should apply to broader coverage groups and was concerned that this would not be possible because a significant number of Medicaid recipients, cutting across usual coverage groups are still exempt from cost sharing.

*Response:* This rule reflects statutory exemptions and exclusions, and does not expand or contract the list of items or services for which no cost sharing can be imposed, the level of cost sharing that could be imposed, the premiums that could be imposed, the populations for which premiums and cost sharing could be imposed, or the enforceability of premiums and/or cost sharing.

Even though a significant number of Medicaid recipients are protected from alternate premiums and cost sharing, there are still important opportunities for States to exercise flexibility in this area. Also, while some of the groups cut across traditional Medicaid eligibility groups (that is, there could be terminally ill individuals accessing hospice care in almost any traditional Medicaid eligibility group), States can implement systems to identify these exempt individuals.

#### 6. General Alternative Cost Sharing Protections (§ 447.70)

Section 1916A(b)(3)(B) of the Act specifies that the State plan may not impose alternative cost sharing under 1916A(a) of the Act for certain services including emergency services and family planning services. We proposed to implement this provision at § 447.70(a)(1).

In addition, section 1916A(c)(1)(B) of the Act prohibits the State plan from imposing otherwise applicable cost sharing for preferred drugs for individuals "for whom cost sharing may not otherwise be imposed under

subsection (a) due to the application of 1916A(b)(3)(B) of the Act." Therefore, in accordance with the statute, at § 447.70(a)(1)(x), we proposed that the State plan exclude these classes of individuals from the imposition of cost sharing for preferred drugs within a class.

Section 1916A(b)(3)(C) of the Act clarifies that a State may exempt additional individuals or services from cost sharing. We proposed to implement this provision at § 447.70(c).

Finally, section 1916A(c)(3) of the Act requires a State to charge cost sharing applicable to a preferred drug in the case of a non-preferred drug if the prescribing physician determines that the preferred drug would not be as effective for the individual or would have adverse effects for the individual or both. We proposed to implement this section at § 447.70(b). We further proposed at § 447.70(b) that the overrides meet State criteria for prior authorization and be approved through the State before the authorization process.

Specific comments on this section and our responses to those comments are as follows:

*Comment:* Several commenters stated that family planning services and supplies should be exempt from cost sharing entirely. Other commenters stated that family planning services and supplies have consistently been treated as a package, and have been exempt from cost sharing entirely. Furthermore, commenters stated that CMS' own guidelines including the State Medicaid Manual and the title XIX Financial Management Review Guide confirm this.

Commenters also stated that the DRA expanded State authority to impose cost sharing for non-preferred prescription drugs, limiting cost sharing to nominal amounts for a clearly defined list of services and recipients, including family planning services and supplies. In addition, some commenters expressed that States may interpret the provisions of the DRA to permit some cost sharing for non-preferred drugs and may interpret this as cost sharing for oral contraceptives. The commenters stated that if this were an acceptable interpretation, the statute would require that cost sharing be limited to no more than a nominal amount and the rule should be revised accordingly.

*Response:* Family planning services and supplies are exempt from cost sharing, except that States have the option under 1916A(c) of the Act to impose nominal cost sharing on non-preferred drugs, including contraceptive drugs. Congress was clear to indicate

that family planning services and supplies are exempt from alternate cost sharing as a service (see section 1916A(b)(3)(B)(vii) of the Act), and Congress clarified in section 405(a)(2) of TRHCA that this exemption extends to preferred prescription drugs within a class of drugs. Nominal cost sharing for non-preferred drugs, including contraceptive drugs, is permitted subject to the limitations by income group and the aggregate cap. In this rule, we neither expand nor contract these protections.

*Comment:* One commenter requested clarification of proposed §§ 447.70 and 447.71 in which cost sharing for non-emergency use of the hospital emergency room can be imposed. The commenter indicated that these proposed sections read as if emergency room physicians cannot impose co-payments against any beneficiary at or below 100 percent, or over 100 percent of the Federal poverty level, unless the regular outpatient provider charges no cost sharing payment for the same service in the same geographic area.

The commenter also asked that we clarify how a State can ensure compliance with this particular requirement and what mechanism a State would use to demonstrate such compliance.

*Response:* We agree that clarification is needed in terms of cost sharing for non-emergency use of the hospital emergency room, and we have revised this final rule accordingly. Specifically, as directed by the DRA for individuals with family incomes at or below 100 percent of the Federal poverty line (FPL), cost sharing for non-emergency use of the hospital emergency room can be imposed at nominal amounts only so long as no cost sharing is imposed to receive the same services from an alternate outpatient provider in the same geographic area. For individuals with family incomes from 100 to 150 percent of the FPL, cost sharing can be imposed at up to two times the nominal amount. For individuals with family incomes that exceed 150 percent of the FPL cost sharing there is no limit as to the amount of cost sharing that can be imposed; however, States must ensure that cost sharing does not exceed the 5 percent total aggregate cap. The 5 percent total aggregate cap also applies to individuals with incomes at or below 100 percent of the FPL and to individuals with family incomes from 100 to at or below 150 percent of the FPL.

The limitation that cost sharing may be imposed only so long as no other cost sharing has been imposed in the same geographic area applies only to

individuals with family incomes at or below 100 percent of poverty and to individuals exempt from cost sharing.

In response to the request for clarification as to how States can comply with this limitation, we believe that the hospital will need to document that it has provided a referral to an alternate provider who can provide the services without imposition of such cost sharing.

*Comment:* Some commenters stated that in considering the experience of a large majority of emergency physicians, imposing cash co-payments on many Medicaid recipients in the emergency department is just not practical. The commenters noted that medical conditions are not easy to ascertain in an episodic setting when doctors have little or no knowledge of the patient. The commenters also asserted that emergency rooms do not typically have separate "screening services" and "management/treatment service." The commenters further asserted that by the time the emergency physician and the emergency department team have completed the EMTALA-required medical screening examination, 90 percent of the resources are expended and most of the work is complete. The commenters thought it would be unpalatable to many doctors to inform the patient that his or her condition is not emergent and he or she has to make a payment before receiving a prescription or some minor additional treatment. The commenters indicated that it is unethical to withhold treatment while the patient is in front of them and even harder to justify when the potential financial gain is so tiny. Commenters also stated that these new requirements would put an excessive burden on hospitals and would be extremely costly to States, with little apparent benefit if any at all.

*Response:* Section 1916A(e) of the Act, as amended by the DRA, provided a State option to impose higher cost sharing for non-emergency care furnished in a hospital emergency department without a waiver. If such cost-sharing is imposed, providers also have the option to waive or reduce cost sharing on a case-by-case basis in accordance with section 1916A(d)(2) of the Act.

The EMTALA screening is an existing statutory requirement and is not particular to this rule.

*Comment:* Several commenters stated that hospitals would have to compile an ever changing roster of available medical care sites that would not charge co-payments. In addition, they stated that it is not clear how the terms in the proposed rule, "available and

accessible," would be defined in order to quantify time and distance. They further stated that it would be nearly impossible for hospitals to keep up-to-date records on these providers.

*Response:* The statute provides that the hospital is responsible for providing a referral to such a provider. We are leaving to States flexibility to determine whether each hospital must maintain a list of available providers, or whether the State or other governmental entity assists in this responsibility.

*Comment:* Several commenters stated that none of these requirements do anything to address the real problem, which is that a significant amount of those that utilize the emergency department are chronically ill patients with poor control of their illness(es)—individuals who will benefit most by having a medical home. The commenters also stated that a State's ability to impose cost sharing amounts for non-emergency services provided in an emergency department merely shifts financial burdens to hospitals and would not address the problem of access to a regular source of care. They also stated that this should be addressed by broadening health care coverage and access to needed services. Furthermore, they stated that to date, the systems designed to increase access to urgent, episodic care have only addressed the systems of the "illness" of an increasingly inadequate primary care system in which there is a growing number of physicians who do not take Medicaid patients because of inadequate payment. They believe that the hospital emergency departments serve as the "safety net" and are often the only source of primary medical care for Medicaid beneficiaries. They also stated that imposing further burdens on the safety net is not the solution.

*Response:* We agree that there is a need to address the problem that some individuals may use the hospital emergency room as their primary care provider and that these individuals will benefit most from a medical home. The DRA provided for \$50 million in grant funding to States to establish alternative non-emergency service providers or networks of these providers. CMS recently awarded the grant funding to 20 States for projects that include innovative programs for providing primary care access to Medicaid beneficiaries. Many of the States' projects include components that will focus on educating beneficiaries on the benefits of care coordination and of having a medical home. Many also focus on case management strategies and disease management. We require, as part of the State applications, a plan for



sustainability so that these State projects for alternative providers and primary care access will continue well into the future.

*Comment:* Several commenters questioned the logic of the prescription drug co-payment structure for patients with income from 100 to 150 percent of the Federal poverty level. They stated that the proposed rule provided that cost sharing for this group cannot exceed 10 percent of the payment the agency makes for the service, but cannot exceed the nominal amounts for non-preferred drugs. They also stated that given that the average Medicaid reimbursement for a brand name drug is \$155, the proposed rule appears to allow the State to charge up to almost \$16 for a preferred brand name drug (10 percent of the payment) but only \$3.30 for a non-preferred brand name drug (which is the maximum nominal co-payment amount). The commenters stated that this appears to encourage the use of non-preferred drugs rather than preferred drugs.

*Response:* This comment is based on a misunderstanding of the cost sharing which may be imposed on "preferred drugs." Section 1916A(c) of the Act provides authority for alternate cost sharing (other than the level permitted under section 1916 of the Act) only for non-preferred drugs. There is no provision in section 1916A(c) of the Act authorizing cost sharing for preferred drugs that would exceed the nominal levels that could be permitted under section 1916 of the Act. In the example given, cost sharing for the preferred drug would be at or below nominal levels, and there would be no financial disincentive for use of the preferred drug.

*Comment:* Commenters stated that the cost sharing permitted for higher income individuals would be excessive. For individuals with incomes above 150 percent of the Federal poverty level, the cost sharing amount would increase to 20 percent, potentially increasing the cost of a medication to \$32, some or all of which the pharmacy would have to absorb if the State doesn't condition payment on the cost of the service, and the patient cannot pay.

*Response:* The statutory framework appears to reflect that States are in the best position to weigh the commenters' concerns and determine the appropriate levels and scope of alternative cost sharing. States have the option to impose lower cost sharing than the maximum levels permitted by the statute, or to exempt additional classes of individuals or additional items or services from cost sharing.

*Comment:* Some commenters stated that the proposed requirement at § 447.70(c)(2) for requesting prior authorization as a condition for an exception to non-preferred drug cost sharing exceeds the scope of the statute and CMS should delete this requirement. Other commenters stated that the prior authorization process should be at the State option, rather than a requirement.

*Response:* We disagree with the commenter that the prior authorization requirement should be deleted. The DRA indicates that a prescribing physician can impose cost sharing for non-preferred drugs at the level of a preferred drug if it is determined that the non-preferred drug would better meet the needs of the beneficiary (that is, a preferred drug for treatment of the same condition either would not be as effective for the individual or would have adverse effects for the individual or both). We have further required that this activity be part of the prior authorization process since States should be aware of these determinations and be part of the approval process. States are responsible for administering their Medicaid programs.

*Comment:* One commenter stated that given the proposed rule would not mandate that the Medicaid patient pay the cost sharing, even for non-preferred drugs, it does not appear that physicians would have incentives to obtain prior authorization for the non-preferred drugs if the patient can simply say they cannot afford the cost sharing on the non-preferred drug.

*Response:* In terms of incentives to obtain prior authorization for non-preferred drugs even if the patient cannot afford cost sharing on the non-preferred drug, the DRA specifies that a physician can impose cost sharing at the level of a preferred drug on a non-preferred drug if it is determined that the non-preferred drug would be more effective in the treatment of the condition and that the non-preferred drug prevents adverse effects for the beneficiary. We require that this process conform to the States' prior authorization process. We note that an incentive exists for beneficiaries since cost sharing can be imposed at the level of the preferred drug. For individuals exempt from cost sharing, this level is \$0; therefore, the beneficiary would be required to pay no cost sharing for the non-preferred drug.

*Comment:* One commenter stated that States should be given the option to allow physicians to use a "dispense as written" process to reduce cost sharing for certain non-preferred drugs.

*Response:* Our proposed rule did not preclude a State from accepting a process to document a physician's finding that the preferred drug would be less effective or would have adverse effects for the individual or both, (the statutory standard). In addition, our proposed rule did not preclude a State from requiring compliance with a prior authorization process, or a more detailed documentation process.

*Comment:* Several commenters request that CMS require States to publish the preferred drug list, just as they are required to make available a public schedule for other cost sharing information. The commenters recommended this requirement since lists are not easily available in a logical section on the State or plan's Web site and it is difficult to access particularly when there are multiple formularies by different managed care plans.

*Response:* We interpreted the proposed rule at § 447.76 requiring States to publish a public schedule of cost sharing charges to implicitly include a reference to schedules of preferred drugs. We envisioned the preferred drug schedule as part of, or as a supplement to, the required public schedule. In response to the comment, we are including in this final rule an express requirement to make available either the preferred drug list itself, or a method to obtain the list upon request.

*Comment:* Several commenters want CMS to define preventive services, well child care, and immunizations and what qualifies as a preventive service under proposed § 447.70. They also stated that this section fails to define terms and provides no other reference to services found in the statute or the proposed rule. In addition, commenters stated that the Bright Futures guidelines, which provide an explanation of the AAP-recommended periodicity schedule for preventive visits and appropriate immunizations should be the appropriate reference and should be included in the rule as the standard by which preventive services should be judged.

One commenter recommended that CMS add a definition for medically frail.

*Response:* We wish to maintain the flexibilities Congress granted in the DRA. We have not defined these terms or what qualifies as a preventive service under § 447.70. States may choose to use the Bright Futures guidelines as a reference, which provide an explanation of the American Academy of Pediatrics-recommended periodicity schedule for preventive visits and appropriate immunizations. We note that we find the States' use of these guidelines to be appropriate. These guidelines are used

as guidelines for well baby and well child care services in the SCHIP program.

**7. Alternative Premium and Cost Sharing Exemptions and Protections for Individuals With Family Income At or Below 100 Percent of the FPL (§ 447.71)**

Under section 1916A(a)(2)(A) of the Act, the State plan may not impose premiums on individuals whose family income is at or below 100 percent of the FPL. In accordance with the statute, at § 447.71(a) we proposed that the State plan exclude these individuals from the imposition of premiums.

Under section 1916A(a)(2)(A) of the Act, the State plan may not impose cost sharing on individuals whose family income is at or below 100 percent of the FPL, with the exception of cost sharing for non-preferred drugs and for non-emergency services furnished in a hospital emergency department. However, section 1916A(c)(2)(A)(i) of the Act prohibits a State from imposing, with respect to a non-preferred drug, cost sharing that exceeds the nominal amount as otherwise determined under section 1916 of the Act and described at § 447.54(a)(3) or § 447.54(4) for those individuals. In addition, section 1916A(e)(2)(B) of the Act prohibits a State from imposing, with respect to non-emergency services furnished in a hospital emergency department, cost sharing that exceeds the nominal amount as otherwise determined under section 1916 of the Act and described at § 447.54(a)(3) or § 447.54(4).

Furthermore, a State may only impose nominal cost sharing with respect to non-emergency services as long as no cost sharing is imposed to receive such care through an outpatient department or other alternative health care provider in the geographic area of the hospital emergency department involved.

In accordance with the statute, we proposed at § 447.71(b)(1), (now § 447.71(b)(2)) that cost sharing for non-preferred drugs for those individuals not exceed the nominal cost sharing amount. In addition, we proposed at § 447.71(b)(2), (now § 447.71(b)(3)) that cost sharing for non-emergency services furnished in a hospital emergency department for those individuals not exceed the nominal cost sharing amount and be imposed only as long as no cost sharing is imposed on those individuals to receive care through an outpatient department or other alternative non-emergency services provider in the geographic area of the hospital emergency department involved.

Section 1916A(a)(2)(B) of the Act provides that the total aggregate amount of cost sharing imposed under sections

1916A(c), 1916A(e), and/or 1916 of the Act upon individuals whose family income is at or below 100 percent of the FPL may not exceed 5 percent of the family income of the family involved, as applied on a quarterly or monthly basis as specified by the State. In accordance with the statute, we proposed at § 447.71(c) that aggregate cost sharing for individuals whose family income is at or below 100 percent of the FPL applicable to a family of the size involved not exceed the maximum permitted under § 447.78(b). At § 447.78(b), we proposed that the total aggregate amount of cost sharing may not exceed 5 percent of such family's income for the monthly or quarterly period, as specified in the State plan.

A comment on this section and our response to the comment is as follows:

*Comment:* Commenters stated that the matrix of cost-sharing is complex and request clarifying information on cost sharing requirements, limitation, and exemptions, as well as cost sharing for non-preferred and preferred prescription drugs, and for non-emergency use of the hospital emergency room.

*Response:* In considering the complexity of the cost-sharing limitations and requirements, we are clarifying that in § 447.71, we indicated in the proposed rule that individuals with family incomes at or below 100 percent of the poverty line were exempt from cost sharing. The Tax Relief and Health Care Act amended the DRA and indicated that for individuals with family incomes at or below 100 percent of the FPL cost sharing cannot be imposed under section 1916A(a) of the Act but can be imposed at nominal amounts under section 1916 of the Act. Consequently, we are updating § 447.71 to insert a new paragraph (b)(1) indicating that the State may impose cost-sharing under the State plan on individuals whose family income is at or below 100 percent of the FPL under the authority provided in section 1916 of the Act and consistent with such section. We are also redesignating § 447.71(b)(1) as § 447.71(b)(2) and § 447.71(b)(2) as § 447.71(b)(3).

This completes the specific comments submitted to this section in terms of cost sharing imposed upon individuals at or below 100 percent of the Federal poverty level. We note, that we did receive comments on prescription drugs and non-emergency use of the hospital emergency room which we addressed in § 447.70—General alternative cost sharing protections.

**8. Alternative Premium and Cost Sharing Exemptions and Protections for Individuals With Family Income Is Above 100 Percent but At or Below 150 Percent of the FPL (§ 447.72)**

Under section 1916A(b)(1)(A) of the Act, the State plan may not impose premiums on individuals whose family income exceeds 100 percent, but does not exceed 150 percent of the FPL applicable to a family of the size involved. In accordance with the statute, at § 447.72(a), we proposed that the State plan exclude these individuals from the imposition of premiums.

Section 1916A(b)(1)(B)(i) of the Act provides that, in the case of individuals whose family income exceeds 100 percent, but does not exceed 150 percent of the FPL applicable to a family of the size involved, cost sharing imposed under the State plan may not exceed 10 percent of the cost of such item or service. However, section 1916A(c)(2)(A)(i) of the Act prohibits a State from imposing, with respect to a non-preferred drug, cost sharing that exceeds the nominal amount as otherwise determined under section 1916 of the Act and described at § 447.54(a)(3) for those individuals. In addition, section 1916A(e)(2)(A) of the Act prohibits a State from imposing, with respect to non-emergency services furnished in a hospital emergency department, cost sharing that exceeds twice the nominal amount as otherwise determined under section 1916 of the Act and described at § 447.54(a)(3) for those individuals.

Therefore, in accordance with the statute, we proposed at § 447.72(b) that cost sharing for those individuals under the State plan not exceed 10 percent of the payment the agency makes for that item or service, with the exception that it not exceed the nominal cost sharing amount for non-preferred drugs or twice the nominal cost sharing amount for non-emergency services furnished in a hospital emergency department. In the case of States that do not have fee-for-service payment rates, we proposed that any copayment that the State imposes for services provided by an MCO may not exceed \$5.20 for FY 2007. Thereafter, any copayment that the State imposes for services provided by an MCO may not exceed this amount as updated each October 1 by the percentage increase in the medical care component of the CPI-U for the period of September to September ending in the preceding calendar year and then rounded to the next highest 10-cent increment.

Section 1916A(b)(1)(B)(ii) of the Act provides that the total aggregate amount

of cost sharing imposed under section 1916 and 1916A of the Act may not exceed 5 percent of the family income of the family involved, as applied on a quarterly or monthly basis as specified by the State. In accordance with the statute, we proposed at § 447.72(c) that aggregate cost sharing for individuals whose family income exceeds 100 percent, but does not exceed 150 percent of the FPL applicable to a family of the size involved, not exceed the maximum permitted under § 447.78(a). At § 447.78(a), we proposed that the total aggregate amount of cost sharing may not exceed 5 percent of such family's income for the monthly or quarterly period, as specified in the State plan.

We did not receive any specific comments on this proposal as it relates to cost sharing imposed upon individuals with incomes from 100 to 150 percent of the Federal poverty level, therefore, we are adopting it in this final rule. We note that we have revised the copayment that the State may impose for services by an MCO not to exceed from \$5.20 per visit for FY 2007 to \$3.15 for FY 2007, to \$3.25 for FY 2008, and \$3.40 for FY 2009. However, we received comments on the rounding up the nominal amounts by the next highest 10-cent increment, the managed care maximum amount, and the cost sharing that can be imposed for prescription drugs and non-emergency use of the hospital emergency room. For comments related to the 10-cent increment and the managed care maximum, we addressed these in § 447.54 in the preamble of this final rule. As noted earlier, for comments related to cost sharing for prescription drugs and non-emergency use of the hospital emergency room, we addressed these in § 447.70 in the preamble of this final rule.

#### 9. Alternative, Premium and Cost Sharing Protections for Individuals With Family Income Above 150 Percent of the FPL (§ 447.74)

Under section 1916A(b)(2) of the Act, the State plan may impose premiums upon individuals whose family income exceeds 150 percent of the FPL applicable to a family of the size involved provided that, as described at section 1916A(b)(2)(A) of the Act, the total aggregate amount of premiums and cost sharing imposed under section 1916 and 1916A of the Act not exceed 5 percent of the family income. In accordance with the statute, at § 447.74(a), we proposed that the State plan can impose premiums upon individuals with family income above 150 percent of the FPL subject to the

aggregate limit on premiums and cost sharing.

Section 1916A(b)(2)(B) of the Act provides that, in the case of individuals whose family income exceeds 150 percent of the FPL applicable to a family of the size involved, cost sharing imposed under the State plan may not exceed 20 percent of the cost of that item (including a non-preferred drug) or service. Therefore, in accordance with the statute, we proposed at § 447.74(b) that cost sharing for those individuals under the State plan not exceed 20 percent of the payment the agency makes for that item or service. In the case of States that do not have fee-for-service payment rates, we proposed that any copayment that the State imposes for services provided by an MCO may not exceed \$5.20 for FY 2007. This proposal would provide greater flexibility to State Medicaid programs consistent with that provided to State SCHIP programs. Thereafter, any copayment that the State imposes for services provided by an MCO may not exceed this amount as updated each October 1 by the percentage increase in the medical care component of the CPI-U for the period of September to September ending in the preceding calendar year and then rounded to the next highest 10-cent increment.

Section 1916A(b)(2)(A) of the Act provides that the total aggregate amount of cost sharing imposed under section 1916 and 1916A of the Act may not exceed 5 percent of the family income of the family involved, as applied on a quarterly or monthly basis as specified by the State. In accordance with the statute, we proposed at § 447.74(c) that aggregate cost sharing for individuals whose family income exceeds 150 percent of the FPL applicable to a family of the size involved, not exceed the maximum permitted under § 447.78(a). At § 447.78(a), we proposed that the total aggregate amount of premiums and cost sharing may not exceed 5 percent of the family's income for the monthly or quarterly period, as specified in the State plan.

We did not receive any specific comments on this proposal; therefore, we are adopting it in this final rule, without change. We note that we did receive comments on rounding up the nominal amounts by the next highest 10-cent increment, the managed care maximum amount and the cost sharing that can be imposed for prescription drugs and non-emergency use of the hospital emergency room. For comments related to the 10-cent increment and the managed care maximum, we addressed these in § 447.54 in this preamble. As noted

earlier, for comments related to cost sharing for prescription drugs and non-emergency use of the hospital emergency room, we addressed these in § 447.70 in this preamble. We note that we revised the copayment that the state may impose for services provided by an MCO not to exceed from \$5.20 per visit for FY 2007 to \$3.15 for FY 2007, \$3.25 for FY 2008 and \$3.40 for FY 2009.

#### 10. Public Schedule (§ 447.76)

As previously discussed, section 1916 and 1916A of the Act provides authority for States to impose premiums and cost sharing for items and services, including prescription drugs and non-emergency use of a hospital emergency department. In addition, it requires a group or groups of individuals to make payment as a condition of eligibility or of receiving that item or service. In § 447.76(a), we proposed that State plans provide for schedules of premiums and cost sharing. In § 447.76(a), we proposed that the public schedule contain the following information: (1) Current premiums, enrollment fees, or similar fees; (2) current cost sharing charges; (3) the aggregate limits on premiums and cost sharing or only cost sharing; (4) mechanisms for making payments for required premiums and charges; (5) the consequences for an applicant or recipient who does not pay a premium or charge; and (6) a list of hospitals charging alternative cost sharing for non-emergency use of the emergency department. In addition, at § 447.76(b), we proposed that the State make the public schedule available to recipients, at the time of enrollment and reenrollment and when charges are revised, to applicants, all participating providers, and the general public.

Specific comments on this section and our responses to those comments are as follows:

*Comment:* One commenter requested that CMS provide for adequate notice to providers and beneficiaries.

*Response:* We agree with the commenter that adequate notice should be provided to providers and beneficiaries. We note that § 447.76 requires that the State make available to recipients, applicants, all participating providers, and the general public, a public schedule that includes, for example, the groups for which premiums and cost sharing will apply, the levels of current cost sharing and the populations for which cost sharing and premiums will be enforceable.

*Comment:* Several commenters believe that education would be imperative for Medicaid beneficiaries. The commenters stated that Medicaid patients are not accustomed to yearly

changes in their co-payments, and it is incumbent upon State Medicaid agencies and providers to educate beneficiaries so that the Medicaid patients know the co-payment amounts that should be paid.

*Response:* In terms of education to beneficiaries, we agree that it is important for individuals to be educated and informed as to the yearly changes and the premiums and cost sharing amounts they could be obligated to pay. In § 447.76 in this final rule, we require that States make available to recipients, applicants, all participating providers, and the general public, among other things, the current premiums, enrollment fees, or similar fees and the current cost sharing charges.

#### 11. Aggregate Limits on Alternative Premiums and Cost Sharing (§ 447.78)

Section 1916A(b)(1)(B)(ii) of the Act provides that the total aggregate amount of cost sharing imposed under section 1916 and 1916A of the Act upon individuals with family income above 100 percent but at or below 150 percent of the FPL may not exceed 5 percent of the family income, as applied on a quarterly or monthly basis as specified by the State. Section 1916A(c)(2)(C) of the Act reiterates that this aggregate limit includes cost sharing for prescription drugs and section 1916A(e)(2)(C) of the Act reiterates that this aggregate limit includes cost sharing for non-emergency use of a hospital emergency department. Section 1916A(b)(2)(A) of the Act provides that the total aggregate amount of premiums and cost sharing imposed under section 1916 and 1916A of the Act upon individuals with family income above 150 percent of the FPL may not exceed 5 percent of the family income, as applied on a quarterly or monthly basis as specified by the State. Again, section 1916A(c)(2)(C) of the Act reiterates that this aggregate limit includes cost sharing for prescription drugs, and section 1916A(e)(2)(C) of the Act reiterates that this aggregate limit includes cost sharing for non-emergency use of a hospital emergency department. Finally, section 1916A(a)(2)(B) of the Act provides that to the extent that cost sharing under section 1916A(c) of the Act for prescription drugs, cost sharing under section 1916A(e) of the Act for non-emergency use of a hospital emergency department, and/or cost sharing under section 1916 of the Act is imposed upon individuals whose family income is at or below 100 percent of the FPL, the total aggregate amount of premiums and cost sharing imposed may not exceed 5 percent of the family income.

In accordance with these provisions, at § 447.78(a), we proposed that for individuals with family income above 100 percent of the FPL the aggregate amount of premiums (when applicable) and cost sharing under section 1916 and 1916A of the Act not exceed 5 percent of a family's income for the monthly or quarterly period, as specified by the State in the State plan. At § 447.78(b), we proposed that for individuals whose family income is at or below 100 percent of the FPL the aggregate amount of cost sharing under sections 1916, 1916A(c), and/or 1916A(e) of the Act not exceed 5 percent of a family's income for the monthly or quarterly period, as specified by the State in the State plan. We also proposed at § 447.78(c) that family income shall be determined in a manner and for that period as specified by the State in the State plan. We clarified that States may use gross income to compute family income and that they may use a different methodology for computing family income for purposes of determining the aggregate limits than for determining income eligibility.

Specific comments on this section and our responses to those comments are as follows:

*Comment:* Several commenters stated that Medicaid patients may not be able to track their cost sharing spending and premiums for a month, and it should not be the responsibility of the pharmacy or provider to have to keep track. The commenters stated that Medicaid patients may not use the same pharmacy and other non-pharmacy Medicaid cost sharing applies to the limits. They further indicated that most States require families in SCHIP to track their own out of pocket spending to prove they have met the 5 percent income limit. Presumably States would also use this "shoebox" method with any Medicaid cost sharing changes. Therefore, the commenters stated that States should be required to track out of pocket spending for families, who will already be under enough burden having to come up with the additional money for cost sharing and premiums.

*Response:* We agree with the commenter's suggestion that States should be required to track premiums and cost sharing. We do not prescribe the way States ensure that the total aggregate amount of premiums and cost sharing for all individuals in the family does not exceed 5 percent of the family income as applied during the monthly or quarterly period specified by the State. We have maintained the flexibility granted to States by the DRA. However, we require at § 447.68 that the State plan describe the methodology the

State will use to ensure that the aggregate amount of premiums and cost sharing imposed for individuals does not exceed 5 percent of the family income. We also require that the State plan describe the State's methods for tracking cost sharing charges, informing recipients and providers of their liability, and notifying recipients and providers when individual recipients have reached their aggregate limit on premiums and cost sharing. States have the flexibility to use the "shoebox" method for tracking the aggregate 5 percent cap. This would require a collection of receipts by beneficiaries and a validation process by the State to ensure that individuals have met their aggregate limits. States may use any other method to track the aggregate 5 percent cap (that is; States can program their automated systems to track and compute recipients' cost sharing).

*Comment:* Several commenters stated that CMS should provide for enhanced administrative match available to States that implement a system to track cost sharing. Commenters believe that CMS should offer states Federal financial participation at the 90/10 match rate to implement Medicaid Management Information System (MMIS) modifications/enhancements to accommodate the tracking of cost sharing.

*Response:* For modifications/enhancements to the MMIS to accommodate the tracking of cost sharing are eligible for MMIS rates 90 percent Federal financial participation (FFP) for design, development and installation of the enhancements, and 75 percent FFP for operation of the system are currently available. The approach States choose to track these costs is left to each State's discretion. Should they elect to make changes to their MMIS, the previously mentioned rates are applicable. Other electronic solutions outside of the MMIS are eligible for a 50 percent FFP administrative match.

*Comment:* Other commenters feel that this information can be generated electronically and should be an important element in the Federal government's efforts to make patient records, e-prescribing, and claims billing inter-operative electronically.

*Response:* States should have systems that best meet their needs in terms of electronic billing, electronic patient records and electronic prescribing for prescription drugs and States are in the best position to determine what best meets their needs. We note that the Federal government is also interested in ways to improve the Medicaid program and Congress provided for \$150 million in grant funds to be awarded to States

for Medicaid transformation. We awarded the funds in 2007 for projects which presented innovative ideas in operating their Medicaid programs and provided for replication and sustainability well into the future. Several of these projects include health information technology components; for example, e-prescribing, electronic patient health records and Web-based patient information for clients that emphasize interoperability. We are not aware of State components that specifically address electronically tracking premiums and cost sharing, however, this activity is not precluded from either the grant awards or as a result of the requirements in the rule at § 447.68.

*Comment:* Some commenters believe that States should not seek to collect payments from pharmacists or providers that provided items and services in good faith if the provider believes that the patient has not yet met their monthly or quarterly aggregate cap. Since States use varying methods to calculate family income and the resulting cost sharing obligations, beneficiaries should not be expected to track their expenses. Individuals with such low incomes should not be expected to recoup money later because it will be very burdensome to them. Commenters stated that this requirement places a large burden on low income families. In addition, it places a burden on Medicaid providers which will need to rely on self-reporting by Medicaid beneficiaries to determine whether to charge a co-payment.

*Response:* We are not attempting to prescribe the way in which States administer their Medicaid programs. However, if overpayments have been made because individuals have reached their 5 percent aggregate cap, and/or co-payments have been collected in error, States are responsible for ensuring that individuals are made whole. As mentioned previously, we require in § 447.68 that States describe the method that will be used for tracking cost sharing and for notifying recipients and providers when individual recipients have reached their 5 percent aggregate cap.

*Comment:* One commenter requests clarification of the total aggregate amount of cost sharing and the provider's discretion to waive or reduce the cost sharing. The commenter stated that § 447.80 in the proposed rule indicates that a provider may waive or reduce cost sharing imposed under section 1916A of the Act on a case-by-case basis. The commenter wonders how or if the waived or reduced co-payment will be factored or counted towards the 5 percent family income

cap even though it was waived. Many commenters agree that providers should be able to decide when to reduce or waive cost sharing on a case-by-case basis.

*Response:* In terms of providers waiving or reducing cost sharing and the calculation of the 5 percent aggregate cap, we note that in order to meet the 5 percent aggregate cap, individuals must have out of pocket spending. If a co-payment is waived, there is no out of pocket spending. In tracking the cost sharing, if a provider chooses to waive the cost sharing obligation, there is no receipt—no payment has been made; thus, the 5 percent cap remains constant and no cost sharing is applied to the cap.

Again, the ability to waive or reduce cost sharing is at provider discretion on a case-by-case basis.

*Comment:* One commenter stated that the proposed rule would implement aggregate cost sharing restrictions by placing percentage-of-income caps "on the total aggregate amount of premiums and cost sharing under section 1916, 1916A(c), or 1916A(e) of the Act." The commenter stated that the language should be revised to include cost sharing that may apply under any provision of law, including those imposed by a State benchmark or benchmark-equivalent plan adopted under section 1937 of the Act.

*Response:* We agree with the commenter recommending that the cost sharing permissible by the DRA should also apply to the benchmark flexibility also added by the DRA.

We promulgated a proposed rule for State Flexibility for Medicaid Benefit Packages (73 FR 9714 through 9727). The proposed rule was published on February 22, 2008 and, similar to this rule, comments were due on March 24, 2008. In that proposed rule, we require that if premiums and/or cost sharing are imposed under one of the benchmark or benchmark-equivalent plans authorized by the DRA, cost sharing and premiums for recipients may not exceed cost sharing limits under the State's plan with respect to Sections 1916 and/or 1916A of the Act.

*Comment:* In determining family income and the resulting cost sharing obligations, commenters believe that the proposed rule encourages States to use gross income standards or methods which will result in more cost sharing. The DRA specifies that "family income shall be determined in a manner specified by the State \* \* \*, including the use of such disregards as the State may provide." Commenters stated that Congress intended that States could be more generous and apply additional

disregards for calculating income to lessen the amount of income and the aggregate level of permissible cost sharing. The commenters stated that CMS should allow States to use the same methodology that States use in determining family income for purposes of determining Medicaid eligibility (including the use of disregards) or a different methodology that results in more disregards, and therefore, less cost sharing for Medicaid beneficiaries.

*Response:* States should have the flexibility to use the same methodology in determining family income as they do in determining eligibility or a different methodology that results in more disregards. We specify in § 447.78 that family income shall be determined in a manner and for the period specified by the State in the State plan, including the use of such disregards as the State may provide. In addition, we specifically provided that States may use gross income or any other methodology to compute family income.

We note that two different tests have been set out in law. For cost sharing, the law provides that family income shall be determined in a manner specified by the State (including the use of State-specified disregards) for purposes of the cost sharing provision. The State is entitled by law to determine family income using a methodology other than the one it uses for eligibility purposes, and the use of disregards is a State option. In this respect, the rule reflects the law and does not contain new discretionary policy. For eligibility determinations, there is a more specific test in Section 1902(r)(2) of the Act which provides that income eligibility for purposes of determining eligibility shall be no more restrictive than the methodologies used by the cash assistance programs (primary SSI for the aged, blind, and disabled, and AFDC for families and children). The use of methodologies that are no more restrictive than cash assistance methodologies (including the cash assistance disregards) is a mandatory requirement under title XIX of the Act and is not at State discretion.

The DRA does not tie the cost sharing family income determinations to the mandatory statutory requirements for determining Medicaid eligibility.

In practice, the impact to beneficiaries for eligibility purposes is in applying a methodology for determining eligibility based on income and the use of income disregards (that is, individuals that may not have previously been determined eligible for Medicaid may now be determined eligible). The impact to beneficiaries for cost sharing purposes is dependent upon how the State exercises

the flexibility the law provides to determine income for purposes of cost sharing. If income disregards are used, the cost sharing amounts would be computed based on a lower income threshold, and, therefore, individuals would pay less cost sharing relative to their total income. If income disregards are not used, individuals are paying cost sharing amounts that are consistent with total income. The DRA does not provide the authority to mandate the use of the eligibility methodologies for determining family income for cost sharing. We note that States have the option to use the same methodologies for determining family income as they do for determining eligibility or to use a different methodology.

We believe it would have been an intrusion on the flexibility given to States for cost sharing to tie the methodologies for determining family income to the eligibility methodologies.

#### 12. Enforceability of Alternative Premiums and Cost Sharing (§ 447.80)

Section 1916A(d)(1) of the Act permits a State to condition Medicaid eligibility upon the prepayment of premiums imposed under section 1916A of the Act or to terminate Medicaid eligibility for the failure to pay a premium for 60 days or more.

In accordance with the statute, we proposed at § 447.80(a), to permit a State to condition eligibility for a group or group of individuals upon prepayment of premiums, to terminate the eligibility of an individual from a group or groups of individuals for failure to pay for 60 days or more, and to waive payment in any case where requiring the payment would create undue hardship.

Section 1916A(d)(2) of the Act permits a State to allow a provider to require that an individual, as a condition of receiving an item or service, pay the cost sharing charge imposed under section 1916A of the Act. The provider is not prohibited by this authority from choosing to reduce or waive cost sharing on a case-by-case basis. However, section 1916A(a)(2)(A) of the Act specifies that section 1916A(d)(2) of the Act shall not apply in the case of an individual whose family income does not exceed 100 percent of the FPL applicable to a family of the size involved.

In accordance with the statute, at § 447.80(b), we proposed that a State may permit a provider, including a pharmacy, to require an individual to pay cost sharing imposed under section 1916A of the Act as a condition of receiving an item or service. However, at § 447.80(b)(1), we specified that a

provider, including a pharmacy or hospital, may not require an individual whose family income is at or below 100 percent of the FPL to pay the cost sharing charge as a condition of receiving the item or service. In addition, at § 447.80(b)(2), we proposed that a hospital that has determined after an appropriate medical screening under section 1867 of the Act that an individual does not have an emergency medical condition must first provide the name and location of an available and accessible alternate non-emergency services provider, the fact that the alternate provider can provide the services without the imposition of that cost sharing, and a referral to coordinate scheduling of treatment before it can require payment of the cost sharing. Finally, at § 447.80(b)(3), we proposed that a provider may reduce or waive cost sharing imposed under section 1916A of the Act on a case-by-case basis.

Specific comments on this section and our responses to those comments are as follows:

*Comment:* Several commenters stated that increasing cost sharing amounts without making them enforceable does little to encourage the use of more cost-effective medications, but potentially shifts the economic burden to the pharmacy.

*Response:* To the extent that pharmacies are precluded from conditioning services on the payment of cost sharing for individuals with family incomes at or below 100 percent of the FPL, this rule reflects the unambiguous provisions of the statute. Congress was clear to protect certain Medicaid beneficiaries from enforceability of premiums and cost sharing. We believe Congress intended to protect our Nation's most vulnerable low-income beneficiaries. For higher income individuals, the law and as specified in this final rule, gives States and providers new tools to enforce cost sharing obligations.

*Comment:* Some commenters request clarification as to whether the refusal of service to individuals who do not pay co-payments also apply to SCHIP and Medicaid managed care enrollees.

*Response:* The only revision to the SCHIP program made by this rule is to update the nominal amounts and the maximum allowable charges imposed (see § 457.555). We do not address the SCHIP program in any other way. If any provision regarding enforceability exists, it would be as a result of the SCHIP statutory and regulatory provisions and not as part of this rule.

Since Medicaid managed care enrollees are participants in the

Medicaid program and these rules apply to Medicaid programs, the enforceability provisions will apply. The specific enforceability provisions apply to beneficiaries enrolled in Medicaid managed plans with family incomes above 100 percent of the FPL if the State has opted to apply the enforceability provisions under section 1916A of the Act.

#### 13. Restrictions on Payments to Providers (§ 447.82)

Proposed § 447.82 requires States to reduce the amount of State payments to providers by the amount of recipients' cost sharing obligations under section 1916A of the Act. However, States have the ability to increase total State plan rates to providers to maintain the same level of State payment when cost sharing is introduced.

Specific comments on this section and our responses to those comments are as follows:

*Comment:* Some commenters stated that CMS has exceeded its authority by interpreting the DRA to mean that States *must* reduce provider reimbursement rates irrespective of whether the provider has successfully collected the co-payments. The commenters indicated that the statute does not suggest that Congress intended to mandate how states set their reimbursement rates. They also indicated that the statutory provision could set a dangerous precedent, the proposed § 447.82 creates an additional, unnecessary barrier to beneficiary access to services. In addition, they indicated that this provision would require States to reduce their provider reimbursement rates by co-payment amounts, irrespective of whether the co-payments were actually collected by the provider. This would severely impact providers' ability to limit cost sharing and ensure that Medicaid beneficiaries receive needed drugs and services.

Some commenters stated that this section should be completely removed from the proposed rule.

Other commenters stated that because of § 447.82, the possibility of providers waiving or reducing the required co-payment is minor since any unpaid amounts would ultimately be borne by the provider. The commenters stated that this is essentially a shift from the States to our nation's safety net providers (including health centers, title X family planning clinics, home health agencies, home and community based service providers), many of whom are already struggling to make ends meet with inadequate Medicaid payment rates. These providers should not be financially penalized further because of

an inability to collect a co-payment from the neediest of patients.

One commenter also stated that, to require States to cut reimbursement rates by cost sharing amounts, but allow them to increase their overall reimbursement rate to providers to offset the cut is insufficient in alleviating the harm to providers as states facing their own budget constraints would unlikely provide an overall rate increase.

*Response:* We disagree that this section of the rule should be deleted in its entirety. We are not intending to prescribe the way States set their provider rates. However, we are ensuring that duplicate payment is not made (that is, Medicaid should not be responsible for paying amounts for which the beneficiary is liable). We have always required in regulations that provider rates, in considering cost sharing obligations, are net of the cost sharing obligations of Medicaid beneficiaries.

**C. SCHIP Regulations**

**1. Maximum Allowable Cost Sharing Charges on Targeted Low-Income Children in Families With Incomes From 101 to 150 Percent of the FPL (§ 457.555)**

We proposed in § 457.555, to update the existing "nominal" SCHIP cost sharing amounts, specifically the copayment amounts described at § 457.555(a)(1) and (2), (c), and (d) and the deductible amount described at § 447.555(a)(4). In the proposed rule, we discussed in detail the statutory basis and the proposed methodology for updating the nominal amounts (73 FR 9727 through 9740). Based on this methodology, we proposed the following copayment maximum amounts:

Total cost of services * * *	Maximum amount * * *
\$15.00 or less .....	\$1.10
\$15.01 to \$40 .....	2.10
\$40.01 to \$80 .....	3.20
\$80.01 or more .....	5.20

We also proposed that the copayments for services provided by an MCO and for emergency services provided by an institution not exceed \$5.20 per visit and that the copayment for non-emergency services furnished in a hospital emergency room to targeted low-income children with family income from 101 to 150 percent of the FPL not exceed \$10.40. Finally, we proposed that a deductible not exceed \$3.20 per family per month.

We proposed that States should use these updated nominal amounts during FY 2007. Thereafter, we proposed to update these amounts each October 1 by the percentage increase in the medical care component of the CPI-U for the period of September to September ending in the preceding calendar year and then rounding to the next higher 10-cent increment.

CMS received comments regarding the updating of the nominal amounts for both Medicaid and SCHIP by the MCPI-U and addressed the issues related to both Medicaid and the specific updates to the SCHIP regulations in our discussion above related to § 447.54. As discussed in that section, in response to comments, we have revised our rounding increment to the next higher 5-cent increment.

**III. Provisions of the Final Rule**

In this final rule, we are adopting the proposed provisions as set forth in the February 22, 2008, proposed rule, subject to the following changes.

*Section 447.54—Maximum Allowable and Nominal Charges by—*

+ Revised paragraph (a)(1) by updating the nominal deductible amount for Federal FY 2009 to not exceed \$2.30 per month per family for each period of Medicaid eligibility. We also updated the nominal amounts for Medicaid, rounded to the next highest 5-cent increment rather than 10 cents to be consistent with the Medicare Part D program.

+ Revised paragraph (a)(3)(i) by updating the maximum copayments for FY 2009 that are imposed under a fee-for-service delivery system, rounded to the next highest 5-cent increment rather than 10 cents to be consistent with the Medicare Part D program. The copayments will not exceed the amounts specified in the table below.

