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Monday, January 23, 2017

ADMINISTRATIVE CONFERENCE OF THE UNITED STATES

1 CFR Part 304

Revisions to Freedom of Information Act Regulations

AGENCY: Administrative Conference of the United States.

ACTION: Direct final rule.

SUMMARY: The Administrative Conference of the United States (''ACUS'' or ''the Conference'') is revising its regulations for disclosure of records under the Freedom of Information Act (FOIA) to comply with the FOIA Improvement Act of 2016.

DATES: This rule is effective on March 14, 2017, without further action, unless significant adverse comment is received by February 22, 2017. If significant adverse comment is received, the Conference will publish a timely withdrawal of the rule together with a modified final rule in the **Federal Register**.

ADDRESSES: Submit comments either by email addressed to *smcgibbon@acus.gov* or by mail addressed to FOIA Comments, Administrative Conference of the United States, Suite 706 South, 1120 20th Street NW., Washington, DC 20036.

FOR FURTHER INFORMATION CONTACT: Shawne C. McGibbon, General Counsel, at 202–480–2088 or *smcgibbon@acus.gov.*

SUPPLEMENTARY INFORMATION: The FOIA Improvement Act of 2016,[1] was signed into law by the President on June 30, 2016. The Act consists of several amendments to the FOIA affecting FOIA administration. The Act requires each agency to review and update its FOIA regulations in accordance with the Act's provisions. The Conference is making changes to its regulations accordingly, including: Correcting citations; highlighting the electronic availability of records; implementing the ''rule of three'' for frequently requested records; notifying requesters of their right to seek assistance from the agency's FOIA Public Liaison and the National Archives and Records Administration's Office of Government Information Services (OGIS); changing the time limit for appeals; implementing the foreseeable harm standard; and describing limitations on assessing search fees if the response time is delayed. The revisions also include some wording changes to the existing regulations for greater clarity.

[1] Public Law. 114–185, 130 Stat. 538.

Regulatory Procedures

a. Administrative Procedure Act (APA)

Pursuant to 5 U.S.C. 553(b), we find that good cause exists for waiving publication of a general notice of proposed rulemaking and provision of a public comment period prior to issuance of the final rule. The amendments to the Conference's FOIA regulations contained herein are technical in nature. They concern matters of agency organization, procedure, and practice. They are being adopted in accordance with the mandated provisions of the FOIA Improvement Act of 2016, do not reflect agency discretion, and provide additional protection to the public. We note further that when the Conference adopted the FOIA regulations now being amended, we received a single set of comments from one person, which suggested various technical amendments, most of which were accepted and incorporated into the final rule. We conclude that a pre-issuance public comment period is unnecessary and not in the public interest. By issuing the current set of amendments as a direct final rule, we are nevertheless offering the public an opportunity to submit comments; but in the absence of any significant adverse comment received within 30 days of publication, the direct final rule will automatically go into effect 50 days after its publication without further notice. If we receive timely significant adverse comment, we will consider modifying this rule, with appropriate public notice.

b. Paperwork Reduction Act

The Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.,* does not apply because these regulations do not contain any new information collection requirements.

c. Regulatory Flexibility Act

Because notice and comment procedures are not required for the current amendments to the Conference's FOIA regulations, as explained above, the regulatory flexibility analyses otherwise required by the Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.,* do not apply to this rulemaking action. Nevertheless, the head of this agency certifies that this rulemaking action will not have a significant economic impact on a substantial number of small entities because it primarily affects individuals requesting records under the FOIA.

d. Unfunded Mandates Reform Act

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

e. Executive Order 12866

In issuing these regulations, ACUS has adhered to the regulatory philosophy and the applicable principles of regulation as set forth in Section 1 of Executive Order 12866, Regulatory Planning and Review, 58 FR 51735. These regulations have not been reviewed by the Office of Management and Budget under the Executive Order since they are not a significant regulatory action within the meaning of the Executive Order.

List of Subjects in 1 CFR Part 304

Administrative practice and procedure, Freedom of information.

For the reasons stated in the preamble, under the authority at 5 U.S.C. 552, 591–96 and Public Law 114–185, 130 Stat. 538, the Administrative Conference of the United States amends 1 CFR part 304 as follows:

PART 304—DISCLOSURE OF RECORDS OR INFORMATION

■ 1. The authority citation for part 304 continues to read as follows:

Authority: 5 U.S.C. 552, 591–96.

Subpart A—Procedures for Disclosure of Records Under the Freedom of Information Act

■ 2. Revise § 304.1 to read as follows:

§ 304.1 General provisions.

(a) This subpart contains the rules that the Administrative Conference of the United States (''ACUS'' or ''the agency'') follows in processing requests for disclosure of records under the Freedom of Information Act (''FOIA'' or ''the Act''), 5 U.S.C. 552, as amended, and in meeting its responsibilities under the Act. Note that electronic records are treated as records for the purposes of the FOIA. These rules should be read together with the text of the FOIA itself and the Uniform Freedom of Information Fee Schedule and Guidelines published by the Office of Management and Budget (OMB Guidelines). They also may be read in conjunction with the agency's ''Freedom of Information Act Reference Guide,'' which provides basic information about use of the Act in relation to the agency's records. Requests made by individuals for records about themselves under the Privacy Act of 1974, 5 U.S.C. 552a, are processed in accordance with the agency's Privacy Act regulations as well as under this subpart.

(b) The agency will withhold records or information only when it reasonably foresees that disclosure would harm an interest protected by an exemption of the FOIA or when disclosure is prohibited by law. Where full disclosure is not possible, the agency will consider whether partial disclosure is possible and, if so, will take reasonable steps to segregate and release nonexempt information. These policies do not create any right enforceable in court.

(c) The agency has designated its General Counsel as its Chief FOIA Officer, who has agency-wide responsibility for efficient and appropriate compliance with the FOIA and these implementing regulations. The Chief FOIA Officer has designated the agency's FOIA Public Liaison, who can assist individuals in locating and obtaining particular agency records. Contact information for the Chief FOIA Officer and the FOIA Public Liaison are clearly indicated on the agency's Web site at *https://www.acus.gov/foia.*

■ 3. Revise § 304.2 to read as follows:

§ 304.2 Proactive disclosures.

(a) Records that the FOIA requires ACUS to make regularly available for public inspection in an electronic format, including any records that have been requested three or more times, or were previously released and are likely to become the subject of subsequent requests or appear to be of general interest, may be accessed through the agency's Web site at *https://www.acus.gov.* A subject matter index of such records (or comparable tool) may also be accessed through the agency's Web site and will be updated on an ongoing basis.

(b) Information routinely provided to the public as part of a regular agency activity, including information posted on the agency's Web site (for example, press releases or recommendations adopted by the Conference pursuant to the Administrative Conference Act, 5 U.S.C. 591 *et seq.*), may be provided to the public without following this subpart.

(c) Any requester needing assistance in locating proactively disclosed or other agency records may contact the agency's FOIA Public Liaison at (202) 480–2080.

■ 4. Revise § 304.3 to read as follows:

§ 304.3 Requirements for making requests.

(a) *How made and addressed.* You may make a request for records by using the FOIA Request form on the ACUS Web site at *https://www.acus.gov/foia.* You may also send a written request letter to the agency either by mail addressed to FOIA Public Liaison, Administrative Conference of the United States, 1120 20th Street NW., Suite 706 South, Washington, DC 20036, or by fax delivery to (202) 386–7190. For the quickest possible handling of a mail request, you should mark both your request letter and the envelope ''Freedom of Information Act Request.'' (You may find the agency's ''Freedom of Information Act Reference Guide''—which is available in electronic format on its Web site and in paper form—helpful in making your request.) If you are making a request for records about yourself, see § 304.21(d) for additional requirements. If you are making a request for records about another individual, then either a written authorization signed by that individual permitting disclosure of those records to you or proof that that individual is deceased (for example, a copy of a death certificate or an obituary notice) will help the processing of your request. Your request will be considered received as of the date upon which it is logged in as received by the agency's FOIA Public Liaison.

(b) *Description of records sought.* (1) You must describe the records that you seek in enough detail to enable agency personnel to locate them with a reasonable amount of effort. Whenever possible, your request should include specific information about each record sought, such as the date, title or name, author, recipient, and subject matter of the record. If known, you should include any file designations or similar descriptions for the records that you want. As a general rule, the more specific you are about the records or type of records that you want, the more likely that the agency will be able to locate those records in response to your request. Before submitting your request, you may contact the agency's FOIA Public Liaison at (202) 480–2080 for assistance in describing the records.

(2) If the agency determines that your request does not reasonably describe records, then it will tell you either what additional information is needed or why your request is otherwise insufficient. It also will give you an opportunity to discuss your request by telephone so that you may modify it to meet the requirements of this section. Additionally, if your request does not reasonably describe the records you seek, the agency's response to it may be delayed as an initial matter.

(c) *Format of records sought.* Requests may specify the preferred form or format (including electronic formats) for the records you seek. The agency will accommodate your request if the record is readily reproducible in that form or format.

(d) *Agreement to pay fees.* When you make a FOIA request, it will be considered to be an agreement by you to pay all applicable fees charged under § 304.9, up to $50.00, unless you specifically request a waiver of fees. The agency ordinarily will confirm this agreement in an acknowledgment letter. When making a request, you may specify a willingness to pay a greater or lesser amount. Your agreement will not prejudice your ability to seek a waiver or reduction of any applicable fee at a later time.

■ 5. Amend § 304.5 by revising paragraphs (b) and (c)(1) to read as follows:

§ 304.5 Timing of responses to requests.

* * * * *

(b) *Multi-track processing.* The agency generally uses two processing tracks that distinguish between simple and complex requests. In determining the appropriate track for a request, the agency considers, among other factors, the number of records requested, the number of pages involved in processing

the request and the need for consultations or referrals. When a request is placed on the complex track, the agency will provide the requester with an opportunity to narrow or modify the request so that it can be placed on the simple track. The agency will contact the requester by telephone, email or letter, whichever is most efficient, in each case.

(c) *Unusual circumstances.* (1) Where the statutory time limit of 20 days for processing a request cannot be met because of ''unusual circumstances,'' as defined in the FOIA, and the agency extends the time limits on that basis, it will, before expiration of the 20-day period, notify the requester in writing of the unusual circumstances and of the date by which the agency estimates processing of the request can be expected to be completed. Where the extension is likely to exceed ten working days, the agency will provide the requester with an opportunity to modify the request or arrange an alternative time period for processing the original or modified request. In such instances, the agency's FOIA Public Liaison will contact the requester, and the requester will be informed of the mediation services offered by the Office of Government Information Services (''OGIS'')—see *https://www.archives.gov/ogis.*

* * * * *

■ 6. Revise § 304.6 to read as follows:

§ 304.6 Responses to requests.

(a) *Acknowledgments of requests.* On receipt of a request, if the agency cannot provide the requested information within two working days, then an acknowledgment letter or email message will be sent to the requester that will confirm the requester's agreement to pay fees under § 304.3(d) and will provide a request tracking number for further reference. Requesters may use this tracking number to determine the status of their request—including the date of its receipt and the estimated date on which action on it will be completed—by calling the agency's FOIA Public Liaison at (202) 480–2080. In some cases, the agency may seek further information or clarification from the requester.

(b) *Grants of requests.* Ordinarily, the agency will have 20 working days from when a request is received to determine whether to grant or deny the request. Once the agency makes such a determination, it will immediately notify the requester in writing. The agency will inform the requester in the notice of any fee charged under § 304.9 and will disclose records to the requester promptly upon payment of any applicable fee. The agency will also inform the requester of the availability of its FOIA Public Liaison to offer assistance.

(c) *Adverse determinations of requests.* Whenever the agency makes an adverse determination denying a request in any respect, it will notify the requester of that determination in writing. Adverse determinations, or denials of requests, consist of: A determination to withhold any requested record in whole or in part; a determination that a requested record does not exist or cannot be located; a determination that a record is not readily reproducible in the form or format sought by the requester; a determination that what has been requested is not a record subject to the FOIA; a determination on any disputed fee matter, including a denial of a request for a fee waiver; and a denial of a request for expedited treatment. The denial letter will include:

(1) The name and title or position of the person responsible for the denial;

(2) A brief statement of the reason(s) for the denial, including any FOIA exemption(s) applied by the agency in denying the request;

(3) An estimate of the volume of records or information withheld, in number of pages or in some other reasonable form of estimation. This estimate does not need to be provided if the volume is otherwise indicated through deletions on records disclosed in part, or if providing an estimate would harm an interest protected by an applicable exemption; and

(4) An indication on the released portion of a record of each exemption applied, at the place at which it was applied, if technically feasible.

(5) A statement that the denial may be appealed under § 304.8(a) and a description of the requirements of § 304.8(a).

(6) A statement notifying the requester of the assistance available from the agency's FOIA Public Liaison and the dispute resolution services offered by OGIS.

(d) *Markings on released documents.* Records disclosed in part will be marked or annotated to show the amount of information deleted, unless doing so would harm an interest protected by an applicable exemption. The location of the information deleted also will be indicated on the record, if technically feasible.

■ 7. Revise § 304.8 to read as follows:

§ 304.8 Appeals.

(a) *Appeals of adverse determinations.* If you are dissatisfied with the response to your request, you may appeal an adverse determination denying your request, in any respect, to the Chairman of the agency. You must make your appeal in writing, by email or letter, and it must be received by the agency within 90 calendar days of the date of the agency's response denying your request. Your appeal should provide reasons and supporting information as to why the initial determination was incorrect. The appeal should clearly identify the particular determination (including the assigned request number, if known) that you are appealing. For the quickest possible handling of a mail request, you should mark your appeal ''Freedom of Information Act Appeal.'' The Chairman or his or her designee will act on the appeal, except that an appeal ordinarily will not be acted on if the request becomes a matter of FOIA litigation.

(b) *Responses to appeals.* The decision on your appeal will be communicated to you by email or letter, ordinarily within 20 working days of receipt of your appeal. A decision affirming an adverse determination in whole or in part will contain a statement of the reason(s) for the affirmance, including any FOIA exemption(s) applied, and will inform you of the FOIA provisions for court review of the decision. The decision will also inform you of the mediation services offered by OGIS as a non-exclusive alternative to FOIA litigation. If the adverse determination is reversed or modified on appeal, in whole or in part, then you will be notified in a written decision and your request will be reprocessed in accordance with that appeal decision.

(c) *Engaging in dispute resolution services provided by OGIS.* Mediation is a voluntary process. If the agency agrees to participate in the mediation services provided by OGIS, it will actively engage in the process in an attempt to resolve the dispute.

(d) *When appeal is required.* As a general rule, if you wish to seek review by a court of any adverse determination, you must first appeal it in a timely fashion under this section.

■ 8. Amend § 304.9 by revising paragraphs (a), (d)(6), (e), (i)(3), and (k) to read as follows:

§ 304.9 Fees.

(a) *In general.* The agency will charge for processing requests under the FOIA in accordance with paragraph (c) of this section and with the OMB Guidelines. The agency ordinarily will collect all applicable fees before sending copies of requested records to a requester. Requesters must pay fees by check or

money order made payable to the Treasury of the United States.

* * * * *

(d) * * *

(6) (i) If the agency fails to comply with the FOIA's time limits in which to respond to a request, it may not charge search fees, or, in the instances of requests from requesters described in paragraph (d)(1) of this section, may not charge duplication fees, except as described in (d)(6)(ii)–(iv).

(ii) If the agency has determined that unusual circumstances as defined by the FOIA apply and the agency provided timely written notice to the requester in accordance with the FOIA, a failure to comply with the time limit will be excused for an additional 10 working days.

(iii) If the agency has determined that unusual circumstances, as defined by the FOIA, apply and more than 5,000 pages are necessary to respond to the request, the agency may charge search fees, or, in the case of requesters described in paragraph (d)(1) of this section, may charge duplication fees, if the following steps are taken. The agency must have provided timely written notice of unusual circumstances to the requester in accordance with the FOIA and the agency must have discussed with the requester via written mail, email, or telephone (or made not less than three good-faith attempts to do so) how the requester could effectively limit the scope of the request in accordance with 5 U.S.C. 552(a)(6)(B)(ii). If this exception is satisfied, the agency may charge all applicable fees incurred in the processing of this request.

(iv) If a court has determined that exceptional circumstances exist, as defined by the FOIA, a failure to comply with the time limits will be excused for the length of time provided by the court order.

(e) *Notice of anticipated fees in excess of $50.00.* (1) When the agency determines or estimates that the fees to be charged under this section will amount to more than $50.00, it will notify the requester of the actual or estimated amount of the fees, unless the requester has indicated a willingness to pay fees as high as those anticipated. If only a portion of the fee can be estimated readily, the agency will advise the requester that the estimated fee might be only a portion of the total fee. In cases in which a requester has been notified that actual or estimated fees amount to more than $50.00, the request will not be considered received and further work will not be done on it until the requester agrees to pay the total anticipated fee. Any such agreement should be memorialized in writing. A notice under this paragraph will offer the requester an opportunity to discuss the matter with agency personnel in order to reformulate the request to meet the requester's needs at a lower cost.

(2) If the requester has indicated a willingness to pay some designated amount of fees, but the agency estimates that the total fee will exceed that amount, the agency will suspend the processing of the request when it notifies the requester of the estimated fees in excess of the amount the requester has indicated a willingness to pay. The agency will inquire whether the requester wishes to revise the amount of fees the requester is willing to pay or modify the request. Once the requester responds, the time to respond will resume from where it was at the date of the notification.

(3) The agency will make its FOIA Public Liaison available to assist any requester in reformulating a request to meet the requester's needs at a lower cost.

* * * * *

(i) * * *

(3) Where a requester has previously failed to pay a properly charged FOIA fee to the agency within 30 calendar days of the date of billing, the agency may require the requester to pay the full amount due, plus any applicable interest, and to make an advance payment of the full amount of any anticipated fee, before it begins to process a new request or continues to process a pending request from that requester.

* * * * *

(k) *Requirements for waiver or reduction of fees.* (1) Requesters may seek a waiver of fees by submitting a written application demonstrating how disclosure of the requested information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government and is not primarily in the commercial interest of the requester.

(2) The agency will furnish records responsive to a request without charge or at a reduced rate when it determines, based on all available information, that the factors described in paragraphs (k)(2)(i) through (iii) of this section are satisfied:

(i) Disclosure of the requested information would shed light on the operations or activities of the government. The subject of the requested records must concern identifiable operations or activities of the Federal Government with a connection that is direct and clear, not remote or attenuated.

(ii) Disclosure of the requested information is likely to contribute significantly to public understanding of those operations or activities. This factor is satisfied when the following criteria are met:

(A) Disclosure of the requested records must be meaningfully informative about government operations or activities. The disclosure of information that already is in the public domain, in either the same or a substantially identical form, would not be meaningfully informative if nothing new would be added to the public's understanding.

(B) The disclosure must contribute to the understanding of a reasonably broad audience of persons interested in the subject, as opposed to the individual understanding of the requester. A requester's expertise in the subject area as well as the requester's ability and intention to convey information effectively to the public will be considered. The agency will presume that a representative of the news media satisfies this consideration.

(iii) The disclosure must not be primarily in the commercial interest of the requester. To determine whether disclosure of the requested information is primarily in the commercial interest of the requester, the agency will consider the following criteria:

(A) Whether the requester has any commercial interest that would be furthered by the requested disclosure. A commercial interest includes any commercial, trade, or profit interest. Requesters will be given an opportunity to provide explanatory information regarding this consideration.

(B) Whether any identified commercial interest is the primary interest furthered by the request. A waiver or reduction of fees is justified when the requirements of paragraphs (k)(2)(i) and (ii) of this section are satisfied and any commercial interest is not the primary interest furthered by the request. The agency ordinarily will presume that when a news media requester has satisfied factors in paragraphs (k)(2)(i) and (ii) of this section, the request is not primarily in the commercial interest of the requester. Disclosure to data brokers or others who merely compile and market government information for direct economic return will not be presumed primarily to serve the public interest.

(3) Where only some of the records to be released satisfy the requirements for a waiver of fees, a waiver will be granted for those records.

(4) Requests for a waiver or reduction of fees should ordinarily be made when the request is first submitted to the agency and should address the criteria referenced above. A requester may submit a fee waiver request at a later time so long as the underlying record request is pending or on administrative appeal. When a requester who has committed to pay fees subsequently asks for a waiver of those fees and that waiver is denied, the requester must pay any costs incurred up to the date the fee waiver request was received.

■ 9. Amend § 304.10 by revising paragraph (a) to read as follows:

§ 304.10 Preservation of records.

(a) The agency will preserve all correspondence pertaining to the requests that it receives under this subpart, as well as copies of all requested records, until disposition or destruction is authorized by title 44 of the United States Code or the National Archives and Records Administration's General Records Schedule 4.2. Records will not be disposed of while they are the subject of a pending request, appeal, or lawsuit under the FOIA.

* * * * *

Dated: January 11, 2017.

David M. Pritzker,

Deputy General Counsel.

[FR Doc. 2017–00891 Filed 1–19–17; 8:45 am]

BILLING CODE 6110–01–P

FEDERAL RESERVE SYSTEM

12 CFR Part 201

[Docket No. R–1558]

RIN 7100 AE–66

Regulation A: Extensions of Credit by Federal Reserve Banks

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Final rule.

SUMMARY: The Board of Governors of the Federal Reserve System (''Board'') has adopted final amendments to its Regulation A to reflect the Board's approval of an increase in the rate for primary credit at each Federal Reserve Bank. The secondary credit rate at each Reserve Bank automatically increased by formula as a result of the Board's primary credit rate action.

DATES: The amendments to part 201 (Regulation A) are effective January 23, 2017. The rate changes for primary and secondary credit were effective as determined by the Board in its December 14, 2016 announcement.

FOR FURTHER INFORMATION CONTACT: Clinton Chen, Attorney (202–452–3952), or Sophia Allison, Special Counsel, (202–452–3565), Legal Division, or Lyle Kumasaka, Senior Financial Analyst (202–452–2382); for users of Telecommunications Device for the Deaf (TDD) only, contact 202–263–4869; Board of Governors of the Federal Reserve System, 20th and C Streets NW., Washington, DC 20551.

SUPPLEMENTARY INFORMATION: The Federal Reserve Banks make primary and secondary credit available to depository institutions as a backup source of funding on a short-term basis, usually overnight. The primary and secondary credit rates are the interest rates that the twelve Federal Reserve Banks charge for extensions of credit under these programs. In accordance with the Federal Reserve Act, the primary and secondary credit rates are established by the boards of directors of the Federal Reserve Banks, subject to the review and determination of the Board.

The Board voted to approve a ¼ percentage point increase in the primary credit rate in effect at each of the twelve Federal Reserve Banks, thereby increasing from 1.00 percent to 1.25 percent the rate that each Reserve Bank charges for extensions of primary credit. In addition, the Board had previously approved to renew the formula for the secondary credit rate, the primary credit rate plus 50 basis points. Under the formula, the secondary credit rate in effect at each of the twelve Federal Reserve Banks increased by ¼ percentage point as a result of the Board's primary credit rate action, thereby increasing from 1.50 percent to 1.75 percent the rate that each Reserve Bank charges for extensions of secondary credit. The amendments to Regulation A reflect these rate changes.

The rate changes for primary and secondary credit were effective as determined by the Board in its December 14, 2016 announcement.[1]

The ¼ percentage point increase in the primary credit rate was associated with an increase in the target range for the federal funds rate (from a target range of ¼ to ½ percent to a target range of ½ to ¾ percent) announced by the Federal Open Market Committee (''Committee'') on December 14, 2016, as described in the Board's amendment of its Regulation D published elsewhere in today's **Federal Register**.

[1] Federal Reserve Implementation Note, ''Decisions Regarding Monetary Policy Implementation'' (Dec. 14, 2016), *https://www.federalreserve.gov/newsevents/press/monetary/20161214a1.htm.*

The presentation of the interest rates for primary and secondary credit has been changed in the Code of Federal Regulations to improve clarity.

Administrative Procedure Act

In general, the Administrative Procedure Act (12 U.S.C. 551 *et seq.*) (''APA'') imposes three principal requirements when an agency promulgates legislative rules (rules made pursuant to congressionally delegated authority): (1) Publication with adequate notice of a proposed rule; (2) followed by a meaningful opportunity for the public to comment on the rule's content; and (3) publication of the final rule not less than 30 days before its effective date. The APA provides that notice and comment procedures do not apply if the agency for good cause finds them to be ''unnecessary, impracticable, or contrary to the public interest.'' 12 U.S.C. 553(b)(3)(A). Section 553(d) of the APA also provides that publication not less than 30 days prior to a rule's effective date is not required for (1) a substantive rule which grants or recognizes an exemption or relieves a restriction; (2) interpretive rules and statements of policy; or (3) an agency finding good cause for shortened notice and publishing its reasoning with the rule. 12 U.S.C. 553(d). The APA further provides that the notice, public comment, and delayed effective date requirements of 5 U.S.C. 553 do not apply ''to the extent that there is involved . . . a matter relating to agency management or personnel or to public property, *loans,* grants, benefits, or contracts.'' 5 U.S.C. 553(a)(2) (emphasis added).

Regulation A establishes the interest rates that the twelve Reserve Banks charge for extensions of primary credit and secondary credit. Accordingly, the Board has determined that the notice, public comment, and delayed effective date requirements of 5 U.S.C. 553 do not apply to the final amendments to Regulation A because the amendments involve a matter relating to loans. In addition, the Board has determined that, were the APA's requirements for notice, public comment, and delayed effective date to apply to the final amendments to Regulation A, those requirements would be unnecessary and contrary to the public interest. Delay in implementation of changes to the rates charged on primary credit and secondary credit would permit insured depository institutions to profit improperly from the difference in the current rate and the announced increased rate. Delay would also undermine the Board's action in

responding to economic data and conditions. For these reasons, the Board has determined that ''good cause'' within the meaning of the APA exists to dispense with the notice, public comment, and delayed effective date procedures of the APA with respect to the final amendments to Regulation A.

Regulatory Flexibility Analysis

The Regulatory Flexibility Act (''RFA'') does not apply to a rulemaking where a general notice of proposed rulemaking is not required.[2] As noted previously, a general notice of proposed rulemaking is not required if the final rule involves a matter relating to loans. Furthermore, the Board has determined that it is unnecessary and contrary to the public interest to publish a general notice of proposed rulemaking for this final rule. Accordingly, the RFA's requirements relating to an initial and final regulatory flexibility analysis do not apply.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act (''PRA'') of 1995 (44 U.S.C. 3506; 5 CFR part 1320 Appendix A.1), the Board reviewed the final rule under the authority delegated to the Board by the Office of Management and Budget. The final rule contains no requirements subject to the PRA.

List of Subjects in 12 CFR Part 201

Banks, banking, Federal Reserve System, Reporting and recordkeeping.

Authority and Issuance

For the reasons set forth in the preamble, the Board is amending 12 CFR Chapter II to read as follows:

12 CFR CHAPTER II

PART 201—EXTENSIONS OF CREDIT BY FEDERAL RESERVE BANKS (REGULATION A)

■ 1. The authority citation for part 201 continues to read as follows:

Authority: 12 U.S.C. 248(i)–(j), 343 *et seq.,* 347a, 347b, 347c, 348 *et seq.,* 357, 374, 374a, and 461.

■ 2. In § 201.51, paragraphs (a) and (b) are revised to read as follows:

§ 201.51 Interest rates applicable to credit extended by a Federal Reserve Bank.[3]

(a) *Primary credit.* The interest rate at each Federal Reserve Bank for primary credit provided to depository institutions under § 201.4(a) is 1.25 percent.

(b) *Secondary credit.* The interest rate at each Federal Reserve Bank for secondary credit provided to depository institutions under § 201.4(b) is 1.75 percent.

* * * * *

By order of the Board of Governors of the Federal Reserve System, January 9, 2017.

Robert deV. Frierson,

Secretary of the Board.

[FR Doc. 2017–00612 Filed 1–19–17; 8:45 am]

BILLING CODE 6210–01–P

[2] 5 U.S.C. 603 and 604.

[3] The primary, secondary, and seasonal credit rates described in this section apply to both advances and discounts made under the primary, secondary, and seasonal credit programs, respectively.

FEDERAL RESERVE SYSTEM

12 CFR Part 204

[Docket No. R–1559]

RIN 7100 AE–67

Regulation D: Reserve Requirements of Depository Institutions

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Final rule.

SUMMARY: The Board of Governors of the Federal Reserve System (''Board'') is amending Regulation D (Reserve Requirements of Depository Institutions) to revise the rate of interest paid on balances maintained to satisfy reserve balance requirements (''IORR'') and the rate of interest paid on excess balances (''IOER'') maintained at Federal Reserve Banks by or on behalf of eligible institutions. The final amendments specify that IORR is 0.75 percent and IOER is 0.75 percent, a 0.25 percentage point increase from their prior levels. The amendments are intended to enhance the role of such rates of interest in moving the Federal funds rate into the target range established by the Federal Open Market Committee (''FOMC'' or ''Committee'').

DATES: The amendments to part 204 (Regulation D) are effective January 23, 2017. The IORR and IOER rate changes were applicable on December 15, 2016, as specified in 12 CFR 204.10(b)(5), as amended.

FOR FURTHER INFORMATION CONTACT: Clinton Chen, Attorney (202–452–3952), or Sophia Allison, Special Counsel (202–452–3198), Legal Division, or Thomas Keating, Financial Analyst (202–973–7401), or Laura Lipscomb, Section Chief (202–973–7964), Division of Monetary Affairs; for users of Telecommunications Device for the Deaf (TDD) only, contact 202–263–4869; Board of Governors of the Federal Reserve System, 20th and C Streets NW., Washington, DC 20551.

SUPPLEMENTARY INFORMATION:

I. Statutory and Regulatory Background

For monetary policy purposes, section 19 of the Federal Reserve Act (''the Act'') imposes reserve requirements on certain types of deposits and other liabilities of depository institutions. Regulation D, which implements section 19 of the Act, requires that a depository institution meet reserve requirements by holding cash in its vault, or if vault cash is insufficient, by maintaining a balance in an account at a Federal Reserve Bank (''Reserve Bank'').[1] Section 19 also provides that balances maintained by or on behalf of certain institutions in an account at a Reserve Bank may receive earnings to be paid by the Reserve Bank at least once each quarter, at a rate or rates not to exceed the general level of short-term interest rates. Institutions that are eligible to receive earnings on their balances held at Reserve Banks (''eligible institutions'') include depository institutions and certain other institutions.[2] Section 19 also provides that the Board may prescribe regulations concerning the payment of earnings on balances at a Reserve Bank.[3] Prior to these amendments, Regulation D specified a rate of 0.50 percent for both IORR and IOER.[4]

II. Amendments to IORR and IOER

The Board is amending § 204.10(b)(5) of Regulation D to specify that IORR is 0.75 percent and IOER is 0.75 percent. This 0.25 percentage point increase in

[1] 12 CFR 204.5(a)(1).

[2] Section 19(b)(1)(A) defines ''depository institution'' as any insured bank as defined in section 3 of the Federal Deposit Insurance Act or any bank which is eligible to make application to become an insured bank under section 5 of such Act; any mutual savings bank as defined in section 3 of the Federal Deposit Insurance Act or any bank which is eligible to make application to become an insured bank under section 5 of such Act; any savings bank as defined in section 3 of the Federal Deposit Insurance Act or any bank which is eligible to make application to become an insured bank under section 5 of such Act; any insured credit union as defined in section 101 of the Federal Credit Union Act or any credit union which is eligible to make application to become an insured credit union pursuant to section 201 of such Act; any member as defined in section 2 of the Federal Home Loan Bank Act; [and] any savings association (as defined in section 3 of the Federal Deposit Insurance Act) which is an insured depository institution (as defined in such Act) or is eligible to apply to become an insured depository institution under the Federal Deposit Insurance Act. See 12 U.S.C. 461(b)(1)(A). Eligible institution also includes any trust company, corporation organized under section 25A or having an agreement with the Board under section 25, or any branch or agency of a foreign bank (as defined in section 1(b) of the International Banking Act of 1978). 12 U.S.C. 461(b)(12)(C); see 12 CFR 204.2(y) (definition of ''eligible institution'').

[3] See 12 U.S.C. 461(b)(12).

[4] See 12 CFR 204.10(b)(5).

the IORR and IOER was associated with an increase in the target range for the federal funds rate, from a target range of ¼ to ½ percent to a target range of ½ to ¾ percent, announced by the FOMC on December 14, 2016 with an effective date of December 15, 2016. The FOMC's press release on the same day as the announcement noted that:

Information received since the Federal Open Market Committee met in November indicates that the labor market has continued to strengthen and that economic activity has been expanding at a moderate pace since mid-year. Job gains have been solid in recent months and the unemployment rate has declined. Household spending has been rising moderately but business fixed investment has remained soft. Inflation has increased since earlier this year but is still below the Committee's 2 percent longer-run objective, partly reflecting earlier declines in energy prices and in prices of non-energy imports. Market-based measures of inflation compensation have moved up considerably but still are low; most survey-based measures of longer-term inflation expectations are little changed, on balance, in recent months.

Consistent with its statutory mandate, the Committee seeks to foster maximum employment and price stability. The Committee expects that, with gradual adjustments in the stance of monetary policy, economic activity will expand at a moderate pace and labor market conditions will strengthen somewhat further. Inflation is expected to rise to 2 percent over the medium term as the transitory effects of past declines in energy and import prices dissipate and the labor market strengthens further. Near-term risks to the economic outlook appear roughly balanced. The Committee continues to closely monitor inflation indicators and global economic and financial developments.

In view of realized and expected labor market conditions and inflation, the Committee decided to raise the target range for the federal funds rate to ½ to ¾ percent. The stance of monetary policy remains accommodative, thereby supporting some further strengthening in labor market conditions and a return to 2 percent inflation.

A Federal Reserve Implementation note released simultaneously with the announcement stated that:

The Board of Governors of the Federal Reserve System voted unanimously to raise the interest rate paid on required and excess reserve balances to 0.75 percent, effective December 15, 2016.

As a result, the Board is amending § 204.10(b)(5) of Regulation D to change IORR to 0.75 percent and IOER to 0.75 percent.

III. Administrative Procedure Act

In general, the Administrative Procedure Act (12 U.S.C. 551 *et seq.*) (''APA'') imposes three principal requirements when an agency promulgates legislative rules (rules made pursuant to congressionally delegated authority): (1) Publication with adequate notice of a proposed rule; (2) followed by a meaningful opportunity for the public to comment on the rule's content; and (3) publication of the final rule not less than 30 days before its effective date. The APA provides that notice and comment procedures do not apply if the agency for good cause finds them to be ''unnecessary, impracticable, or contrary to the public interest.'' 12 U.S.C. 553(b)(3)(A). Section 553(d) of the APA also provides that publication not less than 30 days prior to a rule's effective date is not required for (1) a substantive rule which grants or recognizes an exemption or relieves a restriction; (2) interpretive rules and statements of policy; or (3) an agency finding good cause for shortened notice and publishing its reasoning with the rule. 12 U.S.C. 553(d).

The Board has determined that good cause exists for finding that the notice, public comment, and delayed effective date provisions of the APA are unnecessary, impracticable, or contrary to the public interest with respect to the final amendments to Regulation D. The rate increases for IORR and IOER that are reflected in the final amendments to Regulation D were made with a view towards accommodating commerce and business and with regard to their bearing upon the general credit situation of the country. Notice and public comment would prevent the Board's action from being effective as promptly as necessary in the public interest, and would not otherwise serve any useful purpose. Notice, public comment, and a delayed effective date would create uncertainty about the finality and effectiveness of the Board's action and undermine the effectiveness of that action. Accordingly, the Board has determined that good cause exists to dispense with the notice, public comment, and delayed effective date procedures of the APA with respect to the final amendments to Regulation D.

IV. Regulatory Flexibility Analysis

The Regulatory Flexibility Act (''RFA'') does not apply to a rulemaking where a general notice of proposed rulemaking is not required.[5] As noted previously, the Board has determined that it is unnecessary and contrary to the public interest to publish a general notice of proposed rulemaking for this final rule. Accordingly, the RFA's requirements relating to an initial and final regulatory flexibility analysis do not apply.

[5] 5 U.S.C. 603 and 604.

V. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act (''PRA'') of 1995 (44 U.S.C. 3506; 5 CFR part 1320 Appendix A.1), the Board reviewed the final rule under the authority delegated to the Board by the Office of Management and Budget. The final rule contains no requirements subject to the PRA.

List of Subjects in 12 CFR Part 204

Banks, banking, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Board amends 12 CFR part 204 as follows:

PART 204—RESERVE REQUIREMENTS OF DEPOSITORY INSTITUTIONS (REGULATION D)

■ 1. The authority citation for part 204 continues to read as follows:

Authority: 12 U.S.C. 248(a), 248(c), 371a, 461, 601, 611, and 3105.

■ 2. Section 204.10 is amended by revising paragraph (b)(5) to read as follows:

§ 204.10 Payment of interest on balances.

* * * * *

(b) * * *

(5) The rates for IORR and IOER are:

	Rate (percent)
IORR	0.75
IOER	0.75

* * * * *

By order of the Board of Governors of the Federal Reserve System, January 9, 2017.

Robert deV. Frierson,

Secretary of the Board.

[FR Doc. 2017–00613 Filed 1–19–17; 8:45 am]

BILLING CODE 6210–01–P

NATIONAL CREDIT UNION ADMINISTRATION

12 CFR Part 747

RIN 3133–AE67

Civil Monetary Penalty Inflation Adjustment

AGENCY: National Credit Union Administration (NCUA).

ACTION: Interim final rule.

SUMMARY: The NCUA Board (Board) is amending its regulations to adjust the maximum amount of each civil monetary penalty (CMP) within its

jurisdiction to account for inflation. This action, including the amount of the adjustments, is required under the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996 and the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015.

DATES: This interim final rule is effective January 23, 2017. Comments must be received on or before February 22, 2017.

ADDRESSES: You may submit comments by any of the following methods (Please send comments by one method only):

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *NCUA Web site: https://www.ncua.gov/regulation-supervision/Pages/rules/proposed.aspx.* Follow the instructions for submitting comments.
- *Email:* Address to *regcomments@ncua.gov.* Include ''[Your name] Comments on ''Civil Monetary Penalty Inflation Adjustment'' in the email subject line.
- *Fax:* (703) 518–6319. Use the subject line described above for email.
- *Mail:* Address to Gerard Poliquin, Secretary of the Board, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428.
- *Hand Delivery/Courier:* Same as mail address.

Public Inspection: All public comments are available on the agency's Web site at *http://www.ncua.gov/RegulationsOpinionsLaws/comments* as submitted, except as may not be possible for technical reasons. Public comments will not be edited to remove any identifying or contact information. Paper copies of comments may be inspected in NCUA's law library at 1775 Duke Street, Alexandria, Virginia 22314, by appointment weekdays between 9:00 a.m. and 3:00 p.m. To make an appointment, call (703) 518–6546 or send an email to *OGCMail@ncua.gov.*

FOR FURTHER INFORMATION CONTACT: Ian Marenna, Senior Trial Attorney, at 1775 Duke Street, Alexandria, VA 22314, or telephone: (703) 518–6540.

SUPPLEMENTARY INFORMATION:

I. Legal Background

A. Statutory Requirements and OMB Guidance

The Debt Collection Improvement Act of 1996 [1] (DCIA) amended the Federal Civil Penalties Inflation Adjustment Act of 1990 [2] (FCPIA Act) to require every federal agency to enact regulations that adjust each CMP provided by law under its jurisdiction by the rate of inflation at least once every four years.

In November 2015, Congress further amended the CMP inflation requirements in the Bipartisan Budget Act of 2015,[3] which contains the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (the 2015 amendments).[4] This legislation provided for an initial ''catch-up'' adjustment of CMPs in 2016, followed by annual adjustments. The catch-up adjustment re-set CMP maximum amounts by setting aside the inflation adjustments that agencies made in prior years and instead calculated inflation with reference to the year when each CMP was enacted or last modified by Congress. Agencies were required to publish their catch-up adjustments in an interim final rule by July 1, 2016 and make them effective by August 1, 2016.[5] NCUA complied with these requirements in a June 2016 interim final rule, followed by an October 2016 final rule to confirm the adjustments as final.[6]

The 2015 amendments also specified how agencies must conduct annual inflation adjustments after the 2016 catch-up adjustment. Beginning in 2017, agencies must make the required adjustments and publish them in the **Federal Register** by January 15 of each succeeding year.[7] The statute provides that the adjustments shall be made notwithstanding the section of the Administrative Procedure Act (APA) that requires prior notice and public comment for agency rulemaking.[8] The 2015 amendments also specify that each CMP maximum must be increased by the percentage by which the consumer price index for urban consumers (CPI–U) [9] for October of the year immediately preceding the year the adjustment is made exceeds the CPI–U for October of the prior year.[10] For example, for the adjustment made in 2017, agencies must compare the October 2016 CPI–U with the October 2015 CPI–U.

The 2015 amendments also provide that agencies may forgo the required annual adjustments in certain circumstances. Specifically, in a subsection titled ''Other Adjustments Made,'' the statute provides that an agency is not required to make an annual adjustment to a CMP if it has been increased by a greater amount than the contemplated annual adjustment in the preceding 12 months.[11] When these criteria are met, the agency has discretion not to make the adjustments otherwise required by the statute.

In addition, the 2015 amendments directed the Office of Management and Budget (OMB) to issue guidance to agencies on implementing the inflation adjustments.[12] OMB is required to issue its guidance each December and did so on December 16, 2016.[13] This OMB guidance for the upcoming 2017 adjustments includes an inflationary multiplier (1.01636) to apply to each current CMP maximum amount to determine the adjusted maximum. The guidance also addresses the exception described above for adjustments made in the preceding 12 months, indicating that the exception applies to adjustments made due to a law other than the 2015 amendments.[14] Finally, the guidance addresses rulemaking procedures and agency reporting and oversight requirements.

The next section sets forth the Board's calculation of the adjustments for 2017, in accordance with the foregoing requirements.

B. Application to the 2017 Adjustments

This section applies the statutory requirements and OMB's guidance to NCUA CMPs.

As explained above, the 2015 amendments require NCUA to adjust the

[1] Public Law 104–134, Sec. 31001(s), 110 Stat. 1321–373 (Apr. 26, 1996). The law is codified at 28 U.S.C. 2461 note.

[2] Public Law 101–410, 104 Stat. 890 (Oct. 5, 1990), codified at 28 U.S.C. 2461 note.

[3] Public Law 114–74, 129 Stat. 584 (Nov. 2, 2015).

[4] 129 Stat. 599.

[5] Public Law 114–74, Sec. 701(b)(1), 129 Stat. 584, 599 (Nov. 2, 2015).

[6] 81 FR 40152 (June 21, 2016); 81 FR 78028 (Nov. 7, 2016).

[7] Public Law 114–74, Sec. 701(b)(1), 129 Stat. 584, 599 (Nov. 2, 2015).

[8] Id.

[9] This index is published by the Department of Labor, Bureau of Labor Statistics, and is available at its Web site: *http://www.bls.gov/cpi/.*

[10] Public Law 114–74, Sec. 701(b)(1)(2)(B), 129 Stat. 584, 600 (Nov. 2, 2015).

[11] Public Law 114–74, Sec. 701(b)(1), 129 Stat. 584, 600 (Nov. 2, 2015).

[12] Public Law 114–74, Sec. 701(b)(4), 129 Stat. 584, 601 (Nov. 2, 2015).

[13] Id.; OMB, Implementation of the 2017 Annual Adjustment Pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, M–17–11 (Dec. 16, 2016), *available at https://www.whitehouse.gov/sites/default/files/omb/memoranda/2017/m-17-11_0.pdf* (noting that the applicable 2017 CMP-adjustment multiplier is 1.01636).

[14] Id. at 3.

maximum amounts of its CMPs by the percentage by which the October 2016 CPI–U (241.729) exceeds the October 2015 CPI–U (237.838). This percentage is 1.636. This percentage increase can be expressed as an inflation multiplier (the quotient of the October 2016 figure divided by the October 2015 figure). Accordingly, each CMP maximum amount should be multiplied by 1.01636 to determine the adjusted maximum amount. OMB's guidance identifies the same multiplier.

The Board has considered the exception in the 2015 amendments for adjustments made in the preceding 12 months, discussed above, but has decided not to invoke it. The OMB guidance indicates that this exception applies when the adjustments in the preceding 12 months were made under authority other than the 2015 amendments. The Board finds this reading of the statute reasonable. Even if this exception did apply as a threshold matter, there would be good reasons not to apply it. First, the adjustments calculated below are relatively minor, as the maximums will increase by about 1.6 percent. Second, NCUA is not required to and historically has not assessed CMPs at the maximum levels. Third, if NCUA chose to forgo the increases this year, it would not be able to capture this inflation in later years, which would cause the maximums to fall out of line with annual inflation. Finally, the Board anticipates that the federal banking agencies will not apply this exception to CMPs for which NCUA and the banking agencies have concurrent jurisdiction. Although NCUA is not required to make its adjustments in accord with any other agency, maintaining consistency in this area is desirable. In sum, even if the exception might apply, the Board would not invoke it this year.

The table below presents the adjustment calculations. The current maximums are found at 12 CFR 747.1001, as adjusted in June 2016. This amount is multiplied by the inflation multiplier to calculate the new maximum in the far right column. Only these adjusted maximum amounts, and not the calculations, will be codified at 12 CFR 747.1001 under this interim final rule. The adjusted amounts will be effective January 15, 2017, and can be applied to violations that occurred on or after November 2, 2015, the date the 2015 amendments were enacted.

TABLE—CALCULATION OF MAXIMUM CMP ADJUSTMENTS

Citation	Description/tier [15]	Current maximum ($)	Multiplier	Adjusted maximum ($) (Current maximum × multiplier)
12 U.S.C. 1782(a)(3)	Inadvertent failure to submit a report or the inadvertent submission of a false or misleading report.	3,787	1.01636	3,849.
12 U.S.C. 1782(a)(3)	Non-inadvertent failure to submit a report or the non-inadvertent submission of a false or misleading report.	37,872	1.01636	38,492.
12 U.S.C. 1782(a)(3)	Failure to submit a report or the submission of a false or misleading report done knowingly or with reckless disregard.	Lesser of 1,893,610 or 1% of total CU assets.	1.01636	Lesser of 1,924,589 or 1% of total CU assets.
12 U.S.C. 1782(d)(2)(A)	Tier 1 CMP for inadvertent failure to submit certified statement of insured shares and charges due to NCUSIF, or inadvertent submission of false or misleading statement.	3,462	1.01636	3,519.
12 U.S.C. 1782(d)(2)(B)	Tier 2 CMP for non-inadvertent failure to submit certified statement or submission of false or misleading statement.	34,620	1.01636	35,186.
12 U.S.C. 1782(d)(2)(C)	Tier 3 CMP for failure to submit a certified statement or the submission of a false or misleading statement done knowingly or with reckless disregard.	Lesser of 1,730,990 or 1% of total CU assets.	1.01636	Lesser of 1,759,309 or 1% of total CU assets.
12 U.S.C. 1785(a)(3)	Non-compliance with insurance logo requirements	118	1.01636	120.
12 U.S.C. 1785(e)(3)	Non-compliance with NCUA security requirements	275	1.01636	279.
12 U.S.C. 1786(k)(2)(A)	Tier 1 CMP for violations of law, regulation, and other orders or agreements.	9,468	1.01636	9,623.
12 U.S.C. 1786(k)(2)(B)	Tier 2 CMP for violations of law, regulation, and other orders or agreements and for recklessly engaging in unsafe or unsound practices or breaches of fiduciary duty.	47,340	1.01636	48,114.
12 U.S.C. 1786(k)(2)(C)	Tier 3 CMP for knowingly committing the violations under Tier 1 or 2 (natural person).	1,893,610	1.01636	1,924,589.
12 U.S.C. 1786(k)(2)(C)	Tier 3 (same) (CU)	Lesser of 1,893,610 or 1% of total CU assets.	1.01636	Lesser of 1,924,589 or 1% of total CU assets.
12 U.S.C. 1786(w)(5)(A)(ii)	Non-compliance with senior examiner post-employment restrictions.	311,470	1.01636	316,566.
15 U.S.C. 1639e(k)	Non-compliance with appraisal independence standards (first violation).	10,875	1.01636	11,053.
15 U.S.C. 1639e(k)	Subsequent violations of the same	21,749	1.01636	22,105.
42 U.S.C. 4012a(f)(5)	Non-compliance with flood insurance requirements	2,056	1.01636	2,090.

[15] The table uses condensed descriptions of CMP tiers. Refer to the U.S. Code citations for complete descriptions.

III. Regulatory Procedures

A. Interim Final Rule Under the APA

In the 2015 amendments to the FCPIA Act, Congress provided that agencies shall make the required inflation adjustments in 2017 and subsequent years notwithstanding 5 U.S.C. 553,[16] which requires agencies to follow notice-and-comment procedures in rulemaking and to make rules effective no sooner than 30 days after publication in the **Federal Register**. The 2015 amendments provide a clear exception to these requirements.[17] In addition, the Board finds that notice-and-comment procedures would be impracticable and unnecessary under the APA because of the largely ministerial and technical nature of the rule, which affords agencies limited discretion in promulgating the rule, and the statutory deadline for making the adjustments.[18] In these circumstances, the Board finds good cause to issue an interim final rule without issuing a notice of proposed rulemaking. The Board also finds good cause to make the interim final rule effective upon publication because of the statutory deadline. Accordingly, this interim final rule is issued without prior notice and will become effective immediately upon publication. However, the Board invites comments on all aspects of the interim final rule. The Board will review and consider all comments before issuing a final rule.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act requires the Board to prepare an analysis to describe any significant economic impact a regulation may have on a substantial number of small entities.[19] For purposes of this analysis, the Board considers small credit unions to be those having under $100 million in assets.[20] This interim final rule will not have a significant economic impact on a substantial number of small credit unions because it only affects the maximum amounts of CMPs that may be assessed in individual cases, which are not numerous and generally do not involve assessments at the maximum level. In addition, several of the CMPs are limited to a percentage of a credit union's assets. Finally, in assessing CMPs, the Board generally must consider a party's financial resources.[21] Because this interim final rule will affect few, if any, small credit unions, the Board certifies that the final rule will not have a significant economic impact on small entities.

C. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (PRA) applies to rulemakings in which an agency creates a new paperwork burden on regulated entities or modifies an existing burden.[22] For purposes of the PRA, a paperwork burden may take the form of either a reporting or a recordkeeping requirement, both referred to as information collections. This interim final rule adjusts the maximum amounts of certain CMPs that the Board may assess against individuals, entities, or credit unions but does not require any reporting or recordkeeping. Therefore, this interim final rule will not create new paperwork burdens or modify any existing paperwork burdens.

D. Executive Order 13132

Executive Order 13132 encourages independent regulatory agencies to consider the impact of their actions on state and local interests. In adherence to fundamental federalism principles, NCUA, an independent regulatory agency as defined in 44 U.S.C. 3502(5), voluntarily complies with the executive order. This interim final rule adjusts the maximum amounts of certain CMPs that the Board may assess against individuals, entities, and federally insured credit unions, including state-chartered credit unions. However, the interim final rule does not create any new authority or alter the underlying statutory authorities that enable the Board to assess CMPs. Accordingly, this interim final rule will not have a substantial direct effect on the states, on the connection between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. The Board has determined that this interim final rule does not constitute a policy that has federalism implications for purposes of the executive order.

E. Assessment of Federal Regulations and Policies on Families

The Board has determined that this interim final rule will not affect family well-being within the meaning of Section 654 of the Treasury and General Government Appropriations Act, 1999.[23]

F. Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act of 1996 [24] (SBREFA) provides generally for congressional review of agency rules. A reporting requirement is triggered in instances where the Board issues a final rule as defined by Section 551 of the APA.[25] The Board has submitted this interim final rule to OMB for it to determine whether it is a ''major rule'' within the meaning of the relevant sections of SBREFA.

List of Subjects in 12 CFR Part 747

Civil monetary penalties, Credit unions.

By the National Credit Union Administration Board on January 6, 2017.

Gerard S. Poliquin,

Secretary of the Board.

For the reasons stated above, the NCUA Board amends 12 CFR part 747 as follows:

PART 747—ADMINISTRATIVE ACTIONS, ADJUDICATIVE HEARINGS, RULES OF PRACTICE AND PROCEDURE, AND INVESTIGATIONS

■ 1. The authority citation for part 747 continues to read as follows:

Authority: 12 U.S.C. 1766, 1782, 1784, 1785, 1786, 1787, 1790a, 1790d; 15 U.S.C. 1639e; 42 U.S.C. 4012a; Pub. L. 101–410; Pub. L. 104–134; Pub. L. 109–351; Pub. L. 114–74.

Subpart K—Inflation Adjustment of Civil Monetary Penalties

■ 2. Revise § 747.1001 to read as follows:

§ 747.1001 Adjustment of civil monetary penalties by the rate of inflation.

(a) NCUA is required by the Federal Civil Penalties Inflation Adjustment Act of 1990 (Pub. L. 101–410, 104 Stat. 890, as amended (28 U.S.C. 2461 note)) to adjust the maximum amount of each civil monetary penalty within its jurisdiction by the rate of inflation. The following chart displays those adjusted amounts, as calculated pursuant to the statute:

[16] Public Law 114–74, Sec. 701(b)(1), 129 Stat. 584, 599 (Nov. 2, 2015).

[17] See 5 U.S.C. 559; *Asiana Airlines* v. *Fed. Aviation Admin.,* 134 F.3d 393, 396–99 (D.C. Cir. 1998).

[18] 5 U.S.C. 553(b)(3)(B); see *Mid-Tex Elec. Co-op., Inc.* v. *Fed. Energy Regulatory Comm'n,* 822 F.2d 1123, 1133–34 (D.C. Cir. 1987).

[19] 5 U.S.C. 603(a).

[20] Interpretive Ruling and Policy Statement 15–1, 80 FR 57512 (Sept. 24, 2015).

[21] 12 U.S.C. 1786(k)(2)(G)(i).

[22] 44 U.S.C. 3507(d); 5 CFR part 1320.

[23] Public Law 105–277, 112 Stat. 2681 (Oct. 21, 1998).

[24] Public Law 104–121, 110 Stat. 857 (Mar. 29, 1996).

[25] 5 U.S.C. 551.

U.S. Code citation	CMP description	New maximum amount
(1) 12 U.S.C. 1782(a)(3)	Inadvertent failure to submit a report or the inadvertent submission of a false or misleading report.	$3,849.
(2) 12 U.S.C. 1782(a)(3)	Non-inadvertent failure to submit a report or the non-inadvertent submission of a false or misleading report.	$38,492.
(3) 12 U.S.C. 1782(a)(3)	Failure to submit a report or the submission of a false or misleading report done knowingly or with reckless disregard.	$1,924,589 or 1 percent of the total assets of the credit union, whichever is less.
(4) 12 U.S.C. 1782(d)(2)(A)	Tier 1 CMP for inadvertent failure to submit certified statement of insured shares and charges due to NCUSIF, or inadvertent submission of false or misleading statement.	$3,519.
(5) 12 U.S.C. 1782(d)(2)(B)	Tier 2 CMP for non-inadvertent failure to submit certified statement or submission of false or misleading statement.	$35,186.
(6) 12 U.S.C. 1782(d)(2)(C)	Tier 3 CMP for failure to submit a certified statement or the submission of a false or misleading statement done knowingly or with reckless disregard.	$1,759,309 or 1 percent of the total assets of the credit union, whichever is less.
(7) 12 U.S.C. 1785(a)(3)	Non-compliance with insurance logo requirements	$120.
(8) 12 U.S.C. 1785(e) (3)	Non-compliance with NCUA security requirements	$279.
(9) 12 U.S.C. 1786(k)(2)(A)	Tier 1 CMP for violations of law, regulation, and other orders or agreements.	$9,623.
(10) 12 U.S.C. 1786(k)(2)(A)	Tier 2 CMP for violations of law, regulation, and other orders or agreements and for recklessly engaging in unsafe or unsound practices or breaches of fiduciary duty.	$48,114.
(11) 12 U.S.C. 1786(k)(2)(A)	Tier 3 CMP for knowingly committing the violations under Tier 1 or 2 (natural person).	For a person other than an insured credit union: $1,924,589; For an insured credit union: $1,924,589 or 1 percent of the total assets of the credit union, whichever is less.
(12) 12 U.S.C. 1786(w)(5)(ii)	Non-compliance with senior examiner post-employment restrictions.	$316,566.
(13) 15 U.S.C. 1639e(k)	Non-compliance with appraisal independence requirements.	First violation: $11,053. Subsequent violations: $22,105.
(14) 42 U.S.C. 4012a(f)(5)	Non-compliance with flood insurance requirements	$2,090.

(b) The adjusted amounts displayed in paragraph (a) of this section apply to civil monetary penalties that are assessed after the date the increase takes effect, including those whose associated violation or violations pre-dated the increase and occurred after November 2, 2015.

[FR Doc. 2017–00473 Filed 1–19–17; 8:45 am]

BILLING CODE 7535–01–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Parts 730, 734, 736, 742, 744, and 745

[Docket No. 170103002–7002–01]

RIN 0694–AH22

Updated Statements of Legal Authority for the Export Administration Regulations

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Final rule.

SUMMARY: This rule updates the Code of Federal Regulations (CFR) legal authority citations in the Export Administration Regulations (EAR) to cite the most recent Presidential notice continuing an emergency declared pursuant to the International Emergency Economic Powers Act. This is a non-substantive rule that only updates authority paragraphs of the EAR. It does not alter any right, obligation or prohibition that applies to any person under the EAR.

DATES: The rule is effective January 23, 2017.

FOR FURTHER INFORMATION CONTACT: Nancy Kook, Regulatory Policy Division, Bureau of Industry and Security, Telephone: (202) 482–2440.

SUPPLEMENTARY INFORMATION:

Background

The authority for parts 730, 734, 736, 742, 744, and 745 of the EAR rests, in part, on Executive Order 12938 of November 14, 1994—Proliferation of Weapons of Mass Destruction, 59 FR 59099, 3 CFR, 1994 Comp., p. 950 and on annual notices continuing the emergency declared in that executive order. This rule revises the authority citations for the affected parts of the EAR to cite the most recent such notice, which the President signed on November 8, 2016.

This rule is purely non-substantive and makes no changes other than to revise CFR authority citations for the purpose of making the authority citations current. It does not change the text of any section of the EAR, nor does it alter any right, obligation or prohibition that applies to any person under the EAR.

Rulemaking Requirements

1. Executive Orders 13563 and 12866 direct 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). This rule does not impose any regulatory burden on the public and is consistent with the goals of Executive Order 13563. This rule has been determined to be not significant for purposes of Executive Order 12866.

2. Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork

Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. This rule does not involve any collection of information.

3. This rule does not contain policies with Federalism implications as that term is defined under Executive Order 13132.

4. The Department finds that there is good cause under 5 U.S.C. 553(b)(B) to waive the provisions of the Administrative Procedure Act requiring prior notice and the opportunity for public comment because they are unnecessary. This rule only updates legal authority citations. It clarifies information and is non-discretionary. This rule does not alter any right, obligation or prohibition that applies to any person under the EAR. Because these revisions are not substantive changes, it is unnecessary to provide notice and opportunity for public comment. In addition, the 30-day delay in effectiveness otherwise required by 5 U.S.C. 553(d) is not applicable because this rule is not a substantive rule. Because neither the Administrative Procedure Act nor any other law requires that notice of proposed rulemaking and an opportunity for public comment be given for this rule, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are not applicable. Accordingly, no Final Regulatory Flexibility Analysis is required and none has been prepared.

List of Subjects

15 CFR Part 730

Administrative practice and procedure, Advisory committees, Exports, Reporting and recordkeeping requirements, Strategic and critical materials.

15 CFR Part 734

Administrative practice and procedure, Exports, Inventions and patents, Research, Science and technology.

15 CFR Part 736

Exports.

15 CFR Part 742

Exports, Terrorism.

15 CFR Part 744

Exports, Reporting and recordkeeping requirements, Terrorism.

15 CFR Part 745

Administrative practice and procedure, Chemicals, Exports, Foreign trade, Reporting and recordkeeping requirements.