State payment for the service	Maximum copayment
\$10 or less .....	\$ 0.60
\$10.01 to \$25 .....	1.15
\$25.01 to \$50 .....	2.30
\$50.01 or more .....	3.40

+ Revised paragraph (a)(3)(ii) to clarify that in updating the nominal amounts for Medicaid, we rounded to the next highest 5-cent increment rather than 10 cents to be consistent with the Medicare Part D program. In addition, we clarify that we calculate the update each year without considering any rounding adjustment made in the previous year.

+ Added a new paragraph (a)(4) to update the Federal FY 2009 maximum

Medicaid managed care amount to be aligned with the Medicaid fee-for-service amount and the Federal FY 2009 maximum Medicaid expansion SCHIP managed care amount to be aligned with the SCHIP fee-for-service amount. We note that paragraph (a)(4) now reads: "For Federal FY2009, any copayment for services provided by an MCO may not exceed the copayment permitted under subparagraph (3)(i) for comparable services under a fee-for-service delivery system, except as provided in this paragraph. When there is no fee-for-service delivery system, the copayment may not exceed \$3.40 per visit or for individuals referenced in an approved State child health plan under title XXI of the Act pursuant to § 457.70(c), \$5.70 per visit. In succeeding years \* \* \* ending in the preceding calendar year and then rounded to the next higher 5-cent increment".

*Section 447.71—Alternative Premium and Cost-Sharing Exemptions and Protections for Individuals With Family Income At or Below 100 Percent of the FPL*

+ Redesignated paragraph (b)(1) as paragraph (b)(2), and paragraph (b)(2) as paragraph (b)(3).

+ Added a new paragraph (b)(1) to clarify that States may impose cost sharing under the State plan on individuals whose family income is at or below 100 percent of the FPL in accordance with section 1916 of the Act and consistent with § 447.54.

*Section 447.72—Alternative Premium and Cost Sharing Exemptions and Protections for Individuals With Family Incomes Above 100 Percent but At or Below 150 Percent of the FPL*

+ Revised paragraph (b)(3) by updating the copayment amount to not exceed \$3.40 per visit for Federal FY 2009. We also state that individuals referenced in an approved State child health plan under title XXI of the Act in accordance with § 457.70(c), the copayment is not to exceed \$5.70 per visit for Federal FY 2009. In addition, we updated the nominal amounts for Medicaid, rounded to the next highest 5-cent increment rather than 10 cents to be consistent with the Medicare Part D program.

*Section 447.74—Alternative Premium and Cost Sharing Protections for Individuals With Family Incomes Above 150 Percent of the FPL*

+ Revised paragraph (b) by updating the copayment amount to not exceed \$3.40 per visit for Federal FY 2009. We also stated that individuals referenced

in an approved State child health plan under title XXI of the Act pursuant to § 457.70(c), the copayment is not to exceed \$5.70 for Federal FY 2009. In addition, we updated the nominal amounts for Medicaid, rounded to the next highest 5-cent increment rather than 10 cents to be consistent with the Medicare Part D program.

#### Section 447.76—Public Schedule

Added a new paragraph (a)(7) to specify that the State must make available a public schedule that contains either a list of preferred drugs or a method to obtain such a list upon request.

#### Section 447.78—Aggregate Limits on Alternative Premiums and Cost Sharing

Added to the end of paragraph (c) of this section the phrase, “\* \* \* including the use of such disregards as the State may provide.”

#### Section 457.555—Maximum Allowable Cost Sharing Charges on Targeted Low-Income Children in Families With Income From 101 To 150 Percent of the FPL

+ Revised paragraph (a)(1)(i) by updating the copayment amounts for Federal FY 2009. Any copayment or similar charge the State imposes under a fee-for-service delivery system may not exceed the following amounts:

Total cost	Maximum amount
\$15 or less .....	\$1.15
\$15.01 to \$40 .....	2.30
\$40.01 to \$80 .....	3.40
\$80.01 or more .....	5.70

+ Revised paragraph (a)(1)(ii) by updating the nominal amounts for Medicaid, rounded to the next highest 5-cent increment rather than 10 cents to be consistent with the Medicare Part D program.

+ Revised paragraph (a)(2) by updating the copayment amount to not exceed \$5.70 per visit for Federal FY 2009. We also updated the nominal amounts for Medicaid, rounded to the next highest 5-cent increment rather than 10 cents to be consistent with the Medicare Part D program.

+ Revised paragraph (a)(4) by updating the deductible amount to not exceed \$3.40 per month, per family for each period of eligibility for Federal FY 2009. We also updated the nominal amounts for Medicaid, rounded to the next highest 5-cent increment rather than 10 cents to be consistent with the Medicare Part D program.

+ Revised paragraph (c) “Institutional emergency services,” by updating the

copayment amount to not exceed \$5.70 for Federal FY 2009. We also updated the nominal amounts for Medicaid, rounded to the next highest 5-cent increment rather than 10 cents to be consistent with the Medicare Part D program.

+ Revised paragraph (d) “Non-emergency use of the emergency room,” by updating the maximum amount that the State can charge for non-institutional services to \$11.35 for Federal FY 2009. We also updated the nominal amounts for Medicaid, rounded to the next highest 5-cent increment rather than 10 cents to be consistent with the Medicare Part D program.

#### VI. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the *Federal Register* and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We solicited public comment on each of these issues for the following sections of this document that contain information collection requirements:

#### Section 447.64 Premiums, Enrollment Fees, or Similar Fees: State Plan Requirements

Section 447.64 requires a State imposing premiums, enrollment fees, or similar fees on individuals to describe in the State plan:

- The group or groups of individuals that may be subject to the premiums, enrollment fees, or similar charges.
- The schedule of the premiums, enrollment fees, or similar fees imposed.
- The methodology used to determine family income for purposes of the limitations related to family income level that are described below, including the period and periodicity of those determinations.
- The methodology used to ensure compliance with the requirements of

§ 447.78 that the aggregate amount of premiums and cost sharing imposed for all individuals in the family does not exceed 5 percent of the family income of the family involved.

- The process for informing the recipients, applicants, providers, and the public of the schedule of premiums, enrollment fees, or similar fees for a group or groups of individuals in accordance with § 447.76.

- The notice of, timeframe for, and manner of required premium payments for a group or groups of individuals and the consequences for an individual who does not pay.

The burden associated with this requirement is the time and effort it would take for a State to include this detailed description in the State plan. We estimate it would take one State approximately 20 minutes to incorporate this information in their plan. We believe 56 States will be affected by this requirement for a total annual burden of 18.67 hours.

#### Section 447.68 Copayments, Coinsurance, Deductibles, or Similar Cost Sharing Charges: State Plan Requirements

Section 447.68 requires a State imposing copayments, coinsurance, deductibles, or similar cost sharing charges on individuals to describe in the State plan:

- The group or groups of individuals that may be subject to the cost sharing charge.
- The methodology used to determine family income, for purposes of the limitations on cost sharing related to family income that are described below, including the period and periodicity of those determinations.
- The item or service for which the charge is imposed.
- The methods, such as the use of integrated automated systems, for tracking cost sharing charges, informing recipients and providers of their liability, and notifying recipients and providers when individual recipients have paid the maximum cost sharing charges permitted for the period of time.
- The process for informing recipients, applicants, providers, and the public of the schedule of cost sharing charges for specific items and services for a group or groups of individuals in accordance with § 447.76.
- The methodology used to ensure that:
  - The aggregate amount of premiums and cost sharing imposed for all individuals with family income above 100 percent of the FPL does not exceed 5 percent of the family income of the family involved.



○ The aggregate amount of cost sharing under sections 1916, 1916A(c), and/or 1916A(e) of the Act for individuals with family income at or below 100 percent of the FPL does not exceed 5 percent of the family income of the family involved.

○ The notice of, timeframe for, and manner of required cost sharing and the consequences for failure to pay.

The burden associated with this requirement is the time and effort it would take for a State to include this detailed description in the State plan. We estimate it would take one State approximately 20 minutes to incorporate this information in their plan. We believe 56 States will be affected by this requirement for a total annual burden of 18.67 hours.

*Comment:* Some commenters stated that this regulation poses a much greater administrative burden than that estimated by CMS and believe that the State plan requirements are quite burdensome and CMS' estimate of 20 minutes per state is inaccurate. Among other things, States would need to change State law, State policy would need to be changed, systems would need to be trained, providers would need to be notified, and most importantly, beneficiaries and their families, caretakers, and advocates would need to be informed. The commenter also indicated that the Regulatory Impact Analysis section of the proposed rule makes no reference to such costs on the States. In fact, the only estimate of the administrative burden on the States is in the Collection of Information Requirements where CMS estimates that it will take 20 minutes for a State to incorporate these requirements into a Medicaid State Plan. The commenters strongly disagree with this estimated time. The extensiveness of the requirements means that whenever a state might wish to change even a small portion of its plan, then a State Plan Amendment (SPA) would be required. This would be excessively burdensome on the States. Even with a State plan "pre-print" each State has unique processes for considering and requesting SPAs. In addition, each SPA must be accompanied by a CMS 179. The commenter also stated that CMS often asks one or more round of questions or requests more information, requiring additional State time and resources. Thus CMS' 20 minute estimate is in reality almost always more like tens of hours of staff time.

*Response:* In terms of the commenter's suggestion that the State plan requirements are quite burdensome

and the estimate of 20 minutes per State is inaccurate, we considered these comments and believe that the estimate is accurate. In order to minimize the amount of time needed to complete a SPA imposing alternative premiums and cost sharing, we provided guidance to States in two State Medicaid Director's letters and we designed three State plan preprints that allow States to complete almost all of the sections by checking a box next to each answer. We expect that before completing the CMS 179 and State plan preprint, a State will have fully developed the information that describes the way in which States will provide for alternative premiums and cost sharing and can insert or attach this information to the preprint. With that assumption in mind, we estimated that it would take no more than 20 minutes to check off the appropriate boxes and to insert or attach any already created information concerning the imposition of premiums and cost sharing that is necessary to the completion of the State plan amendment. In this regard, we have made no revisions to the regulatory impact analysis.

*Comment:* Several commenters stated that Medicaid providers would be required to assume a large administrative burden to collect co-payments from Medicaid beneficiaries or take a financial loss if they choose to forgo collection of cost sharing. Hospitals would be placed in a situation in which the hospital must pursue patients for small, unpaid amounts, and at the same time, face lower payments by the State Medicaid program because the state assumes that the hospital has collected the co-payments. Ultimately, hospitals would be forced to write-off these uncollected co-payments as bad debt.

*Response:* We disagree that there will be additional administrative burden and administrative costs associated with imposing premiums and cost sharing. Prior to the DRA, section 1916 of the Act authorized the imposition of premiums and cost sharing and Federal rules on this subject have been in existence since 1974. Several States have already taken advantage of the premiums and cost sharing provision outlined in Section 1916 of the Act. States and providers are already aware of the effort to implement and impose premiums and cost sharing for Medicaid beneficiaries. In fact, we recognize in the regulatory impact analysis that savings will occur because we believe that States that already impose cost sharing will opt to impose the alternative cost sharing permitted under this rule. Thus, no additional administrative costs will be borne. If

additional States choose to implement this option, more savings can accrue. We provide in Federal regulations that administrative costs are matched at 50 percent.

#### Section 447.76 Public schedule

Section 447.76(a) requires States to make available to the groups in paragraph (b) of § 447.76 a public schedule that contains the following information:

- Current premiums, enrollment fees, or similar fees.
- Current cost sharing charges.
- The aggregate limit on premiums and cost sharing.
- Mechanisms for making payments for required premiums and charges.
- The consequences for an applicant or recipient who does not pay a premium or charge.
- A list of hospitals charging alternative cost sharing for non-emergency use of the emergency department.

The burden associated with this requirement is the time and effort it would take the State to prepare and make available to appropriate parties a public schedule. We estimate that it would take 20 minutes per State. We believe 56 States will be affected by this requirement for an annual burden of 18.67 hours.

#### Section 447.80 Enforceability of premiums and cost sharing

Section 447.80(b)(2) states that a hospital that has determined after an appropriate medical screening pursuant to § 489.24, that an individual does not have an emergency medical condition before imposing cost sharing on an individual must provide the name and location of an available and accessible alternate non-emergency services provider as defined in section 1916A(e)(4)(B) of the Act, the fact that the alternate provider can provide the services with the imposition of a lesser cost sharing amount or no cost sharing, and a referral to coordinate scheduling of treatment by this provider before requiring payment of cost sharing.

The burden associated with this requirement is the time and effort it would take for a hospital to provide the name and location of an alternate provider who can provide services of a lesser cost sharing amount or no cost sharing and a referral. We estimate the burden on a hospital to be 30 minutes. We believe the number of hospital visits will be 4 million; therefore, the total annual burden is 2 million hours.

Specific comments on the burden associated with this requirement, and

our responses to those comments are as follows.

**Comment:** Several commenters stated that the Department has determined that this rule would not have a significant impact on the operations of a substantial number of small rural hospitals. Commenters stated the Department is plainly mistaken and that an impact analysis must be performed. Under proposed § 447.80, if a State imposes a co-payment for a beneficiary's non-emergency use of the hospital emergency room, the hospital must "provide the beneficiary the name and location of an available and accessible alternate non-emergency services provider", inform the beneficiary "that the alternate provider can provide the services with the imposition of a lesser cost sharing amount or no cost sharing," and provide "a referral to coordinate scheduling of treatment by" the non-emergency care provider. Presumably, a State may withhold payment from or otherwise penalize a hospital that fails to take these steps. The Department recognizes the requirement would impose a "burden" on hospitals because CMS estimates the burden on a hospital to be 30 minutes. CMS estimated the response burden for these information requirements to be 2 million hours.

One commenter stated that in a hospital emergency room, anything that requires an additional 30 minutes of staff time per patient and that implicates compliance with Medicaid rules would almost certainly have a significant impact on the hospital's operations.

**Response:** We are required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), and Executive Order 13132 on Federalism, and the Congressional Review Act (5 U.S.C. 804(2)) to conduct a regulatory analysis of the impact of any regulatory revision to the Medicare, Medicaid, and/or the SCHIP program before adoption of any rule. A Regulatory Impact Analysis was completed for this rule and estimates in the proposed rule that 2 million hours will be the annual burden in considering cost sharing for non-emergency use of the hospital emergency room.

We agree that the initial estimate of 30 minutes in the proposed rule is incorrect. Upon further review, we have determined that on average, it is estimated that for each patient triaged at the hospital emergency room and found by the hospital emergency room physician to have a non-emergency

medical condition which does not require emergency room treatment or stabilization, approximately five additional minutes will be required by staff to properly implement the requirements included in this rule. Our justification is that it will take no additional time for the emergency room physician or other health care provider to inform the beneficiary that he or she does not have an emergency medical condition which requires (further) care or stabilization in the hospital emergency room. The EMTALA legislation currently includes language that requires that individuals who present to the emergency room are screened for an emergency medical condition. Thus, this information is currently being conveyed to patients.

Since the State plan requirements under § 447.76 provide that the State must have, and make available, a public schedule that includes a listing of hospitals that charge alternative cost sharing for non-emergency use of the hospital emergency room and the current cost sharing charges, we believe hospitals will have the information available to inform Medicaid beneficiaries. We agree that it will not take 30 minutes to provide this information, but rather closer to five additional minutes. This information can and should be provided by the hospital emergency room registrar (that is, the person responsible for taking the information needed from patients to be seen in the emergency room) to inform the beneficiary that because the emergency room physician did not find that the patient has an emergency medical condition which requires (further) treatment (or stabilization) in the hospital emergency room and because the patient is a Medicaid beneficiary, the individual has a choice to go to a nearby alternate Medicaid provider or to receive treatment for the non-emergency medical condition at the emergency room but a higher co-pay can be imposed.

Consequently, we update the Collection of Information Requirements to indicate a revision in the annual burden from 2 million hours to approximately 300,000 hours. In considering this revision, we continue to believe that there is no significant impact on small rural hospitals.

We have updated the Collection of Information Requirements as follows:

**Section 447.80 Enforceability of Premiums and Cost Sharing**

Section 447.80(b)(2) states that a hospital that has determined after an appropriate medical screening pursuant to § 489.24, that an individual does not

have an emergency medical condition before imposing cost sharing on an individual must provide: The name and location of an available and accessible alternate non-emergency services provider as defined in section 1916A(e)(4)(B) of the Act; the fact that the alternate provider can provide the services with the imposition of a lesser cost sharing amount or no cost sharing; and a referral to coordinate scheduling of treatment by this provider before requiring payment of cost sharing.

The burden associated with this requirement is the time and effort it would take for a hospital to provide the name and location of an alternate provider who can provide services of a lesser cost sharing amount or no cost sharing and a referral. We estimate the burden on a hospital to be 5 minutes. We believe the number of hospital visits will be 4,077,000; therefore, the total annual burden is 339,750 hours.

We have submitted a copy of this final rule to OMB for its review of the information collection requirements described above. These requirements are currently approved under OMB number 0938-0993.

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this rule; or
2. Mail copies to the address specified in the **ADDRESSES** section of this rule and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, *Attn:* CMS Desk Officer, *CMS-4064-F@omb.eop.gov*. Fax (202) 395-6974.

**Regulatory Impact Analysis**

**A. Overall Impact**

We have examined the impacts of this final rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), and Executive Order 13132 on Federalism, and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 (as amended by Executive Order 13258), directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential

economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). We estimated that this rule is "economically significant" as measured by the \$100 million threshold, and hence is also a major rule under the Congressional Review Act. Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking.

The RFA requires agencies to analyze options for regulatory relief of small businesses, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the Small Business Administration definition of a small business (having revenues of less than \$6.5 million to \$31.5 million in any 1 year). Individuals and States are not included in the definition of a small

entity. We have determined, and the Secretary certifies, that this rule would not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Core-Based Statistical Area and has fewer than 100 beds. We have determined, and the Secretary certifies, that this rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4) also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditures in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$100 million in 1995, updated annually for inflation. In 2008, that threshold

level is approximately \$130 million. We have determined that this rule would likely result in new spending by Medicaid enrollees in excess of the threshold. Table 2 outlines the total increase to Medicaid enrollees cost sharing as a result of all the provisions of the DRA. This includes an estimated cost increase to Medicaid recipients of \$105 million in 2007, \$155 million in 2008, \$255 million in 2009, \$375 million in 2010, and \$455 million in 2011.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have determined that this rule would not impose substantial direct requirement costs on State and local governments.

*B. Anticipated Effects*

The following chart summarizes our estimate of the anticipated effects of this final rule.

TABLE 1—ESTIMATED SAVINGS OF THE COST SHARING PROVISIONS OF THE DEFICIT REDUCTION ACT (DRA) OF 2005

	Savings in millions of dollars					Total savings over 5 year period
	2007	2008	2009	2010	2011	
<b>Federal Share</b>						
Sec. 6041 Optional alternative premiums/cost sharing .....	65	85	135	190	220	695
Sec. 6042 Cost sharing for prescription drugs .....	40	65	120	185	240	650
Sec. 6043(a) Copays for non-emergency care in ER .....	5	10	15	20	25	75
<b>State Share</b>						
Sec. 6041 Optional alternative premiums/cost sharing .....	50	65	105	145	165	530
Sec. 6042 Cost sharing for prescription drugs .....	30	50	90	140	180	490
Sec. 6043(a) Copays for non-emergency care in ER .....	5	5	10	15	20	55

TABLE 2—MEDICAID ENROLLEES COST SHARING IMPACT AS A RESULT OF THE PROVISIONS OF THE DEFICIT REDUCTION ACT (DRA) OF 2005

	Costs in millions of dollars					Total increase in cost sharing over 5 year period
	2007	2008	2009	2010	2011	
<b>Medicaid Enrollee Share</b>						
Total increase in Medicaid enrollee cost sharing for all provisions .....	105	155	255	375	455	1345

These estimates are based on data regarding copayments in the Medicaid program derived from a 2004 Kaiser Family Foundation survey, and data on premiums from a 2004 report by the U.S. Government Accountability Office. In addition, we have used enrollment data from the Medicaid Statistical Information System and utilization data from the 2002 Medicaid Expenditure Panel Survey conducted by the Agency for Healthcare Research and Quality.

We assume that only states that currently charge copayments and/or premiums for some groups will take advantage of the option to expand the use of premiums and copayments under the DRA provisions. States now charging copayments are assumed to increase them on average to 75 percent of maximum possible levels by 2011, and States currently charging premiums are assumed to add premium requirements for some groups not currently allowed, also reaching 75 percent of the maximum possible by 2011.

In addition to direct savings from increased cost sharing, we assume there

would be declines in utilization as some enrollees subject to new cost sharing requirements choose to decrease their use of services. The decline is assumed to create additional savings of 75 percent of direct savings for physician and outpatient hospital services, 100 percent for drugs, and 125 percent for dental services. These additional savings are assumed to be reduced somewhat as a result of some providers failing to collect copayments. Savings are split between Federal and State governments using an average matching rate of 57 percent.

Table 2 illustrates that the estimated impact for Medicaid enrollees as a result of all of the cost sharing provisions of the DRA are \$105 million for 2007, \$155 million for 2008, \$255 million for 2009, \$375 million for 2010, and \$455 million for 2011. Although these estimates reflect an increase of costs to beneficiaries, we do not believe this will pose a barrier to accessing health care. The law provides that States can impose alternative cost sharing. We believe through the use of alternative cost sharing, States will help recipients

become more educated and efficient health care consumers.

We did not receive any comments on this section.

*C. Alternatives Considered*

This final rule is necessary to implement section 1916A of the Social Security Act, which was established by the Deficit Reduction Act of 2005 (DRA) and amended by the Tax Relief and Health Care Act of 2006 (TRHCA). Therefore, we were not able to consider any alternatives.

*D. Accounting Statement and Table*

As required by OMB Circular A-4 (available at <http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf>), in the table below, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this rule. This table provides our best estimate of the decrease in Medicaid payment as a result of the changes presented in this final rule. All savings are classified as transfers to the Federal government.

TABLE 2—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES, FROM FY 2007 TO FY 2011  
— [In millions]

Category	TRANSFERS				
Annualized Monetized Transfers .....	3% Units Discount Rate \$278.2		7% Units Discount Rate \$270.7		
From Whom To Whom? .....	Beneficiaries to Federal Government				
Category	TRANSFERS				
Year	2007	2008	2009	2010	2011
Annualized Monetized Transfers .....	\$110	\$160	\$270	\$395	\$485
From Whom to Whom? .....	Beneficiaries to Federal Government				
Category	TRANSFERS				
Annualized Monetized Transfers .....	3% Units Discount Rate \$210.6		7% Units Discount Rate \$205.0		
From Whom To Whom? .....	Beneficiaries to State Governments				
Category	TRANSFERS				
Year	2007	2008	2009	2010	2011
Annualized Monetized Transfers .....	\$85	\$120	\$205	\$300	\$365
From Whom to Whom? .....	Beneficiaries to State Governments				

*E. Conclusion*

We expect that this final rule will promote the modernization of the Medicaid program. This final rule will also provide a new option to States to create programs that are aligned with today's Medicaid populations and the

health care environment. Through alternative cost sharing, States will help recipients become more educated and efficient health care consumers.

In accordance with the provisions of Executive Order 12866, this regulation

was reviewed by the Office of Management and Budget.

**List of Subjects**  
42 CFR Part 447

Accounting, Administrative practice and procedure, Drugs, Grant programs—

health, Health facilities, Health professions, Medicaid, Reporting and recordkeeping requirements, Rural areas.

42 CFR Part 457

Administrative practice and procedure, Grant programs—health, Health insurance, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

**PART 447—PAYMENTS FOR SERVICES**

■ 1. The authority citation for part 447 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

- 2. Section 447.54 is amended by—
    - A. Revising the section heading.
    - B. Adding a new introductory text.
    - C. Revising paragraph (a) introductory text.
    - D. Revising paragraph (a)(1) and paragraph (a)(3).
    - E. Adding a new paragraph (a)(4).
- The additions and revisions read as follows.

**§ 447.54 Maximum allowable and nominal charges.**

Except as provided at §§ 447.62 through 447.82 of this part, the following requirements must be met:

(a) *Non-institutional services.* Except as specified in paragraph (b) of this section, for non-institutional services, the plan must provide that the following requirements are met:

(1) For Federal FY 2009, any deductible it imposes does not exceed \$2.30 per month per family for each period of Medicaid eligibility. For example, if Medicaid eligibility is certified for a 3-month period, the maximum deductible which may be imposed on a family is \$6.90. Thereafter, any deductible should not exceed these amounts as updated each October 1 by the percentage increase in the medical care component of the CPI-U for the period of September to September ending in the preceding calendar year, and then rounded to the next higher 5-cent increment.

(3)(i) For Federal FY 2009, any copayments it imposes under a fee-for-service delivery system do not exceed the amounts shown in the following table:

State payment for the service	Maximum copayment
\$10 or less .....	\$0.60

State payment for the service	Maximum copayment
\$10.01 to \$25 .....	1.15
\$25.01 to \$50 .....	2.30
\$50.01 or more .....	3.40

(ii) Thereafter, any copayments should not exceed these amounts as updated each October 1 by the percentage increase in the medical care component of the CPI-U for the period of September to September ending in the preceding calendar year and then rounded to the next higher 5-cent increment.

(4) For Federal FY 2009, any copayment for services provided by an MCO may not exceed the copayment permitted under paragraph (a)(3)(i) of this section for comparable services under a fee-for-service delivery system, except as provided in this paragraph. When there is no fee-for-service delivery system, the copayment may not exceed \$3.40 per visit or for individuals referenced in an approved State child health plan under title XXI pursuant to § 457.70(c), \$5.70 per visit. In succeeding years, any copayment should not exceed these amounts as updated each October 1 by the percentage increase in the medical care component of the CPI-U for the period of September to September ending in the preceding calendar year and then rounded to the next higher 5-cent increment.

■ 3. Section 447.55 is amended by revising paragraph (b) to read as follows:

**§ 447.55 Standard co-payment.**

(b) This standard copayment amount for any service may be determined by applying the maximum copayment amounts specified in § 447.54(a) and (b) to the agency's average or typical payment for that service. For example, if the agency's typical payment for prescribed drugs is \$4 to \$5 per prescription, the agency might set a standard copayment of \$.60 per prescription. This standard copayment may be adjusted based on updated copayments as permitted under § 447.54(a)(3).

■ 4. Add a new undesignated center heading immediately following § 447.60 and add new §§ 447.62, 447.64, 447.66, 447.68, 447.71, 447.72, 447.74, 447.76, 447.78, 447.80, and 447.82 to read as follows:

\* \* \* \* \*

**Alternative Premiums and Cost Sharing Under Section 1916A**

- 447.62 Alternative premiums and cost sharing: Basis, purpose and scope.
- 447.64 Alternative premiums, enrollment fees, or similar fees: State plan requirements.
- 447.66 General alternative premium protections.
- 447.68 Alternative copayments, coinsurance, deductibles, or similar cost sharing charges: State plan requirements.
- 447.70 General alternative cost sharing protections.
- 447.71 Alternative premium and cost sharing exemptions and protections for individuals with family incomes at or below 100 percent of the FPL.
- 447.72 Alternative premium and cost sharing exemptions and protections for individuals with family incomes above 100 percent but at or below 150 percent of the FPL.
- 447.74 Alternative premium and cost sharing protections for individuals with family incomes above 150 percent of the FPL.
- 447.76 Public schedule.
- 447.78 Aggregate limits on alternative premiums and cost sharing.
- 447.80 Enforceability of alternative premiums and cost sharing.
- 447.82 Restrictions on payments to providers.

**Alternative Premiums and Cost Sharing Under Section 1916A**

**§ 447.62 Alternative premiums and cost sharing: Basis, purpose and scope.**

(a) Section 1916A of the Act sets forth options for alternative premiums and cost sharing, which are premiums and cost sharing that are not subject to the limitations under section 1916 of the Act as described in §§ 447.51 through 447.56. For States that impose alternative premiums, §§ 447.64 through 447.66, 447.72, 447.74, 447.78, and 447.80 prescribe State plan requirements and options for alternative premiums and the standards and conditions under which States may impose them. For States that impose alternative cost sharing, §§ 447.68 through 447.72, 447.74, 447.78, and 447.80 prescribe State plan requirements and options for alternative cost sharing and the standards and conditions under which States may impose alternative cost sharing. For other individuals, premiums and cost sharing must comply with the requirements described in §§ 447.50 through 447.60.

(b) Neither section 1916A of the Act nor the regulations referenced in paragraph (a) of this section affect the following:

(1) The Secretary's authority to waive limitations on premiums and cost sharing under this subpart.

(2) Existing waivers with regard to the imposition of premiums and cost sharing.

**§ 447.64 Alternative premiums, enrollment fees, or similar fees: State plan requirements.**

When a State imposes alternative premiums, enrollment fees, or similar fees on individuals, the State plan must describe the following:

(a) The group or groups of individuals that may be subject to the premiums, enrollment fees, or similar charges.

(b) The schedule of the premiums, enrollment fees, or similar fees imposed.

(c) The methodology used to determine family income for purposes of the limitations related to family income level that are described below, including the period and periodicity of those determinations.

(d) The methodology used to ensure compliance with the requirements of § 447.78 that the aggregate amount of premiums and cost sharing imposed for all individuals in the family do not exceed 5 percent of the family income of the family involved.

(e) The process for informing the recipients, applicants, providers, and the public of the schedule of premiums, enrollment fees, or similar fees for a group or groups of individuals in accordance with § 447.76.

(f) The notice of, time frame for, and manner of required premium payments for a group or groups of individuals and the consequences for an individual who does not pay.

**§ 447.66 General alternative premium protections.**

(a) States may not impose alternative premiums upon the following individuals:

(1) Individuals under 18 years of age that are required to be provided medical assistance under section 1902(a)(10)(A)(i) of the Act, and including individuals with respect to whom child welfare services are made available under Part B of title IV of the Act on the basis of being a child in foster care and individuals with respect to whom adoption or foster care assistance is made available under Part E of that title, without regard to age.

(2) Pregnant women.

(3) Any terminally ill individual receiving hospice care, as defined in section 1905(o) of the Act.

(4) Any individual who is an inpatient in a hospital, nursing facility, intermediate care facility, or other medical institution, if the individual is required, as a condition of receiving services in that institution under the State plan, to spend for costs of medical

care all but a minimal amount of the individual's income required for personal needs.

(5) Women who are receiving Medicaid on the basis of the breast or cervical cancer eligibility group under sections 1902(a)(10)(A)(ii)(XVIII) and 1902(aa) of the Act.

(6) Disabled children who are receiving medical assistance by virtue of the application of sections 1902(a)(10)(A)(ii)(XIX) and 1902(cc) of the Act.

(b) States may exempt additional classes of individuals from premiums.

**§ 447.68 Alternative copayments, coinsurance, deductibles, or similar cost sharing charges: State plan requirements.**

When a State imposes alternative copayments, coinsurance, deductibles, or similar cost sharing charges on individuals, the State plan must describe the following:

(a) The group or groups of individuals that may be subject to the cost sharing charge.

(b) The methodology used to determine family income, for purposes of the limitations on cost sharing related to family income that are described below, including the period and periodicity of those determinations.

(c) The item or service for which the charge is imposed.

(d) The methods, such as the use of integrated automated systems, for tracking cost sharing charges, informing recipients and providers of their liability, and notifying recipients and providers when individual recipients have paid the maximum cost sharing charges permitted for the period of time.

(e) The process for informing recipients, applicants, providers, and the public of the schedule of cost sharing charges for specific items and services for a group or groups of individuals in accordance with § 447.76.

(f) The methodology used to ensure that:

(1) The aggregate amount of premiums and cost sharing imposed under section 1916 or section 1916A of the Act for individuals with family income above 100 percent of the FPL does not exceed 5 percent of the family income of the family involved.

(2) The aggregate amount of cost sharing under sections 1916, 1916A(c), and/or 1916A(e) of the Act for individuals with family income at or below 100 percent of the FPL does not exceed 5 percent of the family income of the family involved.

(g) The notice of, time frame for, and manner of required cost sharing and the consequences for failure to pay.

**§ 447.70 General alternative cost sharing protections.**

(a)(1) States may not impose alternative cost sharing for the following items or services. Except as indicated, these limits do not apply to alternative cost sharing for non-preferred prescription drugs within a class of such drugs or non-emergency use of the emergency room.

(i) Services furnished to individuals under 18 years of age who are required to be provided Medicaid under section 1902(a)(10)(A)(i) of the Act, and including services furnished to individuals with respect to whom child welfare services are made available under Part B of title IV of the Act on the basis of being a child in foster care and individuals with respect to whom adoption or foster care assistance is made available under Part E of that title, without regard to age.

(ii) Preventive services (for example, well baby and well child care and immunizations) provided to children under 18 years of age regardless of family income.

(iii) Services furnished to pregnant women, if those services relate to pregnancy or to any other medical condition which may complicate the pregnancy.

(iv) Services furnished to a terminally ill individual who is receiving hospice care (as defined in section 1905(o) of the Act).

(v) Services furnished to any individual who is an inpatient in a hospital, nursing facility, intermediate care facility for the mentally retarded, or other medical institution, if the individual is required, as a condition of receiving services in that institution under the State plan, to spend for costs of medical care all but a minimal amount of the individual's income required for personal needs.

(vi) Emergency services as defined at § 447.53(b)(4), except charges for services furnished after the hospital has determined, based on the screening and any other services required under § 489.24 of this chapter, that the individual does not have an emergency medical condition consistent with the requirements of paragraph (a)(2) of this section and § 447.80(b)(1).

(vii) Family planning services and supplies described in section 1905(a)(4)(C) of the Act.

(viii) Services furnished to women who are receiving medical assistance by virtue of the application of sections 1902(a)(10)(A)(ii)(XVIII) and 1902(aa) of the Act (breast or cervical cancer provisions).

(ix) Services furnished to disabled children who are receiving medical

assistance by virtue of the application of sections 1902(a)(10)(A)(ii)(XIX) and 1902(cc) of the Act.

(x) Preferred drugs within a class for individuals for whom cost sharing may not otherwise be imposed as described in paragraphs (a)(1)(i) through (ix) of this section.

(2) A State may impose nominal cost sharing as defined in § 447.54 for services furnished in a hospital emergency department, other than those required under § 489.24 of this chapter, if the hospital has determined based on the screening required under § 489.24 that the individual does not have an emergency medical condition, the requirements of § 447.80(b)(1) are met, and no cost sharing is imposed to receive the care through an outpatient department or another alternative health care provider in the geographic area of the hospital emergency department involved.

(b) In the case of a drug that is a preferred drug within a class, cost sharing may not exceed the levels permitted under section 1916 of the Act. Cost sharing can be imposed that exceeds section 1916 of the Act levels only for drugs that are not preferred drugs within a class in accordance with section 1916A(c) of the Act.

(c) In the case of a drug that is not a preferred drug, the cost sharing is limited to the amount imposed for a preferred drug if the following conditions are met:

(1) The prescribing physician determines that the preferred drug would be less effective or would have adverse effects for the individual or both.

(2) State criteria for prior authorization, if any, are met.

(d) States may exempt additional individuals, items, or services from cost sharing.

**§ 447.71 Alternative premium and cost sharing exemptions and protections for individuals with family incomes at or below 100 percent of the FPL.**

(a) The State may not impose premiums under the State plan on individuals whose family income is at or below 100 percent of the FPL.

(b) The State may not impose cost sharing under the State plan on individuals whose family income is at or below 100 percent of the FPL, with the following exceptions:

(1) The State may impose cost sharing under the State plan on individuals whose family income is at or below 100 percent of the FPL under authority provided under section 1916 of the Act and consistent with the levels described in such section and § 447.54.

(2) The State may impose cost sharing for non-preferred drugs that does not exceed the nominal amount as defined in § 447.54.

(3) The State may impose cost sharing for non-emergency services furnished in a hospital emergency department that does not exceed the nominal amount as defined in § 447.54 as long as no cost sharing is imposed to receive such care through an outpatient department or other alternative non-emergency services provider in the geographic area of the hospital emergency department involved.

(c) Aggregate cost sharing of the family under sections 1916, 1916A(c), and/or 1916A(e) of the Act may not exceed the maximum permitted under § 447.78(b).

**§ 447.72 Alternative premium and cost sharing exemptions and protections for individuals with family incomes above 100 percent but at or below 150 percent of the FPL.**

(a) The State may not impose premiums under the State plan on individuals whose family income exceeds 100 percent, but does not exceed 150 percent, of the FPL.

(b) Cost sharing may not exceed 10 percent of the payment the agency makes for the item or service, with the following exceptions:

(1) Cost sharing for non-preferred drugs cannot exceed the nominal amount as defined in § 447.54.

(2) Cost sharing for non-emergency services furnished in the hospital emergency department cannot exceed twice the nominal amount as defined in § 447.54. A hospital must meet the requirements described at § 447.80 before the cost sharing can be imposed.

(3) In the case of States that do not have fee-for-service payment rates, any copayment that the State imposes for services provided by an MCO may not exceed \$3.40 per visit for Federal FY 2009 or for individuals referenced in an approved State child health plan under title XXI of the Act pursuant to § 457.70(c), \$5.70 per visit for Federal FY 2009. Thereafter, any copayment may not exceed this amount as updated each October 1 by the percentage increase in the medical care component of the CPI-U for the period of September to September ending in the preceding calendar year and then rounded to the next highest 5-cent increment.

(c) Aggregate cost sharing of the family may not exceed the maximum permitted under § 447.78(a).

**§ 447.74 Alternative premium and cost sharing protections for individuals with family incomes above 150 percent of the FPL.**

(a) States may impose premiums consistent with the aggregate limits set forth in § 447.78(a).

(b) Cost sharing may not exceed 20 percent of the payment the agency makes for the item (including a non-preferred drug) or service, with the following exception: In the case of States that do not have fee-for-service payment rates, any copayment that the State imposes for services provided by an MCO may not exceed \$3.40 per visit for Federal FY 2009 or for individuals referenced in an approved State child health plan under title XXI of the Act pursuant to § 457.70(c), \$5.70 for Federal FY 2009. Thereafter, any copayment may not exceed this amount as updated each October 1 by the percentage increase in the medical care component of the CPI-U for the period of September to September ending in the preceding calendar year and then rounded to the next highest 5-cent increment.

(c) Aggregate premiums and cost sharing of the family may not exceed the maximum permitted under § 447.78(a).

**§ 447.76 Public schedule.**

(a) The State must make available to the groups in paragraph (b) of this section a public schedule that contains the following information:

(1) Current premiums, enrollment fees, or similar fees.

(2) Current cost sharing charges.

(3) The aggregate limit on premiums and cost sharing or just cost sharing.

(4) Mechanisms for making payments for required premiums and charges.

(5) The consequences for an applicant or recipient who does not pay a premium or charge.

(6) A list of hospitals charging alternative cost sharing for non-emergency use of the emergency department.

(7) Either a list of preferred drugs or a method to obtain such a list upon request.

(b) The State must make the public schedule available to the following:

(1) Recipients, at the time of their enrollment and reenrollment after a redetermination of eligibility, and when premiums, cost sharing charges, and the aggregate limits are revised.

(2) Applicants, at the time of application.

(3) All participating providers.

(4) The general public.

**§ 447.78 Aggregate limits on alternative premiums and cost sharing.**

(a) If a State imposes alternative premiums or cost sharing, the total aggregate amount of premiums and cost sharing under section 1916, 1916A(a), 1916A(c) or 1916A(e) of the Act for individuals with family income above 100 percent of the FPL may not exceed 5 percent of the family's income for the monthly or quarterly period, as specified by the State in the State plan.

(b) The total aggregate amount of cost sharing under sections 1916, 1916A(c), and/or 1916A(e) of the Act for individuals with family income at or below 100 percent of the FPL may not exceed 5 percent of the family's income for the monthly or quarterly period, as specified in the State plan.

(c) Family income shall be determined in a manner and for that period as specified by the State in the State plan including the use of such disregards as the State may provide.

(1) States may use gross income or any other methodology.

(2) States may use a different methodology for determining the aggregate limits than they do for determining income eligibility.

**§ 447.80 Enforceability of alternative premiums and cost sharing.**

(a) With respect to alternative premiums, a State may do the following:

(1) Require a group or groups of individuals to prepay.

(2) Terminate an individual from medical assistance on the basis of failure to pay for 60 days or more.

(3) Waive payment of a premium in any case where it determines that requiring the payment would create an undue hardship.

(b) With respect to alternative cost sharing, a State may permit a provider, including a pharmacy to require an individual, as a condition for receiving the item or service, to pay the cost sharing charge, except as specified in paragraphs (b)(1) through (3) of this section.

(1) A provider, including a pharmacy and a hospital, may not require an individual whose family income is at or below 100 percent of the FPL to pay the cost sharing charge as a condition of receiving the service.

(2) A hospital that has determined after an appropriate medical screening pursuant to § 489.24, that an individual does not have an emergency medical condition, before imposing cost sharing on an individual, must provide the name and location of an available and accessible alternate non-emergency services provider as defined in section 1916A(e)(4)(B) of the Act, the fact that

the alternate provider can provide the services with the imposition of a lesser cost sharing amount or no cost sharing, and a referral to coordinate scheduling of treatment by this provider before requiring payment of cost sharing.

(3) The provider is not prohibited by this authority from choosing to reduce or waive cost sharing on a case-by-case basis.

**§ 447.82 Restrictions on payments to providers.**

The plan must provide that the agency reduces the payment it makes to any provider by the amount of a recipient's cost sharing obligation, regardless of whether the provider successfully collects the cost sharing.

**PART 457—ALLOTMENTS AND GRANTS TO STATES**

■ 5. The authority citation for part 457 continues to read as follows:

**Authority:** Section 1102 of the Social Security Act (42 U.S.C. 1302).

■ 6. Section 457.555 is amended by—

■ A. Revising paragraphs (a) introductory text, and (a)(1), (2), and (4).

■ B. Revising paragraph (c).

■ C. Revising paragraph (d).

The revisions read as follows:

**§ 457.555 Maximum allowable cost sharing charges on targeted low-income children in families with income from 101 to 150 percent of the FPL.**

(a) *Non-institutional services.* For targeted low-income children whose family income is from 101 to 150 percent of the FPL, the State plan must provide that for non-institutional services, including emergency services, the following requirements must be met:

(1)(i) For Federal FY 2009, any copayment or similar charge the State imposes under a fee-for-service delivery system may not exceed the following amounts:

Total cost	Maximum amount
\$15 or less .....	\$1.15
\$15.01 to \$40 .....	2.30
\$40.01 to \$80 .....	3.40
\$80.01 or more .....	5.70

(ii) Thereafter, any copayments may not exceed these amounts as updated each October 1 by the percentage increase in the medical care component of the CPI-U for the period of September to September ending in the preceding calendar year and then rounded to the next higher 5-cent increment.

(2) For Federal FY 2009, any copayment that the State imposes for

services provided by a managed care organization may not exceed \$5.70 per visit. Thereafter, any copayment may not exceed this amount as updated each October 1 by the percentage increase in the medical care component of the CPI-U for the period of September to September ending in the preceding calendar year and then rounded to the next higher 5-cent increment.

\* \* \* \* \*

(4) For Federal FY 2009, any deductible the State imposes may not exceed \$3.40 per month, per family for each period of eligibility. Thereafter, any deductible may not exceed this amount as updated each October 1 by the percentage increase in the medical care component of the CPI-U for the period of September to September ending in the preceding calendar year and then rounded to the next higher 5-cent increment.

\* \* \* \* \*

(c) *Institutional emergency services.* For Federal FY 2009, any copayment that the State imposes on emergency services provided by an institution may not exceed \$5.70. Thereafter, any copayment may not exceed this amount as updated each October 1 by the percentage increase in the medical care component of the CPI-U for the period of September to September ending in the preceding calendar year and then rounded to the next higher 5-cent increment.

(d) *Non-emergency use of the emergency room.* For Federal FY 2009, for targeted low-income children whose family income is from 101 to 150 percent of the FPL, the State may charge up to twice the charge for non-institutional services, up to a maximum amount of \$11.35 for services furnished in a hospital emergency room if those services are not emergency services as defined in § 457.10. Thereafter, any charge may not exceed this amount as updated each October 1 by the percentage increase in the medical care component of the CPI-U for the period of September to September ending in the preceding calendar year and then rounded to the next higher 5-cent increment.

\* \* \* \* \*

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)



Dated: July 24, 2008.

**Kerry Weems,**

*Acting Administrator, Centers for Medicare  
& Medicaid Services.*

Approved: August 25, 2008.