Accordingly, parts 730, 734, 736, 742, 744, and 745 of the EAR (15 CFR parts 730 through 774) are amended as follows:

PART 730—GENERAL INFORMATION

■ 1. The authority citation for 15 CFR part 730 is revised to read as follows:

Authority: 50 U.S.C. 4601 *et seq.;* 50 U.S.C. 1701 *et seq.;* 10 U.S.C. 7420; 10 U.S.C. 7430(e); 22 U.S.C. 287c; 22 U.S.C. 2151 note; 22 U.S.C. 3201 *et seq.;* 22 U.S.C. 6004; 42 U.S.C. 2139a; 15 U.S.C. 1824a; 50 U.S.C. 4305; 22 U.S.C. 7201 *et seq.;* 22 U.S.C. 7210; E.O. 11912, 41 FR 15825, 3 CFR, 1976 Comp., p. 114; E.O. 12002, 42 FR 35623, 3 CFR, 1977 Comp., p. 133; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12214, 45 FR 29783, 3 CFR, 1980 Comp., p. 256; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12854, 58 FR 36587, 3 CFR, 1993 Comp., p. 179; E.O. 12918, 59 FR 28205, 3 CFR, 1994 Comp., p. 899; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 12947, 60 FR 5079, 3 CFR, 1995 Comp., p. 356; E.O. 12981, 60 FR 62981, 3 CFR, 1995 Comp., p. 419; E.O. 13020, 61 FR 54079, 3 CFR, 1996 Comp., p. 219; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13099, 63 FR 45167, 3 CFR, 1998 Comp., p. 208; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13224, 66 FR 49079, 3 CFR, 2001 Comp., p. 786; E.O. 13338, 69 FR 26751, 3 CFR, 2004 Comp., p 168; E.O. 13637, 78 FR 16129, 3 CFR, 2014 Comp., p. 223; Notice of January 20, 2016, 81 FR 3937 (January 22, 2016); Notice of May 3, 2016, 81 FR 27293 (May 5, 2016); Notice of August 4, 2016, 81 FR 52587 (August 8, 2016); Notice of September 15, 2016, 81 FR 64343 (September 19, 2016); Notice of November 8, 2016, 81 FR 79379 (November 10, 2016).

PART 734—SCOPE OF THE EXPORT ADMINISTRATION REGULATIONS

■ 2. The authority citation for 15 CFR part 734 is revised to read as follows:

Authority: 50 U.S.C. 4601 *et seq.;* 50 U.S.C. 1701 *et seq.;* E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13020, 61 FR 54079, 3 CFR, 1996 Comp., p. 219; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13637, 78 FR 16129, 3 CFR, 2014 Comp., p. 223;; Notice of August 4, 2016, 81 FR 52587 (August 8, 2016); Notice of November 8, 2016, 81 FR 79379 (November 10, 2016).

PART 736—GENERAL PROHIBITIONS

■ 3. The authority citation for 15 CFR part 736 is revised to read as follows:

Authority: 50 U.S.C. 4601 *et seq.;* 50 U.S.C. 1701 *et seq.;* 22 U.S.C. 2151 note; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13020, 61 FR 54079, 3 CFR, 1996 Comp., p. 219; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13338, 69 FR 26751, 3 CFR, 2004 Comp., p. 168; Notice of May 3, 2016, 81 FR 27293 (May 5, 2016); Notice of August 4, 2016, 81 FR 52587 (August 8, 2016); Notice of November 8, 2016, 81 FR 79379 (November 10, 2016).

PART 742—CONTROL POLICY—CCL BASED CONTROLS

■ 4. The authority citation for 15 CFR part 742 is revised to read as follows:

Authority: 50 U.S.C. 4601 *et seq.;* 50 U.S.C. 1701 *et seq.;* 22 U.S.C. 3201 *et seq.;* 42 U.S.C. 2139a; 22 U.S.C. 7201 *et seq.;* 22 U.S.C. 7210; Sec. 1503, Pub. L. 108–11, 117 Stat. 559; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Presidential Determination 2003–23, 68 FR 26459, 3 CFR, 2004 Comp., p. 320; Notice of August 4, 2016, 81 FR 52587 (August 8, 2016); Notice of November 8, 2016, 81 FR 79379 (November 10, 2016).

PART 744—CONTROL POLICY: END-USER AND END-USE BASED

■ 5. The authority citation for 15 CFR part 744 is revised to read as follows:

Authority: 50 U.S.C. 4601 *et seq.;* 50 U.S.C. 1701 *et seq.;* 22 U.S.C. 3201 *et seq.;* 42 U.S.C. 2139a; 22 U.S.C. 7201 *et seq.;* 22 U.S.C. 7210; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 12947, 60 FR 5079, 3 CFR, 1995 Comp., p. 356; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13099, 63 FR 45167, 3 CFR, 1998 Comp., p. 208; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13224, 66 FR 49079, 3 CFR, 2001 Comp., p. 786; Notice of January 20, 2016, 81 FR 3937 (January 22, 2016); Notice of August 4, 2016, 81 FR 52587 (August 8, 2016); Notice of September 15, 2016, 81 FR 64343 (September 19, 2016); Notice of November 8, 2016, 81 FR 79379 (November 10, 2016).

PART 745—CHEMICAL WEAPONS CONVENTION REQUIREMENTS

■ 6. The authority citation for 15 CFR part 745 is revised to read as follows:

Authority: 50 U.S.C. 1701 *et seq.;* E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950); Notice of November 8, 2016, 81 FR 79379 (November 10, 2016).

Dated: January 6, 2017.

Kevin J. Wolf,

Assistant Secretary for Export Administration.

[FR Doc. 2017–00443 Filed 1–19–17; 8:45 am]

BILLING CODE 3510–33–P

COMMODITY FUTURES TRADING COMMISSION

17 CFR Part 143

RIN 3038–AE51

Annual Adjustment of Civil Monetary Penalties for Inflation—2017

AGENCY: Commodity Futures Trading Commission.

ACTION: Interim final rule.

SUMMARY: The Commodity Futures Trading Commission (Commission) is amending its rule that governs the maximum amount of civil monetary penalties, to adjust for inflation. This rule sets forth the maximum, inflation-adjusted dollar amount for civil monetary penalties (CMPs) assessable for violations of the Commodity Exchange Act (CEA) and Commission rules, regulations and orders thereunder. The rule, as amended, implements the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended.

DATES: *Effective Date:* This interim final rule is effective January 23, 2017.

FOR FURTHER INFORMATION CONTACT: Edward J. Riccobene, Associate Chief Counsel, Division of Enforcement, at (202) 418–5327 or *ericcobene@cftc.gov,* Commodity Futures Trading Commission, 1155 21st Street NW., Washington, DC 20581.

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Civil Penalties Inflation Adjustment Act of 1990 (FCPIAA) [1] requires the head of each Federal agency to periodically adjust for inflation the minimum and maximum amount of CMPs provided by law within the jurisdiction of that agency.[2] A 2015 amendment to the FCPIAA [3] required agencies to make an initial ''catch-up'' adjustment to its civil monetary penalties effective no later than August 1, 2016.[4] For every year thereafter effective not later than January 15, the FCPIAA, as amended, requires agencies to make annual adjustments for inflation, with guidance from the Director of the Office of Management and Budget.[5]

II. Commodity Exchange Act Civil Monetary Penalties

The CEA provides for CMPs that meet the FCPIAA definition [6] and these CMPs are, therefore, subject to the inflation adjustment in the following instances: Sections 6(c), 6(d), 6b, and 6c of the CEA.[7]

Section 6(c) of the CEA,[8] as adjusted by the FCPIAA,[9] currently sets the maximum CMP that may be imposed by the Commission, in a proceeding initiated on or after August 1, 2016, on ''any person (other than a registered entity)'' for: (1) Each violation of Section 6(c) of the CEA or any other provisions of the Act or of the rules, regulations, or orders of the Commission thereunder to the greater of $152,243 or triple the monetary gain to the violator; and (2) any manipulation or attempted manipulation in violation of Section 6(c) or 9(a)(2) of the CEA to the greater of $1,098,190 or triple the monetary gain to the violator.

Section 6(d) of the CEA,[10] as adjusted by the FCPIAA,[11] currently sets the maximum CMP that may be imposed by the Commission, in a proceeding initiated on or after August 1, 2016, on ''any person (other than a registered entity)'' [12] for violations of the CEA or any other provisions of the CEA or of the rules, regulations, or orders of the Commission thereunder to the greater of $152,243 or triple the monetary gain to the violator.

Section 6b of the CEA [13] provides that the Commission, in an administrative proceeding, may impose a CMP on: (1) Any registered entity for not enforcing or has not enforced its rules of government made a condition of its designation or registration as set forth in the CEA, or (2) any registered entity, or any director, officer, agent, or employee of any registered entity, for violations of the CEA or any rules, regulations, or orders of the Commission thereunder. In actions initiated on or after August 1, 2016, for each violation for which a CMP is assessed pursuant to Section 6b, the current, FCPIAA-adjusted maximum penalty is set at: The greater of $1,098,190 or triple the monetary gain to such person for manipulation or attempted manipulation in violation of Section 6(c), 6(d), or 9(a)(2) of the CEA; and the greater of $838,640 or triple the monetary gain to such person for all other violations.[14]

Section 6c of the CEA [15] provides that Commission may bring an action in the proper district court of the United States or the proper United States court of any territory or other place subject to the jurisdiction of the United States and the court may impose on a CMP on ''any registered entity or other person'' found by the court to have committed any violation of any provision of the CEA or any rule, regulation, or order thereunder, or is restraining trading in any commodity for future delivery or any swap. In actions initiated on or after August 1, 2016, for each violation for which a CMP is assessed pursuant to Section 6c(d), the current, FCPIAA-adjusted maximum penalty is set at: The greater of $1,098,190 or triple the monetary gain to such person for manipulation or attempted manipulation in violation of Section 6(c), 6(d), or 9(a)(2) of the CEA; and the greater of $167,728 or triple the monetary gain to such person for all other violations.[16]

III. Annual Inflation Adjustment for Commodity Exchange Act Civil Monetary Penalties

A. Methodology

The annual inflation adjustment under the FCPIAA, in the context of the CFTC's CMPs, is determined by increasing the maximum penalty by a ''cost-of-living adjustment,'' rounded to

[1] The FCPIAA, Public Law 101–410 (1990), as amended, is codified at 28 U.S.C. 2461 note. The FCPIAA states that the purpose of the act is to establish a mechanism that (1) allows for regular adjustment for inflation of civil monetary penalties; (2) maintains the deterrent effect of civil monetary penalties and promote compliance with the law; and (3) improves the collection by the Federal Government of civil monetary penalties.

[2] For the relevant CMPs within the Commission's jurisdiction, the Act provides only for maximum amounts that can be assessed for each violation of the Act or the rules, regulations and orders promulgated thereunder; the Act does not set forth any minimum penalties. Therefore, the remainder of this release will refer only to CMP maximums.

[3] Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, 2015 Act, Public Law 114–74, 129 Stat. 584 (2015), title VII, Section 701.

[4] FCPIAA Sections 4 and 5. See also, Adjustment of Civil Monetary Penalties for Inflation, 81 FR 41435 (June 27, 2016) (to be codified at 17 CFR 143.8).

[5] FCPIAA Sections 4 and 5. See also, Executive Office of the President, Office of Management and Budget Memorandum, M–17–11, Implementation of the 2017 annual adjustment pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Dec. 16, 2016) available at *https://www.whitehouse.gov/sites/default/files/omb/memoranda/2017/m-17-11_0.pdf.*

[6] FCPIAA Section 3(2).

[7] 7 U.S.C. 9, 13a, 13a–1, 13b.

[8] 7 U.S.C. 9.

[9] See 17 CFR 143.8(a)(1)(ii).

[10] 7 U.S.C. 13b.

[11] See 17 CFR 143.8(a)(2)(ii).

[12] The term ''registered entity'' is a defined term under the CEA. Section 1a(40) provides that the term ''registered entity'' means (A) a board of trade designated as a contract market under section 7 of the act; (B) a derivatives clearing organization registered under section 7a–1 of this act; (C) a board of trade designated as a contract market under section 7b–1 of the act; (D) a swap execution facility registered under section 7b–3 of this title; (E) a swap data repository registered under section 24a of the act; and (F) with respect to a contract that the Commission determines is a significant price discovery contract, any electronic trading facility on which the contract is executed or traded. 7 U.S.C. 1a(40).

[13] 7 U.S.C. 13a.

[14] 17 CFR 143.8(a)(3)(ii).

[15] 7 U.S.C. 13a–1.

[16] 17 CFR 143.8(a)(4)(ii).

the nearest multiple of one dollar.[17] Annual inflation adjustments are based on the percent change between the October Consumer Price Index for all Urban Consumers (CPI–U) preceding the date of the adjustment, and the prior year's October CPI–U.[18] In this case, October 2016 CPI–U (241.729)/October 2015 CPI–U (237.838) = 1.01636.[19] In order to complete the 2017 annual adjustment, the CFTC must multiply each of its most recent CMP amounts by the multiplier, 1.01636, and round to the nearest dollar.

B. Civil Monetary Penalty Adjustments

Applying the FCPIAA annual inflation adjustment methodology results in the following amended CMPs:

Citation	Description	Current inflation adjusted CMP amount	2017 Annual inflation adjusted CMP amount
Section 6(c) of the CEA, 7 U.S.C. 9	Prohibition Regarding Manipulation and False Information [Other Violation (Non-Manipulation)].	$152,243	$154,734
Section 6(c) of the CEA, 7 U.S.C. 9	Prohibition Regarding Manipulation and False Information [Manipulation or Attempted Manipulation].	1,098,190	1,116,156
Section 6(d) of the CEA, 7 U.S.C. 13b.	Manipulations or Other Violations; Cease and Desist Orders Against Persons Other Than Registered Entities; Punishment; Misdemeanor or Felony; Separate Offenses.	152,243	154,734
Section 6b of the CEA, 7 U.S.C. 13a.	Nonenforcement of Rules of Government or Other Violations; Cease and Desist Orders; Fines and Penalties; Imprisonment; Misdemeanor; Separate Offenses [Other Violation (Non-Manipulation)].	838,640	852,360
Section 6b of the CEA, 7 U.S.C. 13a.	Nonenforcement of Rules of Government or Other Violations; Cease and Desist Orders; Fines and Penalties; Imprisonment; Misdemeanor; Separate Offenses [Manipulation or Attempted Manipulation].	1,098,190	1,116,156
Section 6c of the CEA, 7 U.S.C. 13a–1.	Enjoining or Restraining Violations [Other Violation (Non-Manipulation)]	167,728	170,472
Section 6c of the CEA, 7 U.S.C. 13a–1.	Enjoining or Restraining Violations [Manipulation or Attempted Manipulation].	1,098,190	1,116,156

The FCPIAA provides that any increase under [the FCPIAA] in a civil monetary penalty shall apply only to civil monetary penalties, including those whose associated violation predated such increase, which are assessed after the date the increase takes effect.[20] Thus, the new CMP amounts established by this rulemaking may be applied only in Commission administrative or civil injunctive enforcement proceedings that are initiated on or after the effective date of this amendment, January 15, 2017.

IV. Administrative Compliance

A. Notice Requirement

The notice and comment procedures of 5 U.S.C. 553 do not apply to this rulemaking because the Commission is acting herein pursuant to statutory language which mandates that the Commission act in a nondiscretionary matter. *Lake Carriers' Ass'n* v. *E.P.A.,* 652 F.3d 1, 10 (D.C. Cir. 2011).[21]

B. Regulatory Flexibility Act

The Regulatory Flexibility Act [22] requires agencies with rulemaking authority to consider the impact of certain of their rules on small businesses. A regulatory flexibility analysis is only required for rules for which the agency publishes a general notice of proposed rulemaking pursuant to section 553(b) or any other law. Because the Commission is not obligated by section 553(b) or any other law to publish a general notice of proposed rulemaking with respect to the revisions being made to regulation 143.8, the Commission additionally is not obligated to conduct a regulatory flexibility analysis.

C. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (PRA),[23] which imposes certain requirements on Federal agencies, including the Commission, in connection with their conducting or sponsoring any collection of information as defined by the PRA, does not apply to this rule. This rule amendment does not contain information collection requirements that require the approval of the Office of Management and Budget.

D. Consideration of Costs and Benefits

Section 15(a) of the CEA [24] requires the Commission to consider the costs and benefits of its action before issuing a new regulation. Section 15(a) further specifies that costs and benefits shall be evaluated in light of five broad areas of market and public concern: (1) Protection of market participants and the public; (2) efficiency, competitiveness, and financial integrity of futures markets; (3) price discovery; (4) sound risk management practices; and (5) other public interest considerations.

The Commission believes that benefits of this rulemaking greatly outweigh the costs, if any. As the Commission understands, the statutory provisions by which it is making cost-of-living adjustments to the CMPs in regulation 143.8 were enacted to ensure that CMPs do not lose their deterrence value because of inflation. An analysis of the costs and benefits of these adjustments were made before enactment of the statutory provisions under which the Commission is operating, and limit the discretion of the Commission to the extent that there are

[17] FCPIAA Sections 4 and 5.

[18] FCPIAA Section 5(b)(1).

[19] The CPI–U is published by the Department of Labor. Interested parties may find the relevant Consumer Price Index on the Internet. To access this information, go to the Consumer Price Index Home Page at: *http://www.bls.gov/cpi/.* Under the ''CPI Databases'' heading, select ''All Urban Consumers (Current Series)'', ''Top Picks.'' Then check the box for ''U.S. All items, 1982–84 = 100 – CUUR0000SA0'', and click the ''Retrieve data'' button.

[20] FCPIAA Section 6.

[21] The Commission has determined that the amendment to rule 143.8 is exempt from the provisions of the Administrative Procedure Act, 5 U.S.C. 553, which generally require notice of proposed rulemaking and provide other opportunities for public participation, but excludes rules of agency practice, such as those found in part 143 of the Commission's regulations, and in particular rule 143.8 being revised herein.

[22] 5 U.S.C. 601–612.

[23] 44 U.S.C. 3507(d).

[24] 7 U.S.C. 19(a).

no regulatory choices the Commission could make that would supersede the pre-enactment analysis with respect to the five factors enumerated in section 15(a), or any other factors.

List of Subjects in 17 CFR Part 143

Civil monetary penalties, Claims.

For the reasons stated in the preamble, the Commodity Futures Trading Commission amends part 17 CFR part 143 as follows:

PART 143—COLLECTION OF CLAIMS OWED THE UNITED STATES ARISING FROM ACTIVITIES UNDER THE COMMISSION'S JURISDICTION

■ 1. The authority citation for part 143 continues to read as follows:

Authority: 7 U.S.C. 9, 15, 9a, 12a(5), 13a, 13a–1(d), 13(a), 13b; 31 U.S.C. 3701–3720E; 28 U.S.C. 2461 note.

■ 2. Amend § 143.8 as follows:
■ a. Revise paragraphs (a)(1)(ii) introductory text, (a)(2)(ii), (a)(3)(ii) introductory text, and (a)(4)(ii) introductory text; and
■ b. Add paragraphs (a)(1)(iii), (a)(2)(iii), (a)(3)(iii), and (a)(4)(iii).

The revisions and additions read as follows:

§ 143.8 Inflation-adjusted civil monetary penalties.

(a) * * *

(1) * * *

(ii) In an administrative proceeding before the Commission or a civil action in Federal court initiated on August 1, 2016 through January 14, 2017:

* * * * *

(iii) In an administrative proceeding before the Commission or a civil action in Federal court initiated on or after January 15, 2017:

(A) For manipulation or attempted manipulation violations, not more than the greater of $1,116,156 or triple the monetary gain to such person for each such violation; and

(B) For all other violations, not more than the greater of $154,734 or triple the monetary gain to such person for each such violation; and

(2) * * *

(ii) In an administrative proceeding before the Commission or a civil action in Federal court initiated on August 1, 2016 through January 14, 2017, not more than the greater of $152,243 or triple the monetary gain to such person for each such violation;

(iii) In an administrative proceeding before the Commission or a civil action in Federal court initiated on or after January 15, 2017, not more than the greater of $154,734 or triple the monetary gain to such person for each such violation; and

(3) * * *

(ii) In an administrative proceeding before the Commission or a civil action in Federal court initiated on August 1, 2016 through January 14, 2017:

* * * * *

(iii) In an administrative proceeding before the Commission or a civil action in Federal court initiated on or after January 15, 2017:

(A) For manipulation or attempted manipulation violations, not more than the greater of $1,116,156 or triple the monetary gain to such person for each such violation; and

(B) For all other violations, not more than the greater of $852,360 or triple the monetary gain to such person for each such violation; and

(4) * * *

(ii) In an administrative proceeding before the Commission or a civil action in Federal court initiated on August 1, 2016 through January 14, 2017:

* * * * *

(iii) In an administrative proceeding before the Commission or a civil action in Federal court initiated on or after January 15, 2017:

(A) For manipulation or attempted manipulation violations, not more than the greater of $1,116,156 or triple the monetary gain to such person for each such violation; and

(B) For all other violations, not more than the greater of $170,472 or triple the monetary gain to such person for each such violation.

* * * * *

Issued in Washington, DC, on January 6, 2017, by the Commission.

Robert N. Sidman,

Deputy Secretary of the Commission.

Note: The following appendix will not appear in the Code of Federal Regulations.

Appendix to Adjustment of Civil Monetary Penalties for Inflation—2017—Commission Voting Summary

On this matter, Chairman Massad and Commissioners Bowen and Giancarlo voted in the affirmative. No Commissioner voted in the negative.

[FR Doc. 2017–00488 Filed 1–19–17; 8:45 am]

BILLING CODE 6351–01–P

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 232

[Release Nos. 33–10265; 34–79519; 39–2513; IC–32387]

Adoption of Updated EDGAR Filer Manual

AGENCY: Securities and Exchange Commission.

ACTION: Final rule.

SUMMARY: The Securities and Exchange Commission (the Commission) is adopting revisions to the Electronic Data Gathering, Analysis, and Retrieval System (EDGAR) Filer Manual and related rules to reflect updates to the EDGAR system. The updates are being made primarily to support the submission of Municipal Advisor submission form types. The EDGAR system is scheduled to be upgraded to support the other functionalities on December 12, 2016.

DATES: Effective January 23, 2017. The incorporation by reference of the EDGAR Filer Manual is approved by the Director of the Federal Register as of January 23, 2017.

FOR FURTHER INFORMATION CONTACT: In the Division of Corporation Finance, for questions concerning Form ABS–EE and Regulation A submission form types, contact Vik Sheth at (202) 551–3818; in the Division of Trading and Markets, for questions concerning Form MA and Form 17–H, contact Kathy Bateman at (202) 551–4345; and in the Division of Economic and Risk Analysis, for questions concerning eXtensible Business Reporting Language (XBRL) submissions; contact Walter Hamscher at (202) 551–5397.

SUPPLEMENTARY INFORMATION: We are adopting an updated EDGAR Filer Manual, Volume I and Volume II. The Filer Manual describes the technical formatting requirements for the preparation and submission of electronic filings through the EDGAR system.[1] It also describes the requirements for filing using EDGARLink Online and the Online Forms/XML Web site.

The revisions to the Filer Manual reflect changes within Volume I entitled EDGAR Filer Manual, Volume I: ''General Information,'' Version 25 (December 2016), and Volume II entitled

[1] We originally adopted the Filer Manual on April 1, 1993, with an effective date of April 26, 1993. Release No. 33–6986 (April 1, 1993) [58 FR 18638]. We implemented the most recent update to the Filer Manual on September 19, 2016. *See* Release No. 33–10217 (September 30, 2016) [81 FR 67118].

EDGAR Filer Manual, Volume II: ''EDGAR Filing,'' Version 39 (December 2016). The updated manual will be incorporated by reference into the Code of Federal Regulations.

The Filer Manual contains all the technical specifications for filers to submit filings using the EDGAR system. Filers must comply with the applicable provisions of the Filer Manual in order to assure the timely acceptance and processing of filings made in electronic format.[2] Filers may consult the Filer Manual in conjunction with our rules governing mandated electronic filing when preparing documents for electronic submission.[3]

The EDGAR system will be upgraded to Release 16.4 on December 12, 2016 and will introduce the following changes:

Filers will be able to submit the Municipal Advisor submission form types MA, MA–A, MA/A, MA–I, MA–I/A, and MA–W in filer-constructed XML format from the EDGAR Filing Web site. For more information, see the ''EDGAR Form MA XML Technical Specification'' document available on the SEC's Public Web site (*https://www.sec.gov/info/edgar/tech-specs*).

Filers will be able to provide up to 200 owners instead of 50 owners for Schedules A–1, A–2, B–1, and B–2 within MA, MA–A, and MA/A submissions (Schedules A–1, A–2, B–1, and B–2 are amended via Schedule C for MA–A and MA/A submissions).

EDGAR will be upgraded to allow an entity with any Standard Industrial Classification (SIC) code value or no value (NULL) to request the creation of ABS Issuing Entities.

EDGAR will be updated to allow duplicate submissions for ABS–EE.

EDGARLink Online will be updated for ABS–EE and ABS–EE/A submissions such that non-existent CIKs will be flagged as errors during header data entry instead of after the submission has been sent and processed by EDGAR.

The ABS–EE Asset Data schema will be updated to introduce the following Asset Class Item with date format MM/YYYY:

- RMBS ABS Asset Class: Item 1(c)(13)(vi), Most Senior Lien Origination Date

In addition, the ABS–EE Asset Data schema will be updated to change the following Asset Class Item from an integer value to a percentage value:

- CMBS ABS Asset Class: Item 2(c)(28)(iv), ARM Margin Number

For more information, see the updated ''EDGAR ABS XML Technical Specification'' document located on the SEC's Public Web site (*https://www.sec.gov/info/edgar/tech-specs*).

EDGAR will transform word expressions for numbers, dates, and word or symbol expressions for QNames and nil expressions into their respective XML representations in Inline XBRL submissions. Filers will be able to provide typed dimensions in XBRL submissions. In addition, the following HTML tags will be usable in traditional XBRL documents: <SPAN>, <TBODY>, <TFOOT>, and <THEAD>.

All ASCII character validations will be removed for broker-dealer entity name fields on submission form types 17HACON, 17HACON/A, 17HQCON, and 17HQCON/A. Broker-dealers now will be able to submit the aforementioned filings, irrespective of the ASCII characters in the broker-dealer entity name.

Filers will be able to shift the order of the uploaded documents, and simultaneously select/de-select all uploaded documents on the ''Attach Documents List'' screen for the Regulation A submission form types DOS, DOS/A, 1–A, 1–A/A, 1–A POS, 1–K, and 1–K/A.

On October 31, 2016, the EDGAR system was upgraded to Release 16.3.3 and now supports the following changes:

The ABS–EE CMBS Asset Class Item 2(e)(17), ''Payment Status Loan Code'' associated types were updated to include the value ''0'' for loan payment status of ''Current''. For more information, see section 4.3.20 of the updated ''EDGAR ABS XML Technical Specification'' document located on the SEC's Public Web site (*https://www.sec.gov/info/edgar/tech-specs*).

The maximum allowable submission size for form types ABS–EE and ABS–EE/A was increased to 600 MB.

EDGAR was updated to remove the timeliness rule check, and to no longer verify if the submission form types NT 10–K, NTN 10K, NT 10–Q, NTN 10Q, NT 15D2, NTN15D2, NT 10–D, NTN 10D, NT 20–F, and NTN 20F were submitted before the filing deadline.

Along with the adoption of the Filer Manual, we are amending Rule 301 of Regulation S–T to provide for the incorporation by reference into the Code of Federal Regulations of today's revisions. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

The updated EDGAR Filer Manual will be available for Web site viewing and printing; the address for the Filer Manual is *https://www.sec.gov/info/edgar/edmanuals.htm.* You may also obtain paper copies of the EDGAR Filer Manual from the following address: Public Reference Room, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m.

Since the Filer Manual and the corresponding rule changes relate solely to agency procedures or practice, publication for notice and comment is not required under the Administrative Procedure Act (APA).[4] It follows that the requirements of the Regulatory Flexibility Act[5] do not apply.

The effective date for the updated Filer Manual and the rule amendments is January 23, 2017. In accordance with the APA,[6] we find that there is good cause to establish an effective date less than 30 days after publication of these rules. The EDGAR system upgrade to Release 16.4 is scheduled to become available on December 12, 2016. The Commission believes that establishing an effective date less than 30 days after publication of these rules is necessary to coordinate the effectiveness of the updated Filer Manual with these system upgrades.

Statutory Basis

We are adopting the amendments to Regulation S–T under Sections 6, 7, 8, 10, and 19(a) of the Securities Act of 1933,[7] Sections 3, 12, 13, 14, 15, 23, and 35A of the Securities Exchange Act of 1934,[8] Section 319 of the Trust Indenture Act of 1939,[9] and Sections 8, 30, 31, and 38 of the Investment Company Act of 1940.[10]

List of Subjects in 17 CFR Part 232

Incorporation by reference, Reporting and recordkeeping requirements, Securities.

Text of the Amendment

In accordance with the foregoing, Title 17, Chapter II of the Code of Federal Regulations is amended as follows:

[2] *See* Rule 301 of Regulation S–T (17 CFR 232.301).

[3] *See* Release No. 33–10217 in which we implemented EDGAR Release 16.3. For additional history of Filer Manual rules, please see the citations therein.

[4] 5 U.S.C. 553(b)(A).

[5] 5 U.S.C. 601–612.

[6] 5 U.S.C. 553(d)(3).

[7] 15 U.S.C. 77f, 77g, 77h, 77j, and 77s(a).

[8] 15 U.S.C. 78c, 78*l,* 78m, 78n, 78o, 78w, and 78*ll.*

[9] 15 U.S.C. 77sss.

[10] 15 U.S.C. 80a–8, 80a–29, 80a–30, and 80a–37.

PART 232—REGULATION S–T—GENERAL RULES AND REGULATIONS FOR ELECTRONIC FILINGS

■ 1. The authority citation for Part 232 continues to read in part as follows:

Authority: 15 U.S.C. 77f, 77g, 77h, 77j, 77s(a), 77z–3, 77sss(a), 78c(b), 78*l,* 78m, 78n, 78o(d), 78w(a), 78*ll,* 80a–6(c), 80a–8, 80a–29, 80a–30, 80a–37, and 7201 *et seq.;* and 18 U.S.C. 1350.

* * * * *

■ 2. Section 232.301 is revised to read as follows:

§ 232.301 EDGAR Filer Manual.

Filers must prepare electronic filings in the manner prescribed by the EDGAR Filer Manual, promulgated by the Commission, which sets out the technical formatting requirements for electronic submissions. The requirements for becoming an EDGAR Filer and updating company data are set forth in the updated EDGAR Filer Manual, Volume I: ''General Information,'' Version 25 (December 2016). The requirements for filing on EDGAR are set forth in the updated EDGAR Filer Manual, Volume II: ''EDGAR Filing,'' Version 39 (December 2016). Additional provisions applicable to Form N–SAR filers are set forth in the EDGAR Filer Manual, Volume III: ''N–SAR Supplement,'' Version 5 (September 2015). All of these provisions have been incorporated by reference into the Code of Federal Regulations, which action was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You must comply with these requirements in order for documents to be timely received and accepted. The EDGAR Filer Manual is available for Web site viewing and printing; the address for the Filer Manual is *https://www.sec.gov/info/edgar/edmanuals.htm.* You can obtain paper copies of the EDGAR Filer Manual from the following address: Public Reference Room, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. You can also inspect the document 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.*

By the Commission.

Dated: December 9, 2016.

Brent J. Fields,

Secretary.

[FR Doc. 2016–32032 Filed 1–19–17; 8:45 am]

BILLING CODE 8011–01–P

DELAWARE RIVER BASIN COMMISSION

18 CFR Part 401

Regulatory Program Fees; Correction

AGENCY: Delaware River Basin Commission.

ACTION: Correcting amendments.

SUMMARY: The Delaware River Basin Commission published a document in the **Federal Register** on December 29, 2016 (81 FR 95860), in relevant part amending the *Rules of Practice and Procedure.* The document failed to include rule text approved by the Commission relating to the annual monitoring and coordination fee. This document corrects the final regulations by incorporating the approved language. In addition, this document corrects the preamble to clarify that in adopting the final rule, the Commission acted by Resolution No. 2016–9, not 2016–8.

DATES: This final rule is effective January 23, 2017.

FOR FURTHER INFORMATION CONTACT: Pamela M. Bush, Commission Secretary and Assistant General Counsel, 609–477–7203.

SUPPLEMENTARY INFORMATION:

Background. When the Commission adopted Resolution No. 2016–9, in relevant part approving amendments to the Rules of Practice and Procedure (18 CFR part 401) concerning regulatory program fees, it approved rule language to expressly exclude from the calculation of the annual monitoring and coordination fee all water for which an entitlement issued pursuant to the Basin Regulations—Water Supply Charges (18 CFR part 420) is in effect. Final rule documents posted on the Commission's Web site included the approved language, but the language was inadvertently omitted from DRBC's **Federal Register** submission and thus from the CFR.

In addition, the preamble to the final rule published in the **Federal Register** incorrectly referred to the Commission's rule adoption resolution as number 2016–8, when the resolution was number 2016–9.

Corrections

Preamble Correction. In final rule FR Doc. 2016–31146, beginning on page 95860 in the issue of December 29, 2016, ''2016–8'' is corrected to read ''2016–9'' in the following locations in the **SUPPLEMENTARY INFORMATION** section: On page 95860 in the second column (first line of the last paragraph) and third column (sixth line from the bottom); and on page 95861 in the first column (first line).

Rule Correction. As published, the final regulations omit language adopted by the Commission in response to comments received. The regulations are thus incorrect and in need of amendment, as set forth below.

List of Subjects in 18 CFR Part 401

Administrative practice and procedure, Project review, Water pollution control, Water resources.

Accordingly, 18 CFR part 401 is corrected by the following correcting amendments:

PART 401—RULES OF PRACTICE AND PROCEDURE

■ 1. The authority citation for part 401 continues to read as follows:

Authority: Delaware River Basin Compact (75 Stat. 688), unless otherwise noted.

Subpart C—Project Review Under Section 3.8 of the Compact

■ 2. In § 401.43, revise paragraph (b)(2) to read as follows:

§ 401.43 Regulatory program fees.

* * * * *

(b) * * *

(2) *Annual monitoring and coordination fee.* (i) Except as provided in paragraph (b)(2)(ii) of this section, an annual monitoring and coordination fee shall apply to each active water allocation or wastewater discharge approval issued pursuant to the *Compact* and implementing regulations, regardless of whether the approval was issued by the Commission in the form of a docket, permit or other instrument, or by a Signatory Party Agency under the One Permit Program rule (§ 401.42). The fee shall be based on the amount of a project's approved monthly water allocation and/or approved daily discharge capacity.

(ii) For any withdrawal or diversion covered in part by a certificate of entitlement issued pursuant to §§ 420.31 and 420.32 of the water supply charges regulations (18 CFR part 420), the annual monitoring and coordination fee shall be based on the allocated amount, if any, in excess of the quantity specified in the entitlement.

* * * * *

Dated: January 5, 2017.

Pamela M. Bush,

Commission Secretary.

[FR Doc. 2017–00413 Filed 1–19–17; 8:45 am]

BILLING CODE 6360–01–P

SOCIAL SECURITY ADMINISTRATION

20 CFR Part 404

[Docket No. SSA–2014–0016]

RIN 0960–AH66

Unsuccessful Work Attempts and Expedited Reinstatement Eligibility; Correction

AGENCY: Social Security Administration.

ACTION: Final rules; correction.

SUMMARY: We published a document in the **Federal Register** revising our rules on October 17, 2016. That document inadvertently omitted a corresponding technical change to § 404.1592f(a) when § 404.1592c(a) was amended with the final rule publication. By making this technical correction we will also need to redesignate the amendatory instructions to incorporate the missing section changes to § 404.1592f(a). This document corrects the final regulation by making these technical corrections.

DATES: The corrections are effective April 17, 2017.

FOR FURTHER INFORMATION CONTACT: Kristine Erwin-Tribbitt, Office of Retirement and Disability Policy, Office of Research, Demonstration, and Employment Support, Social Security Administration, 6401 Security Boulevard, Robert Ball Building 3–A–26, Baltimore, MD 21235–6401, (410) 965–3353. For information on eligibility or filing for benefits, call our national toll-free number, 1–800–772–1213 or TTY 1–800–325–0778, or visit our Internet site, Social Security Online, at *http://www.socialsecurity.gov.*

SUPPLEMENTARY INFORMATION: We published a final rule in the **Federal Register** of October 17, 2016 (81 FR 71367) titled, Unsuccessful Work Attempts and Expedited Reinstatement Eligibility. The final rule, among other things, amended 20 CFR parts 404 and 416. We inadvertently omitted a corresponding technical change to § 404.1592f(a) when § 404.1592c(a) was amended with the final rule publication. This document amends and corrects the final regulation.

(Catalog of Federal Domestic Assistance Program Nos. 9601, Social Security—Disability Insurance; 96.006, Supplemental Security Income; 96.008, Social Security—Work Incentives Planning and Assistance Program.)

In FR Doc. 2016–24873 appearing on page 71369 in the **Federal Register** of Monday, October 17, the following corrections are made:

Corrections

1. On page 71369, in the third column, redesignate amendatory instructions 6 through 9 as 7 through 10 and add new amendatory instruction 6 to read as follows:

■ 6. Amend § 404.1592f by revising paragraph (a) to read as follows:

§ 404.1592f How do we determine reinstated benefits?

(a) If you meet the requirements for reinstatement under § 404.1592c(a), we will then consider in which month to reinstate your entitlement. We will reinstate your entitlement with the earliest month, in the 12-month period that ends with the month before you filed your request for reinstatement, that you would have met all of the requirements under § 404.1592c(a) if you had filed your request for reinstatement in that month. Otherwise, you will be entitled to reinstated benefits beginning with the month in which you filed your request for such benefits if you did not perform substantial gainful activity in that month. If you performed substantial gainful activity in the month of filing, but are no longer able to perform substantial gainful activity, we will reinstate your benefits with the month after the month you filed your request for reinstatement. We cannot reinstate your entitlement for any month prior to January 2001.

* * * * *

Carolyn W. Colvin,

Acting Commissioner of Social Security.

[FR Doc. 2017–00076 Filed 1–19–17; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 73 and 74

[Docket No. FDA–2016–F–0821]

Listing of Color Additives Exempt From Certification; Titanium Dioxide and Listing of Color Additives Subject to Certification; [Phthalocyaninato (2-)] Copper; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA or we) is confirming the effective date of December 2, 2016, for the final rule that appeared in the **Federal Register** of November 1, 2016, and that amended the color additive regulations to provide for the safe use of titanium dioxide and [phthalocyaninato (2-)] copper to color orientation marks for intraocular lenses (IOLs). We are taking this action to ensure clarity that the effective date in the final rule remains December 2, 2016.

DATES: Effective date of final rule published in the **Federal Register** of November 1, 2016 (81 FR 75689), confirmed: December 2, 2016.

FOR FURTHER INFORMATION CONTACT: Laura A. Dye, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740–3835, 240–402–1275.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 1, 2016 (81 FR 75689), we amended the color additive regulations in § 73.3126 (21 CFR 73.3126) and § 74.3045 (21 CFR 74.3045) to provide for the safe use of titanium dioxide and [phthalocyaninato (2-)] copper to color orientation marks for IOLs.

The preamble to the final rule stated that persons who would be adversely affected by one or more provisions in the final rule could file electronic or written objections (81 FR 75689 at 75691). We also stated that the effective date of the final rule would be on December 2, 2016, unless a person properly files an objection or request for a hearing to review any provisions in the final rule (81 FR 75689). We explained that, to file an objection, a person must, among other things, specify with particularity the provision(s) of the regulation to which they object and the grounds for the objection (81 FR 75689 at 75691). Within each objection, a person also must specifically state whether he/she requests a hearing. We received no objections or requests for a hearing on the final rule that met these requirements. We received five general comments, including one that disagreed with the rule, but the comments did not meet the requirements to be considered an objection under 21 CFR 12.22(a)(3). Therefore, we find that the effective date of the final rule that published in the **Federal Register** of November 1, 2016, should be confirmed.

List of Subjects

21 CFR Part 73

Color additives, Cosmetics, Drugs, Medical devices.

21 CFR Part 74

Color additives, Cosmetics, Drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e) and under authority delegated to the Commissioner of Food and Drugs, and redelegated to the Director, Office of Food Additive Safety, we are giving notice that no objections or requests for a hearing were filed in response to the November 1, 2016, final rule. Accordingly, the amendments issued thereby became effective December 2, 2016.

Dated: January 9, 2017.

Dennis M. Keefe,

Director, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition.

[FR Doc. 2017–00534 Filed 1–19–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

25 CFR Parts 140, 141, 211, 213, 225, 226, 227, 243, and 249

[178A2100DD/AAKC001030/A0A501010.999900253G]

RIN 1076–AF35

Civil Penalties Inflation Adjustments; Annual Adjustments

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Final rule.

SUMMARY: This rule provides for annual adjustments to the level of civil monetary penalties contained in Bureau of Indian Affairs (Bureau) regulations to account for inflation under the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 and Office of Management and Budget (OMB) guidance.

DATES: This rule is effective on January 23, 2017.

FOR FURTHER INFORMATION CONTACT: Elizabeth Appel, Director, Office of Regulatory Affairs and Collaborative Action, Office of the Assistant Secretary—Indian Affairs; telephone (202) 273–4680, *elizabeth.appel@bia.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On November 2, 2015, the President signed into law the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Sec. 701 of Pub. L. 114–74) (''the Act''). The Act requires Federal agencies to adjust the level of civil monetary penalties with an initial ''catch-up'' adjustment through rulemaking and then make subsequent annual adjustments for inflation. The purpose of these adjustments is to maintain the deterrent effect of civil penalties and to further the policy goals of the underlying statutes.

The Office of Management and Budget (OMB) issued guidance for Federal agencies on calculating the catch-up adjustment. *See* February 24, 2016, Memorandum for the Heads of Executive Departments and Agencies, from Shaun Donovan, Director, Office of Management and Budget, re: *Implementation of the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015* (M–16–06). Under the guidance, the Department identified applicable civil monetary penalties and calculated the catch-up adjustment. A civil monetary penalty is any assessment with a dollar amount that is levied for a violation of a Federal civil statute or regulation, and is assessed or enforceable through a civil action in Federal court or an administrative proceeding. A civil monetary penalty does not include a penalty levied for violation of a criminal statute, or fees for services, licenses, permits, or other regulatory review. The calculated catch-up adjustment is based on the percent change between the Consumer Price Index for all Urban Consumers (CPI0–U) for the month of October in the year of the previous adjustment (or in the year of establishment, if no adjustment has been made) and the October 2015 CPI–U.

The Bureau issued an interim final rule providing for calculated catch-up adjustments on June 30, 2016 (81 FR 42478) and requesting comments post-promulgation. The Bureau issued a final rule affirming the catch-up adjustments set forth in the interim final rule on December 2, 2016 (81 FR 86953). The final rule adjusted the following civil monetary penalties, effective on August 1, 2016:

CFR citation	Description of penalty	Current penalty	Catchup adjustment multiplier	Adjusted penalty
25 CFR 140.3	Penalty for trading in Indian country without a license	$500	2.50000	$1,250
25 CFR 141.50	Penalty for trading on Navajo, Hopi or Zuni reservations without a license	500	2.50000	1,250
25 CFR 211.55	Penalty for violation of leases of Tribal land for mineral development, violation of part 211, or failure to comply with a notice of noncompliance or cessation order.	1,000	1.50245	1,502
25 CFR 213.37	Penalty for failure of lessee to comply with lease of restricted lands of members of the Five Civilized Tribes in Oklahoma for mining, operating regulations at part 213, or orders.	500	2.50000	1,250
25 CFR 225.37	Penalty for violation of minerals agreement, regulations at part 225, other applicable laws or regulations, or failure to comply with a notice of noncompliance or cessation order.	1,000	1.59089	1,591
25 CFR 226.42	Penalty for violation of lease of Osage reservation lands for oil and gas mining or regulations at part 226, or noncompliance with the Superintendent's order.	500	1.78156	891
25 CFR 226.43(a) ...	Penalty per day for failure to obtain permission to start operations	50	1.78156	89
25 CFR 226.43(b) ...	Penalty per day for failure to file records	50	1.78156	89
25 CFR 226.43(c) ...	Penalty for each well and tank battery for failure to mark wells and tank batteries	50	1.78156	89
25 CFR 226.43(d) ...	Penalty each day after operations are commenced for failure to construct and maintain pits.	50	1.78156	89

CFR citation	Description of penalty	Current penalty	Catchup adjustment multiplier	Adjusted penalty
25 CFR 226.43(e) ...	Penalty for failure to comply with requirements regarding valve or other approved controlling device.	100	1.78156	178
25 CFR 226.43(f)	Penalty for failure to notify Superintendent before drilling, redrilling, deepening, plugging, or abandoning any well.	200	1.78156	356
25 CFR 226.43(g) ...	Penalty per day for failure to properly care for and dispose of deleterious fluids ...	500	1.78156	891
25 CFR 226.43(h) ...	Penalty per day for failure to file plugging and other required reports	50	1.78156	89
25 CFR 227.24	Penalty for failure of lessee of certain lands in Wind River Indian Reservation, Wyoming, for oil and gas mining to comply with lease provisions, operating regulations, regulations at part 227, or orders.	500	2.50000	1,250
25 CFR 243.8	Penalty for non-Native transferees of live Alaskan reindeer who violates part 243, takes reindeer without a permit, or fails to abide by permit terms..	5,000	1.17858	5,893
25 CFR 249.6(b)	Penalty for fishing in violation of regulations at part 249 (Off-Reservation Treaty Fishing)..	500	2.50000	1,250

II. Calculation of Annual Adjustments

OMB recently issued guidance to assist Federal agencies in implementing the annual adjustments required by the Act which agencies must complete by January 15, 2017. *See* December 16, 2016, Memorandum for the Heads of Executive Departments and Agencies, from Shaun Donovan, Director, Office of Management and Budget, re: *Implementation of the 2017 annual adjustment pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015* (M–17–11). The guidance states that the cost-of-living adjustment multiplier for 2017, based on the Consumer Price Index (CPI–U) for the month of October 2016, not seasonally adjusted, is 1.01636. (The annual inflation adjustments are based on the percent change between the October CPI–U preceding the date of the adjustment, and the prior year's October CPI–U. For 2017, OMB explains, October 2016 CPI–U (241.729)/October 2015 CPI–U (237.838) = 1.01636.) The guidance instructs agencies to complete the 2017 annual adjustment by multiplying each applicable penalty by the multiplier, 1.01636, and rounding to the nearest dollar. Further, agencies should apply the multiplier to the most recent penalty amount that includes the catch-up adjustment required by the Act.

The annual adjustment applies to all civil monetary penalties with a dollar amount that are subject to the Act. This final rule adjusts the following civil monetary penalties contained in the Bureau's regulations for 2017 by multiplying 1.01636 (*i.e.,* the cost-of-living adjustment multiplier for 2017) by each penalty amount as updated by the catch-up adjustment made in 2016:

CFR citation	Description of penalty	Current penalty including catchup adjustment	Annual adjustment (multiplier)	Adjusted penalty for 2017
25 CFR 140.3	Penalty for trading in Indian country without a license	$1,250	1.01636	$1,270
25 CFR 141.50	Penalty for trading on Navajo, Hopi or Zuni reservations without a license	1,250	1.01636	1,270
25 CFR 211.55	Penalty for violation of leases of Tribal land for mineral development, violation of part 211, or failure to comply with a notice of noncompliance or cessation order.	1,502	1.01636	1,527
25 CFR 213.37	Penalty for failure of lessee to comply with lease of restricted lands of members of the Five Civilized Tribes in Oklahoma for mining, operating regulations at part 213, or orders.	1,250	1.01636	1,270
25 CFR 225.37	Penalty for violation of minerals agreement, regulations at part 225, other applicable laws or regulations, or failure to comply with a notice of noncompliance or cessation order.	1,591	1.01636	1,617
25 CFR 226.42	Penalty for violation of lease of Osage reservation lands for oil and gas mining or regulations at part 226, or noncompliance with the Superintendent's order.	891	1.01636	906
25 CFR 226.43(a) ...	Penalty per day for failure to obtain permission to start operations	89	1.01636	90
25 CFR 226.43(b) ...	Penalty per day for failure to file records	89	1.01636	90
25 CFR 226.43(c) ...	Penalty for each well and tank battery for failure to mark wells and tank batteries	89	1.01636	90
25 CFR 226.43(d) ...	Penalty each day after operations are commenced for failure to construct and maintain pits.	89	1.01636	90
25 CFR 226.43(e) ...	Penalty for failure to comply with requirements regarding valve or other approved controlling device.	178	1.01636	181
25 CFR 226.43(f)	Penalty for failure to notify Superintendent before drilling, redrilling, deepening, plugging, or abandoning any well.	356	1.01636	362
25 CFR 226.43(g) ...	Penalty per day for failure to properly care for and dispose of deleterious fluids ...	891	1.01636	906
25 CFR 226.43(h) ...	Penalty per day for failure to file plugging and other required reports	89	1.01636	90
25 CFR 227.24	Penalty for failure of lessee of certain lands in Wind River Indian Reservation, Wyoming, for oil and gas mining to comply with lease provisions, operating regulations, regulations at part 227, or orders.	1,250	1.01636	1,270
25 CFR 243.8	Penalty for non-Native transferees of live Alaskan reindeer who violates part 243, takes reindeer without a permit, or fails to abide by permit terms..	5,893	1.01636	5,989
25 CFR 249.6(b)	Penalty for fishing in violation of regulations at part 249 (Off-Reservation Treaty Fishing)..	1,250	1.01636	1,270

Consistent with the Act, the adjusted penalty levels for 2017 will take effect immediately upon the effective date of the adjustment. The adjusted penalty levels for 2017 will apply to penalties assessed after that date including, if consistent with agency policy, assessments associated with violations that occurred on or after November 2, 2015. The Act does not, however, change previously assessed penalties that the Bureau is collecting or has collected. Nor does the Act change an agency's existing statutory authorities to adjust penalties.

III. Procedural Requirements

A. Regulatory Planning and Review (E.O. 12866 and 13563)

Executive Order 12866 provides that the Office of Information and Regulatory Affairs in the Office of Management and Budget will review all significant rules. The Office of Information and Regulatory Affairs has determined that this rule is not significant.

Executive Order 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The executive order directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this rule in a manner consistent with these requirements.

B. Regulatory Flexibility Act

This rule will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) because the rule makes adjustments for inflation.

C. Small Business Regulatory Enforcement Fairness Act

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule:

(a) Does not have an annual effect on the economy of $100 million or more.

(b) Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions.

(c) Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises.

D. Unfunded Mandates Reform Act

This rule does not impose an unfunded mandate on State, local, or tribal governments, or the private sector of more than $100 million per year. The rule does not have a significant or unique effect on State, local, or tribal governments or the private sector. A statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*) is not required.

E. Takings (E.O. 12630)

This rule does not affect a taking of private property or otherwise have taking implications under Executive Order 12630. A takings implication assessment is not required.

F. Federalism (E.O. 13132)

Under the criteria in section 1 of Executive Order 13132, this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement. A federalism summary impact statement is not required.

G. Civil Justice Reform (E.O. 12988)

This rule complies with the requirements of Executive Order 12988. Specifically, this rule:

(a) Meets the criteria of section 3(a) requiring that all regulations be reviewed to eliminate errors and ambiguity and be written to minimize litigation; and

(b) Meets the criteria of section 3(b)(2) requiring that all regulations be written in clear language and contain clear legal standards.

H. Consultation With Indian Tribes (E.O. 13175 and Departmental Policy)

The Department of the Interior strives to strengthen its government-to-government relationship with Indian tribes through a commitment to consultation with Indian tribes and recognition of their right to self-governance and tribal sovereignty. We have evaluated this rule under the Department's consultation policy and under the criteria in Executive Order 13175 and have determined that it has no substantial direct effects on federally recognized Indian tribes and that consultation under the Department's tribal consultation policy is not required.

I. Paperwork Reduction Act

This rule does not contain information collection requirements, and a submission to the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) is not required. We may not conduct or sponsor, and you are not required to respond to, a collection of information unless it displays a currently valid OMB control number.

J. National Environmental Policy Act

This rule does not constitute a major Federal action significantly affecting the quality of the human environment. A detailed statement under the National Environmental Policy Act of 1969 (NEPA) is not required because the rule is covered by a categorical exclusion. This rule is excluded from the requirement to prepare a detailed statement because it is a regulation of an administrative nature. (For further information see 43 CFR 46.210(i).) We have also determined that the rule does not involve any of the extraordinary circumstances listed in 43 CFR 46.215 that would require further analysis under NEPA.

K. Effects on the Energy Supply (E.O. 13211)

This rule is not a significant energy action under the definition in Executive Order 13211. A Statement of Energy Effects is not required.

L. Clarity of This Regulation

We are required by Executive Orders 12866 (section 1 (b)(12)), 12988 (section 3(b)(1)(B)), and 13563 (section 1(a)), and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

(a) Be logically organized;

(b) Use the active voice to address readers directly;

(c) Use common, everyday words and clear language rather than jargon;

(d) Be divided into short sections and sentences; and

(e) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in the **ADDRESSES** section. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that you find unclear, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

M. Administrative Procedure Act

The Act requires agencies to publish annual inflation adjustments by no later than January 15, 2017, and by no later than January 15 each subsequent year, notwithstanding section 553 of the Administrative Procedure Act (APA) (5 U.S.C. 553). OMB has interpreted this direction to mean that the usual APA public procedure for rulemaking—which includes public notice of a proposed rule, an opportunity for public comment, and a delay in the effective date of a final rule—is not required when agencies issue regulations to implement the annual adjustments to civil penalties that the Act requires. Accordingly, we are issuing the 2017 annual adjustments as a final rule without prior notice or an opportunity for comment and with an effective date immediately upon publication in the **Federal Register**.

Section 553(b) of the Administrative Procedure Act (APA) provides that, when an agency for good cause finds that ''notice and public procedure . . . are impracticable, unnecessary, or contrary to the public interest,'' the agency may issue a rule without providing notice and an opportunity for prior public comment. Under section 553(b), the Bureau finds that there is good cause to promulgate this rule without first providing for public comment. It would not be possible to meet the deadlines imposed by the Act if we were to first publish a proposed rule, allow the public sufficient time to submit comments, analyze the comments, and publish a final rule. Also, the Bureau is promulgating this final rule to implement the statutory directive in the Act, which requires agencies to publish a final rule and to update the civil penalty amounts by applying a specified formula. The Bureau has no discretion to vary the amount of the adjustment to reflect any views or suggestions provided by commenters. Accordingly, it would serve no purpose to provide an opportunity for public comment on this rule prior to promulgation. Thus, providing for notice and public comment is impracticable and unnecessary.

Furthermore, the Bureau finds under section 553(d)(3) of the APA that good cause exists to make this final rule effective immediately upon publication in the **Federal Register**. In the Act, Congress expressly required Federal agencies to publish annual inflation adjustments to civil penalties in the **Federal Register** by January 15, 2017, and not later than January 15 of every subsequent year, notwithstanding section 553 of the APA. Under the statutory framework and OMB guidance, the new penalty levels take effect immediately upon the effective date of the adjustment. The statutory deadline does not allow time to delay this rule's effective date beyond publication. Moreover, an effective date after January 15 would delay application of the new penalty levels, contrary to Congress's intent.

List of Subjects

25 CFR 140

Business and industry, Indians, Penalties.

25 CFR 141

Business and industry, Credit, Indians—business and finance, Penalties.

25 CFR 211

Geothermal energy, Indians—lands, Mineral resources, Mines, Oil and gas exploration, Reporting and recordkeeping requirements.

25 CFR 213

Indians—lands, Mineral resources, Mines, Oil and gas exploration, Reporting and recordkeeping requirements.

25 CFR 225

Geothermal energy, Indians—lands, Mineral resources, Mines, Oil and gas exploration, Penalties, Reporting and recordkeeping requirements, Surety bonds.

25 CFR 226

Indians—lands.

25 CFR 227

Indians—lands, Mineral resources, Mines, Oil and gas exploration, Reporting and recordkeeping requirements.

25 CFR 243

Indians, Livestock.

25 CFR 249

Fishing, Indians.

For the reasons given in the preamble, the Department of the Interior amends Chapter 1 of title 25 Code of Federal Regulations as follows.

Title 25—Indians

CHAPTER 1—BUREAU OF INDIAN AFFAIRS, DEPARTMENT OF THE INTERIOR

PART 140—LICENSED INDIAN TRADERS

■ 1. The authority citation for part 140 is revised to read as follows:

Authority: Sec. 5, 19 Stat. 200, sec. 1, 31 Stat. 1066 as amended; 25 U.S.C. 261, 262; 94 Stat. 544, 18 U.S.C. 437; 25 U.S.C. 2 and 9; 5 U.S.C. 301; and Sec. 701, Pub. L. 114–74, 129 Stat. 599, unless otherwise noted.

§ 140.3 [Amended]

■ 2. In § 140.3, remove ''$1,250'' and add in its place ''$1,270''.

PART 141—BUSINESS PRACTICES ON THE NAVAJO, HOPI AND ZUNI RESERVATIONS

■ 3. The authority citation for part 141 is revised to read as follows:

Authority: 5 U.S.C. 301; 25 U.S.C. 2 and 9; and Sec. 701, Pub. L. 114–74, 129 Stat. 599, unless otherwise noted.

§ 141.50 [Amended]

■ 4. In § 141.50, remove ''$1,250'' and add in its place ''$1,270''.

PART 211—LEASING OF TRIBAL LANDS FOR MINERAL DEVELOPMENT

■ 5. The authority citation for part 211 is revised to read as follows:

Authority: Sec. 4, Act of May 11, 1938 (52 Stat. 347); Act of August 1, 1956 (70 Stat. 744); 25 U.S.C. 396a–g; 25 U.S.C. 2 and 9; and Sec. 701, Pub. L. 114–74, 129 Stat. 599, unless otherwise noted.

§ 211.55 [Amended]

■ 6. In § 211.55(a), remove ''$1,502'' and add in its place ''$1,527''.

PART 213—LEASING OF RESTRICTED LANDS FOR MEMBERS OF FIVE CIVILIZED TRIBES, OKLAHOMA, FOR MINING

■ 7. The authority citation for part 213 is revised to read as follows:

Authority: Sec. 2, 35 Stat. 312; sec. 18, 41 Stat. 426; sec. 1, 45 Stat. 495; sec. 1, 47 Stat. 777; 25 U.S.C. 356; and Sec. 701, Pub. L. 114–74, 129 Stat. 599. Interpret or apply secs. 3, 11, 35 Stat. 313, 316; sec. 8, 47 Stat. 779, unless otherwise noted.

§ 213.37 [Amended]

■ 8. In § 213.37, remove ''$1,250'' and add in its place ''$1,270''.

PART 225—OIL AND GAS, GEOTHERMAL AND SOLID MINERALS AGREEMENTS

■ 9. The authority citation for part 225 is revised to read as follows:

Authority: 25 U.S.C. 2, 9, and 2101–2108; and Sec. 701, Pub. L. 114–74, 129 Stat. 599.

§ 225.37 [Amended]

■ 10. In § 225.37(a), remove ''$1,591'' and add in its place ''$1,617''.

PART 226—LEASING OF OSAGE RESERVATION LANDS FOR OIL AND GAS MINING

■ 9. The authority citation for part 226 is revised to read as follows:

Authority: Sec. 3, 34 Stat. 543; secs. 1, 2, 45 Stat. 1478; sec. 3, 52 Stat. 1034, 1035; sec. 2(a), 92 Stat. 1660; and Sec. 701, Pub. L. 114–74, 129 Stat. 599.

§ 226.42 [Amended]

■ 10. In § 226.42, remove ''$891'' and add in its place ''$906''.

§ 226.43 [Amended]

■ 11. In § 226.43:

■ a. Remove ''$89'' each time it appears and add in each place ''$90'' wherever it appears in this section.

■ b. In paragraph (e), remove ''$178'' and add in its place ''$181''.

■ c. In paragraph (f), remove ''$356'' and add in its place ''$362''.

■ d. In paragraph (g), remove ''$891'' and add in its place ''$906''.

PART 227—LEASING OF CERTAIN LANDS IN WIND RIVER INDIAN RESERVATION, WYOMING, FOR OIL AND GAS MINING

■ 12. The authority citation for part 227 is revised to read as follows:

Authority: Sec. 1, 39 Stat. 519; and Sec. 701, Pub. L. 114–74, 129 Stat. 599, unless otherwise noted.

§ 227.24 [Amended]

■ 13. In § 227.24, remove ''$1,250'' and add in its place ''$1,270''.