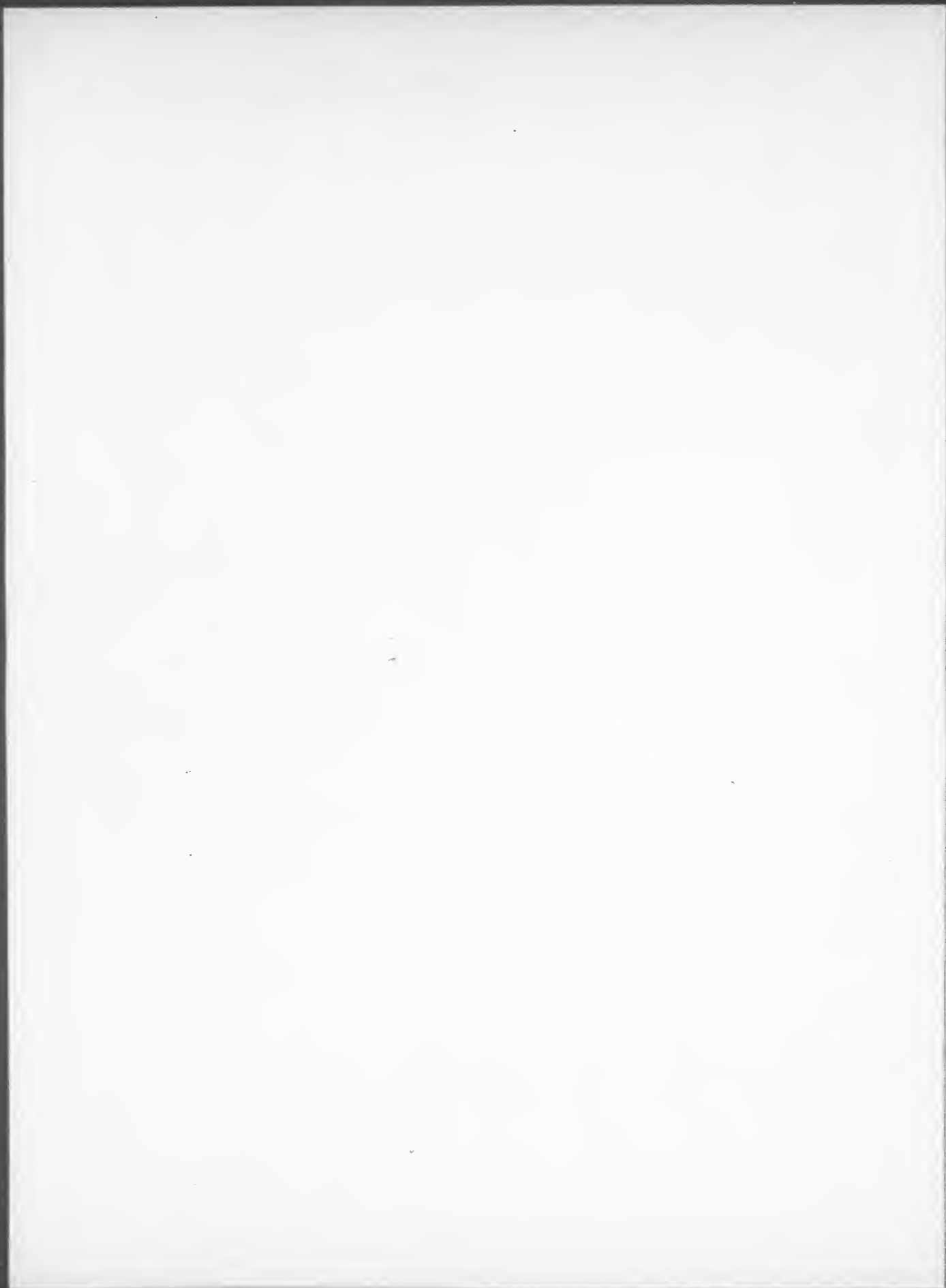
**Michael O. Leavitt,**

*Secretary.*

**Editorial Note:** This document was received in the Office of the Federal Register on November 18, 2008.

[FR Doc. E8-27717 Filed 11-19-08; 11:15 am]

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# Federal Register

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Tuesday,  
November 25, 2008

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**Part V**

## **Department of Health and Human Services**

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**Substance Abuse and Mental Health  
Services Administration**

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**Mandatory Guidelines for Federal  
Workplace Drug Testing Programs; Notice**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Substance Abuse and Mental Health Services Administration****Mandatory Guidelines for Federal Workplace Drug Testing Programs**

**AGENCY:** Substance Abuse and Mental Health Services Administration, HHS.

**ACTION:** Revised Mandatory Guidelines.

**SUMMARY:** This Final Notice of Revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Revisions to Mandatory Guidelines) addresses collection and testing of urine specimens, the requirements for the certification of Instrumented Initial Test Facilities (IITFs), and the role of and standards for collectors and Medical Review Officers (MROs). Additional notices of Proposed Revisions to the Mandatory Guidelines addressing the use of point of collection testing (POCT), oral fluid testing, sweat patch testing, hair testing, and associated issues will be published at a later date. With regard to the use of alternative specimens including hair, oral fluid, and sweat patch specimens in Federal Workplace Drug Testing Programs, significant issues have been raised by Federal agencies during the review process which require further examination, and may require additional study and analysis. As part of the review process for these alternative tests, the Department of Health and Human Services ("HHS" or "Department") plans to issue a notice in the *Federal Register* requesting information and assistance from the general public to provide or identify data and research findings that address specific areas of interest.

**DATES:** *Effective Date:* March 25, 2008.

**FOR FURTHER INFORMATION CONTACT:** Donna M. Bush, Ph.D., Division of Workplace Programs, CSAP, SAMHSA, 1 Choke Cherry Road, Room 2-1033, Rockville, Maryland 20857, (240) 276-2600 (phone), (240) 276-2610 (Fax), or e-mail at [donna.bush@samhsa.hhs.gov](mailto:donna.bush@samhsa.hhs.gov).

**SUPPLEMENTARY INFORMATION:****Background**

The Guidelines were first published in the *Federal Register* on April 11, 1988, (53 FR 11970), and have since been revised in the *Federal Register* on June 9, 1994, (59 FR 29908), on September 30, 1997, (62 FR 51118), on November 13, 1998 (63 FR 63483), and on April 13, 2004, (69 FR 19644). The Guidelines establish the scientific and technical guidelines for Federal workplace drug testing programs and

establish standards for certification of laboratories engaged in drug testing for Federal agencies under authority of section 503 of Public Law 100-71, 5 U.S.C. Section 7301 note, and Executive Order (E.O.) 12564.

The Department also published Proposed Revisions to Mandatory Guidelines in the *Federal Register* on April 13, 2004, (69 FR 19673). These Proposed Revisions to Mandatory Guidelines described changing the Guidelines into a plain language format, expanding the Federal drug testing program to include use of alternative specimens including testing hair, oral fluid, and sweat patch specimens, allowing the use of "point of collection testing" (POCTs) for urine and oral fluid specimens, establishing the requirements for certifying "instrumented initial test facilities" (IITFs) to test specimens, and providing specific standards for collectors, POCT testers, and MROs. There was a 90-day public comment period during which 285 commenters submitted comments on the proposed changes to the Guidelines. These commenters were individuals and public and private entities. The comments are available for public view on the Department's Internet Web site (<http://workplace.samhsa.gov>).

Section 503 of Public Law 100-71, 5 U.S.C. Section 7301 note, required the Department to establish scientific and technical guidelines and amendments in accordance with Executive Order 12564, and to publish Mandatory Guidelines which establish comprehensive standards for all aspects of laboratory drug testing and procedures, including standards that require the use of the best available technology for ensuring the full reliability and accuracy of drug tests and strict procedures governing the chain of custody of specimens collected for drug testing. These revisions to the Mandatory Guidelines promote and establish standards that use the best available technology for ensuring the full reliability and accuracy of urine drug tests, while reflecting the ongoing process of review and evaluation of legal, scientific, and societal concerns.

The submitted public comments and additional comments raised by Federal Agencies during subsequent internal review of the proposed changes to the Guidelines raised significant scientific, legal, and public policy concerns about the use of alternative specimens and POCT devices in Federal agency workplace drug testing programs. Since each alternative specimen and drug testing using POCT devices poses different concerns, the Department established a staggered timeline for

issuing final guidance that allows for further study and research. In assessing the complexity of the task, the Department has decided to publish these final Guidelines with regard to collection and testing urine specimens, establishing the requirements for the certification of IITFs, and establishing specific standards for collectors and MROs. The Department considered several options for issuing one or more Final Notices in the *Federal Register* that may require additional public comment periods, concerning the use of alternative specimens and drug testing technologies such as POCT devices. Since the scientific, legal, and public policy information for drug testing oral fluid, hair, and sweat patch specimens, and using POCT devices is not as complete as it is for the laboratory-based urine drug testing program, developing Final Notices concerning the use of these is more challenging. As described in the notice of Proposed Revisions to Mandatory Guidelines issued April 13, 2004, the performance of alternative specimens in pilot performance testing (PT) programs has been encouraging, with individual laboratory and group performance improving over time. However, there are still three areas of concern. First, the data from the pilot PT programs to date show that not all participants have developed the capability to test for all required drug classes, nor to perform such tests with acceptable accuracy. Second, some drug classes are more difficult to detect than others, for any given type of specimen. Third, the specific drug classes that are difficult to detect vary by type of specimen. As a result, it will require additional study to assist agencies in determining how to select the appropriate type of specimen to be collected from a specific donor, when the use of a specific drug is suspected. Nevertheless, HHS believes that the addition of alternative specimens to the Federal Workplace Drug Testing Program would complement urine drug testing and aid in combating the risks posed from available methods of suborning urine drug testing through adulteration, substitution, and dilution. Thus, HHS will continue to pursue testing using alternative specimens. HHS anticipates issuing further revisions to the Mandatory Guidelines addressing the use of oral fluid, sweat patch, and hair, and the use of POCT devices for urine and oral fluid. These revisions will be published in the *Federal Register*, with opportunity for public comment.

All written comments were reviewed and taken into consideration in the

preparation of these revised Guidelines. The preamble only addresses sections of the draft Guidelines regarding urine testing that were commented on during the public comment period or that the Department is changing. Most section numbers for the Guidelines issued in April 2004 were changed in these Guidelines due to the removal of those sections concerning alternative specimens and POCT as well as for clarity. To make it easier for the public, the preamble refers to the new section number and, where appropriate, the corresponding section number in the Proposed Revisions to Mandatory Guidelines issued in April 2004. Similar comments are considered together in the discussion.

#### Reason for the Effective Date

An effective date of 18 months from the date of publication of these revised Mandatory Guidelines was chosen to permit the following activities:

(1) It will take at least 12 months for manufacturers of immunoassay test kits to modify or manufacture immunoassay test kits and ensure compliance with any applicable statutory and regulatory requirements before commercialization of the modified kits.

(2) It will take the HHS-certified laboratories at least one month to validate and implement the new test kits.

(3) It will take 2 to 3 months for the National Laboratory Certification Program (NLCP) to challenge the HHS-certified laboratories with performance testing (PT) samples to ensure that the test kits and test results satisfy the required performance criteria.

The effective time frame of 18 months will encompass many activities that will overlap or occur at the same time within different industries and Federal agencies.

#### Summary of Public Comments and the HHS Response

The following comments were directed to the information and questions in the preamble.

##### Initial Test Kit Issues

In the proposed Guidelines, the Department requested comments on issues regarding the testing for amphetamine analogs using one or two immunoassay test kits because the laboratory or IITF would be required to test specimens for the target analytes listed under amphetamines. Two commenters believed that two separate initial test kits would be needed to appropriately screen specimens for amphetamines as specified in Section 3.4. One commenter believed three

separate initial test kits may be required. Six commenters believed that one initial test kit could be used to screen for amphetamine, methamphetamine, and their analogs. For the most part, the commenters provided justifications for their comments. The Department has evaluated the comments and has concluded that using either a single initial test kit or multiple initial test kits is acceptable depending on the specificity and sensitivity that the single initial test kit has with amphetamine and methamphetamine and its cross-reactivity with methylenedioxymethamphetamine (MDMA).

##### Subpart A—Applicability

The Department has revised Section 1.1 to state that the requirements in these Guidelines also apply to collectors and MROs. This revision ensures that collectors and MROs are notified of the applicable requirements under these Guidelines.

In Section 1.5, where terms are defined, the Department has added several new definitions for terms that appear in the Guidelines, and revised several definitions that needed clarification even though no comments were received from the public.

The Department has changed the term to be defined from "adulterated" to "adulterated specimen." The meaning of the term has not changed. Only the wording has been changed to make the definition clearer.

Definitions were added for "alternate responsible person" and "alternate responsible technician," the individuals who are pre-approved by HHS to assume responsibility for the HHS-certified drug testing laboratory or IITF, respectively, when the responsible person or responsible technician is absent for an extended period.

The definition for "cancelled test" was reworded for clarification. The definition is the same.

The term "carryover" was defined. Carryover, as used in these Guidelines, refers to the condition that results when the test result for one sample has been affected by a preceding sample during analysis. For example, if the concentration of a drug in one sample is very high and cannot be completely eliminated from the analytical instrument before the next sample is tested, the residual drug in the analytical instrument contributes to the concentration of that drug in the next sample.

The definition for "certifying scientist" was revised to indicate that a certifying scientist can report any test result reported from an HHS-certified

laboratory. The proposed definition referred to "non-negative or invalid result." Since the term "non-negative" was deleted from these Guidelines, the definition for certifying scientist needed to be revised.

The definition for "certifying technician" was revised to state that a certifying technician can report on the chain of custody and scientific reliability of negative, negative/dilute, and rejected for testing results. This revised definition clarifies which types of results a certifying technician can report. The proposed definition incorrectly permitted the certifying technician to report on the chain of custody and scientific reliability of only negative test results.

The term "confirmatory validity test" was changed to "confirmatory specimen validity test." The term "validity test" was changed to "specimen validity test" throughout the Guidelines, to be consistent with current terminology used by the Department.

The definition for a "cutoff" was revised to apply to specimen validity tests, as well as drug tests. The term is used in both contexts.

The definition for "dilute specimen" was revised to state that the term applies to a urine specimen with creatinine and specific gravity values that are lower than expected but still physiologically possible. This change shows that a dilute specimen is different from a substituted specimen.

The definition for "failed to reconfirm" was revised to clarify that the term applies when a second laboratory tests a split (Bottle B) specimen and is unable to corroborate the original test result reported by the primary laboratory.

The definition for "follow-up test" was removed. The definition for "follow-up test" is provided in Federal agency drug testing plans and does not need to be repeated in the Guidelines.

The definition for an "initial validity test" was changed to "initial specimen validity test" throughout the Guidelines to be consistent with current terminology used by the Department. The term was also revised to include an "invalid result" because an "invalid result" requires using an initial specimen validity test as would an adulterated, diluted, or substituted test result.

To avoid confusion, the definitions for an "instrumented initial test facility" and for a "laboratory" were revised to show that these are permanent locations.

The definition for "invalid result" was revised to clarify that this type of result is reported when the test results

satisfy the criteria established in Section 3.8. The definition in the draft issuance did not include all of the criteria described in Section 3.8.

A definition for "limit of detection" (LOD) has been added to these Guidelines because the Guidelines require the laboratory to determine the LOD for each confirmatory drug test during assay validation. In addition, to validate specimen validity tests, laboratories and IITFs are required to demonstrate and document appropriate assay characteristics, which may include the LOD.

A definition for "limit of quantitation" (LOQ) has been added to these Guidelines because the Guidelines require the laboratory to determine the LOQ for each confirmatory drug test during assay validation. In addition, to validate tests used to determine specimen validity, laboratories and IITFs are required to demonstrate and document appropriate assay characteristics, which may include the LOQ. Lastly, laboratories and IITFs are required to use the established LOQ as the decision point for adulterants without a program-specified cutoff.

A definition for a "lot" has been added to these Guidelines because throughout the Guidelines there are requirements to validate or verify the performance characteristics of various items (e.g., drug test kits, reagents, quality control material) and to establish an expiration date. The term "lot" refers to the item(s) manufactured from the same starting materials within a specified period of time which have essentially the same performance characteristics and the same expiration date.

The definition for a "negative result" was revised to clarify that the specimen must not only be negative for drugs but must also be a valid urine specimen. Since these Guidelines require that specimen validity tests be conducted on each specimen, this definition states that a "negative result" indicates that a specimen is not only negative for drugs but also that the specimen validity tests conducted on the specimen indicate that the specimen is a valid specimen.

The definition for a "non-negative" result was removed from the list of definitions and replaced with more specific reporting terms as follows: Positive result, substituted specimen, adulterated specimen, or invalid specimen result.

The definition for a "performance testing (PT) sample" was revised to show that it refers to samples that are program-generated and sent to a testing facility. The proposed definition did not indicate the source of the samples.

The definition for a "post-accident test" was removed. The definition for "post-accident test" is provided in Federal agency drug testing plans and does not need to be repeated in the Guidelines.

The definition for a "pre-employment test" was removed. The definition for "pre-employment test" is provided in Federal agency drug testing plans and does not need to be repeated in the Guidelines.

The definition for a "quality control (QC) sample" was revised to clarify that the term refers to calibrators or controls.

The definition for a "random test" was removed. The definition for "random test" is provided in Federal agency drug testing plans and does not need to be repeated in the Guidelines.

The definition for a "reasonable suspicion/cause test" was removed. The definition for "reasonable suspicion/cause test" is provided in Federal agency drug testing plans and does not need to be repeated in the Guidelines.

The definition for "reconfirmed" was revised to clarify that the definition applies to a split specimen (Bottle B) tested by a second laboratory.

The definition for "return to duty test" was removed. The definition for "return to duty test" is provided in Federal agency drug testing plans and does not need to be repeated in the Guidelines.

The definition for "rejected for testing" was revised to clarify that this result may be reported by an IITF, as well as a laboratory.

Three commenters noted the terms "sample" and "specimen" were used interchangeably throughout the Guidelines and suggested that the definitions be defined and the text updated accordingly. The Department agrees and has revised the definitions for these terms and has revised the Guidelines text to consistently use the terms as they are defined in this section. "Sample" refers to a performance testing (PT) sample, a quality control sample, or a representative portion of a donor specimen. "Specimen" refers to the donor specimen (i.e., urine provided by the donor for the drug test).

The term "split specimen" was replaced by "split specimen collection." The definition of a "split specimen collection" states that one urine specimen of sufficient volume is collected and then divided into two separate specimen bottles. A "split specimen collection" does not permit collecting two different urine specimens at two different times that are, respectively, transferred to a Bottle A and a Bottle B.

The definition for "substituted" was changed to "substituted specimen" and revised to define this as a specimen submitted in place of the donor's urine, as evidenced by creatinine and specific gravity values outside physiologically producible ranges of human urine.

Section 1.6 describes what an agency is required to do to protect employee records. The policy in this section is the same as the policy in the Proposed Revisions to Mandatory Guidelines. The Department has included a discussion on the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

The Department has included a new Section 1.7, to clarify refusals to test and who ultimately determines if the conditions for verifying them are met (i.e., the collector, the MRO, the Federal agency).

#### Subpart B—Specimens

Section 2.1 states that urine is the only specimen that can be collected by a Federal agency under the Guidelines for its workplace drug testing program to clarify that Federal agencies are prohibited from collecting any other type of specimen.

Section 2.2 describes the circumstances under which a Federal agency may collect a specimen. The Department has included this section to ensure that the circumstances described are consistent with the reasons for collecting a specimen as listed on the Federal CCF.

Section 2.3 requires each urine specimen to be collected as a split specimen. This policy is the same as the policy described in the Proposed Revisions to Mandatory Guidelines. Five commenters opposed the part that the single urine specimen collection procedure was being eliminated. The Department disagrees with the commenters and has eliminated the single urine specimen collection procedure, not because the procedure is forensically or scientifically unsupportable, but because the split specimen procedure ensures that the donor will have access to a split specimen that was not opened by the laboratory testing the primary specimen. Additionally, there are a number of Federal employees working for agencies that have employees subject to both Federal drug testing guidelines and Department of Transportation workplace drug testing regulations. Requiring the use of a split specimen collection procedure will ensure that employees working in these dual regulation situations are treated the same.

### Subpart C—Drug and Specimen Validity Tests

Section 3.1 describes the tests that are performed on each urine specimen. The policy in this section applies to each specimen collected by a Federal agency regardless of the circumstance for which it was collected as described in Section 2.2. The Department believes that the wording of the policy in the current and Proposed Revisions to Mandatory Guidelines may be incorrectly interpreted such that the required tests only apply to specimens collected from Federal agency applicants and specimens collected at random. However, this is not the case. The wording in this section has been revised to state that each specimen collected will be tested for the same drugs and specimen validity tests. This section was also revised to describe the specimen validity tests that must be performed on each urine specimen. The requirements and explanations described for the specimen validity tests are the same as those described in the current and Proposed Revisions to Mandatory Guidelines.

Section 3.2 provides guidance on how a Federal agency may test a specimen for additional drugs. Three commenters requested additional guidance on how a Federal agency would request permission to test for an additional drug on a case-by-case basis. The Department believes the policy in Section 3.2(a) adequately describes how a Federal agency would request to test a donor's specimen for a suspected Schedule I or Schedule II drug that is not part of the Federal program.

After further review of Section 3.2(a), however, the Department recognized that the Guidelines do not address how to proceed if the Federal agency is requesting to test for a Schedule I or II drug for which an immunoassay test is not available. The Department thus has added that when the need to test for an additional drug occurs and there is no immunoassay test available, an HHS-certified laboratory should be permitted to test for the drug by testing two separate aliquots of the specimen using the same confirmatory drug test. The confirmatory drug test used by the laboratory must satisfy the requirements in Section 11.13, the laboratory must validate the confirmatory drug test in accordance with the requirements in Section 11.14, and must satisfy the quality control requirements as stated in Section 11.15. The Department believes that testing the specimen twice using a validated confirmatory drug test is scientifically and forensically acceptable. Additionally, when a

specimen is reported as positive, adulterated, or substituted, the Department allows the donor to request that Bottle B be tested at another HHS-certified laboratory by the confirmatory method. The testing of the split specimen by a second HHS-certified laboratory to reconfirm the drug reported positive by the first laboratory is sufficient to protect the donor's interests.

Section 3.3 states that urine specimens collected for Federal agency workplace drug testing programs may only be tested for the purpose of detecting drug use and to determine the validity of the specimen unless otherwise authorized by law. Several commenters expressed concern over the possibility that DNA testing could be conducted on a specimen. The Department states in Section 3.3(a) that "Federal agency specimens \* \* \* must only be tested for drugs and to determine their validity unless otherwise authorized by law." The Department is satisfied that the policy, as stated, prohibits DNA testing on a specimen but has removed the phrase "unless otherwise authorized by law" from this section to clarify that Federal agency specimens must only be tested for drugs and to determine their validity.

Section 3.4 lists the drugs and drug metabolites and the initial and confirmatory cutoff concentrations used to test and report urine specimens as negative or positive for a drug. The initial and confirmatory cutoff concentrations are the same as in the Proposed Revisions to Mandatory Guidelines, but the tables have been combined to make it easier for the readers.

Several commenters suggested including the scientific rationale used to support the proposed changes to the cocaine metabolite (benzoylecgonine) and amphetamine cutoff concentrations. Three commenters disagreed with the proposal to lower the amphetamines initial test cutoff concentration. Two of the three commenters were concerned that the lower cutoff will result in higher costs and more false initial test positives due to medications available over the counter. The third commenter stated that their laboratory currently has customers who use the lower amphetamine cutoff concentration and have no more confirmed positives than compared to a 1000 ng/mL initial test cutoff, but who do have more unconfirmed specimens.

The Department believes the revised cutoff concentrations will increase the window of detection for these drugs, i.e., the number of hours after a drug is

ingested by an individual that the concentration of the drug or drug metabolite in urine will likely remain above the cutoff concentration. Lower cutoff concentrations will increase the number of urine specimens that are identified as containing cocaine metabolites and amphetamines and, thereby, will increase the deterrent effect of the program and improve identification of employees using illicit substances. Based on results reported by laboratories in the current urine PT program, the Department believes that certified laboratories (and IITFs after they are certified) will have the ability to report accurate test results using these revised cutoff concentrations. There is no evidence available to the Department to indicate that lowering these cutoff concentrations will increase the possibility that a donor who has not actually used cocaine or amphetamines will be identified as a drug user. The Department also points out that the individual can always challenge the result with the MRO.

Several commenters raised questions regarding the proposed options for HHS-certified laboratories and IITFs to perform an initial test for 6-AM. The commenters stated that the policy options were unclear as presented in Section 3.4, and recommended that HHS provide additional guidance to prevent inconsistent treatment of specimens. The Department has revised the table and footnotes in Section 3.4 to clarify that all specimens tested for opiates must be tested for 6-AM. This policy allows a laboratory to confirm and report 6-AM by itself, in contrast to the current Guidelines policy which requires 6-AM to be tested and reported in conjunction with a positive morphine result. Data from laboratories indicate that 6-AM is present in specimens even when the morphine concentration is below 2000 ng/mL.

Sections 3.5, 3.6, 3.7, and 3.8 describe the criteria for reporting a urine specimen as adulterated, substituted, dilute, and invalid, respectively. Each section was revised to clarify that only a certified laboratory may report a specimen as adulterated, substituted, or invalid; that only a certified laboratory may report a specimen as dilute when creatinine is equal to or less than 5 mg/dL; and that a laboratory or an IITF may report a specimen as dilute when creatinine is greater than 5 mg/dL. For an adulterated or invalid urine specimen, one commenter requested the rationale for changing from the 20 mcg/mL chromium (VI) [Cr (VI)] initial validity test cutoff in a previous draft (several preliminary versions of the Guidelines were posted on the

SAMHSA workplace Web site before the Proposed Revisions to Mandatory Guidelines were published in the **Federal Register** to 50 mcg/mL in these Guidelines. One commenter recommended using the 20 mcg/mL Cr (VI) cutoff instead of 50 mcg/mL and provided supporting data. Although the Department agrees with the data provided, the 50 mcg/mL cutoff is consistent with the capabilities of current assays' sensitivity and specificity. Additionally, most, but not all, oxidants are quantified at concentrations greater than 50 mcg/mL when they are used as urine adulterants. Unpublished evaluations of samples spiked with Cr (VI) have shown that for Cr (VI) to be effective as an adulterant, the urine concentration is usually much greater than 100 mcg/mL. For these reasons, the Department believes that the 50 mcg/mL Cr (VI) cutoff is sufficient to identify adulteration with Cr (VI) and is appropriate. One commenter recommended using the limit of quantitation (LOQ) instead of the limit of detection (LOD) as the decision point for adulterant tests without a program specified cutoff. The commenter stated that an LOQ ensures that the adulterant has been both appropriately identified and quantified. The Department agrees and has revised the testing requirements in Sections 3.5 and 3.8 to require that the adulterant's concentration be equal to or greater than the LOQ that was determined by the HHS-certified laboratory.

The Department has revised Section 3.7 to clarify that a dilute result may only be reported in conjunction with either a positive test result or a negative test result. When a urine specimen is determined to be adulterated or when an invalid result is being reported, the Department does not consider finding a dilute result for such a specimen as being correct. It is assumed that an adulterated or invalid urine specimen has been tampered with and, if it also happens to satisfy the dilute criteria, the dilute result would actually be meaningless. Additionally, by definition, when a urine specimen is reported as substituted it cannot be a dilute specimen. Therefore, a dilute result cannot be reported in conjunction with a substituted result.

#### **Subpart D—Collectors**

Section 4.1 describes who may collect a specimen for a Federal agency. Three commenters recommended allowing direct supervisors to routinely collect specimens for federal agency applicant tests. The Department disagrees and has always prohibited an immediate supervisor or hiring official from

routinely acting as a collector, unless no other collector is available and only when the supervisor or hiring official is a trained collector.

Section 4.2 describes who may not collect a specimen. Seven commenters were opposed to the policy which prohibits testing facility employees from collecting specimens if they could link the donor's identity to the test results. The Department has always prohibited testing facility (HHS-certified laboratory) employees from collecting specimens if they could link the donor's identity to the test results and believes that this policy is appropriate. The Department revised this section to prohibit an employee who is in a testing designated position and subject to the Federal agency drug testing rules from serving as a collector for co-workers who are in the same testing pool or who work together with that employee on a daily basis, and to prohibit an individual from collecting his or her own urine for a federally regulated drug test.

Section 4.3 describes the requirements for an individual to be a collector for a Federal agency. Seven commenters disagreed with requiring collectors to read and understand the Guidelines and felt this should be limited to the sections pertaining to the collection of specimens. The Department agrees and has revised the policy in Section 4.3(a) to reflect that a collector must be knowledgeable of the collection procedure described in the Guidelines. Four commenters suggested that there should be standardized collector training requirements and documentation requirements for all collectors. The Department has revised Section 4.3 to provide more details on the requirements for collector training and the documentation requirements. The Department believes the requirements as described in this section are sufficient and appropriate to ensure that the collector can properly collect a specimen and correctly complete the Federal Drug Testing Custody and Control Form (Federal CCF).

Several commenters believe it is not sufficient to allow the agency to select the observer if there is no collector of the same gender available, as stated in the Proposed Revisions to Mandatory Guidelines. To address this concern, the Department has included a new Section 4.4 that specifies training requirements for an individual to serve as an observer for a direct observed collection (as described in Section 8.9). The training requirements are designed to ensure that any individual serving as an observer has been trained in procedures for a

direct observed collection, although he or she may not be a trained collector. Other training elements are included to ensure that the observer interacts with the donor in a professional manner, respecting the donor's modesty and privacy, and that he or she maintains the confidentiality of collection information. The Department also revised this section to allow the collector or collection site supervisor to select the observer.

Section 4.5 describes the requirements for an individual to be a trainer for collectors. Three commenters noted that the Guidelines did not address approval and monitoring of the "train the trainer" courses. Currently there are organizations (e.g., manufacturers, private entities, contractors, Federal agencies) that offer "train the trainer" courses. The Department does not believe that it is necessary or appropriate to approve the content of the "train the trainer" courses. If a trainer does not properly train individuals to be collectors, collector errors will result as the Guidelines are enforced and will demonstrate the need to retrain those trainers.

Section 4.6 describes what a Federal agency must do before an individual is permitted to collect specimens. Five commenters disagreed with the requirement for an organization that manages/employs collectors to retain the collector training documents, saying this would be burdensome. The commenters recommend that collectors be responsible for their own documentation. The Department agrees that many collectors currently retain their training records and has revised the policy to indicate that a collector (who may be self-employed) or organization (e.g., collector training company, third party administrator, Federal agency that employs its own collectors) must maintain a copy of the record that documents his or her training. The Department has also revised the question to require the Federal agency to ensure that the requirements of this section are satisfied before a collector is permitted to collect specimens rather than placing the burden on an organization to satisfy the requirements. The Federal agency is always responsible for ensuring that a collector is properly trained.

#### **Subpart E—Collection Sites**

Section 5.1 describes a collection site as a permanent or temporary facility. The requirement for a collection site to have provisions for donor privacy during the collection procedure has been moved from Section 5.1 to Section



5.2, which describes the specific requirements for a facility that is being used as a collection site.

Two commenters recommended including additional criteria in Section 5.2 for a collection site to have a secure working area and donor privacy. The Department agrees and is requiring the collection site in Section 5.2(a) to have provisions to ensure donor privacy. Privacy requirements are set forth in Section 8.1. In addition, Section 5.2(b) has been revised to reflect the need for a suitable clean working area that is not accessible to the donor. The Department believes the clean working area must not be accessible to the donor because, if given an opportunity, a donor may attempt to tamper with records, documents, or supplies. The Department also added Section 5.2(g) to require facilities to have the ability to limit donor access to potential contaminants, adulterants, or diluents.

Section 5.3 describes how long records must be stored by collection sites. The record storage requirements in this section are the same as those described in the Proposed Revisions to Mandatory Guidelines. The Department revised the section to specify the records that must be retained.

#### **Subpart F—Federal Drug Testing Custody and Control Forms**

Section 6.1 states that an OMB-approved Federal CCF must be used to document the collection of a urine specimen. The requirement in this section is the same as the requirement described in the Proposed Revisions to Mandatory Guidelines.

Section 6.2 describes what happens if the correct Federal CCF is not available or is not used. The Department recognizes that occasionally a current Federal CCF will not be available or a non-Federal form or expired Federal CCF will be used by mistake. The Department does not want this discrepancy to cause a laboratory or IITF to automatically reject the specimen for testing, or cause an MRO to automatically cancel the test. If the collector discovers the error before the specimen is packaged for shipment to a laboratory or IITF, the collector must note on the form that the specimen is a Federal agency specimen and give the reason for using the incorrect form. When this information is provided on the form, the laboratory or IITF simply proceeds with testing the specimen as a Federal agency specimen. If the laboratory, IITF, or MRO discovers that an incorrect form was used and there is no explanation given, the laboratory, IITF, or MRO must attempt to obtain a Memorandum For Record (MFR) from

the collector explaining why an incorrect form was used. If a MFR cannot be obtained from the collector, the laboratory or IITF must report a rejected for testing result (i.e., when they discovered the error) and the MRO reports a cancelled test result.

#### **Subpart G—Specimen Collection Containers**

Section 7.1 describes the items to be used to collect a urine specimen. The Department added volume requirements for specimen containers to this section to ensure that the containers used would be of a sufficient size to hold the required amount of urine for primary and split specimens.

Section 7.2 describes the requirement that the collection items used must not affect the specimen collected. The requirement in this section is the same as the requirement described in the Proposed Revisions to Mandatory Guidelines. However, the proposed statements regarding FDA clearance for these collection items has been removed. FDA has regulatory oversight of a collection item as a "device" within the meaning of Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the FFDC) (21 U.S.C. 321(h)), and a manufacturer must comply with all statutory and regulatory requirements for these devices.

#### **Subpart H—Specimen Collection Procedure**

Section 8 establishes the procedures for collection of a urine specimen. The Department revised and reorganized the urine collection procedures in the Proposed Revisions to Mandatory Guidelines for clarity and to address issues raised as described below.

Section 8.1 states the privacy requirements for specimen collections. The procedure used to collect a urine specimen must ensure that a donor is given a sufficient amount of privacy under normal circumstances. That is, a donor is allowed to provide a urine specimen in the privacy of a restroom or an enclosed stall. Four commenters raised concerns with the privacy requirements that should be given a donor. The Department evaluated these comments and believes that it is more appropriate to address the privacy requirements in subpart H (which addresses the collection procedure) rather than discussing the privacy requirements in subpart E (which specifies the requirements for a collection site). Section 8.1(a) addresses the comments submitted by stating who may be present during a collection procedure. Section 8.1(b) states that the collector may be a different gender than

the donor, but the observer of a direct observed collection procedure must be the same gender, and a monitor for a monitored collection must be the same gender unless the monitor is a medical professional. Section 8.1(c) clarifies that the privacy given to a donor is visual privacy because there may be situations where it is not possible to prevent the collector from hearing sounds in the enclosure where the donor is providing the specimen.

Section 8.2 describes what a collector must do before starting a specimen collection procedure. One commenter noted that the proposed requirement to have "no other source of water (e.g., no shower or sink) in the enclosure where urination occurs" may not address temporary collection sites. The commenter recommended that the procedure be revised to state that the collector must disable or secure other sources of water in the restroom before starting the collection procedure. One commenter noted that many public restrooms are equipped with toilets that have sensors for automatic flushing. The Department agrees and has revised this section to read "There must be no other source of water (e.g., no shower or sink) in the enclosure where urination occurs that is not secured during the collection." If the enclosure used by the donor to provide a specimen has a sink or other source of water besides the toilet that cannot be disabled or secured, the collector must perform a monitored collection in accordance with Section 8.11. The monitor will listen for any sounds that may suggest possible attempts by the donor to tamper with the specimen.

Section 8.3 describes the preliminary steps in the collection process. Four commenters recommended that the Guidelines describe the type of identification the collector provides to the donor. The Department has revised Section 8.3(c) and included some examples of the type of identification that may be provided (e.g., driver's license, employee badge issued by the employer, any other picture identification issued by a Federal, State, or local government agency). Two commenters suggested that the collector must point out to the donor, but not require the donor to read, the collection procedure instructions on the back of the Federal CCF. The Department agrees with the comment and has revised Section 8.3(f) to direct the collector only to inform the donor where the donor can find the instructions for the collection on the back of the Federal CCF. The collector will allow the donor to read the procedure if the donor prefers. One commenter suggested that

the donor be given the collector's full name, name of the collector's supervisor, name of the company conducting the test, and the MRO's name, telephone, and address. The Department agrees with this comment. With the exception of the name of the collector's supervisor, the rest of the commenter's request for information is recorded on the donor's copy of the Federal CCF. If some of the information is missing on the Federal CCF, it is the responsibility of the collector to obtain the information and to complete the Federal CCF in accordance with the instructions for the use of the Federal CCF for Federal agency workplace drug testing programs.

Section 8.4 describes the steps that the collector takes in the collection process before the donor provides a urine specimen. The steps are the same as in the Proposed Revisions to Mandatory Guidelines, but include additional detail.

Section 8.5 specifically addresses the situation where a donor states that he or she is unable to provide a urine specimen. Over 50 commenters expressed concern with the Department's urine collection policy. They stated that some individuals have what the commenters refer to as a "shy bladder." The commenters noted that these individuals may be physically unable to provide a urine specimen upon demand, and forcing them to drink fluids creates a great deal of stress and may not change their ability to provide a specimen. The commenters were concerned with how a collector interacts with a donor who is unable to provide a sufficient amount of urine to perform a drug test. The Department's urine collection policy was designed to prevent an individual from intentionally circumventing the requirement to provide a urine specimen during a required collection. The policy is not intended to cause harm to anyone who has a condition that prevents them from providing a urine specimen when requested. The Department has always expected a collector to treat the donor with respect when the donor is unable to provide a specimen within a reasonable period of time (3 hours is considered reasonable). To address the concern, however, the Department has revised the urine specimen collection procedure. If the donor states that he or she cannot provide a specimen, the collector requests the donor to go into the restroom (stall) and attempt to provide a specimen. This attempt demonstrates the donor's inability to provide a specimen when the donor comes out of the stall with an empty collection container. At that time, if the

donor states that he or she could provide a specimen after drinking some fluids, the collector allows the donor to drink some liquid (as stated in Section 8.5(b)(1)) and continues with the collection procedure. If the donor states that he or she simply needs more time, without a need to drink fluids, before attempting to provide a urine specimen, the collector gives the donor up to 3 hours to provide a urine specimen. If the donor states that he or she is unable to provide a urine specimen even after 3 hours, the collector records the reason for not collecting a urine specimen on the Federal CCF, notifies the Federal agency's designated representative, and sends the Federal CCF to the MRO and the Federal agency for further evaluation of the donor. The requirement for the further evaluation of the donor by an MRO will prevent individuals from being falsely accused of a refusal to test.

Sections 8.5(b)(1) and 8.6(e)(2) describe the amount of fluid that a donor may be given at the collection site in order to collect a sufficient amount of urine. The reason why a limit is imposed at all is the concern for the welfare of the donor, as well as the concern that the urine specimen may become diluted. Several commenters expressed concern with the amount of fluids given to a donor at the collection site. The Proposed Revisions to Mandatory Guidelines instruction to the collector to give the donor a reasonable amount of liquid to drink is flexible in the amount given (note that the parenthetical in the Guidelines is stated as an example, not as a requirement). However, in response to the comment, the Department has changed the example in the Proposed Revisions to Mandatory Guidelines ("an 8 ounce glass of water every 30 minutes, but not to exceed a maximum of 24 ounces") to read "an 8 ounce glass of water every 30 minutes, but not to exceed a maximum of 40 ounces over a period of 3 hours or until the donor has provided a sufficient urine specimen." This change retains the flexibility that has always existed in the Federal program and sets a reasonable time limit within which most donors would be able to provide an acceptable amount of urine. Although the Department has changed the guidance on the amount of fluid given the donor, the Department does not require anyone to drink more fluid than he or she could comfortably drink. A statement has also been added to these sections to clearly state that the donor is not required to drink any fluids during this waiting time. The Department believes that most

individuals who are unable to provide a sufficient specimen simply need some additional time to provide the required specimen without having a need to drink fluids.

Section 8.6 describes the steps that the collector takes in the collection process after the donor provides a urine specimen. One commenter recommended that the collector be instructed to inspect the stall for signs of tampering before the donor is permitted to flush the toilet. While this practice is acceptable, the Department has not included this detail in the Guidelines. Sections 8.2 and 8.3 include pre-collection procedures to prevent or detect specimen tampering. Furthermore, Section 8.4(b) instructs the collector to perform a recollection under direct observation if the donor's conduct indicates a possible attempt to adulterate or substitute the specimen.

Section 8.6 also includes procedures for the collector to measure the specimen temperature, visually inspect the specimen, and determine the specimen volume. Three commenters recommended deleting the proposed requirements for a collector to send a Bottle A specimen to the testing facility when there is an insufficient volume of urine collected for the split (Bottle B) specimen as required because this contradicted the proposed policy that a failure to provide 30 mL of urine for the second specimen collection prompts the collector to obtain guidance on the action to be taken. The Department agrees and has revised the collection procedures to stop the collection when the donor does not provide at least 45 mL, the amount required for a split specimen collection, after two attempts. When this occurs, the collector notifies the Federal agency's designated representative immediately, and notes on the Federal CCF the donor's failure to provide sufficient urine. The Federal CCF is sent to the Federal agency and the MRO. Subsequent actions by the MRO are described in Sections 13.5 and 13.6.

Section 8.8 is a new section that combines the reasons that appear in different sections of the current Guidelines regarding when a direct observed collection is used. The reasons are the same; they have simply been combined in one section. Section 8.8(c) requires the collector to notify a collection site supervisor to review and concur with the collector's decision to perform a direct observed collection procedure. Three commenters disagreed with this policy. One commenter recommended requiring an agency representative in addition to the supervisor to review and concur with

the decision. The Department believes obtaining permission from a supervisor is necessary when a decision is needed to conduct a direct observed collection. The concurrence from a supervisor will ensure that the collector is justified in using a direct observed collection procedure. The Department also included in this section the actions a collector must take when the donor refuses to provide a specimen under direct observation.

Section 8.9 is a new section that describes how a direct observed collection procedure is conducted. The Proposed Revisions to Mandatory Guidelines discussed when a direct observed collection procedure is permitted, but did not provide guidance on how it is to be conducted. The Department has included additional information regarding direct observed collections. This information has been available from the Department and has been used since the beginning of the Federal drug testing program. The Department believes that the procedure will ensure that all direct observed collection procedures are conducted the same way regardless of the reason for using the direct observed procedure. In response to submitted comments, in addition to requiring the observer to be the same gender as the donor, the Department has specified in Section 8.9 that individuals must be trained in direct observed collection procedures in order to serve as an observer. Training requirements are included in a new Section 4.4. The Department included two new sections, Sections 8.9 and 8.10, to address when and how monitored collections are performed.

Section 8.12 establishes how the collector reports a donor's refusal to test. The Proposed Revisions to Mandatory Guidelines discussed what constituted a refusal to test during the collection process, but did not provide guidance to the collector on how to report a refusal to test. Additional information regarding urine collection is available from the Department. In addition, the Department included an instruction for the collector to discard any urine collected when a refusal to test occurred during the collection process.

Section 8.13 establishes the responsibilities for Federal agencies regarding collection sites. Many commenters disagreed with requiring Federal agencies to inspect all of their collection sites. The commenters believe this requirement to inspect the hundreds of collection sites would be cost-prohibitive and logistically impossible, and there does not seem to be evidence that errors by collectors are

common enough to justify such an inspection program. Other commenters suggested that, in lieu of annual inspections of all collection sites, HHS require agencies to inspect only collection sites which have generated "fatal flaws." The Department agrees that requiring Federal agencies to investigate and possibly inspect collection sites with "rejected for testing" errors ensures that collectors will receive appropriate training to prevent the recurrence of such errors. However, the Department maintains that random inspections are important to identify any collection procedure problems that may exist, but are not readily evident from the Federal CCF because the forms appear to be properly completed by the collector. The Department has revised the inspection requirements in this section accordingly. Federal agencies must inspect only 5 percent of the current number of collection sites, or up to a maximum of 50, selected randomly, of their collection sites each year. Additionally, Federal agencies are required to investigate reported collection site deficiencies (e.g., "rejected for testing" by either an HHS-certified laboratory or HHS-certified IITF) and take appropriate action which may include inspecting the collection site. The number of collection sites inspected because they have had "rejected for testing" results are not included in the 5 percent or maximum of 50 requirement.

#### **Subpart I—HHS Certification of Laboratories and IITFs**

The proposed section describing the goals and objectives of certifying laboratories and IITFs was removed from the Guidelines. Four commenters suggested that the discussion should be in the preamble rather than in the Guidelines. The Department agrees that the discussion in this section does not establish any specific analytical requirements and was removed from these Guidelines.

Section 9.1 (Section 9.2 in the Proposed Revisions to Mandatory Guidelines) states that the Secretary has the authority to certify laboratories. Four commenters disagreed with the right of the Secretary to review private sector specimen results tested under the Guidelines. The Department understands the concerns expressed by the commenters; however, the review of private sector specimen or non-regulated specimen results, only occurs for those private sector specimens that are tested in batches that contain federally-regulated specimens. This usually occurs with confirmatory test

batches because laboratories assemble these batches by taking the initial test positive specimens from different initial test batches to make the confirmatory test cost effective and efficient. Therefore, the policy described in this section is the same policy as described in the Proposed Revisions to Mandatory Guidelines.