PART 243—REINDEER IN ALASKA

■ 14. The authority citation for part 243 is revised to read as follows:

Authority: Sec. 12, 50 Stat. 902; 25 U.S.C. 500K; and Sec. 701, Pub. L. 114–74, 129 Stat. 599.

§ 243.8 [Amended]

■ 15. In § 243.8(a) introductory text, remove ''$5,893'' and add in its place ''$5,989''.

PART 249—OFF–RESERVATION TREATY FISHING

■ 16. The authority citation for part 249 is revised to read as follows:

Authority: 25 U.S.C. 2, and 9; 5 U.S.C. 301; and Sec. 701, Pub. L. 114–74, 129 Stat. 599, unless otherwise noted.

§ 249.6 [Amended]

■ 17. In § 249.6(b), remove ''$1,250'' and add in its place ''$1,270''.

Dated: January 11, 2017.

Lawrence S. Roberts,

Principal Deputy Assistant Secretary—Indian Affairs.

[FR Doc. 2017–01076 Filed 1–19–17; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

27 CFR Parts 24 and 27

[Docket No. TTB–2016–0014; T.D. TTB–147; Re: Notice No. 168]

RIN 1513–AC31

Implementation of Statutory Amendments Requiring the Modification of the Definition of Hard Cider

AGENCY: Alcohol and Tobacco Tax and Trade Bureau, Treasury.

ACTION: Temporary rule; Treasury decision; cross reference to notice of proposed rulemaking.

SUMMARY: This temporary rule amends the Alcohol and Tobacco Tax and Trade Bureau (TTB) regulations to implement changes made to the definition of ''hard cider'' in the Internal Revenue Code of 1986 by the Protecting Americans from Tax Hikes Act of 2015. The modified definition broadens the range of wines eligible for the hard cider tax rate. TTB is amending its regulations to reflect the modified definition of hard cider effective for products removed on or after January 1, 2017, and to set forth new labeling requirements to identify products to which the hard cider tax rate applies. The new labeling requirements include both a one-year transitional rule and a new labeling requirement that takes effect for products removed on or after January 1, 2018. TTB is also soliciting comments from all interested parties on these amendments through a notice of proposed rulemaking published elsewhere in this issue of the **Federal Register**.

DATES: This temporary rule is effective January 23, 2017.

FOR FURTHER INFORMATION CONTACT: Kara Fontaine, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW., Box 12, Washington, DC 20005; telephone (202) 453–1039 ext. 103.

SUPPLEMENTARY INFORMATION:

I. Background

Protecting Americans From Tax Hikes Act of 2015

On December 18, 2015, the President signed into law the Consolidated Appropriations Act, 2016 (Pub. L. 114–113). Division Q of this Act is titled the Protecting Americans from Tax Hikes Act of 2015 (PATH Act). Section 335(a) of the PATH Act amends the Internal Revenue Code of 1986 (IRC) at 26 U.S.C. 5041 by modifying the definition of hard cider for excise tax classification purposes. Pursuant to section 335(b) of the PATH Act, the amended definition of hard cider applies to such products removed on or after January 1, 2017. The PATH Act does not change the tax rate applicable to wine eligible for the hard cider tax rate; rather, it broadens the range of products to which the hard cider tax rate applies. Among other things, the range of products to which the hard cider tax rate applies will include certain sparkling and carbonated products and certain products that are subject to the requirements of the Federal Alcohol Administration Act (FAA Act).

TTB Authority

The Alcohol and Tobacco Tax and Trade Bureau (TTB) of the Department of the Treasury administers chapter 51 of the IRC, which sets forth the Federal excise taxes on wine and related provisions, including provisions addressing the production and marking of wine (see 26 U.S.C. chapter 51). Section 5041 of the IRC (26 U.S.C. 5041) imposes six excise tax rates, including the hard cider tax rate, on wines. These tax rates are associated with six tax classes that correspond to section 5041(b) subparagraphs (1) through (6), as follows:

- Section 5041(b)(1) imposes a tax of $1.07 per wine gallon [1] on still wines containing not more than 14 percent alcohol by volume.
- Section 5041(b)(2) imposes a tax of $1.57 per wine gallon on still wines containing more than 14 percent and not exceeding 21 percent of alcohol by volume.
- Section 5041(b)(3) imposes a tax of $3.15 per wine gallon on still wines containing more than 21 percent and not exceeding 24 percent of alcohol by volume.
- Section 5041(b)(4) imposes a tax of $3.40 per wine gallon on champagne and other sparkling wines.

[1] The TTB regulations in 27 CFR 24.10 define the term ''wine gallon'' as ''a United States gallon of liquid measure equivalent to the volume of 231 cubic inches.''

• Section 5041(b)(5) imposes a tax of $3.30 per wine gallon on artificially carbonated wines.

• Section 5041(b)(6) imposes a tax of $0.226 per wine gallon on hard cider.

With regard to the hard cider tax class, prior to the effective date of the hard cider provisions of the PATH Act, section 5041(b)(6) defines the term ''hard cider'' as a still wine derived primarily from apples or apple concentrate and water, containing no other fruit product, and containing at least one-half of 1 percent and less than 7 percent alcohol by volume. Under section 5041(a), a ''still wine'' is a wine containing not more than 0.392 gram of carbon dioxide per 100 milliliters of wine, with tolerances ''as may be reasonably necessary in good commercial practice'' as prescribed by regulation.

Section 5041(c) allows a credit of up to 90 cents per wine gallon for small domestic wine producers on the first 100,000 gallons of wine taxed at one of the three still wine tax rates or at the artificially carbonated wine tax rate removed for consumption or sale during a calendar year, under certain prescribed circumstances. The law allows a credit of up to 5.6 cents per wine gallon for small domestic producers on wine that is taxed at the hard cider tax rate. Section 5041(c) does not provide a credit against taxes imposed under section 5041(b)(4) on wine that is taxed at the champagne or other sparkling wine tax rate.

The tax on wine is determined at the time of removal (generally, removal from a bonded wine premises or release from customs custody) for consumption or sale (26 U.S.C. 5041(a)). Wine so removed must be in containers bearing marks and labels evidencing compliance with the IRC as the Secretary of the Treasury may by regulations prescribe (26 U.S.C. 5368(b)). Proprietors of bonded wine premises and importers must keep records, in such a form, and containing such information, as the Secretary may by regulations prescribe (26 U.S.C. 5367 and 26 U.S.C. 5555). Section 7805 of the IRC (26 U.S.C. 7805) provides the Secretary with authority to issue regulations to carry out the provisions of the IRC.

In addition to the IRC requirements, wine is subject to the requirements of the FAA Act. As defined by the FAA Act, the term ''wine'' includes apple and pear wine containing at least 7 percent alcohol by volume (27 U.S.C. 211(a)(6)). Section 105(e) of the FAA Act, codified at 27 U.S.C. 205(e), authorizes the Secretary of the Treasury to prescribe regulations for the labeling of wine to, among other things, prohibit consumer deception and the use of misleading statements on labels and to ensure that the labels provide the consumer with adequate information as to the identity and quality of the product. The FAA Act generally requires bottlers and importers to obtain a TTB certificate of label approval (COLA) prior to bottling wine or removing bottled wine from customs custody for sale in interstate or foreign commerce. Section 103 of the FAA Act, codified at 27 U.S.C. 203, also requires that producers, blenders, wholesalers, and importers of wine that contains at least 7 percent alcohol by volume obtain a ''basic permit'' to engage in such businesses. The Alcoholic Beverage Labeling Act of 1988 (ABLA) requires a health warning statement to appear on containers of all alcoholic beverages, including wine, containing at least one-half of one percent alcohol by volume (27 U.S.C. 214 and 215).

TTB administers chapter 51 of the IRC and the FAA Act, and their implementing regulations, pursuant to section 1111(d) of the Homeland Security Act of 2002, codified at 6 U.S.C. 531(d). The Secretary has delegated various authorities through Treasury Department Order 120–01, dated December 10, 2013 (superseding Treasury Order 120–01, dated January 24, 2003), to the TTB Administrator to perform the functions and duties in the administration and enforcement of these laws. Regulations that implement the provisions of the IRC, as they relate to wine, include regulations in part 24 (27 CFR part 24) for domestic wine and part 27 (27 CFR part 27) for imported wine. Regulations that implement the provisions of FAA Act, as they relate to wine, include regulations in parts 1 and 4 (27 CFR parts 1 and 4). Regulations that implement the provisions of ABLA are in part 16 (27 CFR part 16).

II. History of the Regulatory Definition of Hard Cider for Tax Purposes

The Taxpayer Relief Act of 1997 (TRA), Public Law 105–34, enacted on August 5, 1997, added the tax class for wine called ''hard cider'' in 26 U.S.C. 5041(b)(6), as shown above. The definition of wine eligible for the ''hard cider'' tax classification, as enacted by the TRA, was clarified (to specify that ''hard cider'' is a ''still wine'') by the Internal Revenue Service Restructuring and Reform Act of 1998, Public Law 105–206. This clarification was effective October 1, 1997, the same effective date as the hard cider provisions of the TRA.

On August 21, 1998, pursuant to the TRA, the Bureau of Alcohol, Tobacco, and Firearms (ATF), TTB's predecessor agency, published a temporary rule in the **Federal Register** (T.D. ATF–398, 63 FR 44779) amending part 24 of the TTB regulations to add a definition of wine that was eligible for the new hard cider excise tax rate found in 26 U.S.C. 5041(b)(6). ATF also issued a concurrent notice of proposed rulemaking (Notice No. 859, 63 FR 44819) inviting comments on the temporary rule.

The portion of the temporary rule related to cider generated comments on the proposed definition of cider and the labeling rules. In particular, many commenters expressed concern that the labeling rules for hard cider in T.D. ATF–398 did not allow for the appropriate designation of their products. The temporary rule would have changed both the IRC and the FAA Act labeling rules to require use of the term ''hard cider'' on products that are taxable as hard cider, and prohibit use of that term on any other wine. In response to the comments ATF received regarding T.D. ATF–398, ATF published T.D. ATF–418 (64 FR 51896) on September 27, 1999, postponing the labeling compliance date for the rules in T.D. ATF–398. At the same time, ATF published Notice No. 881 (64 FR 51933) to solicit comments on alternative labeling rules. ATF subsequently published T.D. ATF–430 (65 FR 57734) on September 26, 2000, postponing the labeling compliance date until January 31, 2001.

ATF finalized this temporary rule on November 26, 2001, with the publication of T.D. ATF–470 (66 FR 58938). ATF defined the term ''hard cider'' in 27 CFR 24.10 as a still wine derived primarily from apples or apple concentrate and water (apple juice, or the equivalent amount of concentrate reconstituted to the original brix of the juice prior to concentration, must represent more than 50 percent of the volume of the finished product); containing no other fruit product nor any artificial product which imparts a fruit flavor other than apple; containing at least one-half of 1 percent and less than 7 percent alcohol by volume; having the taste, aroma, and characteristics generally attributed to hard cider, and sold or offered for sale as hard cider and not as a substitute for any other alcohol product.

The regulatory definition clarified the statutory definition in two respects. First, in the preamble of T.D. ATF–398, ATF explained that it interpreted the statutory phrase, ''derived primarily from apples or apple concentrate and water,'' to mean that apple juice or the equivalent amount of concentrate reconstituted to the original brix of the juice prior to concentration must represent more than 50 percent of the

volume of the finished product. (The term ''brix'' in this text refers to the quantity of dissolved solids expressed as grams of sucrose in 100 grams of solution at 60 degrees Fahrenheit. For example, one degree Brix is 1 gram of sucrose in 100 grams of solution and represents the strength of the solution as percentage by mass.)

Second, ATF interpreted the statutory phrase ''containing no other fruit product'' to mean ''containing no other fruit product nor any artificial product which imparts a fruit flavor other than apple.'' As explained in the preamble of T.D. ATF–470, this interpretation is based on the legislative history of the TRA, which states:

> Once fermented, eligible hard cider may not be altered by the addition of other fruit juices, flavor, or other ingredient that alters the flavor that results from the fermentation process. Thus, for example, cider fermented from apples, but which has raspberry flavor added to it prior to bottling and marketing to the public, will not be eligible for the 22.6 cents-per gallon tax rate.[2]

ATF ''d[id] not believe it was Congress's intent to provide a tax incentive for use of artificial ingredients in preference to real ones.'' See 66 FR 58941.

The preamble to T.D. ATF–470 also explained that the regulatory definition does not preclude the use of flavors such as honey or spices, noting that ''[f]lavoring materials will only affect the tax classification of hard cider if they are derived from or impart the flavor of a fruit other than apple.'' See 66 FR 58941. This position is also reflected in current public guidance in the form of an FAQ on the TTB Web site. Specifically, FAQ CID24 states that, because the IRC provides that the hard cider tax rate under section 5041(b)(6) is not available to wines that contain a fruit product other than apple, a cider containing either natural or artificial fruit flavors (other than apple flavors) is not eligible for the hard cider tax rate of 22.6¢ per gallon. Instead, a fruit-flavored cider would be taxed at the appropriate wine excise tax rate. (See *https://www.ttb.gov/faqs/alcohol_faqs.shtml?Cider#Cider.*)

In the preamble to T.D. ATF–470, ATF also addressed the prohibition on ''other fruit products'' with regard to authorized wine treating materials that are derived from fruits other than apple, such as tannin or citric acid. The preamble explained that the final rule did not restrict the use of approved wine treating materials derived from fruit in cider, stating that it would be impractical to make a distinction between fruit-derived wine treating materials and the same materials derived from other sources, unless there were other circumstances that indicated the producer was using these materials as flavorings. One of those circumstances would be the labeling of the product as being ''flavored'' with a fruit other than apple.

ATF noted that, when used as directed in 27 CFR part 24 for natural wines, authorized wine treating materials would not impart a fruit flavor to wine. However, ATF also noted that some ciders are made under approved formulas rather than under the rules for production of natural wine in subparts F and L of part 24, and that for formula wines [3], the use of wine treating materials may be approved at a level beyond the level authorized in part 24 for stabilizing or adjusting the acidity of a natural wine. ATF further noted that while the final rule did not place limits on the use of wine treating materials derived from fruits other than apple in a formula wine eligible for the hard cider tax rate, a formula wine may not contain such treating materials in amounts sufficient to impart a fruit flavor other than apple and still be taxed as hard cider. For example, if a cider contained more citric acid than the amount allowed under subpart L of part 24 for the production of natural wine,[4] and was labeled as ''citrus flavored,'' the product would be classified for tax purposes as a still wine under 14 percent alcohol by volume rather than hard cider.

Finally, ATF recognized that the term ''hard cider'' had broader meaning in the industry and among consumers than the definition given in the regulations. As a result, ATF stated that it would allow the use of the term ''hard cider'' on labels of products that do not belong to the hard cider tax class, as long as other information on the label allows for the identification of the appropriate tax class.

III. PATH Act's Modification of the IRC Definition of Hard Cider for Tax Purposes

The PATH Act amendments to section 5041 of the IRC change the definition of ''hard cider,'' allowing a broader range of products to be eligible for the hard cider tax rate. TTB notes that the PATH Act did not amend the FAA Act, although the definition of hard cider under the PATH Act now includes products to which the FAA Act requirements apply.

Under the PATH Act, effective January 1, 2017, section 5041 of the IRC, Imposition and rate of tax, contains a new paragraph (g), which defines the term ''hard cider'' as a wine.

Under the PATH Act, effective January 1, 2017, section 5041 of the IRC, Imposition and rate of tax, contains a new paragraph (g), which defines the term ''hard cider'' as a wine derived primarily from apples or pears, or from apple juice concentrate or pear concentrate and water, which contains no fruit product or fruit flavoring other than apple or pear. Also, under the revised definition, hard cider cannot contain ''more than 0.64 gram of carbon dioxide per hundred milliliters of wine, except that the Secretary may by regulations prescribe such tolerances to this limitation as may be reasonably necessary in good commercial practice.'' In addition, the revised definition states that the alcohol content of hard cider may range between at least 0.5 percent and less than 8.5 percent alcohol by volume.

The specific changes concerning the hard cider tax rate resulting from the PATH Act are discussed individually below.

Increase in Authorized Amount of Carbon Dioxide

As noted above, prior to the effective date of the hard cider provisions of the PATH Act, to be eligible for the ''hard cider'' tax rate under the IRC, wine must be, among other things, a ''still wine,'' that is, a wine containing not more than 0.392 gram of carbon dioxide per 100 milliliters. The modified definition of hard cider allows wine that is eligible for the hard cider tax rate to contain no more than 0.64 gram of carbon dioxide per 100 milliliters of wine. Prior to the effective date of the hard cider provisions of the PATH Act, wine with a carbon dioxide content greater than 0.392 gram of carbon dioxide per 100 milliliters of wine is an ''effervescent wine'' and is taxed as either ''sparkling wine'' or as ''artificially carbonated wine'' depending on the source of the carbon dioxide. Sparkling wine is an effervescent wine for which the carbon dioxide has resulted solely from the secondary fermentation of the wine within a closed container. Artificially carbonated wine is a wine made effervescent by the injection of carbon

[2] See General Explanation of Tax Legislation Enacted in 1997, published by the Joint Committee on Taxation (JCS–23–97).

[3] The TTB regulations at 27 CFR 24.10 define the term ''formula wine'' as special natural wine, agricultural wine, and other than standard wine (except for distilling material and vinegar stock) produced on bonded wine premises under an approved formula.

[4] Natural wine, under 26 U.S.C. 5381, is the product of the juice or must of sound, ripe grapes or other sound, ripe fruit, made with such cellar treatment as may be authorized under section 5382 of the IRC (26 U.S.C. 5382) and containing not more than 21 percent by weight of total solids.

dioxide. See § 24.10. Sparkling wine and artificially carbonated wine have no maximum level of carbon dioxide.

The definition of hard cider, as modified by the PATH Act, includes certain effervescent wines that contain more than 0.392 gram but no more than 0.64 gram of carbon dioxide per 100 milliliters of wine. This means that, under the modified definition, certain wines that would previously have fallen within the tax classes applicable to sparkling wine or artificially carbonated wine will be eligible for the hard cider tax rate.

Use of Pears and Pear Concentrate in Addition to Apples and Apple Concentrate

Prior to the effective date of the hard cider provisions of the PATH Act, the statutory definition of wine eligible for the hard cider tax rate requires that wine be derived primarily from apples or apple concentrate and water in order to be eligible for that tax rate. The modified definition under the PATH Act provides that wine eligible for the hard cider tax rate must be derived primarily from apples or pears or from apple juice concentrate or pear juice concentrate and water.

According to its legislative history,[5] this amendment was to ''expand the hard cider definition to include pears, or pear juice concentrate and water, in addition to apples and apple juice concentrate and water.'' TTB believes that the amendment to the definition of hard cider was not intended to prevent the use of apples and pears together. In keeping with the current definition of hard cider found in part 24 which provides, in part, ''* * * (apple juice, or the equivalent amount of concentrate reconstituted to the original brix of the juice prior to concentration, must represent more than 50 percent of the volume of the finished product) * * *,'' TTB is interpreting the modified definition to mean that apple juice, pear juice, a combination of apple juice and pear juice, or the equivalent amount of concentrate reconstituted to the original brix of the juice prior to concentration, must represent more than 50 percent of the volume of the finished product. In other words, if apple juice and pear juice (or the equivalent amount of concentrate reconstituted to the original brix of the juice prior to concentration) together represent more than 50 percent of the volume of the finished product, this requirement is met.

[5] See JCX–144–15, ''Technical Explanation of the Protecting Americans From Tax Hikes Act of 2015, House Amendment #2 to the Senate Amendment to H.R. 2029 (Rules Committee Print 114–40).''

Fruit Products and Fruit Flavoring

Prior to the effective date of the hard cider provisions of the PATH Act, the statutory definition of hard cider provides that no fruit product other than apple and apple concentrate may be used in wine eligible for the hard cider tax rate. As described above, the current regulatory definition of hard cider for tax purposes states that, among other things, hard cider must contain ''no other fruit product nor any artificial product which imparts a fruit flavor other than apple.'' Pursuant to the PATH Act, the modified definition of hard cider prohibits the use of any ''fruit product or fruit flavoring other than apple or pear.''

With the exception of the inclusion of pear, the prohibition against other fruit products or fruit flavorings is similar to the current statutory and regulatory text, except that it is even clearer than the prior law that wines eligible for the ''hard cider'' tax rate may not contain either ''fruit products'' (that is, ingredients derived from fruit) or ''fruit flavoring'' (regardless of its source) other than apple or pear. This is consistent (aside from the inclusion of pear) with TTB's current policy with regard to fruit flavors. Accordingly, it is TTB's interpretation that wine is not eligible for the hard cider tax rate if it contains any fruit flavoring that imparts the flavor of a fruit other than apple or pear. The term ''fruit flavoring'' includes a natural fruit flavor, an artificial fruit flavor, and a natural flavor that artificially imparts the flavor of a fruit that is not contained in that flavor.

Increase in Allowed Alcohol Content

Prior to the effective date of the hard cider provisions of the PATH Act, wine is not eligible for the hard cider tax rate unless it contains less than 7 percent alcohol by volume. However, the definition of hard cider as modified by the PATH Act increases the allowable alcohol content to less than (not equal to) 8.5 percent alcohol by volume. The increase in the allowed alcohol content allows a broader range of products to be eligible for the hard cider tax rate, including products that are subject to the FAA Act labeling and permit requirements, which apply to wines that contain at least 7 percent alcohol by volume. The PATH Act did not amend the FAA Act, and this rule does not amend TTB's FAA Act permit or labeling requirements in 27 CFR parts 1 and 4, respectively.

IV. Description of Regulatory Changes Regarding Tax Classification and Operations

New Regulations Setting Forth Eligibility Criteria for the Hard Cider Tax Rate

As a result of the PATH Act amendments to the definition of hard cider, TTB is amending its regulations in part 24 by adding a new Subpart P—Eligibility for the Hard Cider Tax Rate. New subpart P consists of two new sections, 27 CFR 24.331 and 24.332. Section 24.331 sets forth the statutory criteria for eligibility for the hard cider tax rate for wines removed on or after January 1, 2017, while § 24.332 elaborates on those criteria. Consistent with the TTB interpretation of the statutory text discussed above, § 24.332(a) provides that wine will be considered to be derived primarily from apples or pears, or from apple juice concentrate or pear juice concentrate and water, if the apple juice, pear juice, or combination of apple and pear juice, or the equivalent amount of concentrate of apple and/or pear juice reconstituted to the original brix of the juice prior to concentration, or any combination thereof, represents more than 50 percent of the volume of the finished product. Further, § 24.332(b)(1) provides that wine is not eligible for the hard cider tax rate if it contains any fruit product other than apple or pear. Consistent with current policy, § 24.332(b)(1) makes clear that a fruit product is any material derived or made from any fruit or part of a fruit, including but not limited to concentrates, extracts, juices, powders, or wine spirits, of any fruit or part of a fruit.

New § 24.332(b)(2) provides that an authorized wine treating material set forth in § 24.246 that is derived from a fruit other than apple or pear may be used in the production of wine eligible for the hard cider tax rate if it is used for a purpose other than flavoring and it is either used in accordance with the wine treating materials provisions of § 24.246 (if used in a natural wine), or used in amounts insufficient to impart a fruit flavor other than apple or pear (if used in a special natural wine or other than standard wine). Any written or pictorial reference to a material derived from a fruit other than apple or pear (other than the inclusion of a wine treating material in an ingredient labeling statement) in the labeling or advertising of a wine will be treated as evidence that the wine treating material was added for the purpose of flavoring the wine.

Further, new § 24.332(c) prohibits the use, in wine eligible for the hard cider tax rate, of any fruit flavoring that

imparts the flavor of a fruit other than apple or pear. For purposes of this section, a flavoring that imparts the flavor of a fruit other than apple or pear includes a natural fruit flavor, an artificial fruit flavor, and a natural flavor that artificially imparts the flavor of a fruit that is not contained in that flavor.

The preamble to T.D. ATF–470 provided that honey or spices would not disqualify an apple wine from the hard cider tax rate; however, language to that effect did not appear in any regulatory text. TTB is now incorporating such language in the new § 24.332(c) to make this position more easily accessible to industry members and the public. TTB has also received questions about the use of pumpkin flavors in cider. While pumpkins are botanically classified as fruit, they are treated as ''vegetables'' for several other purposes.[6] It has been TTB's position that pumpkins are not ''fruit'' for purposes of part 24. Instead, wines made from pumpkins are classified as wines made from ''other agricultural products'' under 26 U.S.C. 5387 and 27 CFR 24.204. See, *e.g.,* TTB Ruling 2016–2. Accordingly, in new § 24.332(c), TTB clarifies that the use of spices, honey, hops, or pumpkins as a flavoring will not make a wine ineligible for the hard cider tax rate.

New § 24.332(c) also provides that any written or pictorial reference to a fruit flavor other than apple or pear in the labeling or advertising of a wine that contains a flavoring will be treated as evidence that the wine contains a flavoring that imparts a fruit flavor other than apple or pear and thus the wine will not be eligible for the hard cider tax rate.

The new definition in § 24.332, differing from the current definition of hard cider in § 24.10, does not require that hard cider have the taste, aroma, and characteristics generally attributed to hard cider. Nor does it require hard cider to be sold or offered for sale as hard cider. With regard to the reference to ''taste, aroma, and characteristics generally attributed to hard cider,'' these aspects of the definition have been removed because under the PATH Act, wine that is eligible for the hard cider tax rate may contain pear, which TTB believes is not a characteristic generally attributed to hard cider. With regard to the reference to hard cider having to be ''sold or offered for sale as hard cider,'' this aspect has been removed because a wine that meets the criteria of the hard cider tax class and is produced from just pears may be sold as ''perry,'' ''pear wine,'' or ''hard perry.''

Definitional Changes To Implement the PATH Act

The IRC at section 5041(a) provides that ''[s]till wines shall include those wines containing not more than 0.392 gram of carbon dioxide per hundred milliliters * * *.'' Because wine classified as hard cider will no longer necessarily be a ''still wine'' after the PATH Act amendments take effect, and because hard ciders that are defined as ''still wine'' under section 5041(a) are not taxed as ''still wine'' under section 5041(b), TTB is adding a definition of ''still hard cider'' to § 24.10, and excluding ''hard cider'' from the definition of ''still wine'' in that section. As amended, part 24 will use the term ''still wine'' to refer to wine containing not more than 0.392 gram of carbon dioxide per 100 milliliters of wine that falls within one of the three tax classes applicable to still wine set forth at section 5041(b)(1), (b)(2), or (b)(3). The term ''still hard cider,'' when used in the regulations, is used to denote wine that is eligible for the hard cider tax rate at section 5041(b)(6) and that contains not more than 0.392 gram of carbon dioxide per 100 milliliters.

Similarly, TTB is adding definitions of ''artificially carbonated hard cider'' and ''sparkling hard cider'' to describe wine that is eligible for the hard cider tax rate at section 5041(b)(6); that contains more than 0.392 but not more than 0.64 gram of carbon dioxide per 100 milliliters; and that is made effervescent either by artificial injection of carbon dioxide or solely by secondary fermentation within a closed container. Under this temporary rule, TTB is also excluding wine that is eligible for the hard cider tax rate from the definitions of ''artificially carbonated wine,'' and ''sparkling wine or champagne'' set forth in § 24.10.

As a result of these definitional changes, there is no need to amend the regulations in 27 CFR 24.278(a), which provide that ''champagne and other sparkling wine'' are not eligible for the tax credit for certain small producers. This regulation is based on 26 U.S.C. 5041(c)(1), which disqualifies ''wine described in subsection (b)(4)'' from eligibility for the small producer credit. Wine described in section 5041(b)(4) is wine that is taxable at the rate prescribed for ''champagne and other sparkling wines.'' This temporary rule specifies that the term ''sparkling wine'' does not include hard cider that derives its effervescence solely from the secondary fermentation in a closed container (and contains no more than 0.64 gram of carbon dioxide per 100 milliliters of wine); thus, this wine is not precluded from eligibility for the small domestic producers credit described in § 24.278.

These definitional changes also provide that wine that is eligible for the lower hard cider tax rate at section 5041(b)(6) is not subject to the higher tax rates for ''still wine,'' ''sparkling wine,'' or ''artificially carbonated wine'' at section 5041(b)(1)–(b)(5).

TTB is incorporating the terms ''artificially carbonated hard cider,'' ''artificially carbonated wine,'' ''sparkling hard cider'' and ''sparkling wine'' in the definition of ''effervescent wine'' to make it clear that, when used in the regulations, ''effervescent wine'' includes all four terms. The new definition for the existing term ''hard cider'' cross-references the new definitions of ''artificially carbonated hard cider,'' ''sparkling hard cider,'' and ''still hard cider,'' and cites the new eligibility requirements set forth in § 24.331. TTB is removing the current eligibility criteria included in the definition of ''Hard cider'' at § 24.10 that interprets the law as it exists prior to the effective date of the hard cider provisions of the PATH Act.

In addition to amending the definition of ''artificially carbonated wine'' to exclude wine eligible for the hard cider tax rate, TTB is replacing the reference in that definition to wine ''artificially charged with carbon dioxide'' with the phrase ''artificially injected with carbon dioxide.'' This change is not intended to substantively change the provision, but rather to be consistent with the description of wine carbonated by the injection of carbon dioxide used in 27 CFR 24.190. TTB also is amending a cross-reference to the FAA Act that appears in the definition of ''cider'' in § 24.10 to make clear that 27 CFR 4.21(e)(5) provides information regarding the labeling of wine that may be designated as ''cider'' under the FAA Act.

Tolerance and Recordkeeping Requirements for Artificially Carbonated Hard Cider and Sparkling Hard Cider

While there is no maximum allowed carbon dioxide level for wine falling within the sparkling wine and artificially carbonated wine tax classes, under the modified definition of hard cider, wine is not eligible for the hard cider tax rate if it contains more than 0.64 gram of carbon dioxide per 100 milliliters. As amended by the PATH Act, section 5041(g)(1) authorizes TTB to prescribe through regulation ''such tolerances to this limitation as may be

[6] For example, the United States Department of Agriculture's National Nutrient Database for Standard Reference currently lists pumpkin in its ''Vegetables and Vegetable Product'' food group.

reasonably necessary in good commercial practice.'' Current TTB regulations applicable to still wine with added carbon dioxide, at 27 CFR 24.245, prescribe a tolerance of not more than 0.009 gram per 100 milliliters where the amount of carbon dioxide in excess of 0.392 gram per 100 milliliters is due to mechanical variations that cannot be completely controlled under good commercial practice. In this temporary rule, TTB sets forth a new section, 27 CFR 24.251, and extends the same 0.009 gram per 100 milliliters tolerance to artificially carbonated hard cider and sparkling hard cider where the amount of carbon dioxide in excess of 0.64 gram per 100 milliliters is due to mechanical variations or secondary fermentation variations that cannot be completely controlled under good commercial practice. This tolerance will not be allowed where it is found that the proprietor continuously or intentionally exceeds 0.64 gram of carbon dioxide per 100 milliliters of artificially carbonated hard cider or sparkling hard cider or where the variation results from the use of methods or equipment determined by the appropriate TTB officer not to be in accordance with good commercial practice.

Apple or pear wine that has in excess of 0.64 gram of carbon dioxide per 100 milliliters (unless covered by the allowed tolerance) will be classified and taxed at the applicable ''sparkling wine'' or ''artificially carbonated wine'' rate, see section 5041(b)(4) and (b)(5). Accordingly, TTB is amending 27 CFR 24.255(a) to specify that proprietors of a bonded wine premises or a taxpaid wine bottling house premises are responsible for the correct determination of the amount of carbon dioxide in artificially carbonated hard cider or sparkling hard cider. TTB is also amending § 24.302 to require that the amount of carbon dioxide in artificially carbonated hard cider or sparkling hard cider be included in the effervescent wine record, which is required to be kept by proprietors who produce or receive effervescent wine in bond.

Conforming Amendments

Other amendments maintain the existing treatment of still wine and effervescent wine, and apply certain requirements currently applicable to still wine to ''still hard cider'' and certain requirements currently applicable to artificially carbonated wine and sparkling wine to ''artificially carbonated hard cider'' and ''sparkling hard cider,'' respectively. These include amendments to 27 CFR 24.190, 24.191, 24.192, and 24.193 in subpart G (Production of Effervescent Wine); 27 CFR 24.225 and 24.234 in subpart K (Spirits); § 24.246 in subpart L (Storage, Treatment and Finishing of Wine); 27 CFR 24.266 in subpart M (Losses of Wine); §§ 24.290 and 24.291 in subpart N (Removal, Return and Receipt of Wine); 27 CFR 24.301, 24.302, 24.306, 24.308, and 24.319 in subpart O (Records and Reports).

Along with conforming amendments to § 24.245, TTB also is removing a reference to ''authorized test procedures'' for determining the amount of carbon dioxide in still wine to which carbon dioxide has been added. Section 24.245 currently states that ''[t]he proprietor shall determine the amount of carbon dioxide added to wine using authorized test procedures.'' TTB's predecessor agency, ATF, published several authorized test procedures from 1971 to 1983. These are ATF Procedure 73–1 (authorizing the enzymatic method, the manometric method, and the volumetric method), ATF Procedure 77–2 (authorizing the infrared spectrophotometer method), and ATF Procedure 83–2 (authorizing the use of an automated thermal conductivity analyzer). Although TTB still views these methods as valid, TTB currently uses the enzymatic [7] and titrimetric [8] method to determine the carbon dioxide levels in wine.

It is TTB's current policy that producers may use any method that has been formally validated (*e.g.,* that underwent a multi-laboratory performance evaluation) or that is otherwise scientifically valid to determine the carbon dioxide levels in wine. (A scientifically valid method is, among other things, accurate, precise, and specific for its intended purpose, and it has results that are consistently reliable, accurate, and reproducible.) Accordingly, TTB is removing the language in § 24.245 that requires proprietors to use ''authorized'' test procedures, and is revoking ATF Procedure 73–1, ATF Procedure 77–2, and ATF Procedure 83–2.

Finally, TTB is dividing the current text of 27 CFR 24.270, Determination of Tax, into paragraphs (a) and (b), and adding a new paragraph (c) to list the tax rates imposed on wine by 26 U.S.C. 5041(b). With respect to the hard cider tax rate at section 5041(b)(6), TTB is referencing the eligibility requirements set forth in new § 24.331. Also, TTB is incorporating in § 24.270(a) language from the definition of ''wine'' in § 24.10, which explains that a product containing less than one-half of one percent alcohol by volume is not taxable as wine.

V. Labeling of Wine Eligible for the Hard Cider Tax Rate

As noted above, TTB administers the labeling requirements of both the IRC and the FAA Act. TTB bases its labeling requirements in part 24 on section 5368(b) of the IRC, which gives the Secretary of the Treasury general authority to issue labeling regulations that require evidence of compliance with tax provisions.

Labeling Requirements Prior to the Effective Date of Hard Cider Provisions of the PATH Act

Current § 24.257 sets forth the requirements for labeling containers of wine, including wine eligible for the hard cider tax rate, for purposes of the IRC. In general, § 24.257 provides that proprietors must label each bottle or other container of beverage wine prior to removal for consumption or sale, and the label must show: (1) The name and address of the wine premises where the wine is bottled or packed, (2) the brand name, if it is different from the name shown in the name and address statement; (3) the alcohol content of the wine; (4) the kind of wine; and (5) the net contents of the container.

Current § 24.257 provides that conformity with TTB's FAA Act labeling regulations found in part 4 of the TTB regulations is sufficient to identify the appropriate tax class. With regard to alcohol content, § 24.257(a)(3) provides that a label must state the alcohol content as percent by volume or in accordance with part 4.[9]

Current § 24.257(a)(4) also sets out parameters for how the kind of wine should be presented on a label.[10] Wine that contains at least 7 percent alcohol by volume and requires label approval under the FAA Act must be labeled with

[7] AOAC Official Method of Analysis 964.09 (17th Ed). See also *https://www.ttb.gov/ssd/pdf/list_of_beverage_methods.pdf.*

[8] AOAC Official Method of Analysis 988.07 (17th Ed). See also *https://www.ttb.gov/ssd/pdf/list_of_beverage_methods.pdf.*

[9] Thus, for wines with less than 7 percent alcohol by volume, a numerical statement of the percentage of alcohol by volume must appear on the label. 27 CFR 4.32(b)(3) and 4.36 require alcohol content statements on labels. TTB notes that pursuant to § 4.36, in the case of fruit wine containing at least 7 percent but no more than 14 percent or less of alcohol by volume, the alcohol content need not be stated if the type designation ''table wine'' or ''light wine'' (without a numerical statement of alcohol content) appears on the brand label. Because ''hard cider'' is currently defined in part 24 as wine containing less than 7 percent alcohol by volume, ''table wine'' and ''light wine'' designations have been sufficient to identify FAA Act wine as ineligible for the hard cider tax rate.

[10] TTB notes that 27 CFR 24.259 requires each container larger than 4 liters or each case used to remove wine for consumption or sale to be durably marked with the kind of wine, stated in accordance with § 24.257.

the ''kind'' of wine in accordance with part 4.[11] See § 24.257(a)(4)(i).

For wine that contains less than 7 percent alcohol by volume or is the subject of a certificate of exemption from the COLA requirements in part 4, a statement of composition is required to be on the label in order to adequately identify the wine. See § 24.257(a)(4)(ii) and (iii).

The regulations in § 24.257(a)(4)(iv) provide that the statement of composition must include enough information to identify the tax class when viewed with the alcohol content. There are several components to this requirement.

- First, the wine should be identified by the word ''wine,'' ''mead,'' ''cider,'' or ''perry,'' as applicable.
- Second, if the wine contains more than 0.392 gram of carbon dioxide per 100 milliliters, the word ''sparkling'' or ''carbonated,'' as applicable, must be included in the statement of composition.
- Third, if the statement of composition leaves doubt as to the tax class of the wine, the wine must be marked with an appropriate tax class statement (such as the statement ''tax class 5041(b)(1) IRC'').

Section 24.257(a)(4)(iv) provides examples of labels that would or would not leave doubt as to the tax class of the wines. For example, a still wine labeled as ''raspberry hard cider'' and ''9 percent alcohol by volume'' is adequately marked to designate the tax class specified in section 5041(b)(1), which is the tax class for ''still wines containing not more than 14 percent of alcohol by volume.'' That information is sufficient because the wine is clearly not eligible for the hard cider tax rate under current law on two different grounds—it contains raspberries or raspberry flavor, and it is 9 percent alcohol by volume. This example also illustrates that the terms ''cider'' and ''hard cider,'' by themselves, do not indicate that a wine is eligible for the hard cider tax rate. Thus, the regulations provide the example of a still wine marked ''cider'' or ''hard cider'' and ''6 percent alcohol by volume.'' Under current regulations, that wine is adequately marked if it is eligible for the hard cider tax rate, but if it is not eligible for the hard cider tax rate, it is not adequately marked to identify its tax class as falling under section 5041(b)(1), so the tax class must be shown.

As mentioned earlier in this preamble, the current regulations were issued after ATF received comments in opposition to T.D. ATF–398, which would have required use of the term ''hard cider'' on products eligible for the hard cider tax rate, and prohibited use of the ''hard cider'' designation on products not eligible for the hard cider tax rate, including all wines subject to the FAA Act. Accordingly, ATF solicited comments on and adopted an alternative proposal, that allowed use of the term ''hard cider'' on products over 7 percent alcohol by volume.

For products under 7 percent alcohol by volume, ATF wanted to differentiate between ciders that are eligible for the hard cider tax rate and those that are taxable as still wine containing not more than 14 percent alcohol by volume. Some producers have marketed eligible products as ''draft cider,'' ''fermented cider'' or ''apple cider'' and did not wish to use the term ''hard cider'' on labels. Some producers marketed mixed-fruit ciders or low-alcohol ciders that were otherwise excluded from the current definition of hard cider under the name ''hard cider'' and did not wish to rename their products. Accordingly, ATF proposed, where the words on the label leave doubt as to the tax class, that cider makers must include a reference to the tax class by section of the law. ATF noted that this wording was similar to the wording of 27 CFR 25.242, on marking nontaxable cereal beverages. ATF requested industry and consumer comments on these proposals.

In general, the commenters supported ATF's proposal to allow more flexibility in naming hard cider and related products. ATF also noted that it had requested suggestions for other ways of identifying the tax class, but received no suggestions. As a result, the final rule allowed the use of the term ''hard cider'' on labels of products that do not belong to the hard cider tax class, as long as other information on the label allows for the identification of the appropriate tax class.

Need for Revised Labeling Requirements To Implement the PATH Act for the Hard Cider Tax Class

As previously noted, current regulations require wines to be labeled with the ''kind'' of wine, and provide that wines that are not subject to FAA Act labeling requirements must be labeled with a statement of composition that, when viewed with the alcohol content, includes enough information to identify the tax class. Under the statutory definition of ''hard cider'' as it stood prior to the effective date of the hard cider provisions of the PATH Act, this flexibility makes sense. Among other things, any wine eligible for the ''hard cider'' tax rate under current law must be a still wine, and must have less than 7 percent alcohol by volume. Thus, wines subject to the labeling requirements of the FAA Act are, by definition, ineligible for the hard cider tax rate if removed prior to January 1, 2017. Similarly, sparkling wines and carbonated wines are, by definition, ineligible for the hard cider tax rate.

Under the definition of hard cider set forth in the PATH Act, wine taxed at the hard cider tax rate may contain a higher alcohol content (less than 8.5 percent instead of less than 7 percent alcohol by volume) and may be effervescent (containing not more than 0.64 gram of carbon dioxide per 100 milliliters of wine). Under the modified definition, wine may also contain pears in addition to or in place of apples. This affects how the product must be labeled to provide sufficient information to identify the appropriate tax class.

For example, under the modified definition of hard cider, wines that are subject to the FAA Act labeling regulations may be taxed at the hard cider tax rate. The current regulations in § 24.257 do not require wines labeled in accordance with the FAA Act to include enough information to identify the tax class. Such a requirement was not necessary when the definition of hard cider excluded any wines containing 7 percent or more alcohol by volume. Because some (but not all) apple or pear wines subject to the FAA Act labeling regulations may be taxed at the hard cider tax rate under the IRC as modified by the PATH Act, it is now necessary to include language in § 24.257 to require wines (including hard cider) labeled in accordance with the FAA Act labeling regulations to also include enough information to identify the tax class. A designation such as ''apple table wine'' for a wine subject to the FAA Act will no longer suffice to identify whether the wine is eligible for the hard cider tax rate, because it will not identify whether the wine has less than 8.5 percent alcohol by volume.

Similarly, the hard cider tax class is no longer restricted to still wines. Under current regulations, a ''sparkling'' or ''carbonated'' wine statement suffices to indicate that the wine was not eligible for the hard cider tax rate. Under the standards as modified by the PATH Act, some, but not all, sparkling and carbonated apple and/or pear wines may be eligible for the hard cider tax rate. Thus, knowing that an apple and/

[11] Under 27 CFR part 4, wine that requires label approval must be labeled ''sparkling'' or ''carbonated,'' if applicable, see §§ 4.32(a)(2) (requiring the class, type or other designation on wine labels), 4.34 and 4.22 (requiring a truthful and adequate statement of composition if the wine is not defined in 27 CFR 4.21), and 4.21 (setting forth standards of identity for wine and requiring the words ''sparkling'' or ''carbonated'' when applicable).

or pear wine is sparkling or carbonated does not resolve the question of whether it is eligible for the hard cider rate, and such wines are unlikely to be labeled with the exact level of carbon dioxide per 100 milliliters of wine.

Finally, the use of terms such as ''apple'' or ''pear'' wine, or ''cider,'' ''hard cider,'' or ''perry'' may suggest the hard cider tax class, but do not necessarily indicate that the product is eligible for such a classification. Furthermore, a statement of composition such as ''apple cider with natural flavors'' or ''honey pear wine'' does not necessarily indicate the tax class.

VI. Description of Regulatory Changes Regarding Labeling

Accordingly, TTB is amending its regulations in parts 24 and 27 to require the statement ''Tax class 5041(b)(6)'' on the container of any wine for which the hard cider tax rate is claimed. TTB recognizes that industry members who currently produce or import hard cider will need time to comply with such a requirement, and TTB is therefore providing a one-year grace period before the requirement goes into effect.

Amendments to Part 24

As mentioned above, TTB is amending § 24.257 to impose a new labeling requirement for wines eligible for the hard cider tax rate.

As amended by this temporary rule, § 24.257(a)(4) is reorganized. Section 24.257(a)(4)(i) addresses wines that require label approval under the FAA Act. Consistent with current regulations, § 24.257(a)(4)(i)(A), which takes effect for wines removed on or after January 1, 2017, provides that if a wine contains 7 percent or more alcohol by volume and must have label approval under part 4, the required designation of the wine is the class, type or other designation provided in part 4. Section 24.257(a)(4)(i)(B) provides specific labeling rules for those products taxed at the ''hard cider'' tax rate. Section 24.257(a)(4)(i)(B)(1) provides, as part of a transitional rule for ''hard cider'' removed on or after January 1, 2017 and prior to January 1, 2018, that such wines may include the statement ''Tax class 5041(b)(6)'' on the label to adequately identify the appropriate tax class. For products removed from wine premises on or after January 1, 2018, that are taxed at the ''hard cider'' tax rate, the designation must also include the statement ''Tax class 5041(b)(6).'' This statement may appear anywhere on the label.

With regard to wines, including hard cider, that do not require label approval, § 24.257(a)(4)(ii) includes both a rule that takes effect for all wines removed on or after January 1, 2017 and additional labeling rules for hard cider that take effect for products removed on or after January 1, 2018.

The general rule for wine that does not require label approval (either because it is covered by a certificate of exemption from label approval or because it contains less than 7 percent alcohol by volume) is provided in new § 24.257(a)(4)(ii)(A). This kind of wine must bear a designation that includes enough information (when viewed with the alcohol content statement) to identify the tax class under section 5041. The wine must be identified by the term ''wine'' (or a word that signifies a type of wine, such as ''cider,'' ''perry,'' or ''mead,'' as applicable). If the wine contains more than 0.392 gram of carbon dioxide per 100 milliliters, the word ''sparkling'' or ''carbonated,'' as applicable, must be included in the designation.

Section 24.257(a)(4)(ii)(A)(*1*) provides additional labeling rules effective for ''hard cider'' removed from wine premises on or after January 1, 2017. These rules provide that the designation for such products must be consistent with a hard cider tax classification. For example, the designations ''hard cider,'' ''hard perry,'' ''apple wine,'' ''pear wine,'' ''apple cider,'' ''apple perry,'' ''apple pear wine,'' ''cider,'' and ''perry'' are consistent with a hard cider tax classification. The designation ''blueberry cider'' is not consistent with a hard cider tax classification, because it indicates that the product contains either blueberries or blueberry flavors, which are not authorized for use in wine that is eligible for the hard cider tax class. If the hard cider contains more than 0.392 gram of carbon dioxide per 100 milliliters, the word ''sparkling'' or ''carbonated,'' as applicable, must be on the label.

Section 24.257(a)(4)(ii)(A)(*2*) provides a transitional rule for wines removed on or after January 1, 2017 and prior to January 1, 2018. For these wines, a label will not be deemed out of compliance with § 24.257(a)(4)(ii)(A) solely because the label does not provide enough information to identify whether the wine is eligible for a ''hard cider'' tax classification. On an optional basis, wines eligible for the ''hard cider'' tax class may include the statement ''Tax class 5041(b)(6)'' on the label to adequately indicate the appropriate tax class.

Section 24.257(a)(4)(ii)(A)(*3*) provides additional labeling rules effective for ''hard cider'' removed from wine premises on or after January 1, 2018. The regulations provide that the label must also include the statement ''Tax class 5041(b)(6).''

Finally, TTB modified and moved the existing cross-reference to the FDA labeling rules applicable to wines containing less than 7 percent alcohol by volume to § 24.257(a)(4)(ii)(B). Similarly, the existing cross-reference to the health warning statement requirements found in part 16 was modified and moved to § 24.257(a)(6).

Amendments to Part 27

The amendments to the definition of ''hard cider'' in the PATH Act apply to imported wine as well as to wine produced in the United States. Accordingly, TTB is amending part 27, which applies to imported wine, by adding a new definition of ''hard cider'' to section 27.11. Consistent with the definition in part 24, the term ''hard cider'' is defined for imported wines as a wine that meets the eligibility requirements set forth in § 24.331 for the hard cider tax rate set forth in § 24.270.

The labeling regulations for imported wine in 27 CFR 27.59 are also amended by redesignating the existing regulation as § 27.59(a) and adding a new § 27.59(b). The new regulation provides that the container of any imported wine eligible for the ''hard cider'' tax classification set forth in § 24.270 of this chapter must be labeled in accordance with the requirements applicable to wine containers removed from wine premises under § 24.257(a)(4) of this chapter. The regulation also provides a cross-reference to § 24.331 for the eligibility requirements for the hard cider tax rate. Thus, this temporary rule provides that the labeling requirements for imported hard cider are the same as the labeling requirements for hard cider produced in the United States.

Regulatory Analysis and Notices

Public Participation

To submit comments on the regulatory provisions contained in this temporary rule, including the labeling provisions and any alternatives to requiring ''Tax Class 5041(b)(6)'' on the label, please refer to the notice of proposed rulemaking on this subject published in the ''Proposed Rules'' section of this issue of the **Federal Register**.

Executive Order 12866

Certain TTB regulations issued under the IRC, including this one, are exempt from the requirements of Executive Order 12866, as supplemented and reaffirmed by Executive Order 13563. Therefore, a regulatory impact assessment is not required.

Regulatory Flexibility Act

In accordance with the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), TTB certifies that this temporary rule will not have a significant economic impact on a substantial number of small entities. The temporary rule will not impose, or otherwise cause, a significant increase in reporting, recordkeeping, or other compliance burdens on a substantial number of small entities.

The temporary rule implements certain changes made to the Internal Revenue Code of 1986 by the Protecting Americans from Tax Hikes Act of 2015 (see Pub. L. 114–113, Division Q, section 335). These statutory changes broaden the definition of hard cider, which means that more products will be eligible for the lower rate of tax applicable to hard cider. However, to ensure that labels and records adequately reflect the correct tax class of hard cider products, the temporary rule includes provisions that will require certain labeling changes, and will require producers of artificially carbonated hard cider and sparkling hard cider to test for carbon dioxide levels and keep records of those tests. These requirements flow directly from the new statutory criteria for eligibility for the hard cider tax rate. Accordingly, any increased burden associated with establishing eligibility for the hard cider tax rate flows directly from the statutory changes that prescribe the criteria for eligibility. The temporary rule provides industry members with a one-year transition period to make the required labeling changes, thus reducing the burden on industry members.

Pursuant to section 7805(f) of the IRC (26 U.S.C. 7805(f)), TTB will submit the temporary regulations to the Chief Counsel for Advocacy of the Small Business Administration for comment on the impact of the temporary regulations on small businesses.

Paperwork Reduction Act

Nine of the regulatory sections addressed in this temporary rule contain collections of information that have been previously reviewed and approved by the Office of Management and Budget (OMB) in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507) and assigned control numbers 1513–0009, 1513–0088, 1513–0092, and 1513–0115. Those sections are 27 CFR 24.255, 24.257, 24.266, 24.291, 24.301, 24.302, 24.306, 24.308, and 24.319. No changes are being made to the existing approved information collections.

In this temporary rule, TTB is proposing two new recordkeeping requirements, and TTB has received OMB approval for these two requirements under two new OMB control numbers. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by OMB.

The first new recordkeeping requirement is contained in new paragraphs (a)(4)(i)(B)(*2*) and (a)(4)(ii)(A)(*3*) of § 24.257 and paragraph (b) of § 27.59. Specifically, the new information collection will require that industry members who remove wine to which the hard cider tax rate applies place a specific statement, ''Tax class 5041(b)(6),'' on containers of such wine, in order to adequately identify the applicable tax rate. Under § 24.257(a)(4)(i)(B)(*2*) and (a)(4)(ii)(A)(*3*) and § 27.59, this new requirement is imposed on such wine removed on or after January 1, 2018. TTB has determined that this statement is necessary for the enforcement of the Internal Revenue Code, and it is the simplest and clearest way to identify these products without any confusion with other tax classes of wine and without requiring any other changes to statements that industry members may be using or wish to use to identify their products. The delayed effective date provides sufficient time for affected industry members to bring their labels into compliance with the new requirement.

In 2015, 457 domestic manufacturers removed wine that was eligible for the hard cider tax class from their premises. TTB estimates that in addition to those industry members who removed wine eligible for the hard cider tax rate from their premises in 2015, potentially 20 percent more (or 91 manufacturers for a total of 548) may be interested in removing such wine from their premises given the new provisions applicable in 2017. Additionally, in 2015, according to U.S. Customs and Border Protection entry data, TTB determined that 191 importers obtained release from customs custody of products that were identified as cider under the Harmonized Tariff Schedule of the United States (HTSUS). TTB estimates that in addition to those importers who removed cider from customs custody in 2015, another 20 percent (or 38 importers for a total of 229 importers) will be interested in importing products that fall under that HTSUS code starting in 2017. Accordingly, TTB estimates that there are approximately 777 industry members (manufacturers and importers combined) who will be required to comply with this marking requirement. TTB estimates that each industry member will have a one-time burden of one hour to come into compliance with this information collection, but that the continued compliance burden will be negligible. Therefore, TTB estimates that 777 respondents will respond an average of once per year to this information collection, for a total estimate annual burden of 777 hours.

Estimated number of respondents: 777.

Estimated average total annual burden hours: 777.

The second new recordkeeping requirement is contained in new paragraph (k) of § 24.302. Specifically, the new recordkeeping requirement will require proprietors who produce artificially carbonated hard cider and sparkling hard cider to maintain a record of the amount of carbon dioxide contained in the wine. This new requirement is imposed on such wine removed on or after January 1, 2017. TTB has determined that this recordkeeping requirement is necessary for demonstrating compliance with the statutory requirement that, to be eligible for the hard cider tax rate, among other things, the wine must contain no more than 0.64 gram of carbon dioxide per 100 milliliters of wine.

Like the tax class statement requirement, TTB estimates that there are 548 domestic manufacturers who must comply with this new recordkeeping requirement. TTB's laboratory estimates that it will take each industry member on average four hours to test the level of carbon dioxide in the wine using either the titrimetric or enzymatic test method. TTB also estimates that it will take an additional 15 minutes to record the level of carbon dioxide in the wine for a total of four hours and 15 minutes to test and record the carbon dioxide for one batch of artificially carbonated hard cider or sparkling hard cider. TTB is also estimating that each industry member will perform this recordkeeping requirement for 25 batches over one year. This equals 106.25 burden hours for each industry member in one year, for a total of 58,225 burden hours.

Estimated number of respondents: 548.

Estimated average total annual burden hours: 58,225.

As noted above, TTB has submitted these new information collection requirements to the OMB for review. Comments on this new recordkeeping requirement should be sent to OMB at Office of Management and Budget, Attention: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503 or by email to

OIRA_submissions@omb.eop.gov. A copy should also be sent to TTB by any of the methods described in the notice of proposed rulemaking related to this temporary rule published elsewhere in this issue of the **Federal Register**. Comments on the information collection should be submitted no later than March 24, 2017. Comments are specifically requested concerning:

- Whether the collection of information submitted to OMB is necessary for the proper performance of the functions of the Alcohol and Tobacco Tax and Trade Bureau, including whether the information will have practical utility;
- The accuracy of the estimated burden associated with the collection of information submitted to OMB; and
- How to enhance the quality, utility, and clarity of the information to be collected.

Inapplicability of Prior Notice and Public Comment and Delayed Effective Date Procedures

Based on the January 1, 2017, effective date of the PATH Act amendments to section 5041 of the IRC, TTB believes that proper administration and enforcement of those provisions necessitate the immediate adoption of implementing regulations as a temporary rule.

TTB is issuing this temporary rule without prior notice and comment pursuant to authority under section 4(a) of the Administrative Procedure Act, as amended (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and comment when a rule is interpretive or when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.''

The majority of the regulatory provisions contained in this temporary rule are exempt from prior notice and comment because they are interpretive.

TTB finds that it has good cause to dispense with prior notice and comment for the substantive provisions of this rule that set forth labeling requirements, recordkeeping requirements for artificially carbonated hard cider and sparkling hard cider, and a carbon dioxide tolerance for artificially carbonated hard cider and sparkling hard cider. Because this document implements provisions of law that are effective on January 1, 2017, and because immediate guidance is necessary to implement these provisions, it is found to be impracticable to issue this Treasury decision with prior notice and public procedure under 5 U.S.C. 553(b). TTB is also including in this temporary rule additional labeling rules effective for ''hard cider'' removed from wine premises on or after January 1, 2018 (see § 24.257(a)(4)(i)(B)(*2*) and (a)(4)(ii)(A)(*3*)) and for imported wines removed on or after January 1, 2018 (see § 27.59(b)), to provide certainty to industry members regarding how they will be required to identify the appropriate tax class of their products.

TTB is issuing this temporary rule without a delayed effective date pursuant to authority under section 4(c) of the APA (5 U.S.C. 553(d)). TTB finds good cause under 5 U.S.C. 553(d)(3) to dispense with the effective date limitation in 5 U.S.C. 553(d). A 30-day delayed effective date is impracticable because this temporary rule implements statutory changes that are effective after December 31, 2016. Accordingly, the effective date of this temporary rule is January 1, 2017.

TTB is providing a delayed effective date for the requirement that all wine that qualifies for the hard cider tax rate must be labeled with ''Tax class 5041(b)(6)'' (see § 24.257(a)(4)(i)(B)(*2*) and (a)(4)(ii)(A)(*3*) and § 27.59(b)) in order to provide the industry with sufficient time to make arrangements for compliance. This requirement is effective January 1, 2018.

Drafting Information

Dana Register and Kara Fontaine of the Regulations and Rulings Division drafted this document with the assistance of other Alcohol and Tobacco Tax and Trade Bureau personnel.

List of Subjects

27 CFR Part 24

Administrative practice and procedure, Cider, Claims, Electronic funds transfers, Excise taxes, Exports, Food additives, Fruit juices, Hard Cider, Labeling, Liquors, Packaging and containers, Reporting and recordkeeping requirements, Research, Scientific equipment, Spices and flavorings, Surety bonds, Vinegar, Warehouses, Wine.

27 CFR Part 27

Alcohol and alcoholic beverages, Beer, Cosmetics, Customs duties and inspections, Electronic funds transfers, Excise taxes, Imports, Labeling, Liquors, Packaging and containers, Reporting and Recordkeeping requirements, Wine.

Amendments to the Regulations

For the reasons discussed in the preamble, TTB is amending 27 CFR chapter I, parts 24 and 27 as follows:

PART 24—WINE

■ 1. The authority citation for part 24 continues to read as follows:

Authority: 5 U.S.C. 552(a); 26 U.S.C. 5001, 5008, 5041, 5042, 5044, 5061, 5062, 5121, 5122–5124, 5173, 5206, 5214, 5215, 5351, 5353, 5354, 5356, 5357, 5361, 5362, 5364–5373, 5381–5388, 5391, 5392, 5511, 5551, 5552, 5661, 5662, 5684, 6065, 6091, 6109, 6301, 6302, 6311, 6651, 6676, 7302, 7342, 7502, 7503, 7606, 7805, 7851; 31 U.S.C. 9301, 9303, 9304, 9306.

■ 2. In § 24.10:
■ a. The definition of ''Artificially carbonated hard cider'' is added in alphabetical order;
■ b. The definitions of ''Artificially carbonated wine'', ''Cider'', ''Effervescent wine'', and ''Hard cider'' are revised;
■ c. The definition of ''Sparkling hard cider'' is added in alphabetical order;
■ d. The definition of ''Sparkling wine or champagne'' is revised;
■ e. The definition of ''Still hard cider'' is added in alphabetical order; and
■ f. The definition of ''Still wine'' is revised.

The revisions and additions read as follows:

§ 24.10 Meaning of terms.

* * * * *

Artificially carbonated hard cider. Hard cider artificially injected with carbon dioxide and containing more than 0.392 but not more than 0.64 gram of carbon dioxide per 100 milliliters.

Artificially carbonated wine. Wine (other than hard cider) artificially injected with carbon dioxide and containing more than 0.392 gram of carbon dioxide per 100 milliliters.

* * * * *

Cider. See definitions for hard cider and tax exempt cider. For the labeling of wine that may be designated as ''cider'' under the Federal Alcohol Administration Act, see § 4.21(e)(5) of this chapter.

* * * * *

Effervescent wine. A wine containing more than 0.392 gram of carbon dioxide per 100 milliliters, including artificially carbonated hard cider, artificially carbonated wine, sparkling hard cider, and sparkling wine.

* * * * *

Hard cider. A wine that meets the eligibility requirements set forth in § 24.331 for the hard cider tax rate set forth in § 24.270. See the definitions for artificially carbonated hard cider, sparkling hard cider, and still hard cider.

* * * * *

Sparkling hard cider. Hard cider containing more than 0.392 but not

more than 0.64 gram of carbon dioxide per 100 milliliters of wine, resulting solely from the secondary fermentation of the wine within a closed container.

Sparkling wine or champagne. Wine (other than hard cider) containing more than 0.392 gram of carbon dioxide per 100 milliliters of wine resulting solely from the secondary fermentation of the wine within a closed container.

* * * * *

Still hard cider. A hard cider containing not more than 0.392 gram of carbon dioxide per 100 milliliters.

Still wine. Wine (other than hard cider) containing not more than 0.392 gram of carbon dioxide per 100 milliliters.

* * * * *

■ 3. Section 24.190 is revised to read as follows:

§ 24.190 General.

(a) Effervescent wine may be made on bonded wine premises. Where the effervescence results from fermentation of the wine within a closed container, the wine is classified and taxed as sparkling wine or as hard cider, as applicable. In such wine, the use of carbon dioxide, nitrogen gas, or a combination of both, is permitted to maintain counterpressure during transfer and bottling. Wine carbonated by injection of carbon dioxide is classified and taxed as artificially carbonated wine or as hard cider, as applicable. (For wine to be classified and taxed at the hard cider tax rate, it must meet the requirements set forth in § 24.331, including the limitation of not more than 0.64 gram of carbon dioxide per 100 milliliters.)

(b) Effervescent wine and any wine used as a base in the production of effervescent wine may not have an alcohol content in excess of 14 percent by volume. However, wine containing more than 14 percent alcohol by volume may be used in preparing a dosage for finishing effervescent wine.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1383, as amended (26 U.S.C. 5382))

■ 4. Section 24.191 is revised to read as follows:

§ 24.191 Segregation of operations.

Where more than one process of producing effervescent wine is used, the appropriate TTB officer may require the portion of the premises used for the production and storage of wine made by each process (bottle fermenting, bulk fermenting, or injecting carbon dioxide) to be segregated as provided by § 24.27.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1381, as amended (26 U.S.C. 5365))

§ 24.192 [Amended]

■ 5. Section 24.192 is amended by:

■ a. Adding the words ''or still hard cider'' after the words ''still wine'' in the first sentence;

■ b. Removing the words ''sparkling wine or artificially carbonated wine'' wherever they appear in the first six sentences of the section and adding, in their place, the words ''effervescent wine'';

■ c. Removing the word ''which'' in the sixth sentence and adding, in its place, the word ''that''; and

■ d. Adding the words ''or sparkling hard cider'' after the words ''sparkling wine'' in the last sentence.

§ 24.193 [Amended]

■ 6. Section 24.193 is amended by:

■ a. Adding the words ''or still hard cider'' after the words ''still wine'' in the section heading;

■ b. Removing the words ''Sparkling wine or artificially carbonated wine'' and adding, in their place, the words ''Effervescent wine''; and

■ c. Adding the words ''or still hard cider'' after the words ''still wine''.

§ 24.225 [Amended]

■ 7. Section 24.225 is amended by adding the words ''or natural still hard cider'' after the words ''still wine''.

§ 24.234 [Amended]

■ 8. Section 24.234 is amended by removing the words ''sparkling wine, artificially carbonated wine'' and adding, in their place, the words ''effervescent wine''.

■ 9. Section 24.245 is revised to read as follows:

§ 24.245 Use of carbon dioxide in still wine and still hard cider.

(a) *Use of carbon dioxide.* The addition of carbon dioxide to (and retention of carbon dioxide in) still wine and still hard cider is permitted if at the time of removal for consumption or sale, the still wine or still hard cider does not contain more than 0.392 gram of carbon dioxide per 100 milliliters of wine.

(b) *Tolerance limit.* A tolerance of not more than 0.009 gram per 100 milliliters to the maximum limitation of carbon dioxide in still wine and still hard cider will be allowed where the amount of carbon dioxide in excess of 0.392 gram per 100 milliliters is due to mechanical variations that cannot be completely controlled under good commercial practice. A tolerance will not be allowed where it is found by the appropriate TTB officer that the proprietor continuously or intentionally exceeds 0.392 gram of carbon dioxide per 100 milliliters of wine or where the variation results from the use of methods or equipment determined by the appropriate TTB officer to be not in accordance with good commercial practice.

(c) *Penalties.* Penalties are provided in 26 U.S.C. 5662 for any person who, whether by manner of packaging or advertising or by any other form of representation, misrepresents any still wine or still hard cider to be effervescent wine or a substitute for effervescent wine.

(d) *Records.* Records for the use of carbon dioxide in still wine must be maintained in accordance with § 24.319 of this section.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1331, as amended, 1381, as amended, 1407, as amended (26 U.S.C. 5041, 5367, 5662))

§ 24.246 [Amended]

■ 10. Section 24.246 is amended by removing the words ''sparkling wines'' from the description of the use of ammonium phosphate in the ''Materials and use column'' of the table, and adding, in their place, the words ''sparkling wine or sparkling hard cider''.

■ 11. Section 24.251 is added immediately after § 24.250 to read as follows:

§ 24.251 Tolerance for artificially carbonated hard cider and sparkling hard cider.

(a) *Tolerance.* A tolerance of not more than 0.009 gram per 100 milliliters to the maximum limitation of carbon dioxide in artificially carbonated hard cider and sparkling hard cider will be allowed where the amount of carbon dioxide in excess of 0.64 gram per 100 milliliters is due to mechanical variations or secondary fermentation variations that cannot be completely controlled under good commercial practice. A tolerance will not be allowed where it is found by the appropriate TTB officer that the proprietor continuously or intentionally exceeds 0.64 gram of carbon dioxide per 100 milliliters of artificially carbonated hard cider or sparkling hard cider or where the variation results from the use of methods or equipment determined by the appropriate TTB officer to be not in accordance with good commercial practice. (See Subpart P of this part for the definition of hard cider for purposes of determining eligibility for the hard cider tax rate.)

(b) *Records.* See § 24.302 of this chapter for recordkeeping requirements.

(Sec. 335, Pub. L. 114–113, 129 Stat. 3109, as amended (26 U.S.C. 5041)

§ 24.255 [Amended]

■ 12. In § 24.255(a), the first sentence is revised by adding, after the word ''removed'', the words ''as well as for the correct determination of carbon dioxide in artificially carbonated hard cider and in sparkling hard cider'', and the Office of Management and Budget control number reference is revised by removing the numbers ''1512–0298 and 1512–0503'' and adding, in their place, the numbers ''1513–0115 and 1513–0092''.

■ 13. Section 24.257 is amended by:
■ a. Revising paragraph (a)(4);
■ b. Adding paragraph (a)(6); and
■ c. Revising the Office of Management and Budget control number reference.

The revisions and addition read as follows:

§ 24.257 Labeling wine containers.

(a) * * *

(4) An appropriate designation of the kind of wine, as follows:

(i) *Wines that require label approval*—(A) *General.* If the wine contains 7 percent or more alcohol by volume and must have label approval under 27 CFR part 4, the designation is the class, type, or other designation required by that part.

(B) *Labeling rules for wines eligible for the ''hard cider'' tax class*—(*1*) *Transitional rule for ''hard cider'' removed on or after January 1, 2017 and prior to January 1, 2018.* On an optional basis, wines that are taxed at the ''hard cider'' tax rate may include the statement ''Tax class 5041(b)(6)'' on the label to adequately indicate the appropriate tax class.

(*2*) *Additional labeling rules effective for ''hard cider'' removed from wine premises on or after January 1, 2018.* For wines removed from wine premises on or after January 1, 2018 that are taxed at the ''hard cider'' tax rate, the label must also include the statement ''Tax class 5041(b)(6).'' This statement may appear anywhere on the label.

(ii) *Wines that do not require label approval*—(A) *Adequate designation.* If the wine is not subject to label approval under 27 CFR part 4 because it either is covered by a certificate of exemption from label approval or contains less than 7 percent alcohol by volume, its label must bear a designation that includes enough information (when viewed with the alcohol content statement) to identify the tax class under 26 U.S.C. 5041. The wine must be identified by the term ''wine'' (or a word that signifies a type of wine, such as ''cider,'' ''perry,'' or ''mead,'' as applicable). If the wine contains more than 0.392 gram of carbon dioxide per 100 milliliters, the word ''sparkling'' or ''carbonated,'' as applicable, must be included in the designation.

(*1*) *Additional labeling rules effective for wines eligible for the ''hard cider'' tax class.* For wines removed from wine premises on or after January 1, 2017, that are taxed at the ''hard cider'' tax rate, the designation must be consistent with a hard cider tax class. For example, the designations ''hard cider,'' ''hard perry,'' ''apple wine,'' ''pear wine,'' ''apple cider,'' ''apple perry,'' ''apple pear wine,'' ''cider'' and ''perry'' are consistent with the hard cider tax class. The designation ''blueberry cider'' is not consistent with the hard cider tax class, because it indicates that the product contains either blueberries or blueberry flavors, which are not authorized for use in wine that is eligible for the hard cider tax class. If the hard cider contains more than 0.392 gram of carbon dioxide per 100 milliliters, the word ''sparkling'' or ''carbonated,'' as applicable, must be on the label.

(*2*) *Transitional rule for wines removed on or after January 1, 2017 and prior to January 1, 2018.* For wines removed on or after January 1, 2017 and prior to January 1, 2018, a label will not be deemed out of compliance with § 24.257(a)(4)(ii)(A) on the sole ground that the label does not provide enough information to identify whether the wine is eligible for a ''hard cider'' tax classification. On an optional basis, wines eligible for the ''hard cider'' tax class may include the statement ''Tax class 5041(b)(6)'' on the label to adequately indicate the appropriate tax class.

(*3*) *Additional labeling rules effective for ''hard cider'' removed from wine premises on or after January 1, 2018.* For wines removed from wine premises on or after January 1, 2018, that are taxed at the ''hard cider'' tax rate, the label must also include the statement ''Tax class 5041(b)(6).'' This statement may appear anywhere on the label.

(B) *Cross reference.* For additional labeling rules applicable to wines containing less than 7 percent alcohol by volume, see the food labeling regulations issued by the U.S. Food and Drug Administration.

* * * * *

(6) *Cross reference.* For regulations requiring a health warning statement on the container of any alcoholic beverage containing not less than one-half of one percent alcohol by volume, see part 16 of this chapter.

* * * * *

(Approved by the Office of Management and Budget under control numbers 1513–0115 and 1513–XXXX)

■ 14. Section 24.266 is amended by revising paragraph (b)(2) and the reference to the Office of Management and Budget control number, to read as follows:

§ 24.266 Inventory losses.

* * * * *

(b) * * *

(2)(i)(A) Where the loss of wine on bonded wine premises during the annual period exceeds three percent of the aggregate volume of wine on-hand at the beginning of the annual period and the volume of wine received in bond during the annual period;

(B) The loss exceeds six percent of the still wine or still hard cider produced by fermentation;

(C) The loss exceeds six percent of the sparkling wine or sparkling hard cider produced by fermentation in bottles;

(D) The loss exceeds three percent of the special natural wine produced under § 24.195 or other wine produced under § 24.218;

(E) The loss exceeds three percent of the artificially carbonated wine or artificially carbonated hard cider produced; or

(F) The loss exceeds three percent of the bulk process sparkling wine or bulk process sparkling hard cider produced.

(ii) The percentage applicable to each tax class of wine will be calculated separately, unless the calculation is impracticable because of the mixture of different tax classes by addition of wine spirits or blending during the annual period, in which case the percentage will be calculated on the aggregate volume. Wine removed immediately after production for use as distilling material and on which the usual racking, clarifying, and filtering losses are not sustained, will not be included in the calculations.

* * * * *

(Approved by the Office of Management and Budget under control number 1513–0088)

■ 15. Section 24.270 is revised to read as follows:

§ 24.270 Determination of tax.

(a) *General.* The tax on wine is determined at the time of removal from a bonded wine premises for consumption or sale. Section 5041 of 26 U.S.C., imposes an excise tax, at the rates prescribed, on all wine (including imitation, substandard, or artificial wine, and compounds sold as wine, which contain 24 percent or less of alcohol by volume) produced in or imported into the United States. Wine containing more than 24 percent of alcohol by volume is classified as distilled spirits and taxed accordingly.

A wine product containing less than one-half of one percent alcohol by volume is not taxable as wine when removed from the bonded wine premises.

(b) *Tax determined and paid on the volume of wine.* The tax is determined and paid on the volume of wine:

(1) In bottles or other containers filled according to United States measure recorded to the nearest 10th gallon; or,

(2) In bottles or other containers filled according to metric measure, on the volume of wine in United States wine gallons to the nearest 10th gallon; or

(3) In the case of pipeline removals, on the volume of bulk wine removed recorded to the nearest whole gallon, five-tenths gallon being converted to the next full gallon.

(c) *Tax rates imposed on wine.* The following taxes are imposed on wine:

(1) *Tax class 5041(b)(1).* On still wines containing not more than 14 percent alcohol by volume, $1.07, per wine gallon;

(2) *Tax class 5041(b)(2).* On still wines containing more than 14 percent and not exceeding 21 percent alcohol by volume, $1.57 per wine gallon;

(3) *Tax class 5041(b)(3).* On still wines containing more than 21 percent and not exceeding 24 percent alcohol by volume, $3.15 per wine gallon;

(4) *Tax class 5041(b)(4).* On champagne and other sparkling wines, $3.40 per wine gallon;

(5) *Tax class 5041(b)(5).* On artificially carbonated wines, $3.30 per wine gallon; and

(6) *Tax class 5041(b)(6).* On hard cider, 22.6 cents per wine gallon. See § 24.331 for the definition of hard cider for purposes of determining eligibility for the hard cider tax class.

(d) *Small domestic producer tax credit.* For eligibility for the small producer tax credit, see §§ 24.278 and 24.279.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1331, and Sec. 335, Pub. L. 114–113, 129 Stat. 3109, as amended (26 U.S.C. 5041))

§ 24.290 [Amended]

■ 16. Section 24.290(a) is amended by adding the words ''or still hard cider'' after the words ''still wine'' in the first sentence.

§ 24.291 [Amended]

■ 17. Section 24.291 is amended:

■ a. In the first sentence of paragraph (a), by adding the words ''or still hard cider'' after the words ''still wine''; and,

■ b. In the Office of Management and Budget control number reference, by removing the numbers ''1512–0058, 1512–0292 and 1512–0298'', and adding, in their place, the numbers ''1513–0009 and 1513–0115''.

§ 24.301 [Amended]

■ 18. Section 24.301 is amended:

■ a. In the section heading, by adding the words ''and bulk still hard cider'' after the words ''still wine'';

■ b. In the first sentence of the introductory text, by adding the words ''or bulk still hard cider'' after the words ''still wine'' each time they appear;

■ c. In the second sentence of the introductory text, by adding the words ''or for hard cider'' after the words ''still wine'';

■ d. In the third sentence of the introductory text, by adding the words ''and bulk still hard cider'' after the words ''still wine'';

■ e. In paragraph (b), by adding the words ''or sparkling hard cider'' after the words ''sparkling wine''; and

■ f. In the Office of Management and Budget control number reference, by removing the number ''1512–0298'' and adding, in its place, the number ''1513–0115''.

■ 19. Section 24.302 is amended by:

■ a. Revising the introductory text and paragraphs (a), (d), (e), (g), (i), and (j);

■ b. Adding paragraph (k); and

■ c. Revising the Office of Management and Budget control number reference.

The revisions and addition read as follows:

§ 24.302 Effervescent wine record.

A proprietor who produces or receives effervescent wine in bond shall maintain records showing the transaction date and details of production, receipt, storage, removal, and any loss incurred. Records will be maintained for each specific process used (bulk or bottle fermented, injection of carbon dioxide) and by the specific kind of wine, *e.g.,* grape, apple, pear, cherry, hard cider. The record will contain the following:

(a) The volume of still wine or still hard cider filled into bottles or pressurized tanks prior to secondary fermentation or prior to the addition of carbon dioxide;

* * * * *

(d) The volume of bottle fermented sparkling wine or bottle fermented sparkling hard cider in process, transferred and received;

(e) The volume returned to still wine or still hard cider;

* * * * *

(g) The volume of finished effervescent wine bottled or packed (amount produced);

* * * * *

(i) An explanation of any unusual transaction;

(j) If the proprietor is an importer of wine to which the provisions of § 27.140 of this chapter apply, any certification or other records required at the time of release from customs custody under that section; and

(k) The amount of carbon dioxide in artificially carbonated hard cider or sparkling hard cider.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1381, as amended (26 U.S.C. 5367))

(Approved by the Office of Management and Budget under control number 1513–0115 and 1513–XXXX)

§ 24.306 [Amended]

■ 20. Section 24.306 is amended by adding in the words ''and bulk still hard cider'' after the words ''still wine'' in the last sentence, and, in the Office of Management and Budget control number reference, by removing the number ''1512–0298'' and adding, in its place, the number ''1513–0115''.

§ 24.308 [Amended]

■ 21. Section 24.308 is amended by adding the words ''or bottle fermented sparkling hard cider'' after the words ''bottle fermented sparkling wine'' in the last sentence of paragraph (a), and, in the Office of Management and Budget control number reference, by removing the number ''1512–0298'' and adding, in its place, the number ''1513–0115''.

§ 24.319 [Amended]

■ 22. Section 24.319 is amended by adding the words ''or still hard cider'' after the words ''still wine'', and, in the Office of Management and Budget control number reference, by removing the number ''1512–0298'' and adding, in its place, the number ''1513–0115''.

■ 23. Subpart P, consisting of §§ 24.331 and 24.332, is added to read as follows:

Subpart P—Eligibility for the Hard Cider Tax Rate

§ 24.331 Wine eligible for the hard cider tax rate.

A wine removed on or after January 1, 2017 is eligible for the hard cider tax rate listed in § 24.270 if:

(a) It contains no more than 0.64 gram of carbon dioxide per 100 milliliters of wine;

(b) It is derived primarily from apples or pears, or from apple juice concentrate or pear juice concentrate and water, as described in § 24.332(a);

(c) It contains no fruit product or fruit flavoring other than apple or pear, as described in § 24.332(b) and (c); and

(d) It contains at least one-half of 1 percent and less than 8.5 percent alcohol by volume.

(Sec. 335, Pub. L. 114–113, 129 Stat. 3109, as amended (26 U.S.C. 5041))

§ 24.332 Hard cider materials.

This section pertains to wine that is eligible for the hard cider tax rate as set out in § 24.331.

(a) *Apples and pears.* Wine will be considered to be derived primarily from apples or pears, or from apple juice concentrate or pear juice concentrate and water, if the apple juice, pear juice, or combination of apple and pear juice, or the equivalent amount of concentrate of apple and/or pear juice reconstituted to the original brix of the juice prior to concentration, or any combination thereof, represents more than 50 percent of the volume of the finished product.

(b) *Fruit products.* (1) Wine is not eligible for the hard cider tax rate if it contains any fruit product other than apple or pear. A fruit product is any material derived or made from any fruit or part of a fruit, including but not limited to, concentrates, extracts, juices, powders, or wine spirits.

(2) Notwithstanding the provisions of § 24.332(b)(1), an authorized wine treating material set forth in § 24.246 that is derived from a fruit other than apple or pear may be used in the production of wine otherwise eligible for the hard cider tax rate if it is used for a purpose other than flavoring and it is either used in accordance with the wine treating materials provisions of § 24.246 (if used in a natural wine), or used in amounts insufficient to impart a fruit flavor other than apple or pear (if used in a special natural wine or other than standard wine). In determining whether the use of wine treating materials derived from a fruit other than apple or pear is for a purpose other than flavoring, TTB will consider such factors as the labeling and advertising of the product. Any written or pictorial reference to a material derived from a fruit other than apple or pear (other than the inclusion of a wine treating material in an ingredient labeling statement) in the labeling or advertising of a wine will be treated as evidence that the wine treating material was added for the purpose of flavoring the wine.

(c) *Flavorings.* Wine is not eligible for the hard cider tax rate if it contains any fruit flavoring other than apple or pear. For purposes of this section, a fruit flavoring other than apple or pear is any flavoring that imparts the flavor of a fruit other than apple or pear and includes a natural fruit flavor, an artificial fruit flavor, and a natural flavor that artificially imparts the flavor of a fruit that is not contained in that flavor. In determining whether the use of a flavoring imparts the flavor of a fruit other than apple or pear, TTB will consider such factors as the labeling and advertising of the product. Any written or pictorial reference to a fruit flavor other than apple or pear in the labeling or advertising of a wine that contains a flavoring will be treated as evidence that the wine contains a flavoring that imparts a fruit flavor other than apple or pear and thus the wine is not eligible for the hard cider tax rate. The use of spices, honey, hops, or pumpkins as a flavoring will not make a wine ineligible for the hard cider tax rate.

(Sec. 335, Pub. L. 114–113, 129 Stat. 3109, as amended (26 U.S.C. 5041))

PART 27—IMPORTATION OF DISTILLED SPIRITS, WINES, AND BEER

■ 24. The authority citation for part 27 continues to read as follows:

Authority: 5 U.S.C. 552(a), 19 U.S.C. 81c, 1202; 26 U.S.C. 5001, 5007, 5008, 5010, 5041, 5051, 5054, 5061, 5121, 5122–5124, 5201, 5205, 5207, 5232, 5273, 5301, 5313, 5382, 5555, 6109, 7805.

■ 25. Section 27.11 is amended by adding the definition of ''Hard cider'' in alphabetical order to read as follows:

§ 27.11 Meaning of terms.

* * * * *

Hard cider. A wine that meets the eligibility requirements set forth in § 24.331 for the hard cider tax rate set forth in § 24.270.

* * * * *

■ 26. Section 27.59 is revised by:

■ a. Designating the current paragraph as paragraph (a);

■ b. Adding a paragraph heading to newly designated paragraph (a);

■ c. Adding paragraph (b); and

■ d. Adding an Office of Management and Budget control number reference.

The designation and additions read as follows:

§ 27.59 Wines.

(a) *General.* * * *

(b) *Hard cider.* The container of any wine eligible for the ''hard cider'' tax class set forth in § 24.270 of this chapter must be labeled in accordance with the requirements applicable to wine containers removed from wine premises under § 24.257(a)(4) of this chapter. (See § 24.331 of this chapter for the eligibility requirements for the hard cider tax rate).

(Approved by the Office of Management and Budget under control number 1513–XXXX)

Signed: December 7, 2016.

John J. Manfreda,

Administrator.

Approved: January 4, 2017.

Timothy E. Skud,

Deputy Assistant Secretary (Tax, Trade and Tariff Policy).

[FR Doc. 2017–00333 Filed 1–19–17; 8:45 am]

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DEPARTMENT OF LABOR

Office of the Secretary

29 CFR Part 70

RIN 1290–AA30

Revision of FOIA Regulations

AGENCY: Office of the Secretary, Department of Labor.

ACTION: Final rule.

SUMMARY: This final rule amends the Department of Labor's regulations under the Freedom of Information Act (''FOIA''). The regulations have been revised to update and streamline the language of several procedural provisions and to incorporate changes brought about by the amendments to the FOIA under the OPEN Government Act of 2007 and the FOIA Improvement Act of 2016. Additionally, the regulations have been updated to incorporate changes in the agency's administrative structure.

DATES: This final rule is effective January 23, 2017.

FOR FURTHER INFORMATION CONTACT: Ramona Branch Oliver, Director, Office of Information Services, 202–693–5391 (this is not a toll free number) or 1–877–889–5627 (TTY). Individuals with hearing or speech impairments may access the telephone number above via TTY by calling the toll-free Federal Information Relay Service at (800) 877–8839.

SUPPLEMENTARY INFORMATION: On August 17, 2016, the Department of Labor published a Notice of Proposed Rule Making (NPRM) to revise its existing regulations under the FOIA found at 29 CFR part 70, to update and streamline the language of several procedural provisions and to incorporate changes brought about by the amendments to the FOIA under the OPEN Government Act of 2007, Public Law 110–175, 121 Stat. 2524, and the FOIA Improvement Act of 2016, Public Law 114–185, 130 Stat. 538 (enacted June 30, 2016). The Department invited comments through October 17, 2016.

Discussion of Comments: Preparation of the NPRM and this finalization of the

Department's updated FOIA regulation satisfied the requirement in Section 3 of the FOIA Improvement Act of 2016 that each agency review and revise its FOIA regulation to be consistent with the statutory requirements.

Interested persons were afforded the opportunity to participate in the rulemaking process through submission of written comments to the proposed rule during the open comment period. In total, the Department received six submissions in response to its proposed rule, including comments from two Federal agencies, as well as internal comments from a component of the Department. Due consideration has been given to each of the comments received and, in response, the Department has made several modifications to the rule. These modifications include clarifying, revising, or expanding various provisions, withdrawing a provision, retaining existing language for certain other provisions, and making technical edits, such as correcting Web site links.

Discussion of each of the comments, and the Departments response follows:

Section 70.2 Definitions

One commenter expressed concern that the use of the phrase ''or financial'' is superfluous in the first clause of subsection § 70.2(j) (defining submitter), because that phrase is already included in the definition of ''confidential commercial information'' in subsection (b). The Department has determined that including ''or financial'' is helpful in identifying different types of information. As such, DOL declines to make the requested change.

One commenter suggested that the definition of ''unusual circumstances'' in § 70.2(k)(3) should state that consultation could occur ''. . . with another agency or among two or more components of the Department having a substantial interest in the determination of the request.'' The Department agrees that the proposed change will enhance the rule's clarity, and so the revised final rule adopts this proposed language.

Section 70.3 Policy

One commenter suggested changing the title of § 70.3 from ''Policy'' to ''Presumption of Openness,'' because, following the June 2016 statutory amendments to FOIA, this section addresses not a matter of policy, but of law. The Department agrees with this comment. The final rule modifies this section to be titled, ''Presumption of Openness.''

One commenter suggested that the regulation does not include the use of exclusions and that if DOL would have any opportunity to use an exclusion, they should be addressed. The Department agrees with this comment and has incorporated by reference the law enforcement exclusions in subsection (c) of the FOIA at §§ 70.3 and 70.20(b).

Section 70.4 Proactive Disclosure of Departmental Records

One commenter noted that the Department makes many (a)(2) proactive disclosures by posting materials on DOL Web sites other than the Department's specific FOIA Web site pages, for which a URL was included in this section of the NPRM. Accordingly, the commenter suggested removing a specific link to the Department's FOIA Web page and instead stating more generally that records may be accessed through the Department's Web site. The Department agrees with the comment, and the final rule has been revised to remove the specific URL.

Section 70.19 Requirements for Making a Request

Three commenters expressed concern regarding DOL's decision to continue to have a single central email box for the receipt of FOIA requests, and raised a number of points regarding whether this creates inefficiencies in DOL's FOIA processing. Specifically, § 70.19(a) of the NPRM states, consistent with the Department's existing FOIA regulation at 29 CFR 70.19(b), that any FOIA request submitted electronically, by email, must be submitted to a single email address.

One commenter requested that DOL clarify that even though DOL's FOIA program is decentralized, DOL will receive all electronic submission to one inbox and that each request will then be sent to the appropriate component for processing. That same commenter expressed concern that the NPRM language regarding a central email inbox may be in conflict with the NPRM at § 70.19(b), which states that requesters should submit their request directly to the component that maintains the records sought. The same commenter suggested that if DOL has a single email address for electronic submissions, it should make clear that the requester must designate the component to which the request is directed. One of the commenters sought to confirm that requests submitted electronically are not automatically subject to the ''routing'' provision, under which the time processing clock does not begin until a request is received in the proper component or until ten days after receipt anywhere in the Department. This same commenter flagged that § 70.19(b)(2) of the NPRM provides that requesters who do not know where to submit their request can email it to the same central email address indicated for all requests submitted electronically in (a), and that ''routing'' procedures might then apply. The same commenter asked how DOL will know which requests need to be ''routed'' vs. those that are just being submitted electronically to a particular component. The commenter also stated that when requesters indicate the component (or components if they are submitting to more than one), it does not seem appropriate for DOL to ''route'' these requests because this is the only way they may be submitted electronically. The commenter asked whether DOL considered establishing email addresses to receive electronic submissions for all components. The commenter noted that this approach would seem to allow requests to get where they need to go more efficiently.

DOL has considered these comments and—for the reasons explained below—has determined that DOL's FOIA program can be administered most effectively with a single central email inbox for receipt of FOIA requests, but that some clarification to the regulatory text of § 70.19 can be made to explain DOL's process and address the commenters' concerns. DOL has established an effective method to receive and assign incoming FOIA requests received by email. DOL has established a single centralized FOIA mailbox, which is actively monitored by staff within the Department's central FOIA office, the Office of Information Services. Staff who monitor the FOIA mailbox are responsible for ensuring that FOIA requests are appropriately directed to the agency component(s) identified by the requester or to the appropriate component(s) in instances where the requester has failed to identify a component or has identified the wrong component. Receipt in the central FOIA email inbox does not automatically add 10 additional days for ''routing,'' rather, the Department has established an operational performance measure that tracks whether requests are routed to the agency component(s) likely to maintain responsive records within two business days of receipt. By having a centralized FOIA email inbox monitored by FOIA staff, the Department has ensured that FOIA requests are not received at email addresses that are not regularly monitored, or sent to DOL staff who are not involved in FOIA processing and may not know what to do with an incoming FOIA request.

For these reasons, the Department has determined to retain the concept of a

central incoming FOIA email inbox. However, DOL has modified the language of § 70.19(a) in several ways to increase public clarity and promote efficient logging and assignment of incoming FOIA requests. The final text adds language to § 70.19(a) and (b) further explaining the Department's process, and indicating that requesters should, when emailing in requests, identify the component or components to which they are submitting their FOIA request in order to facilitate the timely assignment and processing of their request. The final rule also seeks to clarify the circumstances under which the time to respond begins to run, by moving the last clause of § 70.19(b)(2) from the NPRM into a separate provision at § 70.19(b)(3), and clarifying that if a requester submits a FOIA request to the incorrect DOL FOIA component, or sends a request to the Department's central FOIA office or mailbox without identifying the component(s) to which the request is submitted, the time to respond begins to run when the request is received by the proper component, but no later than 10 working days after receipt in any component identified in Appendix A or in the Office of Information Services.

One commenter raised a concern that the language in the NPRM at § 70.19(d)(3) is overly broad regarding when the processing of a FOIA request can be tolled. The commenter suggested that the rule track the language of the statute more closely to indicate a request can be tolled only once if the agency is seeking clarification from the requester about their request. The Department concurs, and in response to this comment, the final rule has been modified to read, ''While an agency component awaits a requester's modified FOIA request, the processing time limits described in Sec. 70.25(a)(1) will be tolled (that is, the processing time clock will be stopped on one occasion only) until clarification is received from the requester.''

Section 70.20 Responsibility for Responding to Requests

One commenter raised concerns with the provision at § 70.20(a) providing that the Department's Office of Information Services may coordinate responses when ''it is determined that records responsive to a request may be located in multiple components of the Department.'' The commenter suggested that this provision might add an obligation beyond the requirements of the FOIA, for example, requiring one component to conduct searches at those other components and process those records.

The Department disagrees that this provision, which is not a procedural change from the existing regulation, creates new or additional responsibilities. This provision does not mandate that OIS coordinate responses, or that one component undertake searches of other components' records. Rather this provision recognizes that there may be circumstances where similar or the same documents are maintained by multiple components of the Department, and it is appropriate to coordinate search, review and response, for example, through use of coordinated search terms. Although DOL's FOIA program is decentralized, it remains one agency and seeks to speak in one voice on matters of disclosure of documents that may be duplicative or have overlapping equities across the agency. In addition, this comment raises a policy question related to how DOL structures its FOIA operation, and the Department has determined that it will continue its present program administration and flexibility in the operation of the Department's FOIA program. Accordingly, the final rule adopts the provision as proposed.

Regarding the provisions at § 70.20(d) related to consultations and referrals, one commenter suggested that the first sentence should be edited to clarify that consults and referrals are only appropriate when a component has actually located records. The Department agrees that the language could more clearly identify when consultations and referrals are appropriate and, therefore, the Department is making the following change in the final rule: ''Consultations and referrals. When a component is reviewing records in response to a request, it will determine if another component of the Department, or of the Federal Government, is better able to determine whether the record can be disclosed or is exempt from disclosure under the FOIA.''

Also, in reference to § 70.20(d), one commenter suggested that the language be altered because, as written, it does not authorize the Department to consult with the Office of White House Counsel, which is neither an ''agency'' nor a Department component. The Department does not believe a revision is necessary because the regulatory language recognizes that consultation or referral may occur with ''another component . . . of the Federal Government.'' The Department believes that this adequately covers instances where DOL might need to consult with the Office of White House Counsel.

One commenter suggested that § 70.20 should include language on ''coordination'' to cover situations where referring records may not be appropriate, and gave as an example instances where a referral would reveal classified information. The Department does not believe this change is necessary, as the Department does not have original classification authority pursuant to the prevailing executive order on national security classification and, likewise, does not have the authority to downgrade or declassify documents.

Section 70.21 Responses to Requests

One commenter suggested that § 70.21(b) should require the Department's acknowledgement letter to indicate the date of receipt of the request. The Department declines to make this change as it is beyond the scope of the current statutory requirement. It is also unnecessary to DOL's FOIA program because Departmental policy is that acknowledgment letters should provide requesters with a link to the public FOIA portal, which provides the requester with the date of receipt. The final rule adopts the provision as proposed.

One commenter suggested that § 70.21(c) should be revised to add that written communications notifying a requester of the grant of a request will include notice of the availability of the FOIA Public Liaison, as required by the FOIA Improvement Act of 2016. The Department concurs and has modified this provision in the final rule to read, ''The component must notify the requester of the right to seek assistance from the Department's FOIA Public Liaison.''

One commenter suggested that the wording of § 70.21(e)(5) of the NPRM, regarding the ''Content of the denial,'' incorrectly implies that ''adverse determination'' and ''denial'' are different in kind, and suggested combining the subparts of (5) into (e). The commenter stated that any denial is an adverse determination and must include notification of appeal rights as well as the availability of OGIS and the FOIA Public Liaison. The Department concurs that the language of § 70.21(e)(5) in the NPRM potentially led to confusion. In response to this comment, the Department has combined subsections (4) and (5) of this provision in the final rule.

The Final Rule includes a new provision of Section 70.21(e)(5) that states ''Engaging in dispute resolution services provided by OGIS is a voluntary process. If the Department agrees to participate in the mediation services provided by OGIS, it will

actively engage as a partner to the process in an attempt to resolve the dispute.'' This change is in response to a comment received on Section 70.22.

Section 70.22 Appeals From Denials of Requests

The NPRM at Sec. 70.22(a) identified as one circumstance in which a FOIA requester could file an appeal ''a component's failure to respond to the request within the time limits.'' One commenter objected to this language on grounds that there is no response to appeal when the DOL component to which a FOIA request was submitted has not provided a timely response, and that a requester does not need to administratively appeal in order to exhaust administrative remedies. The Department declines to remove the reference to ''a component's failure to respond to the request within the time limits'' as an example of a circumstance that may prompt an administrative appeal because many requesters are not inclined to seek judicial review on the basis of a delayed response to a pending FOIA request and would rather seek to obtain disclosure of information through the administrative appeals process. Although a requester does not have to exhaust his or her administrative remedies on timeliness issues where no initial response has been provided, the Department believes that the better practice under FOIA is to continue to make an administrative appeal available to requesters, and that eliminating this option may result in requesters believing that litigation is necessary when an administrative process may more quickly and cost effectively address the requester's concern.

One commenter raised a concern with the wording of § 70.22(a) in that it does not identify the ability of a requester to appeal from a failure of the Department to respond in a timely manner to a request for expedited processing, or to appeal in the event that the Department refuses to provide responsive records in a requested format. As Sec. 70.21 provides, a FOIA requester may file an administrative appeal in response to any denial or adverse determination. Section 70.22(a) provides examples of when a requester may seek a *de novo* review through the Department's FOIA administrative appeal process, but the list is not intended to be an exhaustive identification of the bases for appeal. To assist the public, the Department has revised this provision in the final rule to make clear that it provides examples rather than an exhaustive list.

One commenter suggested that using the word ''must'' in the second sentence of § 70.22(b) regarding items to be provided along with a FOIA appeal creates an administrative hurdle that is counter to the spirit of FOIA. The Department agrees with this comment and has modified the language in the final rule to replace the word ''must'' with ''should.''

One commenter suggested adding language about engaging with OGIS somewhere in § 70.22 or its own section to satisfy the requirement of the FOIA Improvement Act that agency FOIA regulations include procedures for engaging with OGIS. The commenter suggested including the following language in the Final Rule: ''Engaging in dispute resolution services provided by OGIS. Mediation is a voluntary process. If an agency agrees to participate in the mediation services provided by OGIS, it will actively engage as a partner to the process in an attempt to resolve the dispute.'' In response to this comment, the Department has included language in Section 70.21(e)(5), which it believes is a more appropriate place for this language. The new provision of Section 70.21(e)(5) states ''Engaging in dispute resolution services provided by OGIS is a voluntary process. If the Department agrees to participate in the mediation services provided by OGIS, it will actively engage as a partner to the process in an attempt to resolve the dispute.''

Section 70.24 Form and Content of Action on Appeals

One commenter suggested that in the third sentence, ''Consistent with the statute'' should be removed, noting that the Freedom of Information Act, as amended, does not require notification about services provided by OGIS in appeals letters, but rather that any such inclusion is based on guidance from the Office of Information Policy. In response to this comment, the Department has modified the language in the final rule and removed the phrase ''consistent with the statute'' from this provision.

Section 70.25 Time Limits and Order in Which Requests and Appeals Must Be Processed

One commenter suggested that § 70.25(a) should note that the routing of requests may impact timing. The commenter recommended adding the following language, ''In instances involving misdirected requests that are re-routed pursuant to § 70.20(c) of this subpart, the response time will commence on the date that the request is received by the proper component's office that is designated to receive requests, but in any event not later than 10 working days after the request is first received by any component's office that is designated by these regulations to receive requests.'' The Department agrees with this comment and has added the suggested language to the final rule.

One commenter suggested removing the clause ''unless there are exceptional circumstances within the meaning of 5 U.S.C. 552(a)(6)(C)'' from § 70.25(a) and noted that only a court can make a determination that there are exceptional circumstances. The Department agrees with this comment, and has removed this provision from the final rule.

In relation to § 70.25(c)(1), one commenter suggested that, as a practical matter and looking at agency response times, agencies tend to need more than ten additional days when there are unusual circumstances requiring extension of processing times. The commenter suggested that the language stating ''this extension should not ordinarily exceed ten business days'' be removed. The Department agrees with this comment, and has removed this phrase from the final rule.

One commenter suggested that the Department was creating an unnecessary administrative burden by requiring in § 70.25(e)(3) that a person seeking expedited processing as a member of the media establish that ''he or she is a person whose main professional activity or occupation is information dissemination . . .'' Consistent with administrative guidance, the Department believes that to meet the standard for expedited processing under the FOIA statute (see 5 U.S.C. 552(a)(6)(E)(v)(II)) a requester who is not a full-time member of the news media must establish that he or she is a person whose primary professional activity or occupation is information dissemination, though it need not be the requester's sole occupation. DOL does not believe that requiring the requester to meet the statutory standard is unnecessarily burdensome. Therefore, the final rule adopts the provision as proposed in the NPRM.

Section 70.26 Confidential Commercial Information

One commenter recommended that Executive Order 12,600 be cited consistently in §§ 70.26(a) and (g)(3). The Department agrees with this comment and has edited these sections for consistency in the final rule.

One commenter suggested that § 70.26(e) and (f)(3) should be modified to provide that the ''reasonable period'' that a submitter has to object to the agency's proposed treatment of the submitter's material will be at least five business days from the date that the

submitter receives the agency's notice. The Department declines to make this change. The NPRM provision at § 70.26(e) indicates that a submitter will be provided with a ''reasonable time to respond'' to a notice from the agency, but also notes that the response date will be specified in the submitter's notice provided in accordance with Executive Order 12,600. Furthermore, the time provided to a submitter for responding is based upon the volume and complexity of the materials requested. Section 70.26(f)(3) does not discuss response time periods. The final rule adopts both provisions as proposed.

Section 70.38 Definitions Related to Costs

One commenter suggested a change to § 70.38(a), which states that ''request'' in the costs subpart includes any request and any appeal. The commenter suggested removing the reference to the FOIA appeal stage on grounds that no fees are assessed on appeal, noting that while a request may be remanded on appeal for further processing, any subsequent fees apply to the underlying request, not the appeal. The Department agrees with this comment, and the final rule removes references to FOIA appeals.

Regarding § 70.38(c), one commenter suggested using the term ''duplication'' throughout instead of ''reproduction'' in order to be consistent with the FOIA statute, which states that fees shall be limited to search, duplication, and review, and OMB guidelines. The Department agrees with this comment and has modified the final rule to use the term ''duplication.''

Three commenters made suggestions related to the definition of educational institutions for cost purposes in the NPRM at § 70.38(g)(2). The commenters suggested that this provision should reflect and adopt the holding of *Sack* v. *Department of Defense,* 823 F.3d 687 (D.C. Cir. 2016), which found that students may qualify as educational institution requesters in some circumstances. In response to these comments and to retain flexibility to determine a student's eligibility for a fee waiver based on any future judicial interpretations or guidance issued by Department of Justice, the Department has removed the following sentence from the final rule, ''A request from a student enrolled in an individual course of study at an education institution would not qualify as a request from the institution.''

Regarding the definition of ''representative of the news media'' in the NPRM at § 70.38(i)(3), one commenter asked that DOL remove two uses of the word ''qualifying'' from the phrase ''qualifying news media entity'' because inclusion of the word ''qualifying'' gives the impression that a news media entity must meet some separate or additional qualification standard. The commenter suggested that the phrase ''news media entity'' is sufficient. The Department agrees with this comment. The final rule removes the word ''qualifying'' from this provision.

70.40 Charges Assessed for the Production of Records

Two commenters noted that, in § 70.40(c) and (d), DOL has identified four types of requesters for fee purposes, and suggested that these groups could be combined into three. The Department has determined that identifying four types of requesters is helpful to distinguish between different types of requesters that communicate with the Department. As such, the Department declines to make the change requested, and the final rule adopts the provision as proposed.

One commenter noted that § 70.40(e)(1)(iii) of the NPRM states that if a search requires transportation of the searcher to the location of the records, or of the records to the searcher, all transportation costs in excess of $5 may be added to search costs. The commenter raised questions about this provision and whether it was an appropriate cost to pass on to the requester. In response to the comments received, the Department is removing this provision from the final rule as unnecessary. The Department notes that this provision has been in effect since 2006 when the DOL last published its FOIA regulations (see 71 FR 30762), but is not aware of any instance in which such costs have been assessed.

One commenter noted that § 70.40(e)(2) of the NPRM states that a FOIA component may require the requester to provide any medium requested other than paper. The commenter raised questions about this provision and whether it was an appropriate burden to pass on to the requester. In response, the Department is removing this provision from the final rule as unnecessary. The Department notes that this provision has been in effect since 2006 when DOL last published its FOIA regulations (see 71 FR 30762), but is not aware of any instances where this provision was applied.

One commenter asked if DOL has evaluated the actual cost of reproducing paper copies identified in § 70.40(e)(2) (FOIA requests) and 70.53(c) (requests for documents from the Office of Labor-Management Standards). The commenter suggested that, with the use of commercial vendors, actual costs are likely close to 5 or 10 cents per page, rather than the 15 cent per page costs included in the NPRM. DOL notes that it does not typically use commercial vendors to help fulfill requests for paper-based records in response to FOIA requests, and therefore that comparison may not be applicable here. Furthermore, as the NPRM states, reproduction cost also reflects the time associated with reproducing the documents being provided. Accordingly, DOL declines to make a change to the cost of the duplication of paper-based records. The final rule adopts the provision as proposed.

Regarding the NPRM provisions regarding limitations on fee charges, one commenter suggested that § 70.40(e)(4)(i) should use language that more closely matches the statutory language. The commenter suggested that section (4) should note what the ''certain fees'' are, and suggested, that, as written, this provision does not account for the possibility of the exception in § 70.40(e)(4)(ii). Additionally, the commenter suggested that § 70.40(e)(4)(ii) should be edited to state ''and more than 5,000 pages are necessary to respond to the request,'' noting that ''deemed to be responsive'' is potentially more restrictive. The Department agrees that this comment has identified some potentially confusing language, and has accordingly modified § 70.40(e)(4) to incorporate the recommended change.

In addition to the changes made as a result of specific comments and Departmental feedback, this final rule includes changes already identified in the NRPM (see 81 FR 54770) to include changes in language and structure of the existing regulation and to codify changes based on the FOIA Improvement Act of 2016. As an additional administrative update, the Department is also making a change to § 70.27 (Preservation of records) to update the National Archives and Records Administration's General Records Schedule which governs the disposition of FOIA case files and related records from GRS 14 to GRS 4.2: Information Access and Protection Records.

Regulatory Flexibility Act: The Secretary of Labor, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this regulation and by approving it certifies that this regulation will not have a significant economic impact on a substantial number of small entities. Under the FOIA, agencies may recover only the

direct costs of searching for, reviewing, and duplicating the records processed for requesters, and only for certain classes of requester and when particular conditions are satisfied. Thus, fees assessed by the Department are nominal. Further, the ''small entities'' that make FOIA requests, as compared with individual requesters and other requesters, are relatively few in number.

Executive Order 12,866: This regulation has been drafted and reviewed in accordance with Executive Order 12,866, § 1(b), Principles of Regulation. The Office of Management and Budget has determined that this rule is not a ''significant regulatory action'' under Executive Order 12,866, § 3(f), Regulatory Planning and Review, and accordingly this rule has not been reviewed by OMB.

Unfunded Mandates Reform Act of 1995: This rule will not result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1995: This rule is not a major rule as defined by section 251 of the Small Business Regulatory Enforcement Fairness Act of 1996 (as amended), 5 U.S.C. 804. This rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

List of Subjects in 29 CFR Part 70

Administrative Practice and Procedure; Freedom of Information Act; Privacy.

■ For the reasons stated in the preamble, the Department of Labor revises 29 CFR part 70 to read as follows:

PART 70—PRODUCTION OR DISCLOSURE OF INFORMATION OR MATERIALS

Subpart A—General

Sec.

Subpart B—Procedures for Disclosure of Records Under the Freedom of Information Act

Subpart C—Costs for Production of Records

Subpart D—Public Records and Filings

Authority: 5 U.S.C. 301; 29 U.S.C. 551 *et seq.;* 5 U.S.C. 552, as amended; Reorganization Plan No. 6 of 1950, 5 U.S.C. Appendix, 29 U.S.C. 1026 (106), 5 U.S.C. app. 11., Executive Order. 12,600, 52 FR 23781, 3 CFR, 1988 Comp., p. 235. This part also implements the public information provisions of the Labor-Management Reporting and Disclosure Act (LMRDA), 29 U.S.C. 435, see § 70.53 below; the Employee Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. 1026 (106), see § 70.54 below; and the Federal Advisory Committee Act (FACA), 5 U.S.C. app. 11, see § 70.40(i) below.

Subpart A—General

§ 70.1 General provisions.

(a) This part is organized as follows: Subpart A contains general information about Department of Labor policies and procedures; subpart B sets forth the procedures for obtaining access to records of the Department; subpart C contains the Department's regulations on fees; and subpart D sets forth the procedures for obtaining access to certain public records. Appendix A contains a list of all Department of Labor FOIA components from which records may be obtained.

(b) This part contains the rules that the Department of Labor follows in processing requests for records under the Freedom of Information Act (FOIA), as amended, 5 U.S.C. 552. The rules in this part should be read together with the text of the FOIA, which provides additional information about access to records maintained by the Department. Additionally, the Department's ''Guide to Submitting Requests under the FOIA'' and related documents contain helpful information about the specific procedures particular to the Department with respect to making FOIA requests, and descriptions of the types of records maintained by different components of the Department. These references are available at *http://www.dol.gov/dol/foia/guide6.html.*

(c) Requests made by individuals for records about themselves under the Privacy Act of 1974, 5 U.S.C. 552a, are processed under 29 CFR part 71 as well as under this part. Information routinely provided to the public as part of a regular Department activity (for example, press releases issued by the Office of Public Affairs (OPA)) may be provided to the public without following this subpart.

(d) As set forth in § 70.3 of this part, the Department operates its FOIA program with a presumption of openness and withholds records or information under the FOIA only when the Department reasonably foresees that disclosure would harm an interest protected by a FOIA exemption or when disclosure is prohibited by law.

(e) The Department has a decentralized system for processing requests, with each component handling requests for its own records. Each component has a FOIA Customer Service Center that can assist individuals in locating records and address questions regarding pending FOIA requests. A list of the Department's Customer Service Centers is available at *http://www.dol.gov/dol/foia/RequestorServiceCenters.htm.*

(f) The Secretary has designated a Chief FOIA Officer for the Department. Contact information for the Chief FOIA Officer is available on the Department's FOIA Web site, *http://www.dol.gov/dol/foia/.* The Office of Information Services (OIS), which is located within the Office of the Solicitor, provides Department level guidance and oversight for the Department's FOIA program and supports the statutorily-based responsibilities of the DOL Chief FOIA Officer.

(g) The Department has a designated FOIA Public Liaison who can assist individuals in locating records of a particular component and with resolving issues relating to the processing of a pending FOIA request. Information concerning the DOL FOIA

Public Liaison is available at *http://www.dol.gov/sol/foia/liaison.htm.* The DOL FOIA Public Liaison is responsible for assisting in reducing delays in FOIA processing, increasing transparency and understanding, providing information concerning the status of requests, and assisting in the resolution of disputes.

§ 70.2 Definitions.

As used in this part:

(a) The terms agency, person, party, rule, order, and adjudication have the meaning attributed to these terms by the definitions in 5 U.S.C. 551.

(b) Confidential commercial information means commercial or financial information received or obtained by the Department from a submitter, directly or indirectly, that arguably may be protected from disclosure under Exemption 4 of the FOIA.

(c) The Department means the Department of Labor.

(d) FOIA Component means an official component of the Department that has authority to disclose or withhold records under the FOIA and to which requests to inspect or copy records in its custody should be addressed. Department of Labor components are listed in Appendix A to this part.

(e) Record means any information that would be an agency record subject to the requirements of this part when maintained by an agency in any format, including an electronic format, and any information described under this part that is maintained for an agency by an entity under Government contract, for the purposes of records management.

(f) Request means any written request for records made pursuant to 5 U.S.C. 552(a)(3) and which meets the requirements of this part.

(g) Requester means any person who makes a request.

(h) Search means to look for, manually or by automated means, Department records for the purpose of locating them in response to a pending request.

(i) The Secretary means the Secretary of Labor.

(j) Submitter means any person or entity from whom the Department receives or obtains confidential commercial or financial information, directly or indirectly. The term submitter includes, but is not limited to, corporations, labor organizations, non-profit organizations, and local, state, and tribal and foreign governments.

(k) Unusual circumstances means, to the extent reasonably necessary for the proper processing of a FOIA request:

(1) The need to search for and collect the requested records from physically separate facilities;

(2) The need to search for, collect, and appropriately examine a voluminous amount of separate and distinct records that are demanded in a single request; or

(3) The need for consultation, which will be conducted with all practicable speed, with another agency or among two or more components of the Department having a substantial interest in the determination of the request.

§ 70.3 Presumption of openness.

All agency records, except those exempt from mandatory disclosure by one or more provisions of 5 U.S.C. 552(b) or the law enforcement exclusions in 5 U.S.C. 552(c), will be made promptly available to any person submitting a written request in accordance with the procedures of this part. The Department will withhold records under the FOIA only when the Department reasonably foresees that disclosure would harm an interest protected by a FOIA exemption or is prohibited by law. Whenever the Department determines that full disclosure of a requested record is not possible, the Department will consider whether partial disclosure is possible and will take reasonable steps to segregate and release nonexempt material. As set forth in Sec. 70.4, the Department proactively identifies and discloses records of interest to the public.

§ 70.4 Proactive disclosure of Departmental records.

Records that are required by the FOIA, 5 U.S.C. 552(a)(2), to be made available for public inspection in an electronic format may be accessed through the Department's Web site. Each component is responsible for determining which of its records are required to be made publicly available, as well as identifying additional records of interest to the public that are appropriate for public disclosure, and for posting and indexing such records. Each component must review and update its Web site of posted records and indices on an ongoing basis.

§ 70.5 Compilation of new records.

Nothing in 5 U.S.C. 552 or this part requires that any agency or component create a new record in order to respond to a request for records. A component must, however, make reasonable efforts to search for records that already exist in electronic form or format, except when such efforts would significantly interfere with the operation of the component's automated information systems. The component will determine what constitutes a reasonable effort on a case-by-case basis.

§ 70.6 Disclosure of originals.

(a) No original record or file in the custody of the Department of Labor, or of any component or official thereof, will on any occasion be given to any agent, attorney, or other person not officially connected with the Department without the written consent of the Secretary, the Solicitor of Labor or the Inspector General.

(b) The individual authorizing the release of the original record or file must ensure that a copy of the document or file is retained in the component that had custody and/or control when an original document or file is released pursuant to this subpart.

§§ 70.7–70.18 [Reserved]

Subpart B—Procedures for Disclosure of Records Under the Freedom of Information Act

§ 70.19 Requirements for making a request.

(a) *General information.* The Department of Labor has a decentralized system for responding to requests submitted under the FOIA, as explained in § 70.1 of this part. In addition to processing requests for its own records, each agency component has the ability to receive FOIA requests in writing by mail, delivery service/courier or facsimile at its designated mailing address. However, to enable proper handling, any FOIA request submitted electronically, by email, must be submitted to the Department's central FOIA mailbox at *foiarequests@dol.gov.* FOIA requests sent electronically to any other email address will not be accepted. A FOIA request submitted via email should designate the component or components to which the requester is submitting his/her request. The Department's central FOIA mailbox is regularly monitored, and requests will be assigned to the appropriate DOL FOIA component.

(b) *Request for records.* To make a request for records of the Department, whenever possible, a requester should write directly to the FOIA office of the component that maintains the records sought or, if emailing a request to the DOL central FOIA mailbox, should identify the component(s) to which the request is directed. Submitting the request directly to the FOIA office of the component that maintains the records sought, or identifying that component when sending a FOIA request via email, will facilitate the quickest response. The

requester must provide a mailing address to receive correspondence, and it may facilitate processing if telephone and email contact information are provided.

(1) The Department's components for the purposes of the FOIA are listed in Appendix A to this part. The function and mailing address of each Department of Labor component is available on the Department's FOIA Web site at *http://www.dol.gov/dol.foia.* This page also provides other information that is helpful in determining where to make a request.

(2) Requesters who cannot determine the proper FOIA office component or who are requesting records from multiple components may also send requests to the Office of the Solicitor, Office of Information Services, 200 Constitution Avenue NW., Room N–2420, Washington, DC 20210 or by email to *foiarequests@dol.gov.*

(3) Pursuant to § 70.25(a), if a requester submits a FOIA request to the incorrect DOL FOIA component, or sends a request to the Department's central FOIA office or mailbox without identifying the component(s) to which the request is submitted, the time to respond begins to run when the request is received by the proper component, but no later than 10 working days after receipt in any component identified in Appendix A or in the Office of Information Services.

(c) *Description of records sought.* Requesters must describe the record or records sought in sufficient detail to enable Department personnel to locate them with a reasonable amount of effort. To the extent possible, the request should provide enough identifying information to help the component identify the requested records, such as the subject of the record, the date or approximate date when the record was created, the record's title or name, case or file number, reference number, the person or office or the office location that created it, and any other pertinent identifying details. Prior to submitting the request, a requester may wish to consult the references provided in § 70.1 of this part, the relevant FOIA Requester Service Center or the FOIA Public Liaison to discuss the records they are seeking and to receive assistance on how to describe the records.

(d) *Deficient descriptions and revised requests.* If the description is insufficient, so that a knowledgeable employee who is familiar with the subject area of the request cannot identify the record with a reasonable amount of effort, the component processing the request will notify the requester and describe what additional information is needed to process the request.

(1) Requesters who are attempting to modify or reformulate their requests may discuss their requests with the component's designated FOIA contact, the FOIA Public Liaison, or a representative of OIS, each of whom is available to assist the requester in reasonably describing the records sought. Every reasonable effort will be made to assist a requester in the identification and location of the records sought. If the requester fails to reasonably describe the records sought, the agency's response to the request may be delayed.

(2) Any amended request must be confirmed in writing and meet the requirements for a request under this part.

(3) While an agency component awaits a requester's modified FOIA request, the processing time limits described in § 70.25(a)(1) will be tolled (that is, the processing time clock will be stopped on one occasion only) until clarification is received from the requester.

§ 70.20 Responsibility for responding to requests.

(a) *In general.* Except in the instances stated in paragraph (d) of this section, the component that first receives a request for a record and maintains that record is the component responsible for responding to the request. In determining which records are responsive to a request, a component ordinarily will include only records in its possession as of the date that the component begins the search; if any other date is used, the component will inform the requester of that date. A record that is excluded from the requirements of the FOIA pursuant to 5 U.S.C. 552(c), is not considered responsive to a request. When it is determined that records responsive to a request may be located in multiple components of the Department, the Office of Information Services may coordinate the Department's response. If the Office of Information Services deems a consolidated response appropriate, it will issue such a response on behalf of the Department.

(b) *Authority to grant or deny requests.* Pursuant to relevant exemptions under 5 U.S.C. 552(b) or an exclusion under 5 U.S.C. 552(c), the head of a component, or designee, is authorized to grant or to deny any requests for records that are maintained by that component.

(c) *Re-routing of misdirected requests.* Where a component's FOIA office determines that a request was misdirected within the Department, the receiving component's FOIA office will work with OIS to facilitate the routing of the request to the FOIA office of the proper component(s).

(d) *Consultations and referrals.* When a component is reviewing records in response to a request, it will determine if another component of the Department, or of the Federal Government, is better able to determine whether the record can be disclosed or is exempt from disclosure under the FOIA. If the receiving component determines that it is not best able to process the record, then the receiving component will either:

(1) Respond to the request after consulting with the component or agency best able to determine whether to disclose the record and with any other component or agency that has a substantial interest in the record; or

(2) Refer the responsibility for responding to the request regarding that record to the component best able to determine whether to disclose it, or to another agency that originated the record (but only if that entity is subject to the FOIA). Ordinarily, the component or agency that originated the record will be presumed to be best able to determine whether to disclose it.

(e) *Notice of referral.* Whenever a component refers all or any part of the responsibility for responding to a request to another component or agency, the component will notify the requester of the referral and inform the requester of the name of each component or agency to which the request has been referred and provide contact information for that component or agency.

(f) *Classified records.* Any request for classified records which are in the custody of the Department of Labor will be referred to the classifying agency under paragraphs (d) and (e) of this section.

§ 70.21 Responses to requests.

(a) *In general.* Components should, to the extent practicable, communicate with requesters using the method that is most likely to increase the speed and efficiency of the communication, including by electronic means, such as by email.

(b) *Acknowledgements of requests.* A component will acknowledge each new request and assign it an individualized tracking number. Components will include in the acknowledgment a brief description of the records sought to allow the requesters to more easily keep track of their requests.

(c) *Granting a request.* After a component makes a determination to

grant a request in full or in part, the component will notify the requester in writing. The component will provide the record in the form or format requested if the record is readily reproducible in that form or format, provided the requester has agreed to pay and/or has paid any fees required by subpart C of this part. The component will determine on a case-by-case basis what constitutes a readily reproducible format. Each component should make reasonable efforts to maintain its records in commonly reproducible forms or formats. The component must notify the requester of the right to seek assistance from the Department's FOIA Public Liaison.

(d) *Adverse determinations of requests.* A component making an adverse determination denying a request in any respect must notify the requester in writing. Adverse determinations, or denials of requests, include decisions that: The requested record is exempt, in whole or in part, from release pursuant to one or more exemptions under the FOIA, 5 U.S.C. 552; the request does not reasonably describe the records sought; the information requested is not a record subject to the FOIA; the requested record does not exist, cannot be located, or has been destroyed; or the requested record is not readily producible in the form or format sought by the requester. Adverse determinations also include denials involving fees or fee waiver matters or denials for requests for expedited processing.