Section 9.2 (Section 9.3 of the Proposed Revisions to Mandatory Guidelines) describes the application process for a laboratory or IITF, procedures for maintaining certification, and what a laboratory or IITF must do when its certification is not maintained. In the Proposed Revisions to Mandatory Guidelines, the term "imminent harm" is used as a reason to require a laboratory to immediately stop testing Federal agency specimens. Three commenters objected to using the term "imminent harm" because they believe the term limits the Department's ability to suspend a laboratory or IITF. Although the Department has successfully suspended a number of laboratories using "imminent harm" as the basis for an immediate suspension, the term has been removed from these Guidelines. The reasons for taking action against a laboratory or IITF are more appropriately discussed in Sections 9.12, 9.13, and 9.14. The Department has revised Section 9.2(c) to clarify the requirements when a laboratory or IITF does not maintain its HHS certification.

Section 9.3 (Section 9.5 of the Proposed Revisions to Mandatory Guidelines) describes the composition requirements for the PT samples that are used to challenge a laboratory or IITF's drug and specimen validity tests. The requirements in this section are the same as those contained in the current Guidelines, except for the pH specifications in Section 9.3(b)(2). These specifications were revised to challenge the pH tests used by IITFs, as described in Section 12.14(c)(1), as well as laboratory pH screening tests with a narrow dynamic range, as described in Section 11.18(c)(1).

Section 9.4 (Section 9.9 of the Proposed Revisions to Mandatory Guidelines) describes the requirements that an applicant laboratory must satisfy when testing the 3 consecutive sets of PT samples sent to the laboratory during the initial certification process. Section 9.5 (Section 9.13 of the Proposed Revisions to Mandatory Guidelines) describes the requirements that a certified laboratory must satisfy when testing the quarterly sets of PT samples sent to the laboratory as part of the maintenance PT program. In both sections, the requirements are the same

as in the current Guidelines with two exceptions concerning the evaluation of specific gravity results. The Department has retained the acceptable range of no more than  $\pm 0.0003$  specific gravity units from the mean for PT samples with a mean less than 1.0100, but has increased the acceptable range to  $\pm 0.0004$  specific gravity units when a PT sample's mean is equal to or greater than 1.0100. The Department has retained the limit of  $\pm 0.0006$  specific gravity units from the mean for assessing errors for PT samples with a mean less than 1.0100, but has increased the limit to  $\pm 0.0007$  specific gravity units when the PT sample's mean is equal to or greater than 1.0100. The Department has been evaluating the performance of the instruments used to measure specific gravity to 4 decimal places and believes increasing the precision limits for high specific gravity readings is reasonable and appropriate due to the nature of the refractive index and calibration methods using oil to calibrate the instruments.

Section 9.6 (Section 9.17 of the Proposed Revisions to Mandatory Guidelines) describes the PT requirements an applicant IITF must satisfy to conduct urine testing and Section 9.7 (Section 9.21 of the Proposed Revisions to Mandatory Guidelines) describes the PT requirements that an HHS-certified IITF must satisfy to conduct urine testing. Both sections were revised to be consistent with PT challenges for the initial testing part of a laboratory (i.e., requirements addressing confirmatory test challenges were deleted). One commenter noted the requirement to correctly identify and report the total drug challenges over 3 sets of PT samples was 80 percent for applicant and certified IITFs, while it is 90 percent for applicant and certified laboratories. The commenter recommended that the requirement be the same for IITFs and laboratories. The Department agrees and has revised the requirement in Section 9.6(a)(1) to be 90 percent for applicant IITFs for initial testing.

Section 9.8 (Section 9.22 of the Proposed Revisions to Mandatory Guidelines) describes the inspection requirements for an applicant laboratory or IITF and Section 9.9 (Section 9.23 of the Proposed Revisions to Mandatory Guidelines) describes the inspection requirements for an HHS-certified laboratory or IITF. The Proposed Revisions to Mandatory Guidelines required using at least two inspectors to inspect an applicant laboratory or IITF. Three commenters expressed concern with requiring at least two inspectors to

inspect an applicant laboratory or IITF, while the Proposed Revisions to Mandatory Guidelines permit only one inspector to potentially be used to inspect an HHS-certified laboratory or IITF. The Department has revised Section 9.8 to require two inspectors rather than the proposed "at least two inspectors." The Department believes that the inspection of an applicant laboratory or IITF must be conducted using two inspectors because this minimizes the possibility of a laboratory or IITF disputing the findings of one inspector as opposed to the findings from two inspectors. With regard to HHS-certified laboratories and IITFs, the Department retained the Proposed Revisions to Mandatory Guidelines requirement which states that an HHS-certified laboratory or IITF "is inspected by one or more inspectors." The Department believes that one inspector is appropriate to inspect an HHS-certified laboratory or IITF when the facility is very small, has an extremely small workload, and has a history of acceptable performance on testing the PT samples and on previous inspections. The Department believes that using one inspector is sufficient to conduct a thorough inspection and makes it cost-effective for very small HHS-certified laboratories and IITFs to remain in the certification program.

Section 9.10 specifies the criteria an individual must satisfy to be eligible for selection as an inspector for the Secretary under these Guidelines. This section also states that the Secretary of a Federal Agency may inspect an HHS-certified laboratory or IITF at any time. The requirements in this section are the same as in Section 9.24 of the Proposed Revisions to Mandatory Guidelines, but the section has been reworded for clarity.

Section 9.11 describes what happens when an applicant laboratory or IITF fails to satisfy the minimum requirements for either the PT program or the inspection program. The Department believes that an applicant laboratory or IITF must successfully satisfy all of the initial certification process requirements or be required to begin the process from the very beginning. That is, submit a new application with corrective actions indicated and then successfully satisfy the requirements for the 3 sets of PT samples. These requirements are the same as in the Proposed Revisions to Mandatory Guidelines, Section 9.25.

Section 9.12 describes what happens when a certified laboratory or IITF does not satisfy the minimum requirements for either the PT program or the inspection program. The policy in this

section is the same as that contained in the current and Proposed Revisions to Mandatory Guidelines in Section 9.26.

Section 9.13 describes the factors that are considered when determining whether to revoke a laboratory's or IITF's certification. The factors described are the same as those contained in the current and Proposed Revisions to Mandatory Guidelines in Section 9.27.

Section 9.14 states that the Secretary may suspend a laboratory's or IITF's certification to protect the interests of the United States. This policy is the same as that contained in the current and Proposed Revisions to Mandatory Guidelines in Section 9.28.

Section 9.15 describes how the Secretary notifies a laboratory or IITF that action is being taken against the laboratory or IITF. The policy in this section is the same as the policy described in the current and Proposed Revisions to Mandatory Guidelines in Section 9.29.

Section 9.16 describes how a laboratory that has had its certification revoked can apply for recertification. The policy is the same policy as described in the current and Proposed Revisions to Mandatory Guidelines in Section 9.30.

Section 9.17 states that the list of HHS-certified laboratories and IITFs will be published monthly in the **Federal Register**. This policy is the same policy as described in the current and Proposed Revisions to Mandatory Guidelines in Section 9.31.

#### **Subpart J—Blind Samples Submitted by an Agency**

Section 10.1 describes the requirements for Federal agencies to submit blind samples to certified laboratories or IITFs. Four commenters expressed concern that the proposed requirement to submit only 1 percent blind samples was too low. The Department agrees and has revised Section 10.1(b) to require each agency to submit 3 percent blind samples each year rather than having one requirement for the first 90 days (3 percent) and a different requirement after 90 days (1 percent). The Department also notes that the HHS-certified laboratories and IITFs will also be evaluated using quarterly PT samples and will be receiving the 3 percent blind samples from several agencies to ensure that they are properly handling and testing donor specimens. The policy in Section 10.1(c) describing the percentage of negative, positive, and adulterated or substituted blind samples to be submitted was revised. The proposed 80 percent negative blind samples was changed to 75 percent

negative blind samples, and 20 percent non-negative was changed to 15 percent positive and 10 percent adulterated or substituted.

Section 10.2 describes the specific requirements for each blind sample and the requirements are the same as those contained in the current and Proposed Revisions to Mandatory Guidelines.

Section 10.3 describes how a collector submits a blind sample to be tested. The requirements in this section are the same as those in the Proposed Revisions to Mandatory Guidelines. Section 10.4 describes what happens when an inconsistent result is reported on a blind sample. The requirements in this section are the same as those in the Proposed Revisions to Mandatory Guidelines.

#### Subpart K—Laboratory

Section 11.1 requires each certified laboratory to have a standard operating procedure manual and describes what information must be contained in the manual. The requirements in this section are the same as those in the current and Proposed Revisions to Mandatory Guidelines.

Section 11.2 describes the responsibilities of the individual who has responsibility for the day-to-day management of the urine drug testing laboratory. This individual is called the responsible person (RP). The responsibilities described in this section are the same as those described in the current and Proposed Revisions to Mandatory Guidelines, except the requirement that the RP qualify as a certifying scientist was moved to Section 11.3(e). The Department believes the requirement that the RP qualify as a certifying scientist is more appropriately included as a qualification rather than a responsibility.

Section 11.3 describes the scientific qualifications that an individual must have to serve as an RP. Three commenters believe the requirement for an RP to have experience with the collection and analysis of biological specimens is too general. The Department believes the qualification as stated in Section 11.3(b) is appropriate and does not need to specifically focus on collecting urine specimens. The primary purpose for this qualification is that the RP has experience and knowledge of the general procedures and issues that may arise with the collection and analysis of biological specimens (e.g., chain of custody, storage, handling, troubleshooting problems). The qualifications described in this section are the same as those

described in the current and Proposed Revisions to Mandatory Guidelines.

Section 11.4 describes what happens when an RP is absent or leaves a certified laboratory. This section has been revised to require a laboratory to have multiple RPs or one RP and an alternate RP. The requirement in the Proposed Revisions to Mandatory Guidelines did not make it clear that the laboratory must have an alternate RP when there is only one RP. The Department believes this requirement and establishing time limits for the alternate RP to assume RP duties when an RP is absent from a laboratory will minimize the impact on the laboratory, and enable the laboratory's continued compliance with the Guidelines when the RP is absent. The Department has revised Section 11.4(c) to state that an alternate RP must be found acceptable during an on-site inspection of the laboratory. This requirement ensures that the alternate RP is pre-approved. The Department believes an individual must be pre-approved as an alternate RP to ensure that someone with the appropriate knowledge and qualifications can assume RP responsibilities when the RP is absent from the laboratory.

Section 11.5 describes the qualifications an individual must have to certify a result reported by an HHS-certified laboratory. An individual who certifies results may be either a certifying scientist (CS) or a certifying technician (CT) depending on the type of test result he or she is certifying. The Department has decided to retain the bachelor's degree or equivalent requirement for the certifying scientist qualifications as described in the current Guidelines. The Department believes the training and experience specified in the Proposed Revisions to Mandatory Guidelines for a CT are sufficient to ensure that the CT can properly certify a negative, negative/dilute, or rejected for testing result. One commenter stated that the qualifications for a CT in an HHS-certified laboratory were not consistent with the qualifications for a CT in an HHS-certified IITF as described in the Proposed Revisions to Mandatory Guidelines. The same requirements are specified for a CT in the laboratory and IITF sections (i.e., Sections 11.5(b) and 12.5, respectively). The Department has further clarified that qualifications for a CT are the same in a laboratory and in an IITF by revising the definition for a certifying technician in Section 1.5. The revised definition states that a CT can verify negative, negative/dilute, and rejected for testing results reported by a laboratory or IITF.

Section 11.6 describes the qualifications and training other laboratory personnel must have. The policy in this section is the same as the policy described in the current and Proposed Revisions to Mandatory Guidelines, except that the current and Proposed Revisions to Mandatory Guidelines do not specifically state that the training must be documented.

Section 11.7 describes the security measures that a certified laboratory must maintain. This section has been revised to require the authorized escort to enter his or her name in the record used to document the entry of authorized visitors. The current and Proposed Revisions to Mandatory Guidelines did not require such documentation.

Section 11.8 describes internal laboratory chain of custody requirements. The policy in this section is the same as the policy in the Proposed Revisions to Mandatory Guidelines.

Section 11.9 describes the tests an HHS-certified laboratory must conduct on a specimen received from an IITF. Three commenters expressed concern with requiring an HHS-certified laboratory to conduct only the confirmatory test(s) on specimens received from an HHS-certified IITF. The commenters recommended that an HHS-certified laboratory test all specimens received from an HHS-certified IITF as if the specimens had not been previously tested. The commenters believe it is important that all analytical results supporting a positive, adulterated, substituted, or invalid result should be generated within the same facility. The Department agrees and has revised this section to require an HHS-certified laboratory to test each specimen received from an HHS-certified IITF in the same manner as if it had not been previously tested. This revision ensures that the final analytical results (both the initial and confirmatory data) and internal chain of custody documents are generated by one HHS-certified laboratory and can be properly reviewed and certified before the test result is released.

Section 11.10 describes the requirements for an initial drug test. One commenter stated that paragraph (c) of the Proposed Revisions to Mandatory Guidelines did not clearly state that the initial drug test kits must be "FDA-cleared." The Department agrees and clarified that drug tests must be approved, cleared, or otherwise recognized by FDA as accurate and reliable for the testing of a specimen for identifying drugs of abuse or their

metabolites. Therefore, it is more appropriate to refer to "FDA requirements" rather than limit the language to "FDA-cleared." We note that only those test kits subject to FDA premarket notification requirements must be "FDA-cleared." One commenter believes that the purpose for conducting a second initial test was not clearly stated in paragraph (d). The Department agrees and has revised this paragraph to indicate that a second initial drug test may be used when the second initial drug test has a different specificity than the first initial drug test. The second initial test must satisfy the batch quality control requirements for an initial drug test.

Section 11.11 describes what a laboratory must do to validate an initial drug test before using it to test donor specimens. One commenter recommended that the requirements to validate an initial drug test should be more stringent. The Department believes these requirements are appropriate and that they give an HHS-certified laboratory the flexibility it needs to validate the initial drug tests based on the instruments they are using. The Department also moved the requirement from Section 11.13 to document the effect of carryover to this section, because it is more appropriate to evaluate the possibility of carryover when the initial drug test is validated. Knowing when and if carryover can affect donor specimen results allows a laboratory to determine when corrective action must be taken to control for carryover.

Section 11.12 describes the batch quality control requirements when conducting initial drug tests. The requirements in this section are the same as those described in the current and Proposed Revisions to Mandatory Guidelines.

Section 11.13 describes the requirements for a confirmatory drug test. Four commenters disagreed with allowing the use of other chromatographic separation and mass spectrometry techniques for the confirmatory drug tests. They believe that gas chromatography/mass spectrometry (GC/MS) has been the gold standard since the Federal Workplace Drug Testing Program began and should be the only accepted confirmatory method until other methods are proven to be reliable and scientifically supportable. The Department disagrees and believes that other methods, such as liquid chromatography/mass spectrometry (LC/MS), LC/MS/MS, and GC/MS/MS, have been proven to be reliable to test specimens. While GC/MS remains the most common confirmatory

testing technology used in forensic drug testing laboratories, the Department does not want to prohibit laboratories from using technologies that provide forensically and scientifically supportable results. The Department proposed that these additional technologies be allowed in Federal workplace drug testing programs only after a thorough review of extensive information obtained through technical working groups consisting of drug testing and analytical chemistry experts. No comments were submitted that justified removal of these technologies from the proposed Guidelines. Since the proposed revisions to the Guidelines were published in April 2004, the use of these technologies has become even more widespread and there have been numerous studies employing these methods, providing additional data to demonstrate their forensic and scientific acceptability. These methods may offer some benefits over traditional GC/MS methods. For example, GC and LC provide a means to separate drugs of abuse from other compounds found in urine. The advantage of LC methods is that they may require less specimen preparation prior to analysis, thereby saving time and costs. Likewise MS and MS/MS methods are highly selective, reducing the chance that other substances present in the urine might interfere with the analysis and prevent the laboratory from obtaining a valid result. MS/MS technology provides an advantage in that it is also more sensitive than GC/MS. A properly validated and controlled GC/MS method is sensitive enough to meet the requirements of these Guidelines for forensic urine drug testing. However, the increased sensitivity provided by MS/MS can enable laboratories to use less specimen volume, which may have implications in some cases (e.g., when there are multiple drugs present in a specimen). Furthermore, many laboratories have implemented instruments and test methods using these different chromatographic and/or mass spectrometry technologies for forensic applications other than federally regulated workplace testing. Therefore, laboratories that are currently certified or plan to seek certification under these Guidelines may already have the experience and capability to employ these methods in Federal workplace testing programs or they may want to add these newer technologies to their testing protocols.

Section 11.14 describes what a laboratory must do to validate a confirmatory drug test before using it to test donor specimens. The Department

moved the requirement from Section 11.16 to document the effect of any carryover to this section, because it is more appropriate to evaluate the possibility of carryover when the confirmatory drug test method is validated. Knowing when and if carryover can affect donor specimen results allows a laboratory to determine when corrective action must be taken to control for carryover.

Section 11.15 describes the batch quality control requirements when conducting confirmatory drug tests. Three commenters recommended that this section be revised to allow using a multi-point calibration as well as a single-point calibration for each batch of specimens when conducting a confirmatory test. The Department agrees and has revised Section 11.15(a)(1) to read "A calibrator with its drug concentration at the cutoff." This revision allows multi-point calibration, while still requiring a cutoff calibrator.

Section 11.16 describes the analytical and quality control requirements for conducting specimen validity tests. The requirements are the same as those described in the current Guidelines, except that Section 11.16(b) specifically refers to the requirements specified in Section 11.18 rather than simply stating that appropriate calibrators and controls must be included. The Department believes this revision will ensure that each laboratory will use the same calibrators and controls when conducting specimen validity tests.

Section 11.17 is a new section that describes what a certified laboratory must do to validate a specimen validity test. The Department is establishing these requirements to ensure that specimen validity tests, like drug tests, are validated before they are used for donor specimens. The policy has been intentionally written as a general requirement because each type of specimen validity test has different performance characteristics.

Section 11.18 describes the requirements for conducting each type of specimen validity test on a urine specimen. One commenter recommended allowing an HHS-certified laboratory to use a three decimal place refractometer as a preliminary specific gravity test to determine if the initial specific gravity test must be conducted. The Department agrees and has revised Section 11.18(b)(1) to allow a laboratory to use a refractometer measuring to at least three decimal places as a specific gravity screening test when the creatinine is greater than 5.0 mg/dL and less than 20 mg/dL. However, laboratories must use a four decimal

place refractometer to measure specific gravity for specimens when the initial creatinine test result is equal to or less than 5.0 mg/dL or when the screening specific gravity test result using a three decimal place refractometer is less than 1.002. These criteria were selected for deciding whether a three or four decimal refractometer must be used because the test results are approaching the criteria for reporting a substituted specimen which may lead to adverse personnel action. The Department also added the quality control requirements for conducting the specific gravity screening test. One commenter recommended that colorimetric specific gravity assays be permitted for use as the initial specific gravity test. The Department disagrees because these assays lack the required accuracy and precision to serve as an initial specific gravity test. One commenter recommended that pH meters used for the initial and confirmatory pH tests should print a paper copy report or be interfaced with a Laboratory Information Management System (LIMS) or computer. The commenter noted that the Guidelines include this requirement for refractometers used to conduct the initial and confirmatory specific gravity tests, and the same forensic considerations apply for pH tests. The Department agrees and has added Section 11.18(c)(2) specifying that a pH meter used for the initial and confirmatory pH tests must report and display pH to at least one decimal place, and must be interfaced with a LIMS or computer, and/or generate a paper copy of the digital electronic display to document the numerical values of the pH test results.

Section 11.19 describes the requirements for a certified laboratory to report results to an MRO. One commenter was opposed to requiring an HHS-certified laboratory to provide the concentration of a drug in a specimen at the time the test result is reported to the MRO. The Department disagrees and believes this policy is appropriate because, in keeping with the paperwork reduction and elimination acts, it eliminates the need for the MRO to generate a request in writing to obtain the concentrations for positive specimens. One commenter stated that reporting a positive and invalid result on the same specimen is confusing and recommended that the positive result and "the reason for the invalid result" be reported, rather than using the term "invalid result" along with the reason for the invalid result. The Department recognizes that requiring the laboratory to report both results to the MRO may

be confusing; however, the MRO must discuss both results with the donor. The invalid result may only have an impact on the testing of the split specimen if requested by the donor. One commenter recommended that specific guidance be included on the content of any computer-generated report. The Department does not believe detailed guidance is needed, but has revised the appropriate Section 11.19(o) to state that the computer-generated report must contain sufficient information to ensure that the test result is properly associated with the Federal CCF that the MRO received from the collector. The Department added Section 11.19(g) to maintain the policy in the current Guidelines which requires the laboratory to contact the MRO prior to reporting specimens meeting certain "invalid result" criteria. This policy is important to ensure that the laboratory and the MRO discuss those specimens for which a positive or adulterated result could be determined, using different or additional tests at another certified laboratory. If additional testing does not appear to be feasible, the laboratory reports the invalid result. The MRO can initiate action immediately upon receipt of the report, in accordance with Section 13.4.

Section 11.20 describes how long a certified laboratory must retain a specimen. Section 11.20(c) was revised to require a Federal agency to specify a period of time rather than "an additional period of time" when requesting a laboratory to retain a specimen beyond the normal one year specimen storage period. Also, the statement that a laboratory must maintain any specimen under legal challenge for an indefinite period of time has been deleted. The laboratory must be instructed by the agency as to the period of time the specimen under legal challenge will need to be retained beyond the normal one year storage period.

Section 11.21 describes how long a certified laboratory must retain records. This section has been revised to specify the records that the HHS-certified laboratory must maintain when there is a legal challenge to the test result for a particular specimen. The revision allows a Federal agency to request a laboratory to maintain a copy of the documentation package for the specimen result being challenged for a specified period of time. The revision also permits the HHS-certified laboratory to retain records other than those included in the documentation package beyond the 2 year period of time that records are normally maintained.

Section 11.22 describes the statistical summary report that a certified laboratory must provide to an agency. The summary report is the same as the report described in the current and Proposed Revisions to Mandatory Guidelines. Four commenters expressed concern with requiring an HHS-certified laboratory to make qualified personnel available to testify in a proceeding against a Federal employee. They were concerned that several individuals may be required to testify, thereby disrupting the laboratory's ability to continue testing specimens. The Department agrees and has revised Section 11.22(d) to require an HHS-certified laboratory to make only one qualified individual available to testify. This change is consistent with what normally happens in proceedings where laboratory results are being challenged by a donor.

Section 11.23 describes the information a laboratory must make available to a Federal employee. The Department has revised this section to require that the curriculum vitae for the responsible person(s) be included along with the curriculum vitae for the certifying scientist that certified the test result.

Section 11.24 describes the type of relationship that is prohibited between a certified laboratory and an MRO. Three commenters recommended that this section be revised to include additional restrictions or requirements that can be found in other regulated programs. The Department believes the requirements are sufficient to ensure that an MRO would report a potential problem with an HHS-certified laboratory to a Federal agency or to the appropriate regulatory office within HHS. In addition, the requirements in this section have been used successfully by HHS in previous versions of the Guidelines. The section has been reworded to clarify the requirements.

Section 11.25 was added, addressing the type of relationship allowed between an HHS-certified laboratory and an IITF. This section was added for clarity, and is consistent with the requirements specified in the IITF sections of the Proposed Revisions to Mandatory Guidelines.

The Department removed the requirement that a certified laboratory must inform its private sector clients when it uses testing procedures different from those used for Federal agency specimens. Although this requirement has been a program policy for many years, the Department is confident that HHS-certified laboratories would not intentionally mislead their private sector clients into believing that regulated procedures

would be used to test their specimens when, in fact, less stringent procedures are being used.

#### **Subpart L—Instrumented Initial Test Facility (IITF)**

Section 12.1 describes what an HHS-certified IITF must include in its standard operating procedure manual. The requirements in this section are the same as the requirements described in the Proposed Revisions to Mandatory Guidelines, except that a 2 year period was specified for retaining archived SOPs, consistent with the requirement for laboratories in Section 11.1.

Section 12.2 describes the responsibilities of the responsible technician (RT). The Department moved the requirement that the RT qualify as a certifying technician to Section 12.3(e), because this is a qualification rather than a responsibility. All other requirements in this section are the same as the requirements described in the Proposed Revisions to Mandatory Guidelines.

Section 12.3 describes the qualifications that the RT must have. One commenter recommended that the qualifications for the RT be the same as those for an alternate RP working in an HHS-certified laboratory. The Department disagrees with the recommendation because the qualifications for an alternate RP include responsibilities and expertise in technical areas (i.e., confirmatory testing) that the RT does not need to know to fulfill the responsibilities as an RT. However, the requirements are similar to those of a CS at an HHS-certified laboratory in Section 11.5. The requirement that the RT qualify as a certifying technician ensures that the RT can properly review the same results that a certifying technician reviews and reports at an HHS-certified laboratory or IITF.

Section 12.4 describes what happens when the RT is absent or leaves an HHS-certified IITF. The Department has revised Section 12.4(c) to state that an alternate RT must be found acceptable during an on-site inspection of the IITF. This requirement ensures that the alternate RT is pre-approved. The Department believes an individual must be pre-approved as an alternate RT to ensure that someone with the appropriate knowledge and qualifications can assume RT responsibilities when the RT is absent from the IITF.

Section 12.5 describes the qualifications an individual must have to certify a result reported by an HHS-certified IITF. The requirements in this section are the same as the requirements

described in the Proposed Revisions to Mandatory Guidelines, and are the same as those for a CT in a laboratory, specified in Section 11.5(b).

Section 12.6 describes the qualifications and training other personnel must have who work in an IITF. The requirements in this section are the same as the requirements described in the Proposed Revisions to Mandatory Guidelines, except that the Proposed Revisions to Mandatory Guidelines did not specifically state that the training must be documented.

Section 12.7 describes the security measures that an HHS-certified IITF must maintain. The Department has revised this section to require the authorized escort to enter his or her name in the record used to document the entry of authorized visitors. These requirements are the same as for an HHS-certified laboratory, as specified in Section 11.7. The change in this requirement clarifies that the record must always indicate all of the individuals who may have had access to specimens maintained in secure areas. It is not any different than requiring any employee (whether serving as an escort or not) to document every time he or she enters or leaves a secured area.

Section 12.8 describes internal IITF chain of custody requirements. The requirements in this section are the same as the requirements described in the Proposed Revisions to Mandatory Guidelines.

Section 12.9 describes the requirements for an initial drug test used by an HHS-certified IITF. The Department has added this section to ensure that the drug tests used by an HHS-certified IITF satisfy the same initial drug test requirements as required for HHS-certified laboratories.

Section 12.10 was added to describe validation requirements for initial drug tests in an HHS-certified IITF. The requirements are the same as for initial drug tests in an HHS-certified laboratory.

Section 12.11 describes the batch quality control requirements for initial drug tests in an IITF. These are the same as the requirements in the Proposed Revisions to Mandatory Guidelines, in that the requirements are the same as for an HHS-certified laboratory. For clarity, this section has been revised to list the required quality control samples, rather than referring to the relevant laboratory section.

A single section, Section 13.14, was included in the Proposed Revisions to Mandatory Guidelines to address specimen validity testing in IITFs, referring to the relevant laboratory sections. The Department has expanded

the information into three sections to address the requirements in a manner consistent with the format of Subpart K for HHS-certified laboratories.

Section 12.12 addresses the IITF analytical and quality control requirements for specimen validity tests, specifying that testing is performed on a single aliquot. Since IITFs do not report adulterated, substituted, or invalid specimens, there is no need to perform two tests on separate aliquots, as required in a laboratory.

Section 12.13 describes the validation requirements for specimen validity tests. The requirements in this section are the same as for an HHS-certified laboratory.

Section 12.14 describes the requirements for an HHS-certified IITF to conduct each specimen validity test. One commenter recommended that an HHS-certified IITF be permitted to use a pH screening test to determine the pH rather than requiring the use of a pH meter. The Department agrees and has specified in this section that an HHS-certified IITF may use a pH screening test to determine if an initial pH validity test must be performed. The HHS-certified IITF will forward specimens with pH test results outside the acceptable range to an HHS-certified laboratory where the laboratory will conduct the initial pH validity test and, if needed, the confirmatory pH validity test. This policy permits an HHS-certified IITF to determine pH without a requirement to have a pH meter available for conducting the initial pH test.

Section 12.15 describes the requirements for an HHS-certified IITF to report a negative or rejected for testing result to an MRO. One commenter recommended that this section be revised to allow an HHS-certified IITF to report a urine specimen that is negative/dilute to the MRO. The Proposed Revisions to Mandatory Guidelines stated that only a negative result could be reported by an HHS-certified IITF to an MRO. The Department agrees and has revised the section to permit an HHS-certified IITF to report negative, negative/dilute (when creatinine is greater than 5 mg/dL), and rejected for testing results directly to the MRO. All other requirements in this section are the same as the requirements described in the Proposed Revisions to Mandatory Guidelines.

Section 12.16 describes how an HHS-certified IITF handles a specimen that tested as positive, adulterated, substituted, or invalid at the IITF. The Department has revised this section by



removing the proposed requirement for the HHS-certified IITF to record these types of results on the OMB-approved chain of custody form. The Department revised the Guidelines (Section 11.10) to require an HHS-certified laboratory to perform both initial and confirmatory testing for specimens received for testing from an IITF.

Section 12.17 describes how long an HHS-certified IITF must retain a specimen. The Department added this section to specifically state that an HHS-certified IITF is permitted to discard specimens that are reported negative, negative/dilute, or rejected for testing. This policy is the same as those for an HHS-certified laboratory.

Section 12.18 describes how long an HHS-certified IITF must retain records. The Department has revised Section 12.18(b) to specify the records that the HHS-certified IITF must maintain when there is a legal challenge to the test result for a particular specimen. The revision requires a Federal agency to specify the period of time that an IITF must maintain a copy of the documentation package (as described in Section 12.20) for the specimen result being challenged rather than requiring an indefinite period of time as stated in the Proposed Revisions to Mandatory Guidelines. Section 12.18(c) was added to permit an HHS-certified IITF to retain records other than those included in the documentation package beyond the 2 year period of time that records are normally maintained.

Section 12.19 describes the statistical summary report that an HHS-certified IITF must provide semiannually to an agency. One commenter noted that this section must be revised because an HHS-certified IITF cannot report an invalid result. The Department agrees and has revised this section to clarify that an IITF indicates the number of specimens that were reported negative, negative/dilute, and rejected for testing on the statistical summary report. The Department also revised the section to clarify that an IITF indicates the number of specimens forwarded to an HHS-certified laboratory for additional drug and/or specimen validity testing. Three commenters raised concern with the proposed requirement that an HHS-certified IITF must make available qualified personnel to testify in a proceeding against a Federal employee when that proceeding is based on a test result reported by the HHS-certified IITF. The Department agrees and has revised the policy to specifically indicate that one qualified individual must be made available to testify. This change is consistent with what normally occurs in legal proceedings and is

consistent with the policy that applies to an HHS-certified laboratory.

Section 12.20 describes the information an IITF must make available to a Federal employee. The Department has revised this section to require that the curriculum vitae for the responsible technician be included along with the curriculum vitae for the certifying technician that certified the test result.

Section 12.21 describes the type of relationship that is prohibited between an HHS-certified IITF and an MRO. The policy in this section is the same policy as described in the Proposed Revisions to Mandatory Guidelines. This section was reworded to clarify the requirements.

Section 12.22 describes the type of relationship that can exist between an HHS-certified IITF and an HHS-certified laboratory. Three commenters raised concern over allowing any type of relationship to exist between an HHS-certified IITF and an HHS-certified laboratory. The Department believes any relationship is acceptable because HHS-certified laboratories and IITFs are certified independently. Therefore, the Department has no objection if an HHS-certified laboratory wants to establish and own one or more HHS-certified IITFs.

#### **Subpart M—Medical Review Officer (MRO)**

Section 13.1 describes who may serve as an MRO. Several commenters disagreed with the proposed policy in Section 13.1(b) to require MRO organizations to submit their training programs for review and approval by HHS before their trained MROs would be permitted to serve as MROs for Federal agencies. Other commenters stated that the Guidelines should include objective criteria that will be used to assess and approve the MRO organization's training programs. The Department believes that approving these MRO training courses is necessary to ensure that MROs receive all the information needed to properly evaluate drug test results and that they demonstrate and document their knowledge of the drug testing program by passing an examination. With regard to the criteria used by HHS to assess these training courses, the training requirements in Section 13.2 will serve as the basis for approving each MRO organization's training course.

Section 13.2 describes the training requirements before a physician can serve as an MRO. The training requirements in this section will serve as the basis for approving an MRO organization's training course. HHS

approval will focus on how well the course presents the materials for each requirement listed in this section and how well the organization documents each MRO's understanding of the material by examination.

Section 13.3 describes the responsibilities of an MRO. The Department revised this section to address the requirement for the MRO to medically evaluate donors who were unable to provide a sufficient amount of urine for a drug test, as described in Section 13.5 and to address the requirement for the MRO and laboratory to discuss specimens meeting certain "invalid result" criteria, as described in Section 11.19(g). One commenter pointed out that the preamble for the Proposed Revisions to Mandatory Guidelines required the MRO to review 5 percent of the negative results reported by staff to ensure that the staff is properly performing the review process, but the text did not specify the 5 percent requirement. The Department has revised Section 13.3(a) to include this requirement. Three commenters recommended deleting the sentence which stated that "The MRO must cancel the result for any agency's specimen that is not collected or tested in accordance with these Guidelines." The commenters believed it places a burden on MROs to be finders of fact concerning alleged irregularities at the collection site. The Department agrees and has deleted the sentence.

Section 13.4 describes what an MRO must do when reviewing a drug test result. Three commenters stated that the proposed section referring to invalid results reported by an HHS-certified IITF should be revised, because IITFs will not report such results. The Department agrees and has deleted any reference to an HHS-certified IITF reporting an invalid result in Section 13.4. If an HHS-certified IITF finds a presumptive invalid result for a specimen, the IITF must forward the specimen to an HHS-certified laboratory for testing. Recent research supports that high temperature for an extended time may increase urine pH up to 9.5. This means that conditions during specimen transport and/or storage may cause pH to fall within the invalid range (i.e., greater than or equal to 9.0, but less than 11.0). The Department has added guidance to MROs in paragraph f of this section on interpreting an invalid result based on pH in the range of 9.0 to 9.5. This allows the MRO to consider time and temperature as an alternative, non-medical explanation for this invalid result. The Department has removed the sections addressing MRO actions in response to a second specimen collected

after an invalid result for which there is no valid medical explanation. The Department will provide detailed guidance for MROs outside of these Guidelines.

The Department added new Sections 13.5 and 13.6 to describe action the MRO must take when a collector reports that a donor was unable to provide a sufficient urine specimen. Sections 8.5(b)(2) and 8.6(e)(2)(ii) require the collector to document when a donor did not provide a urine specimen or when a donor provided an insufficient amount (i.e., less than 45 mL). Section 13.5 provides a detailed description of what the MRO and the Federal agency must do to determine the reason for the donor's inability to provide a urine specimen. Section 13.6 describes what the MRO and the Federal agency must do when a donor has a permanent or long-term medical condition that precludes him or her from providing a sufficient specimen when a negative result is required (i.e., for a Federal agency applicant/pre-employment test, a follow-up test, or a return-to-duty test).

Section 13.7 describes when the donor has the opportunity to request the testing of a split (Bottle B) specimen. The policy in this section is the same policy as described in the Proposed Revisions to Mandatory Guidelines.

Section 13.8 describes how an MRO reports a primary (Bottle A) specimen test result to an agency. The requirements in this section are the same as those described in the Proposed Revisions to Mandatory Guidelines.

Section 13.9 describes the type of relationship that is prohibited between an MRO and an HHS-certified laboratory or an HHS-certified IITF. The Department has revised the question and policy in this section to delete references to a POCT.

#### **Subpart N—Split Specimen Tests**

Section 14.1 describes when a split specimen may be tested. Several commenters disagreed with the requirement that the donor must request the testing of his or her split specimen in writing. The commenters believe the requirement places an unreasonable burden on the donor and may cause unnecessary delays in testing and reporting split specimen results. The Department agrees that requiring a written request may be an obstacle to getting the split specimen tested in a timely manner and, therefore, has revised Section 14.1(b) to allow the MRO to have a split specimen tested based on a verbal request from the donor. However, the MRO is required to document in his or her records (e.g., a

donor interview sheet) that the donor made a verbal request. The Department believes this documentation is acceptable to ensure that the donor properly initiated the request within 72 hours after being informed of the result by the MRO. The Department has revised the proposed policy for MRO action when the split (Bottle B) specimen cannot be tested by a second laboratory (e.g., insufficient specimen, lost in transit, split not available, no second laboratory available to perform the test). The Proposed Revisions to Mandatory Guidelines (Section 15.1) had required the MRO to direct the agency to immediately collect another specimen in these cases. In response to comments received, the Department has revised this section, now Section 14.1(c), to require an immediate recollection under direct observation. This is consistent with the current Guidelines.

Sections 14.2, 14.3, and 14.4 describe the requirements to test split specimens when the primary specimens are tested positive, adulterated, or substituted, respectively. The requirements in these sections are the same as the requirements described in the current and Proposed Revisions to Mandatory Guidelines.

Section 14.5 requires the second certified laboratory to report the split specimen result directly to the MRO. The policy in this section is the same as the policy described in the Proposed Revisions to Mandatory Guidelines.

Section 14.6 describes the specific action(s) that an MRO must take after receiving the split specimen result from the second certified laboratory. The actions described in this section are the same as the actions described in the current and Proposed Revisions to Mandatory Guidelines.

Section 14.7 describes the different ways that an MRO can report split specimen results to an agency. The policies in this section are the same as those described in the Proposed Revisions to Mandatory Guidelines.

Section 14.8 describes how long a certified laboratory must retain a split (Bottle B) specimen. The policy in this section is the same as the policy described in the Proposed Revisions to Mandatory Guidelines.

#### **Subpart O—Criteria for Rejecting a Specimen or Cancelling a Test**

Section 15.1 describes those discrepancies (i.e., "fatal flaws") that require an HHS-certified laboratory or an HHS-certified IITF to report a urine specimen as rejected for testing. The fatal flaws described in this section are the same as those described in the

Proposed Revisions to Mandatory Guidelines. Section 15.2 describes the discrepancies that require an HHS-certified laboratory or an HHS-certified IITF to report a urine specimen as rejected for testing unless the discrepancy is corrected. The discrepancies described in this section are the same as those described in the Proposed Revisions to Mandatory Guidelines.

Section 15.3 describes the deficiencies that are not sufficient to require an HHS-certified laboratory or an HHS-certified IITF to reject a urine specimen for testing or for an MRO to cancel a test. Several commenters stated the requirement in this section directing an MRO to track the frequency of omissions and discrepancies to determine when a collector, laboratory, or IITF should take immediate corrective action to prevent the recurrence of an error was unduly burdensome. The Department believes this requirement is necessary because the MRO is the only individual who reviews all of the information before making a final determination and reporting a test result to an agency. If a collector, laboratory, or IITF continues to make the same error even though the error may be insignificant, eliminating the error on future Federal CCFs is preferable than having it appear on every Federal CCF.

Section 15.4 describes the discrepancies that may require an MRO to cancel a test. Three commenters stated that this section contains correctable discrepancies that should be included in Section 15.2. The Department believes that the correctable discrepancies in this section cannot be included in Section 15.2 because they can only be identified as discrepancies by the MRO. The discrepancies in Section 15.2 are those that should be identified by the HHS-certified laboratory or HHS-certified IITF when the Federal CCFs and specimens are received for testing. Four commenters requested clarification in Section 15.4(c) and Section 15.4(d), respectively, on the consequences if the MRO does not obtain a statement from the certifying scientist that he or she inadvertently forgot to sign the Federal CCF and the HHS-certified laboratory or IITF did not retransmit a modified electronic report. The Department agrees and revised Sections 15.4(c) and (d) to require the MRO to cancel the test when the required corrective action was not taken.

**Subpart P—Laboratory or IITF Suspension/Revocation Procedures**

The requirements in this entire subpart are the same as the requirements described in the Proposed Revisions to Mandatory Guidelines.

**Executive Order 12866: Economic Impact**

In accordance with Executive Order 12866, the Department submitted the Guidelines for review by the Office of Management and Budget (OMB). However, because the Guidelines will not have an annual impact of \$100 million or more, and will not have a material adverse effect on the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments, they are not subject to the detailed analysis requirements of Section 6(a)(3)(C) of Executive Order 12866.

The Department asked the Department of Transportation (DOT) for its estimate of the annual economic impact of the revised Guidelines on their regulated entities. Specifically, DOT requires that certain industries (e.g., Federal Motor Carrier Safety Administration) use the drug testing standards for HHS-certified laboratories and HHS-certified IITFs under these Guidelines. The Department notes that lowering testing cutoffs for existing drugs and establishing capability to test for new drugs, such as MDMA, will not impose additional costs or burdens on DOT-regulated entities, since most

laboratories currently use similar testing standards on many non-regulated client specimens. It is estimated that there may be 10 percent more users of amphetamines and cocaine identified using the lowered cutoffs and testing for new drugs. The incidence and prevalence of amphetamines and cocaine use are very low (approximately 19,000 amphetamines positive and approximately 40,000 cocaine positive specimens in more than 6,500,000 tests conducted in 2007) in the DOT-regulated industries, and identification of 10 percent more positives should not impose a significant economic impact or burden for either the testing or the MRO review of the results.

**Paperwork Reduction Act of 1995**

These revised Guidelines contain information collections which are subject to review by OMB under the Paperwork Reduction Act of 1995 (the PRA)(44 U.S.C. 3507(d)). The title, description and respondent description of the information collections are shown in the following sections with an estimate of the annual reporting, disclosure, and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

*Title:* Mandatory Guidelines for Federal Workplace Drug Testing Programs.

*Description:* The Mandatory Guidelines establish the scientific and technical guidelines for Federal workplace drug testing programs and establish standards for certification of laboratories engaged in drug testing for Federal agencies under authority of section 503 of Public Law 100-71, 5 U.S.C. 7301 note, and Executive Order 12564. Federal agencies test applicants to sensitive positions, individuals involved in accidents, individuals for cause, and random testing of persons in sensitive positions. The program has depended on urine testing since 1988; the reporting, recordkeeping, and disclosure requirements associated with urine testing are approved under OMB control number 0930-0158.

In an effort to shorten the time for negative results to be reported to the Federal agency, the changes also establish criteria for an IITF that will only perform initial tests.

*Description of Respondents:* Individuals or households; Businesses or other for-profit institutions; Not-for-profit institutions.

*The burden estimates in the tables below are based on the following number of respondents:* 38,000 Federal agency applicants who apply for employment in testing designated positions, 100 collectors, 50 urine testing laboratories, 25 IITFs, and 100 MROs.

ESTIMATE OF ANNUAL REPORTING BURDEN

Section	Purpose	Number of respondents	Responses/respondent	Hours/response	Total hours
9.2(a)(1)	Lab or IITF required to submit application for certification.	28	1	3	84
9.10(a)(3)	Materials to submit to become an HHS inspector.	25	1	2	50
11.4(c)	Lab submits qualifications of new RPs and alternate RPs to HHS.	75	1	2	150
11.22(a)	Specifications for lab semi-annual statistical report of test results to each Federal agency.	75	2	0.5	75
12.4(c)	IITF submits qualifications of new RTs and alternate RTs to HHS.	50	1	2	100
12.19(a)	Specifies contents of IITF semi-annual statistical report to Federal agencies served.	25	5	0.5	63
14.7	Specifies that MRO must report verified split specimen test results to the Federal agency.	100	5	0.05 (3 min)	25
16.1(b); 16.5(a)	Specifies content of request for informal review of suspension/proposed revocation of certification.	1	1	3	3
16.4	Specifies information appellant provides in first written submission when lab or IITF suspension/revocation is proposed.	1	1	0.5	0.5

## ESTIMATE OF ANNUAL REPORTING BURDEN—Continued

Section	Purpose	Number of respondents	Responses/respondent	Hours/response	Total hours
16.6	Requires appellant to notify reviewing official of resolution status at end of abeyance period.	1	1	0.5	0.5
16.7(a)	Specifies contents of appellant submission for review.	1	1	50	50
16.9(a)	Specifies content of appellant request for expedited review of suspension or proposed revocation.	1	1	3	3
16.9(c)	Specifies contents of review file and briefs.	1	1	50	50
<b>TOTAL</b>		<b>384</b>			<b>654</b>

The following reporting requirements are also in the Proposed Revisions to Mandatory Guidelines, but have not been addressed in the above reporting burden table: Collector must report any unusual donor behavior or unusual physical appearance of the urine

specimen on the Federal CCF (Sections 8.4(3) and 8.6(d)(1)); collector annotates the Federal CCF when a specimen is a blind sample (Section 10.3(a)); and MRO notifies the Federal agency and HHS when an error occurs on a blind sample (Section 10.4(c)). SAMHSA has

not calculated a separate reporting burden for these requirements because they are included in the burden hours estimated for collectors to complete Federal CCFs and for MROs to report results to Federal agencies.

## ESTIMATE OF ANNUAL DISCLOSURE BURDEN

Section	Purpose	Number of respondents	Responses/respondent	Hours/response	Total hours
4.5(c)	Collector is given name and phone of Federal agency point of contact.	100	1	0.05 (3 min)	5
11.23(b)	Information on drug test that lab must provide to donor through MRO.	50	10	3	1,500
12.20(b)	Drug test information that IITF must provide to donor through MRO.	25	10	2	500
13.7(b)	MRO must inform donor of right to request split specimen test when a positive, adulterated, or substituted result is reported.	100	5	3	1,500
<b>Total</b>		<b>275</b>			<b>3,505</b>

The following disclosure requirements are also included in the Proposed Revisions to Mandatory Guidelines, but have not been addressed in the above disclosure burden table:

The collector must explain the basic collection procedure to the donor and answer any questions (Sections 8.3(e) and (g)). SAMHSA believes having the collector explain the collection

procedure to the donor and to answer any questions is a standard business practice and not a disclosure burden.

## ESTIMATE OF ANNUAL RECORDKEEPING BURDEN

Section	Purpose	Number of respondents	Responses/respondent	Hours/response	Total hours
8.3, 8.4, 8.5, 8.6, and 8.7	Collector completes Federal CCF for specimen collected.	100	380	0.07 (4 min)	2,660
11.8 and 11.19(a) and (o)	Lab completes Federal CCF upon receipt of specimen and before reporting result.	50	760	0.05 (3 min)	1,900
12.8(a) and 12.15(f)	IITF completes Federal CCF upon receipt of specimen and before reporting result.	25	1520	0.05 (3 min)	1,900
13.3(c)(4)	MRO completes the Federal CCF before reporting result.	100	380	0.05 (3 min)	1,900
14.1(b)	MRO documents donor's request to have split specimen tested.	300	1	0.05 (3 min)	15
<b>Total</b>		<b>575</b>			<b>8,375</b>

The revised Mandatory Guidelines contain a number of recordkeeping requirements that SAMHSA considers not to be an additional recordkeeping burden. In subpart D, a trainer is required to document the training of an individual to be a collector (Section 4.3(a)(4)(ii)) and the documentation must be maintained in the collector's training file (Section 4.3(c)). SAMHSA believes this training documentation is common practice and is not considered an additional burden. In subpart F, if a collector uses an incorrect form to collect a Federal agency specimen, the collector is required to provide a statement (Section 6.2(b)) explaining why an incorrect form was used to document collecting the specimen. SAMHSA believes this is an extremely infrequent occurrence and does not create a significant additional recordkeeping burden. Subpart H (Section 8.6(d)(1)) requires collectors to enter any information on the Federal CCF of any unusual findings during the urine specimen collection procedure. These recordkeeping requirements are an integral part of the collection procedure and are essential to documenting the chain of custody for the specimens collected. The burden for these entries is included in the recordkeeping burden estimated to complete the Federal CCF and is, therefore, not considered an additional recordkeeping burden. Subparts K and L describe a number of recordkeeping requirements for laboratories and IITFs associated with their testing procedures, maintaining chain of custody, and keeping records (i.e., Sections 11.1(a), 11.1(d), 11.2(b), 11.2(c), 11.2(d), 11.6(a), 11.7(c), 11.8(b), 11.8(c), 11.8(e), 11.11, 11.14, 11.17, 11.21, 12.1(a), 12.1(d), 12.2(b), 12.2(c), 12.2(d), 12.6(b), 12.7(c), 12.8(b), 12.10, 12.13, and 12.18). These recordkeeping requirements are necessary for any laboratory or IITF to conduct forensic drug testing and to ensure the scientific supportability of the test results. Therefore, they are considered to be standard business practice and are not considered a burden for this analysis. This same opinion applies to the recordkeeping requirements for MROs in Section 13.3(c)(5).

Thus the total annual response burden associated with the testing of urine specimens by the laboratories and IITFs is estimated to be 13,768 hours (that is, the sum of the total hours from the above tables). This is in addition to the 1,786,809 hours currently approved by OMB under control number 0930-0158 for urine testing under the current Mandatory Guidelines.

As required by section 3507(d) of the PRA, the Secretary has submitted a copy of these revised Mandatory Guidelines to OMB for its review. Comments on the information collection requirements are specifically solicited in order to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of HHS's functions, including whether the information will have practical utility; (2) evaluate the accuracy of HHS'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.

OMB is required to make a decision concerning the collection of information contained in these Guidelines between 30 and 60 days after publication of this document in the *Federal Register*. Therefore, a comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication.

Organizations and individuals desiring to submit comments on the information collection requirements should direct them to the Office of Information and Regulatory Affairs, OMB, New Executive Office Building, 725 17th Street, NW., Washington, DC 20502, Attn: Desk Officer for SAMHSA. Because of delays in receipt of mail, comments may also be sent to 202-395-6974 (fax).

Dated: July 23, 2008.

**Terry L. Cline,**  
Administrator, SAMHSA.

Dated: July 29, 2008.

**Michael O. Leavitt,**  
Secretary.

The Mandatory Guidelines as revised are hereby adopted in accordance with Section 503 of Public Law 100-71 and Executive Order 12564.

#### **Mandatory Guidelines for Federal Workplace Drug Testing Programs**

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- 12.7 What security measures must an HHS-certified IITF maintain?
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- 12.9 What are the requirements for an initial drug test?
- 12.10 What must an HHS-certified IITF do to validate an initial drug test?
- 12.11 What are the batch quality control (QC) requirements when conducting an initial drug test?
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- 13.3 What are the responsibilities of an MRO?
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- 13.7 Who may request a test of a split specimen?
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- 15.1 What discrepancies require an HHS-certified laboratory or an HHS-certified IITF to report a specimen as rejected for testing?
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- 15.3 What discrepancies are not sufficient to require an HHS-certified laboratory or an HHS-certified IITF to reject a specimen for testing or an MRO to cancel a test?
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- 16.1 When may an HHS-certified laboratory or IITF be suspended?
- 16.2 What definitions are used for this subpart?
- 16.3 Are there any limitations on issues

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- 16.4 Who represents the parties?
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- 16.6 What is an abeyance agreement?
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- 16.13 What administrative records are maintained?
- 16.14 What are the requirements for a written decision?
- 16.15 Is there a review of the final administrative action?

**Subpart A—Applicability**

**Section 1.1 To whom do these Guidelines apply?**

- (a) These Guidelines apply to:
- (1) Executive Agencies as defined in 5 U.S.C. 105;
- (2) The Uniformed Services, as defined in 5 U.S.C. 2101(3) (but excluding the Armed Forces as defined in 5 U.S.C. 2101(2));
- (3) Any other employing unit or authority of the Federal Government except the United States Postal Service, the Postal Rate Commission, and employing units or authorities in the Judicial and Legislative Branches; and
- (4) The Intelligence Community, as defined by Executive Order 12333, is subject to these Guidelines only to the extent agreed to by the head of the affected agency;
- (5) Laboratories and instrumented initial test facilities (IITFs) that provide drug testing services to the Federal agencies;
- (6) Collectors that provide specimen collection services to the Federal agencies; and
- (7) Medical Review Officers (MROs) that provide drug testing review and interpretation of results services to the Federal agencies.
- (b) The Guidelines do not apply to drug testing under authority other than Executive Order 12564, including testing of persons in the criminal justice system, such as, arrestees, detainees, probationers, incarcerated persons, or parolees.<sup>1</sup>

<sup>1</sup> Although HHS has no authority to regulate the transportation industry, the Department of Transportation (DOT) does have such authority. DOT is required by law to develop requirements for its regulated industry that "incorporate the Department of Health and Human Services scientific and technical guidelines dated April 11,

**Section 1.2 Who is responsible for developing and implementing these Guidelines?**

- (a) Executive Order 12564 and Public Law 100-71 require the Department of Health and Human Services (HHS) to establish scientific and technical guidelines for Federal workplace drug testing programs.
- (b) The Secretary has the responsibility to implement these Guidelines.

**Section 1.3 How does a Federal agency request a change from these Guidelines?**

- (a) Each Federal agency must ensure that its workplace drug testing program complies with the provisions of these Guidelines unless a waiver has been obtained from the Secretary.
- (b) To obtain a waiver, a Federal agency must submit a written request to the Secretary that describes the specific change for which a waiver is sought and a detailed justification for the change.

**Section 1.4 How are these Guidelines revised?**

- (a) In order to ensure the full reliability and accuracy of drug and specimen validity tests, the accurate reporting of test results, and the integrity and efficacy of Federal drug testing programs, the Secretary may make changes to these Guidelines to reflect improvements in the available science and technology.
- (b) The changes will be published in final as a notice in the *Federal Register*.

**Section 1.5 What do the terms used in these Guidelines mean?**

- The following definitions are adopted:
- Accessioner.* The individual who receives the specimens at the laboratory or IITF and signs the Federal drug testing custody and control form.
- Adulterated Specimen.* A specimen that has been altered, as evidenced by test results showing either a substance that is not a normal constituent for that type of specimen or showing an abnormal concentration of an endogenous substance.
- Aliquot.* A fractional part of a specimen used for testing, representing the whole specimen.
- Alternate Responsible Person.* The person who assumes professional, organizational, educational, and

1988, and any amendments to those guidelines \* \* \* See, e.g., 49 U.S.C. 20140(c)(2). In carrying out its mandate, DOT requires by regulation at 49 CFR Part 40 that its federally-regulated employers use only HHS-certified laboratories in the testing of employees, 49 CFR 40.81, and incorporates the scientific and technical aspects of the HHS Mandatory Guidelines.

administrative responsibility for the day-to-day management of the HHS-certified laboratory when the responsible person is unable to fill these obligations.

**Alternate Responsible Technician.** The person who assumes professional, organizational, educational, and administrative responsibility for the day-to-day management of the HHS-certified IITF when the responsible technician is unable to fill these obligations.

**Batch.** A number of specimens that are being handled and tested as a group.

**Calibrator.** A solution of known concentration in the appropriate matrix that is used to define expected outcomes of a measurement procedure or to compare the response obtained with the response of a test specimen aliquot/sample. The concentration of the analyte of interest in the calibrator is known within limits ascertained during its preparation. Calibrators may be used to establish a calibration curve over a concentration range.

**Cancelled Test.** The result reported by the MRO to the Federal agency when a specimen has been reported to the MRO as invalid result (and the donor has no legitimate explanation) or rejected for testing, when a split specimen fails to reconfirm, or when the MRO determines that a fatal flaw or unrecovered correctable error exists in the forensic records (as described in Sections 15.1 and 15.2).

**Carryover.** The effect that occurs when a sample's result (e.g., drug concentration) has been affected by a preceding sample during analysis.

**Certifying Scientist (CS).** The individual responsible for verifying the chain of custody and scientific reliability of any test result reported by an HHS-certified laboratory.

**Certifying Technician (CT).** The individual responsible for verifying the chain of custody and scientific reliability of negative, negative/dilute, and rejected for testing results reported by a laboratory or IITF.

**Chain of Custody (COC).** Procedures to account for the integrity of each specimen or aliquot by tracking its handling and storage from point of specimen collection to final disposition of the specimen and its aliquots.

**Chain of Custody Document.** A form used to document the security of the specimen and all aliquots of a specimen. The document, which may account for an individual specimen, aliquot, or batch, must include the names and signatures of all individuals who handled the specimen or aliquots and the date and purpose of the access.

**Collection Site.** A place where donors present themselves for the purpose of providing a specimen.

**Collector.** A person who instructs and assists donors at a collection site and receives the specimen provided by the donor.

**Confirmatory Drug Test.** A second analytical procedure performed on a different aliquot of the original specimen to identify and quantify the presence of a specific drug or drug metabolite.

**Confirmatory Specimen Validity Test.** A second test performed on a different aliquot of the original specimen to further support a specimen validity test result.

**Control.** A sample used to evaluate whether an analytical procedure or test is operating within predefined tolerance limits.

**Cutoff.** The decision point or value used to establish and report a specimen as negative, positive, adulterated, substituted, or invalid.

**Dilute Specimen.** A urine specimen with creatinine and specific gravity values that are lower than expected but are still within the physiologically producible ranges of human urine.

**Donor.** The individual from whom a specimen is collected.

**Failed to Reconfirm.** The result reported for a split specimen when the second laboratory is unable to corroborate the original result reported for the primary specimen.

**Federal Drug Testing Custody and Control Form (Federal CCF).** The Office of Management and Budget (OMB) approved form that is used to document the collection, custody, and transport of a specimen from the time the specimen is collected until it is received by the testing site (i.e., certified laboratory, instrumented initial test facility). The form may also be used to report the test result to the Medical Review Officer.

**HHS.** The Department of Health and Human Services.

**Initial Drug Test.** The test used to differentiate a negative specimen from one that requires further testing for drugs or drug metabolites.

**Initial Specimen Validity Test.** The first test used to determine if a specimen is adulterated, diluted, substituted, or invalid.

**Instrumented Initial Test Facility (IITF).** A permanent location where initial testing, reporting of results, and recordkeeping are performed under the supervision of a responsible technician.

**Invalid Result.** The result reported by an HHS-certified laboratory in accordance with the criteria established in Section 3.8 when a positive, negative, adulterated, or substituted result cannot

be established for a specific drug or specimen validity test.

**Laboratory.** A permanent location where initial and confirmatory testing, reporting of results, and recordkeeping is performed under the supervision of a responsible person.

**Limit of Detection.** The lowest concentration at which a measurand can be identified, but (for quantitative assays) the concentration cannot be accurately calculated.

**Limit of Quantitation.** For quantitative assays, the lowest concentration at which the identity and concentration of the measurand can be accurately established.

**Lot.** A number of units of an item (e.g., drug test kits, reagents, quality control material) manufactured from the same starting materials within a specified period of time for which the manufacturer states that the items have essentially the same performance characteristics and the same expiration date.

**Medical Review Officer (MRO).** A licensed physician who reviews, verifies, and reports a specimen test result to the agency.

**Negative Result.** The result reported by an HHS-certified laboratory or an HHS-certified IITF to an MRO when a specimen contains no drug or the concentration of the drug is less than the cutoff concentration for that drug or drug class and the specimen is a valid specimen.

**Oxidizing Adulterant.** A substance that acts alone or in combination with other substances to oxidize drug or drug metabolites to prevent the detection of the drugs or drug metabolites, or affects the reagents in either the initial or confirmatory drug test.

**Performance Testing (PT) Sample.** A program-generated sample sent to laboratory or IITF that is used to evaluate performance.

**Positive Result.** The result reported by an HHS-certified laboratory when a specimen contains a drug or drug metabolite equal to or greater than the cutoff concentration.

**Quality Control (QC) Sample.** A calibrator or control used to verify that an analytical test is providing accurate test results.

**Reconfirmed.** The result reported for a split specimen when the second laboratory is able to corroborate the original result reported for the primary specimen.

**Rejected for Testing.** The result reported by an HHS-certified laboratory or HHS-certified IITF when no tests are performed for a specimen because of a fatal flaw or an unrecovered correctable



error (as described in Sections 15.1 and 15.2).

**Responsible Person (RP).** The person who assumes professional, organizational, educational, and administrative responsibility for the day-to-day management of the HHS-certified laboratory.

**Responsible Technician (RT).** The person who assumes professional, organizational, educational, and administrative responsibility for the day-to-day management of the HHS-certified IITF.

**Sample.** A performance testing sample, quality control material used for testing, or a representative portion of a donor specimen.

**Secretary.** The Secretary of Health and Human Services or the Secretary's designee. The Secretary's designee may be a contractor or other recognized organization which acts on behalf of the Secretary in implementing these Guidelines.

**Specimen.** Fluid or material collected from a donor at the collection site for the purpose of a drug test. Urine is the only specimen allowed for Federal workplace drug testing programs.

**Split Specimen Collection.** A collection in which the urine collected is divided into two separate specimen bottles, the primary specimen (Bottle A) and the split specimen (Bottle B).

**Standard.** Reference material of known purity or a solution containing a reference material at a known concentration.

**Substituted Specimen.** A specimen that has been submitted in place of the donor's urine, as evidenced by creatinine and specific gravity values that are outside the physiologically producible ranges of human urine.

#### **Section 1.6 What is an agency required to do to protect employee records?**

Consistent with 5 U.S.C. 552(a) and 48 CFR 24.101-24.104, all agency contracts with laboratories, IITFs, collectors, and MROs must require that they comply with the Privacy Act, 5 U.S.C. 552(a). In addition, the contracts must require compliance with employee access and confidentiality provisions of Section 503 of Public Law 100-71. Each Federal agency must establish a Privacy Act System of Records or modify an existing system, or use any applicable Government-wide system of records to cover the records of employee drug test results. All contracts and the Privacy Act System of Records must specifically require that employee records be maintained and used with the highest regard for employee privacy.

In addition, the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule, 45 CFR Parts 160 and 164, Subparts A and E, is applicable to certain health care providers with whom a Federal agency may contract. If a health care provider is a HIPAA covered entity, the provider must protect the individually identifiable health information it maintains in accordance with the requirements of the Privacy Rule, which includes not using or disclosing the information except as permitted by the Rule and ensuring there are reasonable safeguards in place to protect the privacy of the information. For more information regarding HIPAA Privacy Rule, please visit <http://www.hhs.gov/ocr/hipaa>.

#### **Section 1.7 What is a refusal to take a federally regulated drug test, and what are the consequences?**

(a) As a donor for a federally regulated drug test, you have refused to take a drug test if you:

(1) Fail to appear for any test (except a pre-employment test) within a reasonable time, as determined by the Federal agency, consistent with applicable agency regulations, after being directed to do so by the Federal agency;

(2) Fail to remain at the collection site until the collection process is complete (with the exception of a donor who leaves the collection site before the collection process begins for a pre-employment test);

(3) Fail to provide a urine specimen for any drug test required by these Guidelines or Federal agency regulations (with the exception of a donor who leaves the collection site before the collection process begins for a pre-employment test);

(4) In the case of a direct observed or monitored collection, fail to permit the observation or monitoring of your provision of a specimen when required as described in sections 8.8 and 8.10;

(5) Fail to provide a sufficient amount of urine when directed, and it has been determined, through a required medical evaluation, that there was no adequate medical explanation for the failure as determined by the process described in section 13.5;

(6) Fail or decline to take an additional drug test or collection as directed by the Federal agency or collector (i.e., as described in section 8.6);

(7) Fail to undergo a medical examination or evaluation, as directed by the MRO as part of the verification process (i.e., section 13.5) or as directed by the Federal agency. In the case of a

Federal agency applicant/pre-employment drug test, the donor is deemed to have refused to test on this basis only if the Federal agency applicant/pre-employment test is conducted following a contingent offer of employment. If there was no contingent offer of employment, the MRO will cancel the test; or

(8) Fail to cooperate with any part of the testing process (e.g., refuse to empty pockets when directed by the collector, disrupt the collection process, fail to wash hands after being directed to do so by the collector).

(9) For an observed collection, fail to follow the observer's instructions related to the collection process;

(10) Possess or wear a prosthetic or other device that could be used to interfere with the collection process; or

(11) Admit to the collector or MRO that you have adulterated or substituted the specimen.

(b) As a Federal agency applicant or employee, if the MRO reports that you have a verified adulterated or substituted test result, you have refused to take a drug test.

(c) As a Federal agency applicant or employee, refusal to submit to testing will result in initiation of disciplinary action, up to and including dismissal.

(d) As a collector or an MRO, when a donor refuses to participate in the part of the testing process in which you are involved, you must terminate the portion of the testing process in which you are involved, document the refusal on the Federal CCF, and immediately notify the Federal agency's designated representative by any means (e.g., telephone or secure fax machine) that ensures that the refusal notification is immediately received. As a referral physician (e.g., physician evaluating whether medical condition preventing the donor from providing a sufficient amount of urine for a drug test or evaluating a claim of a legitimate medical explanation in a specimen validity testing situation), you must notify the MRO, who in turn will notify the Federal agency.

(1) As the collector, you must note the refusal on the Federal CCF and sign and date the CCF in accordance with section 8.12.

(2) As the MRO, you must note the refusal and the reason on the MRO copy of the Federal CCF and sign and date the CCF.

#### **Subpart B—Specimens**

##### **Section 2.1 What type of specimen may be collected?**

Urine is the only specimen a Federal agency may collect under the

Guidelines for its workplace drug testing program.

### Section 2.2 Under what circumstances may specimens be collected?

A Federal agency may collect a specimen for the following reasons:

- (a) Federal agency applicant/Pre-employment test;
- (b) Random test;
- (c) Reasonable suspicion/cause test;
- (d) Post-accident test;
- (e) Return to duty test; or
- (f) Follow-up test.

### Section 2.3 How is each specimen collected?

Each specimen is collected as a split specimen as described in Section 2.5.

### Section 2.4 What volume of urine is collected?

A donor is expected to provide at least 45 mL of urine for a specimen to be tested at an HHS-certified laboratory or IITF.

### Section 2.5 How does the collector split the urine collected?

The collector pours at least 30 mL into a specimen bottle that is labeled Bottle A (primary) and then pours at least 15 mL into a specimen bottle that is labeled Bottle B (split).

## Subpart C—Urine Drug and Specimen Validity Tests

### Section 3.1 Which drug and specimen validity tests are conducted on a urine specimen?

A Federal agency:

- (a) Must ensure that each specimen is tested for marijuana and cocaine metabolites as provided under Section 3.4;

(b) Is authorized to test each specimen for opiates, amphetamines, and phencyclidine, as provided under Section 3.4; and

(c) Must ensure that the following specimen validity tests are conducted on each specimen:

- (1) Determine the creatinine concentration on every specimen;
- (2) Determine the specific gravity on every specimen for which the creatinine concentration is less than 20 mg/dL;
- (3) Determine the pH on every specimen; and
- (4) Perform one or more specimen validity tests for oxidizing adulterants on every specimen.

(d) If a specimen exhibits abnormal physical characteristics (e.g., unusual odor or color, semi-solid characteristics), causes reactions or responses characteristic of an adulterant during initial or confirmatory drug tests (e.g., non-recovery of standards, unusual response), or contains an unidentified substance that interferes with the confirmatory analysis, then additional testing may be performed.

### Section 3.2 May a specimen be tested for additional drugs?

(a) A specimen may be tested for additional drugs, on a case-by-case basis, when a Federal agency is conducting a specimen collection for reasonable suspicion, post accident, or unsafe practice testing. A specimen collected from a Federal agency employee may be tested by the Federal agency for any drugs listed in Schedule I or II of the Controlled Substances Act (other than the drugs listed in Section 3.1, or when used pursuant to a valid prescription or when used as otherwise authorized by law). The Federal agency must request the HHS-certified

laboratory to test for the additional drug, include a justification to test a specific specimen for the drug, and ensure that the HHS-certified laboratory has the capability to test for the drug and has established properly validated initial and confirmatory analytical methods. If an initial test procedure is not available upon request for a suspected Schedule I or Schedule II drug, the Federal agency can request an HHS-certified laboratory to test for the drug by directing two separate aliquots of the specimen for the confirmatory analytical method. Additionally, the split (Bottle B) specimen will be available for testing if the donor requests a retest at another HHS-certified laboratory.

(b) A Federal agency covered by these Guidelines must petition the Secretary in writing for approval to routinely test for any drug class not listed in Section 3.1. Such approval must be limited to the use of the appropriate science and technology and must not otherwise limit agency discretion to test for any drug tested under paragraph (a) of this section.

### Section 3.3 May any of the specimens be used for other purposes?

(a) Federal agency specimens collected pursuant to Executive Order 12564, Public Law 100-71, and these Guidelines must only be tested for drugs and to determine their validity unless otherwise authorized by law.

(b) These Guidelines are not intended to prohibit any Federal agency specifically authorized by law to test a specimen for additional classes of drugs in its workplace drug testing program.

### Section 3.4 What are the cutoff concentrations for drug tests?

Initial test analyte	Initial test cutoff concentration	Confirmatory test analyte	Confirmatory test cutoff concentration
Marijuana metabolites .....	50 ng/mL .....	THCA <sup>1</sup> .....	15 ng/mL
Cocaine metabolites .....	150 ng/mL .....	Benzoylcegonine .....	100 ng/mL
Opiate metabolites. Codeine/Morphine <sup>2</sup> .....	2000 ng/mL .....	Codeine .....	2000 ng/mL
6-Acetylmorphine .....	10 ng/mL .....	Morphine .....	2000 ng/mL
Phencyclidine .....	25 ng/mL .....	6-Acetylmorphine .....	10 ng/mL
Amphetamines <sup>3</sup> . AMP/MAMP <sup>4</sup> .....	500 ng/mL .....	Phencyclidine .....	25 ng/mL
MDMA <sup>6</sup> .....	500 ng/mL .....	Amphetamine .....	250 ng/mL
		Methamphetamine <sup>5</sup> .....	250 ng/mL
		MDMA .....	250 ng/mL
		MDA <sup>7</sup> .....	250 ng/mL
		MDEA <sup>8</sup> .....	250 ng/mL

<sup>1</sup> Delta-9-tetrahydrocannabinol-9-carboxylic acid (THCA).

<sup>2</sup> Morphine is the target analyte for codeine/morphine testing.

<sup>3</sup> Either a single initial test kit or multiple initial test kits may be used provided the single test kit detects each target analyte independently at the specified cutoff.

<sup>4</sup> Methamphetamine is the target analyte for amphetamine/methamphetamine testing.

<sup>5</sup> To be reported positive for methamphetamine, a specimen must also contain amphetamine at a concentration equal to or greater than 100 ng/mL.

<sup>6</sup> Methylendioxyamphetamine (MDMA).

<sup>7</sup> Methylendioxyamphetamine (MDA).

<sup>8</sup> Methyleneedioxyethylamphetamine (MDEA).

### Section 3.5 What criteria are used to report a specimen as adulterated?

An HHS-certified laboratory reports a primary (Bottle A) specimen as adulterated when:

(a) The pH is less than 3 or equal to or greater than 11 using either a pH meter or a colorimetric pH test for the initial test on the first aliquot and a pH meter for the confirmatory test on the second aliquot;

(b) The nitrite concentration is equal to or greater than 500 mcg/mL using either a nitrite colorimetric test or a general oxidant colorimetric test for the initial test on the first aliquot and a different confirmatory test (e.g., multi-wavelength spectrophotometry, ion chromatography, capillary electrophoresis) on the second aliquot;

(c) The presence of chromium (VI) is verified using either a general oxidant colorimetric test (with an equal to or greater than 50 mcg/mL chromium (VI)-equivalent cutoff) or a chromium (VI) colorimetric test (chromium (VI) concentration equal to or greater than 50 mcg/mL) for the initial test on the first aliquot and a different confirmatory test (e.g., multi-wavelength spectrophotometry, ion chromatography, atomic absorption spectrophotometry, capillary electrophoresis, inductively coupled plasma-mass spectrometry) with the chromium (VI) concentration equal to or greater than the limit of quantitation (LOQ) of the confirmatory test on the second aliquot;

(d) The presence of halogen (e.g., bleach, iodine, fluoride) is verified using either a general oxidant colorimetric test (with an equal to or greater than 200 mcg/mL nitrite-equivalent cutoff or an equal to or greater than 50 mcg/mL chromium (VI)-equivalent cutoff) or halogen colorimetric test (halogen concentration equal to or greater than the LOQ) for the initial test on the first aliquot and a different confirmatory test (e.g., multi-wavelength spectrophotometry, ion chromatography, inductively coupled plasma-mass spectrometry) with a specific halogen concentration equal to or greater than the LOQ of the confirmatory test on the second aliquot;

(e) The presence of glutaraldehyde is verified using either an aldehyde test (aldehyde present) or the characteristic immunoassay response on one or more drug immunoassay tests for the initial test on the first aliquot and a different confirmatory test (e.g., GC/MS) for the confirmatory test with the glutaraldehyde concentration equal to or

greater than the LOQ of the analysis on the second aliquot;

(f) The presence of pyridine (pyridinium chlorochromate) is verified using either a general oxidant colorimetric test (with an equal to or greater than 200 mcg/mL nitrite-equivalent cutoff or an equal to or greater than 50 mcg/mL chromium (VI)-equivalent cutoff) or a chromium (VI) colorimetric test (chromium (VI) concentration equal to or greater than 50 mcg/mL) for the initial test on the first aliquot and a different confirmatory test (e.g., GC/MS) for the confirmatory test with the pyridine concentration equal to or greater than the LOQ of the analysis on the second aliquot;

(g) The presence of a surfactant is verified by using a surfactant colorimetric test with an equal to or greater than 100 mcg/mL dodecylbenzene sulfonate-equivalent cutoff for the initial test on the first aliquot and a different confirmatory test (e.g., multi-wavelength spectrophotometry) with an equal to or greater than 100 mcg/mL dodecylbenzene sulfonate-equivalent cutoff on the second aliquot; or

(h) The presence of any other adulterant not specified in paragraphs (b) through (g) of this section is verified using an initial test on the first aliquot and a different confirmatory test on the second aliquot.

### Section 3.6 What criteria are used to report a specimen as substituted?

An HHS-certified laboratory reports a primary (Bottle A) specimen as substituted when the creatinine concentration is less than 2 mg/dL on both the initial and confirmatory creatinine tests on two separate aliquots (i.e., the same colorimetric test may be used to test both aliquots) and the specific gravity is less than or equal to 1.0010 or equal to or greater than 1.0200 on both the initial and confirmatory specific gravity tests on two separate aliquots (i.e., a refractometer is used to test both aliquots).

### Section 3.7 What criteria are used to report a specimen as dilute?

A dilute result may be reported only in conjunction with the positive or negative drug test results for a specimen.

(a) An HHS-certified laboratory or an HHS-certified IITF reports a primary (Bottle A) specimen as dilute when the creatinine concentration is greater than 5 mg/dL but less than 20 mg/dL and the specific gravity is equal to or greater

than 1.002 but less than 1.003 on a single aliquot.

(b) In addition, an HHS-certified laboratory reports a primary (Bottle A) specimen as dilute when the creatinine concentration is equal to or greater than 2 mg/dL but less than or equal to 5 mg/dL and the specific gravity is greater than 1.0010 but less than 1.0030.

### Section 3.8 What criteria are used to report an invalid result for a specimen?

An HHS-certified laboratory reports a primary (Bottle A) specimen as an invalid result when:

(a) Inconsistent creatinine concentration and specific gravity results are obtained (i.e., the creatinine concentration is less than 2 mg/dL on both the initial and confirmatory creatinine tests and the specific gravity is greater than 1.0010 but less than 1.0200 on the initial and/or confirmatory specific gravity test, the specific gravity is less than or equal to 1.0010 on both the initial and confirmatory specific gravity tests and the creatinine concentration is equal to or greater than 2 mg/dL on either or both the initial or confirmatory creatinine tests);

(b) The pH is equal to or greater than 3 and less than 4.5 or equal to or greater than 9 and less than 11 using either a colorimetric pH test or pH meter for the initial test and a pH meter for the confirmatory test on two separate aliquots;

(c) The nitrite concentration is equal to or greater than 200 mcg/mL using a nitrite colorimetric test or equal to or greater than the equivalent of 200 mcg/mL nitrite using a general oxidant colorimetric test for both the initial (first) test and the second test or using either initial test and the nitrite concentration is equal to or greater than 200 mcg/mL but less than 500 mcg/mL for a different confirmatory test (e.g., multi-wavelength spectrophotometry, ion chromatography, capillary electrophoresis) on two separate aliquots;

(d) The possible presence of chromium (VI) is determined using the same chromium (VI) colorimetric test with a cutoff equal to or greater than 50 mcg/mL chromium (VI) for both the initial (first) test and the second test on two separate aliquots;

(e) The possible presence of a halogen (e.g., bleach, iodine, fluoride) is determined using the same halogen colorimetric test with a cutoff equal to or greater than the LOQ for both the initial (first) test and the second test on

two separate aliquots or relying on the odor of the specimen as the initial test;

(f) The possible presence of glutaraldehyde is determined by using the same aldehyde test (aldehyde present) or characteristic immunoassay response on one or more drug immunoassay tests for both the initial (first) test and the second test on two separate aliquots;

(g) The possible presence of an oxidizing adulterant is determined by using the same general oxidant colorimetric test (with an equal to or greater than 200 mcg/mL nitrite-equivalent cutoff, an equal to or greater than 50 mcg/mL chromium (VI)-equivalent cutoff, or a halogen concentration is equal to or greater than the LOQ) for both the initial (first) test and the second test on two separate aliquots;

(h) The possible presence of a surfactant is determined by using the same surfactant colorimetric test with an equal to or greater than 100 mcg/mL dodecylbenzene sulfonate-equivalent cutoff for both the initial (first) test and the second test on two separate aliquots or a foam/shake test for the initial test;

(i) Interference occurs on the immunoassay drug tests on two separate aliquots (i.e., valid immunoassay drug test results cannot be obtained);

(j) Interference with the drug confirmatory assay occurs on two separate aliquots of the specimen and the laboratory is unable to identify the interfering substance;

(k) The physical appearance of the specimen (e.g., viscosity) is such that testing the specimen may damage the laboratory's instruments; or

(l) The specimen has been tested and the physical appearances of Bottles A and B (e.g., color) are clearly different.

#### Subpart D—Collectors

##### Section 4.1 Who may collect a specimen?

(a) A collector who has been trained to collect urine specimens in accordance with these Guidelines.

(b) The immediate supervisor of a Federal employee donor may only collect that donor's specimen when no other collector is available. The supervisor must be a trained collector.

(c) The hiring official of a Federal agency applicant may only collect that Federal agency applicant's specimen when no other collector is available. The hiring official must be a trained collector.

##### Section 4.2 Who may not collect a specimen?

(a) A Federal agency employee who is in a testing designated position and subject to the Federal agency drug testing rules must not be a collector for co-workers who are in the same testing pool or who work together with that employee on a daily basis.

(b) A Federal agency applicant or employee must not collect his or her own urine.

(c) An employee working for an HHS-certified laboratory or IITF must not act as a collector if the employee could link the identity of the donor to the donor's drug test result.

(d) To avoid a potential conflict of interest, a collector should not be someone that is related to the employee (e.g., spouse, ex-spouse, relative) or a close personal friend (e.g., fiancé).

##### Section 4.3 What are the requirements to be a collector?

(a) An individual may serve as a collector when the individual:

(1) Is knowledgeable about the collection procedure described in these Guidelines;

(2) Is knowledgeable about any guidance provided by the Federal agency's Drug-Free Workplace Program or additional information provided by the Secretary relating to these Guidelines;

(3) Has received training from a qualified trainer for collectors on the following subjects:

(i) All steps necessary to complete a collection correctly and the proper completion and transmission of the Federal CCF;

(ii) Problem collections;

(iii) Fatal flaws, correctable flaws, and how to correct problems in collections; and

(iv) The collector's responsibility for maintaining the integrity of the collection process, ensuring the privacy of individuals being tested, ensuring the security of the specimen, and avoiding conduct or statements that could be viewed as offensive or inappropriate.

(4) Has demonstrated proficiency in collections by completing five consecutive error-free mock collections.

(i) The five mock collections must include two uneventful collection scenarios, one insufficient quantity of urine scenario, one temperature out of range scenario, and one scenario in which the donor refuses to sign the Federal CCF and initial the specimen bottle tamper-evident seal.

(ii) A qualified trainer for collectors must monitor and evaluate the individual being trained, in person or by

a means that provides real-time observation and interaction between the trainer and the individual being trained, and attest in writing that the mock collections are "error-free."

(b) A trained collector must complete refresher training on the requirements in paragraph a of this section no less frequently than every five years from the date on which he or she was first trained.

(c) The collector must maintain the documentation of his or her training and provide it to a Federal agency when requested.

(d) An individual may not collect specimens for a Federal agency until his or her training as a collector has been properly documented.

##### Section 4.4 What are the requirements to be an observer for a direct observed collection?

(a) An individual may serve as an observer for a direct observed collection when the individual has satisfied the requirements:

(1) Is knowledgeable about the direct observed collection procedure described in Section 8.9 of these Guidelines;

(2) Is knowledgeable about any guidance provided by the Federal agency's Drug-Free Workplace Program or additional information provided by the Secretary relating to the direct observed collection procedure described in these Guidelines;

(3) Has received training on the following subjects:

(i) All steps necessary to perform a direct observed collection correctly; and

(ii) The observer's responsibility for maintaining the integrity of the collection process, ensuring the privacy of individuals being tested, ensuring that the observation is done in a professional manner that minimizes the discomfort to the employee so observed, ensuring the security of the specimen by maintaining visual contact with the collection container until it is delivered to the collector, and avoiding conduct or statements that could be viewed as offensive or inappropriate.

(b) The observer must be the same gender as the donor.

(c) The observer is not required to be a trained collector.

##### Section 4.5 What are the requirements to be a trainer for collectors?

(a) An individual is considered to be a qualified trainer for collectors and may train others to collect specimens when the individual has:

(1) Qualified as a trained collector and regularly conducted drug test collections for a period of at least one year; or

(2) Successfully completed a "train the trainer" course given by an organization (e.g., manufacturer, private entity, contractor, Federal agency).

(b) A qualified trainer for collectors must complete refresher training in accordance with the collector requirements in Section 4.3(a) no less frequently than every five years from the date on which he or she was first trained.

(c) A qualified trainer for collectors must maintain the documentation of his or her training and provide it to a Federal agency when requested.

#### **Section 4.6 What must a Federal agency do before an individual is permitted to collect a specimen?**

A Federal agency must:

(a) Ensure that the individual that serves as a collector has satisfied the requirements described in Section 4.3;

(b) Ensure that the collector (who may be self-employed) or an organization (e.g., third party administrator that provides a collection service, collector training company, Federal agency that employs its own collectors) maintains a copy of the record(s) that document the individual's training as a collector; and

(c) Provide to the collector the name and telephone number of the Federal agency representative to contact about problems or issues that may arise during a specimen collection procedure.

#### **Subpart E—Collection Sites**

##### **Section 5.1 Where can a collection for a drug test take place?**

(a) A collection site may be a permanent or temporary facility located either at the work site or at a remote site.

(b) In the event that an agency-designated collection site is not accessible and there is an immediate requirement to collect a specimen (e.g., an accident investigation), a public restroom may be used for the collection, using the procedures for a monitored collection described in Section 8.11.

##### **Section 5.2 What are the requirements for a collection site?**

A facility that is used as a collection site must have the following:

(a) Provisions to ensure donor privacy during the specimen collection procedure in accordance with Section 8.1;

(b) A suitable clean surface area not accessible to the donor, for handling the specimens and completing the required paperwork;

(c) A secure temporary storage capability to maintain a specimen until it is transferred to an HHS-certified laboratory or IITF;

(d) The ability to restrict access to only authorized personnel during the collection;

(e) The ability to restrict access to collection supplies;

(f) The ability to store records securely; and

(g) The ability to restrict the donor access to potential diluents in accordance with Section 8.2.

#### **Section 5.3 How long must collection site records be stored?**

Collection site records (e.g., collector copies of the OMB-approved Federal CCF) must be stored for a minimum of 2 years by the collector or the collector's employer.

#### **Section 5.4 How does the collector ensure the security and integrity of a specimen at the collection site?**

(a) A collector must do the following to maintain the security and integrity of a specimen:

(1) Not allow unauthorized personnel to enter the collection site during the collection procedure;

(2) Perform only one specimen collection at a time;

(3) Restrict access to collection supplies before and during the collection;

(4) Ensure only the collector and the donor are allowed to handle the unsealed specimen;

(5) Ensure the chain of custody is maintained and documented throughout the entire collection procedure;

(6) Ensure that the Federal CCF is enclosed with the specimens and sealed for shipment to an HHS-certified laboratory or IITF; and

(7) Ensure that specimens transported to an HHS-certified laboratory or IITF are placed in containers designed to minimize the possibility of damage during shipment (e.g., specimen boxes, padded mailers, or other suitable shipping container), and those containers are securely sealed to eliminate the possibility of undetected tampering;

(b) Since specimens are sealed in packages that would indicate any tampering during transit to the HHS-certified laboratory or IITF and couriers, express carriers, and postal service personnel do not have access to the Federal CCF or split specimens, there is no requirement that such personnel document chain of custody for the package during transit.

#### **Subpart F—Federal Drug Testing Custody and Control Form**

##### **Section 6.1 What form is used for collecting a specimen?**

An OMB-approved Federal CCF must be used to document the collection of each urine specimen at the collection site.

##### **Section 6.2 What happens if the correct Federal CCF is not available or is not used?**

(a) When the collector either by mistake or as the only means to document a collection under difficult circumstances (e.g., post-accident test with insufficient time to obtain the correct CCF) uses a non-Federal form or an expired Federal CCF for a Federal agency specimen collection, the use of the incorrect form is not, by itself, a reason for the laboratory or IITF to automatically reject the specimen for testing or for the MRO to cancel the test.

(b) If the collector realizes that an incorrect form was used before the specimen bottles are packaged for transit to the laboratory or IITF, the collector must show on the form that it is a Federal agency specimen collection and give the reason why an incorrect form was used. Based on the information provided by the collector, the laboratory or IITF must handle and test the specimen as a Federal agency specimen.

(c) If the laboratory, IITF, or MRO discovers that an incorrect form was used by the collector, the laboratory, IITF, or MRO must obtain a memorandum for the record from the collector stating the reason why the correct Federal CCF was not used to collect the Federal agency specimen. If after 5 business days a memorandum for the record cannot be obtained, the laboratory or IITF reports a rejected for testing result and the MRO cancels the test.

#### **Subpart G—Specimen Collection Containers**

##### **Section 7.1 What is used to collect a urine specimen?**

(a) A single-use collection container/cup that is capable of holding at least 55 mL; and

(b) Two specimen bottles which can be sealed for transport; one of which can hold at least 35 mL and the other at least 20 mL.

**Section 7.2 Are there any restrictions on the containers and bottles used to collect urine specimens?**

Collection containers/cups and specimen bottles must not substantially affect the specimen collected.

**Subpart H—Specimen Collection Procedure**

**Section 8.1 What privacy must the donor be given when providing a specimen?**

The following privacy requirements apply when a donor is providing a specimen:

(a) Only authorized personnel and the donor may be present at the collection site while the collector is collecting a specimen.

(b) The collector does not need to be the same gender as the donor. The observer for a direct observed collection (i.e., as described in Section 8.9) must be the same gender as the donor. The monitor for a monitored collection (i.e., as described in Section 8.11) must be the same gender as the donor, unless the monitor is a medical professional (e.g., nurse, doctor, physician's assistant, technologist, or technician licensed or certified to practice in the jurisdiction in which the collection takes place).

(c) The collector must give the donor visual privacy while providing the specimen. The donor is allowed to provide a urine specimen in an enclosed stall within a multi-stall restroom or in a single person restroom.

**Section 8.2 What must the collector do at the collection site before starting a specimen collection procedure?**

The collector must deter the dilution or substitution of a specimen at the collection site by:

(a) Placing a toilet bluing agent in a toilet bowl or toilet tank, so the reservoir of water in the toilet bowl always remains blue. If no bluing agent is available or if the toilet has an automatic flushing system, the collector shall turn off the water supply to the toilet and flush the toilet to remove the water in the toilet when possible.

(b) Securing any other source of water (e.g., no shower or sink) in the enclosure where urination occurs that is not secured during the collection. If the enclosure used by the donor to provide a specimen has a source of water that cannot be disabled or secured, a monitored collection must be conducted in accordance with Section 8.10.

**Section 8.3 What are the preliminary steps in the collection process?**

The collector must take the following steps before beginning a collection:

(a) If a donor fails to arrive at the collection site at the assigned time, the collector must contact the Federal agency representative to obtain guidance on action to be taken.

(b) When the donor arrives at the collection site, the collector begins the testing process without undue delay. For example, the collection is not delayed because the donor says he or she is not ready or is unable to urinate or because an authorized employer or employer representative is late in arriving.

(c) The collector requests the donor to present photo identification (e.g., driver's license, employee badge issued by the employer, any other picture identification issued by a Federal, state, or local government agency). If the donor does not have proper photo identification, the collector shall contact the supervisor of the donor or the Federal agency representative who can positively identify the donor. If the donor's identity cannot be established, the collector shall not proceed with the collection.

(d) The collector must provide identification (e.g., employee badge, employee list) to the donor if the donor asks.

(e) The collector explains the basic collection procedure to the donor.

(f) The collector informs the donor that he or she may read the instructions for completing the custody and control form which are located on the back of the Federal CCF.

(g) The collector answers any reasonable and appropriate questions the donor may have regarding the collection procedure.

(h) The collector asks the donor to remove any unnecessary outer garments such as a coat or jacket that might conceal items or substances that could be used to adulterate or substitute the urine specimen:

(1) The collector must ensure that all personal belongings such as a purse or briefcase remain with the outer garments; the donor may retain his or her wallet.

(2) The collector asks the donor to empty his or her pockets and display the items to ensure that no items are present that could be used to adulterate or substitute the specimen;

(3) If nothing is present that can be used to adulterate or substitute a specimen, the donor places the items back into the pockets and the collection procedure continues;

(4) If an item is found that appears to have been brought to the collection site with the intent to adulterate or substitute the specimen, a direct observed collection procedure is used in

accordance with Section 8.9. If the item appears to be inadvertently brought to the collection site, the collector must secure the item and continue with the normal collection procedure.

(5) If the donor refuses to show the collector the items in his or her pockets, this is considered a "refusal to test." The collector must stop the collection and report the refusal to test as described in Section 8.12.

(i) The collector shall instruct the donor to wash and dry his or her hands prior to urination. After washing hands, the donor must remain in the presence of the collector and must not have access to any water fountain, faucet, soap dispenser, cleaning agent, or any other materials which could be used to adulterate or substitute the specimen.

**Section 8.4 What steps does the collector take in the collection process before the donor provides a urine specimen?**

(a) The collector gives the donor or allows the donor to select a specimen collection container. The collector instructs the donor to provide his or her specimen in the privacy of a stall or otherwise partitioned area that allows for individual privacy. The collector directs the donor to provide a specimen of at least 45 mL, to not flush the toilet, and to return with the specimen as soon as the donor has completed the void.