(e) *Content of the denial.* The denial notice must be signed by the component agency head or a designee and will include:

(1) The name and title or position of the person responsible for the denial;

(2) A brief statement of the reason or reasons for the denial, including any FOIA exemption or exemptions applied or procedural reasons relied upon by the component in denying the request;

(3) An estimate of the volume of records or information withheld, in number of pages or in some other reasonable form of estimation. This estimate does not need to be provided if the volume is otherwise indicated through deletions on records disclosed in part, or if providing an estimate would harm an interest protected by the exemption under which the deletion was made;

(4) A statement that the denial may be appealed as described under Sec. 70.22; and

(5) A statement notifying the requester of the right to seek dispute resolution services from the Department's FOIA Public Liaison or the Office of Government Information Services (within the National Archives and Records Administration). Engaging in dispute resolution services provided by OGIS is a voluntary process. If the Department agrees to participate in the mediation services provided by OGIS, it will actively engage as a partner to the process in an attempt to resolve the dispute.

(f) *Markings on released documents.* Markings on released documents must be clearly visible to the requester. Records disclosed in part shall be marked to show the amount of information deleted and the exemption(s) under which the deletion was made unless doing so would harm an interest protected by an applicable exemption. The location of the information deleted shall also be indicated on the records, if technically feasible.

§ 70.22 Appeals from denial of requests.

(a) A requester may appeal to the Solicitor of Labor from any adverse determination, including but not limited to when one or more of the following has occurred: A request for access to records has been denied in whole or in part; a requester disputes a determination that records cannot be located or have been destroyed; a requester disputes a determination by a component concerning the assessment or waiver of fees; a requester disputes the denial of a request for expedited processing; or a component fails to respond to a request within the time limits set forth in the FOIA and referenced in 70.25(a). The appeal must be filed within 90 days of the date of the action being appealed.

(b) The appeal must state in writing the grounds for appeal, and it may include any supporting statements or arguments, but such statements are not required. In order to facilitate processing of the appeal, the appeal should include the assigned request number (if applicable), appellant's mailing address and daytime telephone number, as well as copies of the initial request and the component's response. If mailed, the envelope and the letter of appeal should be clearly marked: ''Freedom of Information Act Appeal.'' Any amendment to the appeal must be in writing and received prior to a decision on the appeal.

(c) The appeal should be addressed to the Solicitor of Labor, Office of the Solicitor, FOIA Appeals Unit, Division of Management and Administrative Legal Services, U.S. Department of Labor, 200 Constitution Avenue NW., Room N–2420, Washington, DC 20210. Appeals also may be submitted by fax to 202–693–5538 or by email to *foiaappeal@dol.gov.* Appeals submitted to any other email address will not be accepted.

§ 70.23 Action on appeals.

The Solicitor of Labor, or designee, will review the appellant's appeal and make a determination de novo whether the action of the component was proper and in accordance with the applicable law.

§ 70.24 Form and content of action on appeals.

The disposition of an appeal will be issued by the Solicitor of Labor or designee in writing. A decision affirming, in whole or in part, the decision below will include a brief statement of the reason or reasons for the affirmance, including the FOIA exemption or exemptions relied upon, and its relation to each record withheld. The appeal determination will advise the requester of the availability of the mediation services of the Office of Government Information Services (OGIS) as a non-exclusive alternative to litigation. The appeal will also notify the requester of the statutory right to judicial review of the denial by the United States District Court for the judicial district in which the requester resides or maintains his or her principal place of business, the judicial district in which the requested records are located, or the District of Columbia. If it is determined on appeal that a record should be disclosed, the record will be provided in accordance with the decision on appeal. If it is determined that records should be denied in whole or in part, the appeal determination will include an estimate of the volume of records or information withheld, in number of pages or in some other reasonable form of estimation. This estimate does not need to be provided if the volume is otherwise indicated through deletions on records disclosed in part, or if providing an estimate would harm an interest protected by an applicable exemption.

§ 70.25 Time limits and order in which requests and appeals must be processed.

(a) *Time limits.* The FOIA establishes a 20 business day deadline for regular requests and appeals, and a 10 calendar day time limit for making determinations regarding expedited processing. Components of the Department of Labor will comply with the time limits required by the FOIA for responding to and processing requests and appeals. In instances involving misdirected requests that are re-routed pursuant to § 70.20(c) of this subpart,

the response time will commence on the date that the request is received by the proper component's office that is designated to receive requests, but in any event not later than 10 working days after the request is first received by any component's office that is designated by these regulations to receive requests. A component or the designated appeal authority will notify a requester whenever they are unable to respond to or process the request or appeal within the time limits established by the FOIA.

(b) *Multitrack processing.* All components must designate a specific track for requests that are granted expedited processing, in accordance with the standards set forth in paragraph (d) of this section. A component may also designate additional processing tracks that distinguish between simple and complex requests based on the estimated amount of work and/or time needed to process the request, including based on the number of pages involved and the need for consultations or referrals. Components shall advise the requesters of the track into which their request falls and, when appropriate, shall offer the requester an opportunity to limit the scope of their requests in order to qualify for faster processing within the specified limits of the component's faster track.

(c) *Unusual circumstances.* (1) Where the statutory time limits for processing a request cannot be met because of ''unusual circumstances,'' as set forth in the FOIA at 5 U.S.C. 552(a)(6)(B)(i)–(iii), and the component determines to extend the time limits on that basis, the component shall, before the expiration of the 20 working day deadline to respond, notify the requester in writing of the unusual circumstances and of the date by which processing of the request can be expected to be completed. If the component intends to extend the deadline to respond by more than ten working days, the component must:

(i) Provide the requester with an opportunity either to modify the request so that it may be processed within the time limits or to arrange an alternative time period with the component for processing the request or a modified request;

(ii) Make available to the requester the contact information for the designated FOIA contact and the FOIA Public Liaison to assist the requester; and

(iii) Notify the requester of the right to seek dispute resolution services from the Office of Government Information Services (OGIS).

(d) *Aggregating requests.* Where a component reasonably believes that multiple requests submitted by a requester, or by a group of requesters acting in concert, constitute a single request that would otherwise involve unusual circumstances, and the requests involve clearly related matters, they may be aggregated. Components shall not aggregate multiple requests involving unrelated matters.

(e) *Expedited processing.* (1) Requests and appeals will be taken out of order and given expedited treatment whenever it is determined that they involve:

(i) Circumstances in which the lack of expedited treatment could reasonably be expected to pose an imminent threat to the life or physical safety of an individual;

(ii) An urgency to inform the public about an actual or alleged federal government activity, if made by a person primarily engaged in disseminating information;

(iii) The loss of substantial due process rights; or

(iv) A matter of widespread and exceptional media interest in which there exists possible questions about the government's integrity which affect public confidence.

(2) A request for expedited processing may be made at the time of the initial request for records or at any later time. For a prompt determination, a request for expedited processing must be received by the proper component. Requests based on paragraphs (e)(1)(i) through (iv) of this section must be submitted to the component that maintains the records requested.

(3) A requester who seeks expedited processing must submit a statement, certified to be true and correct to the best of that person's knowledge and belief, explaining in detail the basis for requesting expedited processing. For example, a requester within the category in paragraph (e)(1)(ii) of this section, if not a full-time member of the news media, must establish that he or she is a person whose main professional activity or occupation is information dissemination, though it need not be his or her sole occupation. Such a requester also must establish a particular urgency to inform the public about the government activity involved in the request—one that goes beyond the public's general right to know about government activity. The existence of numerous articles published on a given subject can be helpful in establishing the requirement that there be an ''urgency to inform'' the public on a topic. As a matter of administrative discretion, a component may waive the formality of certification.

(4) Within ten calendar days of its receipt of a request for expedited processing, the proper component will decide whether to grant the request and will notify the requester of the decision. If a request for expedited treatment is granted, the request will be given priority and will be processed as soon as practicable. If a request for expedited processing is denied, any appeal of that decision will be acted on expeditiously.

§ 70.26 Confidential commercial information.

(a) *In general.* Confidential commercial information will be disclosed under the FOIA only in accordance with this section and Executive Order 12,600, ''Predisclosure Notification Procedures for Confidential Commercial Information'' (3 CFR 1988 Comp., p.235).

(b) *Designation of confidential commercial information.* A submitter of confidential commercial information will use good-faith efforts to designate, by appropriate markings, either at the time of submission or at a reasonable time thereafter, any portions of its submission that it considers to be protected from disclosure under Exemption 4. These designations will expire ten years after the date of the submission unless the submitter requests, and provides justification for, a longer designation period.

(c) *Notice to submitters.* A component will provide a submitter with prompt written notice of a FOIA request that seeks its confidential commercial information whenever required under paragraph (d) of this section, except as provided in paragraph (g) of this section, in order to give the submitter an opportunity to object in writing to disclosure of any specified portion of that information under paragraph (e) of this section. The notice will either describe the confidential commercial information requested or include copies of the requested records or record portions containing the information. When notification to a voluminous number of submitters is required, notification may be made by posting or publishing notice reasonably likely to accomplish such notification.

(d) *When notice is required.* Notice will be given to a submitter whenever:

(1) The information requested under the FOIA has been designated in good faith by the submitter as information considered protected from disclosure under Exemption 4; or

(2) A component has reason to believe that the information requested under the FOIA may be protected from disclosure under Exemption 4, but has not yet determined whether the information is

protected from disclosure under that exemption or any other applicable exemption.

(e) *Opportunity to object to disclosure.* A component will allow a submitter a reasonable time to respond to the notice described in paragraph (c) of this section taking into account the amount of material the submitter has to review and the deadlines imposed by the FOIA or agreed to with the requester. If a submitter has any objection to disclosure, it is required to submit a detailed written statement. The statement must show why the information is a trade secret or commercial or financial information that is privileged or confidential. In the event that a submitter fails to respond to the notice within the time specified, the submitter will be considered to have no objection to disclosure of the information. Information provided by a submitter under this paragraph may itself be subject to disclosure under the FOIA.

(f) *Notice of intent to disclose.* A component will consider a submitter's timely objections and specific grounds for non-disclosure in deciding whether to disclose confidential commercial information. Whenever a component decides to disclose confidential commercial information over the objection of a submitter, the component will give the submitter written notice, which will include:

(1) A statement of the reason(s) why each of the submitter's disclosure objections were not sustained;

(2) A description of the confidential commercial information to be disclosed; and

(3) A specified disclosure date, which will be a reasonable time subsequent to the notice.

(g) *Exceptions to notice requirements.* The notice requirements of paragraphs (c) and (f) of this section will not apply if:

(1) The component determines that the information should not be disclosed;

(2) The information lawfully has been published or has been officially made available to the public;

(3) Disclosure of the information is required by statute (other than the FOIA) or by a regulation issued in accordance with the requirements of Executive Order 12,600; or

(4) The designation made by the submitter under paragraph (b) of this section appears obviously frivolous or such a designation would be unsupportable—except that, in such a case, the component will, within a reasonable time prior to a specified disclosure date, give the submitter written notice of any final decision to disclose the information.

(h) *Notice of a FOIA lawsuit.* Whenever a requester files a lawsuit seeking to compel the disclosure of confidential commercial information, the component will promptly notify the submitter.

(i) *Corresponding notice to requesters.* Whenever a component provides a submitter with notice and an opportunity to object to disclosure under paragraphs (d) and (e) of this section, the component will also notify the requester(s). Whenever a component notifies a submitter of its intent to disclose requested information under paragraph (f) of this section, the component will also notify the requester(s). Whenever a submitter files a lawsuit seeking to prevent the disclosure of confidential commercial information, the component will notify the requester(s).

(j) *Notice requirements.* The component will fulfill the notice requirements of this section by addressing the notice to the confidential commercial submitter or its legal successor at the address indicated on the records, or the last known address. If the notice is returned, the component will make a reasonable effort to locate the confidential commercial submitter or its legal successor. Where notification of a voluminous number of submitters is required, such notification may be accomplished by posting and publishing the notice in a place reasonably calculated to accomplish notification.

§ 70.27 Preservation of records.

Each component will preserve all correspondence relating to the requests it receives under this part, and all records processed pursuant to such requests, until disposition or destruction of such correspondence and records is authorized by Title 44 of the United States Code or the National Archives and Records Administration's General Records Schedule 4.2. Records are not to be destroyed while they are the subject of a pending request, appeal, or lawsuit under the Act.

§§ 70.28–70.37 [Reserved]

Subpart C—Costs for Production of Records

§ 70.38 Definitions related to costs.

The following definitions apply to this subpart:

(a) *Request,* in this subpart, includes any request, as defined by § 70.2(f) of this part.

(b) *Direct costs* means those expenditures which a component actually incurs in searching for and duplicating (and in the case of commercial use requests, reviewing) records to respond to a FOIA request. Direct costs include, for example, the salary of the Federal employee performing work (the basic rate of pay for the Federal employee plus 16 percent of that rate to cover benefits) and the cost of operating duplication machinery. Not included in direct costs are overhead expenses such as costs of space, heating or lighting the facility in which the records are kept.

(c) *Duplication* means the process of making a copy of a record necessary to respond to a request. Such copy can take the form of paper, microform, audio-visual materials or electronic records (such as a CD or other media).

(d) *Search* means the process of looking for and retrieving records or information that are responsive to a FOIA request. It includes page-by-page or line-by-line identification of information within records and also includes reasonable efforts to locate and retrieve information from records maintained in electronic form or format. FOIA components will ensure that searches are done in the most efficient and least expensive manner reasonably possible. A search does not include the review of material, as defined in paragraph (e) of this section, which is performed to determine whether material is exempt from disclosure.

(e) *Review* means the process of examining records, including audio-visual, electronic mail, etc., located in response to a request to determine whether any portion of the located record is exempt from disclosure, and accordingly may be withheld. It also includes the act of preparing materials for disclosure, *i.e.,* doing all that is necessary to excise them and otherwise prepare them for release. Review time includes time spent contacting any submitter, and considering and responding to any objections to disclosure made by a submitter under Sec. 70.26, but does not include time spent resolving general legal or policy issues regarding the application of exemptions.

(f) *Commercial use request* means a request from or on behalf of a person who seeks information for a use or purpose that furthers his or her commercial, trade or profit interests, which can include furthering those interests through litigation. When considering fee issues, components will determine, whenever reasonably possible, the use to which a requester will put the requested records. When it appears that the requester will put the records to a commercial use, either because of the nature of the request

itself or because a component has reasonable cause to doubt a requester's stated use, the component will provide the requester a reasonable opportunity to submit further clarification.

(g) *Educational institution* means an institution which:

(1) Is a preschool, public or private elementary or secondary school, an institution of undergraduate higher education, an institution of graduate higher education, an institution of professional education, or an institution of vocational education; or

(2) Operates a program or programs of scholarly research. To qualify under this definition, the program of scholarly research in connection with which the information is sought must be carried out under the auspices of the academic institution itself as opposed to the individual scholarly pursuits of persons affiliated with an institution. For example, a request from a professor predicated upon research funding granted to the institution would meet its requirements. A request from a professor seeking information that will assist in the writing of a book, independent of his or her institutional responsibilities, would not qualify under this definition.

(h) *Non-commercial scientific institution* means an institution that is not operated on a commercial basis and that is operated solely for the purpose of conducting scientific research, the results of which are not intended to promote any particular product or industry.

(i) *Representative of the news media* means any person or entity that gathers information of potential interest to a segment of the public, uses its editorial skills to turn the raw materials into a distinct work, and distributes that work to an audience. Examples of news media entities include television or radio stations that broadcast ''news'' to the public at large and publishers of periodicals that disseminate ''news'' and make their products available through a variety of means to the general public, as well as news organizations that operate solely on the internet. Alternative media may be considered to be news media entities. These examples are not all inclusive.

(1) Factors indicating status as a news media representative include press accreditation, guild membership, a history of continuing publication, business registration, and/or Federal Communication Commission licensing, among others.

(2) For purposes of this definition, news contemplates information that is about current events or that would be of current interest to the public.

(3) A freelance journalist will be treated as a representative of the news media if the person can demonstrate a solid basis for expecting publication of matters related to the requested information through a news media entity. A publication contract with a news media entity satisfies this requirement. An individual's past publication record with such organizations is also relevant in making this determination.

§ 70.39 Statutes specifically providing for setting of fees.

This subpart will not apply to fees charged under any statute, other than the FOIA, that specifically requires an agency to set and collect fees for particular types of records.

§ 70.40 Charges assessed for the production of records.

(a) *General.* Components shall charge for processing requests under the FOIA in accordance with the provisions of this section and with the OMB Guidelines. In order to resolve any fee issues that arise under this section, a component may contact a requester for additional information. Components will ensure that searches, review, and duplication are conducted in the most efficient and least expensive manner. A component ordinarily will collect all applicable fees before sending copies of records to the requester.

(b) *Types of charges.* There are three types of charges assessed in connection with the production of records in response to a request, specifically, charges for costs associated with:

(1) Searching for or locating responsive records (search costs),

(2) Duplicating such records (duplication costs), and

(3) Reviewing records to determine whether any materials are exempt (review costs).

(c) *Types of requesters.* (1) There are four types of requesters:

(i) Commercial use requesters,

(ii) Educational and non-commercial scientific institutions,

(iii) Representatives of the news media, and

(iv) All other requesters.

(2) Depending upon the type of requester, as set forth in paragraph (c)(1) of this section, the charges outlined in paragraph (d) of this section may be assessed.

(d) *Types of charges that will be assessed for each type of request*—(1) *Commercial use request.* When a requester makes a commercial use request, search costs, duplication costs and review costs will be assessed in their entirety.

(2) *Educational or non-commercial scientific institution request.* When an educational or non-commercial scientific institution makes a request, only duplication costs will be assessed, excluding charges for the first 100 pages.

(3) *Request by representative of news media.* When a representative of the news media makes a request, only duplication costs will be assessed, excluding charges for the first 100 pages.

(4) *All other requesters.* Requesters making a request which does not fall within paragraph (d)(1), (2), or (3) of this section will be charged search costs and duplication costs, except that the first 100 pages of duplication and the first two hours of search time will be furnished without charge. Where computer searches are involved, the monetary equivalent of two hours of search time by a professional employee will be deducted from the total cost of computer processing time.

(e) *Charges for each type of activity*—(1) *Search costs.* (i) When a search for records is performed by a clerical employee, a rate of $5.00 per quarter hour will be applicable. When a search is performed by professional or supervisory personnel, a rate of $10.00 per quarter hour will be applicable. Components will charge for time spent searching even if they do not locate any responsive records or they withhold the records located as exempt from disclosure.

(ii) For computer searches of records, requesters will be charged the direct costs of conducting the search, except as provided in paragraph (e)(4) of this section.

(2) *Duplication costs.* The standard copying charge for records in black and white paper copy is $0.15 per page. This charge includes the operator's time to duplicate the record. When responsive information is provided in a format other than 8½ x 11 or 11 x 14 inch black and white paper copy, such as computer tapes, disks and color copies, the requester may be charged the direct costs of the tape, disk, audio-visual or whatever medium is used to produce the information, as well as the direct cost of duplication, including operator time.

(3) *Review costs.* Costs associated with the review of records, as defined in § 70.38(e), will be charged for work performed by a clerical employee at a rate of $5.00 per quarter hour when applicable. When professional or supervisory personnel perform work, a rate of $10.00 per quarter hour will be charged, when applicable. Except as noted in this paragraph, charges may

only be assessed for review the first time the records are analyzed to determine the applicability of specific exemptions to the particular record or portion of the record. Thus a requester would not be charged for review at the administrative appeal level with regard to the applicability of an exemption already applied at the initial level. When, however, a record has been withheld pursuant to an exemption which is subsequently determined not to apply and is reviewed again at the appellate level to determine the potential applicability of other exemptions, the costs attendant to such additional review will be assessed.

(4) *Limitations on charging fees.* If a component fails to comply with the time limits in which to respond to a request, it shall not assess certain fees except:

(i) If there are unusual circumstances (as that term is defined in § 70.25(c)) and the component has provided timely written notice, the component is permitted ten additional days to respond to the request. After the expiration of the ten additional days, the component is no longer permitted to assess search fees or, in the instances of requests from requesters described in § 70.38(h) and (i), duplication fees except as described in paragraph (e)(4)(ii) of this section.

(ii) If there are unusual circumstances (as that term is defined in § 70.25(c)), and more than 5,000 pages of documents are necessary to respond to the request, the component may continue to charge assessable fees for as long as it takes to process the request, provided that the component has provided timely written notice and discussed with the requester via telephone, email, or written mail (or made at least three good-faith attempts to do so) how the requester could effectively limit the scope of the pending request.

(iii) If a court has determined that exceptional circumstances exist, as defined in the FOIA, 5 U.S.C. 552(a)(6)(C) the agency's failure to comply with any time limits of the FOIA are excused for the length of time provided by the court order.

(5) *Mailing cost.* Where responses are sent by mail, no postage charge will be made for transmitting by regular mail a single copy of the requested record to the requester, or for mailing additional copies where the total postage cost does not exceed $5.00. However, where the volume of paper or other produced material or the requested method of transmittal requested is in excess of $5.00, the transmittal costs will be added.

(f) *Aggregating requests for purposes of assessing costs.* (1) Where a component reasonably believes that a requester or a group of requesters acting together is attempting to divide a request into a series of requests for the purpose of avoiding fees, the disclosure officer may aggregate those requests and charge accordingly.

(2) Components may presume that multiple requests of this type made within a 30-day period have been submitted in order to avoid fees. Where requests are separated by a longer period, disclosure officers will aggregate them only where a solid basis exists for determining that aggregation is warranted under all of the circumstances involved. Multiple requests involving unrelated matters will not be aggregated.

(g) *Interest charges.* Components will assess interest on an unpaid bill starting on the 31st day following the date of billing the requester. Interest charges will be assessed at the rate provided in 31 U.S.C. 3717 and will accrue from the date of the billing until payment is received by the component. Components will follow the provisions of the Debt Collection Act of 1982 (Pub. L. 97–365, 96 Stat. 1749), as amended, and its administrative procedures, including the use of consumer reporting agencies, collection agencies, and offset.

(h) *Authentication of copies*—(1) *Fees.* The FOIA does not require certification or attestation under seal of copies of records provided in accordance with its provisions. Pursuant to provisions of the general user-charger statute, 31 U.S.C. 9701 and Subchapter II of title 29 U.S.C., the following charges will be made when, upon request, such services are rendered by the agency in its discretion:

(i) For certification of true copies, $10.00 each certification.

(ii) For attestation under the seal of the Department, $10.00 each attestation under seal.

(2) *Authority and form for attestation under seal.* Authority is hereby given to any officer or officers of the Department of Labor designated as authentication officer or officers of the Department to sign and issue attestations under the seal of the Department of Labor.

(i) *Transcripts.* Fees for transcripts of an agency proceeding, as defined in the Administrative Procedure Act, 5 U.S.C. 5521(12) will be assessed in accordance with the provisions of this subpart.

(j) *Privacy Act requesters.* A request from an individual or on behalf of an individual for a record maintained by that individual's name or other unique identifier which is contained within a component's system of records, will be treated under the fee provisions at 29 CFR 71.6.

§ 70.41 Waiver or reduction of fees.

(a) *Requirements for waiver or reduction of fees.* (1) Records responsive to a request will be furnished without charge or at a charge reduced below that established under § 70.40(e) of this subpart, where a component determines, based on all available information, that the requester has demonstrated that:

(i) Disclosure of the requested information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government, and

(ii) Disclosure of the information is not primarily in the commercial interest of the requester.

(2) To determine whether the requirement of paragraph (a)(1)(i) of this section is met, components will consider the following factors:

(i) The subject of the request: Whether the subject of the requested records concerns ''the operations or activities of the government.'' The subject of the requested records must concern identifiable operations or activities of the federal government, with a connection that is direct and clear, not remote or attenuated.

(ii) The informative value of the information to be disclosed: Whether the disclosure is ''likely to contribute'' to an understanding of government operations or activities. The disclosable portions of the requested records must be meaningfully informative about government operations or activities in order to be ''likely to contribute'' to an increased public understanding of those operations or activities. The disclosure of information that already is in the public domain, in either a duplicative or a substantially identical form, would not be as likely to contribute to such understanding where nothing new would be added to the public's understanding.

(iii) The contribution to an understanding of the subject by the public likely to result from disclosure: Whether disclosure of the requested information will contribute to ''public understanding.'' The disclosure must contribute to the understanding of a reasonably broad audience of persons interested in the subject, as opposed to the individual understanding of the requester. A requester's expertise in the subject area and ability and intention to effectively convey information to the public will be considered. It will be presumed that a representative of the

news media will satisfy this consideration.

(iv) The significance of the contribution to public understanding: Whether the disclosure is likely to contribute ''significantly'' to the public understanding of government operations or activities. The public's understanding of the subject in question must be enhanced by the disclosure to a significant extent.

(3) To determine whether the requirement of paragraph (a)(1)(ii) of this section is met, components will consider the following factors:

(i) The existence and magnitude of a commercial interest: Whether the requester has a commercial interest that would be furthered by the requested disclosure. The component will consider any commercial interest of the requester (with reference to the definition of ''commercial use request'' in § 70.38(f) of this subpart), or of any person on whose behalf the requester may be acting, that would be furthered by the requested disclosure. Requesters will be given an opportunity in the administrative process to provide explanatory information regarding this consideration.

(ii) The primary interest in disclosure: Whether any identified commercial interest of the requester is sufficiently large, in comparison with the public interest in disclosure, that disclosure is ''primarily in the commercial interest of the requester.'' A fee waiver or reduction is justified where the public interest standard is satisfied and that public interest is greater in magnitude than that of any identified commercial interest in disclosure. The component ordinarily will presume that where a news media requester has satisfied the public interest standard, the public interest will be the interest primarily served by disclosure to that requester. Disclosure to data brokers or others who merely compile and market government information for direct economic return will not be presumed to primarily serve the public interest.

(4) Where only some of the records to be released satisfy the requirements for a waiver of fees, a waiver will be granted only for those records.

(5) Requests for the waiver or reduction of fees should address the factors listed in paragraph (a) of this section, insofar as they apply to each request.

(b) *Submission.* Requests for a waiver or reduction of fees should be made when the request is first submitted to the component and should address the criteria referenced above. A requester may submit a fee waiver request at a later time so long as the underlying record request is pending or on administrative appeal. When a requester who has committed to pay fees subsequently asks for a waiver of those fees and that waiver is denied, the requester will be required to pay any costs incurred up to the date the fee waiver request was received.

(c) *Appeal rights.* Requesters dissatisfied with treatment of fee waiver or reduction requests may follow the procedures for appeal under Sections 70.22 and 70.23.

§ 70.42 Consent to pay fees.

(a) The Department will not assess or collect fees where the fee to be assessed, after deducting any free pages and/or search time, is less than $25.00. When making a request, a requester may specify a willingness to pay up to a certain amount, *e.g.,* $50.00 or $200.

(b) No request will be processed if a component reasonably believes that the fees are likely to exceed the amount to which the requester has originally consented, absent supplemental written consent by the requester to proceed after being notified of this determination.

(c) When a component determines or estimates that the fees to be assessed in accordance with this section will exceed $25.00, the component shall notify the requester of the actual or estimated amount of the fees, including a breakdown of the fees for search, review or duplication, unless the requester has indicated a willingness to pay fees as high as those anticipated. If only a portion of the fee can be estimated readily, the component must advise the requester accordingly. Such notice may invite the requester to reformulate the request to satisfy his or her needs at a lower cost.

(d) Components must make available their FOIA contact to assist any requester in reformulating a request to meet the requester's needs at a lower cost.

§ 70.43 Payment of fees.

(a) *De minimis costs.* As noted in § 70.42(a) of this subpart, the Department has determined it will not assess or collect fees below $25.00. In these cases, the cost of collecting and processing a fee equals or exceeds the amount of the fee which would otherwise be assessed. The Department will assess fees where the costs to be assessed, after deduction of any free pages and/or search time, is $25.00 or higher.

(b) *How payment will be made.* Requesters will pay fees assessed by check or money order made payable to the Treasury of the United States, and sent to the component that is processing the request.

(c) *Advance payments and billing.* (1) Prior to beginning to process a request, the component will make a preliminary assessment of the amount that can properly be charged to the requester for search and review time and copying costs. Where a component determines or estimates that a total fee to be charged under this section will be more than $250.00, the component will require the requester to make an advance payment of an amount up to the entire anticipated fee before beginning to process the request. The component may waive the advance payment where the component receives a satisfactory assurance of full payment from a requester who has a history of prompt payment of an amount similar to the one anticipated by the request.

(2) Where a requester has previously failed to pay a properly charged FOIA fee to any component of the Department of Labor within 30 days of the date of billing, a component will require the requester to pay the full amount due, plus any applicable interest as provided in Sec. 70.40(f) and to make an advance payment of the full amount of any anticipated fee, before the component begins to process a new request or appeal or continues to process a pending request or appeal from that requester.

(3) For a request other than those described in paragraphs (c)(1) and (2) of this section, a component will not require the requester to make an advance payment before beginning to process a request. Payment owed for work already completed on a request pursuant to consent of the requester is not an advance payment and a component may require the requester to make a payment for such work prior to releasing any records to the requester.

(d) *Time limits to respond extended when advance payments are requested.* When a component has requested an advance payment of fees in accordance with paragraph (c) of this section, the time limits prescribed in Sec. 70.25 will only begin to run after the component has received the advance payment.

§ 70.44 Other rights and services.

Nothing in this subpart will be construed to entitle any person, as of right, to any service or to the disclosure of any records to which such person is not entitled under the FOIA.

§§ 70.45–70.52 [Reserved]

Subpart D—Public Records and Filings

§ 70.53 Office of Labor-Management Standards.

(a) The following documents in the custody of the Office of Labor-Management Standards are public information available for inspection and/or purchase of copies in accordance with paragraphs (b) and (c) of this section.

(1) Data and information contained in any report or other document filed pursuant to sections 201, 202, 203, 211, 301 of the Labor-Management Reporting and Disclosure Act of 1959 (73 Stat. 524–28, 530, 79 Stat. 888, 73 Stat. 530, 29 U.S.C. 431–433, 441, 461).

(2) Data and information contained in any report or other document filed pursuant to the reporting requirements of 29 CFR part 458, which are the regulations implementing the standards of conduct provisions of the Civil Service Reform Act of 1978, 5 U.S.C. 7120, and the Foreign Service Act of 1980, 22 U.S.C. 4117. The reporting requirements are found in 29 CFR 458.3.

(3) Data and information contained in any report or other document filed pursuant to the Congressional Accountability Act of 1995, 2 U.S.C. 1351, 109 Stat. 19.

(b) The documents listed in paragraph (a) of this section are available from: U.S. Department of Labor, Office of Labor-Management Standards, Public Disclosure Room, N–1519, 200 Constitution Avenue NW., Washington, DC 20210. Reports filed pursuant to section 201 of the Labor-Management Reporting and Disclosure Act of 1959 and pursuant to 29 CFR 458.3 implementing the Civil Service Reform Act of 1978 and the Foreign Service Act of 1980 for the year 2000 and thereafter are also available at *http://www.union-reports.dol.gov.*

(c) Pursuant to 29 U.S.C. 435(c) which provides that the Secretary will by regulation provide for the furnishing of copies of the documents listed in paragraph (a) of this section, upon payment of a charge based upon the cost of the service, these documents are available at a cost of $ .15 per page for record copies furnished. Authentication of copies is available in accordance with the fee schedule established in Sec. 70.40. In accordance with 5 U.S.C. 552(a)(4)(A)(vi), the provisions for fees, fee waivers and fee reductions in subpart C of this part do not supersede these charges for these documents.

(d) Upon request of the Governor of a State for copies of any reports or documents filed pursuant to sections 201, 202, 203, or 211 of the Labor-Management Reporting and Disclosure Act of 1959 (73 Stat. 524–528, 79 Stat. 888; 29 U.S.C. 431–433, 441), or for information contained therein, which have been filed by any person whose principal place of business or headquarters is in such State, the Office of Labor-Management Standards will:

(1) Make available without payment of a charge to the State agency designated by law or by such Governor, such requested copies of information and data, or

(2) Require the person who filed such reports and documents to furnish such copies or information and data directly to the State agency thus designated.

§ 70.54 Employee Benefits Security Administration.

(a) The annual financial reports (Form 5500) and attachments/schedules as filed by employee benefit plans under the Employee Retirement Income Security Act (ERISA) are in the custody of the Employee Benefits Security Administration (EBSA) at the address indicated in paragraph (b) of this section, and the right to inspect and copy such reports, as authorized under ERISA, at the fees set forth in this part, may be exercised at such office.

(b) The mailing address for the documents described in this section is: U.S. Department of Labor, Employee Benefits Security Administration, Public Documents Room, 200 Constitution Avenue NW., Washington, DC 20210.

Appendix A to Part 70—FOIA Components

The following list identifies the individual agency components of the Department of Labor for the purposes of the FOIA. Each component is responsible for making records in its custody available for inspection and copying, in accordance with the provisions of the FOIA and this part. Unless otherwise specified, the mailing addresses for the following national office components are listed below. Updated contact information for national and regional offices can be found on the DOL Web site at *http://www.dol.gov/dol/foia.*

U.S. Department of Labor
200 Constitution Avenue NW.
Washington, DC 20210.

1. Office of the Secretary (OSEC).
2. Office of the Solicitor (SOL).
3. Office of Administrative Law Judges (ALJ), 800 K Street NW., Suite N–400, Washington, DC 20001–8002.
4. Office of the Assistant Secretary for Administration and Management (OASAM).
5. Office of the Assistant Secretary for Policy (OASP).
6. Office of the Chief Financial Officer (OCFO).
7. Office of Congressional and Intergovernmental Affairs (OCIA).
8. Office of Disability Employment Policy (ODEP).
9. Office of Federal Contract Compliance Programs (OFCCP).
10. Office of the Inspector General (OIG).
11. Office of Labor Management Standards (OLMS).
12. Office of Public Affairs (OPA).
13. Office of Workers' Compensation Programs (OWCP).
14. Bureau of International Labor Affairs (ILAB).
15. Bureau of Labor Statistics (BLS), Postal Square Building, Room 4040, 2 Massachusetts Avenue NE., Washington, DC 20212–0001.
16. Employment and Training Administration (ETA). Job Corps (part of ETA).
17. Mine Safety and Health Administration (MSHA), 201 12th Street, South, Arlington, Virginia 22202.
18. Occupational Safety and Health Administration (OSHA).
19. Employee Benefits Security Administration (EBSA).
20. Veterans' Employment and Training Service (VETS).
21. Employees' Compensation Appeals Board (ECAB).
22. Administrative Review Board (ARB).
23. Benefits Review Board (BRB).
24. Wage and Hour Division (WHD).
25. Women's Bureau (WB).

Appendix B to Part 70—[Reserved]

Thomas E. Perez,

Secretary of Labor .

[FR Doc. 2017–00453 Filed 1–19–17; 8:45 am]

BILLING CODE P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

30 CFR Parts 56 and 57

[Docket No. MSHA–2014–0030]

RIN 1219–AB87

Examinations of Working Places in Metal and Nonmetal Mines

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Final rule.

SUMMARY: The Mine Safety and Health Administration's final rule amends the Agency's standards for the examination of working places in metal and nonmetal mines. This final rule requires that an examination of the working place be conducted before miners begin working in that place, that operators notify miners in the affected areas of any conditions found that may adversely affect their safety or health, that operators promptly initiate corrective action, and that a record be made of the examination. The final rule

also requires that the examination record include: The name of the person conducting the examination, the date of the examination, the location of all areas examined, a description of each condition found that may adversely affect the safety or health of miners, and the date of the corrective action. In addition, the final rule requires that mine operators make the examination record available for inspection by authorized representatives of the Secretary and miners' representatives and provide a copy upon request.

DATES: Effective date: May 23, 2017.

FOR FURTHER INFORMATION CONTACT: Sheila A. McConnell, Director, Office of Standards, Regulations, and Variances, MSHA, at *mcconnell.sheila.a@dol.gov* (email); 202–693–9440 (voice); or 202–693–9441 (facsimile).

SUPPLEMENTARY INFORMATION:

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Availability of Information

Federal Register Publications: Access rulemaking documents electronically at *http://www.msha.gov/regsinfo.htm* or *http://www.regulations.gov* [Docket Number: MSHA–2014–0030]. Obtain a copy of a rulemaking document from the Office of Standards, Regulations, and Variances, MSHA, by request to 202–693–9440 (voice) or 202–693–9441 (facsimile). (These are not toll-free numbers.)

Email Notification: MSHA maintains a list that enables subscribers to receive an email notification when the Agency publishes rulemaking documents in the **Federal Register.** To subscribe, go to *http://www.msha.gov/subscriptions/subscribe.aspx.*

I. Introduction

Under the Mine Act, mine operators, with the assistance of miners, have the primary responsibility to prevent the existence of unsafe and unhealthful conditions and practices. Operator compliance with safety and health standards and implementation of safe work practices provide a substantial measure of protection against hazards that cause accidents, injuries, and fatalities. The Mine Safety and Health Administration (MSHA) has determined that examinations of working places are an important part of an effective accident prevention strategy; they are a first line of defense because they allow operators to find and fix conditions. The existing standards for metal and nonmetal (MNM) mines requiring that workplace examinations be conducted at least once each shift potentially expose miners to adverse conditions during the shift because mine operators can perform the workplace examination anytime during the shift, which exposes miners to adverse conditions during the shift before any corrective action is taken. The final rule, like the proposed rule, amends this provision to require that each working place be examined before miners or other employees begin work in that place. The new requirement that mine operators notify miners of adverse conditions in their working places will make miners aware of such conditions and allow them to take appropriate protective measures or avoid the adverse conditions altogether until such conditions are corrected.

The existing standards do not require the operator to include in the record adverse conditions that may contribute to an accident, injury, or fatality, or to document that corrective actions were taken. MSHA believes that by making a record of adverse conditions, mine operators and miners will become more proactive in their approach to correcting adverse conditions and avoiding reoccurrences, thereby improving the protection of miners.

In addition, the final rule requires that mine operators make the examination record available for inspection by authorized representatives of the Secretary and miners' representatives and provide a copy upon request. Under the Mine Act, mine operators, with the assistance of miners, have the primary responsibility to prevent the existence of adverse conditions, which is why MSHA concluded that the final rule should require operators to make examination records available to miners' representatives as well as provide copies of such records to them upon request.

The final rule will result in more effective and consistent working place examinations by helping to ensure that adverse conditions will be timely identified, communicated to miners, and corrected, thereby improving miners' safety and health.

A. Statutory and Regulatory History

On July 31, 1969, MSHA's predecessor, the Department of the Interior's Bureau of Mines, published a final rule (34 FR 12503) addressing health and safety standards for Metal and Nonmetallic Open Pit Mines; Sand, Gravel, and Crushed Stone Operations; and Metal and Nonmetallic Underground Mines. These standards were promulgated pursuant to the 1966 Federal Metal and Nonmetallic Mine Safety Act (MNM Act). The final rule included some mandatory standards and some advisory standards. The final rule set forth advisory standards at §§ 55.18–8, 56.18–8, and 57.18–8 stating that each working place ''should be visited by a supervisor or a designated person at least once each shift and more frequently as necessary to insure that work is being done in a safe manner.''

The Federal Mine Safety and Health Act of 1977 (Mine Act) amended the Federal Coal Mine Health and Safety Act of 1969 (Coal Act) to include MNM mines and repealed the MNM Act. The Mine Act retained the mandatory standards and regulations promulgated under the Coal Act and the MNM Act. In addition, section 301(b)(2) of the Mine Act required the Secretary of Labor to establish an advisory committee to review all advisory standards under the MNM Act and to either revoke them or make them mandatory (with or without revision). On August 17, 1979 (44 FR 48490), MSHA revised, renumbered, and made mandatory the Agency's advisory standards regarding working place examinations. This resulted in standards, set forth at §§ 55.18–2, 56.18–2, and 57.18–2, that were the same as the language that currently exists at §§ 56.18002 and 57.18002.

On January 29, 1985 (50 FR 4048), MSHA combined and recodified the standards in 30 CFR parts 55 and 56 into a single part 56 that applies to all surface MNM mines. As a part of this effort, the MNM working place examination standards were redesignated as 30 CFR 56.18002 (surface) and 57.18002 (underground). No change was made to the language of the standards.

On June 8, 2016 (81 FR 36818), MSHA published a proposed rule on Examinations of Working Places in Metal and Nonmetal Mines. The Agency received comments on the proposed rule and held four public hearings in July and August 2016. These hearings were held in Salt Lake City, Utah; Pittsburgh, Pennsylvania; Arlington, Virginia; and Birmingham, Alabama. On August 25, 2016, in response to

stakeholder requests, MSHA published a document in the **Federal Register** (81 FR 58422) extending the deadline for submission of comments from September 6, 2016, to September 30, 2016.

B. Executive Order 12866 Summary

MSHA is not claiming a monetized benefit for this rule. MSHA anticipates, however, that there will be benefits from the final rule as a result of more effective and consistent working place examinations that will help to ensure that adverse conditions will be timely identified, communicated to miners, and corrected. MSHA anticipates that the enhanced record requirements will improve accident prevention by helping mine operators identify any patterns or trends of adverse conditions and preventing these conditions from recurring. In response to comments, MSHA reviewed studies that examined the effectiveness of programs for the monitoring, detecting, and correction of hazards. Maxey (2013) [1] found that injury and illness prevention programs help employers find hazards and fix them before injuries, illnesses, or deaths occur. Maxey's article notes one study which showed that after a short period, five States that implemented injury and safety programs that have the basic elements common in safety and health programs saw reductions in accidents ranging from 17.4 to 23 percent (Huang et al., 2009). In another study cited by Maxey, the author found that mandatory injury and illness prevention programs were effective in reducing injury and illness incidence rates (Smitha et al., 2001).

In response to comments, MSHA also notes that it is not the only regulatory agency to recognize the importance of working place examinations and records of examinations. The West Virginia Office of Miners' Health, Safety and Training revised its rules that govern the safety of those employed in and around quarries. The new rulemaking that went into effect July 1, 2015 requires daily inspection of working places and records, among other requirements, and this includes: (1) Examinations within 3 hours prior to the beginning of any shift; and (2) that records be made of hazardous conditions or violations and the action taken to correct them.

[1] Maxey, H., Safety & Small Business, 2013, pp.12–22. *http://www.asse.org/assets/1/7/Maxey_TheCompass.pdf.* The article points out that 34 states, OSHA, and many other nations require safety and health programs that include monitoring, detecting, and correction of hazards and that have resulted in substantial reduction in loss of life and reduced injuries.

MSHA estimates that the final rule will result in $34.5 million in annual costs for the MNM industry: $10.6 million for mines with 1–19 employees; $22.2 million for mines with 20–500 employees; and $1.7 million for mines with 501+ employees. The Agency estimates that the total undiscounted cost of the final rule over 10 years will be $345.1 million; at a 3 percent discount rate, $294.4 million; and at a 7 percent discount rate, $242.4 million. Additional details on MSHA's analysis are found in Section III of this preamble.

C. Background Information

Mining continues to be one of the nation's most hazardous occupations. Mining operations have dynamic work environments where working conditions can change rapidly and without warning. For this rulemaking, MSHA reviewed accident investigation reports from January 2010 through mid-December 2015. During this period 122 miners were killed in 110 accidents at MNM mines. MSHA conducted investigations into each of these 110 fatal accidents of which 16 accidents (18 fatalities) citations were issued to mine operators for unwarrantable failure to comply for purposes of Section 104(d) of the Mine Act. Because unwarrantable failures involve serious conditions that the operator should have known about, MSHA believes that for these 16 accidents, had the person making the examination recorded these adverse conditions, the records may have alerted operators to take prompt corrective action thus preventing the accidents.

II. Section-by-Section Analysis

A. Sections 56.18002(a) and 57.18002(a)—Requirements for Conducting Working Place Examinations

Final §§ 56.18002(a) and 57.18002(a), like the existing standards and proposed rule, require that a competent person designated by the operator examine each working place at least once each shift for conditions that may adversely affect safety or health. The existing standards permit the examination to be made at any time during the shift. The final rule, like the proposed rule, requires that the competent person examine each working place before miners begin work in that place.

In the proposed rule, MSHA requested specific comments on whether the Agency should require that examinations be conducted within a specified time period, (*e.g.,* 2 hours) before miners start work in an area. Many commenters did not support the proposed provision but did support the existing standards, which do not specify a time frame for the working place examination to be conducted. Some commenters rejected a 2-hour time frame before miners start work as arbitrary; other commenters with operations with shifts that begin before daylight opposed any specified time period. A commenter interpreted the 2-hour time period mentioned in the proposal to mean that, if miners do not enter the area within a 2-hour window, but instead enter 3 hours after the examination was made, the area would have to be reexamined. A few commenters suggested that the examination be performed as close to the start of the next shift as possible, but no more than 2 hours. One commenter who supported conducting the working place examinations before miners begin working in that place did support a 2-hour time period, unless only one employee is responsible for examining multiple areas. In that case, the commenter stated that additional time would be needed for the one employee to inspect each area properly.

Some commenters suggested that examinations should start immediately before a shift begins. One commenter stated that making the examinations prior to someone working in that area is common sense. Several commenters supported conducting the examination before work begins as this practice alerts miners of adverse conditions before they begin work.

Another commenter stated that the wording of the proposed rule, ''before miners begin work'' and ''once each shift'', creates ambiguity and implies that the working place examination would occur during each shift but before miners begin work. MSHA acknowledges that, in the existing rule, ''once each shift'' may have been interpreted to mean ''once during each shift.'' However, for this final rule, MSHA clarifies that ''once each shift'' means that examinations must be conducted at least once for each separate shift.

The final rule provides mine operators flexibility on when to conduct an examination. Operators, however, should use their judgment to ensure that the time between the examination and the start of work is such that the operator would reasonably not expect conditions in the examined area to have been able to change adversely during that period. Thus, operators have the flexibility to determine how close in time the examination must be performed based on conditions in the mine and how dynamic those conditions are.

Moreover, examinations can be conducted before or after the shift begins, so long as the examinations are conducted close in time ''before work begins.'' We note that this allows for the competent person to examine a work area before workers begin working there, rather than requiring the competent person to examine all possible work areas before a shift can begin.

Another commenter opposed the requirement to conduct the examination prior to beginning work, noting that MSHA's existing standards for surface coal mines in § 77.1713 requires an examination ''at least once during each working shift, or more often if necessary.'' The commenter further stated that, due to the physical and operational differences between underground and surface mining, conducting a workplace examination before work begins in a surface mine is more burdensome than in an underground mine. MSHA recognizes that there are operational differences between surface and underground mining. In recognition of these differences, the final rule only requires that the operator examine each working place before miners begin work in that place. As stated during the rulemaking process and as is the practice under the existing rule, if miners are not scheduled for work in a particular area or place in the mine, that place does not need to be examined. Similarly, if miners are not scheduled to work for some time (*e.g.,* 4 hours) after the shift begins; the final rule would only require that the examination be performed prior to the beginning of work. Therefore, the final rule provides mine operators the needed flexibility on how to structure workplace examinations so that operational differences between surface and underground mines can be addressed and limit any additional burden.

Other commenters indicated that the proposed provision would limit mine operators to a single examination. Some of these commenters stated that an examination before work begins may not ensure all hazards are addressed, noting that since mining is dynamic and conditions are always changing, adverse conditions need to be addressed as they occur. Another commenter stated that while an industry standard practice is to examine for unsafe conditions before miners begin work in an area, unsafe conditions can occur anytime during a shift. Therefore, these conditions must be identified and corrected throughout the shift, not just at the beginning.

MSHA agrees with comments indicating that because mine conditions are subject to change, mine operators and miners need to be aware of conditions that may occur at any time that could affect the safety and health of miners. As discussed above, examinations must be conducted sufficiently close in time to the start of work that the operator would not reasonably expect conditions to have changed. Moreover, the final rule does not limit operators to a single examination or prevent ongoing examinations throughout the shift. The final rule, like the proposed rule, requires examinations ''at least'' once per shift before miners begin work in that place. However, operators should continue to identify and correct adverse conditions in the workplace regardless of when they occur.

A number of commenters representing both small and large operations were concerned that conditions such as lack of daylight and inclement weather make it impractical or impossible to conduct a workplace examination at the beginning of a shift or even within 2 hours of a shift. Some commenters suggested that MSHA modify the proposed requirement to allow mine examinations to begin at the beginning of a shift at daybreak and continue throughout a shift as mining conditions change. As stated earlier, under the final rule, operators must conduct a workplace examination before miners begin work in an area. The Agency assumes that if miners can work in an area, then weather and lighting conditions are sufficient to permit working place examinations to be conducted.

Some commenters stated that multi-shift operations will be at a disadvantage since all work would need to be halted to accommodate an examination before work begins, even if a company had a sufficient number of competent persons available to conduct the examination before the area would be deemed safe to proceed. A commenter stated that for some site-specific work conditions, personnel would be unable to do inspections between shift changes. Other commenters noted that conducting an examination before work begins would be difficult for operations with overlapping or maintenance shifts and questioned when an examination would be required. Other commenters noted that conducting an examination within a specified time period, *i.e.,* within 2 hours before the shift starts, is not practical for mines scheduled to operate on a 24-hour, 365-day basis with multiple crews working over multiple shifts. A few commenters suggested that MSHA consider allowing the previous shift to conduct examinations for the next shift.

The final rule requires that a competent person conduct an examination before work begins so that conditions that may adversely affect miners' safety and health are identified before they begin work and are potentially exposed. In response to these comments, MSHA's final rule provides operators with flexibility on how to structure workplace examinations as long as they are conducted before miners begin work in that place. As noted previously, the final rule does not require a specific time frame for the examination to be conducted before work begins.

The purpose of the rule is to ensure that for each shift the examinations occur at a time that is sufficiently close to when miners begin their work. MSHA acknowledges that for mines with consecutive shifts or those that operate on a 24-hour, 365-day basis, it may be appropriate to conduct the examination for the next shift at the end of the previous shift to ensure that the examination is complete before the next shift begins work in those places. However, because conditions at mines can change, operators should examine at a time sufficiently close to the start of the shift, before miners begin work at that working place, to minimize potential exposure to conditions that may adversely affect their safety or health. For this reason, MSHA does not believe that the protective purpose of the examinations would be accomplished if, at single-shift mines for example, the examination for one day's shift were performed at the end of the previous day's shift.

In response to commenters' concerns, if an examination was made for miners before work began in that place and incoming miners on an overlapping or maintenance shift are to begin work in that place, an additional examination is not needed provided that the incoming shift begins work close to when the examination was conducted and mining conditions would not be expected to have changed adversely.

The final rule, like the existing standards and the proposed rule, would continue to require that operators examine each working place at least once each shift. Existing §§ 56.2 and 57.2 define ''working place'' as ''any place in or about a mine where work is being performed.'' Some commenters expressed concerns that the phrase ''working place'' was vague or needed clarification. A number of commenters stated that the phrase ''working place'' needs to be defined beyond what is in existing §§ 56.2 and 57.2. Other

commenters stated that further clarification is needed to distinguish between regular working places and the occasional or sudden assignment that requires a miner to enter into a place that is not a regularly active production area or where mining activities are not present. For such areas, commenters asserted that the examination should occur when work begins, even if work begins in this location mid-shift. Some commenters expressed concern that the proposed rule would require mine operators to conduct an examination of the entire mine before the start of each shift. Some of these commenters also stated that it is impractical to expect the entire mine to be inspected prior to the start of the shift because of changing work needs during the course of a shift.

It is not MSHA's intent for the mine operator to examine the entire mine before work begins, unless work is beginning in the entire mine. As previously noted, ''before work begins,'' may or may not coincide with the start of any particular shift; it depends on when miners actually will be working in any particular working place. The final rule, like the existing standards and proposed rule, would require examinations in only those areas where work will be performed.

As MSHA stated in the preamble to the proposed rule, a ''working place'' applies to all locations at a mine where miners work in the extraction or milling processes (81 FR 36821). MSHA clarifies that consistent with the existing definition of ''working place,'' this includes roads traveled to and from a work area (81 FR 58422). MSHA further clarifies that a working place would not include roads not directly involved in the mining process, administrative office buildings, parking lots, lunchrooms, toilet facilities, or inactive storage areas. Unless required by other standards, mine operators would be required to examine isolated, abandoned, or idle areas of mines or mills only when miners have to perform work in these areas during the shift (81 FR 58423).

Final §§ 56.18002(a) and 57.18002(a), like the existing standards and the proposed rule, require that operators examine each working place for conditions that may adversely affect safety or health. Many commenters expressed concerns that the term ''adverse'' is ambiguous, lacks specificity, and is open to interpretation. A few commenters provided examples of conditions that could adversely affect safety and health such as slips, trips, and falls, or cause a fatal injury. MSHA notes that the final rule, like the existing standards, requires that an operator examine each working place for conditions that ''adversely affect safety or health.'' MSHA believes that the mining community understands the meaning of ''adverse'' in these standards because it has been in place since 1979.

One commenter stated that, even among MSHA inspectors from the same field office, there can be variability in judgments of inspectors whether a stated condition is ''adverse.'' Another commenter noted that for mine operators to better train their competent persons, MSHA must better define ''adversely affect'' so that laymen can understand it and apply it consistently; otherwise, mine operators could be subject to ever-changing interpretations when MSHA inspects the mine.

MSHA regularly trains its inspectors and managers. A central focus of the Agency's enforcement training and retraining is consistency. In addition, MSHA will develop outreach and compliance assistance materials related to the final rule and will include these materials in stakeholder seminars to be held in locations accessible to the mining public. As part of this process, MSHA will identify best practices that can be shared with the mining community.

Final §§ 56.18002(a) and 57.18002(a), like the existing standards and the proposed rule, require that the working place examination be made by a competent person designated by the mine operator. Under §§ 56.2 and 57.2, a competent person means a person having abilities and experience that fully qualify him to perform the duty to which he is assigned. In Program Policy Letter (PPL) No. P15–IV–01, MSHA emphasizes that the competent person designated by the operator should be able to recognize hazards and adverse conditions that are expected or known to occur in a specific work area or that are predictable to someone familiar with the mining industry.[2] In this same PPL, MSHA states that a best practice is for a foreman or other supervisor to conduct the examination, and that an experienced non-supervisory person may also be ''competent.'' The PPL emphasizes that a competent person designated by the operator under §§ 56.18002(a) and 57.18002(a) must have the experience and training to be able to perform the examination and identify safety and health hazards.

In the proposed rule, MSHA requested comment on whether the Agency should require that the competent person conducting a working place examination have a minimum level of experience or particular training or knowledge to identify workplace hazards. Many commenters expressed concern over the possibility that MSHA might restrict the ''competent person'' to supervisors or foremen. Some commenters suggested that MSHA develop training and templates for workplace examinations for various commodities that would highlight hazards and typical work tasks in different mining environments. As previously stated, MSHA will develop outreach and compliance assistance materials to be made available at stakeholder seminars.

Other commenters suggested that there needs to be a minimum level of experience, ability, or knowledge to be a competent person. These commenters stated that such miners need specific task training in recognizing hazards. One commenter suggested at least 8 hours of retraining each year on identifying workplace hazards, while another suggested 24 to 40 hours of training. A few commenters were concerned that MSHA might require formal training for surface miners, as is required for underground miners in MSHA's system for certification of competency in underground coal mining. Other commenters suggested that mine operators, and not MSHA, should determine the training necessary for the competent person at their locations.

This final rule does not change the definition of ''competent person'' under existing §§ 56.2 and 57.2. MSHA believes that existing experience and training requirements allow for needed flexibility while still requiring the level of competency necessary to conduct adequate examinations. In the final rule, like the existing standards and the proposed rule, the competent person is designated by the mine operator.

Final rule §§ 56.18002(a)(1) and 57.18002(a)(1) are similar to the proposed rule. Like the proposal, they contain a provision requiring mine operators to notify miners in any affected areas of any conditions found that may adversely affect their safety or health. Miners need to know about adverse conditions in their working

[2] MSHA's PPL guidance on the meaning of ''competent person'' was informed by the Commission decision in *Secretary of Labor (MSHA)* v. *FMC Wyoming Corporation,* 11 FMSHRC 1622 (1989), which held that: ''As with many safety and health standards, §§ 57.18002(a) and 57.2 are drafted in general terms in order to be broadly adaptable to the varying circumstances of a mine. Kerr-McGee Corp., *3 FMSHRC 2496, 97* (November 1981). We conclude that the term 'competent person' within the meaning of §§ 57.18002(a) and 57.2 must contemplate a person capable of recognizing hazards that are known by the operator to be present in a work area or the presence of which is predictable in the view of a reasonably prudent person familiar with the mining industry.''

place so that they can take protective measures or avoid the adverse conditions altogether. Several commenters expressed concern that there is no need to notify miners of conditions found, if such conditions, such as a hose across a walkway, were corrected immediately. Many commenters added that only conditions that cannot or have not been corrected require miner notification; if the hazard has been corrected, there is no benefit for requiring miner notification. The Agency recognizes that if adverse conditions are corrected before miners begin work, notification is not required because there are no ''affected areas.''

MSHA received other comments addressing the notification provision. Many commenters stated that they already notify miners of hazards through tagging, signage, and posting. One commenter asked that MSHA suggest methods of notification to all miners for typical conditions found on a workplace examination. The commenter then requested clarification on who would receive the notification—that is, whether operators would be required to notify incoming shift workers not yet in the area or not yet at work. The same commenter also was concerned about the logistics for notifying miners when many examinations are being conducted at the same time. Another commenter stated that prompt notification to employees if they are not in an affected area could take considerable time and resources resulting in operational downtime and lost revenue. The commenter added that, as a logistical matter, this process will be nearly impossible to manage on a mine site with thousands of employees and contractors.

Another commenter wrote that the term ''promptly notify'' is vague. This same commenter was also concerned that the proposed rule was unclear about who would need to be notified. The commenter stated that notifying miners who are not affected by the hazard carries no safety benefit and distracts them, thereby risking work slowdowns. This commenter expressed concerns about diverting a mine's resources to notify miners needlessly just to avoid MSHA citations for failing to communicate such hazards to all miners.

In its August 25, 2016, comment extension document in the **Federal Register** (81 FR 58422), MSHA clarified that to ''promptly notify miners'' means any notification to miners that alerts them to adverse conditions in their working place so that they can take necessary precautions to avoid the adverse condition. MSHA added that this notification could take any form that effectively notifies miners of an adverse condition: Verbal notification, prominent warning signage, other written notification, etc. MSHA believes that, in most cases, verbal notification or descriptive warning signage would be needed to ensure that all affected miners received actual notification of any adverse condition. MSHA also clarified that a ''prompt'' notification is one that occurs before miners are potentially exposed to the condition; *e.g.,* before miners begin work in the affected areas, or as soon as possible after work begins if the condition is discovered while they are working in an area. For example, this notification could occur when miners are given work assignments (81 FR 58422). Consistent with the comment extension document, the final rule requires notification only of those miners ''in any affected areas.'' Therefore, not all miners need to be notified, only those miners that would be affected by the adverse condition.

Final rule §§ 56.18002(a)(1) and 57.18002(a)(1), like the proposed rule, incorporate requirements from existing §§ 56.18002(a) and 57.18002(a) that the mine operator promptly initiate action to correct conditions that may adversely affect miners' safety or health that are found during the examination. A commenter suggested that the proposed requirement would encourage narrower examinations to avoid the need to engage in remedial efforts in non-working places, which could lead to more hazardous conditions if a miner wanders into these unexamined areas. A few commenters stated that the existing rule has long required mine operators to identify and ''promptly initiate action to correct'' any ''conditions which may adversely affect safety or health.'' The final rule is not changed from the existing standards.

Final rule §§ 56.18002(a)(2) and 57.18002(a)(2), like the proposed provisions, are redesignated from and substantively the same as existing §§ 56.18002(c) and 57.18002(c). These provisions require that if the competent person finds conditions that may present an imminent danger, these conditions must be brought to the immediate attention of the operator who must withdraw all persons from the area affected (except persons referred to in section 104(c) of the Mine Act) until the danger is abated. In response to comments, MSHA clarified that the proposed rule would not change the existing standards regarding conditions that present imminent danger (81 FR 58422). ''Imminent danger'' is defined in section 3(j) of the Mine Act as ''the existence of any condition or practice which could reasonably be expected to cause death or serious physical harm before such condition or practice can be abated.'' Although MSHA received comments on this aspect of the proposal, the final rule is not changed from the existing standards and is consistent with the statute.