(1) Except in the case of a direct observed collection (i.e., as described in Section 8.9) or a monitored collection (i.e., as described in Section 8.11), neither the collector nor anyone else may go into the room with the donor.

(2) The collector may set a reasonable time limit for voiding.

(b) The collector notes any unusual behavior or appearance of the donor on the Federal CCF. If the collector detects any conduct that clearly indicates an attempt to tamper with a specimen (e.g., substitute urine in plain view or an attempt to bring into the collection site an adulterant or urine substitute), the collector must conduct an immediate collection under direct observation in accordance with Section 8.8. The collector must note the conduct and the fact that the collection was observed on the CCF.

**Section 8.5 What procedure is used when the donor states that he or she is unable to provide a specimen?**

(a) If the donor states that he or she is unable to provide a specimen during the collection process, the collector requests that the donor enter the restroom (stall) and attempt to provide a specimen.

(b) The donor demonstrates his or her inability to provide a specimen when he or she comes out of the stall with an empty collection container.

(1) If the donor states that he or she could provide a specimen after drinking some fluids, the collector gives the donor a reasonable amount of liquid to drink for this purpose (e.g., an 8 ounce glass of water every 30 minutes, but not to exceed a maximum of 40 ounces over a period of 3 hours or until the donor has provided a sufficient urine specimen). If the donor simply needs more time before attempting to provide a urine specimen, the donor is not required to drink any fluids during this waiting time.

(2) If the donor states that he or she is unable to provide a urine specimen, the collector records the reason for not collecting a urine specimen on the Federal CCF, notifies the Federal agency's designated representative, and sends the appropriate copies of the Federal CCF to the MRO and to the Federal agency's designated representative. The collector stops the collection procedure and requests that the donor leave the collection site.

#### **Section 8.6 What steps does the collector take in the collection process after the donor provides a urine specimen?**

The collector must take the following steps after the donor provides the urine specimen:

(a) After providing the specimen, the donor gives the specimen collection container to the collector. Both the donor and the collector must keep the specimen container in view at all times until the collector seals the specimen bottles as described in Section 8.7.

(b) After the donor has given the specimen to the collector, whenever practical, the donor shall be allowed to wash his or her hands and the donor may flush the toilet.

(c) The collector must measure the temperature of the specimen within 4 minutes of receiving the specimen from the donor. The collector records on the Federal CCF whether or not the temperature is in the acceptable range of 32°–38 °C/90°–100 °F.

(1) The temperature measuring device must accurately reflect the temperature of the specimen and not contaminate the specimen.

(2) If the temperature of the specimen is outside the range of 32°–38 °C/90°–100 °F, that is a reason to believe that the donor may have adulterated or substituted the specimen. Another specimen must be collected under direct observation in accordance with Section 8.8. The collector will forward both

specimens (i.e., from the first and second collections) to an HHS-certified laboratory for testing and records a comment on the Federal CCF.

(d) The collector must inspect the specimen to determine if there is any sign indicating that the specimen may not be a valid urine specimen (e.g., unusual color, presence of foreign objects or material, unusual odor).

(1) The collector notes any unusual finding on the Federal CCF. A specimen suspected of not being a valid urine specimen must be forwarded to an HHS-certified laboratory for testing.

(2) When there is any reason to believe that a donor may have adulterated or substituted the specimen, another specimen must be obtained as soon as possible under direct observation in accordance with Section 8.8. The collector will forward both specimens (i.e., from the first and second collections) to an HHS-certified laboratory for testing and records a comment on the Federal CCF.

(e) The collector must determine the volume of urine in the specimen container. The collector must never combine urine collected from separate voids to create a specimen.

(1) If the volume is at least 45 mL, the collector will proceed with steps described in Section 8.7.

(2) If the volume is less than 45 mL, the collector discards the specimen and immediately collects a second specimen using the same procedures as for the first specimen (including steps in paragraphs c and d of this section).

(i) The collector may give the donor a reasonable amount of liquid to drink for this purpose (e.g., an 8 ounce glass of water every 30 minutes, but not to exceed a maximum of 40 ounces over a period of 3 hours or until the donor has provided a sufficient urine specimen). However, the donor is not required to drink any fluids during this waiting time.

(ii) If the donor provides a sufficient urine specimen (i.e., at least 45 mL), the collector proceeds with steps described in Section 8.7.

(iii) If the employee has not provided a sufficient specimen (i.e., at least 45 mL) within three hours of the first unsuccessful attempt to provide the specimen, the collector stops the collection procedure and:

(A) Notes on the Federal CCF that the donor has not provided a sufficient volume of urine for the drug test;

(B) Notifies the Federal agency's designated representative;

(C) Discards the insufficient specimen;

(D) Requests that the donor leave the collection site;

(E) Sends the appropriate copies of the Federal CCF to the MRO and to the Federal agency.

(f) If the donor fails to remain present through the completion of the collection, declines to have a direct observed collection as required in steps (c)(2) or (d)(2) above, or refuses to provide a second specimen as required in step (e)(2) above, the collector stops the collection and reports the refusal to test in accordance with Section 8.12.

#### **Section 8.7 How does the collector prepare the specimens?**

(a) All Federal agency collections are to be split specimen collections.

(b) The collector, in the presence of the donor, pours the urine from the collection container into two specimen bottles to be labeled Bottle A and Bottle B. The collector pours at least 30 mL of urine into Bottle A and at least 15 mL into Bottle B, and caps each bottle.

(c) In the presence of the donor, the collector places a tamper-evident label/seal from the Federal CCF over each specimen bottle cap. The collector records the date of the collection on the tamper-evident labels/seals.

(d) The donor initials the tamper-evident labels/seals on each specimen bottle. If the donor refuses to initial the labels/seals, the collector notes the refusal on the Federal CCF and continues with the collection process.

(e) The collector asks the donor to read and sign a statement on the Federal CCF certifying that the specimens identified were collected from him or her. If the donor refuses to sign the certification statement, the collector notes the refusal on the Federal CCF and continues with the collection process.

(f) The collector signs and prints his or her name on the Federal CCF, completes the Federal CCF, and distributes the copies of the CCF as required.

(g) The collector seals the specimens (Bottle A and Bottle B) and Federal CCF in a package in accordance with instructions on the back of the Federal CCF for transfer to an HHS-certified laboratory or IITF.

(h) If the specimen bottles and Federal CCF are not immediately prepared for transfer to an HHS-certified laboratory or IITF, they must be appropriately safeguarded until the transfer occurs.

(i) The collector must discard any urine left over in the collection container after both specimen bottles have been appropriately filled and sealed. There is one exception to this requirement: The collector may use excess urine to conduct clinical tests (e.g., protein, glucose) if the collection was conducted in conjunction with a

physical examination required by a Federal agency regulation. Neither the collector nor anyone else may conduct further testing (such as specimen validity testing) on the excess urine.

#### **Section 8.8 When is a direct observed collection conducted?**

A direct observed collection procedure must be conducted when:

(a) The agency has authorized a direct observed collection because:

(1) The donor's previous drug test result was reported by an MRO as positive, adulterated, or substituted; or  
(2) The certified laboratory reports to the MRO that a specimen is invalid, and the MRO reported to the agency that there was not an adequate medical explanation for the result; or  
(3) The MRO reported to the agency that the primary bottle (A) specimen was positive, adulterated, or substituted result had to be cancelled because the test of the split specimen could not be tested and/or the split specimen bottle (B) failed to reconfirm; or

(b) At the collection site, an immediate collection of a second urine specimen is required because:

(1) The temperature of the specimen collected during a routine collection is outside the acceptable temperature range;

(2) The collector suspects that the donor has tampered with the specimen during a routine collection (e.g., unusual physical characteristic such as abnormal color and/or odor, and/or excessive foaming when shaken);  
(3) The collector observes conduct by the donor that indicates a possible attempt to adulterate or substitute the specimen; or  
(4) The collector observed materials brought by the donor to the collection site for the purpose of adulterating, substituting, or diluting the specimen.

(c) The collector must contact a collection site supervisor to review and concur in advance with any decision by the collector to obtain a specimen under direct observation.

(d) If the donor declines to have a direct observed collection, the collector reports a refusal to test (i.e., as described in Section 8.12).

#### **Section 8.9 How is a direct observed collection conducted?**

A direct observed collection procedure is the same as that for a routine collection, except an observer watches the donor urinate into the collection container. The observer must be the same gender as the donor with no exception to this requirement. If there is no collector available of the same gender as the donor, the collector or

collection site supervisor shall select an observer trained in direct observed specimen collection as described in Section 4.4. The observer may be an individual that is not a trained collector.

At the point in a routine collection where the donor enters the restroom with the collection container, a direct observed collection includes the following additional steps:

(a) The observer enters the restroom with the donor;

(b) The observer must directly watch the urine go from the donor's body into the collection container (the use of mirrors or video cameras is not permitted);

(c) The observer must not touch or handle the collection container unless the observer is also serving as the collector;

(d) After the donor has completed urinating into the collection container:

(1) If the same person serves as the observer and collector, he or she may receive the collection container from the donor while they are both in the restroom;

(2) If the observer is not serving as the collector, the donor and observer leave the restroom and the donor hands the collection container directly to the collector. The observer must maintain visual contact of the collection container until the donor hands the container to the collector.

(e) The collector checks the box for an observed collection on the Federal CCF and writes the name of the observer and the reason for an observed collection on the Federal CCF; and

(f) The collector then continues with the routine collection procedure in Section 8.7.

#### **Section 8.10 When is a monitored collection conducted?**

(a) In the event that an agency-designated collection site is not available and there is an immediate requirement to collect a specimen (e.g., an accident investigation), a public restroom may be used for the collection, using the procedures for a monitored collection described in Section 8.11.

(b) If the enclosure used by the donor to provide a specimen has a source of water that cannot be disabled or secured, a monitored collection must be conducted.

(c) If the donor declines to permit a collection to be monitored when required, the collector reports a refusal to test (i.e., as described in Section 8.12).

#### **Section 8.11 How is a monitored collection conducted?**

A monitored collection is the same as that for a routine collection, except that

a monitor accompanies the donor into the restroom to check for signs that the donor may be tampering with the specimen. The monitor remains in the restroom, but outside the stall, while the donor is providing the specimen. A person of the same gender as the donor shall serve as the monitor, unless the monitor is a medical professional (e.g., nurse, doctor, physician's assistant, technologist, or technician licensed or certified to practice in the jurisdiction in which the collection takes place). The monitor may be an individual other than the collector and need not be a qualified collector.

(a) The collector secures the restroom being used for the monitored collection so that no one except the employee and the monitor can enter the restroom until after the collection has been completed.

(b) The monitor enters the restroom with the donor.

(c) The monitor must not watch the employee urinate into the collection container. If the monitor hears sounds or makes other observations indicating an attempt by the donor to tamper with a specimen, there must be an additional collection under direct observation in accordance with Section 8.8.

(d) The monitor must not touch or handle the collection container unless the monitor is also the collector.

(e) After the donor has completed urinating into the collection container:

(1) If the same person serves as the monitor and collector, he or she may receive the collection container from the donor while they are both in the restroom;

(2) If the monitor is not serving as the collector, the donor and monitor leave the restroom and the donor hands the collection container directly to the collector. The monitor must ensure that the employee takes the collection container directly to the collector as soon as the employee has exited the enclosure.

(f) If the monitor is not serving as the collector, the collector writes the name of the monitor on the Federal CCF.

(g) The collector then continues with the routine collection procedure in Section 8.7.

#### **Section 8.12 How does the collector report a donor's refusal to test?**

The collector stops the collection, discards any urine collected, and reports the refusal to test by:

(a) Notifying the Federal agency by means (e.g., telephone, e-mail, or secure fax) that ensures that the notification is immediately received,

(b) Documenting the refusal to test on the Federal CCF, and



(c) Sending all copies of the Federal CCF to the Federal agency's designated representative.

**Section 8.13 What are a Federal agency's responsibilities for a collection site?**

(a) A Federal agency must ensure that collectors and collection sites satisfy all requirements in subparts D, E, F, G, and H.

(b) A Federal agency (or only one Federal agency when several agencies are using the same collection site) must inspect 5 percent or up to a maximum of 50 collection sites each year, selected randomly from those sites used to collect agency specimens.

(c) A Federal agency must investigate reported collection site deficiencies (e.g., specimens reported "rejected for testing" by an HHS-certified IITF or HHS-certified laboratory) and take appropriate action which may include inspecting the collection site. The inspections of these additional collection sites may not be included in the 5 percent or maximum of 50 collection sites inspected annually.

**Subpart I—HHS Certification of Laboratories and IITFs**

**Section 9.1 Who has the authority to certify laboratories and IITFs to test specimens for Federal agencies?**

(a) The Secretary has broad discretion to take appropriate action to ensure the full reliability and accuracy of drug testing and reporting, to resolve problems related to drug testing, and to enforce all standards set forth in these Guidelines. The Secretary has the authority to issue directives to any laboratory or IITF suspending the use of certain analytical procedures when necessary to protect the integrity of the testing process; ordering any laboratory or IITF to undertake corrective actions to respond to material deficiencies identified by an inspection or through performance testing; ordering any laboratory or IITF to send specimens or specimen aliquots to another laboratory for retesting when necessary to ensure the accuracy of testing under these Guidelines; ordering the review of results for specimens tested under the Guidelines for private sector clients to the extent necessary to ensure the full reliability of drug testing for Federal agencies; and ordering any other action necessary to address deficiencies in drug testing, analysis, specimen collection, chain of custody, reporting of results, or any other aspect of the certification program.

(b) A laboratory or IITF is prohibited from stating or implying that it is

certified by HHS under these Guidelines to test specimens for Federal agencies unless it holds such certification.

**Section 9.2 What is the process for a laboratory or IITF to become certified and maintain HHS certification and the process when certification is not maintained?**

(a) A laboratory or IITF seeking HHS certification must:

(1) Submit a completed OMB-approved application form (i.e., the applicant laboratory or IITF provides detailed information on both the administrative and analytical procedures to be used for Federal agency specimens after it is certified);

(2) Have its application reviewed as complete and accepted by HHS;

(3) Successfully complete the PT challenges in 3 consecutive sets of initial PT samples;

(4) Satisfy all the requirements for an initial inspection; and

(5) Receive a letter of certification from the Secretary before being able to test specimens for Federal agencies.

(b) To maintain HHS certification, a laboratory or IITF must:

(1) Successfully participate in both the maintenance PT and inspection programs (i.e., successfully test the required quarterly sets of maintenance PT samples, undergo an inspection 3 months after being certified, and undergo maintenance inspections every 6 months thereafter);

(2) Respond in an appropriate, timely, and complete manner to required corrective action in the event of problems identified in either the maintenance PT or inspection program or in operations and reporting; and

(3) Satisfactorily complete corrective remedial action and undergo a special inspection and, as necessary, special PT sets to maintain or restore certification when material deficiencies occur in either the PT program, inspection program, or in operations and reporting.

(c) A laboratory or IITF that does not maintain its HHS certification must:

(1) Stop testing Federal agency specimens;

(2) Ensure the security of Federal agency specimens and records throughout the required storage period described in Sections 11.20, 11.21, 12.18, and 14.8;

(3) Ensure access to Federal agency specimens and records in accordance with Sections 11.23, 12.20, and subpart N; and

(3) When suspension and revocation procedures are imposed by the Secretary, follow the HHS procedures in subpart P that will be used for all actions associated with the suspension and/or revocation of HHS-certification.

**Section 9.3 What are the qualitative and quantitative specifications of a performance test (PT) sample?**

(a) PT samples used to evaluate drug tests will be formulated as follows:

(1) A PT sample may contain one or more of the drugs and metabolites in the drug classes listed in Section 3.4 and satisfy one of the following parameters:

(i) The concentration of a drug or metabolite will be at least 20 percent above the initial test cutoff concentration for the drug;

(ii) The concentration of a drug or metabolite may be as low as 40 percent of the confirmatory test cutoff concentration when the PT sample is designated as a retest sample; or

(iii) The concentration of a drug or metabolite may be at another concentration for a special purpose.

(2) A PT sample may contain an interfering substance, an adulterant, or satisfy the criteria for a substituted specimen, dilute specimen, or invalid result.

(3) A negative PT sample will not contain a measurable amount of a target analyte.

(b) PT samples used to evaluate specimen validity tests shall satisfy, but are not limited to, one of the following criteria:

(1) The nitrite concentration will be at least 20 percent above the cutoff;

(2) The pH will be between 1.5 and 5.0 or between 8.5 and 12.5;

(3) The concentration of an oxidant will be at a level sufficient to challenge a laboratory's ability to identify and confirm the oxidant;

(4) The creatinine concentration will be between 0 and 20 mg/dL; or

(5) The specific gravity will be less than or equal to 1.0050 or between 1.0170 and 1.0230.

(c) For each PT cycle, the set of PT samples going to each laboratory or IITF will vary but, within each calendar year, each laboratory or IITF will analyze essentially the same total set of samples.

(d) The laboratory or IITF must, to the greatest extent possible, handle, test, and report a PT sample in a manner identical to that used for a donor specimen, unless otherwise specified.

**Section 9.4 What are the PT requirements for an applicant laboratory?**

(a) An applicant laboratory that seeks certification under these Guidelines must satisfy the following criteria on 3 consecutive sets of PT samples:

(1) Have no false positive results;

(2) Correctly identify, confirm, and report at least 90 percent of the total drug challenges over the 3 sets of PT samples;

(3) Correctly identify at least 80 percent of the drug challenges for each initial drug test over the 3 sets of PT samples;

(4) For the confirmatory drug tests, correctly determine that the concentrations for at least 80 percent of the total drug challenges are no more than  $\pm 20$  percent or  $\pm 2$  standard deviations (whichever is larger) from the appropriate reference or peer group means over the 3 sets of PT samples;

(5) For the confirmatory drug tests, must not obtain any drug concentration on a PT sample that differs by more than  $\pm 50$  percent from the appropriate reference or peer group mean;

(6) For each confirmatory drug test, correctly identify and determine that the concentrations for at least 50 percent of the drug challenges are no more than  $\pm 20$  percent or  $\pm 2$  standard deviations (whichever is larger) from the appropriate reference or peer group means over the 3 sets of PT samples;

(7) Correctly identify at least 80 percent of the total specimen validity testing challenges over the 3 sets of PT samples;

(8) Correctly identify at least 80 percent of the challenges for each individual specimen validity test over the 3 sets of PT samples;

(9) For quantitative specimen validity tests, obtain quantitative values for at least 80 percent of the total challenges over the 3 sets of PT samples that satisfy the following criteria:

(i) Nitrite and creatinine concentrations are no more than  $\pm 20$  percent or  $\pm 2$  standard deviations from the appropriate reference or peer group mean; and

(ii) pH values are no more than  $\pm 0.3$  pH units from the appropriate reference or peer group mean using a pH meter; and

(iii) Specific gravity values are no more than  $\pm 0.0003$  specific gravity units from the appropriate reference or peer group mean when the mean is less than 1.0100 and specific gravity values are no more than  $\pm 0.0004$  specific gravity units from the appropriate reference or peer group mean when the mean is equal to or greater than 1.0100;

(10) Must not obtain any quantitative value on a specimen validity test PT sample that differs from the appropriate reference or peer group mean by more than  $\pm 50$  percent for nitrite and creatinine concentrations,  $\pm 0.8$  pH units using a pH meter,  $\pm 0.0006$  specific gravity units when the mean is less than 1.0100, or  $\pm 0.0007$  specific gravity units when the mean is equal to or greater than 1.0100; and

(11) Must not report any sample as adulterated with a compound that is not

present in the sample, adulterated based on pH when the appropriate reference or peer group mean is within the acceptable pH range, or substituted when the appropriate reference or peer group means for both creatinine and specific gravity are within the acceptable range.

(b) Failure to satisfy these requirements will result in disqualification.

#### Section 9.5 What are the PT requirements for an HHS-certified laboratory?

(a) A laboratory certified under these Guidelines must satisfy the following criteria on the maintenance PT samples to maintain its certification:

(1) Have no false positive results;

(2) Correctly identify, confirm, and report at least 90 percent of the total drug challenges over 2 consecutive PT cycles;

(3) Correctly identify at least 80 percent of the drug challenges for each initial drug test over 2 consecutive PT cycles;

(4) For the confirmatory drug tests, correctly determine that the concentrations for at least 80 percent of the total drug challenges are no more than  $\pm 20$  percent or  $\pm 2$  standard deviations (whichever is larger) from the appropriate reference or peer group means over 2 consecutive PT cycles;

(5) For the confirmatory drug tests, obtain no more than one drug concentration on a PT sample that differs by more than  $\pm 50$  percent from the appropriate reference or peer group mean over 2 consecutive PT cycles;

(6) For each confirmatory drug test, correctly identify and determine that the concentrations for at least 50 percent of the drug challenges for an individual drug are no more than  $\pm 20$  percent or  $\pm 2$  standard deviations (whichever is larger) from the appropriate reference or peer group means over 2 consecutive PT cycles;

(7) Correctly identify at least 80 percent of the total specimen validity test challenges over 2 consecutive PT cycles;

(8) Correctly identify at least 80 percent of the challenges for each individual specimen validity test over 2 consecutive PT cycles;

(9) For quantitative specimen validity tests, obtain quantitative values for at least 80 percent of the total challenges over 2 consecutive PT cycles that satisfy the following criteria:

(i) Nitrite and creatinine concentrations are no more than  $\pm 20$  percent or  $\pm 2$  standard deviations from the appropriate reference or peer group mean;

(ii) pH values are no more than  $\pm 0.3$  pH units from the appropriate reference or peer group mean using a pH meter; and

(iii) Specific gravity values are no more than  $\pm 0.0003$  specific gravity units from the appropriate reference or peer group mean when the mean is less than 1.0100 and specific gravity values are no more than  $\pm 0.0004$  specific gravity units from the appropriate reference or peer group mean when the mean is equal to or greater than 1.0100;

(10) Obtain no more than one quantitative value over 2 consecutive PT cycles on a specimen validity test PT sample that differs from the appropriate reference or peer group mean by more than  $\pm 50$  percent for nitrite and creatinine concentrations,  $\pm 0.8$  pH units using a pH meter,  $\pm 0.0006$  specific gravity units when the mean is less than 1.0100, or  $\pm 0.0007$  specific gravity units when the mean is equal to or greater than 1.0100; and

(11) Do not report any PT sample as adulterated with a compound that is not present in the sample, adulterated based on pH when the appropriate reference or peer group mean is within the acceptable pH range, or substituted when the appropriate reference or peer group means for both creatinine and specific gravity are within the acceptable range.

(b) Failure to participate in a PT cycle or to satisfy these requirements may result in suspension or revocation of an HHS-certified laboratory's certification.

#### Section 9.6 What are the PT requirements for an applicant IITF?

(a) An applicant IITF that seeks certification under these Guidelines must satisfy the following criteria on 3 consecutive sets of PT samples:

(1) Correctly identify at least 90 percent of the total drug challenges over the 3 sets of PT samples;

(2) Correctly identify at least 80 percent of the drug challenges for each individual drug test over the 3 sets of PT samples;

(3) Correctly identify at least 80 percent of the total specimen validity test challenges over the 3 sets of PT samples;

(4) Correctly identify at least 80 percent of the challenges for each individual specimen validity test over the 3 sets of PT samples;

(5) For quantitative specimen validity tests, obtain quantitative values for at least 80 percent of the total specimen validity test challenges over the 3 sets of PT samples that satisfy the following criteria:

(i) Creatinine concentrations are no more than  $\pm 20$  percent or  $\pm 2$  standard

deviations (whichever is larger) from the appropriate reference or peer group mean; and

(ii) Specific gravity values are no more than  $\pm 0.001$  specific gravity units from the appropriate reference or peer group mean; and

(6) Must not obtain any quantitative value on a specimen validity test PT sample that differs from the appropriate reference or peer group mean by more than  $\pm 50$  percent for creatinine concentration, or  $\pm 0.002$  specific gravity units for specific gravity.

(b) Failure to satisfy these requirements will result in disqualification.

#### **Section 9.7 What are the PT requirements for an HHS-certified IITF?**

(a) An IITF certified under these Guidelines must satisfy the following criteria on the maintenance PT samples to maintain its certification:

(1) Correctly identify at least 90 percent of the total drug challenges over 2 consecutive PT cycles;

(2) Correctly identify at least 80 percent of the drug challenges for each individual drug test over 2 consecutive PT cycles;

(3) Correctly identify at least 80 percent of the total specimen validity test challenges over 2 consecutive PT cycles;

(4) Correctly identify at least 80 percent of the challenges for each individual specimen validity test over 2 consecutive PT cycles;

(5) For quantitative specimen validity tests, obtain quantitative values for at least 80 percent of the total specimen validity test challenges over 2 consecutive PT cycles that satisfy the following criteria:

(i) Creatinine concentrations are no more than  $\pm 20$  percent or  $\pm 2$  standard deviations (whichever is larger) from the appropriate reference or peer group mean; and

(ii) Specific gravity values are no more than  $\pm 0.001$  specific gravity units from the appropriate reference or peer group mean; and

(6) Obtain no more than one quantitative value over 2 consecutive PT cycles on a specimen validity test PT sample that differs from the appropriate reference or peer group mean by more than  $\pm 50$  percent for creatinine concentration, or  $\pm 0.002$  specific gravity units for specific gravity.

(b) Failure to participate in a PT cycle or to satisfy these requirements may result in suspension or revocation of an HHS-certified IITF's certification.

#### **Section 9.8 What are the inspection requirements for an applicant laboratory or IITF?**

(a) An applicant laboratory or IITF is inspected by a team of two inspectors.

(b) Each inspector conducts an independent review and evaluation of all aspects of the laboratory's or IITF's testing procedures and facilities using an inspection checklist.

(c) To become certified, an applicant laboratory or IITF must satisfy the minimum requirements as stated in these Guidelines.

#### **Section 9.9 What are the maintenance inspection requirements for an HHS-certified laboratory or IITF?**

(a) An HHS-certified laboratory or IITF must undergo an inspection 3 months after becoming certified and an inspection every 6 months thereafter.

(b) An HHS-certified laboratory or IITF is inspected by one or more inspectors. The number of inspectors is determined according to the number of specimens reviewed. Additional information regarding inspections is available from SAMHSA.

(c) Each inspector conducts an independent evaluation and review of the HHS-certified laboratory's or IITF's procedures, records, and facilities using guidance provided by the Secretary.

(d) To remain certified, an HHS-certified laboratory or IITF must continue to satisfy the minimum requirements as stated in these Guidelines.

#### **Section 9.10 Who can inspect an HHS-certified laboratory or IITF and when may the inspection be conducted?**

(a) An individual may be selected as an inspector for the Secretary if he or she satisfies the following criteria:

(1) Has experience and an educational background similar to that required for either the responsible person or the certifying scientist as described in subpart K for a laboratory or as a responsible technician as described in subpart L;

(2) Has read and thoroughly understands the policies and requirements contained in these Guidelines and in other guidance consistent with these Guidelines provided by the Secretary;

(3) Submits a resume and documentation of qualifications to HHS;

(4) Attends approved training; and

(5) Performs acceptably as an inspector on an inspection of an HHS-certified laboratory or IITF under these Guidelines.

(b) The Secretary or a Federal agency may conduct an inspection at any time.

#### **Section 9.11 What happens if an applicant laboratory or IITF does not satisfy the minimum requirements for either the PT program or the inspection program?**

If an applicant laboratory or IITF fails to satisfy the requirements established for the initial certification process, the applicant laboratory or IITF must start the initial certification process from the beginning.

#### **Section 9.12 What happens if an HHS-certified laboratory or IITF does not satisfy the minimum requirements for either the PT program or the inspection program?**

(a) If an HHS-certified laboratory or IITF fails to satisfy the minimum requirements for certification, the laboratory or IITF is given a period of time (e.g., 5 or 30 working days depending on the nature of the issue) to provide any explanation for its performance and evidence that any deficiency has been corrected.

(b) A laboratory's or IITF's certification may be revoked, suspended, or no further action taken depending on the seriousness of the errors and whether there is evidence that any deficiency has been corrected and that current performance meets the requirements for a certified laboratory or IITF.

(c) An HHS-certified laboratory or IITF may be required to undergo a special inspection or to test additional PT samples, depending on the nature of the performance, to verify that any deficiency has been corrected.

(d) If an HHS-certified laboratory's or IITF's certification is revoked or suspended in accordance with the process described in subpart P, the laboratory or IITF is not permitted to test specimens for Federal agencies until the suspension is lifted or the laboratory or IITF has successfully completed the certification requirements as a new applicant laboratory or IITF.

#### **Section 9.13 What factors are considered in determining whether revocation of a laboratory's or IITF's certification is necessary?**

(a) The Secretary shall revoke certification of any laboratory or IITF certified in accordance with these Guidelines if the Secretary determines that revocation is necessary to ensure the full reliability and accuracy of drug and specimen validity tests and the accurate reporting of test results.

(b) The Secretary shall consider the following factors in determining whether revocation is necessary:

(1) Unsatisfactory performance in analyzing and reporting the results of

drug and specimen validity tests; for example, a laboratory reporting a false positive result for an employee's drug test;

(2) Unsatisfactory participation in performance testing evaluations or inspections;

(3) A material violation of a certification standard or a contract term or other condition imposed on the laboratory or IITF by a Federal agency using the laboratory's or IITF's services;

(4) Conviction for any criminal offense committed incident to operation of the laboratory or IITF; or

(5) Any other cause that materially affects the ability of the laboratory or IITF to ensure the full reliability and accuracy of drug and specimen validity tests and the accurate reporting of results.

(c) The period and terms of revocation shall be determined by the Secretary and shall depend upon the facts and circumstances of the revocation and the need to ensure accurate and reliable drug and validity testing of Federal employee specimens.

**Section 9.14 What factors are considered in determining whether to suspend a laboratory or IITF?**

(a) Whenever the Secretary has reason to believe that revocation may be required and that immediate action is necessary in order to protect the interests of the United States and its employees, the Secretary may immediately suspend (either partially or fully) a laboratory's or IITF's certification to conduct drug and specimen validity testing for Federal agencies.

(b) The period and terms of suspension shall be determined by the Secretary and shall depend upon the facts and circumstances of the suspension and the need to ensure accurate and reliable drug and specimen validity testing of Federal employee specimens.

**Section 9.15 How does the Secretary notify a laboratory or IITF that action is being taken against the laboratory or IITF?**

(a) When a laboratory or IITF is suspended or the Secretary seeks to revoke certification, the Secretary shall immediately serve the laboratory or IITF with written notice of the suspension or proposed revocation by facsimile, mail, personal service, or registered or certified mail, return receipt requested. This notice shall state the following:

(1) The reasons for the suspension or proposed revocation;

(2) The terms of the suspension or proposed revocation; and

(3) The period of suspension or proposed revocation.

(b) The written notice shall state that the laboratory or IITF will be afforded an opportunity for an informal review of the suspension or proposed revocation if it so requests in writing within 30 days of the date the laboratory or IITF received the notice, or if expedited review is requested, within 3 days of the date the laboratory or IITF received the notice. Subpart P contains detailed procedures to be followed for an informal review of the suspension or proposed revocation.

(c) A suspension must be effective immediately. A proposed revocation must be effective 30 days after written notice is given or, if review is requested, upon the reviewing official's decision to uphold the proposed revocation. If the reviewing official decides not to uphold the suspension or proposed revocation, the suspension must terminate immediately and any proposed revocation shall not take effect.

(d) The Secretary will publish in the **Federal Register** the name, address, and telephone number of any laboratory or IITF that has its certification revoked or suspended under Section 9.13 or Section 9.14, respectively, and the name of any laboratory or IITF that has its suspension lifted. The Secretary shall provide to any member of the public upon request the written notice provided to a laboratory or IITF that has its certification suspended or revoked, as well as the reviewing official's written decision which upholds or denies the suspension or proposed revocation under the procedures of subpart P.

**Section 9.16 May a laboratory or IITF that had its certification revoked be recertified to test Federal agency specimens?**

Following revocation, a laboratory or IITF may apply for recertification. Unless otherwise provided by the Secretary in the notice of revocation under Section 9.13(a) or the reviewing official's decision under Section 16.9(e) or 16.14(a), a laboratory or IITF which has had its certification revoked may reapply for certification as an applicant laboratory or IITF.

**Section 9.17 Where is the list of HHS-certified laboratories and IITFs published?**

(a) The list of HHS-certified laboratories and IITFs is published monthly in the **Federal Register**.

(b) An applicant laboratory or IITF is not included on the list.

**Subpart J—Blind Samples Submitted by an Agency**

**Section 10.1 What are the requirements for Federal agencies to submit blind samples to HHS-certified laboratories or IITFs?**

(a) Each Federal agency is required to submit blind samples for its workplace drug testing program. The blind samples are to be sent to the HHS-certified laboratory or HHS-certified IITF to which the collector sends employee specimens for the Federal agency.

(b) Each Federal agency must submit at least 3 percent blind samples along with its donor specimens based on the projected total number of donor specimens collected per year. Every effort should be made to ensure that some of the blind samples are submitted quarterly.

(c) Of the blind samples submitted each year by an agency, approximately 75 percent of the blind samples must be negative, 15 percent must be positive for one or more drugs, and 10 percent must either be adulterated or substituted.

**Section 10.2 What are the requirements for a blind sample?**

(a) A blind sample that is drug positive must be validated by the supplier as to its content using appropriate initial and confirmatory tests.

(b) A blind sample that is negative (*i.e.*, certified to contain no drug) must be validated by the supplier as negative using appropriate initial and confirmatory tests.

(c) The supplier must provide information regarding the shelf life of the blind sample.

(d) For a blind sample that is drug positive, the concentration of the drug it contains should be between 1.5 and 2 times the initial drug test cutoff concentration and must be spiked or contain one or more of the drugs or metabolites listed in Section 3.4.

(e) A blind sample that is adulterated must have the characteristics to clearly show that it is an adulterated sample at the time it is validated by the supplier.

(f) A blind sample that is substituted must have the characteristics to clearly show that it is a substituted sample at the time it is validated by the supplier.

**Section 10.3 How is a blind sample submitted to an HHS-certified laboratory or IITF?**

(a) A blind sample is submitted using the same Federal CCF as used for a donor specimen. The collector provides the required information to ensure that the Federal CCF has been properly completed as well as providing

fictitious initials on the specimen label/seal. The collector must indicate that the specimen is a blind sample on the MRO copy where a donor would normally provide a signature.

(b) A collector should attempt to distribute the required number of blind samples throughout the total number of donor specimens rather than submitting all of the blind samples as a single group.

#### Section 10.4 What happens if an inconsistent result is reported on a blind sample?

If an HHS-certified laboratory or IITF reports a result for a blind sample that is inconsistent with the expected result (e.g., a laboratory or IITF reports a negative result for a blind sample that was supposed to be positive, a laboratory reports a positive result for a blind sample that was supposed to be negative):

(a) The MRO must contact the supplier of the blind sample and attempt to determine if the supplier made a mistake when preparing the blind sample;

(b) The MRO must contact the collector and determine if the collector made an error when preparing the blind sample for transfer to the laboratory or IITF;

(c) If there is no obvious reason for the inconsistent result, the MRO must notify both the Federal agency for which the blind sample was submitted and the Secretary; and

(d) The Secretary shall investigate the blind sample error. A report of the Secretary's investigative findings and the corrective action taken by the HHS-certified laboratory or IITF must be sent to the Federal agency. The Secretary shall ensure notification of the finding to all other Federal agencies for which the laboratory or IITF is engaged in drug testing and coordinate any necessary action to prevent the recurrence of the error.

#### Subpart K—Laboratory

##### Section 11.1 What must be included in the HHS-certified laboratory's standard operating procedure manual?

(a) An HHS-certified laboratory must have a standard operating procedure (SOP) manual that describes, in detail, all laboratory operations. When followed, it ensures that all specimens are tested using the same procedures and in a consistent manner.

(b) The SOP manual must include, but is not limited to, a detailed description of the following:

- (1) Chain of custody procedures;
- (2) Accessioning;

(3) Security;

(4) Quality control/quality assurance programs;

(5) Analytical methods and procedures;

(6) Equipment and maintenance programs;

(7) Personnel training;

(8) Reporting procedures; and

(9) Computers, software, laboratory information management systems.

(c) All procedures in the SOP manual must be in compliance with these Guidelines and other guidance provided by the Secretary.

(d) A copy of all procedures that have been replaced or revised and the dates on which they were in effect must be maintained for 2 years to allow the laboratory to retrieve the procedures that were used to test a specimen.

##### Section 11.2 What are the responsibilities of the responsible person (RP)?

(a) Manage the day-to-day operations of the drug testing laboratory even where another individual has overall responsibility for an entire multi-specialty laboratory.

(b) Ensure that there are enough personnel with adequate training and experience to supervise and conduct the work of the drug testing laboratory. The RP must ensure the continued competency of laboratory personnel by documenting their in-service training, reviewing their work performance, and verifying their skills.

(c) Maintain a complete, current SOP manual that is available for personnel in the drug testing laboratory, and followed by those personnel. The SOP manual must be reviewed, signed, and dated by the RP(s) whenever procedures are first placed into use or changed or when a new individual assumes responsibility for management of the drug testing laboratory.

(d) Maintain a quality assurance program to assure the proper performance and reporting of all test results; verify and monitor acceptable analytical performance for all controls and standards; monitor quality control testing; document the validity, reliability, accuracy, precision, and performance characteristics of each test and test system.

(e) Implement all remedial actions necessary to maintain satisfactory operation and performance of the laboratory in response to quality control systems not being within performance specifications, errors in result reporting or in analysis of performance testing samples, and deficiencies identified during inspections. This individual must ensure that specimen results are

not reported until all corrective actions have been taken and he or she can assure that the results provided are accurate and reliable.

##### Section 11.3 What scientific qualifications in analytical toxicology must the RP have?

The RP must have documented scientific qualifications in analytical toxicology. Minimum qualifications are:

(a) Be certified as a laboratory director by the State in forensic or clinical laboratory toxicology, have a Ph.D. in one of the natural sciences, or have training and experience comparable to a Ph.D. in one of the natural sciences with training and laboratory/research experience in biology, chemistry, and pharmacology or toxicology;

(b) Have experience in forensic toxicology with emphasis on the collection and analysis of biological specimens for drugs of abuse;

(c) Have experience in forensic applications of analytical toxicology (e.g., publications, court testimony, conducting research on the toxicology of drugs of abuse) or qualify as an expert witness in forensic toxicology;

(d) Be found to fulfill RP responsibilities and qualifications upon interview by HHS-trained inspectors during each on-site inspection of the laboratory; and

(e) Qualify as a certifying scientist.

##### Section 11.4 What happens when the RP is absent or leaves an HHS-certified laboratory?

(a) All HHS-certified laboratories must have multiple RPs or one RP and an alternate RP. When an RP or multiple RPs are absent at the same time, an alternate RP must be present and able to maintain the responsibilities of the RP.

(1) When an HHS-certified laboratory is without the RP and alternate RP for 14 calendar days or less (e.g., vacation, illness, business trip), the certified laboratory may continue testing Federal agency specimens under the direction of a certifying scientist.

(2) The Secretary, in accordance with these Guidelines, will suspend a laboratory's certification for all specimens if the laboratory does not have an RP or alternate RP for a period of more than 14 calendar days. The suspension will be lifted upon the Secretary's approval of a new permanent RP or alternate RP.

(b) When an RP permanently leaves an HHS-certified laboratory:

(1) An HHS-certified laboratory may maintain its certification and continue testing Federal agency specimens under the direction of an alternate RP for a period of up to 180 days while seeking

to hire and receive the Secretary's approval of the new permanent RP.

(2) The Secretary, in accordance with these Guidelines, will suspend a laboratory's certification for all specimens if the laboratory does not have a permanent RP within 180 days. The suspension will be lifted upon the Secretary's approval of the new permanent RP.

(c) To nominate an individual as an RP or alternate RP, the laboratory must submit to the Secretary the candidate's current resume or curriculum vitae, copies of diplomas and any licensures, a training plan (not to exceed 90 days) to transition into the RP position, an itemized defense of the candidate's qualifications compared to the minimum RP qualifications described in the Guidelines, and arrange to have official academic transcript(s) submitted by the candidate's institution(s) of higher learning. The candidate must be found acceptable during an on-site inspection of the laboratory.

(d) The laboratory must fulfill other inspection and PT criteria as required prior to conducting Federal agency testing under a new RP.

**Section 11.5 What qualifications must an individual have to certify a result reported by an HHS-certified laboratory?**

(a) The certifying scientist must have:

(1) At least a bachelor's degree in the chemical or biological sciences or medical technology, or equivalent;

(2) Training and experience in the analytical methods and forensic procedures used by the laboratory that are relevant to the results that the individual certifies; and

(3) Training and experience in reviewing and reporting forensic test results, maintenance of chain of custody, and understanding proper remedial action in response to problems that may arise.

(b) The certifying technician must have:

(1) Training and experience in the analytical methods and forensic procedures used by the laboratory that are relevant to the results that the individual certifies; and

(2) Training and experience in reviewing and reporting forensic test results, maintenance of chain of custody, and understanding proper remedial action in response to problems that may arise.

**Section 11.6 What qualifications and training must other laboratory personnel have?**

(a) All laboratory staff (e.g., technicians, administrative staff) must

have the appropriate training and skills for the tasks assigned.

(b) Each individual working in an HHS-certified laboratory must be properly trained (i.e., receive training in each area of work that the individual will be performing, including training in forensic procedures related to their job duties) before he or she is permitted to work independently with regulated specimens and the training must be documented.

**Section 11.7 What security measures must an HHS-certified laboratory maintain?**

(a) An HHS-certified laboratory must control access to the drug testing facility, specimens, aliquots, and records.

(b) Authorized visitors must be escorted at all times, except for individuals conducting inspections (i.e., for the Department, a Federal agency, a state, or other accrediting agency) or emergency personnel (such as, firefighters and medical rescue teams).

(c) A laboratory must maintain a record that documents the dates, time of entry and exit, and purpose of entry of authorized escorted visitors accessing secured areas, and their authorized escorts.

**Section 11.8 What are the internal laboratory chain of custody requirements for a specimen or an aliquot?**

(a) An HHS-certified laboratory must use chain of custody procedures to maintain control and accountability of specimens from receipt through completion of testing, reporting of results, during storage, and continuing until final disposition of the specimens.

(b) An HHS-certified laboratory must use chain of custody procedures to document the handling and transfer of aliquots throughout the testing process and until final disposal.

(c) The date and purpose must be documented on an appropriate chain of custody document each time a specimen or aliquot is handled or transferred, and every individual in the chain must be identified.

(d) Chain of custody must be maintained and documented by using either paper copy or electronic procedures.

(e) Each individual that handles a specimen or aliquot must sign and complete the appropriate entries on the chain of custody document when the specimen or aliquot is received.

**Section 11.9 What test(s) does an HHS-certified laboratory conduct on a specimen received from an IITF?**

An HHS-certified laboratory must test the specimen in the same manner as a specimen that had not been previously tested.

**Section 11.10 What are the requirements for an initial drug test?**

(a) An initial drug test must be an immunoassay test.

(b) A laboratory must validate an initial drug test before using it to test specimens.

(c) Initial drug test kits must be approved, cleared, or otherwise recognized by FDA as accurate and reliable for the testing of a specimen for identifying drugs of abuse or their metabolites.

(d) A laboratory may conduct a second initial drug test using a method with different specificity, to rule out cross-reacting compounds. This second initial drug test must satisfy the batch quality control requirements specified in Section 11.12.

**Section 11.11 What must an HHS-certified laboratory do to validate an initial drug test?**

(a) An HHS-certified laboratory must demonstrate and document for each initial test:

(1) The ability to differentiate positive and negative specimens;

(2) The performance of the test around the cutoff concentration, using samples at several concentrations between 0 and 150 percent of the cutoff concentration;

(3) The effective concentration range of the test; and

(4) The effect of carryover that may occur between aliquots.

(b) Each new lot of an initial drug test reagent must be verified prior to being placed into service.

**Section 11.12 What are the batch quality control requirements when conducting an initial drug test?**

(a) Each batch of specimens must contain the following QC samples:

(1) At least one control certified to contain no drug or drug metabolite;

(2) At least one positive control with the drug or drug metabolite targeted at 25 percent above the cutoff;

(3) At least one control with the drug or drug metabolite targeted at 75 percent of the cutoff; and

(4) At least one control that appears as a donor specimen to the laboratory analysts.

(b) A minimum of 10 percent of the total specimens and quality control samples in each batch must be quality

control samples (*i.e.*, calibrators or controls).

**Section 11.13 What are the requirements for a confirmatory drug test?**

(a) The analytical method used must combine chromatographic separation and mass spectrometric identification (*e.g.*, GC/MS, liquid chromatography/mass spectrometry (LC/MS), GC/MS/MS, LC/MS/MS).

(b) A confirmatory drug test must be validated before the laboratory can use it to test specimens.

**Section 11.14 What must an HHS-certified laboratory do to validate a confirmatory drug test?**

(a) An HHS-certified laboratory must demonstrate and document for each confirmatory drug test:

- (1) The linear range of the analysis;
- (2) The limit of detection;
- (3) The limit of quantitation;
- (4) The accuracy and precision at the cutoff concentration;
- (5) The accuracy and precision at 40 percent of the cutoff concentration; and
- (6) The potential for interfering substances.

(7) The effect of carryover that may occur between aliquots.

(b) An HHS-certified laboratory must re-verify its confirmatory drug test methods periodically or at least annually.

**Section 11.15 What are the quality control requirements when conducting a confirmatory drug test?**

(a) Each batch of specimens must contain, at a minimum, the following QC specimens:

- (1) A calibrator with its drug concentration at the cutoff;
- (2) At least one control certified to contain no drug or drug metabolite;
- (3) At least one positive control with the drug or drug metabolite targeted at 25 percent above the cutoff; and
- (4) At least one control targeted at or below 40 percent of the cutoff.

(b) A minimum of 10 percent of the total specimens and quality control samples in each batch must be quality control samples (*i.e.*, calibrators or controls).

**Section 11.16 What are the analytical and quality control requirements for conducting specimen validity tests?**

(a) Each specimen validity test result must be based on performing an initial specimen validity test on one aliquot and a second or confirmatory test on a second aliquot;

(b) Each specimen validity test must satisfy the QC requirements in Section 11.18; and

(c) Controls must be analyzed concurrently with specimens.

**Section 11.17 What must an HHS-certified laboratory do to validate a specimen validity test?**

An HHS-certified laboratory must demonstrate and document for each specimen validity test the appropriate performance characteristics of the test; and must re-verify the test periodically, or at least annually.

**Section 11.18 What are the requirements for conducting each specimen validity test?**

(a) The requirements for measuring creatinine concentration are as follows:

- (1) The creatinine concentration must be measured to one decimal place on both the initial creatinine test and the confirmatory creatinine test;
- (2) The initial creatinine test must have a calibrator at 2 mg/dL;
- (3) The initial creatinine test must have a control in the range of 1.0 mg/dL to 1.5 mg/dL, a control in the range of 3 mg/dL to 20 mg/dL, and a control in the range of 21 mg/dL to 25 mg/dL; and
- (4) The confirmatory creatinine test (performed on those specimens with a creatinine concentration less than 2 mg/dL on the initial test) must have a calibrator at 2 mg/dL, a control in the range of 1.0 mg/dL to 1.5 mg/dL, and a control in the range of 3 mg/dL to 4 mg/dL.

(b) The requirements for measuring specific gravity are as follows:

- (1) For specimens with initial creatinine test results greater than 5 mg/dL and less than 20 mg/dL, laboratories may perform a screening test using a refractometer that measures urine specific gravity to at least three decimal places to identify specific gravity values that are acceptable (equal to or greater than 1.003) or dilute (equal to or greater than 1.002 and less than 1.003). Specimens must be subjected to an initial specific gravity test using a four decimal place refractometer when the initial creatinine test result is less than or equal to 5 mg/dL or when the screening specific gravity test result using a three decimal place refractometer is less than 1.002. The screening specific gravity test must have the following controls:

- (i) A calibrator or control at 1.000;
- (ii) One control targeted at 1.002;
- (iii) One control in the range of 1.004 to 1.018.

(2) For the initial and confirmatory specific gravity tests, the refractometer must report and display specific gravity to four decimal places. The refractometer must be interfaced with a

laboratory information management system (LIMS), computer, and/or generate a paper copy of the digital electronic display to document the numerical values of the specific gravity test results;

(3) The initial and confirmatory specific gravity tests must have a calibrator or control at 1.0000; and

- (4) The initial and confirmatory specific gravity tests must have the following controls:
  - (i) One control targeted at 1.0020;
  - (ii) One control in the range of 1.0040 to 1.0180; and
  - (iii) One control equal to or greater than 1.0200 but not greater than 1.0250.

(c) Requirements for measuring pH are as follows:

(1) Colorimetric pH tests that have the dynamic range of 2 to 12 to support the 3 and 11 pH cutoffs and pH meters must be capable of measuring pH to one decimal place. Colorimetric pH tests, dipsticks, and pH paper (*i.e.*, screening tests) that have a narrow dynamic range and do not support the cutoffs may be used only to determine if an initial pH specimen validity test must be performed;

(2) For the initial and confirmatory pH tests, the pH meter must report and display pH to at least one decimal place. The pH meter must be interfaced with a LIMS, computer, and/or generate a paper copy of the digital electronic display to document the numerical values of the pH test results;

(3) pH screening tests must have, at a minimum, the following controls:

- (i) One control below the lower decision point in use;
  - (ii) One control between the decision points in use; and
  - (iii) One control above the upper decision point in use;
- (4) An initial colorimetric pH test must have the following calibrators and controls:
- (i) One calibrator at 3;
  - (ii) One calibrator at 11;
  - (iii) One control in the range of 2 to 2.8;
  - (iv) One control in the range 3.2 to 4;
  - (v) One control in the range of 4.5 to 9;
  - (vi) One control in the range of 10 to 10.8; and
  - (vii) One control in the range of 11.2 to 12;

(5) An initial pH meter test, if a pH screening test is not used, must have the following calibrators and controls:

- (i) One calibrator at 4;
- (ii) One calibrator at 7;
- (iii) One calibrator at 10;
- (iv) One control in the range of 2 to 2.8;
- (v) One control in the range 3.2 to 4;

(vi) One control in the range of 10 to 10.8; and

(vii) One control in the range of 11.2 to 12;

(6) An initial or confirmatory pH meter test, if a pH screening test is used, must have the following calibrators and controls when the screening result indicates that the pH is below the lower decision point in use:

(i) One calibrator at 4;

(ii) One calibrator at 7;

(iii) One control in the range of 2 to 2.8; and

(iv) One control in the range 3.2 to 4; and

(7) An initial or confirmatory pH meter test, if a pH screening test is used, must have the following calibrators and controls when the screening result indicates that the pH is above the upper decision point in use:

(i) One calibrator at 7;

(ii) One calibrator at 10;

(iii) One control in the range of 10 to 10.8; and

(iv) One control in the range of 11.2 to 12.

(d) Requirements for performing oxidizing adulterant tests are as follows:

(1) The initial test must include an appropriate calibrator at the cutoff specified in Sections 11.19(d)(2), (3), or (4) for the compound of interest, a control without the compound of interest (i.e., a certified negative control), and at least one control with one of the compounds of interest at a measurable concentration; and

(2) A confirmatory test for a specific oxidizing adulterant must use a different analytical method than that used for the initial test. Each confirmatory test batch must include an appropriate calibrator, a control without the compound of interest (i.e., a certified negative control), and a control with the compound of interest at a measurable concentration.

(e) The requirements for measuring the nitrite concentration are that the initial and confirmatory nitrite tests must have a calibrator at the cutoff concentration, a control without nitrite (i.e., certified negative urine), one control in the range of 200 mcg/mL to 250 mcg/mL, and one control in the range of 500 mcg/mL to 625 mcg/mL.

#### Section 11.19 What are the requirements for an HHS-certified laboratory to report a test result?

(a) An HHS-certified laboratory must report a test result directly to the agency's MRO within an average of 5 working days after receipt of the specimen using the Federal CCF and/or an electronic report. Before any test result is reported, it must be certified by

a certifying scientist or a certifying technician, as appropriate.

(b) A primary (Bottle A) specimen is reported negative when each initial drug test is negative or it is negative on a confirmatory drug test and each specimen validity test result indicates that the specimen is a valid urine specimen.

(c) A primary (Bottle A) specimen is reported positive for a specific drug when the initial drug test is positive and the confirmatory drug test is positive in accordance with Section 3.4.

(d) A primary (Bottle A) specimen is reported adulterated when:

(1) The pH is less than 3 or equal to or greater than 11 using either a pH meter or a colorimetric pH test for the initial test on the first aliquot and a pH meter for the confirmatory test on the second aliquot;

(2) The nitrite concentration is equal to or greater than 500 mcg/mL using either a nitrite colorimetric test or a general oxidant colorimetric test for the initial test on the first aliquot and a different confirmatory test (e.g., multi-wavelength spectrophotometry, ion chromatography, capillary electrophoresis) on the second aliquot;

(3) The presence of chromium (VI) is verified using either a general oxidant colorimetric test (with an equal to or greater than 50 mcg/mL chromium (VI)-equivalent cutoff) or a chromium (VI) colorimetric test (chromium (VI) concentration equal to or greater than 50 mcg/mL) for the initial test on the first aliquot and a different confirmatory test (e.g., multi-wavelength spectrophotometry, ion chromatography, atomic absorption spectrophotometry, capillary electrophoresis, inductively coupled plasma-mass spectrometry) with the chromium (VI) concentration equal to or greater than the LOQ of the confirmatory test on the second aliquot;

(4) The presence of halogen (e.g., bleach, iodine, fluoride) is verified using either a general oxidant colorimetric test (with an equal to or greater than 200 mcg/mL nitrite-equivalent cutoff or an equal to or greater than 50 mcg/mL chromium (VI)-equivalent cutoff) or halogen colorimetric test (halogen concentration equal to or greater than the LOQ) for the initial test on the first aliquot and a different confirmatory test (e.g., multi-wavelength spectrophotometry, ion chromatography, inductively coupled plasma-mass spectrometry) with a specific halogen concentration equal to or greater than the LOQ of the confirmatory test on the second aliquot;

(5) The presence of glutaraldehyde is verified using either an aldehyde test

(aldehyde present) or the characteristic immunoassay response on one or more drug immunoassay tests for the initial test on the first aliquot and a different confirmatory method (e.g., GC/MS) for the confirmatory test with the glutaraldehyde concentration equal to or greater than the LOQ of the analysis on the second aliquot;

(6) The presence of pyridine (pyridinium chlorochromate) is verified using either a general oxidant colorimetric test (with an equal to or greater than 200 mcg/mL nitrite-equivalent cutoff or an equal to or greater than 50 mcg/mL chromium (VI)-equivalent cutoff) or a chromium (VI) colorimetric test (chromium (VI) concentration equal to or greater than 50 mcg/mL) for the initial test on the first aliquot and a different confirmatory method (e.g., GC/MS) for the confirmatory test with the pyridine concentration equal to or greater than the LOQ of the analysis on the second aliquot;

(7) The presence of a surfactant is verified by using a surfactant colorimetric test with an equal to or greater than 100 mcg/mL dodecylbenzene sulfonate-equivalent cutoff for the initial test on the first aliquot and a different confirmatory test (e.g., multi-wavelength spectrophotometry) with an equal to or greater than 100 mcg/mL dodecylbenzene sulfonate-equivalent cutoff on the second aliquot; or

(8) The presence of any other adulterant not specified in paragraphs d(2) through d(7) of this section is verified using an initial test on the first aliquot and a different confirmatory test on the second aliquot.

(e) A primary (Bottle A) specimen is reported substituted when the creatinine concentration is less than 2 mg/dL and the specific gravity is less than or equal to 1.0010 or equal to or greater than 1.0200 on both the initial and confirmatory creatinine tests (i.e., the same colorimetric test may be used to test both aliquots) and on both the initial and confirmatory specific gravity tests (i.e., a refractometer is used to test both aliquots) on two separate aliquots.

(f) A primary (Bottle A) specimen is reported dilute when the creatinine concentration is equal to or greater than 2 mg/dL but less than 20 mg/dL and the specific gravity is greater than 1.0010 but less than 1.0030 on a single aliquot.

(g) For a specimen that has an invalid result for one of the reasons stated in items (h)4 through (h)12 below, the laboratory shall contact the MRO and both will decide if testing by another certified laboratory would be useful in being able to report a positive or



adulterated result. If no further testing is necessary, the laboratory then reports the invalid result to the MRO.

(h) A primary (Bottle A) specimen is reported as an invalid result when:

(1) Inconsistent creatinine concentration and specific gravity results are obtained (i.e., the creatinine concentration is less than 2 mg/dL on both the initial and confirmatory creatinine tests and the specific gravity is greater than 1.0010 but less than 1.0200 on the initial and/or confirmatory specific gravity test, the specific gravity is less than or equal to 1.0010 on both the initial and confirmatory specific gravity tests and the creatinine concentration is equal to or greater than 2 mg/dL on either or both the initial or confirmatory creatinine tests);

(2) The pH is equal to or greater than 3 and less than 4.5 or equal to or greater than 9 and less than 11 using either a colorimetric pH test or pH meter for the initial test and a pH meter for the confirmatory test on two separate aliquots;

(3) The nitrite concentration is equal to or greater than 200 mcg/mL using a nitrite colorimetric test or equal to or greater than the equivalent of 200 mcg/mL nitrite using a general oxidant colorimetric test for both the initial (first) test and the second test or using either initial test and the nitrite concentration is equal to or greater than 200 mcg/mL but less than 500 mcg/mL for a different confirmatory test (e.g., multi-wavelength spectrophotometry, ion chromatography, capillary electrophoresis) on two separate aliquots;

(4) The possible presence of chromium (VI) is determined using the same chromium (VI) colorimetric test with a cutoff equal to or greater than 50 mcg/mL chromium (VI) for both the initial (first) test and the second test on two separate aliquots;

(5) The possible presence of a halogen (e.g., bleach, iodine, fluoride) is determined using the same halogen colorimetric test with a cutoff equal to or greater than the LOQ for both the initial (first) test and the second test on two separate aliquots or relying on the odor of the specimen as the initial test;

(6) The possible presence of glutaraldehyde is determined by using the same aldehyde test (aldehyde present) or characteristic immunoassay response on one or more drug immunoassay tests for both the initial (first) test and the second test on two separate aliquots;

(7) The possible presence of an oxidizing adulterant is determined by using the same general oxidant

colorimetric test (with an equal to or greater than 200 mcg/mL nitrite-equivalent cutoff, an equal to or greater than 50 mcg/mL chromium (VI)-equivalent cutoff, or a halogen concentration is equal to or greater than the LOQ) for both the initial (first) test and the second test on two separate aliquots;

(8) The possible presence of a surfactant is determined by using the same surfactant colorimetric test with an equal to or greater than 100 mcg/mL dodecylbenzene sulfonate-equivalent cutoff for both the initial (first) test and the second test on two separate aliquots or a foam/shake test for the initial test;

(9) Interference occurs on the immunoassay drug tests on two separate aliquots (i.e., valid immunoassay drug test results cannot be obtained);

(10) Interference with the confirmatory drug test occurs on at least two separate aliquots of the specimen and the laboratory is unable to identify the interfering substance;

(11) The physical appearance of the specimen is such that testing the specimen may damage the laboratory's instruments; or

(12) The physical appearance of Bottles A and B are clearly different and Bottle A tested negative for drugs.

(i) An HHS-certified laboratory shall reject a primary (Bottle A) urine specimen for testing when a fatal flaw occurs as described in Section 15.1 or when a correctable flaw as described in Section 15.2 is not recovered. The laboratory will indicate on the Federal CCF that the specimen was rejected for testing and provide the reason for reporting the rejected for testing result.

(j) An HHS-certified laboratory must report all positive, adulterated, substituted, and invalid test results for a specimen. For example, a specimen can be positive for a specific drug and adulterated.

(k) An HHS-certified laboratory must report the concentration of the drug or drug metabolite for a positive result.

(l) An HHS-certified laboratory must report numerical values of the specimen validity test results that support a specimen that is reported adulterated, substituted, or invalid (as appropriate).

(m) When the concentration of an analyte exceeds the linear range of the standard curve, an HHS-certified laboratory may report to the MRO that the quantitative value exceeds the linear range of the test, that the quantitative value is greater than "insert the actual value for the upper limit of the linear range," or may report an accurate quantitative value above the upper limit of the linear range that was obtained by diluting an aliquot of the specimen.

(n) An HHS-certified laboratory may transmit a result to the MRO by various electronic means (e.g., teleprinter, facsimile, or computer) in a manner designed to ensure confidentiality of the information. A result may not be reported verbally by telephone. A laboratory must ensure the security of the data transmission and limit access to any data transmission, storage, and retrieval system.

(o) For all test results, an HHS-certified laboratory may fax, courier, mail, or electronically transmit a legible image or copy of the completed Federal CCF, and/or forward a computer-generated electronic report. The computer-generated report must contain sufficient information to ensure that the test result is properly associated with the custody and control form that the MRO received from the collector. For positive, adulterated, substituted, and invalid results, the laboratory must fax, courier, mail, or electronically transmit a legible image or copy of the completed Federal CCF.

#### **Section 11.20 How long must an HHS-certified laboratory retain a specimen?**

(a) An HHS-certified laboratory must retain a specimen that was reported either drug positive, adulterated, substituted, or as an invalid result for a minimum of 1 year.

(b) A retained specimen must be kept in a secured frozen storage ( $-20^{\circ}\text{C}$  or less) to ensure its availability for any necessary retesting during an administrative or judicial proceeding.

(c) Within the 1-year storage period, a Federal agency may request a laboratory to retain a specimen for an additional specified period of time.

#### **Section 11.21 How long must an HHS-certified laboratory retain records?**

(a) An HHS-certified laboratory must retain all records generated to support test results for at least 2 years.

(b) A Federal agency may request an HHS-certified laboratory to maintain a copy of the documentation package (as described in Section 11.23 that supports the chain of custody, testing, and reporting of a donor's specimen that is under legal challenge by a donor. The Federal agency's request to the laboratory must be in writing and must specify the period of time to maintain the documentation package.

(c) The laboratory may retain records other than those included in the documentation package beyond the normal 2 year period of time to ensure that it can fully support the reported test result.

**Section 11.22 What statistical summary report must an HHS-certified laboratory provide?**

(a) An HHS-certified laboratory must provide to each Federal agency for which testing is conducted a semiannual statistical summary report that contains the following information:

(1) Reporting period (inclusive dates);  
 (2) Laboratory name and address;  
 (3) Federal agency name;  
 (4) Total number of specimen results reported;

(5) Number of specimens collected by reason for test;

(6) Number of specimens reported negative and the number reported negative/dilute;

(7) Number of specimens rejected for testing because of a fatal flaw and the number rejected for testing because of an uncorrected flaw;

(8) Number of specimens reported positive;

(9) Number of specimens reported positive for each drug;

(10) Number of specimens reported adulterated;

(11) Number of specimens reported substituted; and

(12) Number of specimens reported as invalid result.

(b) The report must be submitted by mail, fax, or e-mail within 14 working days after the end of the semiannual period. The summary report must not include any personal identifying information.

(c) The HHS-certified laboratory must make available copies of an agency's test results when requested by the Secretary or by the Federal agency for which the laboratory is performing drug-testing services.

(d) The HHS-certified laboratory must make available a qualified individual to testify in a proceeding against a Federal employee when that proceeding is based on a test result reported by the HHS-certified laboratory.

**Section 11.23 What laboratory information is available to a Federal employee?**

(a) A Federal employee who is the subject of a drug test may, upon written request through the MRO and the Federal agency, have access to any records relating to his or her drug test, any records relating to the results of any relevant certification, review, or revocation of certification proceedings, and access to a documentation package.

(b) A standard documentation package provided by an HHS-certified laboratory must consist of the following items:

(1) A cover sheet that provides a brief description of the drug testing

procedures and specimen validity tests performed on the donor's specimen;

(2) A table of contents page that lists by page number all documents and materials in the package;

(3) A copy of the Federal CCF with any attachments, internal chain of custody records for the specimen, memoranda (if any) generated by the laboratory, and a copy of the electronic report (if any) generated by the laboratory;

(4) A brief description of the laboratory's initial drug and specimen validity test procedures, instrumentation, batch quality control requirements, and copies of the initial test data for the donor's specimen with all calibrators and controls identified and copies of all internal chain of custody documents related to the initial tests;

(5) A brief description of the laboratory's confirmatory drug and specimen validity test procedures, instrumentation, batch quality control requirements, and copies of the confirmatory test data for the donor's specimen with all calibrators and controls identified and copies of all internal chain of custody documents related to the confirmatory tests; and

(6) A copy of the resume or curriculum vitae for the RP(s) and the certifying scientist that certified the test result.

**Section 11.24 What type of relationship is prohibited between an HHS-certified laboratory and an MRO?**

A certified laboratory must not enter into any relationship with a Federal agency's MRO that may be construed as a potential conflict of interest or derive any financial benefit by having a Federal agency use a specific MRO.

This means an MRO may be an employee of the agency or a contractor for the agency; however, an MRO shall not be an employee or agent of or have any financial interest in the laboratory for which the MRO is reviewing drug testing results. Additionally, an MRO shall not derive any financial benefit by having an agency use a specific drug testing laboratory or have any agreement with the laboratory that may be construed as a potential conflict of interest.

**Section 11.25 What type of relationship can exist between an HHS-certified laboratory and an HHS-certified IITF?**

An HHS-certified laboratory can enter into any relationship with an HHS-certified IITF.

**Subpart L—Instrumented Initial Test Facility (IITF)**

**Section 12.1 What must be included in the HHS-certified IITF's standard operating procedure manual?**

(a) An HHS-certified IITF must have a standard operating procedure (SOP) manual that describes, in detail, all IITF operations.

(b) The SOP manual must include, but is not limited to, a detailed description of the following:

(1) Chain of custody procedures;  
 (2) Accessioning;  
 (3) Security;  
 (4) Quality control/quality assurance programs;

(5) Analytical methods and procedures;

(6) Equipment and maintenance programs;

(7) Personnel training;

(8) Reporting procedures; and

(9) Computers, software, and laboratory information management systems.

(c) All procedures in the SOP manual must be in compliance with these Guidelines and other guidance documents.

(d) A copy of all procedures that have been replaced or revised and the dates on which they were in effect must be maintained by the HHS-certified IITF for two years to allow the IITF to retrieve the procedures that were used to test a specimen.

**Section 12.2 What are the responsibilities of the responsible technician (RT)?**

(a) Manage the day-to-day operations of the IITF even where another individual has overall responsibility for an entire multi-specialty facility.

(b) Ensure that there are enough personnel with adequate training and experience to supervise and conduct the work of the IITF. The RT must ensure the continued competency of IITF personnel by documenting their in-service training, reviewing their work performance, and verifying their skills.

(c) Maintain a complete, current SOP manual that is available for personnel at the IITF, and followed by those personnel. The SOP manual must be reviewed, signed, and dated by the RT whenever procedures are first placed into use or changed or when a new individual assumes responsibility for management of the IITF.

(d) Maintain a quality assurance program to assure the proper performance and reporting of all test results; verify and monitor acceptable analytical performance for all controls and standards; monitor quality control

testing; document the validity, reliability, accuracy, precision, and performance characteristics of each test and test system.

(e) Implement all remedial actions necessary to maintain satisfactory operation and performance of the IITF in response to quality control systems not being within performance specifications, errors in result reporting or in analysis of performance testing samples, and deficiencies identified during inspections. This individual must ensure that specimen results are not reported until all corrective actions have been taken and he or she can assure that the results provided are accurate and reliable.

### Section 12.3 What qualifications must the RT have?

An RT must:

(a) Have at least a bachelor's degree in the chemical or biological sciences or medical technology, or equivalent;

(b) Have training and experience in the analytical methods and forensic procedures used by the IITF that are relevant to the results;

(c) Have training and experience in reviewing and reporting forensic test results, maintenance of chain of custody, recordkeeping, and understanding proper remedial action in response to problems that may arise;

(d) Be found to fulfill RT responsibilities and qualifications upon interview by HHS-trained inspectors during each on-site inspection of the HHS-certified IITF; and

(e) Qualify as a certifying technician.

### Section 12.4 What happens when the RT is absent or leaves an HHS-certified IITF?

(a) All HHS-certified IITFs must have an RT and an alternate RT. When an RT is absent, an alternate RT must be present and able to maintain the responsibilities of the RT.

(1) When an HHS-certified IITF is without the RT and alternate RT for 14 calendar days or less (e.g., vacation, illness, business trip), the HHS-certified IITF may continue testing Federal agency specimens under the direction of a certifying technician.

(2) The Secretary, in accordance with these Guidelines, will suspend an IITF's certification for all specimens if the IITF does not have an RT or alternate RT for a period of more than 14 calendar days. The suspension will be lifted upon the Secretary's approval of a new permanent RT or alternate RT.

(b) When an RT permanently leaves an HHS-certified IITF:

(1) The HHS-certified IITF may maintain its certification and continue

testing Federal agency specimens under the direction of an alternate RT for a period of up to 180 days while seeking to hire and receive the Secretary's approval of the new permanent RT.

(2) The Secretary, in accordance with these Guidelines, will suspend an IITF's certification for all specimens if the IITF does not have a permanent replacement RT within 180 days. The suspension will be lifted upon the Secretary's approval of the new permanent RT.

(c) To nominate an individual as RT or alternate RT, the IITF must submit to the Secretary the candidate's current resume or curriculum vitae, copies of diplomas and any licensures, a training plan (not to exceed 90 days) to transition into the RT position, an itemized defense of the candidate's qualifications compared to the minimum RT qualifications described in the Guidelines, and arrange to have official academic transcript(s) submitted by the candidate's institution(s) of higher learning. The candidate must be found acceptable during an on-site inspection of the IITF.

(d) The HHS-certified IITF must fulfill other inspection and PT criteria as required prior to conducting Federal agency testing under a new RT.

### Section 12.5 What qualifications must an individual have to certify a result reported by an HHS-certified IITF?

The certifying technician must have:

(a) Training and experience in the analytical methods and forensic procedures used by the IITF that are relevant to the results that the individual certifies; and

(b) Training and experience in reviewing and reporting forensic test results, maintenance of chain of custody, and understanding proper remedial action in response to problems that may arise.

### Section 12.6 What qualifications and training must other IITF personnel have?

(a) All IITF staff (e.g., technicians, administrative staff) must have the appropriate training and skills for the tasks assigned.

(b) Each individual working in an HHS-certified IITF must be properly trained (i.e., receive training in each area of work that the individual will be performing, including training in forensic procedures related to their job duties) before he or she is permitted to work independently in any area of the facility with Federal agency specimens and the training must be documented.

### Section 12.7 What security measures must an HHS-certified IITF maintain?

(a) An HHS-certified IITF must control access to the facility and ensure that no unauthorized individual can gain access to specimens, aliquots, or records.

(b) Authorized visitors must be escorted at all times except for individuals authorized to conduct inspections on behalf of Federal, state, or other accrediting agencies or emergency personnel (e.g., firefighters and medical rescue teams).

(c) An HHS-certified IITF must maintain a record that documents the dates, time of entry and exit, and purpose of entry of authorized escorted visitors accessing secured areas, and their authorized escorts.

### Section 12.8 What are the internal IITF chain of custody requirements for a specimen or an aliquot?

(a) An HHS-certified IITF must use chain of custody procedures to maintain control and accountability of specimens from receipt through completion of testing, reporting of results, during storage, and continuing until final disposition of the specimens.

(b) An HHS-certified IITF must use chain of custody procedures to document the handling and transfer of aliquots throughout the testing process and until final disposal.

(c) The date and purpose must be documented on an appropriate chain of custody document each time a specimen or aliquot is handled or transferred, and every individual in the chain must be identified.

(d) Chain of custody must be maintained and documented by using either paper copy or electronic procedures.

(e) Each individual that handles a specimen or aliquot must sign and complete the appropriate entries on the chain of custody document when the specimen or aliquot is received.

### Section 12.9 What are the requirements for an initial drug test?

(a) An initial drug test must be an immunoassay test.

(b) An IITF must validate an initial drug test before using it to test specimens;

(c) Initial drug test kits must be approved, cleared, or otherwise recognized by FDA as accurate and reliable for the testing of a specimen for identifying drugs of abuse or their metabolites.

(d) An IITF may conduct a second initial drug test using a method with different specificity, to rule out cross-

reacting compounds. This second initial drug test must satisfy the batch quality control requirements specified in Section 12.11.

**Section 12.10 What must an HHS-certified IITF do to validate an initial drug test?**

(a) An HHS-certified IITF must demonstrate and document for each initial drug test:

(1) The ability to differentiate positive and negative specimens;

(2) The performance of the test around the cutoff concentration, using samples at several concentrations between 0 and 150 percent of the cutoff concentration;

(3) The effective concentration range of the test; and

(4) The effect of carryover that may occur between aliquots.

(b) Each new lot of a drug test reagent must be verified prior to being placed into service.

**Section 12.11 What are the batch quality control (QC) requirements when conducting an initial drug test?**

(a) Each batch of specimens must contain the following QC samples:

(1) At least one control certified to contain no drug or drug metabolite;

(2) At least one positive control with the drug or drug metabolite targeted at 25 percent above the cutoff;

(3) At least one control with the drug or drug metabolite targeted at 75 percent of the cutoff; and

(4) At least one control that appears as a donor specimen to the IITF analysts.

(b) A minimum of 10 percent of the total specimens and QC samples in each batch must be QC samples (i.e., calibrators or controls).

**Section 12.12 What are the analytical and quality control requirements for conducting specimen validity tests?**

(a) Each specimen validity test result must be based on a single test on one aliquot;

(b) Each specimen validity test must satisfy the QC requirements in Section 12.14; and

(c) Controls must be analyzed concurrently with specimens.

**Section 12.13 What must an HHS-certified IITF do to validate a specimen validity test?**

An HHS-certified IITF must demonstrate and document for each specimen validity test the appropriate performance characteristics of the test; and must re-verify the test periodically, or at least annually.

**Section 12.14 What are the requirements for conducting each specimen validity test?**

(a) The requirements for measuring creatinine concentration are as follows:

(1) The creatinine concentration must be measured to one decimal place on the test;

(2) The creatinine test must have a calibrator at 2 mg/dL; and

(3) The creatinine test must have a control in the range of 1.0 mg/dL to 1.5 mg/dL, a control in the range of 3 mg/dL to 20 mg/dL, and a control in the range of 21 mg/dL to 25 mg/dL.

(b) The requirements for measuring specific gravity are as follows:

(1) For specimens with creatinine test results less than 20 mg/dL and greater than 5.0 mg/dL, an IITF must perform a screening test using a refractometer to identify specific gravity values that are acceptable (equal to or greater than 1.003) or dilute (equal to or greater than 1.002 and less than 1.003). Specimens must be forwarded to an HHS-certified laboratory when the creatinine test result is equal to or less than 5.0 mg/dL or when the screening specific gravity test result is less than 1.002.

(2) The screening specific gravity test must have the following QC samples:

(i) A calibrator or control at 1.000; and

(ii) One control targeted at 1.002; and

(iii) One control in the range of 1.004 to 1.018.

(c) The requirements for measuring pH are as follows:

(1) The IITF may perform the pH test using a pH meter, colorimetric pH test, dipsticks, or pH paper. Specimens must be forwarded to an HHS-certified laboratory when the pH is less than 4.5 or equal to or greater than 9.0.

(2) The pH test must have, at a minimum, the following QC samples:

(i) One control below 4.5;

(ii) One control between 4.5 and 9.0;

(iii) One control above 9.0; and

(iv) One or more calibrators as appropriate for the test. For a pH meter: Calibrators at 4, 7, and 10.

(d) The requirements for measuring the nitrite concentration are that the nitrite test must have a calibrator at 200 mcg/mL nitrite, a control without nitrite (i.e., certified negative urine), one control in the range of 200 mcg/mL to 250 mcg/mL, and one control in the range of 500 mcg/mL to 625 mcg/mL. Specimens with a nitrite concentration equal to or greater than 200 mcg/mL must be forwarded to an HHS-certified laboratory; and,

(e) Requirements for performing oxidizing adulterant tests are that the test must include an appropriate calibrator at the cutoff specified in

Sections 11.19(d)(3), (4), or (6) for the compound of interest, a control without the compound of interest (i.e., a certified negative control), and at least one control with one of the compounds of interest at a measurable concentration. Specimens with an oxidizing adulterant result equal to or greater than the cutoff must be forwarded to an HHS-certified laboratory.

**Section 12.15 What are the requirements for an HHS-certified IITF to report a test result?**

(a) An HHS-certified IITF must report a test result directly to the agency's MRO within an average of 3 working days after receipt of the specimen using the Federal CCF and/or electronic report. Before any test result is reported, it must be certified by a certifying technician.

(b) A primary (Bottle A) specimen is reported negative when each drug test is negative and each specimen validity test result indicates that the specimen is a valid urine specimen.

(c) A primary (Bottle A) urine specimen is reported dilute when the creatinine concentration is greater than 5 mg/dL but less than 20 mg/dL and the specific gravity is equal to or greater than 1.002 but less than 1.003.

(d) An HHS-certified IITF shall reject a urine specimen for testing when a fatal flaw occurs as described in Section 15.1 or when a correctable flaw as described in Section 15.2 is not recovered. The IITF will indicate on the Federal CCF that the specimen was rejected for testing and provide the reason for reporting the rejected for testing result.

(e) An HHS-certified IITF may transmit a result to the MRO by various electronic means (e.g., teleprinter, facsimile, or computer) in a manner designed to ensure confidentiality of the information. A result may not be reported verbally by telephone. An IITF must ensure the security of the data transmission and limit access to any data transmission, storage, and retrieval system.

(f) For all test results, an HHS-certified IITF may fax, courier, mail, or electronically transmit a legible image or copy of the completed Federal CCF, and/or forward a computer-generated electronic report. The computer-generated report must contain sufficient information to ensure that the test result is properly associated with the custody and control form that the MRO received from the collector.

**Section 12.16 How does an HHS-certified IITF handle a specimen that tested positive, adulterated, substituted, or invalid at the IITF?**

(a) The remaining specimen is resealed using a tamper-evident label/seal;

(b) The individual resealing the remaining specimen initials and dates the tamper-evident label/seal; and

(c) The resealed specimen and split specimen and the Federal CCF are sealed in a leak-proof plastic bag, and are sent to an HHS-certified laboratory under chain of custody within one day after completing the drug and specimen validity tests.

**Section 12.17 How long must an HHS-certified IITF retain a specimen?**

A specimen that is negative, negative/dilute, or rejected for testing is discarded.

**Section 12.18 How long must an HHS-certified IITF retain records?**

(a) An HHS-certified IITF must retain all records generated to support test results for at least 2 years.

(b) A Federal agency may request an HHS-certified IITF to maintain a copy of the documentation package (as described in Section 12.20(b)) that supports the chain of custody, testing, and reporting of a donor's specimen that is under legal challenge by a donor. The Federal agency's request to the IITF must be in writing and must specify the period of time to maintain the documentation package.

(c) The IITF may retain records other than those included in the documentation package beyond the normal 2 year period of time to ensure that it can fully support the reported test result.

**Section 12.19 What statistical summary report must an HHS-certified IITF provide?**

(a) An HHS-certified IITF must provide to each Federal agency for which testing is conducted a semiannual statistical summary report that contains the following information:

- (1) Reporting period (inclusive dates);
- (2) IITF name and address;
- (3) Federal agency name;
- (4) Total number of specimens tested;
- (5) Number of specimens collected by reason for test;

(6) Number of specimens reported negative and the number reported negative/dilute;

(7) Number of specimens rejected for testing because of a fatal flaw and the number rejected for testing because of an uncorrected flaw;

(8) Number of specimens forwarded to an HHS-certified laboratory for additional drug testing and/or specimen validity testing.

(b) The report must be submitted by mail, fax, or e-mail within 14 working days after the end of the semiannual period.

(c) The HHS-certified IITF must make available copies of an agency's test results when requested by the Secretary or by the Federal agency for which the IITF is performing drug-testing services.

(d) The HHS-certified IITF must make available a qualified individual to testify in a proceeding against a Federal employee when that proceeding is based on a test result reported by the HHS-certified IITF.

**Section 12.20 What IITF information is available to a Federal employee?**

(a) A Federal employee who is the subject of a drug test may, upon written request through the MRO and the Federal agency, have access to any records relating to his or her drug test, any records relating to the results of any relevant certification, review, or revocation of certification proceedings, and access to a documentation package.

(b) A standard documentation package provided by an HHS-certified IITF must contain the following items:

(1) A cover sheet that provides a brief description of the drug testing procedures and specimen validity tests performed on the donor's specimen;

(2) A table of contents page that lists by page number all documents and materials in the package;

(3) A copy of the Federal CCF with any attachments, copies of all internal chain of custody records for the specimen, memoranda (if any) generated by the IITF, and a copy of the electronic report (if any) generated by the IITF;

(4) A brief description of the IITF's drug and specimen validity test procedures, instrumentation, batch QC requirements;

(5) Copies of all test data for the donor's specimen with all calibrators and controls identified and copies of all internal chain of custody documents related to the tests; and

(6) Copies of the resume or curriculum vitae for the responsible technician and for the certifying technician that certified the test result.

**Section 12.21 What type of relationship is prohibited between an HHS-certified IITF and an MRO?**

An HHS-certified IITF must not enter into any relationship with a Federal agency's MRO that may be construed as a potential conflict of interest or derive

any financial benefit by having a Federal agency use a specific MRO.

This means an MRO may be an employee of the agency or a contractor for the agency; however, an MRO shall not be an employee or agent of or have any financial interest in an HHS-certified IITF for which the MRO is reviewing drug testing results. Additionally, an MRO shall not derive any financial benefit by having an agency use a specific HHS-certified IITF or have any agreement with an HHS-certified IITF that may be construed as a potential conflict of interest.

**Section 12.22 What type of relationship can exist between an HHS-certified IITF and an HHS-certified laboratory?**

An HHS-certified IITF can freely enter into any relationship with an HHS-certified laboratory.

**Subpart M—Medical Review Officer (MRO)**

**Section 13.1 Who may serve as an MRO?**

(a) A licensed physician who has:  
(1) Either a Doctor of Medicine (M.D.) or Doctor of Osteopathy (D.O.) degree;  
(2) Knowledge regarding the pharmacology and toxicology of illicit drugs;

(3) The training necessary to serve as an MRO as set out in Section 13.2; and

(4) Satisfactorily passed an examination administered by a nationally recognized entity that certifies MROs or subspecialty board for physicians performing a review of Federal employee drug test results, which has been approved by the Secretary.

(b) Nationally recognized entities that certify MROs or subspecialty boards for physicians performing a review of Federal employee drug test results that seek approval by the Secretary must submit their qualifications and a sample examination. Based on an annual objective review of the qualifications and content of the examination, the Secretary shall annually publish a list in the *Federal Register* of those entities and boards that have been approved.

**Section 13.2 What are the training requirements before a physician can serve as an MRO?**

A physician must receive training that includes a thorough review of:

(a) The collection procedures used to collect Federal agency specimens;

(b) How to interpret test results reported by laboratories;

(c) Chain of custody, reporting, and recordkeeping requirements for Federal agency specimens;

(d) The HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs; and

(e) Procedures for interpretation, review, and reporting of results specified by any Federal agency for which the individual may serve as MRO.

### Section 13.3 What are the responsibilities of an MRO?

(a) The MRO must review all positive, adulterated, substituted, rejected for testing, and invalid test results. Staff under the direct, personal supervision of the MRO may review and report negative and negative/dilute test results to the agency's designated representative. The MRO must review at least 5 percent of all negative results reported by the MRO staff to ensure that the MRO staff are properly performing the review process.

(b) The MRO must discuss potential invalid results with the laboratory as addressed in Section 11.19(g), to determine whether testing at another certified laboratory may be warranted.

(c) After receiving a report from an HHS-certified laboratory or HHS-certified IITF, the MRO must:

(1) Review the information on the MRO copy of the Federal CCF that was received from the collector and the report received from the HHS-certified laboratory or HHS-certified IITF;

(2) Interview the donor when required;

(3) Make a determination regarding the test result;

(4) Report the verified result to the Federal agency;

(5) Maintain the records (for a minimum of 2 years) and the confidentiality of the information;

(6) Review all positive, adulterated, substituted, and invalid test results before the result is transmitted to the agency's designated representative; and

(d) The MRO must conduct a medical evaluation when a collector reports that the donor was unable to provide a urine specimen, as addressed in Section 13.5.

### Section 13.4 What must an MRO do when reviewing a test result?

(a) When an HHS-certified laboratory or HHS-certified IITF reports a negative result on the primary (Bottle A) specimen, the MRO reports a negative result to the agency.

(b) When an HHS-certified laboratory or HHS-certified IITF reports a negative/dilute result on the primary (Bottle A) urine specimen, the MRO reports a negative/dilute result to the agency and directs the agency to immediately collect another specimen from the donor.

(c) When an HHS-certified laboratory reports a positive result on the primary (Bottle A) urine specimen, the MRO contacts the donor to determine if there is any legitimate medical explanation for the positive result.

(1) If the donor provides a legitimate medical explanation for the positive result, the MRO reports the test result as negative to the agency. If a laboratory also reports that the specimen is dilute, the MRO reports a negative/dilute result to the agency and directs the agency to immediately collect another specimen from the donor.

(2) If the donor is unable to provide a legitimate medical explanation, the MRO reports a positive result to the agency. If a laboratory also reports that the specimen is dilute, the MRO may choose not to report the dilute result.

(d) When an HHS-certified laboratory reports a positive result for opiates on the primary (Bottle A) urine specimen, the MRO must determine that there is clinical evidence in addition to the urine test result of illegal use of any opium, opiate, or opium derivative (e.g., morphine/codeine) listed in Schedule I or II of the Controlled Substances Act. However, this requirement does not apply if the laboratory confirms the presence of 6-acetylmorphine (*i.e.*, the presence of this metabolite is proof of heroin use) or the morphine or codeine concentration is equal to or greater than 15,000 ng/mL and the donor does not present a legitimate medical explanation for the presence of morphine or codeine at or above this concentration. Consumption of food products must not be considered a legitimate medical explanation for the donor having morphine or codeine at or above this concentration.

(e) When an HHS-certified laboratory reports an adulterated or substituted result on the primary (Bottle A) urine specimen, the MRO contacts the donor to determine if the donor has a legitimate medical explanation for the adulterated or substituted result.

(1) If the donor provides a medical explanation that is legitimate, the MRO reports a negative result to the Federal agency.

(2) If the donor is unable to provide a legitimate medical explanation, the MRO reports a refusal to test to the Federal agency because the specimen was adulterated or substituted.

(f) When an HHS-certified laboratory reports an invalid result on the primary (Bottle A) urine specimen, the MRO contacts the donor to determine if there is a legitimate medical explanation for the invalid result. In the case of an invalid result based on pH of 9.0 to 9.5, when an employee has no other medical

explanation for the pH in this range, the MRO must consider whether there is evidence of elapsed time and high temperature that could account for the pH value. The MRO may contact the collection site, IITF, and/or laboratory to discuss time and temperature issues (e.g., time elapsed from collection to receipt at the testing facility, likely temperature conditions between the time of the collection and transportation to the testing facility, specimen storage conditions).

(i) If the donor provides a medical explanation that appears to be legitimate (e.g., a valid prescription medication) or if the MRO determines that time and temperature account for the pH in the 9.0–9.5 range, the MRO reports a test cancelled result with the reason for the invalid result and informs the Federal agency that a recollection is not required because there is an acceptable explanation for the invalid result.

(ii) If the donor is unable to provide an acceptable medical explanation or if the MRO determines that time and temperature fail to account for the pH in the 9.0–9.5 range, the MRO reports a test cancelled result with the reason for the invalid result and directs the Federal agency to immediately collect another specimen from the donor using a direct observed collection.

(g) When an HHS-certified laboratory or HHS-certified IITF reports a rejected for testing result on the primary (Bottle A) urine specimen, the MRO reports a test cancelled result to the agency and directs the agency to immediately collect another specimen from the donor.

### Section 13.5 What action does the MRO take when the collector reports that the donor did not provide a sufficient amount of urine for a drug test?

(a) For purposes of this section, a medical condition includes an ascertainable physiological condition (e.g., a urinary system dysfunction) or a medically documented pre-existing psychological disorder, but does not include unsupported assertions of "situational anxiety" or dehydration. Permanent or long-term medical conditions are those physiological, anatomic, or psychological abnormalities documented as being present prior to the attempted collection, and considered not amenable to correction or cure for an extended period of time, if ever. Examples would include destruction (any cause) of the glomerular filtration system leading to renal failure; unrepaired traumatic disruption of the urinary tract; or a severe psychiatric disorder focused on

genitor-urinary matters. Acute or temporary medical conditions, such as cystitis, urethritis or prostatitis, though they might interfere with collection for a limited period of time, cannot receive the same exceptional consideration as the permanent or long-term conditions discussed in the previous sentence.

(b) When the collector reports that the donor did not provide a sufficient amount of urine, the MRO consults with the Federal agency. The Federal agency immediately directs the donor to obtain, within five days, an evaluation from a licensed physician, acceptable to the MRO, who has expertise in the medical issues raised by the donor's failure to provide a specimen. (The MRO may perform this evaluation if the MRO has appropriate expertise.)

(1) As the MRO, if another physician will perform the evaluation, you must provide the other physician with the following information and instructions:

(i) That the donor was required to take a federally regulated drug test, but was unable to provide a sufficient amount of urine to complete the test;

(ii) The consequences of the appropriate Federal agency regulation for refusing to take the required drug test;

(iii) That the referral physician must agree to follow the requirements of paragraphs (c) through (e) of this section.

(c) As the referral physician conducting this evaluation, you must recommend that the MRO make one of the following determinations:

(1) A medical condition as defined in paragraph (a) of this section has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of urine. As the MRO, if you accept this recommendation, you must report a test cancelled result to the Federal agency.

(2) There is not an adequate basis for determining that a medical condition has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of urine. As the MRO, if you accept this recommendation, you must report a refusal to test to the Federal agency.

(d) As the referral physician making the evaluation, after completing your evaluation, you must provide a written statement of your recommendations and the basis for them to the MRO. You must not include in this statement detailed information on the employee's medical condition beyond what is necessary to explain your conclusion.