B. Sections 56.18002(b) and 57.18002(b)—Requirements for Records of Working Place Examinations

Final rule §§ 56.18002(b) and 57.18002(b) require that a record of each examination be made before the end of the shift for which the examination was conducted. The requirement that the operator make a record is not a new provision; existing §§ 56.18002(b) and 57.18002(b) require a record that the examination was conducted. The final rule, like the proposal, requires the record to include: (1) The name of the person conducting the examination; (2) the date of the examination; (3) the location of all areas examined, and (4) a description of each condition found that may adversely affect the safety or health of miners. The final rule does not include the proposed requirements that the record contain: (1) The signature of the competent person conducting the working place examination and (2) the description of the corrective actions taken.

The Agency received a number of comments on proposed provisions of paragraph (b) asking if MSHA would require the person conducting the working place examination to wait until the end of the shift to make the record. MSHA clarified that the proposal would allow the competent person conducting the examination to make the record at any time before the end of the shift (81 FR 58422).

As previously noted, final rule §§ 56.18002(b) and 57.18002(b), like the proposed rule, add requirements for the contents of the examination record. Final paragraph (b), unlike the proposed rule, does not require that the competent person conducting the working place examination sign the record; instead, the record must include only the name of the competent person. Many commenters stated that the proposed requirement to sign the examination record would increase the potential for liability under Section 110(c) of the Mine Act for miners who conduct workplace examinations. Some commenters were concerned that the designated competent person would be liable under 110(c) for individual civil penalties. Other commenters stated that the signature requirement is unproductive, does not improve safety, and that competent persons are taking

the risk that they will be criminally prosecuted for knowing and willful violations. Commenters stated that it is difficult to get individuals to take on the responsibility of becoming a competent person. Some commenters were concerned that the signature requirement would discourage miners from conducting working place examinations and would have a negative impact on the quality of the examination.

MSHA believes that the single act of signing one's name adds no more and no less to the substantive duties and qualifications of the person who conducts the examination. For that reason, MSHA does not agree with commenters who believe that a signature would increase exposure to personal liability under Section 110(c). However, as will be discussed, MSHA also believes that it is the identity of the examiner, rather than the signature, that is important to record. For this reason, the final rule does not require the signature of the competent person conducting the working place examination.

Some commenters were not in favor of including the name of the competent person in the record. MSHA maintains that, like a signature, printing one's initials or name adds no more and no less to the substantive duties and qualifications of the person who conducts the examination. Historically, MSHA has taken the position that a meaningful record should at least contain the name of the competent person who conducted the examination. In addition, MSHA believes that the mine operator would need to know who conducted the working place examination. It is important to know the identity of the examiner for a number of reasons, such as clarifying the condition noted or following up with the examiner regarding areas examined or conditions noted.

Final rule §§ 56.18002(a) and 57.18002(b), like the proposal, require that the record be dated. A few commenters supported including the date in the record; some stated that they already include the date in their examination record. MSHA has determined that dating the record is a key element for record management and for identifying trends that would be useful in promoting a mine's safety and health efforts.

Final rule §§ 56.18002(a) and 57.18002(b), like the proposal, also require that the record contain the location of all areas examined and a description of each condition found that may adversely affect the safety or health of miners.

Many commenters opposed including in the record the locations of all areas examined and a description of each condition that may adversely affect the safety and health of miners, citing burden and cost concerns. A few commenters objected to recording every work location examined, indicating that this provision was costly and burdensome and would not improve miners' safety. These commenters also noted that the proposed requirement to include the locations of all areas examined would increase the number of records significantly. Several of these commenters recommended that MSHA allow operators to use a form or checklist for the examination record, noting that this would reduce burden and assist in operators' compliance with this requirement. Some commenters questioned how specific the description of adverse conditions should be because requiring more detail would limit the use of forms or checklists. Several other commenters supported the provision to include the locations of all areas examined and noted that they are currently including this information as part of their examination records. MSHA has determined that requiring that the record include locations of areas examined ensures that the mine operator is aware that all locations in a working place have been examined.

The final rule allows mine operators the flexibility to record the results of an examination using a checklist or any other format, as long as the record includes the information listed in paragraph (b). Regarding the specificity of a description of an adverse condition, MSHA clarifies that the description should provide sufficient information which allows mine operators to notify miners of the condition and to take prompt corrective action.

Several commenters supported the proposed provision to record a description of each condition found that may adversely affect the safety or health of miners. Another commenter noted that many companies follow the ''best practices'' MSHA advocated in its policy documents in terms of memorializing what hazards are identified. Other commenters objected to including a description of all adverse conditions found in the examination record. Specifically, one commenter stated that requiring a description of every adverse condition is a burdensome requirement and does not provide any benefit to miners if it was immediately corrected by the competent person who performed the examination. This commenter stated that only the adverse conditions that cannot or have not been corrected should be required to be documented as these could affect miners. The commenter noted that this would provide an incentive to immediately correct adverse conditions. Another commenter stated that there are certain adverse conditions that occur regularly during normal mining operations. The commenter provided an example of entering an area in which a round of explosives has recently been blasted creating adverse conditions such as unsupported ground at the face, loose rock that presents tripping hazards, and dusty conditions caused by the blast. The commenter believed that requiring the competent person conducting the examination to record these regularly occurring adverse conditions and the corrective actions, would add no value since these conditions will be expected. The commenter further stated that this would unnecessarily add to the duties of the competent person conducting the examination.

MSHA believes that, by making a record of adverse conditions, mine operators and miners will become more proactive in their approach to correcting the conditions and avoiding recurrence, thereby improving protections for miners. The Agency believes that a record that notes the adverse conditions prior to miners working in an area expedites the correction of these conditions, notwithstanding the regularity in which the adverse conditions occur. Also, MSHA believes that recording all adverse conditions, even those that are corrected immediately, will be useful as a means of identifying trends. This information should help inform mine management regarding areas or subjects that may benefit from increased safety emphasis.

Some commenters questioned if correcting the condition takes a significant amount of time, would the adverse condition have to be recorded each shift until it is corrected. MSHA clarifies that if not immediately corrected, the continuing adverse condition does not need to be recorded each shift. The final rule requires that, once the condition is corrected, the record include, or be supplemented to include, the date of corrective action.

Regardless of how long an adverse condition has existed, mine operators must ensure that all affected miners are promptly notified of all adverse conditions on each shift as required in final paragraph (a)(1), so that miners can take the necessary precautions to avoid an accident or injury.

Another commenter stated that requiring that examinations include descriptions of unsafe conditions would require separate records for each and every examination. The commenter

added that for medium and large-sized operations this requirement would necessitate the generation, management, and storage of hundreds of thousands of individual examination records each year. The commenter stated that this may not be feasible for many operators, or would require the operators to add additional personnel and incur the associated costs without any proven benefit.

MSHA believes that a key element in any safety and health program includes the identification of adverse conditions. MSHA further believes that this information is essential to inform operators and miners of these conditions, so that they can be found and fixed before miners are exposed to them. Under the existing standards, a competent person is not required to record adverse conditions. MSHA's experience is that if adverse conditions are not recorded, these conditions may exist for more than one shift, causing or contributing to an accident, injury, or fatality. The final rule allows mine operators the flexibility to record the results of an examination using electronic or hard copy checklists or any other format, as long as the record includes the information listed in paragraph (b). In addition, MSHA has reduced the recordkeeping requirements in the final rule to address commenters' concerns regarding costs and burden.

Many commenters were concerned that the Agency will use the examination record to write citations based solely on the adverse conditions identified in the record. This is not MSHA's intent, nor do we plan to train our inspectors to do this. MSHA reiterates that the Agency's intent is to ensure that conditions that adversely affect the safety or health of miners are found and fixed before miners begin work.

MSHA proposed in §§ 56.18002(b)(2) and 57.18002(b)(2) that the record include a description of the corrective action taken and the date it was taken, the name of the person who made the record of the corrective action, and the date the record of corrective action was made. The final rule in paragraph (c), similar to the proposed rule, requires when a condition that may adversely affect safety or health is corrected, the examination record must include the date of the corrective action. The final rule, unlike the proposed rule, does not require that the name of the person who made the record of the corrective action be included in the record.

Many commenters opposed the proposed requirement that the record contain a description of every corrective action, stating that this was burdensome, especially for small operations. One commenter noted that for conditions not immediately corrected, the proposal would result in leaving open indefinitely the mandatory records, raising the potential for records to be misplaced. Other commenters noted that including a description of corrective actions in the examination record is duplicative since operators have systems in place that track work orders and repairs that document corrective actions taken. Other commenters stated that this provision would not enhance miners' safety. In response to these comments, the final rule does not require that the record include a description of corrective action. MSHA believes that a single requirement to record the date the corrective action is completed will result in similar safety benefits for less time and cost, as it will still encourage prompt corrective action.

Many commenters did not support the provisions in proposed paragraph (b)(2) to record the name of the person who made the record of the corrective action, the date the corrective action was taken, and the date the record of corrective action was made, stating that they were unnecessary and confusing. These commenters added that these proposed requirements may overly complicate recordkeeping and add little protective value. MSHA notes that while the final rule does not require the name of the person who made the record of corrective action, it does require that the record include the date of the corrective action. MSHA expects that most corrective actions will be completed before the end of the shift on which the adverse condition was found and that, therefore, the date of the corrective action will be the same as the date of the examination. However, regardless of when the corrective action is completed, the examination record noting the adverse condition must include or must be updated with the date of the corrective action. MSHA believes that including the date of corrective action alerts the mine operator, the authorized representative of the Secretary, and miners' representatives whether adverse conditions have been corrected.

A few commenters stated that the person taking the corrective action is not necessarily the same person who dates the record of corrective action. Recognizing these commenters' concerns, MSHA clarifies that under the final rule, unlike the preamble discussion to the proposed rule, the person who takes the corrective action does not need to be the person who records the date of corrective action under final paragraph (c).

MSHA received comments requesting that the Agency allow alternative means of documenting corrective action other than the examination record, such as closed-out work orders or invoices. MSHA believes, however, that all information related to adverse conditions should be in one record, including the date of corrective action, to ensure a complete record is available for inspection and the Agency will not accept alternate documentation for corrective action taken.

Final rule §§ 56.18002(d) and 57.18002(d), like the existing standards and proposed §§ 56.18002(b)(3) and 57.18002(b)(3), require that the operator maintain the examination records for one year and make them available to the Secretary or his authorized representative. The final rule, like the proposed rule, adds requirements that: (1) The record also be made available for inspection by miners' representatives and (2) that a copy be provided to the Secretary or his authorized representative and miners' representatives upon request.

Some commenters suggested that the requirement for a one-year record retention period be changed to six months since MSHA inspections are on a six-month inspection schedule. Historically, mine operators have been required to retain examination records for one year. The Mine Act requires that surface mines be inspected at least twice a year but does not mandate that the inspections be six months apart; inspection schedules vary. Also, retaining examination records for one year allows operators and miners to identify trends that may not be apparent in a shorter period of time. The final rule retains the existing requirement.

A few commenters suggested that examination records be made and kept electronically since they currently complete these records electronically. MSHA agrees; however, when records are collected electronically, such records must be secured in a computer system that is not susceptible to alteration. These electronic records must be made available for inspection by authorized representatives of the Secretary and representatives of miners, and an electronic or paper copy must be provided upon request.

Several commenters opposed the proposed requirement to make records available upon request to representatives of miners. They stated that obligating an operator to make its examination records available to the miners' representatives and to provide copies upon request will not improve or benefit safety. One commenter stated that making records available for review

by MSHA to confirm compliance is one thing, but forcing operators to make books and records available to its rank-and-file personnel shows lack of respect by MSHA for the integrity of mine management. Several commenters did not oppose making the records available to miners and their representatives.

MSHA notes that the final rule, like the proposal, includes the requirement that records be made available for inspection by miners' representatives. This is consistent with the Mine Act which requires miners be provided with information concerning safety and health hazards. Under the Mine Act, mine operators, with the assistance of miners, have the primary responsibility to prevent the existence of adverse conditions, which is why MSHA concluded that the final rule should require operators to make examination records available to miners' representatives as well as to provide copies of such records to them upon request. Also, under other MSHA safety and health standards, operators provide records to miners' representatives.

A few commenters suggested that mine operators have a ''workplace inspection program'', which could be documented or submitted to MSHA for approval, noting that MSHA could use this document to check for compliance. Other commenters suggested additional miner training could be an alternative to modifying the existing standards. MSHA did not propose or solicit comments regarding a workplace inspection program or additional miner training: either would have necessitated a discussion of various options in the proposed rule. For this reason, both of these issues are beyond the scope of this rulemaking.

III. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

Executive Orders (E.O.) 13563 and 12866 direct 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). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

Under E.O. 12866, a significant regulatory action is one that meets any of a number of specified conditions, including the following: Having an annual effect on the economy of $100 million or more, creating a serious inconsistency or interfering with an action of another agency, materially altering the budgetary impact of entitlements or the rights of entitlement recipients, or raising novel legal or policy issues. MSHA has determined that the final rule is an ''other significant'' regulatory action because it raises novel legal and policy issues. However, MSHA has determined that this final rule will not have an annual effect of $100 million or more on the economy and, therefore, will not be an economically significant regulatory action pursuant to section 3(f) of E.O. 12866.

A. Population at Risk

The final rule will apply to all MNM mines in the United States. In 2015, there were approximately 11,660 MNM mines employing 144,408 miners, excluding office workers, and 74,465 contractors working at MNM mines.

Table 1 presents the number of MNM mines and employment by mine size.

TABLE 1—MNM MINES AND EMPLOYMENT IN 2015

Mine size	Number of mines	Total employment at mines, excluding office workers
1–19 Employees	10,451	52,310
20–500 Employees	1,187	74,545
501+ Employees	22	17,553
Contractors	.....	74,465
Total	11,660	218,873

Source: MSHA MSIS Data (reported on MSHA Form 7000–2) September 21, 2016.

The U.S. Department of the Interior (DOI) estimated revenues of the U.S. mining industry's MNM output in 2015 to be $78.3 billion.[3] Table 2 presents the hours worked and revenues for MNM mines by mine size.

TABLE 2—MNM TOTAL HOURS AND REVENUES IN 2015

Mine size	Total hours reported for year	Revenue (in millions of dollars)
1–19 Employees	88,661,855	$22,149
20–500 Employees	159,361,570	43,652
501+ Employees	37,470,328	12,499
Total	285,493,753	78,300

Source: MSHA MSIS Data (total hours worked at MNM mines reported on MSHA Form 7000–2) and estimated DOI reported mine revenues for 2015 by mine size.

[3] Production revenue estimates are from DOI, U.S. Geological Survey (USGS), Mineral Commodity Summaries 2016, February 2016, page 8.

B. Benefits

The purpose of this final rule is to ensure that MNM mine operators identify and correct conditions that may adversely affect miners' safety or health. Effective workplace examinations are a fundamental accident prevention tool; they allow operators to find and fix adverse conditions and violations of safety and health standards before they cause injury or death to miners.

Under MSHA's existing standards, mine operators can perform the examinations anytime during the shift. If the examination is performed after miners begin work, miners may be exposed to conditions that may adversely affect their safety and health. In addition, the existing standard does not specify the contents of the examination record.

Over the years, MSHA has issued Program Policy Letters (PPL) regarding working place examinations. The PPLs are MSHA's guidance and best practices regarding compliance with the existing standards. In the PPLs, MSHA provided guidance on what the examination record should include, such as: (1) The date of the examination; (2) name of the person conducting the examination; (3) the working places examined; and (4) a description of the conditions found that adversely affect safety or health. In the Agency's experience, despite MSHA guidance and best practices, under the existing standard working place examinations are not always done at a point during the shift when the results of the examination would provide the necessary protections as intended by the Mine Act and the existing standard.

MSHA's final rule amends the existing standards to require that the examination of each working place be conducted at least once each shift before miners begin work in that place, and that mine operators notify miners in affected areas of any conditions found that may adversely affect their safety or health. The final rule also requires that the examination record contain the name of the person conducting the examination, the date of the examination, the location of all areas examined, a description of each condition found that may adversely affect the safety or health of miners, and the date the corrective action was made.

A number of commenters observed that MSHA was unable to quantify the benefits of the proposed rule. Another commenter stated that MSHA should show that the Agency's proposed revision of the existing rule will not negatively impact the safety and health of miners as required by the Mine Act. Under the Mine Act, MSHA is not required to use monetized benefits or estimated net benefits as the basis for the Agency's decision on standards designed to protect the health and safety of miners. However, in the proposed rule, MSHA stated that, while the Agency was unable to quantify the benefits, it anticipated there would be unquantified benefits from the proposed requirements.

MSHA recognizes that under the existing standards, many mine operators have safe workplace operations and safety programs that include many of the provisions in this final rule. However, as noted above, the Agency's experience is that there is a significant degree of variability in how safety programs are operationalized. MSHA has concluded that the final rule will reduce the variability in how operators conduct examinations of working places and thereby improve miners' safety and health. MSHA believes that several features of this rule will contribute to this reduction in variability in workplace examinations and reporting. These features are conducting the workplace examination before work begins; and a record that will include locations examined, a description of adverse conditions found, and the date they were corrected. Under the existing standard, MSHA does not specify the timing of the examination or the contents of the record. In addition, the final rule adds a new requirement that mine operators notify miners of adverse conditions in their working places that will ensure that miners are aware of such conditions and avoid them until they are corrected. MSHA anticipates that there will be benefits from these provisions that will result in more effective and consistent workplace examinations and ensure that adverse conditions will be timely identified, communicated to miners, and corrected.

However, MSHA is unable to separate the benefits of the new requirements under the final rule from those benefits attributable to conducting a workplace examination under the existing standards. The Agency has concluded that the combined effect of all the provisions (existing standards that have been in place since 1979 and the final rule) will improve miners' safety and health. While unable to quantify the benefits, the Agency has concluded that the final rule will have benefits.

MSHA also anticipates that there will be additional unquantifiable financial benefits, such as reduced insurance premiums, from effective working place examinations that will help mine operators, miners, and their representatives to become more aware of potential dangers, and be more proactive in correcting adverse conditions and violations of health and safety standards before these conditions cause an accident.

C. Compliance Costs

MSHA estimated the costs for MNM mine operators to comply with the final rule. Table 3 provides a summary of the annual costs by mine size.

TABLE 3—SUMMARY OF ANNUAL COSTS TO MNM MINE OPERATORS *

[$ millions]

Requirement	Mine size			Totals
	1–19	20–500	501+	
56/57.18002 (a) Conduct Exam Before Work Begins	$4.96	$20.22	$1.69	$26.88
56/57.18002 (b)& (c) Additional Time to Make Record	5.51	1.73	0.04	7.29
56/57.18002 (d) Provide Miners' Representative a Copy of Record	0.13	0.21	0.01	0.35
*Totals (may not sum due to rounding)	10.61	22.16	1.75	34.51

Examination of Working Places—Final §§ 56.18002(a) and 57.18002(a)

Final §§ 56.18002(a) and 57.18002(a) require that a competent person designated by the operator must examine each working place at least once each shift, before miners begin work in that place, for conditions that may adversely affect safety or health.

In the proposed rule, MSHA believed that the cost associated with examining areas before miners begin work in that area would be de minimis. However, several commenters stated that requiring

the working place examination to occur before miners can begin work would impose additional costs on mine operators. Commenters also expressed concern that there could be considerable downtime and lost productivity as miners waited for a working place examination to be completed before starting work. Some commenters stated that it could take between two to six hours for larger mines to conduct the examination, which they stated might require paying overtime to the competent person to arrive well before the shift begins.

Based on these comments, MSHA concludes that MNM mine operators will use a variety of scheduling methods to conduct an examination of a working place before miners begin work. In developing this cost estimate, MSHA considered the following variables: (1) Percent of mine operators currently compliant with this requirement; (2) number of shifts by mine size; (3) average time to conduct a workplace examination by mine size; (4) hourly wage rate; and (5) number of days a mine operates, on average, by mine size. Operators may use overtime, use different people to backfill for the time shifted to the examination, and perhaps lengthen the examination time to comply with the final rule. Based on analysis of comments received about overtime, MSHA assigned an overtime rate to the new time adjustments to appropriately estimate the change to costs.

Small mine operators, with 1–19 employees, represent 90 percent of all MNM mines. Of these small mines, 62 percent have 1–5 employees. It is MSHA's experience that small mine operators with 5 or fewer employees are currently in compliance with the final rule or will be able to adjust work schedules to comply without incurring additional costs and burden. MSHA also determined from the public comments that a greater percentage of larger mines will incur compliance costs due to large physical spaces, complex work schedules, and larger numbers of miners assigned to such schedules. In response to comments, the Agency estimated that 15 percent of mines with 1–19 employees, 65 percent of mines with 20–500 employees, and 85 percent of mines with 501+ employees will incur some additional cost as a result of requiring operators to conduct working place examinations before miners begin work in those places.

For the proposed rule, MSHA assumed that mines with 1–19 employees operated 1 shift per day, while those with 20 or more employees operated 2 shifts per day. Five commenters submitted concerns about 24/7 operations or overlapping shifts in large mines. MSHA re-examined the availability of internal data and revised the number of shifts. For the final rule, MSHA estimates that, on average: A mine with 1–19 employees operates 1.1 shifts per day; a mine with 20–500 employees operates 1.8 shifts per day; and a mine with 501+ employees operates 2.2 shifts per day. As with all averages, the data include a range of values.

In response to comments and based on the Agency's experience, MSHA estimates that, on average, the time to conduct workplace examinations before work begins is: 20 minutes in mines with 1–19 employees; 1 hour in mines with 20–500 employees; and 2.5 hours in mines with 501+ employees.

In the proposed rule, MSHA assumed that all MNM mines operate 300 days per year. Commenters provided various estimates on the number of days that MNM mines operate. In response to comments, MSHA reevaluated the Agency's estimate. MSHA reviewed employment, average shifts per week, and average hours per employee to estimate average days per year worked in MNM mines for 2015.[4] MSHA's estimate shows that, on average, a mine with 1–19 employees operates 169 days per year, a mine with 20–500 employees operates 285 days per year, and a mine with more than 500 employees operates 322 days per year.

In the proposed rule, MSHA used a 2014 hourly wage rate of $31.14 (including benefits). One commenter stated that $51.25 was the 2016 average miner hourly wage rate for large mines that the commenter represents. Another commenter stated that for the mine operators it represents the pay, on average, is $35 to $55 per hour, excluding benefits. However, this commenter did not specify whether this hourly wage rate range was for a supervisor or a miner. Another commenter provided calculations that used MSHA's proposed wage rate of $31.14 per hour.

The hourly wage rate used in MSHA's analysis assumes an average rate for all MNM mines. For the final rule, like the proposal, MSHA used wage data from BLS's Occupational Employment Survey (OES).[5] [6] For the final rule, the hourly wage rate, updated for 2015, is $34.06 (including benefits).

As noted above, several commenters stated that compliance with §§ 56.18002(a) and 57.18002(a) would require a mine operator to pay overtime for a competent person to arrive before the shift begins to conduct the working place examination. In response to comments, MSHA estimated the cost for overtime as time and a half ($51.09/hr = $34.06 × 1.5). MSHA estimates that it will cost approximately $26.9 million per year for mine operators to comply with the final provision that requires mine operators to examine each working place at least once each shift before miners begin work. This annual cost consists of:

- $5 million = 10,451 mines with 1–19 employees × 15% × 20 minutes × 1 hr/60 min × $51.09 wage × 1.1 shifts per day × 1 exam × 169 workdays per year;
- $20.2 million = 1,187 mines with 20–500 employees × 65% × 1 hour × $51.09 wage × 1.8 shifts per day × 1 exam × 285 workdays per year; and
- $1.7 million = 22 mines with 501+ employees × 85% × 2.5 hours × $51.09 wage × 2.2 shifts per day × 1 exam × 322 workdays per year;

Records of Working Place Examinations—Final §§ 56.18002(b) and (c) and 57.18002(b) and (c)

The requirement that the operator make a record is not a new provision; existing §§ 56.18002(b) and 57.18002(b) require that a record of the examination be made. The final rule revises §§ 56.18002(b) and 57.18002(b) to require that the record of each examination be made before the end of the shift for which the examination was conducted. The record shall contain: (1) The name of the person conducting the examination; (2) the date of the examination; (3) the location of the areas examined; and (4) a description of

[4] MSHA MSIS data, 2015.

[5] OES data are available at *http://www.bls.gov/oes/tables.htm* or at *http://www.bls.gov/oes/oes_ques.htm.* The employment-weighted mean wage is for Extraction Workers (Standard Occupational Classification code, SOC, 475000) for Metal Ore Mining (NAICS 212200) and Nonmetallic Mineral Mining and Quarrying (NAICS 212300). The OES wages represent the average for the entire industry and are used nationally for many federal estimates and programs. As with any average, there are always examples of higher and lower values but the national average is the appropriate value for a rule regulating an entire industry.

[6] The wage rate without benefits was increased for a benefit-scalar of 1.48. The benefit-scalar comes from BLS Employer Costs for Employee Compensation access by menu *http://www.bls.gov/data/* or directly with *http://download.bls.gov/pub/time.series/cm/cm.data.0.Current.* The data series CMU2030000405000P, Private Industry Total benefits for Construction, extraction, farming, fishing, and forestry occupations, is divided by 100 to convert to a decimal value. MSHA used the latest 4-quarter moving average 2015 Qtr. 3–2016 Qtr. 2 to determine that 32.65 percent of total loaded wages are benefits. The scaling factor is a detailed calculation, but may be approximated with the formula and values 1 + (benefit percentage/(1-benefit percentage)) = 1 + (0.3265/(1 − 0.3265)) = 1.48.

each condition found that may adversely affect the safety or health of miners. Under final §§ 56.18002(c) and 57.18002(c), the record also must include the date of corrective action.

Under the proposed rule, the mine operator would have been required to record a description of the adverse conditions found during the examinations and a description of the corrective actions taken. MSHA received numerous comments and heard testimony at the public hearings opposing these requirements. Commenters were concerned that recording every condition and every corrective action would be an excessive burden to mine operators, especially small operators. Several commenters noted that MSHA's estimate of 5 minutes to complete the record was an underestimate. One commenter stated that MSHA's proposed estimate was not enough time to document every hazard found in every active part of the mine and all corrective actions. In response to comments, the final rule does not require the record to include a description of the corrective action taken. However, the final rule retains the requirement that the record include the date when corrective action was made.

MSHA proposed that the competent person conducting the working place examination would be required to sign and date the record before the end of the shift for which the examination was made. MSHA received numerous comments and testimony opposing this requirement. In response to the concerns from commenters, the final rule does not require that the competent person who conducted the examination sign the record. However, the final rule requires that the examination record contain the name of the person conducting the examination.

The proposed record requirements were interpreted by commenters as requiring substantially more time than the 5 minutes the Agency estimated. For purposes of this final rule, MSHA accepts that the proposed record requirements may have required more time than MSHA's estimate. However, the Agency now has clarified and narrowed the record requirements in the final rule. MSHA has concluded the original time estimates are appropriate given these changes. The Agency estimates that it will take all MNM mine operators an additional 5 minutes to record the information as required. MSHA estimates that a miner, earning $34.06 per hour, will take 5 additional minutes to include into the existing record the additional information required by final §§ 56.18002(b) and (c) and 57.18002(b) and (c). MSHA estimates that the annual cost for this provision will be approximately 7.3 million. This annual cost consists of:

- $5.5 million = 10,451 mines with 1–19 employees × 1.1 shift per day × 1 exam record × 169 workdays per year × 5 additional minutes × 1 hr/60 min × $34.06 per hour;
- $1.7 million = 1,187 mines with 20–500 employees × 1.8 shifts per day × 1 exam record × 285 workdays per year × 5 additional minutes × $34.06 per hour; and
- $44,235 = 22 mines with 501+ employees × 2.2 shifts per day × 1 exam record × 322 workdays per year × 5 additional minutes × $34.06 per hour.

Making Records Available to Miners' Representatives—§§ 56.18002(d) and 57.18002(d)

Final §§ 56.18002(d) and 57.18002(d) require that the operator maintain the examination records for at least one year, make the records available for inspection by authorized representatives of the Secretary and the representatives of the miners, and provide these representatives a copy on request. Several commenters have stated that this requirement would place an additional burden on mine operators without MSHA showing any benefit. MSHA did not estimate a cost for this provision in the proposed rule. The existing information collection already allows time for record keeping and making copies for representatives of the Secretary. MSHA believes that on average the time already allowed for recordkeeping and providing copies to the Secretary's representative will increase only slightly with regard to providing information to the mining representative. MSHA has increased the time for the copying from 20 seconds to an average of 1 minute. For the final rule, MSHA estimates that the number of times a copy of the examination record will be requested is: 10 percent in mines with 1–19 employees; 50 percent in mines with 20–500 employees; and 100 percent in mines with 501+ employees. Also, MSHA estimates that it will take a clerical employee, earning $22.43 per hour,[7] [8] 1 minute to make a copy of the examination record and provide it to the representative of the miners, and that copying costs will be $0.30 per examination (2 pgs. × $0.15 per page). Thus, MSHA estimates that the compliance costs for mine operators to make copies of examination records for the representative of the miners will be $346,578 annually. This annual cost consists of:

- $130,916 = 10,451 mines with 1–19 employees × 10 percent × 1.1 shifts per day × 169 workdays per year × ((1 minute × $22.43 per hour) + $0.30 copy costs);
- $205,160 = 1,187 mines with 20–500 employees × 50 percent × 1.8 shifts per day × 285 workdays per year × ((1 minute × $22.43 per hour) + $0.30 copy costs); and
- $10,502 = 22 mines with 501+ employees × 100 percent × 2.2 shifts per day × 322 workdays per year × ((1 minute × $22.43 per hour) + $0.30 copy costs).

Summary of Compliance Costs

The total annual compliance cost of the final rule is $34.5 million: $10.6 million for mines with 1–19 employees; $22.2 million for mines with 20–500 employees; and $1.7 million for mines with 501+ employees.

Discounting

Discounting is a technique used to apply the economic concept that the preference for the value of money decreases over time. In this analysis, MSHA provides cost totals at zero, 3, and 7 percent discount rates. The zero percent discount rate is referred to as the undiscounted rate. MSHA used the Excel Net Present Value (NPV) function to determine the present value of costs and computed an annualized cost from the present value using the Excel PMT function.[9] The negative value of the

[7] OES data are available at *http://www.bls.gov/oes/tables.htm* or at *http://www.bls.gov/oes/oes_ques.htm.* The employment-weighted mean wage is for Office Clerks, General (Standard Occupational Classification code, SOC, 439061) for Metal Ore Mining (NAICS 212200) and Nonmetallic Mineral Mining and Quarrying (NAICS 212300). The OES wages represent the average for the entire industry and are used nationally for many federal estimates and programs. As with any average, there are always higher and lower values but the national average is the appropriate value for a rule regulating an entire industry.

[8] The wage rate without benefits was increased for a benefit-scalar of 1.48. The benefit-scalar comes from BLS Employer Costs for Employee Compensation access by menu *http://www.bls.gov/data/* or directly with *http://download.bls.gov/pub/time.series/cm/cm.data.0.Current.* The data series CMU2030000405000P, Private Industry Total benefits for Construction, extraction, farming, fishing, and forestry occupations, is divided by 100 to convert to a decimal value. MSHA used the latest 4-quarter moving average 2015 Qtr. 3–2016 Qtr. 2 to determine that 32.65 percent of total loaded wages are benefits. The scaling factor is a detailed calculation, but may be approximated with the formula and values 1 + (benefit percentage/(1-benefit percentage)) = 1 + (0.3265/(1 − 0.3265)) = 1.48.

[9] Office of Management and Budget, Office of Information and Regulatory Affairs, Regulatory Impact Analysis: Frequently Asked Questions, February 7, 2011. [*http://www.whitehouse.gov/sites/default/files/omb/assets/OMB/circulars/a004/a-4_FAQ.pdf*].

PMT function provides the annualized cost over 10 years at 3 and 7 percent discount rates.

MSHA estimates that the total undiscounted cost of the final rule over a 10-year period will be approximately $345.1 million, $294.4 million at a 3 percent discount rate, and $242.4 million at a 7 percent discount rate. The total undiscounted cost annualized over 10 years will be approximately $34.5 million, $33.5 million at a 3 percent discount rate, and $32.3 million at a 7 percent discount rate.

IV. Feasibility

A. Technological Feasibility

MSHA concludes that the final rule is technologically feasible because it requires only that the operator conduct the working place exam before work begins in that place and requires additional information to be included in the operators' existing examination records. There are no technology issues raised by the final rule.

B. Economic Feasibility

MSHA has traditionally used a revenue screening test—whether the yearly impacts of a regulation are less than one percent of revenues—to establish presumptively that the regulation is economically feasible for the mining community. The final rule is projected to cost $34.5 million per year and the MNM industry has estimated annual revenues of $78.3 billion. The final rule cost is less than one percent of revenues. Therefore, MSHA concludes that the final rule will be economically feasible for the MNM mining industry.

MSHA intends to conduct a retrospective study beginning January 20, 2022. Using the results of this study, MSHA will determine to what extent the provisions of the final rule ensure that operators find and fix adverse conditions and violations of safety and health standards before they cause injury or death to miners, and reduce the variability in how operators conduct examinations of working places and thereby improve miners' safety and health. Under the Department's Plan for Retrospective Analysis of Existing Rules, MSHA intends to consult with industry, labor, and other stakeholders in conducting this review.

This retrospective study will be conducted in accordance with the Department of Labor's Plan for Retrospective Analysis of Existing Rules which complies with Executive Order (E.O.) 13563 ''Improving Regulation and Regulatory Review'' (76 FR 3821).

V. Regulatory Flexibility Analysis and Small Business Regulatory Enforcement Fairness Act

Pursuant to the Regulatory Flexibility Act (RFA) of 1980, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA), MSHA has analyzed the impact of the final rule on small entities. Based on that analysis, MSHA certifies that the final rule will not have a significant economic impact on a substantial number of small entities. The Agency, therefore, is not required to develop an initial regulatory flexibility analysis. The factual basis for this certification is presented below.

A. Definition of a Small Mine

Under the RFA, in analyzing the impact of a rule on small entities, MSHA must use the Small Business Administration's (SBA's) definition for a small entity, or after consultation with the SBA Office of Advocacy, establish an alternative definition for the mining industry by publishing that definition in the **Federal Register** for notice and comment. MSHA has not established an alternative definition and, therefore, must use SBA's definition. On February 26, 2016, SBA's revised size standards became effective. SBA updated the small business thresholds for mining by establishing a number of different levels. MSHA used the new SBA standards for the screening analysis of this final rule.

The SBA uses North American Industry Classification System (NAICS) codes, generally at the 6-digit NAICS level, to set thresholds for small business sizes for each industry. See the SBA size standard tables and methodology at *https://www.sba.gov/contracting/getting-started-contractor/make-sure-you-meet-sba-size-standards/summary-size-standards-industry-sector.*

MSHA has also examined the impact of the final rule on MNM mines with fewer than 20 employees, which MSHA and the mining community have traditionally referred to as ''small mines.'' These small mines differ from larger mines not only in the number of employees, but also in economies of scale in material produced, in the type and amount of production equipment, and in supply inventory. Therefore, the impact of MSHA's rules and the costs of complying with them will also tend to differ for these small mines. This analysis complies with the requirements of the RFA for an analysis of the impact on ''small entities'' using both SBA's definition as well as MSHA's traditional mine size definition.

B. Factual Basis for Certification

MSHA initially evaluates the impacts on small entities by comparing the estimated compliance costs of a rule for small entities in the sector affected by the rule to the estimated revenues for the affected sector. When estimated compliance costs are less than one percent of the estimated revenues, the Agency believes it is generally appropriate to conclude that there is no significant economic impact on a substantial number of small entities. When estimated compliance costs exceed one percent of revenues, MSHA investigates whether further analysis is required. MSHA evaluated a number of data sources related to the number of firms, employment, and revenue. MSHA concluded that the most useful data was MSHA's 2015 MSIS MNM mine data (datasets are publicly available at *http://arlweb.msha.gov/OpenGovernmentData/OGIMSHA.asp*). MSHA summed employment using the MSHA data element ''Controller'' [10] to best align with the SBA concept of firm as either an owner or exercising decision making. Each mine was assigned a size of large or small using the SBA size standard for each NAIC code in the MSHA data. MSHA estimated mine revenue as it has in the past using U.S. Geological reports (USGS, 2016) to obtain national revenue numbers for 2015 that MSHA then allocated to mines on a dollar per hour basis. Using the traditional definition of small, MSHA estimated that final compliance costs for MNM mines with 1 to 19 employees is $10.6 million, which is less than one percent of the $22.1 billion in revenues for these mines in 2015. Table 4 shows the estimated revenues, costs, size standards (Feb. 2016), and the summary level screening test results. The summary level data is consistent with evaluating the impact on a mine-by-mine basis without providing detail on the approximately ten thousand small mines. MSHA identified numerous data records that were either incomplete or numerous mines that are intermittent with very few producing hours during the year. For these reasons, the analysis by NAICS code does not exactly match the total mine count or totals using MSHA's traditional methodology. However, the error is small enough to not affect MSHA's decision to certify that there is no significant economic

[10] Official definition in data set: Legal Entity acting as a controller of an operator.

impact on a substantial number of small entities.

TABLE 4—SUMMARY OF SCREENING ANALYSIS BY NAICS CODE

NAICS	NAICS description	Small standard (maximum employees)	Number small mines	Estimated revenue small mines ($millions)	One percent of revenues ($millions)	Cost to small mines ($millions)	Cost exceeds 1 percent
212210	Iron Ore Mining	750	26	$1,803.7	*$18.0*	$0.5	No.
212221	Gold Ore Mining	1,500	137	2,357.2	23.6	0.9	No.
212222	Silver Ore Mining	250	9	223.8	2.2	0.1	No.
212231	Lead Ore and Zinc Ore Mining	750	5	439.5	4.4	0.2	No.
212234	Copper Ore and Nickel Ore Mining	1,500	17	1,383.6	13.8	0.3	No.
212291	Uranium-Radium-Vanadium Ore Mining	250	5	109.7	1.1	0.0	No.
212299	All Other Metal Ore Mining	750	28	726.4	7.3	0.3	No.
212311	Dimension Stone Mining and Quarrying	500	793	2,821.7	28.2	1.6	No.
212312	Crushed and Broken Limestone Mining and Quarrying.	750	1,415	7,375.5	73.8	4.1	No.
212313	Crushed and Broken Granite Mining and Quarrying	750	152	1,162.8	11.6	0.6	No.
212319	Other Crushed and Broken Stone Mining and Quarrying.	500	963	3,069.8	30.7	1.7	No.
212321	Construction Sand and Gravel Mining	500	5,684	9,358.9	93.6	5.1	No.
212322	Industrial Sand Mining	500	271	1,395.2	14.0	0.8	No.
212324	Kaolin and Ball Clay Mining	750	11	293.0	2.9	0.2	No.
212325	Clay and Ceramic and Refractory Minerals Mining	500	243	1,459.7	14.6	0.8	No.
212391	Potash, Soda, and Borate Mineral Mining	750	9	650.4	6.5	0.3	No.
212392	Phosphate Rock Mining	1,000	8	529.5	5.3	0.3	No.
212393	Other Chemical and Fertilizer Mineral Mining	500	45	667.0	6.7	0.4	No.
212399	All Other Nonmetallic Mineral Mining	500	185	1,044.1	10.4	0.6	No.
325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing.	500	3	53.1	0.5	0.0	No.
327310	Cement Manufacturing	1,000	50	2,513.3	25.1	1.4	No.
327410	Lime Manufacturing	750	30	849.9	8.5	0.4	No.
331313	Alumina Refining and Primary Aluminum Production	1,000	7	1,467.3	14.7	0.4	No.
Grand Total.			10,096	41,755.1	417.5	21.0	No.

VI. Paperwork Reduction Act of 1995

A. Summary

This final rule contains changes that affect the burden in an existing paperwork package with OMB Control Number 1219–0089 (Safety Defects-Examination, Correction, and Records). MSHA estimates that the final rule will result in an additional 222,519 burden hours with an associated additional cost of $7.6 million annually. Public comments relating to collection requirements were also applicable to the cost analysis section. MSHA has not repeated those comments as they appear above in this preamble.

Burden for Final §§ 56.18002(b) and (c) and 57.18002(b) and (c)

Final §§ 56.18002(b) and (c) and 57.18002(b) and (c) require the existing record to include the following additional information: The name of the person conducting the examination; the date of the examination; the location of all areas examined; a description of each condition found that may adversely affect the safety or health of miners; and the date when a condition that may adversely affect safety or health is corrected. MSHA estimates that a MNM competent person, earning $34.06 per hour, will take 5 additional minutes to add the information required by the final rule to the existing record. Burden hours and costs are shown below:

- 161,903 hours = 10,451 mines with 1–19 employees × 1.1 shifts per day × 1 exam record × 169 workdays per year × 5 additional minutes;
- 50,744 hours = 1,187 mines with 20–500 employees × 1.8 shifts per day × 1 exam record × 285 workdays per year × 5 additional minutes; and
- 1,299 hours = 22 mines with 501+ employees × 2.2 shifts per day × 1 exam record × 322 workdays per year × 5 additional minutes.

Total additional burden hours for final §§ 56.18002(b) and (c) and 57.18002(b) and (c) are 213,946 hours.

Burden Hour Costs

Total burden hour costs for final §§ 56.18002(b) and (c) and 57.18002(b) and (c) are $7,287,001 (213,946 hours × $34.06 per hour).

Burden for Final §§ 56.18002(d) and 57.18002(d)

Final §§ 56.18002(d) and 57.18002(d) require that the operator provide miners' representatives with a copy of the examination record on request. MSHA estimates that a MNM clerical employee, earning $22.43 an hour, will take 1 minute to make and provide a copy of the examination record to the representative of the miners. MSHA estimates that the number of times that a copy of the examination record will be requested is: 10 percent in mines with 1–19 employees; 50 percent in mines with 20–500 employees; and 100 percent in mines with 501+ employees. Burden hours and costs are shown below:

- 3,238 hours = 10,451 mines with 1–19 employees × 10 percent × 1.1 shift per day × 169 workdays per year × 1 minute;
- 5,074 hours = 1,187 mines with 20–500 employees × 50 percent × 1.8 shifts per day × 285 workdays per year × 1 minute; and
- 260 hours = 22 mines with 501+ employees × 100 percent × 2.2 shifts per day × 322 workdays per year × 1 minute.

Total burden hours for final §§ 56.18002(d) and 57.18002(d) are 8,572 hours.

Burden Hour Costs

Total Burden Hour Costs for final §§ 56.18002(d) and 57.18002(d) are $192,270 (8,572 hours × $22.43 per hour).

Copy Cost Burden Related to Final §§ 56.18002(d) and 57.18002(d)

On average, MSHA estimates that copy costs will be $0.30 (2 pages × $0.15 per page). Burden costs are shown below:

• $58,285 = 10,451 mines with 1–19 employees × 10 percent × 1.1 shift per day × 169 workdays per year × $0.30 per copy;

• $91,340 = 1,187 mines with 20–500 employees × 50 percent × 1.8 shifts per day × 285 workdays per year × $0.30 per copy; and

• $4,675 = 22 mines with 501+ employees × 100 percent × 2.2 shifts per day × 322 workdays per year × $0.30 per copy.

Total copy costs for burden related to final §§ 56.18002(d) and 57.18002(d) are $154,300.

VII. Other Regulatory Considerations

A. The Unfunded Mandates Reform Act of 1995

MSHA has reviewed the final rule under the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1501 *et seq.*). MSHA has determined that this final rule does not include any federal mandate that may result in increased expenditures by State, local, or tribal governments; nor will it increase private sector expenditures by more than $100 million (adjusted for inflation) in any one year or significantly or uniquely affect small governments. Accordingly, the Unfunded Mandates Reform Act requires no further Agency action or analysis.

B. The Treasury and General Government Appropriations Act of 1999: Assessment of Federal Regulations and Policies on Families

Section 654 of the Treasury and General Government Appropriations Act of 1999 (5 U.S.C. 601 note) requires agencies to assess the impact of Agency action on family well-being. MSHA has determined that this final rule will have no effect on family stability or safety, marital commitment, parental rights and authority, or income or poverty of families and children. Accordingly, MSHA certifies that this final rule will not impact family well-being.

C. Executive Order 12630: Government Actions and Interference With Constitutionally Protected Property Rights

Section 5 of E.O. 12630 requires Federal agencies to ''identify the takings implications of final regulatory actions. . . .'' MSHA has determined that this final rule does not include a regulatory or policy action with takings implications. Accordingly, E.O. 12630 requires no further Agency action or analysis.

D. Executive Order 12988: Civil Justice Reform

Section 3 of E.O. 12988 contains requirements for Federal agencies promulgating new regulations or reviewing existing regulations to minimize litigation by eliminating drafting errors and ambiguity, providing a clear legal standard for affected conduct rather than a general standard, promoting simplification, and reducing burden. MSHA has reviewed this final rule and has determined that it will meet the applicable standards provided in E.O. 12988 to minimize litigation and undue burden on the Federal court system.

E. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

MSHA has determined that this final rule will have no adverse impact on children. Accordingly, E.O. 13045 requires no further Agency action or analysis.

F. Executive Order 13132: Federalism

MSHA has determined that this final rule does not have federalism implications because 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 the various levels of government. Accordingly, E.O. 13132 requires no further Agency action or analysis.

G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

MSHA has determined that this final rule does not have tribal implications because it will not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. Accordingly, E.O. 13175 requires no further Agency action or analysis.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

E.O. 13211 requires agencies to publish a statement of energy effects when a rule has a significant energy action that adversely affects energy supply, distribution, or use. MSHA has reviewed this final rule for its energy effects because the final rule applies to the MNM mining sector. Although this final rule will result in yearly costs of approximately $34.5 million to the MNM mining industry, only the impact on uranium mines is applicable in this case. MSHA data show only three active uranium mines in 2015. The Energy Information Administration's annual uranium report for 2015 [11] shows 4 million pounds at an average price of $42.86 per pound, for sales of approximately $171.4 million. Using average annual costs of the final rule, the impact to all active uranium mine operators is $57,010. MSHA has concluded that it is not a significant energy action because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Accordingly, under this analysis, no further Agency action or analysis is required.

I. Executive Order 13272: Proper Consideration of Small Entities in Agency Rulemaking

MSHA has reviewed the final rule to assess and take appropriate account of its potential impact on small businesses, small governmental jurisdictions, and small organizations. MSHA has determined that the final rule will not have a significant economic impact on a substantial number of small entities.

VIII. References

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List of Subjects in 30 CFR Parts 56 and 57

Explosives, Fire prevention, Hazardous substances, Metals, Mine safety and health, Reporting and recordkeeping requirements.

Joseph A. Main,

Assistant Secretary of Labor for Mine Safety and Health.

For the reasons set out in the preamble, and under the authority of the Federal Mine Safety and Health Act of 1977, as amended by the Mine Improvement and New Emergency Response Act of 2006, MSHA is amending chapter I of title 30 of the Code of Federal Regulations as follows:

PART 56—SAFETY AND HEALTH STANDARDS—SURFACE METAL AND NONMETAL MINES

■ 1. The authority citation for part 56 continues to read as follows:

Authority: 30 U.S.C. 811.

■ 2. Revise § 56.18002 to read as follows:

§ 56.18002 Examination of working places.

(a) A competent person designated by the operator shall examine each working place at least once each shift before miners begin work in that place, for conditions that may adversely affect safety or health.

(1) The operator shall promptly notify miners in any affected areas of any conditions found that may adversely affect safety or health and promptly initiate appropriate action to correct such conditions.

(2) Conditions noted by the person conducting the examination that may present an imminent danger shall be brought to the immediate attention of the operator who shall withdraw all persons from the area affected (except persons referred to in section 104(c) of the Federal Mine Safety and Health Act of 1977) until the danger is abated.

(b) A record of each examination shall be made before the end of the shift for which the examination was conducted. The record shall contain the name of the person conducting the examination; date of the examination; location of all areas examined; and description of each condition found that may adversely affect the safety or health of miners.

(c) When a condition that may adversely affect safety or health is corrected, the examination record shall include, or be supplemented to include, the date of the corrective action.

(d) The operator shall maintain the examination records for at least one year, make the records available for inspection by authorized representatives of the Secretary and the representatives of miners, and provide these representatives a copy on request.

PART 57—SAFETY AND HEALTH STANDARDS—UNDERGROUND METAL AND NONMETAL MINES

■ 3. The authority citation for part 57 continues to read as follows:

Authority: 30 U.S.C. 811.

■ 4. Revise § 57.18002 to read as follows:

§ 57.18002 Examination of working places.

(a) A competent person designated by the operator shall examine each working place at least once each shift before miners begin work in that place, for conditions that may adversely affect safety or health.

(1) The operator shall promptly notify miners in any affected areas of any conditions found that may adversely affect safety or health and promptly initiate appropriate action to correct such conditions.

(2) Conditions noted by the person conducting the examination that may present an imminent danger shall be brought to the immediate attention of the operator who shall withdraw all persons from the area affected (except persons referred to in section 104(c) of the Federal Mine Safety and Health Act of 1977) until the danger is abated.

(b) A record of each examination shall be made before the end of the shift for which the examination was conducted. The record shall contain the name of the person conducting the examination; date of the examination; location of all areas examined; and description of each condition found that may adversely affect the safety or health of miners.

(c) When a condition that may adversely affect safety or health is corrected, the examination record shall include, or be supplemented to include, the date of the corrective action.

(d) The operator shall maintain the examination records for at least one year, make the records available for inspection by authorized representatives of the Secretary and the representatives of miners, and provide these representatives a copy on request.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–HQ–OAR–2016–0764; FRL–9958–26–OAR]

Extension of Deadline for Action on the November 28, 2016 Section 126 Petition From Delaware

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: In this action, the Environmental Protection Agency (EPA) is determining that 60 days is insufficient time to complete the technical and other analyses and public notice-and-comment process required for our review of a petition submitted by the state of Delaware pursuant to section 126 of the Clean Air Act (CAA). The petition requests that the EPA make a finding that Conemaugh Generating Station, located in Indiana County, Pennsylvania, emits air pollution that significantly contributes to nonattainment and interferes with maintenance of the 2008 and 2015 ozone national ambient air quality standards (NAAQS) in the state of Delaware. Under section 307(d)(10) of CAA, the EPA is authorized to grant a time extension for responding to a petition if the EPA determines that the extension is necessary to afford the public, and the agency, adequate opportunity to carry out the purposes of the section 307(d) notice-and-comment rulemaking requirements. By this action, the EPA is making that determination. The EPA is, therefore, extending the deadline for acting on the petition to no later than August 3, 2017.

DATES: This final rule is effective on January 23, 2017.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR–2016–0764. All documents in the docket are listed on the *http://www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information or other information whose disclosure is

restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Mr. Benjamin Gibson, Office of Air Quality Planning and Standards (C545–E), U.S. EPA, Research Triangle Park, North Carolina 27709, telephone number (919) 541–3277, email: *gibson.benjamin@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background and Legal Requirements for Interstate Air Pollution

This is a procedural action to extend the deadline for the EPA to respond to a petition from the state of Delaware filed pursuant to CAA section 126(b). The EPA received the petition on December 5, 2016. The petition requests that the EPA make a finding under section 126(b) of the CAA that the Conemaugh Generating Station, located in Indiana County, Pennsylvania, is operating in a manner that emits air pollutants in violation of the provisions of section 110(a)(2)(D)(i) of the CAA with respect to the 2008 and 2015 ozone NAAQS.

Section 126(b) of the CAA authorizes states to petition the EPA to find that a major source or group of stationary sources in upwind states emits or would emit any air pollutant in violation of the prohibition of CAA section 110(a)(2)(D)(i) [1] by contributing significantly to nonattainment or maintenance problems in downwind states. Section 110(a)(2)(D)(i)(I) of the CAA prohibits emissions of any air pollutant in amounts which will contribute significantly to nonattainment in, or interfere with maintenance by, any other state with respect to any NAAQS. The petition asserts that emissions from Conemaugh Generating Station's two electric generating units emit air pollutants in violation of CAA section 110(a)(2)(D)(i) with respect to the 2008 8-hour ozone NAAQS, set at 0.075 parts per million (ppm), and the revised 2015 8-hour ozone NAAQS, set at 0.070 ppm.[2]

Pursuant to CAA section 126(b), the EPA must make the finding requested in the petition, or must deny the petition within 60 days of its receipt. Under CAA section 126(c), any existing sources for which the EPA makes the requested finding must cease operations within 3 months of the finding, except that the source may continue to operate if it complies with emission limitations and compliance schedules (containing increments of progress) that the EPA may provide to bring about compliance with the applicable requirements as expeditiously as practical but no later than 3 years from the date of the finding.

CAA section 126(b) further provides that the EPA must hold a public hearing on the petition. The EPA's action under CAA section 126 is also subject to the procedural requirements of CAA section 307(d). *See* CAA section 307(d)(1)(N). One of these requirements is notice-and-comment rulemaking, under section 307(d)(3)–(6).

In addition, CAA section 307(d)(10) provides for a time extension, under certain circumstances, for a rulemaking subject to CAA section 307(d). Specifically, CAA section 307(d)(10) provides:

> Each statutory deadline for promulgation of rules to which this subsection applies which requires promulgation less than six months after date of proposal may be extended to not more than six months after date of proposal by the Administrator upon a determination that such extension is necessary to afford the public, and the agency, adequate opportunity to carry out the purposes of the subsection.

CAA section 307(d)(10) may be applied to CAA section 126 rulemakings because the 60-day time limit under CAA section 126(b) necessarily limits the period for promulgation of a final rule after proposal to less than 6 months.

II. Final Rule

A. Rule

In accordance with CAA section 307(d)(10), the EPA is determining that the 60-day period afforded by CAA section 126(b) for responding to the petition from the state of Delaware is not adequate to allow the public and the agency the opportunity to carry out the purposes of CAA section 307(d). Specifically, the 60-day period is insufficient for the EPA to complete the necessary technical review, develop an adequate proposal, and allow time for notice and comment, including an opportunity for public hearing, on a proposed finding regarding whether the Conemaugh Generating Station identified in the CAA section 126 petition contributes significantly to nonattainment or interferes with maintenance of the 2008 ozone NAAQS or the 2015 ozone NAAQS in Delaware. Moreover, the 60-day period is insufficient for the EPA to review and develop response to any public comments on a proposed finding, or testimony supplied at a public hearing, and to develop and promulgate a final finding in response to the petition. The EPA is in the process of determining an appropriate schedule for action on the CAA section 126 petition. This schedule must afford the EPA adequate time to prepare a proposal that clearly elucidates the issues to facilitate public comment, and must provide adequate time for the public to comment and for the EPA to review and develop responses to those comments prior to issuing the final rule. As a result of this extension, the deadline for the EPA to act on the petition is August 3, 2017.

B. Notice and Comment Under the Administrative Procedures Act (APA)

This document is a final agency action, but may not be subject to the notice-and-comment requirements of the APA, 5 U.S.C. 553(b). The EPA believes that, because of the limited time provided to make a determination, the deadline for action on the CAA section 126 petition should be extended. Congress may not have intended such a determination to be subject to notice-and-comment rulemaking. However, to the extent that this determination otherwise would require notice and opportunity for public comment, there is good cause within the meaning of 5 U.S.C. 553(b)(3)(B) not to apply those requirements here. Providing for notice and comment would be impracticable because of the limited time provided for making this determination, and would be contrary to the public interest because it would divert agency resources from the substantive review of the CAA section 126 petition.

C. Effective Date Under the APA

This action is effective on January 23, 2017. Under the APA, 5 U.S.C. 553(d)(3), agency rulemaking may take effect before 30 days after the date of publication in the **Federal Register** if the agency has good cause to mandate an earlier effective date. This action—a deadline extension—must take effect immediately because its purpose is to extend by 6 months the deadline for action on the petition. As discussed earlier, the EPA intends to use the 6-month extension period to develop a proposal on the petition and provide time for public comment before issuing

[1] The text of CAA section 126 codified in the United States Code cross references CAA section 110(a)(2)(D)(ii) instead of CAA section 110(a)(2)(D)(i). The courts have confirmed that this is a scrivener's error and the correct cross reference is to CAA section 110(a)(2)(D)(i). *See Appalachian Power Co.* v. *EPA,* 249 F.3d 1032, 1040–44 (D.C. Cir. 2001).

[2] On October 1, 2015, the EPA strengthened the ground-level ozone NAAQS, based on extensive scientific evidence about ozone's effects on public health and welfare. *See* 80 FR 65291 (October 26, 2015).

the final rule. It would not be possible for the EPA to complete the required notice and comment and public hearing process within the original 60-day period noted in the statute. These reasons support an immediate effective date.

III. Statutory and Executive Order Reviews

A. Executive Orders 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is exempt from review by the Office of Management and Budget because it simply extends the date for the EPA to take action on a petition.

B. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA. This good cause final action simply extends the date for the EPA to take action on a petition and does not impose any new obligations or enforceable duties on any state, local or tribal governments or the private sector. It does not contain any recordkeeping or reporting requirements.

C. Regulatory Flexibility Act (RFA)

This action is not subject to the RFA. The RFA applies only to rules subject to notice-and-comment rulemaking requirements under the APA, 5 U.S.C. 553, or any other statute. This rule is not subject to notice-and-comment requirements because the agency has invoked the APA good cause exemption under 5 U.S.C. 553(b).

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments or the private sector.

E. Executive Order 13132: Federalism

This action 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 the various levels of government.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications, as specified in Executive Order 13175. This good cause final action simply extends the date for the EPA to take action on a petition. Thus, Executive Order 13175 does not apply to this rule.

G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution or Use

This action is not subject to Executive Order 13211 because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes that this action is not subject to Executive Order 12898 (59 FR 7629, February 16, 1994) because it does not establish an environmental health or safety standard. This good cause final action simply extends the date for the EPA to take action on a petition and does not have any impact on human health or the environment.

K. Congressional Review Act (CRA)

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. The CRA allows the issuing agency to make a rule effective sooner than otherwise provided by the CRA if the agency makes a good cause finding that notice-and-comment rulemaking procedures are impracticable, unnecessary or contrary to the public interest (5 U.S.C. 808(2)). The EPA has made a good cause finding for this rule as discussed in Section II.B of this document, including the basis for that finding.

IV. Statutory Authority

The statutory authority for this action is provided by sections 110, 126 and 307 of the CAA as amended (42 U.S.C. 7410, 7426 and 7607).

V. Judicial Review

Under section 307(b)(1) of the CAA, judicial review of this final rule is available only by the filing of a petition for review in the U.S. Court of Appeals for the appropriate circuit by March 24, 2017. Under section 307(b)(2) of the CAA, the requirements that are the subject of this final rule may not be challenged later in civil or criminal proceedings brought by us to enforce these requirements.

List of Subjects in 40 CFR Part 52

Environmental protection, Administrative practices and procedures, Air pollution control, Electric utilities, Incorporation by reference, Intergovernmental relations, Nitrogen oxides, Ozone.

Dated: January 9, 2017.

Gina McCarthy,

Administrator.

[FR Doc. 2017–00760 Filed 1–19–17; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 64

[Docket ID FEMA–2016–0002; Internal Agency Docket No. FEMA–8463]

Suspension of Community Eligibility

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final rule.

SUMMARY: This rule identifies communities where the sale of flood insurance has been authorized under the National Flood Insurance Program (NFIP) that are scheduled for suspension on the effective dates listed within this rule because of noncompliance with the floodplain management requirements of the program. If the Federal Emergency Management Agency (FEMA) receives documentation that the community has adopted the required floodplain management measures prior to the effective suspension date given in this rule, the suspension will not occur and a notice of this will be provided by publication in the **Federal Register** on a subsequent date. Also, information identifying the current participation status of a community can be obtained from FEMA's Community Status Book

(CSB). The CSB is available at *https://www.fema.gov/national-flood-insurance-program-community-status-book.*

DATES: The effective date of each community's scheduled suspension is the third date (''Susp.'') listed in the third column of the following tables.

FOR FURTHER INFORMATION CONTACT: If you want to determine whether a particular community was suspended on the suspension date or for further information, contact Patricia Suber, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 400 C Street SW., Washington, DC 20472, (202) 646–4149.

SUPPLEMENTARY INFORMATION: The NFIP enables property owners to purchase Federal flood insurance that is not otherwise generally available from private insurers. In return, communities agree to adopt and administer local floodplain management measures aimed at protecting lives and new construction from future flooding. Section 1315 of the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits the sale of NFIP flood insurance unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed in this document no longer meet that statutory requirement for compliance with program regulations, 44 CFR part 59. Accordingly, the communities will be suspended on the effective date in the third column. As of that date, flood insurance will no longer be available in the community. We recognize that some of these communities may adopt and submit the required documentation of legally enforceable floodplain management measures after this rule is published but prior to the actual suspension date. These communities will not be suspended and will continue to be eligible for the sale of NFIP flood insurance. A notice withdrawing the suspension of such communities will be published in the **Federal Register**.