(e) If, as the referral physician making this evaluation, you determine that the employee's medical condition is a serious and permanent or long-term

disability (as defined in paragraph (a) of this section) that is highly likely to prevent the employee from providing a sufficient amount of urine for a very long or indefinite period of time, you must set forth your determination and the reasons for it in your written statement to the MRO. As the MRO, upon receiving such a report, you must follow the requirements of Section 13.6, where applicable.

(f) As the MRO, you must seriously consider and assess the referral physician's recommendations in making your determination about whether the employee has a medical condition that has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of urine. You must report your determination to the Federal agency in writing as soon as you make it.

(g) When a Federal agency receives a report from the MRO indicating that a test is cancelled as provided in paragraph (c)(1) of this section; the agency takes no further action with respect to the donor. The donor remains in the random testing pool.

**Section 13.6 What happens when an individual is unable to provide a sufficient amount of urine for a Federal agency applicant/pre-employment test, a follow-up test, or a return-to-duty test because of a permanent or long-term medical condition?**

(a) This section concerns a situation in which the donor has a medical condition that precludes him or her from providing a sufficient specimen for a Federal agency applicant/pre-employment test, a follow-up test, or a return-to-duty test; and the condition involves a permanent or long-term disability (as defined in paragraph (a) of Section 13.5). As the MRO in this situation, you must do the following:

(1) You must determine if there is clinical evidence that the individual is an illicit drug user. You must make this determination by personally conducting, or causing to be conducted, a medical evaluation and through consultation with the donor's physician and/or the physician who conducted the evaluation under Section 13.5.

(2) If you do not personally conduct the medical evaluation, you must ensure that one is conducted by a licensed physician acceptable to you.

(b) If the medical evaluation reveals no clinical evidence of drug use, as the MRO, you must report the result to the Federal agency as a negative test with written notations regarding results of both the evaluation conducted under Section 13.5 and any further medical examination. This report must state the

basis for the determination that a permanent or long-term medical condition exists, making provision of a sufficient urine specimen impossible, and for the determination that no signs and symptoms of drug use exist.

(c) If the medical evaluation reveals clinical evidence of drug use, as the MRO, you must report the result to the Federal agency as a cancelled test with written notations regarding results of both the evaluation conducted under Section 13.5 and any further medical examination. This report must state that a permanent or long-term medical condition (as defined in Section 13.5(a)) exists, making provision of a sufficient urine specimen impossible, and state the reason for the determination that signs and symptoms of drug use exist. Because this is a cancelled test, it does not serve the purposes of a negative test (e.g., the Federal agency is not authorized to allow the donor to begin or resume performing official functions, because a negative test is needed for that purpose).

**Section 13.7 Who may request a test of a split specimen?**

(a) For a positive, adulterated, or substituted result reported on a primary (Bottle A) specimen, a donor may request through the MRO that the split (Bottle B) specimen be tested by a second HHS-certified laboratory to verify the result reported by the first laboratory.

(b) The donor has 72 hours (from the time the MRO notified the donor that his or her specimen was reported positive, adulterated, or substituted) to request a test of the split (Bottle B) specimen. The MRO must inform the donor that he or she has the opportunity to request a test of the split (Bottle B) specimen when the MRO informs the donor that a positive, adulterated, or substituted result is being reported to the Federal agency on the primary (Bottle A) specimen.

**Section 13.8 How does an MRO report a primary (Bottle A) specimen test result to an agency?**

(a) The MRO must report all verified results to an agency by faxing a completed MRO copy of the Federal CCF, transmitting a scanned image of the completed MRO copy of the Federal CCF, or faxing a separate report using a letter/memorandum format.

(b) A verified result may not be reported to the agency until the MRO has completed the review process.

(c) The MRO must send a paper copy of either the completed MRO copy of the Federal CCF or the separate letter/

memorandum report for all positive, adulterated, and substituted results.

(d) The MRO must not disclose numerical values of drug test results to the agency.

**Section 13.9 What type of relationship is prohibited between an MRO and an HHS-certified laboratory or an HHS-certified IITF?**

An MRO must not be an employee, agent of, or have any financial interest in an HHS-certified laboratory or an HHS-certified IITF for which the MRO is reviewing drug test results.

This means an MRO must not derive any financial benefit by having an agency use a specific HHS-certified laboratory or HHS-certified IITF, or have any agreement with the HHS-certified laboratory or the HHS-certified IITF that may be construed as a potential conflict of interest.

**Subpart N—Split Specimen Tests**

**Section 14.1 When may a split specimen be tested?**

(a) A donor has the opportunity to request through the MRO that the split (Bottle B) specimen be tested at a different (i.e., second) HHS-certified laboratory when the primary (Bottle A) specimen was determined by the MRO to be positive, adulterated, or substituted.

(b) A donor has 72 hours to initiate the request after being informed of the result by the MRO. The MRO must document in his or her records the verbal request from the donor to have the split (Bottle B) specimen tested.

(c) If the split (Bottle B) specimen cannot be tested by a second laboratory (e.g., insufficient specimen, lost in transit, split not available, no second laboratory available to perform the test), the MRO reports to the Federal agency and the donor that the test must be cancelled and the reason for the cancellation. The MRO directs the Federal agency to ensure the immediate recollection of another specimen from the donor under direct observation, with no notice given to the donor of this collection requirement until immediately before the collection.

(d) If a donor chooses not to have the split (Bottle B) specimen tested by a second laboratory, a Federal agency may have a split (Bottle B) specimen retested as part of a legal or administrative proceeding to defend an original positive, adulterated, or substituted result.

**Section 14.2 How does an HHS-certified laboratory test a split (Bottle B) specimen when the primary (Bottle A) specimen was reported positive?**

(a) The testing of a split (Bottle B) specimen for a drug or metabolite is not subject to the testing cutoff concentrations established.

(b) The laboratory is only required to confirm the presence of the drug or metabolite that was reported positive in the primary (Bottle A) specimen.

(c) If the second laboratory fails to reconfirm the presence of the drug or drug metabolite that was reported by the first laboratory, the second laboratory must conduct specimen validity tests in an attempt to determine the reason for being unable to reconfirm the presence of the drug or drug metabolite. The second laboratory should conduct the same specimen validity tests as it would conduct on a primary (Bottle A) specimen and reports those results to the MRO.

**Section 14.3 How does an HHS-certified laboratory test a split (Bottle B) specimen when the primary (Bottle A) specimen was reported adulterated?**

(a) A laboratory must use one of the following criteria to reconfirm an adulterated result when testing a split (Bottle B) specimen:

(1) pH must be measured using the laboratory's confirmatory pH test with the appropriate cutoff (i.e., either less than 3 or equal to or greater than 11);

(2) Nitrite must be measured using the laboratory's confirmatory nitrite test with a cutoff concentration of equal to or greater than 500 mcg/mL;

(3) Surfactant must be measured using the laboratory's confirmatory surfactant test with a cutoff concentration of equal to or greater than 100 mcg/mL dodecylbenzene sulfonate-equivalent cutoff; or

(4) For adulterants without a specified cutoff (e.g., glutaraldehyde, chromium (VI), pyridine, halogens (such as, bleach, iodine), peroxidase, peroxide, other oxidizing agents), the laboratory must use its confirmatory specimen validity test at an established limit of quantitation (LOQ) to reconfirm the presence of the adulterant.

(b) The second laboratory may only conduct the confirmatory specimen validity test(s) needed to reconfirm the adulterated result reported by the first laboratory.

**Section 14.4 How does an HHS-certified laboratory test a split (Bottle B) specimen when the primary (Bottle A) specimen was reported substituted?**

(a) A laboratory must use the following criteria to reconfirm a

substituted result when testing a split (Bottle B) specimen:

(1) The creatinine must be measured using the laboratory's confirmatory creatinine test with a cutoff concentration of less than 2 mg/dL; and

(2) The specific gravity must be measured using the laboratory's confirmatory specific gravity test with the specified cutoffs of less than or equal to 1.0010 or equal to or greater than 1.0200.

(b) The second laboratory may only conduct the confirmatory specimen validity test(s) needed to reconfirm the substituted result reported by the first laboratory.

**Section 14.5 Who receives the split specimen result?**

The second HHS-certified laboratory must transmit the result directly to the MRO.

**Section 14.6 What action(s) does an MRO take after receiving the split (Bottle B) specimen result from the second HHS-certified laboratory?**

The MRO takes the following actions when the second laboratory reports the result for the split urine specimen as:

(a) *Reconfirmed the drug(s), adulteration, and/or substitution result.* The MRO reports reconfirmed to the agency.

(b) *Failed to reconfirm a single or all drug positive results and adulterated.* If the donor provides a legitimate medical explanation for the adulteration result, the MRO reports a failed to reconfirm (specify drug(s)) and cancels both tests. If there is no legitimate medical explanation, the MRO reports a failed to reconfirm (specify drug(s)) and a refusal to test to the agency and indicates the adulterant that is present in the urine specimen. The MRO gives the donor 72 hours to request that Laboratory A retest the primary (Bottle A) specimen for the adulterant. If Laboratory A reconfirms the adulterant, the MRO reports refusal to test and indicates the adulterant present. If Laboratory A fails to reconfirm the adulterant, the MRO cancels both tests and directs the agency to immediately collect another specimen using a direct observed collection procedure. The MRO shall notify the appropriate regulatory office about the failed to reconfirm and cancelled test.

(c) *Failed to reconfirm a single or all drug positive results and substituted.* If the donor provides a legitimate medical explanation for the substituted result, the MRO reports a failed to reconfirm (specify drug(s)) and cancels both tests. If there is no legitimate medical explanation, the MRO reports a failed to



reconfirm (specify drug(s)) and a refusal to test (substituted) to the agency. The MRO gives the donor 72 hours to request Laboratory A to review the creatinine and specific gravity results for the primary (Bottle A) specimen. If the original creatinine and specific gravity results confirm that the specimen was substituted, the MRO reports a refusal to test (substituted) to the agency. If the original creatinine and specific gravity results from Laboratory A fail to confirm that the specimen was substituted, the MRO cancels both tests and directs the agency to immediately collect another specimen using a direct observed collection procedure. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program about the failed to reconfirm and cancelled test.

(d) *Failed to reconfirm a single or all drug positive results and not adulterated or substituted.* The MRO reports to the agency a failed to reconfirm result (specify drug(s)), cancels both tests, and notifies the HHS office responsible for coordination of the drug-free workplace program.

(e) *Failed to reconfirm a single or all drug positive results and invalid result.* The MRO reports to the agency a failed to reconfirm result (specify drug(s)) and gives the reason for the invalid result, cancels both tests, directs the agency to immediately collect another specimen using a direct observed collection procedure, and notifies the HHS office responsible for coordination of the drug-free workplace program.

(f) *Failed to reconfirm one or more drugs, reconfirmed one or more drugs, and adulterated.* The MRO reports to the agency a reconfirmed result (specify drug(s)) and a failed to reconfirm result (specify drug(s)). The MRO tells the agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs and found that the specimen was adulterated. The MRO shall notify the HHS office official responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(g) *Failed to reconfirm one or more drugs, reconfirmed one or more drugs, and substituted.* The MRO reports to the agency a reconfirmed result (specify drug(s)) and a failed to reconfirm result (specify drug(s)). The MRO tells the agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs and found that the specimen was substituted. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace

program regarding the test results for the specimen.

(h) *Failed to reconfirm one or more drugs, reconfirmed one or more drugs, and not adulterated or substituted.* The MRO reports a reconfirmed result (specify drug(s)) and a failed to reconfirm result (specify drug(s)). The MRO tells the agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(i) *Failed to reconfirm one or more drugs, reconfirmed one or more drugs, and invalid result.* The MRO reports to the agency a reconfirmed result (specify drug(s)) and a failed to reconfirm result (specify drug(s)). The MRO tells the agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs and reported an invalid result. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(j) *Failed to reconfirm substitution or adulteration.* The MRO reports to the agency a failed to reconfirm result (specify adulterant or not substituted) and cancels both tests. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(k) *Failed to reconfirm a single or all drug positive results and reconfirmed an adulterated or substituted result.* The MRO reports to the agency a reconfirmed result (adulterated or substituted) and a failed to reconfirm result (specify drug(s)). The MRO tells the agency that it may take action based on the reconfirmed result (adulterated or substituted) although Laboratory B failed to reconfirm the drug(s) result.

(l) *Failed to reconfirm a single or all drug positive results and failed to reconfirm the adulterated or substituted result.* The MRO reports to the agency a failed to reconfirm result (specify drug(s) and specify adulterant or substituted) and cancels both tests. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(m) *Failed to reconfirm at least one drug and reconfirmed the adulterated result.* The MRO reports to the agency a reconfirmed result (specify drug(s) and adulterated) and a failed to reconfirm result (specify drug(s)). The MRO tells the agency that it may take action based

on the reconfirmed drug(s) and the adulterated result although Laboratory B failed to reconfirm one or more drugs.

(n) *Failed to reconfirm at least one drug and failed to reconfirm the adulterated result.* The MRO reports to the agency a reconfirmed result (specify drug(s)) and a failed to reconfirm result (specify drug(s) and specify adulterant). The MRO tells the agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs and failed to reconfirm the adulterated result.

(o) *Failed to reconfirm an adulterated result and failed to reconfirm a substituted result.* The MRO reports to the agency a failed to reconfirm result ((specify adulterant) and not substituted) and cancels both tests. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(p) *Failed to reconfirm an adulterated result and reconfirmed a substituted result.* The MRO reports to the agency a reconfirmed result (substituted) and a failed to reconfirm result (specify adulterant). The MRO tells the agency that it may take action based on the substituted result although Laboratory B failed to reconfirm the adulterated result.

(q) *Failed to reconfirm a substituted result and reconfirmed an adulterated result.* The MRO reports to the agency a reconfirmed result (adulterated) and a failed to reconfirm result (not substituted). The MRO tells the agency that it may take action based on the adulterated result although Laboratory B failed to reconfirm the substituted result.

#### **Section 14.7 How does an MRO report a split (Bottle B) specimen test result to an agency?**

(a) The MRO must report all verified results to an agency by faxing a completed MRO copy of the Federal CCF, transmitting a scanned image of the completed MRO copy of the Federal CCF, or faxing a separate report using a letter/memorandum format.

(b) A verified result may not be reported to the agency until the MRO has completed the review process.

(c) The MRO must send a paper copy of either the completed MRO copy of the Federal CCF or the separate letter/memorandum report for all positive, adulterated, and substituted results.

(d) The MRO must not disclose the numerical values of the drug test results to the agency.

**Section 14.8 How long must an HHS-certified laboratory retain a split (Bottle B) specimen?**

A split (Bottle B) specimen is retained for the same period of time that a primary (Bottle A) specimen is retained and under the same storage conditions. This applies even for those cases when the split (Bottle B) specimen is tested by a second laboratory and the second laboratory does not confirm the original result reported by the first laboratory on the primary (Bottle A) specimen.

**Subpart O—Criteria for Rejecting a Specimen for Testing**

**Section 15.1 What discrepancies require an HHS-certified laboratory or an HHS-certified IITF to report a specimen as rejected for testing?**

The following discrepancies are considered to be fatal flaws. The laboratory or IITF must stop the testing process, reject the specimen for testing, and indicate the reason for rejecting the specimen on the Federal CCF when:

(a) The specimen ID number on the specimen label/seal does not match the ID number on the Federal CCF, or the ID number is missing either on the Federal CCF or on the specimen label/seal;

(b) The specimen label/seal is broken or shows evidence of tampering on the primary (Bottle A) specimen and the split (Bottle B) specimen cannot be re-designated as the primary (Bottle A) specimen;

(c) The collector's printed name and signature are omitted on the Federal CCF; or

(d) There is an insufficient amount of specimen for analysis in the primary (Bottle A) specimen unless the split (Bottle B) specimen can be re-designated as the primary (Bottle A) specimen.

**Section 15.2 What discrepancies require an HHS-certified laboratory or an HHS-certified IITF to report a specimen as rejected for testing unless the discrepancy is corrected?**

The following discrepancies are considered to be correctable:

(a) If a collector failed to sign the Federal CCF, the HHS-certified laboratory or IITF must attempt to recover the collector's signature before reporting the test result. If the collector can provide a memorandum for record recovering the signature, the laboratory or IITF may report the test result for the specimen. If after 5 business days the laboratory or IITF cannot recover the collector's signature, the laboratory or IITF must report a rejected for testing result and indicate the reason for the

rejected for testing result on the Federal CCF.

(b) If a specimen is submitted using a non-Federal form or an expired Federal CCF, the laboratory or IITF must test the specimen and also attempt to obtain a memorandum for record explaining why a non-Federal form or an expired Federal CCF was used and ensure that the form used contains all the required information. If after 5 business days the laboratory or IITF cannot obtain a memorandum for record from the collector, the laboratory or IITF must report a rejected for testing result and indicate the reason for the rejected for testing result on the report to the MRO.

**Section 15.3 What discrepancies are not sufficient to require an HHS-certified laboratory or an HHS-certified IITF to reject a specimen for testing or an MRO to cancel a test?**

(a) The following omissions and discrepancies on the Federal CCF that are received by the laboratory or IITF are considered insignificant and should not cause a laboratory or IITF to reject a specimen or cause an MRO to cancel a test:

(1) An incorrect laboratory name and address appears at the top of the form;

(2) Incomplete/incorrect/unreadable employer name or address;

(3) MRO name is missing;

(4) Incomplete/incorrect MRO

address;

(5) A transposition of numbers in the donor's SSN;

(6) A phone number is missing/incorrect;

(7) A fax number is missing/incorrect;

(8) A "reason for test" box is not marked;

(9) A "drug tests to be performed" box is not marked;

(10) A "specimen collection" box is not marked;

(11) The "observed" box is not marked (if applicable);

(12) The collection site address is missing;

(13) The collector's printed name is missing but the collector's signature is properly recorded;

(14) The time of collection is not indicated;

(15) The date of collection is not indicated;

(16) Incorrect name of delivery service;

(17) The collector has changed or corrected information by crossing out the original information on either the Federal CCF or specimen label/seal without dating and initialing the change; or

(18) The donor's name inadvertently appears on the laboratory copy of the

Federal CCF or on the tamper-evident labels used to seal the specimens.

(19) The collector failed to check the specimen temperature box and the "Remarks" line did not have a comment regarding the temperature being out of range. If after 5 business days the collector cannot provide a memorandum for record to attest to the fact that he or she did measure the specimen temperature, the laboratory or IITF may report the test result for the specimen but indicates that the collector could not provide a memorandum to recover the omission.

(b) The following omissions and discrepancies on the Federal CCF that are made at the laboratory or IITF are considered insignificant and should not cause an MRO to cancel a test:

(1) The testing laboratory or IITF fails to indicate the correct name and address in the results section when a different laboratory or IITF name and address is printed at the top of the Federal CCF;

(2) The accessioner fails to print his or her name;

(3) The certifying scientist or certifying technician fails to print his or her name;

(4) The certifying scientist or certifying technician accidentally initials the Federal CCF rather than signing for a specimen reported as rejected for testing;

(5) The accessioner fails to mark one of the "primary (Bottle A) specimen bottle seal intact" boxes, but the laboratory or IITF reported a "rejected for testing" result with an appropriate comment on the "Remarks" line.

(c) The above omissions and discrepancies are considered insignificant only when they occur no more than once a month. The expectation is that each trained collector and HHS-certified laboratory or IITF will make every effort to ensure that the Federal CCF is properly completed and that all the information is correct. When an error occurs more than once a month, the MRO must direct the collector, laboratory, or IITF (whichever is responsible for the error) to immediately take corrective action to prevent the recurrence of the error.

**Section 15.4 What discrepancies may require an MRO to cancel a test?**

(a) An MRO must attempt to correct the following errors:

(1) The donor's signature is missing on the MRO copy of the Federal CCF and the collector failed to provide a comment that the donor refused to sign the form;

(2) The certifying scientist failed to sign the paper copy (Copy 1) of the Federal CCF for a specimen being

reported drug positive, adulterated, substituted, or invalid result; or

(3) The electronic report provided by the HHS-certified laboratory or HHS-certified IITF does not contain all the data elements required for the HHS standard electronic laboratory or IITF report for a specimen being reported drug positive, adulterated, substituted, invalid result, or rejected for testing test result.

(b) If error (a)(1) occurs, the MRO must contact the collector to obtain a statement to verify that the donor refused to sign the MRO copy. If after 5 business days the collector cannot provide such a statement, the MRO must cancel the test.

(c) If error (a)(2) occurs, the MRO must obtain a statement from the certifying scientist that he or she inadvertently forgot to sign the Federal CCF, but did, in fact, properly conduct the certification review. If after 5 business days the MRO cannot get a statement from the certifying scientist, the MRO must cancel the test.

(d) If error (a)(3) occurs, the MRO must contact the HHS-certified laboratory or HHS-certified IITF. If after 5 business days the laboratory or IITF does not retransmit a corrected electronic report, the MRO must cancel the test.

#### Subpart P—Laboratory or IITF Suspension/Revocation Procedures

##### Section 16.1 When may an HHS-certified laboratory or IITF be suspended?

These procedures apply when:

(a) The Secretary has notified an HHS-certified laboratory or IITF in writing that its certification to perform drug testing under these Guidelines has been suspended or that the Secretary proposes to revoke such certification.

(b) The HHS-certified laboratory or IITF has, within 30 days of the date of such notification or within 3 days of the date of such notification when seeking an expedited review of a suspension, requested in writing an opportunity for an informal review of the suspension or proposed revocation.

##### Section 16.2 What definitions are used for this subpart?

**Appellant.** Means the HHS-certified laboratory or IITF which has been notified of its suspension or proposed revocation of its certification to perform drug and/or specimen validity testing and has requested an informal review thereof.

**Respondent.** Means the person or persons designated by the Secretary in implementing these Guidelines.

**Reviewing Official.** Means the person or persons designated by the Secretary who will review the suspension or proposed revocation. The reviewing official may be assisted by one or more of his or her employees or consultants in assessing and weighing the scientific and technical evidence and other information submitted by the appellant and respondent on the reasons for the suspension and proposed revocation.

##### Section 16.3 Are there any limitations on issues subject to review?

The scope of review shall be limited to the facts relevant to any suspension or proposed revocation, the necessary interpretations of those facts, the Mandatory Guidelines for Federal Workplace Drug Testing Programs, and other relevant law. The legal validity of these Guidelines shall not be subject to review under these procedures.

##### Section 16.4 Who represents the parties?

The appellant's request for review shall specify the name, address, and phone number of the appellant's representative. In its first written submission to the reviewing official, the respondent shall specify the name, address, and phone number of the respondent's representative.

##### Section 16.5 When must a request for informal review be submitted?

(a) Within 30 days of the date of the notice of the suspension or proposed revocation, the appellant must submit a written request to the reviewing official seeking review, unless some other time period is agreed to by the parties. A copy must also be sent to the respondent. The request for review must include a copy of the notice of suspension or proposed revocation, a brief statement of why the decision to suspend or propose revocation is wrong, and the appellant's request for an oral presentation, if desired.

(b) Within 5 days after receiving the request for review, the reviewing official will send an acknowledgment and advise the appellant of the next steps. The reviewing official will also send a copy of the acknowledgment to the respondent.

##### Section 16.6 What is an abeyance agreement?

Upon mutual agreement of the parties to hold these procedures in abeyance, the reviewing official will stay these procedures for a reasonable time while the laboratory or IITF attempts to regain compliance with the Guidelines or the parties otherwise attempt to settle the dispute. As part of an abeyance

agreement, the parties can agree to extend the time period for requesting review of the suspension or proposed revocation. If abeyance begins after a request for review has been filed, the appellant shall notify the reviewing official at the end of the abeyance period advising whether the dispute has been resolved. If the dispute has been resolved, the request for review will be dismissed. If the dispute has not been resolved, the review procedures will begin at the point at which they were interrupted by the abeyance agreement with such modifications to the procedures as the reviewing official deems appropriate.

##### Section 16.7 What procedure is used to prepare the review file and written argument?

The appellant and the respondent each participate in developing the file for the reviewing official and in submitting written arguments. The procedures for development of the review file and submission of written argument are:

(a) **Appellant's Documents and Brief.** Within 15 days after receiving the acknowledgment of the request for review, the appellant shall submit to the reviewing official the following (with a copy to the respondent):

(1) A review file containing the documents supporting appellant's argument, tabbed and organized chronologically, and accompanied by an index identifying each document. Only essential documents should be submitted to the reviewing official.

(2) A written statement, not to exceed 20 double-spaced pages, explaining why respondent's decision to suspend or propose revocation of appellant's certification is wrong (appellant's brief).

(b) **Respondent's Documents and Brief.** Within 15 days after receiving a copy of the acknowledgment of the request for review, the respondent shall submit to the reviewing official the following (with a copy to the appellant):

(1) A review file containing documents supporting respondent's decision to suspend or revoke appellant's certification to perform drug and/or specimen validity testing, tabbed and organized chronologically, and accompanied by an index identifying each document. Only essential documents should be submitted to the reviewing official.

(2) A written statement, not exceeding 20 double-spaced pages in length, explaining the basis for suspension or proposed revocation (respondent's brief).

(c) **Reply Briefs.** Within 5 days after receiving the opposing party's

submission, or 20 days after receiving acknowledgment of the request for review, whichever is later, each party may submit a short reply not to exceed 10 double-spaced pages.

(d) *Cooperative Efforts.* Whenever feasible, the parties should attempt to develop a joint review file.

(e) *Excessive Documentation.* The reviewing official may take any appropriate step to reduce excessive documentation, including the return of or refusal to consider documentation found to be irrelevant, redundant, or unnecessary.

#### Section 16.8 When is there an opportunity for oral presentation?

(a) *Electing Oral Presentation.* If an opportunity for an oral presentation is desired, the appellant shall request it at the time it submits its written request for review to the reviewing official. The reviewing official will grant the request if the official determines that the decision-making process will be substantially aided by oral presentations and arguments. The reviewing official may also provide for an oral presentation at the official's own initiative or at the request of the respondent.

(b) *Presiding Official.* The reviewing official or designee will be the presiding official responsible for conducting the oral presentation.

(c) *Preliminary Conference.* The presiding official may hold a prehearing conference (usually a telephone conference call) to consider any of the following: simplifying and clarifying issues; stipulations and admissions; limitations on evidence and witnesses that will be presented at the hearing; time allotted for each witness and the hearing altogether; scheduling the hearing; and any other matter that will assist in the review process. Normally, this conference will be conducted informally and off the record; however, the presiding official may, at his or her discretion, produce a written document summarizing the conference or transcribe the conference, either of which will be made a part of the record.

(d) *Time and Place of Oral Presentation.* The presiding official will attempt to schedule the oral presentation within 30 days of the date appellant's request for review is received or within 10 days of submission of the last reply brief, whichever is later. The oral presentation will be held at a time and place determined by the presiding official following consultation with the parties.

(e) *Conduct of the Oral Presentation.*

(1) *General.* The presiding official is responsible for conducting the oral

presentation. The presiding official may be assisted by one or more of his or her employees or consultants in conducting the oral presentation and reviewing the evidence. While the oral presentation will be kept as informal as possible, the presiding official may take all necessary steps to ensure an orderly proceeding.

(2) *Burden of Proof/Standard of Proof.* In all cases, the respondent bears the burden of proving by a preponderance of the evidence that its decision to suspend or propose revocation is appropriate. The appellant, however, has a responsibility to respond to the respondent's allegations with evidence and argument to show that the respondent is wrong.

(3) *Admission of Evidence.* The Federal Rules of Evidence do not apply and the presiding official will generally admit all testimonial evidence unless it is clearly irrelevant, immaterial, or unduly repetitious. Each party may make an opening and closing statement, may present witnesses as agreed upon in the prehearing conference or otherwise, and may question the opposing party's witnesses. Since the parties have ample opportunity to prepare the review file, a party may introduce additional documentation during the oral presentation only with the permission of the presiding official. The presiding official may question witnesses directly and take such other steps necessary to ensure an effective and efficient consideration of the evidence, including setting time limitations on direct and cross-examinations.

(4) *Motions.* The presiding official may rule on motions including, for example, motions to exclude or strike redundant or immaterial evidence, motions to dismiss the case for insufficient evidence, or motions for summary judgment. Except for those made during the hearing, all motions and opposition to motions, including argument, must be in writing and be no more than 10 double-spaced pages in length. The presiding official will set a reasonable time for the party opposing the motion to reply.

(5) *Transcripts.* The presiding official shall have the oral presentation transcribed and the transcript shall be made a part of the record. Either party may request a copy of the transcript and the requesting party shall be responsible for paying for its copy of the transcript.

(f) *Obstruction of Justice or Making of False Statements.* Obstruction of justice or the making of false statements by a witness or any other person may be the basis for a criminal prosecution under 18 U.S.C. 1505 or 1001.

(g) *Post-hearing Procedures.* At his or her discretion, the presiding official may require or permit the parties to submit post-hearing briefs or proposed findings and conclusions. Each party may submit comments on any major prejudicial errors in the transcript.

#### Section 16.9 Are there expedited procedures for review of immediate suspension?

(a) *Applicability.* When the Secretary notifies a laboratory or IITF in writing that its certification to perform drug and specimen validity testing has been immediately suspended, the appellant may request an expedited review of the suspension and any proposed revocation. The appellant must submit this request in writing to the reviewing official within 3 days of the date the laboratory or IITF received notice of the suspension. The request for review must include a copy of the suspension and any proposed revocation, a brief statement of why the decision to suspend and propose revocation is wrong, and the appellant's request for an oral presentation, if desired. A copy of the request for review must also be sent to the respondent.

(b) *Reviewing Official's Response.* As soon as practicable after the request for review is received, the reviewing official will send an acknowledgment with a copy to the respondent.

(c) *Review File and Briefs.* Within 7 days of the date the request for review is received, but no later than 2 days before an oral presentation, each party shall submit to the reviewing official the following:

(1) A review file containing essential documents relevant to the review, tabbed, indexed, and organized chronologically; and

(2) A written statement, not to exceed 20 double-spaced pages, explaining the party's position concerning the suspension and any proposed revocation. No reply brief is permitted.

(d) *Oral Presentation.* If an oral presentation is requested by the appellant or otherwise granted by the reviewing official, the presiding official will attempt to schedule the oral presentation within 7-10 days of the date of appellant's request for review at a time and place determined by the presiding official following consultation with the parties. The presiding official may hold a prehearing conference in accordance with Section 16.8(c) and will conduct the oral presentation in accordance with the procedures of Sections 16.8(e), (f), and (g).

(e) *Written Decision.* The reviewing official shall issue a written decision upholding or denying the suspension or

proposed revocation and will attempt to issue the decision within 7-10 days of the date of the oral presentation or within 3 days of the date on which the transcript is received or the date of the last submission by either party, whichever is later. All other provisions set forth in Section 16.14 will apply.

(f) *Transmission of Written Communications.* Because of the importance of timeliness for these expedited procedures, all written communications between the parties and between either party and the reviewing official shall be by facsimile, secured electronic transmissions, or overnight mail.

**Section 16.10 Are any types of communications prohibited?**

Except for routine administrative and procedural matters, a party shall not communicate with the reviewing or presiding official without notice to the other party.

**Section 16.11 How are communications transmitted by the reviewing official?**

(a) Because of the importance of a timely review, the reviewing official should normally transmit written communications to either party by facsimile, secured electronic transmissions, or overnight mail in which case the date of transmission or day following mailing will be considered the date of receipt. In the case of communications sent by regular mail, the date of receipt will be considered 3 days after the date of mailing.

(b) In counting days, include Saturdays, Sundays, and Federal holidays. However, if a due date falls on a Saturday, Sunday, or Federal holiday, then the due date is the next Federal working day.

**Section 16.12 What are the authority and responsibilities of the reviewing official?**

In addition to any other authority specified in these procedures, the reviewing official and the presiding official, with respect to those authorities involving the oral presentation, shall have the authority to issue orders; examine witnesses; take all steps necessary for the conduct of an orderly hearing; rule on requests and motions; grant extensions of time for good reasons; dismiss for failure to meet deadlines or other requirements; order the parties to submit relevant information or witnesses; remand a case for further action by the respondent; waive or modify these procedures in a specific case, usually with notice to the parties; reconsider a decision of the reviewing official where a party promptly alleges a clear error of fact or law; and to take any other action necessary to resolve disputes in accordance with the objectives of these procedures.

**Section 16.13 What administrative records are maintained?**

The administrative record of review consists of the review file; other submissions by the parties; transcripts or other records of any meetings, conference calls, or oral presentation; evidence submitted at the oral presentation; and orders and other documents issued by the reviewing and presiding officials.

**Section 16.14 What are the requirements for a written decision?**

(a) *Issuance of Decision.* The reviewing official shall issue a written decision upholding or denying the suspension or proposed revocation. The decision will set forth the reasons for

the decision and describe the basis therefore in the record. Furthermore, the reviewing official may remand the matter to the respondent for such further action as the reviewing official deems appropriate.

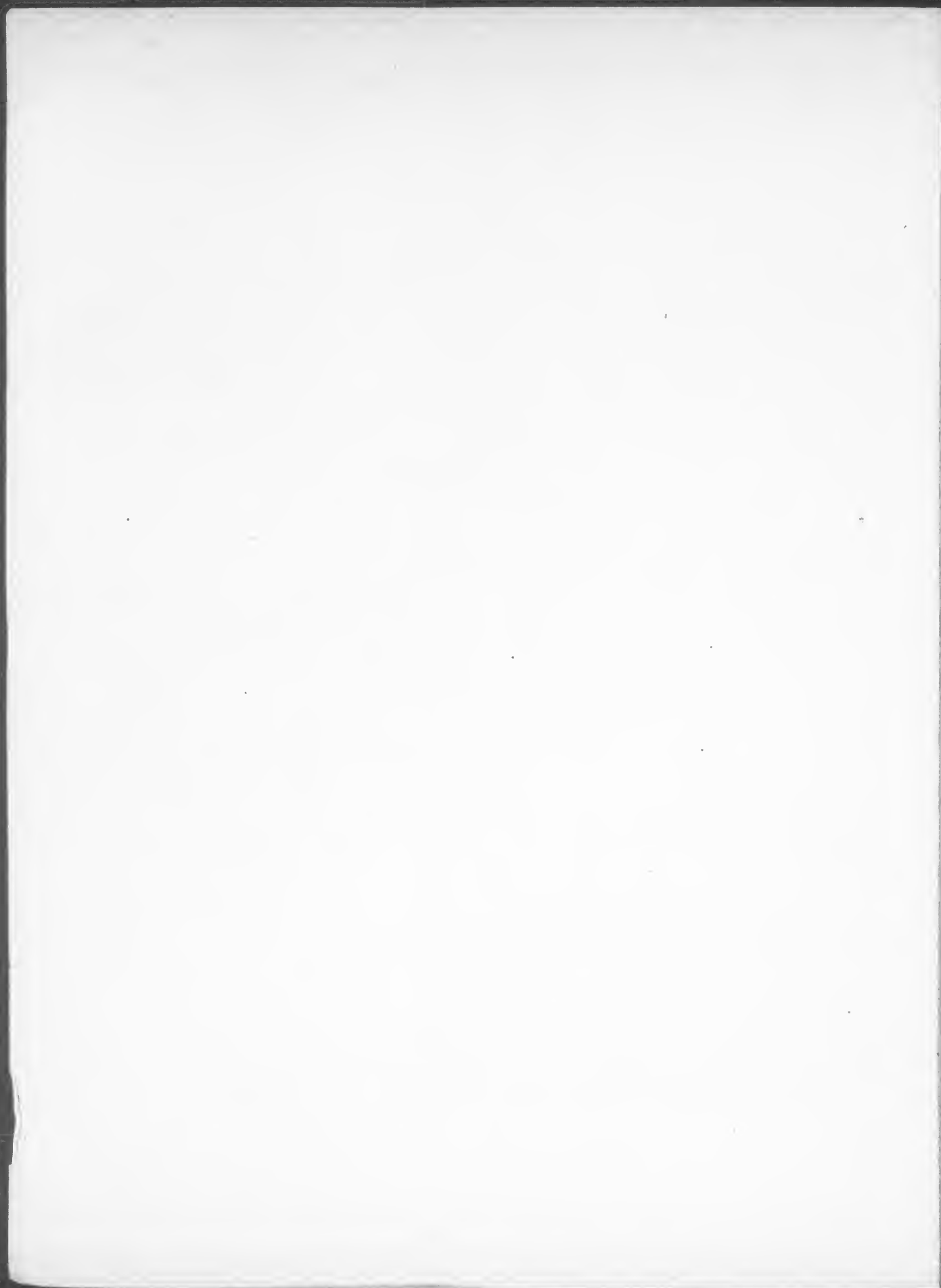
(b) *Date of Decision.* The reviewing official will attempt to issue his or her decision within 15 days of the date of the oral presentation, the date on which the transcript is received, or the date of the last submission by either party, whichever is later. If there is no oral presentation, the decision will normally be issued within 15 days of the date of receipt of the last reply brief. Once issued, the reviewing official will immediately communicate the decision to each party.

(c) *Public Notice.* If the suspension and proposed revocation are upheld, the revocation will become effective immediately and the public will be notified by publication of a notice in the **Federal Register**. If the suspension and proposed revocation are denied, the revocation will not take effect and the suspension will be lifted immediately. Public notice will be given by publication in the **Federal Register**.

**Section 16.15 Is there a review of the final administrative action?**

Before any legal action is filed in court challenging the suspension or proposed revocation, respondent shall exhaust administrative remedies provided under this subpart, unless otherwise provided by Federal law. The reviewing official's decision, under Section 16.9(e) or 16.14(a), constitutes final agency action and is ripe for judicial review as of the date of the decision.

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De Minimis U.S. Content in Foreign Made Items; comments due by 12-1-08; published 10-1-08 [FR E8-23142]

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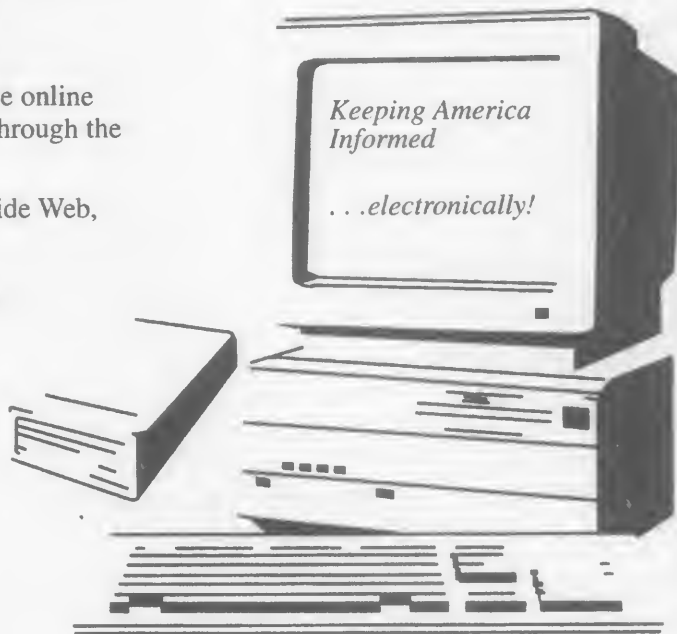
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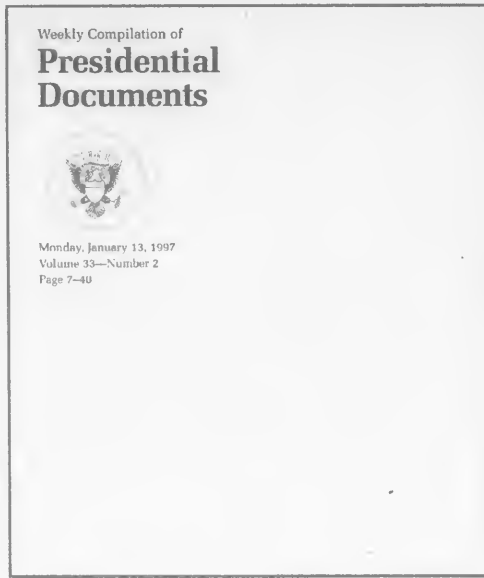
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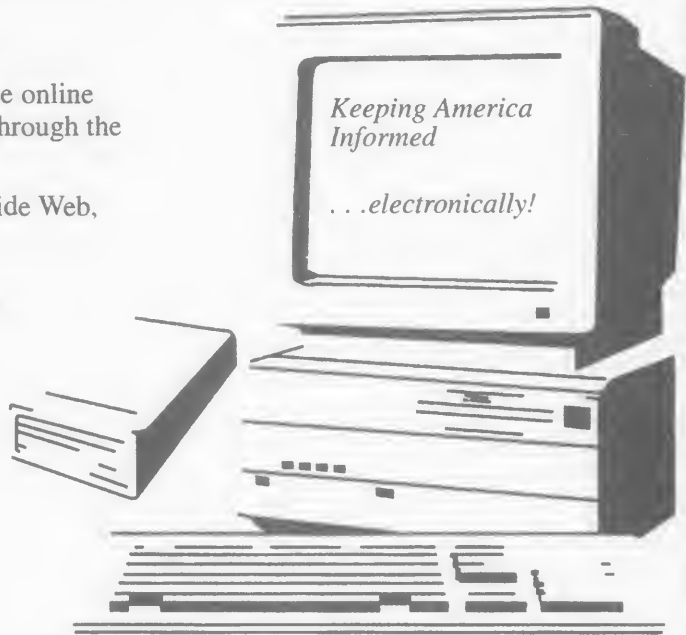
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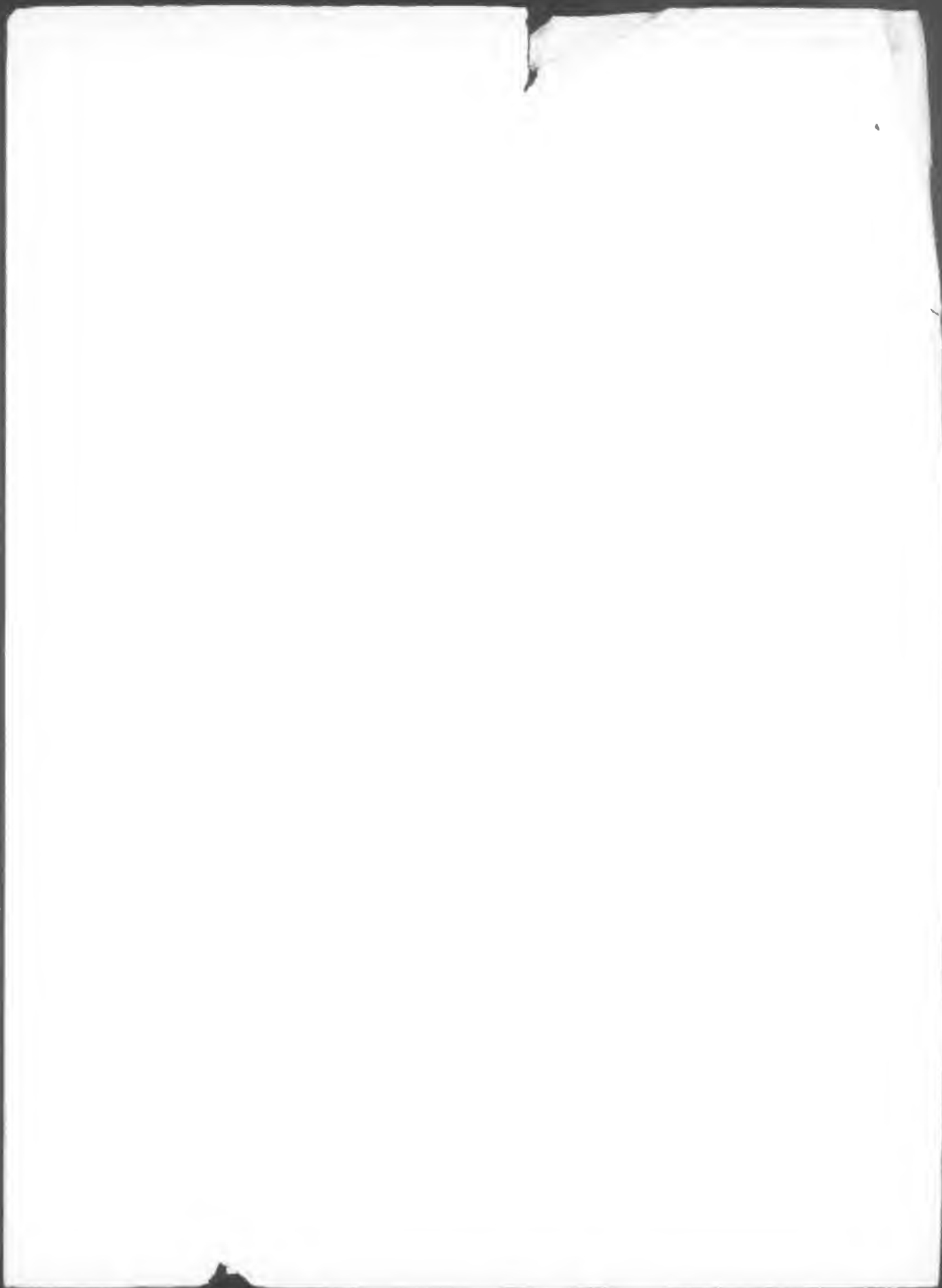


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