In addition, FEMA publishes a Flood Insurance Rate Map (FIRM) that identifies the Special Flood Hazard Areas (SFHAs) in these communities. The date of the FIRM, if one has been published, is indicated in the fourth column of the table. No direct Federal financial assistance (except assistance pursuant to the Robert T. Stafford Disaster Relief and Emergency Assistance Act not in connection with a flood) may be provided for construction or acquisition of buildings in identified SFHAs for communities not participating in the NFIP and identified for more than a year on FEMA's initial FIRM for the community as having flood-prone areas (section 202(a) of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4106(a), as amended). This prohibition against certain types of Federal assistance becomes effective for the communities listed on the date shown in the last column. The Administrator finds that notice and public comment procedures under 5 U.S.C. 553(b), are impracticable and unnecessary because communities listed in this final rule have been adequately notified.

Each community receives 6-month, 90-day, and 30-day notification letters addressed to the Chief Executive Officer stating that the community will be suspended unless the required floodplain management measures are met prior to the effective suspension date. Since these notifications were made, this final rule may take effect within less than 30 days.

National Environmental Policy Act. FEMA has determined that the community suspension(s) included in this rule is a non-discretionary action and therefore the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) does not apply.

Regulatory Flexibility Act. The Administrator has determined that this rule is exempt from the requirements of the Regulatory Flexibility Act because the National Flood Insurance Act of 1968, as amended, Section 1315, 42 U.S.C. 4022, prohibits flood insurance coverage unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed no longer comply with the statutory requirements, and after the effective date, flood insurance will no longer be available in the communities unless remedial action takes place.

Regulatory Classification. This final rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 13132, Federalism. This rule involves no policies that have federalism implications under Executive Order 13132.

Executive Order 12988, Civil Justice Reform. This rule meets the applicable standards of Executive Order 12988.

Paperwork Reduction Act. This rule does not involve any collection of information for purposes of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

List of Subjects in 44 CFR Part 64

Flood insurance, Floodplains.

Accordingly, 44 CFR part 64 is amended as follows:

PART 64—[AMENDED]

■ 1. The authority citation for Part 64 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.;* Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp.; p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp.; p. 376.

§ 64.6 [Amended]

■ 2. The tables published under the authority of § 64.6 are amended as follows:

State and location	Community No.	Effective date authorization/cancellation of sale of flood insurance in community	Current effective map date	Date certain Federal assistance no longer available in SFHAs
Region VII				
Missouri:				
Jackson County, Unincorporated Areas	290492	June 19, 1974, Emerg; September 29, 1978, Reg; January 20, 2017, Susp	Jan. 20, 2017	Jan. 20, 2017.
Raytown, City of, Jackson County	290176	February 27, 1975, Emerg; September 15, 1978, Reg; January 20, 2017, Susp	.....do	do.

*do = Ditto.

Code for reading third column: Emerg. —Emergency; Reg. —Regular; Susp. —Suspension.

Dated: January 6, 2017.

Michael M. Grimm,

Assistant Administrator for Mitigation, Federal Insurance and Mitigation Administration, Department of Homeland Security, Federal Emergency Management Agency.

[FR Doc. 2017–01102 Filed 1–19–17; 8:45 am]

BILLING CODE 9110–12–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 6, 7, 14, 20, 64, and 67

[CG Docket No. 16–145 and GN Docket No. 15–178; FCC 16–169]

Transition From TTY to Real-Time Text Technology

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Commission adopts amendments to its rules to facilitate a transition from outdated text telephone (TTY) technology to a reliable and interoperable means of providing real-time text (RTT) communication for people who are deaf, hard of hearing, deaf-blind, or have a speech disability over Internet Protocol (IP) enabled networks and services.

DATES: Document FCC 16–169 will become effective February 22, 2017. The incorporation by reference of certain publications listed in the rules is approved by the Director of the Federal Register as of February 22, 2017.

ADDRESSES: Federal Communications Commission, 445 12th Street SW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Michael Scott, Consumer and Governmental Affairs Bureau, at (202) 418–1264; email: *Michael.Scott@fcc.gov* or Suzy Rosen Singleton, Consumer and Governmental Affairs Bureau, at (202) 510–9446; email: *Suzanne.Singleton@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Transition from TTY to Real-Time Text Technology; Petition for Rulemaking to Update the Commission's Rules for Access to Support the Transition from TTY to Real-Time Text Technology, and Petition for Waiver of Rules Requiring Support of TTY Technology,* Report and Order, document FCC 16–169, adopted on December 15, 2016 and released on December 16, 2016, in CG Docket No. 16–145, GN Docket No. 15–178. The Further Notice of Proposed Rulemaking, FCC 16–169, adopted on December 15, 2016 and released on December 16, 2016, is published elsewhere in this issue. The full text of document FCC 16–169 will be available for public inspection and copying via ECFS, and during regular business hours at the FCC Reference Information Center, Portals II, 445 12th Street SW., Room CY–A257, Washington, DC 20554. To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (844) 432–2272 (videophone), or (202) 418–0432 (TTY).

Incorporation by Reference

The Office of Federal Register (OFR) recently revised its regulations to require that agencies must discuss in the preamble of a final rule ways that the materials the agency is incorporating by reference are reasonably available to interested parties or how it worked to make those materials reasonably available to interested parties. In addition, the preamble of the final rule must summarize the material. The Internet Engineering Task Force (IETF) Request for Comments (RFC) 4103, Real-time Transport Protocol Payload for Text Conversation, June 2005, Gunnar Hellstrom & Paul E. Jones, provides technical specifications for carrying real-time text conversation session contents in RTP packets on Internal Protocol-based communications networks. This document is available for download at the Internet Engineering Task Force Web site at *http://ietf.org* or directly at *https://www.ietf.org/rfc/rfc4103.txt,* and is available for inspection at the Federal Communications Commission, 445 12th St. SW., Reference Information Center, Room CY–A257, Washington, DC 20554, (202) 418–0270. It is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030 or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Congressional Review Act

The Commission will send a copy of document FCC 16–169 to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

Final Paperwork Reduction Act of 1995 Analysis

Paragraphs 42 and 43 of document FCC 16–169 contain new information collection requirements, which are not applicable until approved by the Office of Management and Budget (OMB). The Commission, as part of its continuing effort to reduce paperwork burdens, will invite the general public to comment on these information collection requirements as required by the Paperwork Reduction Act (PRA) of 1995, Public Law 104–13. The Commission will publish a separate document in the **Federal Register** announcing approval of the information collection requirements contained in document FCC 16–169. In addition, the Commission notes that, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, 44 U.S.C. 3506(c)(4), the Commission previously sought comment on how the Commission might ''further reduce the information burden for small business concerns with fewer than 25 employees.'' *Transition from TTY to Real-Time Text Technology; Petition for Rulemaking to Update the Commission's Rules for Access to Support the Transition from TTY to Real-Time Text Technology, and Petition for Waiver of Rules Requiring Support of TTY Technology,* Notice of Proposed Rulemaking, published at 81 FR 33170, May 25, 2016 (*NPRM*).

Synopsis

1. In document FCC 16–169, the Commission amends its rules to facilitate a transition from text telephone (TTY) technology to real-time text (RTT) as a reliable and interoperable universal text solution over wireless Internet protocol (IP) enabled networks for people who are deaf, hard of hearing, deaf-blind, or have a speech disability (collectively, ''people with disabilities'' or ''text-reliant users''). The instant proceeding responds to a petition filed by AT&T in June 2015, requesting the Commission to update its accessibility rules to allow RTT to replace TTY technology over IP-based networks. On April 28, 2016, the Commission adopted an *NPRM* proposing to amend its rules to facilitate an effective and seamless transition from TTY technology to RTT over wireless IP-based networks and services. In response, 25 parties filed comments and 13 filed reply comments.

RTT Is an Effective and Efficient Replacement for TTY Technology

2. There is consensus among the commenters that, in light of its technical and functional limitations, TTY technology needs to be replaced with an alternative text technology for IP-based networks. The Commission adopts its tentative conclusion that RTT is an effective alternative to TTY technology

for the IP environment. RTT is a native IP technology designed for the packet-switched network environment that allows users to make RTT calls using the built-in functionality of numerous off-the-shelf devices. Commenters confirm that RTT features, including its full duplex operation, seamless integration of voice and text, international character set, and speed, will greatly improve the availability, efficiency and reliability of text-based communications sent over IP-based networks. In addition, RTT has the potential to enhance the ability of telecommunications relay services (TRS) to provide functionally equivalent telephone service, while at the same time reducing reliance on some forms of TRS. Finally, all of the major and several smaller wireless service providers already have committed to deploying this technology.

3. RTT is a superior accessibility technology to messaging-type text communication services because it provides a more natural and efficient way to meet the communication needs of consumers with disabilities, especially in the event of an emergency, when the need for effective and timely communication with a 911 center is at a premium. Because RTT allows instant transmissions and the improved delivery of messages, it is the text alternative that is the most functionally equivalent to voice communication. Specifically, RTT messages are immediately conveyed to and received by the recipient as the message is composed, as compared to all other text-based messaging services, which require parties to press a key to transmit the message. This enables the user to see what the other person is typing and begin developing a response before the entire message has been conveyed, similar to voice conversations. This capability also lets a user know that the other party is indeed responding to the message, which allows for a more direct exchange of information and avoids confusion, crossed answers, and errors. The transition to RTT is also expected to help facilitate the transition to Next Generation 911 (NG911)—which will allow the transmission of voice, text and video to public safety answering points (PSAPs)—because broadly supported NG911 standards, such as i3, specify support standards for RTT communications. Further, RTT has built-in redundancy and the capacity to detect when information is lost, provides a more conversational flow, and avoids the out-of-sequence and delay pitfalls of short message service (SMS) text messaging.

Permitting RTT Support in Lieu of TTY Support Over IP-Based Wireless Voice Services and Devices

4. The Commission adopts rules permitting IP-based wireless providers and manufacturers (covered entities) to support RTT in lieu of supporting TTY technology. These rule changes cover only those entities that are involved in the provision of IP-based wireless voice communication service, and only to the extent that their services are subject to existing TTY technology support requirements under parts 6, 7, 14, 20, or 64 of the Commission's rules. Given the relative novelty of RTT, it is not appropriate for these rules to apply to entities who were not already subject to an equivalent obligation to support TTY technology.

5. The Commission concludes that it would be premature at this time to address application of RTT to the wireline environment. However, given RTT's superiority to TTY technology, the Commission will keep this docket open to receive further input and conduct continued exploration on the appropriateness of using this technology as an alternative to TTY technology to achieve a universal, integrated text solution for voice service accessibility on wireline IP-based voice services and end user devices.

Wireless Service Support for RTT

6. To establish an effective and timely transition to RTT, the Commission amends parts 6, 7, 14, 20, and 64 of its rules to permit wireless service providers offering IP-based voice communications, in lieu of supporting TTY technology:

- To support 911 access, pursuant to § 20.18 of the Commission's rules, through RTT communications;
- To support RTT over telecommunications services and interconnected voice-over-IP (VoIP) services covered by parts 6 and 7 of the Commission's rules, if readily achievable;
- To support RTT over interconnected VoIP services covered by part 14 of the Commission's rules, unless not achievable;
- To support TRS access, pursuant to § 64.603 of the Commission's rules, through RTT communications, including 711 abbreviated dialing access.

For purposes of this transition, ''to support'' is defined in a new part 67 of the Commission's rules as ''to enable users to initiate, send, transmit, receive, and display RTT communications in accordance with the applicable provisions of this part.''

7. The Commission finds that it has sufficient legal authority to amend the above rule parts to allow support for RTT in lieu of TTY technology. The Commission affirms that its RTT amendments to § 20.18(c) are within the Commission's general Title III authority to regulate wireless service providers. Section 106 of the Twenty-First Century Communications and Video Accessibility Act of 2010, Public Law 111–260 (CVAA), 47 U.S.C. 615c(g), section 251 of the Communications Act (the Act), 47 U.S.C. 251(e)(3), the Wireless Communications and Public Safety Act of 1999, 47 U.S.C. 615–615(b), and the NET 911 Improvement Act of 2008, 47 U.S.C. 615a–l, further support the Commission's adoption of RTT as a superior solution for enabling text-reliant users to access 911.

8. The Commission next affirms that it is within the Commission's authority under sections 255 and 716 of the Communications Act (the Act) to amend parts 6, 7, and 14 of the Commission's rules to permit wireless telecommunications and interconnected VoIP service providers to support RTT in lieu of supporting TTY technology. Given the limitations of TTY technology in an IP environment, this action is necessary to fulfill the intent of the CVAA to ''update the communications laws to help ensure that individuals with disabilities are able to fully utilize communications services and equipment'' as these continue to undergo a ''fundamental transformation.''

9. Finally, the Commission concludes that the Commission has sufficient authority under section 225 of the Act, 47 U.S.C. 225, to amend its TRS rules to permit common carriers and interconnected VoIP service providers to support the transmission of RTT calls to and from TRS providers, including 711 abbreviated dialing. Section 225 of the Act directs the Commission to ensure that TRS is available ''in the most efficient manner'' and to ''ensure that regulations prescribed to implement this section encourage . . . the use of existing technology and do not discourage or impair the development of improved technology.''

End User Device Support for RTT

10. The Commission amends § 20.18 of its rules to allow new IP-enabled wireless devices used for voice communications that have the capability to send, receive, and display text activated for wireless voice services transmitted over IP facilities (hereinafter, text-capable) to support RTT in lieu of TTY communications. In addition, the Commission amends parts

6, 7, and 14 to provide manufacturers of end user equipment for use with wireless interconnected VoIP services with the option of supporting RTT communications in lieu of TTY technology ''if readily achievable'' or ''unless not achievable,'' as applicable. The Commission concludes that the same statutory provisions that provide the Commission with authority to allow RTT support in lieu of TTY support requirements for wireless services also provide authority to allow support for RTT on end user devices in lieu of support for TTYs.

11. The Commission does not require service providers and manufacturers to add RTT capability by recalling or retrofitting end user devices already in service or manufactured prior to the applicable compliance dates. At the same time, the Commission encourages covered entities to ''push out'' downloadable RTT applications to existing text-capable user devices, to the extent practicable, to help consumers who use IP-based voice services make the transition to RTT technology without necessarily incurring the cost of a new device.

Regulatory Relief

12. Covered entities that support RTT in compliance with the Commission's rules will be relieved of their TTY support requirements on all wireless networks and equipment, including services and devices used for legacy (non-IP) facilities, as of the applicable compliance dates. Given the declining use of TTYs, especially with wireless services, elimination of the TTY support obligation on wireless services is not expected to impose a hardship for text-reliant consumers. Additionally, given the progress being made to move ahead with the swift deployment of RTT, the Commission believes that allowing RTT to replace TTY technology on all IP-based wireless services will allow companies to devote greater time and resources to the effective deployment of RTT, instead of continuing to invest in outdated TTY technology.

Performance Objectives

13. The Act defines an electronic messaging service as ''a service that provides real-time or near real-time non-voice messages in text form between individuals over communications networks.'' Because RTT is similar to other examples of two-way interactive electronic messaging services cited in the legislative history of the CVAA—such as text messaging, instant messaging, and electronic mail—the Commission concludes that RTT is an electronic messaging service for purposes of section 716 of the Act. Thus, services and equipment used for RTT must comply more generally with the performance objectives contained in part 14 of the Commission's rules unless these are not achievable.

Minimum Functionalities of RTT

14. The Commission believes that in order to meet the objectives of sections 225, 255, and 716 of the Act, communications services and equipment that support RTT should be as accessible, usable, and effective for people with disabilities as voice-based services over IP-networks. To achieve this goal, the Commission concludes that RTT communications must be interoperable, backward compatible with TTY technology, and capable of supporting certain basic features and capabilities that are routinely available to users of wireless voice services.

Interoperability

15. The Commission concludes that effective RTT communications can only be achieved if the communications transmissions carried across, and the devices used with, various RTT-supporting platforms and networks are interoperable with one another. Absent interoperability, consumers, TRS call centers, and PSAPs would be burdened with having to support multiple versions of RTT. The record supports the use of a safe harbor technical standard to achieve interoperability while preserving technological neutrality and flexibility for the covered entities. This approach provides industry the flexibility to have individual internal RTT standards, so long as they can support the minimum functions and capabilities defined by the Commission's rules and can interoperate in a format specified in the common standard (or a mutually agreed alternative) where they connect with other providers' systems and transport technologies.

16. The Commission adopts RFC 4103, a non-proprietary, freely available standard that has been widely referenced by leading standards organizations and has been designated for RTT implementation by numerous domestic and foreign carriers as well as emergency communications groups, as the appropriate safe harbor standard for compliance with RTT interoperability requirements and certain performance objectives. Accordingly, any service or device that enables the initiation, transmission, reception, and display of RTT communications in conformity with RFC 4103 will meet the RTT interoperability requirement. Because RFC 4103 is subject to modification, service providers may use subsequent versions of RFC 4103 or a successor protocol, by mutual agreement.

Backward Compatibility with TTY Technology

17. To ensure that TTY-reliant consumers continue to have a method of communicating during the transition to RTT technology, the Commission requires wireless service providers to ensure that their RTT technology is backward compatible with TTY technology. A migration to RTT without backward compatibility to TTY technology could leave certain people who are still reliant on TTYs without communication options, including persons who cannot afford high speed access, people in rural areas for whom IP service is not available, and senior citizens who might be reluctant to try new technology. Further, because many PSAPs are still reliant on TTY technology to receive calls from people with disabilities and it may be a while before they migrate to RTT, enabling RTT users to reach 911 emergency services during the transition period is particularly compelling.

18. No parties suggest that the costs of carrying out a backward compatibility requirement would be burdensome, and the record generally supports the feasibility of implementing this requirement through, for example, the use of gateways and RFC 4103. Some commenters recommend limiting backward compatibility to 911 and 711 (TRS) calls, to ensure that congestion does not prevent RTT calls from getting through to these essential services. However, these concerns can be avoided by letting transcoding of such calls be performed by 911 service providers or TRS providers, and ongoing testing should allow service providers to identify and find TTY–RTT and RTT–TTY solutions to the extent that technical issues arise.

19. Commenters point out that incompatibilities between RTT and TTY technologies, namely differences in transmission speed, character sets, and other features, may impact user experience, particularly if the RTT user is unfamiliar with TTY protocols and etiquette. With the exception of providing guidance on transliterations between characters, discussed below, the Commission does not address specific solutions to resolve RTT–TTY incompatibility issues, but instead allows service providers and other stakeholders the flexibility to develop their own technical solutions to resolve inconsistencies between the two technologies. The Commission stresses that public outreach and consumer

education about the transition will play an important role in minimizing any adverse effects that RTT–TTY incompatibilities might have on users.

20. The Commission will allow use of ITU–T Recommendation V.18, which contains a table showing transliterations from the most commonly used characters in the United States to TTY characters, to serve as a safe harbor for transliterating RTT to TTY characters. While the Commission concludes that this approach may provide one effective means of transliterating characters between the two technologies, the Commission also will permit covered entities to choose their own transliteration approach, so long as it can effectively convey the meaning of characters sent to the receiving party. The Commission further encourages use of a standard missing-symbol signal, as well as consumer outreach and education, to help minimize inconsistencies that users may experience as a result of differences between the two character sets.

21. Given the uncertainty as to how soon RTT will be universally available and familiar to users of wireline and wireless services, the Commission concludes that it is premature at this time to set a date by which the TTY backward compatibility obligation should expire.

Support for 911 Communications

22. Commercial mobile radio service (CMRS) providers transmitting over an IP network that choose to enable the transmission and receipt of communications via RTT—in lieu of TTY technology—to and from any PSAP served by their network, must do so in a manner that fully complies with all applicable 911 rules. Support for RTT in lieu of TTY technology is especially beneficial in emergency situations, and the record shows that the use of RTT for emergency communications is technically and economically feasible in the IP environment. There are a variety of existing options for configuring PSAP systems to receive RTT calls, and many PSAPs have installed or will soon install capabilities that will permit them to accept and effectively process RTT calls. Accordingly, to the extent RTT is the accessibility method chosen, RTT must be delivered without RTT–TTY conversion to PSAPs that are able to receive RTT after the dates specified for compliance by CMRS providers in document FCC 16–169.

23. The Commission amends its rules to require that once a PSAP is capable of receiving RTT communications, a service provider receiving a service request must begin delivering RTT communications in an RTT format within six months after such request is made—to the extent the provider has selected RTT as its accessible text communication method. The Commission does not dictate the manner in which RTT–RTT communications must be transmitted to PSAPs, so long as they are otherwise in compliance with the rules adopted in document FCC 16–169. In the event that there are compelling reasons why it would not be feasible for a wireless service provider to transport RTT communications to the PSAP, the service provider may apply for a waiver from this requirement.

24. Many commenters agree that transcoding gateways offer an effective, feasible, and available means to allow TTY users to reach RTT-enabled PSAPs and RTT users to reach legacy PSAPs. T-Mobile, however, claims that this obligation would shift certain burdens now borne by PSAPs onto wireless carriers. Because the components of 911 call delivery referenced by T-Mobile are all basic 911 elements that carriers have been required to provide when transmitting calls from TTYs under § 20.18 of the Commission's rules, the Commission does not believe that requiring the delivery of RTT 911 calls to PSAPs with the elements required by § 20.18 of the rules would involve any burden shifting. T-Mobile also claims that wireless carriers should not be held responsible for RTT-to-TTY conversion of 911 calls, but providers of 911 services commenting in this proceeding affirm the feasibility of accepting RTT calls. Given this record and the lack of a basis to conclude otherwise, the Commission rejects T-Mobile's argument.

25. The Commission encourages carriers and state and local governments to conduct testing of RTT and training of 911 call-takers in consultation with consumers, prior to RTT deployment, and to share the results with other jurisdictions.

26. Under the Commission's rules, wireless CMRS providers supporting TTY calling to 911 must ensure that location information is provided in accordance with the applicable requirements of § 20.18. Given the importance of this feature, RTT 911 calls should be subject to the same location information requirements as TTY 911 calls, and the Commission amends its rules accordingly. However, given concerns raised about the feasibility of achieving compliance with this requirement via RTT provided through a downloadable application, the Commission will entertain requests for waivers from this requirement that allege that this is not technically feasible.

27. Regarding non-service initialized (NSI) devices, because the Commission has an open proceeding to sunset or revise rules for 911 calling from such devices, the Commission defers consideration of the use of NSI devices for RTT calling to 911 to that proceeding.

Core RTT Features

28. The following RTT features are needed to take the place of TTY technology and provide an effective communication alternative to voice communications. Two of these—initiating and receiving calls via the same ten-digit numbers used for voice calls and simultaneous voice and text—will be required for entities seeking to support RTT in lieu of TTY technology.

29. *Initiating and Receiving Calls Using RTT.* The Commission adopts its proposal that for wireless service providers and manufacturers to meet their accessibility obligations by supporting RTT, their networks and devices must be configured so that RTT communications can be initiated to and received from the same telephone number that can be used to initiate and receive voice communications on a given terminal device. The ability to initiate RTT communications through ten-digit telephone numbers will encourage and promote seamless integration of RTT and enabling access to ten-digit numbers is necessary to reach and be reached by any other person with a phone number and to ensure that RTT users can access 911 services. No commenters question the feasibility of providing this feature, or suggest that it would be overly burdensome.

30. *Accessible Indicators.* The Commission agrees with some commenters that without an accessible indicator that a call is being received, text-reliant users will not have communications equivalent to voice service, which produces an audio ring or other sounds to alert people who can hear. Given the importance of this feature for individuals who cannot hear and individuals who can neither hear nor see, the Commission recommends that device manufacturers and service providers incorporate accessible indicators in their RTT implementation to alert users to the receipt of, and audio activity on, an RTT call.

31. *Simultaneous voice and text.* The Commission adopts its proposal that users of RTT must be able to send and receive both text and voice simultaneously in both directions over IP on the same call session and via a

single device. Providing the ability to send and receive simultaneous voice and text is feasible, is supported by RFC 4103, and is an essential feature of RTT. Simultaneous voice and text also can allow for more robust exchanges between RTT users and PSAPs. Further, it can be particularly beneficial to people for whom speech is their primary mode of communication, but who find it necessary to augment speech with text, such as older adults who have progressive hearing loss, many of whom currently rely on relay services to make telephone calls. Finally, this feature can prove to be life-saving in emergencies, when a person in distress may want to type out an emergency's exact location to a 911 call taker to ensure accuracy, or when a person is no longer able to speak. Because TTY users currently have the ability to use both voice and text in the same call session, requiring this for RTT implementation will ensure that people with disabilities do not lose access to services they have had, should their providers opt to support RTT in lieu of TTY technology. Accordingly, an essential element of RTT support for entities choosing to support RTT over TTY technology will be the ability of users to have simultaneous voice and text capability on the same call session as of the compliance deadlines for CMRS providers opting to provide RTT support for all new authorized user devices activated on their networks.

32. *Latency and Error Rate of Text Transmittal.* The Commission believes that ensuring a latency and error rate that is functionally equivalent to the real-time nature of voice telephone communications is important to making real-time text effective for text-reliant users. It is the Commission's understanding that this component is addressed through the safe harbor standard RFC 4103, which sets a maximum typing-to-transmission latency. The Commission recommends that industry and consumer stakeholders work together to determine appropriate latency and error rate parameters. The Commission believes that this approach will provide much needed flexibility for industry, while minimizing delays and errors that could impede effective communication for people with disabilities.

33. *Device Functionality.* A significant advantage to RTT is that it will allow text-reliant users to select off-the-shelf IP-based wireless devices offered to the public for their telephone communications.

34. The extent to which RTT is successful as a replacement for TTY and as an alternative to voice communications, however, will turn in large part on its ease of use by not only text-reliant users, but also members of the public with whom they are likely to converse. For this reason various commenters have urged inclusion of RTT as a pre-installed feature of end-user devices that is enabled by a default function. The Commission is concerned that some of the advantages of RTT as a universal text solution might not be realized if RTT is not enabled by default. The Commission strongly encourages covered entities seeking to meet their accessibility obligations by supporting RTT in lieu of TTY technology to take measures that facilitate, rather than discourage RTT use. While the Commission does not impose mandates for RTT to be pre-installed or accessed through a default function at this time, the Commission notes that the success of RTT's deployment and use may turn on its ease of use, and that its swift adoption is likely to expedite the date for phasing out requirements for TTY support, including the requirement for RTT to be backward compatible with TTYs. The Commission encourages collaboration among industry and consumer stakeholders to reach agreement on the appropriate features and technical aspects of RTT implementation.

35. *Calling Features.* In the *NPRM,* the Commission tentatively concluded that certain calling features that are commonly available to voice telephone users are necessary to ensure that RTT is as accessible, usable, and effective for people with disabilities as wireless voice communications service is for people without disabilities, including the ability to transfer calls, enable multi-party teleconferencing, and utilize automated attendant, interactive voice response systems, and caller identification features. Given that the deployment of RTT is still in its infancy in the U.S., rather than mandate specific calling features or capabilities, the Commission notes more generally the overarching goal of enabling RTT to serve as a universally integrated accessibility solution that is functionally equivalent to voice communications. Consideration of the above calling features may be relevant as wireless voice communications service providers and equipment manufacturers work to identify and eliminate barriers to accessibility and usability during the design and development phases of their RTT products and services. The Commission also reminds companies that parts 6 and 7 of the rules require inclusion of people with disabilities in market research, product design, testing, pilot demonstrations, and product trials. These rules also require covered entities to work cooperatively with disability-related organizations, and to keep records of their efforts to implement parts 6, 7, and 14, including information about their efforts to consult with people with disabilities regarding RTT accessibility features.

Timeline for RTT Implementation by Service Providers

36. At present all Commission waivers from the TTY support obligations expire on December 31, 2017, or upon the effective date of rules providing for alternative IP-based wireless accessibility solutions, whichever is earlier. To the extent that a service provider prefers to support RTT access in lieu of TTY technology and does not wish to seek an extension of the current waiver, it can meet the following compliance timelines, which will supersede the December 31, 2017 deadline: By December 31, 2017, each Tier I service provider must either (1) offer a downloadable application or plug-in that supports RTT or (2) comply with the following: (i) Implement in its core network the capability to support RTT; (ii) offer at least one new handset that supports native RTT functionality, and (iii) for all authorized end user devices specified on or after that date, include in future design specifications the requirement to support RTT. For all other (non-Tier I) carriers opting to provide RTT support, such compliance must be achieved by June 30, 2020. A carrier must meet these obligations except to the extent that it is not achievable for a particular manufacturer to support RTT on that carrier's network.

37. By December 31, 2019, each Tier I service provider opting to support RTT in lieu of TTY technology must provide such support for all new authorized user devices activated on its networks. Non-Tier I service providers (including resellers) that opt to support RTT must do so for all new authorized user devices activated on their networks by June 30, 2021. A carrier must meet these obligations except to the extent that it is not achievable for a particular manufacturer to support RTT on that carrier's network. A carrier may rely in good faith on a manufacturer's representations that it has complied with its obligations under sections 716 and 717 of the Communications Act.

38. These deadlines are set in order to accommodate variances in manufacturer product lifecycles, while still ensuring that devices with native RTT functionality are available by a date certain. Among other things, they allow

CMRS providers that do not fall into Tier I with additional time to comply with the RTT support requirements because they serve small subscriber populations, have fewer device options, often acquire the latest handset models much later than Tier I providers, and have limited influence on the technical ecosystem and standards setting. The Commission expects that handsets offered pursuant to these timelines will be compatible with at least the current versions of the operating systems available on text-capable handsets offered for sale by the service providers.

Timeline for RTT Implementation by Manufacturers

39. The Commission requires manufacturers opting to provide RTT support, in lieu of supporting TTY technology, to provide RTT functionality in handsets and other text-capable end user devices for wireless IP-based voice services, subject to the readily achievable or achievable limitation, as applicable, for all devices manufactured on or after December 31, 2018.

Other Compliance Deadlines and Related Matters

40. Although all compliance timelines contained in this section are prospective only, in that they do not require covered entities to retrofit ''in-service'' devices, pursuant to parts 6, 7, and 14 of the Commission's rules, entities covered under sections 255 and 716 of the Act are required to meet accessibility obligations as natural opportunities occur. As discussed earlier, the Commission encourages covered entities, to the extent practicable, to ''push out'' downloadable apps or upgrades to operating systems to any in-service handsets that can support those apps or upgrades after each applicable compliance deadline.

41. The Commission clarifies that a wireless service provider or manufacturer in compliance with the RTT obligations adopted in this Report and Order will be relieved of its TTY support obligations on all wireless networks and equipment, including services and devices used for legacy (non-IP) facilities. To provide an incentive for early implementation of RTT, a provider or manufacturer that achieves early compliance with the RTT support requirements will be relieved of its TTY support obligations as of the date upon which such provider or manufacturer achieves such RTT support compliance. The Commission further provides that, for those carriers currently subject to a limited waiver of their TTY support requirements that would expire prior to their earliest applicable RTT compliance date, the Commission extends the waiver to that date.

Education, Outreach, and Notifications

42. To inform the public about the transition from TTY technology to RTT and the mechanics of how RTT technology will work, the Commission encourages consumer outreach and education efforts to include (1) the development and dissemination of educational materials that contain information pertinent to the nature, purpose and timelines of the RTT transition; (2) Internet postings, in an accessible format, of information about the TTY to RTT transition on the Web sites of covered entities; (3) the creation of a telephone hotline and online interactive and accessible service that can answer consumer questions about RTT; and (4) appropriate training of staff to effectively respond to consumer questions. All consumer outreach and education needs to be provided in a manner that is accessible to individuals with disabilities. The Commission encourages service providers and manufacturers to coordinate with consumer, public safety, and industry stakeholders to develop and distribute education and outreach materials. The Commission further directs the Commission's Consumer and Governmental Affairs Bureau (CGB) to implement an outreach plan to complement industry's efforts to fully inform the public about RTT.

43. The Commission also adopts its proposal to have the notice conditions imposed in the Bureau's waiver orders remain in effect until the full implementation of the rules adopted in this proceeding. The continued provision of this information is necessary to ensure consumers with disabilities do not expect that TTY technology will be supported by IP-based wireless services when calling 911 services, to educate consumers about the availability of RTT, including its limitations when communicating with PSAPs that have only TTY capability, and to ensure these consumers know alternative accessible telecommunications options exist for this purpose. These notifications should also be provided in formats that are fully accessible to consumers with disabilities.

Final Regulatory Flexibility Analysis

44. As required by the Regulatory Flexibility Act of 1980, as amended (RFA), the Commission incorporated an Initial Regulatory Flexibility Analyses (IRFA) into the *NPRM.* The Commission sought written public comment on the proposals in the *NPRM,* including comment on the IRFA. No comments were received on the IRFA.

Need for, and Objectives of, the Report and Order

45. In document FCC 16–169, the Commission takes specific steps to amend its rules to facilitate a transition from outdated TTY technology to a reliable and interoperable means of providing RTT communication over IP enabled networks and services for people who are deaf, hard of hearing, speech disabled, and deaf-blind. Real-time text is a mode of communication that permits text to be sent immediately as it is being created. In response to various proposals made in the *NPRM* adopted earlier this year, the Commission adopts rules to:

- Permit CMRS providers to support RTT in lieu of TTY technology for communications using wireless IP-based voice services;
- Allow providers of telecommunications and interconnected VoIP services provided over wireless IP facilities and manufacturers of equipment used with such services to support RTT in lieu of supporting TTY technology, ''if readily achievable'' or ''unless not achievable'';
- Relieve wireless service providers and equipment manufacturers of all TTY support obligations to the extent they support RTT on IP facilities in accordance with Commission rules;
- Establish the following criteria defining what constitutes support for RTT:
  - RTT communications must be interoperable across networks and devices, and this may be achieved through adherence to RFC 4103, as a ''safe harbor'' standard for RTT;
  - RTT communications must be backward compatible with TTY technology;
  - RTT must support 911 communications and 711 relay communications; and
- Establish that support for RTT includes support for the ability to initiate and receive calls with the same telephone numbers as are used for voice communications and simultaneous voice and text in the same call session;
- Recognize that the provision of accessible indicators for call answering and activity, appropriate latency and error rates, and pre-installed and default functionality on devices can facilitate making RTT service functionally equivalent to voice communications;
- Permit manufacturers and service providers, to the extent the latter are responsible for the accessibility of end

user devices activated on their IP-based wireless voice communications networks, to ensure that devices that have the ability to send, receive, and display text include RTT capability in lieu of supporting TTY technology, subject to the readily achievable and achievable limitations for parts 6, 7, and 14, as applicable;

• Find that RTT is an ''electronic messaging service'' that is subject to the performance objectives of parts 6, 7, and 14 of the Commission's rules, if readily achievable or unless not achievable, as applicable.

• Establish the following timelines for implementation of RTT:

○ By December 31, 2017, each Tier I CMRS provider and, by June 30, 2020, each non-Tier I provider choosing to support RTT in lieu of TTY over IP facilities shall support RTT either (1) through a downloadable RTT application or plug-in that supports RTT; or (2) by implementing native RTT functionality into its core network, offering at least one handset model that supports RTT, and including the requirement to support RTT in future design specifications for all authorized user devices specified on or after these dates;

○ By December 31, 2018, manufacturers that provide devices for CMRS providers' IP-based voice services and that choose to support RTT in lieu of TTY technology shall implement RTT in newly manufactured equipment, if readily achievable or unless not achievable, as applicable.

○ By December 31, 2019, each Tier I CMRS provider and, by June 30, 2021, each non-Tier I CMRS provider choosing to support RTT in lieu of TTY over IP facilities shall support RTT for all new authorized user devices;

○ A carrier is subject to the above timelines except to the extent that it is not achievable for a particular manufacturer to support RTT on that carrier's network, in which case a carrier may rely in good faith on a manufacturer's representations in this regard; and

• Establish consumer outreach, education, and notice guidelines to inform the public about the transition from TTY Technology to RTT, including how this technology will work.

Summary of Significant Issues Raised by Public Comments in Response to the IRFA

46. No comments were filed in response to the IRFA.

Listing of the Number of Small Entities Impacted

47. The majority of the rules adopted in document FCC 16–169 will affect obligations on telecommunications carriers and providers, VoIP service providers, wireline and wireless service providers, advanced communications services (ACS) providers, and telecommunications equipment and software manufacturers. Other entities, however, that choose to object to the substitution of RTT for TTY technology under the Commission's amended rules may be economically impacted by document FCC 16–169. Affected small entities as defined by industry are as follows.

• *Wired Telecommunications Carriers;*
• *Local Exchange Carriers (LECs);*
• *Incumbent Local Exchange Carriers (Incumbent LECs);*
• *Competitive Local Exchange Carriers (Competitive LECs), Competitive Access Providers (CAPs), Shared-Tenant Service Providers, and Other Local Service Providers;*
• *Interexchange Carriers;*
• *Other Toll Carriers;*
• *Wireless Telecommunications Carriers (except Satellite);*
• *Cable Companies and Systems (Rate Regulation);*
• *All Other Telecommunications;*
• *TRS Providers;*
• *Electronic Computer Manufacturing;*
• *Telephone Apparatus Manufacturing (wireline);*
• *Computer Terminal and Other Computer Peripheral Equipment Manufacturing;*
• *Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing;*
• *Other Communications Equipment Manufacturing; and*
• *Software Publishers.*

Description of Projected Reporting, Record Keeping and Other Compliance Requirements

48. The rule changes adopted in document FCC 16–169 to permit support for RTT in lieu of TTY Technologies in all IP-based wireless services do not modify reporting, recordkeeping, and other compliance requirements. However, document FCC 16–169 requires that notice conditions imposed on waiver recipients remain in effect until the full implementation of the rules adopted in document FCC 16–169. The waiver recipients must continue to apprise their customers, through effective and accessible channels of communication, that (1) until TTY is sunset, TTY technology will not be supported for calls to 911 services over IP-based wireless services, and (2) there are alternative public switched telephone network (PSTN)-based and IP-based accessibility solutions for people with communication disabilities to reach 911 services. These notices must be developed in coordination with PSAPs and national consumer organizations, and include a listing of text-based alternatives to 911, including, but not limited to, TTY capability over the PSTN, various forms of PSTN-based and IP-based TRS, and text-to-911 (where available). The waiver recipients must also file a report every six months regarding their progress toward and the status of the availability of new IP-based accessibility solutions, such as RTT. The only entities that will be affected by this requirement are those entities that have previously petitioned for and received or will receive a waiver of the TTY obligations. The Commission believes the only burden associated with the reporting requirement will be the time required to continue to prepare and send out notifications to customers and to complete the progress and status report every six months.

Steps Taken To Minimize Significant Impact on Small Entities and Significant Alternatives Considered

49. In amending its rules, the Commission believes that it has minimized the effect on small entities while facilitating an effective and seamless transition from TTY technology to RTT. The Commission had considered other possible proposals and sought comment on the requirements and the analysis presented. The requirements adopted by the Commission to provide notices to customers and file reports with the Commission apply only to entities that have specifically sought waivers of the TTY obligations. Further, RTT technology may simplify the accessibility obligations of small businesses, because RTT allows calls to be made using the built-in functionality of a wide selection of off-the shelf devices such as cellphones, and thus may alleviate the high costs and challenges faced by small businesses and customers in locating dedicated external assistive devices, such as specialty phones. Additionally, in phasing out TTY technology, the burden is reduced for small entities and emergency call centers to maintain such technology in the long term.

50. The Commission also establishes a phased timeline for implementation of RTT technology. In response to

comments in the proceeding and to reduce the burden and relieve possible adverse economic impact on small entities, by December 31, 2017, each Tier I CMRS provider and, by June 30, 2020, each non-Tier I provider may choose to support RTT in lieu of TTY over IP facilities. The Commission establishes a second period for each Tier I CMRS provider and non-Tier I CMRS provider choosing to support RTT in lieu of TTY over IP facilities to be required to support RTT for all new authorized user devices. Tier I CMRS providers must meet this requirement by December 31, 2019, and non-Tier I providers must meet this requirement by June 30, 2021. Manufacturers that provide devices for CMRS providers' IP-based voice services and that choose to support RTT in lieu of TTY technology shall implement RTT in newly manufactured equipment by December 31, 2018, if readily achievable or unless not achievable, as applicable.

51. In addition, the Commission is permitting rather than requiring service providers to support RTT. With regards to implementing RTT, while the Commission adopts a ''safe harbor'' technical standard to ensure RTT interoperability, it also allows service providers to use alternative protocols for RTT, provided that they are interoperable. Further, throughout the item, flexibility is integrated into the criteria for RTT support in order to take into consideration the limitations of small businesses. For example, a service provider choosing to support RTT rather than TTY is not required to support RTT on new authorized end user devices to the extent that is not achievable for a particular manufacturer to support RTT on that provider's network. As such, the Commission anticipates that the requirements will have little to no impact on small entities that are eligible to rely on the claim that supporting RTT on a particular device is not achievable.

52. The Commission also determined to establish outreach and education guidelines to encourage rather than require service providers and manufacturers to implement efforts to notify consumers about the transition from TTY technology to RTT, and to allow small entities to determine the extent of resources they allocate to inform consumers of the changes in the services and associated equipment they will be receiving.

Ordering Clauses

53. Pursuant to sections 4(i), 225, 255, 301, 303(r), 316, 403, 715, and 716 of the Communications Act of 1934, as amended, and section 106 of the CVAA, 47 U.S.C. 154(i), 225, 255, 301, 303(r), 316, 403, 615c, 616, 617, document FCC 16–169 IS ADOPTED and parts 6, 7, 14, 20, and 64 of the Commission's rules ARE AMENDED and part 67 IS ADOPTED.

54. The Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, SHALL SEND a copy of document FCC 16–169, including the Final Regulatory Flexibility Analysis to the Chief Counsel for Advocacy of the Small Business Administration.

List of Subjects

47 CFR Part 6

Individuals with disabilities, access to telecommunication service and equipment, and customer premise equipment.

47 CFR Part 7

Individuals with disabilities, access to voice mail and interactive menu services and equipment.

47 CFR Part 14

Individuals with disabilities, access to advanced communication services and equipment.

47 CFR Part 20

Commercial mobile services, individuals with disabilities, access to 911 services.

47 CFR Part 64

Telecommunications relay services, individuals with disabilities.

47 CFR Part 67

Real-time text, individuals with disabilities, incorporation by reference.

Federal Communications Commission.

Katura Howard,

Federal Register Liaison, Office of the Secretary.

For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR parts 6, 7, 14, 20, 64, and adds 67 as follows:

PART 6—ACCESS TO TELECOMMUNICATIONS SERVICE, TELECOMMUNICATIONS EQUIPMENT AND CUSTOMER PREMISES EQUIPMENT BY PERSONS WITH DISABILITIES

■ 1. The authority citation for part 6 is revised to read as follows:

Authority: 47 U.S.C. 151–154, 208, 255, and 303(r).

■ 2. Amend § 6.3 by adding paragraphs (a)(3), (b)(5), (m), and (n) to read as follows:

§ 6.3 Definitions.

(a) * * *

(3) *Real-Time Text.* Voice communication services subject to this part that are provided over wireless IP facilities and handsets and other text-capable end user devices used with such service that do not themselves provide TTY functionality, may provide TTY connectability and signal compatibility pursuant to paragraphs (b)(3) and (4) of this section, or support real-time text communications, in accordance with 47 CFR part 67.

(b) * * *

(5) *TTY Support Exemption.* Voice communication services subject to this part that are provided over wireless IP facilities and equipment used with such services are not required to provide TTY connectability and TTY signal compatibility if such services and equipment support real-time text, in accordance with 47 CFR part 67.

* * * * *

(m) The term *real-time text* shall have the meaning set forth in § 67.1 of this chapter.

(n) The term *text-capable end user device* means customer premises equipment that is able to send, receive, and display text.

PART 7—ACCESS TO VOICEMAIL AND INTERACTIVE MENU SERVICES AND EQUIPMENT BY PEOPLE WITH DISABILITIES

■ 3. The authority citation for part 7 is revised to read as follows:

Authority: 47 U.S.C. 151–154, 208, 255, and 303(r).

■ 4. Amend § 7.3 by adding paragraphs (a)(3), (b)(5), (n), and (o) to read as follows:

§ 7.3 Definitions.

(a) * * *

(3) *Real-Time Text.* Voice communication services subject to this part that are provided over wireless IP facilities and handsets and other text-capable end user devices used with such service that do not themselves provide TTY functionality, may provide TTY connectability and signal compatibility pursuant to paragraphs (b)(3) and (4) of this section, or support real-time text communications, in accordance with 47 CFR part 67.

(b) * * *

(5) *TTY Support Exemption.* Voice communication services subject to this part that are offered over wireless IP facilities and equipment used with such services are not required to provide TTY connectability and TTY signal compatibility if such services and equipment support real-time text, in accordance with 47 CFR part 67.

* * * * *

(n) The term *real-time text* shall have the meaning set forth in § 67.1 of this chapter.

(o) The term *text-capable end user device* means customer premises equipment that is able to send, receive, and display text.

PART 14—ACCESS TO ADVANCED COMMUNICATIONS SERVICES AND EQUIPMENT BY PEOPLE WITH DISABILITIES

■ 5. The authority citation for part 14 continues to read as follows:

Authority: 47 U.S.C. 151–154, 255, 303, 403, 503, 617, 618, 619 unless otherwise noted.

■ 6. Amend § 14.10 by adding paragraphs (w) and (x) to read as follows:

§ 14.10 Definitions.

* * * * *

(w) The term *real-time text* shall have the meaning set forth in § 67.1 of this chapter.

(x) The term *text-capable end user device* means end user equipment that is able to send, receive, and display text.

■ 7. Amend § 14.21 by adding paragraphs (b)(3) and (d)(5) to read as follows:

§ 14.21 Performance Objectives.

* * * * *

(b) * * *

(3) *Real-Time Text.* Wireless interconnected VoIP services subject to this part and text-capable end user devices used with such services that do not themselves provide TTY functionality, may provide TTY connectability and signal compatibility pursuant to paragraphs (b)(3) and (4) of this section, or support real-time text communications, in accordance with 47 CFR part 67.

* * * * *

(d) * * *

(5) *TTY Support Exemption.* Interconnected and non-interconnected VoIP services subject to this part that are provided over wireless IP facilities and equipment are not required to provide TTY connectability and TTY signal compatibility if such services and equipment support real-time text, in accordance with 47 CFR part 67.

PART 20—COMMERCIAL MOBILE SERVICES

■ 8. The authority citation for part 20 continues to read as follows:

Authority: 47 U.S.C. 151, 152(a), 154(i), 157, 160, 201, 214, 222, 251(e), 301, 302, 303, 303(b), 303(r), 307, 307(a), 309, 309(j)(3), 316, 316(a), 332, 615, 615a, 615b, 615c.

■ 9. Amend § 20.18 by revising paragraph (c) to read as follows:

§ 20.18 911 Service.

* * * * *

(c) *Access to 911 services.* CMRS providers subject to this section must be capable of transmitting 911 calls from individuals with speech or hearing disabilities through means other than mobile radio handsets, *e.g.,* through the use of Text Telephone Devices (TTY). CMRS providers that provide voice communications over IP facilities are not required to support 911 access via TTYs if they provide 911 access via real-time text (RTT) communications, in accordance with 47 CFR part 67, except that RTT support is not required to the extent that it is not achievable for a particular manufacturer to support RTT on the provider's network.

* * * * *

PART 64—MISCELLANEOUS RULES RELATING TO COMMON CARRIERS

■ 10. The authority citation for part 64 is revised to read as follows:

Authority: 47 U.S.C. 154, 225, 403(b)(2)(B), (c), 715, Pub. L. 104–104, 110 Stat. 56. Interpret or apply 47 U.S.C. 201, 218, 222, 225, 226, 227, 228, 254(k), 616, 620, and the Middle Class Tax Relief and Job Creation Act of 2012, Pub. L. 112–96, unless otherwise noted.

■ 11. Amend § 64.601 by revising paragraph (a)(15) and adding paragraph (a)(46) to read as follows:

§ 64.601 Definitions and provisions of general applicability.

(a) * * *

(15) *Internet-based TRS (iTRS).* A telecommunications relay service (TRS) in which an individual with a hearing or a speech disability connects to a TRS communications assistant using an Internet Protocol-enabled device via the Internet, rather than the public switched telephone network. Except as authorized or required by the Commission, Internet-based TRS does not include the use of a text telephone (TTY) or RTT over an interconnected voice over Internet Protocol service.

* * * * *

(46) *Real-Time Text (RTT).* The term *real-time text* shall have the meaning set forth in § 67.1 of this chapter.

* * * * *

■ 12. Revise § 64.603 to read as follows:

§ 64.603 Provision of services.

(a) Each common carrier providing telephone voice transmission services shall provide, in compliance with the regulations prescribed herein, throughout the area in which it offers services, telecommunications relay services, individually, through designees, through a competitively selected vendor, or in concert with other carriers. Interstate Spanish language relay service shall be provided. Speech-to-speech relay service also shall be provided, except that speech-to-speech relay service need not be provided by IP Relay providers, VRS providers, captioned telephone relay service providers, and IP CTS providers. In addition, each common carrier providing telephone voice transmission services shall provide access via the 711 dialing code to all relay services as a toll free call. CMRS providers subject to this 711 access requirement are not required to provide 711 dialing code access to TTY users if they provide 711 dialing code access via real-time text communications, in accordance with 47 CFR part 67.

(b) A common carrier shall be considered to be in compliance with this section:

(1) With respect to intrastate telecommunications relay services in any state that does not have a certified program under § 64.606 and with respect to interstate telecommunications relay services, if such common carrier (or other entity through which the carrier is providing such relay services) is in compliance with § 64.604; or

(2) With respect to intrastate telecommunications relay services in any state that has a certified program under § 64.606 for such state, if such common carrier (or other entity through which the carrier is providing such relay services) is in compliance with the program certified under § 64.606 for such state.

PART 67—REAL-TIME TEXT

■ 13. Add new part 67 to read as follows:

PART 67—REAL-TIME TEXT

Sec.

Authority: 47 U.S.C. 151–154, 225, 251, 255, 301, 303, 307, 309, 316, 615c, 616, 617.

§ 67.1 Definitions.

(a) *Authorized end user device* means a handset or other end user device that is authorized by the provider of a covered service for use with that service and is able to send, receive, and display text.

(b) *CMRS provider* means a CMRS provider as defined in § 20.18(c) of this chapter.

(c) *Covered service* means a service that meets accessibility requirements by supporting RTT pursuant to part 6, 7, 14, 20, or 64 of this chapter.

(d) *RFC 4103* means IETF's Request for Comments (RFC) 4103 (incorporated by reference, *see* § 67.3 of this part).

(e) *RFC 4103-conforming service or user device* means a covered service or authorized end user device that enables initiation, sending, transmission, reception, and display of RTT communications in conformity with RFC 4103.

(f) *RFC 4103–TTY gateway* means a gateway that is able to reliably and accurately transcode communications between (1) RFC 4103-conforming services and devices and (2) circuit-switched networks that support communications between TTYs.

(g) *Real-time text (RTT)* or *RTT communications* means text communications that are transmitted over Internet Protocol (IP) networks immediately as they are created, *e.g.,* on a character-by-character basis.

(h) *Support RTT* or *support RTT communications* means to enable users to initiate, send, transmit, receive, and display RTT communications in accordance with the applicable provisions of this part.

§ 67.2 Minimum Functionalities of RTT.

(a) *RTT–RTT Interoperability.* Covered services and authorized end user devices shall be interoperable with other services and devices that support RTT in accordance with this part. A service or authorized end user device shall be deemed to comply with this paragraph (a) if:

(1) It is an RFC 4103-conforming end user device;

(2) RTT communications between such service or end user device and an RFC 4103-conforming service or end user device are reliably and accurately transcoded—

(i) to and from RFC 4103, or

(ii) to and from an internetworking protocol mutually agreed-upon with the owner of the network serving the RFC 4103-conforming service or device.

(b) *RTT–TTY Interoperability.* Covered services and authorized end user devices shall be interoperable with TTYs connected to other networks. Covered services and authorized end user devices shall be deemed to comply with this paragraph (b) if communications to and from such TTYs:

(1) Pass through an RFC 4103–TTY gateway, or

(2) are reliably and accurately transcoded to and from an internetworking protocol mutually agreed-upon with the owner of the network serving the TTY.

(c) *Features and Capabilities.* Covered services and authorized end user devices shall enable the user to:

(1) Initiate and receive RTT calls to and from the same telephone numbers for which voice calls can be initiated and received;

(2) transmit and receive RTT communications to and from any 911 public safety answering point (PSAP) in the United States; and

(3) send and receive text and voice simultaneously in both directions on the same call using a single device.

§ 67.3 Incorporation by Reference.

(a) Certain material is incorporated by reference into this part with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All approved material is available for inspection at the Federal Communications Commission, 445 12th St. SW., Reference Information Center, Room CY–A257, Washington, DC 20554, (202) 418–0270, and is available from the sources listed below. It is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030 or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(b) Internet Engineering Task Force (IETF), c/o Association Management Solutions, LLC (AMS) 5177 Brandin Court, Fremont, California 94538, phone (510) 492–4080, Web site at *http://ietf.org* or directly at *https://www.ietf.org/rfc/rfc4103.txt.*

(1) Request for Comments (RFC) 4103, Real-time Transport Protocol Payload for Text Conversation (2005), IBR approved for § 67.1.

(2) [Reserved]

[FR Doc. 2017–01377 Filed 1–19–17; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Parts 13 and 22

[Docket No. FWS–R9–MB–2011–0094; FF09M20300–167–FXMB123109EAGLE]

RIN 1018–AY30

Eagle Permits; Revisions to Regulations for Eagle Incidental Take and Take of Eagle Nests

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule; information collection requirements.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), recently published a final rule that revises the regulations for eagle nonpurposeful take permits and eagle nest take permits. In that final rule, we stated that the Office of Management (OMB) had not yet approved the information collection requirements associated with the rule. This document announces that OMB has now approved the information collection requirements.

DATES: OMB approved the information collection requirements on January 6, 2017, for the final rule that published at 81 FR 91494 on December 16, 2016.

ADDRESSES: Relevant information and documents related to the eagle permit rule may be found on the internet at *http://www.regulations.gov* in Docket No. FWS–R9–MB–2011–0094. You may review the information collection request online at *http://www.reginfo.gov.* Follow the instructions to review Department of the Interior collections.

FOR FURTHER INFORMATION CONTACT: Tina Campbell, Chief, Division of Policy, Performance, and Management Programs; 703–358–2676.

SUPPLEMENTARY INFORMATION:

Background

We, the U.S. Fish and Wildlife Service (Service), published a final rule in the December 16, 2016, **Federal Register** (81 FR 91494) that revises the regulations in part 22 of title 50 of the Code of Federal Regulations (CFR) for eagle nonpurposeful take permits and eagle nest take permits. Revisions included changes to permit issuance criteria and duration, definitions, compensatory mitigation standards, criteria for eagle nest removal permits, permit application requirements, and fees. In the final rule, we stated that the Office of Management (OMB) had not yet approved the information collection requirements associated with the rule. We also stated that we would announce the approval via a separate notification in the **Federal Register**. This document provides that notification.

The following text sets forth the information collection requirements approved by OMB:

Title: Eagle Take Permits and Fees, 50 CFR part 22.

OMB Control Number: 1018–0167.

Service Form Number(s): 3–200–71, 3–200–72.

Description of Respondents: Individuals and businesses. We expect that the majority of applicants seeking

long-term permits will be in the energy production and electrical distribution business.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: On occasion.

Table 1 cites the total burden for this information collection. Table 2 sets forth the changes in nonhour burden fees for eagle take permits.

TABLE 1—ESTIMATED HOUR AND COST BURDEN FOR LONG-TERM EAGLE TAKE PERMITS

Activity/requirement	Annual number of responses	Average completion time per response (hours)	Total annual burden (hours)	Cost/hour	$ Value of annual burden hours (rounded)
Preconstruction Monitoring Surveys	15	650	9,750	$34.26	$334,035
Preparation of Eagle Conservation Plan	15	200	3,000	34.26	102,780
Postconstruction Monitoring	15	700	10,500	34.26	359,730
Reporting Take of Eagles	10	2	20	34.26	685
Reporting Take of Threatened and Endangered Species	1	2	2	34.26	69
§ 22.26(c)(7)(ii)—*Permit reviews.* At no more than 5 years from the date a permit that exceeds 5 years is issued, and every 5 years thereafter, the permittee compiles and submits to the Service, eagle fatality data or other pertinent information that is site-specific for the project.[8] (Footnote 8 may be found below table 2. Note that the dollar value of the annual burden cost is included in the $8,000 permit 5-year permit review fee.)	4	8	32	34.26	1,096
Total	60	1,562	23,304	.....	798,395

TABLE 2—CHANGES IN NONHOUR BURDEN FEES FOR EAGLE TAKE PERMITS

Activity/requirement	Previous approval under OMB Control No. 1018–0022	Previous fee	New fee	Total previously approved nonhour burden costs	Total new approved nonhour burden costs	Difference between previous 1018–0022 approval and new approval
3–200–71—application, Eagle Incidental Take (not programmatic or long-term) [1].	Approval covered number of responses and annual burden hours. The rule revises fees and nonhour costs.	$500 Non-commercial ..... $500 Commercial	$500 Non-commercial ..... $2,500 Commercial	$12,500 Non-commercial .. $60,000 Commercial	$12,500 Non-commercial .. $300,000 Commercial	$0 Non-commercial. +$240,000 Commercial.
3–200–72—application, Eagle Nest Take–single nest (formerly "standard") [2].	Approval covered number of responses and annual burden hours. The rule revises fees and nonhour costs.	$500 Non-commercial ..... $500 Commercial	$500 Non-commercial ..... $2,500 Commercial	$5,000 Non-commercial .... $10,000 Commercial	$5,000 Non-commercial .... $50,000 Commercial	$0 Non-commercial. +$40,000 Commercial.
3–200–72—application, Eagle Nest Take–multiple nests (formerly "programmatic") [3].	Approval covered number of responses and annual burden hours. The rule revises fees and nonhour costs.	$1,000	$500 Non-commercial ..... $5,000 Commercial	$0 [3]	$500 Non-commercial ..... $40,000 Commercial	+$500 Non-commercial. +$40,000 Commercial.
3–200–71—Eagle Incidental Take Amendment–less than 5 years (formerly "standard") [4].	Approval covered number of responses and annual burden hours. The rule revises fees and nonhour costs.	$150 Non-commercial ..... $150 Commercial	$150 Non-commercial ..... $500 Commercial	$300 Non-commercial ..... $2,700 [5] Commercial	$300 Non-commercial ..... $9,000 Commercial	$0 Non-commercial. +$6,300 Commercial.
3–200–72—Eagle Nest Take Amendment–single nest (formerly "standard") [4].	Approval covered number of responses and annual burden hours. The rule revises fees and nonhour costs.	$150 Non-commercial ..... $150 Commercial	$150 Non-commercial ..... $500 Commercial	$150 Non-commercial ..... $600 [6] Commercial	$150 Non-commercial ..... $2,000 Commercial	$0 Non-commercial. +$1,400 Commercial.
3–200–71—Amendment–Eagle Incidental Take–programmatic.	Approval covered number of responses and annual burden hours.	$1,000 Commercial	No Fee [7]	$1,000 Commercial	.....	– $1,000 Commercial.
NEW REPORTING REQUIREMENT AND NEW ADMINISTRATION FEE						
§ 22.26(c)(7)(ii)—*Permit reviews.* At no more than 5 years from the date a permit that exceeds 5 years is issued, and every 5 years thereafter, the permittee compiles and submits to the Service eagle fatality data or other pertinent information that is site-specific for the project.[8].	.....	0	$8,000	0	$32,000	+$32,000.
Total	.....	.....	.....	$92,250	$431,450	$359,200.

[1] Approved under 1018–0022: 145 annual responses (25 from individuals/households (homeowners) and 120 from the private sector (commercial), totaling 2,320 annual burden hours) (400 burden hours for individuals and 1,920 annual burden hours for private sector); $500 permit fee for both individuals and private sector for a total nonhour burden cost of $72,500. The rule changes the application fees: Homeowner fee remains $500; private sector fee (commercial) increases to $2,500. Total for 25 homeowners = $12,500; total for 125 commercial applicants = $300,000.

[2] Approved under 1018–0022 (standard and programmatic permits were combined): 30 responses (10 from individuals/homeowners and 20 from private sector (commercial), totaling 480 burden hours) (160 hours (individuals) and 320 hours (private sector)). Homeowner fee remains $500; private sector fee (commercial) increases to $2,500. Total for 10 homeowners = $5,000.; total for 20 commercial applicants = $50,000.

[3] Approved under 1018–0022 (standard and programmatic permits were combined): 9 responses (1 from individuals/homeowners (noncommercial) and 8 from private sector (commercial), totaling 360 burden hours) (40 hours (individuals) and 320 hours (private sector)). The homeowner fee increases to $500; private sector fee (commercial) increases to $5,000. Total for 1 homeowner = $500; total for 8 commercial = $40,000.

[4] The amendments for standard nonpurposeful eagle take permits and standard eagle nest take permits are combined in the approved collection for a total of 25. Here they are split into 20 eagle incidental take permit amendments and 5 eagle nest take permit amendments.

[5] Two homeowner; 18 commercial.

[6] One homeowner; four commercial.

[7] The amendment fee for long-term programmatic permits was approved under 1018–0022. However, the rule removes this fee because the costs associated with it are included under the administration fee.

[8] This is a new reporting requirement as well as a new administration fee and applies only to commercial permittees. We will not receive any reports or assess the administration fee until after a permittee has had a permit for 5 years (earliest probably 2022). We estimate that we will receive 19 responses every 5 years, which, annualized over the 3-year period of OMB approval, results in 4 responses annually. We estimate that each response will take 8 hours, for a total of 32 annual burden hours. We will assess an $8,000 administration fee for each permittee for a total of $32,000. **Note:** This burden reflects what will be imposed in 5 years. Each 5 years thereafter, the burden and nonhour costs will increase because of the number of permittees holding 5-year or longer term permits.

Estimated Total Hour Burden: 23,304 hours; the total number of new respondents is 60.

Estimated Total Hour Burden Cost: $798,395 for gathering information required to support an application, which may include preparation of an Eagle Conservation Plan (ECP). This amount includes 650 hours for preconstruction monitoring surveys of eagle use of the project site and 700 hours of postconstruction monitoring for each respondent. Preparation of the application, which may include preparation of an ECP, will take approximately 200 hours per respondent. These burden hours apply only to those seeking a long-term eagle take permit. In addition, those that receive a permit are required to report take of eagles and threatened or endangered species within 48 hours of discovery of the take. It is estimated that of the 15 projects permitted to take eagles each year, 10 will actually take eagles, requiring 2 hours per respondent to report. Take of threatened or endangered species is expected to be a rare event, and occur at only 1 of the 15 projects permitted each year, requiring only 2 hours to report. The burden hours also include the costs for the 5-year permit review. We estimate 8 hours per respondent to complete the requirements of the permit review for a total of 32 hours.

Estimated New Total Nonhour Burden Cost: $359,200 for administration fees and application fees associated with changes implemented by this rule. This amount does not include the nonhour cost burden for eagle or eagle nest take permits approved under OMB Control No. 1018–0022. States, local governments, and tribal governments are exempt from paying these fees.

An agency may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number.

Dated: January 12, 2017.

Michael J. Bean,

Principal Deputy Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 2017–01284 Filed 1–19–17; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Parts 223, 224, and 226

[Docket No. 160524463–7001–02]

RIN 0648–XE657

Endangered and Threatened Species; Removal of the Puget Sound/Georgia Basin Distinct Population Segment of Canary Rockfish From the Federal List of Threatened and Endangered Species and Removal of Designated Critical Habitat, and Update and Amendment to the Listing Descriptions for the Yelloweye Rockfish DPS and Bocaccio DPS

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

ACTION: Final rule.

SUMMARY: We, NMFS, are issuing a final rule to remove the Puget Sound/Georgia Basin canary rockfish (*Sebastes pinniger*) Distinct Population Segment (DPS) from the Federal List of Threatened and Endangered Species and remove its critical habitat designation. We proposed these actions based on newly obtained samples and genetic analysis that demonstrates that the Puget Sound/Georgia Basin canary rockfish population does not meet the DPS criteria and therefore does not qualify for listing under the Endangered Species Act (ESA). Following public and peer review of the proposed rule and supporting scientific information, this final rule implements the changes to the listing and critical habitat for canary rockfish.

We also update and amend the listing description for the Puget Sound/Georgia Basin yelloweye rockfish (*S. ruberrimus*) DPS based on a geographic description to include fish within specified boundaries. Further, although the current listing description is not based on boundaries, with this final rule we are also correcting a descriptive boundary for the DPS depicted on maps to include an area in the northern Johnstone Strait and Queen Charlotte Channel in waters of Canada consistent with newly obtained genetic information on yelloweye rockfish population grouping.

We also update and amend the listing description for the bocaccio DPS based on a geographic description and to include fish within specified boundaries.

DATES: This final rule is effective on March 24, 2017.

FOR FURTHER INFORMATION CONTACT: Dan Tonnes, NMFS, West Coast Region, Protected Resources Division, 206–526–4643; or Chelsey Young, NMFS, Office of Protected Resources, 301–427–8491.

SUPPLEMENTARY INFORMATION:

Background

On April 9, 2007, we received a petition from Mr. Sam Wright (Olympia, Washington) to list DPSs of five rockfish species (yelloweye, canary, bocaccio, greenstriped and redstripe) in Puget Sound, as endangered or threatened species under the ESA and to designate critical habitat. We found that this petition did not present substantial scientific or commercial information to suggest that the petitioned actions may be warranted (72 FR 56986; October 5, 2007). On October 29, 2007, we received a letter from Mr. Wright presenting information that was not included in the April 2007 petition, and requesting reconsideration of the decision not to initiate a review of the species' status. We considered the supplemental information as a new petition and concluded that there was enough information in this new petition to warrant conducting status reviews of these five rockfish species. The status review was initiated on March 17, 2008 (73 FR 14195) and completed in 2010 (Drake *et al.,* 2010).

In the 2010 status review, the Biological Review Team (BRT) used the best scientific and commercial data available at that time, including environmental and ecological features of the Puget Sound/Georgia Basin, but noted that the limited genetic and demographic data for the five petitioned rockfish species populations created some uncertainty in the DPS determinations (Drake *et al.,* 2010). The BRT assessed genetic data from the Strait of Georgia (inside waters of eastern Vancouver Island) for yelloweye rockfish (Yamanaka *et al.,* 2006) that indicated a distinct genetic cluster that differed consistently from coastal samples of yelloweye rockfish, but also observed that genetic data from Puget Sound were not available for this species. The BRT also noted there was genetic information for canary rockfish (Wishard *et al.,* 1980) and bocaccio (Matala *et al.,* 2004, Field *et al.,* 2009) in coastal waters, but no genetic data for either species from inland Puget Sound waters. The BRT found that in spite of these data limitations there was other evidence to conclude that each noted population of rockfish within inland waters of the Puget Sound/Georgia

Basin was discrete from its coastal counterpart.

Specifically, the BRT noted similar life histories of rockfish and based their determinations, in part, on the status review of brown rockfish, copper rockfish, and quillback rockfish (Stout *et al.,* 2001) and the genetic information for those species that supported separate DPSs for inland compared to coastal populations (Drake *et al.,* 2010). Thus, based on information related to rockfish life history, genetic variation among populations, and the environmental and ecological features of Puget Sound and the Georgia Basin, the BRT identified Puget Sound/Georgia Basin DPSs for yelloweye rockfish, canary rockfish, and bocaccio, and a Puget Sound proper DPS for greenstriped rockfish and redstripe rockfish (Drake *et al.,* 2010).

Informed by the BRT recommendations and our interpretation of best available scientific and commercial data, on April 28, 2010, we listed the Puget Sound/Georgia Basin DPSs of yelloweye rockfish and canary rockfish as threatened under the ESA, and the Puget Sound/Georgia Basin DPS of bocaccio as endangered (75 FR 22276). The final critical habitat rule for the listed DPSs of rockfishes was published in the **Federal Register** on November 1, 2014 (79 FR 68041). We determined that greenstriped rockfish (*S. elongatus*) and redstripe rockfish (*S. proriger*) within Puget Sound proper each qualified as a DPS, but these DPSs were not at risk of extinction throughout all or a significant portion of their ranges (Drake *et al.,* 2010).

In 2013, we appointed a recovery team and initiated recovery planning for the listed rockfish species. Through the process of recovery planning, priority research and recovery actions emerged. One such action was to seek specific genetic data for each of these rockfish species to better evaluate and determine whether differences exist in the genetic structure of the listed species' populations between inland basins where the DPSs occur and the outer coast. Analysis of the geographical distribution of genetic variation is a powerful method of identifying discrete populations (Drake *et al.,* 2010); thus, genetic analysis provides useful information to address the uncertainties associated with the limited information that informed our initial discreteness determinations for yelloweye rockfish, canary rockfish and bocaccio.

In 2014 and 2015, we partnered with the Washington Department of Fish and Wildlife (WDFW), several local fishing guides, and Puget Sound Anglers to collect samples between the different basins of the Puget Sound/Georgia Basin DPSs area and the outer coast. We collected biological samples for genetic analysis several ways. Over the course of 74 fishing trips, biological samples were gathered from listed rockfishes using hook-and-line recreational fishing methods in Puget Sound and the Strait of Juan de Fuca. Additional samples were gathered from archived sources from Fisheries and Oceans Canada, the NMFS Southwest Fisheries Science Center's Fisheries Resource Division, and the NMFS Northwest Fisheries Science Center's West Coast groundfish bottom trawl survey.

Samples collected from these sources were used to examine the population structure for each species. Population structure was examined using three methods: Principal components analysis (PCA), calculation of F_{ST} (fixation index—which is a measure of population differentiation) among geographic groups, and a population genetics based model clustering analysis (termed STRUCTURE) (NMFS 2016a).

In 2015, we announced a 5-year review (80 FR 6695; February 6, 2015) for the three rockfish DPSs. The 5-year review was completed on May 5, 2016 (NMFS 2016a), and is available at: *http://www.westcoast.fisheries.noaa.gov/publications/protected_species/other/rockfish/5.5.2016_5yr_review_report_rockfish.pdf.* To complete the review, we collected, evaluated, and incorporated all information on the species that has become available since April 2010, the date of the listing, including the 2014 final critical habitat designation and newly obtained samples and analysis of genetic information (Ford 2015, NMFS 2016a).

NMFS' Puget Sound/Georgia Basin rockfish BRT reviewed the results from the new genetic information. Their recommendations (Ford 2015) informed and were further evaluated during the five-year review (NMFS 2016a) which confirmed the DPS identity and listing status for yelloweye rockfish and bocaccio but concluded that the canary rockfish of the Puget Sound/Georgia Basin do not meet the criteria to be considered a DPS.

Policies for Delineating and Listing Species Under the ESA

Under the ESA, the term ''species'' means a species, a subspecies, or a DPS of a vertebrate species (16 U.S.C. 1532(16)). A joint NMFS–USFWS policy clarifies the Services' interpretation of the phrase ''Distinct Population Segment,'' or DPS (61 FR 4722; February 7, 1996). The DPS Policy requires the consideration of two elements when evaluating whether a vertebrate population segment qualifies as a DPS under the ESA: (1) Discreteness of the population segment in relation to the remainder of the species/taxon; and, if discrete, (2) the significance of the population segment to the species/taxon to which it belongs. Thus, under the DPS policy a population segment is considered a DPS if it is both discrete from other populations within its taxon and significant to its taxon.

A population may be considered discrete if it satisfies either one of the following conditions: (1) It is markedly separated from other populations of the same taxon as a consequence of physical, physiological, ecological, or behavioral factors; or (2) it is delimited by international governmental boundaries within which differences in control of exploitation, management of habitat, conservation status, or regulatory mechanisms exist that are significant in light of section 4(a)(1)(D) of the ESA (61 FR 4722; February 7, 1996). According to the policy, quantitative measures of genetic or morphological discontinuity can be used to provide evidence for item (1) above.

Consideration of the significance of a discrete population may include, but is not limited to the following conditions: (1) Persistence of the discrete segment in an ecological setting unusual or unique for the taxon; (2) evidence that loss of the discrete segment would result in a significant gap in the range of the taxon; (3) evidence that the discrete segment represents the only surviving natural occurrence of a taxon that may be more abundant elsewhere as an introduced population outside its historical range; or (4) evidence that the discrete segment differs markedly from other populations of the species in its genetic characteristics.

The ESA gives us clear authority to make listing determinations and to revise the Federal list of endangered and threatened species to reflect these determinations. Section 4(a)(1) of the ESA authorizes us to determine by regulation whether ''any species,'' which is defined to include species, subspecies, and DPSs, is an endangered species or a threatened species based on certain factors. Review of a species' status may be commenced at any time, either on the Services' own initiative—through a status review or in connection with a five-year review under Section 4(c)(2)—or in response to a petition. Because a DPS is not a scientifically recognized entity, but rather one created under the language of the ESA and effectuated through our DPS Policy (61 FR 4722; February 7, 1996), we have some discretion to determine whether populations of a species should be

identified as DPSs, and, based upon their range and propensity for movement, what boundaries should be recognized for a DPS. Section 4(c)(1) of the ESA gives us authority to update the Federal list of threatened and endangered species to reflect these determinations. This can include revising the list to remove a species or reclassify the listed entity.

Under sections 4(c)(1) and 4(a)(1) of the ESA the Secretary shall undertake a five-year review of a listed species and consider, among other things, whether a species' listing status should be continued. Pursuant to implementing regulations at 50 CFR 424.11(d), a species shall be removed from the list if the Secretary of Commerce determines, based on the best scientific and commercial data available after conducting a review of the species' status, that the species is no longer threatened or endangered because of one or a combination of the section 4(a)(1) factors. A species may be delisted only if such data substantiate that it is neither endangered nor threatened for one or more of the following reasons:

(1) Extinction. Unless all individuals of the listed species had been previously identified and located, and were later found to be extirpated from their previous range, a sufficient period of time must be allowed before delisting to indicate clearly that the species is extinct.

(2) Recovery. The principal goal of the Services is to return listed species to a point at which protection under the ESA is no longer required. A species may be delisted on the basis of recovery only if the best scientific and commercial data available indicate that it is no longer endangered or threatened.

(3) Original data for classification in error. Subsequent investigations may show that the best scientific or commercial data available when the species was listed, or the interpretation of such data, were in error (50 CFR 424.11(d)).

To make our final listing determinations, we reviewed all information provided during the 60-day public comment period on the proposed rule. Additionally we reviewed additional genetic analysis developed by the Northwest Fisheries Science Center (NWFSC) after the proposed rule (Andrews and Nichols 2016). This additional information supplemented, and supported, the information presented in the proposed rule. Where new information was received we have reviewed it and presented our evaluation in this final rule.

Proposed Rule

Informed by the BRT recommendations (Ford 2015), our interpretation of best available scientific and commercial data, and the conclusions of the five-year review, on July 6, 2016 we issued a proposed rule (81 FR 43979) to remove the Puget Sound/Georgia Basin canary rockfish (*Sebastes pinniger*) which included the following findings for each listed rockfish species.

Yelloweye Rockfish

Several different analytical methods indicated significant genetic differentiation between the inland and coastal samples of yelloweye rockfish at a level consistent with the limited genetic data for this species (Yamanaka *et al.,* 2006) that were available at the time of the 2010 status review. The BRT concluded that this new genetic information represents the best available scientific and commercial data and are consistent with and confirm the existence of an inland population of Puget Sound/Georgia Basin yelloweye rockfish that is discrete from coastal yelloweye rockfish (Ford 2015, NMFS 2016a). In addition, this genetic information demonstrates that yelloweye rockfish from Hood Canal are genetically differentiated from other Puget Sound/Georgia Basin fish, indicating a previously unknown degree of population differentiation within the DPS (Ford 2015, NMFS 2016a).

The BRT also found that new genetic information from Canada demonstrates that yelloweye rockfish occurring in the northern Johnstone Strait and Queen Charlotte Channel clustered genetically with yelloweye rockfish occurring in the northern Strait of Georgia, the San Juan Islands, and Puget Sound (Ford 2015). This is consistent with additional genetic analysis identifying a population of yelloweye rockfish inside the waters of eastern Vancouver Island (Yamanaka et. al. 2006, COSEWIC 2008, Yamanaka *et al.,* 2012, Siegle *et al.,* 2013). Based on this information and the five-year review, we proposed to correct the previous description of the northern boundary of the threatened Puget Sound/Georgia Basin yelloweye rockfish (*S. ruberrimus*) DPS to include this area. We also proposed to update and amend the description of the DPS as fish residing within certain boundaries (including this geographic area farther north in the Strait of Georgia waters in Canada). We proposed this change because this description better aligns with yelloweye rockfish life-history and their sedentary behavior as adults, rather than the current description of fish originating from the Puget Sound/Georgia Basin.

In the five-year review, our analysis of the ESA section 4(a)(1) factors found that the collective risk to the persistence of the Puget Sound/Georgia Basin DPS of yelloweye rockfish has not changed significantly since our final listing determination in 2010 (75 FR 22276; April 28, 2010), and they remain listed as threatened (NMFS 2016a).

Canary Rockfish

The same analytical methods (described in Ford 2015, NMFS 2016a and Andrews and Nichols 2016) as used for yelloweye rockfish were used to analyze population structure in canary rockfish. These analyses indicate a lack of genetic differentiation of canary rockfish between coastal and inland Puget Sound/Georgia Basin samples. F_{ST} values, a metric of population differentiation, among groups were not significantly different from zero among geographic regions, and STRUCTURE analysis did not provide evidence supporting population structure in the data. None of these analyses provided any evidence of genetic differentiation between canary rockfish along the coast from the canary rockfish within the boundaries of the Puget Sound/Georgia Basin DPS (Ford 2015, NMFS 2016a, Andrews and Nichols 2016).

The BRT noted that the very large number of loci provided considerable power to detect differentiation among sample groups and concluded that the lack of such differentiation indicated that it is unlikely the inland Puget Sound/Georgia Basin samples are discrete from coastal areas (Ford 2015). In the context of this newly obtained genetic information, the BRT considered whether other factors that supported the original discreteness determination, such as oceanography and ecological differences among locations, continue to support a finding of discreteness for this population (Ford 2015). In considering this newly obtained genetic data in the context of the other evidence, the BRT found that their original interpretation of the scientific data informing discreteness is no longer supported (Ford 2015). Rather, they concluded that the lack of genetic differentiation indicates sufficient dispersal to render a discreteness determination based on environmental factors implausible. The BRT found that current genetic data evaluated and interpreted in the context of all available scientific information now provides strong evidence that canary rockfish of the Puget Sound/Georgia Basin are not discrete from coastal area canary rockfish. Based on the BRT findings, the five-year review,

and best available science and commercial information, and in accordance with the DPS policy, we determined that the canary rockfish of the Puget Sound/Georgia Basin did not meet the criteria to be considered a DPS. Rather, the new genetic data reveal that canary rockfish of the Puget Sound/Georgia Basin are part of the larger population occupying the Pacific coast (Ford 2015, NMFS 2016a, Andrews and Nichols 2016).

Canary rockfish of the Pacific coast was declared overfished in 2000 and a rebuilding plan under the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) was put in place in 2001. NMFS determined the stock to be ''rebuilt'' in 2015 (Thorson and Wetzel 2015, NMFS 2016b).

Based on the discussion above and the recommendation of the five-year review, we proposed to remove Puget Sound/Georgia Basin canary rockfish from the Federal List of Threatened and Endangered Species because the new genetic data evaluated and interpreted in the context of all best available science indicate they are not a discrete population (81 FR 43979; July 6, 2016). Under section 4(c)(1) of the ESA and the implementing regulations at 50 CFR 424.11(d)(3), we may delist canary rockfish if, among other things, subsequent investigation demonstrates that our interpretation of best scientific or commercial information was in error. After considering this newly obtained genetic data in the context of the other evidence supporting discreteness, we determined that our original interpretation of discreteness for Puget Sound/Georgia Basin canary rockfish is no longer supported and was in error. Based on this reasoning, there is no need for a post-delisting monitoring plan.

Bocaccio

Bocaccio were also evaluated by the BRT (Ford 2015) and during the five-year review (NMFS 2016a). Bocaccio are particularly rare within the DPS area and thus the NWFSC was only able to obtain three samples from within the DPS area for the genetic analysis. The BRT determined that this is not sufficient information to support a change to our prior status review and listing determination that Puget Sound/Georgia Basin bocaccio are discrete from coastal fish (Ford 2015).

The BRT noted that bocaccio have a propensity for greater adult movement than more benthic rockfish species, similar to the case for canary rockfish. The BRT considered that the lack of genetic differentiation between coastal and Puget Sound/Georgia Basin canary rockfish might suggest a similar lack of genetic differentiation for bocaccio because of similarities in the life history of the two species. Nevertheless, the BRT concluded that the new information was not sufficient to change the conclusions of the previous BRT documented in Drake *et al.,* (2010) or suggest a change in listing status (Ford 2015). This is consistent with the five-year review recommendation (NMFS 2016a) and is based upon best available scientific data and commercial information.

However, similarly to yelloweye rockfish, we proposed to update and amend the listing description of the bocaccio DPS to describe boundaries to include fish residing within the Puget Sound/Georgia Basin rather than fish originating from the Puget Sound/Georgia Basin.

In the five-year review, our analysis of the ESA section 4(a)(1) factors found that the collective risk to the persistence of the Puget Sound/Georgia Basin DPS of bocaccio has not changed significantly since our final listing determination in 2010 (75 FR 22276; April 28, 2010), and they remain listed as endangered (NMFS 2016a).

Peer Review and Public Comment

The scientific information considered by the BRT and summarized in our five-year review (NMFS 2016a) was peer reviewed and the proposed rule was subject to public comment. Following those reviews, there are no changes to the actions as proposed.

Summary of Comments

On July 6, 2016, we solicited comments during a 60-day public comment period from all interested parties including the public, other concerned governments and agencies, the scientific community, industry, and other interested parties on the proposed rule (81 FR 43979).

We received four public comments, and three peer reviews on the proposed rule. Summaries of the substantive comments received, and our responses, are provided below and organized by topic.

Comments on Sampling and Genetic Analysis

Two of the three peer reviewers had questions and observations about the genetic analyses for both canary rockfish and yelloweye rockfish provided in the five-year review. NOAA's Northwest Fisheries Science Center (NWFSC) reviewed the genetic and sampling questions and provided responses within a memorandum (Andrews and Nichols 2016). This memorandum also reported on additional genetic analysis of samples collected in 2014 and 2015 that had not yet been analyzed and available in the five-year review (NMFS 2016a) or by the BRT (2015).

The results of the updated genetic analysis are consistent with and did not change the outcome of the genetic assessment presented to the Biological Review Team in November 2015 (Ford 2015) and in the five-year review (NMFS 2016a) that informed the proposed rule. The information from the new analysis (Andrews and Nichols 2016) is included in the responses below.

Comment 1: Two of the three scientific peer reviewers and two commenters agreed that canary rockfish sampled from the Puget Sound/Georgia Basin are not genetically differentiated from canary rockfish sampled outside of this area.

Response: We agree.

Comment 2: One peer reviewer did not agree that there was sufficient evidence to support our finding that canary rockfish are not genetically differentiated.

Response: We disagree with the peer reviewer based on the analysis provided in the five-year review (NMFS 2016a) and BRT report (Ford 2015) in addition to the supplemental analysis provided by Andrews and Nichols (2016) and elaborated in this final rule. The best available information provides strong evidence that canary rockfish sampled in the Puget Sound/Georgia Basin are not genetically differentiated from coastal canary rockfish.

Comment 3: Regarding the yelloweye rockfish and canary rockfish genetic analysis, one reviewer suggested that analytical methods conducted by the NWFSC (such as FST and STRUCTURE) should be described in our final rule.

Response: We agree. While additional information on these analyses was included in documents supporting the proposed rule (81 FR 43979; July 6, 2016), we include clarifying information in this final rule as well (and as detailed in Andrews and Nichols 2016). The NWFSC conducted Principal Component Analysis (PCA), STRUCTURE, and F_{ST} analyses for yelloweye rockfish and canary rockfish, which are detailed in Andrews and Nichols (2016). These analyses for yelloweye rockfish support our findings that fish collected in the Puget Sound/Georgia Basin DPS are discrete from yelloweye rockfish collected on the outer coast. Similar analyses for canary rockfish support our findings that there is no discrete Puget Sound/Georgia

Basin population (Andrews and Nichols 2016).

Comment 4: One peer reviewer questioned the relatively low proportion of overall variation explained by PCA one and PCA two described in our five-year review and the proposed rule.

Response: For yelloweye rockfish, the NWFSC used over 5,000 Restriction Site Associated DNA Sequencing loci in the analyses presented in the five-year review and over 7,000 loci in its final dataset (Andrews and Nichols 2016). There is a large amount of variation possible among this many loci leading to a relatively low proportion of the variance explained by the first two principal component scores.

Comment 5: One reviewer questioned how the number of samples collected and analyzed by the NWFSC affects the estimate of statistical power and the ability to detect genetic differentiation for yelloweye rockfish and canary rockfish.

Response: The NWFS did not conduct power analyses. Andrews and Nichols (2016) state that ''. . . the magnitude of the FST confidence intervals, and the upper bound of those confidence intervals provide compelling evidence that differentiation among the sampled regions for canary rockfish is not significantly different from zero, and in many cases orders of magnitude lower than that observed for yelloweye rockfish.'' This analysis bolsters the conclusion that canary rockfish are not genetically differentiated between the Puget Sound and the outer coast.

Comment 6: One peer reviewer suggested that we provide details about the PCA scores, and which loci loaded most prominently onto those principal components.

Response: The three analyses conducted by the NWFSC used this information to inform the integrative comparisons among individuals (PCA), population assignments (STRUCTURE) and statistical comparisons of F_{ST} values as documented in the five-year review and updated in Andrews and Nichols (2016). These integrative comparisons further support the evidence of genetic differentiation for yelloweye rockfish, and the lack thereof for canary rockfish.

Comment 7: One peer reviewer stated that our proposal to delist canary rockfish should have taken into account environmental and/or life history characteristics that would ''produce'' a seemingly genetically homogeneous population, and questioned whether it is logical that yelloweye constitute a DPS but canary do not.

Response: Our proposal to delist canary rockfish (81 FR 43979; July 6, 2016), in addition to the five-year review (NMFS 2016a), did discuss the known life-history characteristics of canary rockfish and yelloweye rockfish. Yelloweye rockfish have been found to have limited movements as adults (Hannah and Rankin 2011), while canary rockfish are known to move over large distances at both short and long time scales (DeMott 1983, Lea *et al.,* 1999, Love *et al.,* 2002, Hannah and Rankin 2011). This life-history characteristic suggests that there is limited probability of adult yelloweye from Puget Sound/Georgia Basin reproducing with adults from the outer coast, and therefore providing the necessary conditions for genetic differentiation to develop over time. The relatively quick and long-range movements of some adult canary rockfish suggest the high potential for breeding among individuals throughout their range and thus leading to a panmictic population (Andrews and Nichols 2016).

A second relevant life-history trait supporting discreteness and identification of yelloweye rockfish as a DPS, in contrast to canary rockfish, is the timing of larval release. In waters off British Columbia, yelloweye rockfish release larvae from April to September with peaks in May and June. This timing of larval release could significantly affect the dispersal and/or retention of larval rockfish depending on the prevailing oceanographic currents and freshwater flows into and out of the Puget Sound/Georgia Basin (Andrews and Nichols 2016). Canary rockfish experience peak release of larvae from February to March (Love et. al. 2002) and thus this different release period may influence dispersal of larvae because of different oceanic and current conditions.

Comment 8: A peer reviewer asked if there was any information regarding where canary rockfish reproduction takes place, whether canary rockfish spawn in aggregates, and if they have philopatric tendencies (a behavior where individuals return to their birthplace to breed).

Response: We are not aware of information regarding where canary rockfish spawn on the Pacific coast or Puget Sound, but note that in locations where they are observed as gravid, it is logical that they release larvae nearby. Similarly, we are not aware of information regarding if canary rockfish mate or release larvae in aggregates.

Comment 9: One peer reviewer asked if our proposal to delist canary rockfish accounted for the possibility that they were historically depleted in local waters, as documented in the 2010 Status Review (Drake *et al.,* 2010), and replaced by the immigration of canary rockfish from the Pacific coast.

Response: We do not have samples of canary rockfish from within the Puget Sound/Georgia Basin prior to their listing in 2010—thus it is not possible to test the scenario hypothesized by the reviewer genetically. However, it is unlikely that the process of recruitment or immigration of individual canary rockfish to/from the Puget Sound/Georgia Basin would have changed as theorized by the peer reviewer (Andrews and Nichols 2016). If recruitment or immigration of canary rockfish from the outer coast to the Puget Sound/Georgia Basin occurs today, which the genetic analysis suggests (see Figs. 2b, 4c and 6 and Table 2 in Andrews and Nichols 2016), it was very likely happening historically. The historical overfishing of canary rockfish in Puget Sound/Georgia Basin would not have altered the process of adults or larval dispersal of canary rockfish from the Pacific Coast into Puget Sound. If larval/juvenile canary rockfish dispersal among the two regions occurred historically, it is unlikely that canary rockfish in Puget Sound/Georgia Basin would have been genetically differentiated and yet the sampling would have missed these fish (Andrews and Nichols 2016).

Comment 10: One peer reviewer asked how much genetic exchange is going on between the outer coast and the Puget Sound, and speculated that if canary rockfish are extirpated from the Puget Sound/Georgia Basin, that the population may not rebuild if there is limited movement of fish from the Pacific coast.

Response: The genetic analysis indicates that genetic exchange of canary rockfish in the Pacific coast and the Puget Sound/Georgia Basin occurs frequently enough to develop one population across these areas (Andrews and Nichols 2016). For these reasons, it is unlikely that a hypothesized extirpation of canary rockfish within the Puget Sound/Georgia Basin would occur so long as there are canary rockfish outside of the Puget Sound/Georgia Basin that move amongst these areas.

Comment 11: One peer reviewer disagreed that genetic information for canary rockfish, as detailed in the five-year review (NMFS 2016a) and BRT memo (Ford 2015), indicate ''strong'' evidence that fish sampled from the Puget Sound/Georgia Basin are not discrete from coastal fish. The reviewer questioned this characterization because of sample size, sample integrity, and sample representativeness of canary rockfish collected in this research. In addition, the reviewer questioned the

reliance on principal coordinate cluster plots to portray genetic similarity because of the potential for misinterpretation of the results. The reviewer questioned why STRUCTURE plots and analysis of molecular variance results were not provided in the five-year review and asked what the average magnitude of F_{ST} values for canary rockfish were compared to yelloweye rockfish.

Response: The STRUCTURE and F_{ST} information was included in supporting documents, and we agree that additional information would be useful to further explain the genetic data. Updated genetic analysis (based on an analysis of additional samples) and additional explanatory text are now documented in Andrews and Nichols (2016). The BRT considered not only the PCA, but also results from STRUCTURE and tests for pairwise population differentiation based on F_{ST} (Andrews and Nichols 2016). Those analyses were conducted on the number of samples outlined in the status review published in May 2016, but have since also been extended to additional samples with the same conclusions (see Andrews and Nichols 2016). All of these analyses show clear evidence for population structure in yelloweye rockfish, but not in the canary rockfish samples.

Comment 12: One peer reviewer stated that a primary reason the yelloweye rockfish genetic analysis shows significant differentiation relative to canary rockfish is because we were able to collect samples of yelloweye rockfish samples in Canada and Hood Canal, in addition to the Central Puget Sound and from the Georgia Basin. The reviewer noted that the NWFSC was not able to collect canary rockfish samples from Canada (the Georgia Basin) and Hood Canal, and asked what the genetic analysis may have shown if samples could have been collected from these areas.

Response: We were unable to collect canary rockfish samples in Hood Canal. We also searched for existing canary rockfish samples by contacting the Department of Fisheries and Oceans Canada, but were not able to find any from Canadian waters. Based on the lack of genetic differentiation between more geographically disparate locations such as the Central Puget Sound (where the NWFSC was able to collect samples) and the outer Pacific Coast, we would not expect genetic differentiation of canary rockfish if samples from Canadian coastal or inland waters were included (Andrews and Nichols 2016).

As previously noted, canary rockfish have been documented to travel long distances, thus we would also not expect canary rockfish collected in Hood Canal to be genetically different even though there is a large sill at the entrance of Hood Canal (Drake *et al.,* 2010) that may restrict dispersal due to restricted water movement into and out of this water body (Andrews and Nichols 2016). As suggested by this reviewer, the NWFSC examined the results from the PCA analysis for yelloweye rockfish as if we did not have the samples from Hood Canal and Canada (Fig. 7 in Andrews and Nichols 2016) and this analysis gives the same conclusion—that Puget Sound is significantly differentiated from the coastal collections in yelloweye rockfish.

This conclusion is also supported by other genetic analyses, including pairwise differentiation of collections from these more limited regions. Therefore it is likely that if there were significant genetic differentiation for canary rockfish, the NWFSC would have detected it from the samples in Puget Sound and the Pacific coast as for yelloweye rockfish sampled in these regions.

Comment 13: One peer reviewer stated that the absence of observed structure in the canary rockfish sample does not necessarily equate to the absence of structure in the population and questioned whether or not the sampled fish are actually representative of the population.

Response: There are two reasons we believe the sampled canary rockfish are representative of the population. First, the sampling design consisted of 74 days of fishing across four regions of the DPS (South Puget Sound, Central Puget Sound, Hood Canal and the San Juan Islands) and one region outside the DPS (Strait of Juan de Fuca including locations near Neah Bay and Sekiu, WA). The sampling locations within these regions were derived from the knowledge of recreational charter boat captains, recent and past Remotely Operated Vehicle (ROV) surveys, and historical recreational catch information to target habitats where canary rockfish had been observed. This information and the number of sampling days provided ample effort to target canary rockfish in each of these regions, and we indeed collected canary rockfish from three of these five regions, including 50 from within the DPS (47 of these samples had sufficient readings during sequencing to be used in subsequent analyses) (Andrews and Nichols 2016). Second, the genetic sequencing methods used by the NWFSC allowed for detailed examination of the genome of each individual fish—increasing the power of these analyses to detect differences between individuals and differences among regions as compared to traditional analyses (Andrews and Nichols 2016).

Comment 14: One peer reviewer suggested we collect larval canary rockfish for additional genetic analysis.

Response: Given the strength of the genetic analysis we do not believe that additional samples from larval rockfish (or any other life-stage of canary rockfish) are needed to clarify the lack of structure of canary rockfish sampled within the Puget Sound/Georgia Basin and the Pacific coast. The samples collected from canary rockfish provide ample sample size to support the overall conclusion regarding the lack of genetic differentiation discussed in the five-year review and the proposal to delist canary rockfish (81 FR 43979; July 6, 2016), Ford (2015) and Andrews and Nichols (2016).

Comment 15: One peer reviewer questioned whether our genetic analysis and proposal to delist canary rockfish was potentially influenced by potential misidentification of canary rockfish and yelloweye rockfish, including misidentification by scuba-divers. The reviewer was concerned that canary rockfish used in the genetics samples may have actually been yelloweye rockfish, (and vice versa).

Response: All fish sampled in the genetic study were collected by professional fishing charter guides, biologists with NOAA Fisheries and the Washington State Department of Fish and Wildlife, thus we are confident that all canary rockfish and yelloweye rockfish sampled were identified to species correctly. The peer reviewer is correct, however, that yelloweye rockfish and canary rockfish look similar and the identification of rockfish to species can be difficult (Sawchuk *et al.,* 2015). If such an incorrect species labeling were to occur within the genetic analysis, the analysis itself would have indicated this.

Comments on Species Status and Protections

Comment 16: Two peer reviewers observed that available information indicates that the number of canary rockfish individuals in the Puget Sound/Georgia Basin is relatively small. One reviewer acknowledged that canary rockfish in the Puget Sound/Georgia Basin do not appear to be a DPS, but expressed concern that fish in this area may nonetheless become extirpated. Another reviewer stated our decision to propose delisting should have been more precautionary because of the ''. . . dearth of information for canary rockfish and scarcity of available data''

regarding their abundance. Similarly, in the five-year review we noted that six canary rockfish were observed during recent ROV surveys, and one peer reviewer asked in how many years of surveys these six fish were observed.

Response: We agree that there is little data regarding canary rockfish abundance in the Puget Sound/Georgia Basin, as described in our five-year review, and that it appears that canary rockfish in this area declined significantly in the latter half of the 20th century (as described in Drake *et al.,* 2010). However, the determination to delist canary rockfish is based not on abundance information, but rather on determining if canary rockfish in the Puget Sound/Georgia Basin meet the criteria of a DPS (61 FR 4722; February 7, 1996), which allows them to be listed under the ESA.

Though we are not required to implement a post-delisting monitoring plan for canary rockfish, there are research projects underway that will help us understand the numbers and distribution of rockfish in the Puget Sound, including canary rockfish. We have contracted with the Washington State Department of Wildlife to conduct an ROV survey within the Puget Sound. This two-year survey will be completed in early 2017 and data analysis and report writing will likely take a year or two after the completion date. This research will eventually provide additional data about rockfish abundance and distribution. In our five-year review we reported that this ROV survey had documented six canary rockfish; most of these fish were documented in the first year of the survey (2015) because the data from the second year of the survey is not yet fully available. In addition to the ROV survey, we have begun to seek information on where recreational divers observe juvenile yelloweye rockfish, canary rockfish and bocaccio. Similarly, the NWFSC is developing a young-of-the-year rockfish monitoring plan for the Puget Sound. As this monitoring plan is implemented we will gather additional information regarding the abundance and recruitment of rockfish, including canary rockfish.

Comment 17: One peer reviewer stated that the declaration of the canary rockfish stock as ''rebuilt'' under the Magnuson-Stevens Act, as documented in Thorson and Wetzel (2015) and NMFS (2016b), was a ''major consideration for the recommendation to delist'' the Puget Sound/Georgia Basin DPS.

Response: The reviewer is incorrect. Our removal of canary rockfish of the Puget Sound/Georgia Basin from the Federal List of Threatened and Endangered Species is based on the best available science and commercial information. In accordance with the DPS Policy (61 FR 4722; February 7, 1996), we have determined that the canary rockfish of the Puget Sound/Georgia Basin do not meet the criteria to be considered a DPS based on genetic information documented in the five-year review (NMFS 2016a), Ford (2015) and Andrews and Nichols (2016).

Comment 18: One peer reviewer stated that information in the five-year review indicated that canary rockfish are rare in Puget Sound, and questioned how they could be declared ''rebuilt'' under the authority of the Magnuson-Stevens Act.

Response: The peer reviewers were not tasked with evaluating the previous agency decision to declare canary rockfish of the Pacific coast as ''rebuilt'' subject to the criteria defined in the Magnuson-Stevens Act. Federal canary rockfish stock assessments performed pursuant to the Magnuson-Stevens Act do not include data regarding canary rockfish in Puget Sound waters within the Puget Sound/Georgia Basin. Rather the 2015 canary rockfish stock assessment under the Magnuson-Stevens Act was conducted with data collected along the Pacific coast (outside of the Puget Sound/Georgia Basin).

Comment 19: One peer reviewer asked how canary rockfish in the Puget Sound/Georgia Basin are going to be protected if they are removed from the ESA.

Response: Since the listing of yelloweye rockfish, canary rockfish and bocaccio in 2010, WDFW has changed fisheries regulations for several non-tribal commercial fisheries in Puget Sound in order to protect rockfish populations. The WDFW closed the active set net, set line, and bottom trawl fisheries, and the inactive pelagic trawl and bottomfish pot fishery. As a precautionary measure, WDFW closed the above commercial fisheries westward of the ESA-listed rockfish DPSs' boundary to Cape Flattery. WDFW extended the closure west of the rockfish DPSs' boundary to prevent applicable commercial fishers from concentrating gear in that area. The WDFW also implemented a rule that recreational anglers targeting bottomfish not fish deeper than 120 feet. These fisheries regulations are unlikely to change, and will benefit canary rockfish and nearly all rockfish species within the Puget Sound.

On August 16, 2016, we released a Draft Recovery Plan for yelloweye rockfish and bocaccio (listed rockfish) of the Puget Sound/Georgia Basin (81 FR 54556). The Draft Recovery Plan identifies approximately 45 research and recovery actions for listed rockfish, and though these actions are not specifically designed for canary rockfish, they would nonetheless benefit from Plan implementation because of the similarity of habitats occupied for each species.

We expect the Plan to inform section 7 consultations with Federal agencies under the ESA and to support other ESA decisions, such as considering permits under section 10. Mitigation incorporated into section 7 and section 10 actions to reduce impacts on listed rockfish will also likely reduce impacts to canary and other rockfish species. We have already begun implementation of several actions as described in the Plan, such as partnering with the WDFW to conduct ROV surveys to assess listed rockfish abundance, distribution, and habitat use.

After the adoption of the Final Recovery Plan, we will continue to implement actions for which we have authority, work cooperatively on implementation of other actions, and encourage other Federal and state agencies to implement recovery actions for which they have responsibility and authority. Collectively, the management of fisheries, section 7 and 10 actions, and implementation of the listed-rockfish Recovery Plan will also benefit many species of non-listed rockfish of the Puget Sound/Georgia Basin, including canary rockfish.

Summary of Changes From the Proposed Listing Rule

We reviewed the best available scientific and commercial information, including the information in the peer reviews of the proposed rule (81 FR 43979; July 6, 2016), public comments, and information and analysis (Andrews and Nichols 2016) that have become available since the publication of the proposed rule. Based on this information, we have made no changes in this final rule.

Final DPS and Status Determinations

As proposed on July 6, 2016 (81 FR 43979), in this final rule we: (1) Correct the previous description of the northern boundary of the threatened Puget Sound/Georgia Basin yelloweye rockfish DPS to include an area farther north of the Johnstone Strait in Canada. We also update and amend the description of the DPS as fish residing within certain boundaries (including this geographic area farther north in the Strait of Georgia waters in Canada); (2) we remove Puget Sound/Georgia Basin canary rockfish DPS from the Federal List of Threatened

and Endangered Species and their critical habitat, and (3) similar to yelloweye rockfish, we update and amend the listing description of the bocaccio DPS to describe boundaries to include fish residing within the Puget Sound/Georgia Basin rather than fish originating from the Puget Sound/Georgia Basin.

Effects of the New Determinations

Based on the new information and the BRT's determination, and consideration of public and peer review comments, we are removing canary rockfish of the Puget Sound/Georgia Basin from the Federal List of Threatened and Endangered Species. The Puget Sound/Georgia Basin yelloweye rockfish DPS shall remain threatened under the ESA, and the Puget Sound/Georgia Basin bocaccio DPS shall remain endangered.

We are also removing designated critical habitat for canary rockfish. The critical habitat designation for the Puget Sound/Georgia Basin yelloweye rockfish and bocaccio DPSs remain in place. The area removed as designated critical habitat for canary rockfish will continue to be designated critical habitat for bocaccio and, thus, there will be no change to the spatial area that was originally designated. Maps of critical habitat can be found on our Web site at *http://www.westcoast.fisheries.noaa.gov* and in the final critical habitat rule (79 FR 68041; November 13, 2014).

Additionally, we correct the listing description of the yelloweye rockfish DPS to define geographical boundaries including an area farther north of the Johnstone Strait in Canada (Figure 1). This boundary would not have an effect on critical habitat, because we do not designate critical habitat outside U.S. territory.

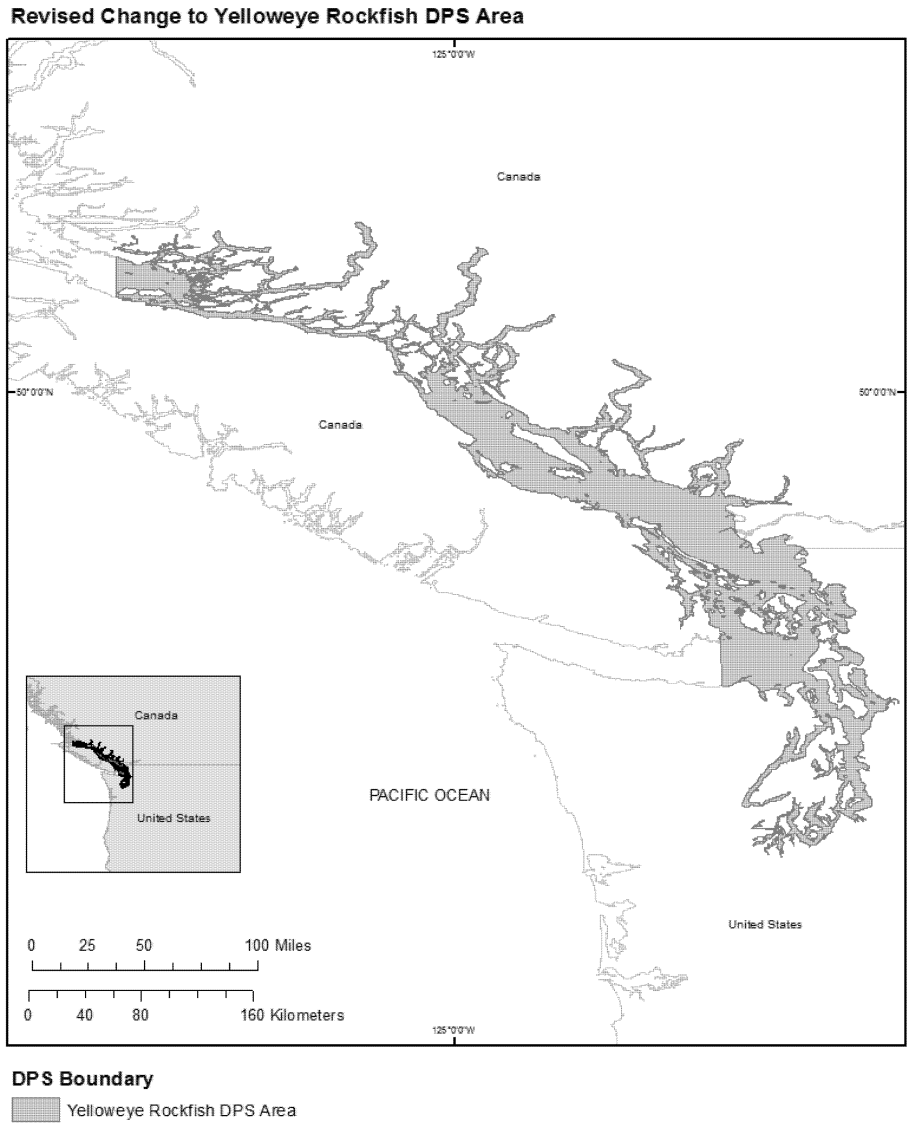

FIGURE 1. Updated Yelloweye Rockfish DPS Area, which extends farther north into Canada.

With the Puget Sound/Georgia Basin canary rockfish DPS delisting, the requirements under section 7 of the ESA no longer apply. Federal agencies are relieved of the need to consult with us on their actions that may affect Puget Sound/Georgia Basin canary rockfish and their designated critical habitat and to insure that any action they authorize,

fund, or carry out is not likely to jeopardize the continued existence of canary rockfish or adversely modify their critical habitat. ESA section 7 consultation requirements remain in place for the Puget Sound/Georgia Basin yelloweye rockfish and bocaccio DPSs. Recovery planning efforts will continue for these listed DPSs and a Draft Recovery Plan was released on August 16, 2016 (81 FR 54556).

References Cited

The complete citations for the references used in this document can be obtained by contacting NMFS (See **ADDRESSES** and **FOR FURTHER INFORMATION CONTACT**) or on our Web page at: *http://www.westcoast.fisheries.noaa.gov.*

Information Quality Act and Peer Review

In December 2004, OMB issued a Final Information Quality Bulletin for Peer Review pursuant to the Information Quality Act. The Bulletin was published in the **Federal Register** on January 14, 2005 (70 FR 2664). The Bulletin established minimum peer review standards, a transparent process for public disclosure of peer review planning, and opportunities for public participation with regard to certain types of information disseminated by the Federal Government. Peer review under the OMB Peer Review Bulletin ensures that our listing determinations are based on the best available scientific and commercial information. To satisfy our requirements under the OMB Bulletin, we obtained independent peer review of the proposed rule and underlying scientific information by three independent scientists with expertise in rockfish biology and/or genetics. All peer review comments were addressed in this final rule (see the Summary of Comments heading in this preamble).

Classification

National Environmental Policy Act (NEPA)

The 1982 amendments to the ESA, in section 4(b)(1)(A), restrict the information that may be considered when assessing species for listing. Based on this limitation of criteria for a listing decision and the opinion in *Pacific Legal Foundation* v. *Andrus,* 657 F. 2d 829 (6th Cir. 1981), we have concluded that NEPA does not apply to ESA listing actions. (See NOAA Administrative Order 216–6.).

Executive Order 12866, Regulatory Flexibility Act, and Paperwork Reduction Act

As noted in the Conference Report on the 1982 amendments to the ESA, economic impacts cannot be considered when assessing the status of a species. Therefore, the economic analysis requirements of the Regulatory Flexibility Act are not applicable to the listing process. In addition, this final rule is exempt from review under Executive Order 12866. This final rule does not contain a collection of information requirement for the purposes of the Paperwork Reduction Act.

Executive Order 13122, Federalism

In accordance with E.O. 13132, we determined that this final rule does not have significant federalism effects and that a federalism assessment is not required. In keeping with the intent of the Administration and Congress to provide continuing and meaningful dialogue on issues of mutual state and Federal interest, this final rule will be shared with the relevant state agencies in Washington state.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

The longstanding and distinctive relationship between the Federal and tribal governments is defined by treaties, statutes, executive orders, judicial decisions, and co-management agreements, which differentiate tribal governments from the other entities that deal with, or are affected by, the Federal government. This relationship has given rise to a special Federal trust responsibility involving the legal responsibilities and obligations of the United States toward Indian Tribes. E.O. 13175—Consultation and Coordination with Indian Tribal Governments—outlines the responsibilities of the Federal Government in matters affecting tribal interests.

We have coordinated with tribal governments that may be affected by the action.

List of Subjects

50 CFR Part 223

Endangered and threatened species, Exports, Imports, Transportation.

50 CFR Part 224

Endangered and threatened species.

50 CFR Part 226

Designated Critical Habitat.

Dated: January 9, 2017.

Samuel D Rauch, III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR parts 223. 224, and 226 are amended as follows:

PART 223—THREATENED MARINE AND ANADROMOUS SPECIES

■ 1. The authority citation for part 223 continues to read as follows:

Authority: 16 U.S.C. 1531–1543; subpart B, § 223.201–202 also issued under 16 U.S.C. 1361 *et seq.;* 16 U.S.C. 5503(d) for § 223.206(d)(9).

■ 2. In § 223.102, in the table in paragraph (e), under the subheading ''Fishes,'' remove the entry for ''Rockfish, canary (Puget Sound/Georgia Basin DPS)''; and revise the table entries for ''Rockfish, yelloweye (Puget Sound/Georgia Basin DPS).''

The revision reads as follows:

§ 223.102 Enumeration of threatened marine and anadromous species.

* * * * *

(e) * * *

Species [1]			Citation(s) for listing determination(s)	Critical habitat	ESA rules
Common name	Scientific name	Description of listed entity			
Fishes					
*	*	* *	*	*	*
Rockfish, yelloweye (Puget Sound/ Georgia Basin DPS).	*Sebastes ruberrimus*.	Yelloweye rockfish residing within the Puget Sound/Georgia Basin, inclusive of the Queen Charlotte Channel to Malcom Island, in a straight line between the western shores of Numas and Malcom Islands—N 50 50′46″, W 127 5′55″ and N 50 36′49″, W 127 10′17″. The Western Boundary of the U.S. side in the Strait of Juan de Fuca is N 48 7′16″, W123 17′15″ in a straight line to the Canadian side at N 48 24′40″, 123 17′38″.	75 FR 22276, Apr 28, 2010.	226.224	NA
*	*	* *	*	*	*

[1] Species includes taxonomic species, subspecies, distinct population segments (DPSs) (for a policy statement, see 61 FR 4722, February, 1996), and evolutionarily significant units (ESUs) (for a policy statement, see 56 FR 58612, November 20, 1991).

PART 224—ENDANGERED MARINE AND ANADROMOUS SPECIES.

■ 3. The authority citation for part 224 continues to read as follows:

Authority: 16 U.S.C. 1531–1543 and 16 U.S.C. 1361 *et seq.*

■ 4. In § 224.101, paragraph (h), under the subheading ''Fishes,'' revise the table entry for ''Bocaccio (Puget Sound/ Georgia Basin DPS)'' to read as follows:

§ 224.101 Enumeration of endangered marine and anadromous species.

* * * * *

(h) * * *

Species [1]			Citation(s) for listing determination(s)	Critical habitat	ESA rules
Common name	Scientific name	Description of listed entity			
Fishes					
*	*	* *	*	*	*
Bocaccio (Puget Sound/Georgia Basin DPS).	*Sebastes paucispinis*.	Bocaccio residing within the Puget Sound/Georgia Basin to the Northern Boundary of the Northern Strait of Georgia along the southern contours of Quadra Island, Maurelle Island and Sonora Island, all of Bute Inlet. The Western Boundary of the U.S. side in the Strait of Juan de Fuca is N 48 7′16″, W123 17′15″ in a straight line to the Canadian side at N 48 24′40″, 123 17′38″.	75 FR 22276, Apr 28, 2010.	226.224	NA
*	*	* *	*	*	*

[1] Species includes taxonomic species, subspecies, distinct population segments (DPSs) (for a policy statement, see 61 FR 4722, February, 1996), and evolutionarily significant units (ESUs) (for a policy statement, see 56 FR 58612, November 20, 1991).

PART 226—DESIGNATED CRITICAL HABITAT

■ 5. The authority citation for Part 226 continues to read as follows:

Authority: 16 U.S.C. 1533.

■ 6. In § 226.224:

■ a. Revise the section heading;

■ b. Remove the entry for canary rockfish in the table in paragraph (a); and

■ c. Revise paragraphs (b), (c), and (d).

The revisions read as follows:

§ 226.224 Critical habitat for the Puget Sound/Georgia Basin DPS of yelloweye rockfish (*Sebastes ruberrimus*), and Bocaccio (*S. paucispinus*).

* * * * *

(b) *Critical habitat boundaries.* In delineating nearshore (shallower than 30 m (98 ft)) areas in Puget Sound, we define critical habitat for bocaccio, as depicted in the maps below, as occurring from the shoreline from extreme high water out to a depth no greater than 30 m (98 ft) relative to mean lower low water. Deepwater critical habitat for yelloweye rockfish and bocaccio occurs in some areas, as depicted in the maps below, from depths greater than 30 m (98 ft). The critical habitat designation includes the marine waters above (the entire water column) the nearshore and deepwater areas depicted in the maps in this section.

(c) *Essential features for juvenile bocaccio.* (1) Juvenile settlement habitats located in the nearshore with substrates such as sand, rock and/or

cobble compositions that also support kelp are essential for conservation because these features enable forage opportunities and refuge from predators and enable behavioral and physiological changes needed for juveniles to occupy deeper adult habitats. Several attributes of these sites determine the quality of the area and are useful in considering the conservation value of the associated feature and in determining whether the feature may require special management considerations or protection. These features also are relevant to evaluating the effects of an action in an ESA section 7 consultation if the specific area containing the site is designated as critical habitat. These attributes include:

(i) Quantity, quality, and availability of prey species to support individual growth, survival, reproduction, and feeding opportunities; and

(ii) Water quality and sufficient levels of dissolved oxygen to support growth, survival, reproduction, and feeding opportunities.

(2) Nearshore areas are contiguous with the shoreline from the line of extreme high water out to a depth no greater than 30 meters (98 ft) relative to mean lower low water.

(d) *Essential features for adult bocaccio and adult and juvenile yelloweye rockfish.* Benthic habitats and sites deeper than 30 m (98 ft) that possess or are adjacent to areas of complex bathymetry consisting of rock and or highly rugose habitat are essential to conservation because these features support growth, survival, reproduction, and feeding opportunities by providing the structure for rockfish to avoid predation, seek food and persist for decades. Several attributes of these sites determine the quality of the habitat and are useful in considering the conservation value of the associated feature, and whether the feature may require special management considerations or protection. These attributes are also relevant in the evaluation of the effects of a proposed action in an ESA section 7 consultation if the specific area containing the site is designated as critical habitat. These attributes include:

(1) Quantity, quality, and availability of prey species to support individual growth, survival, reproduction, and feeding opportunities;

(2) Water quality and sufficient levels of dissolved oxygen to support growth, survival, reproduction, and feeding opportunities; and

(3) The type and amount of structure and rugosity that supports feeding opportunities and predator avoidance.

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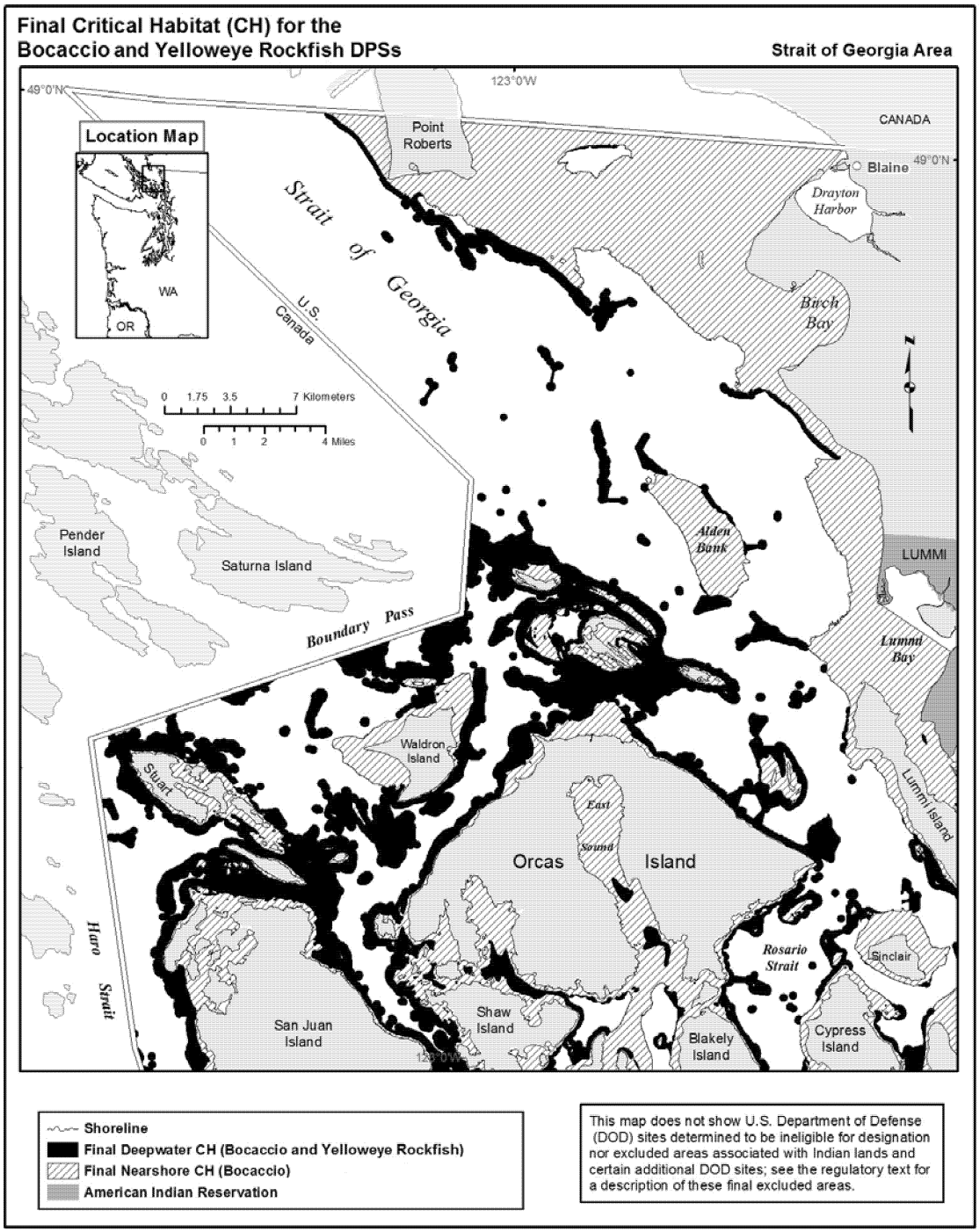
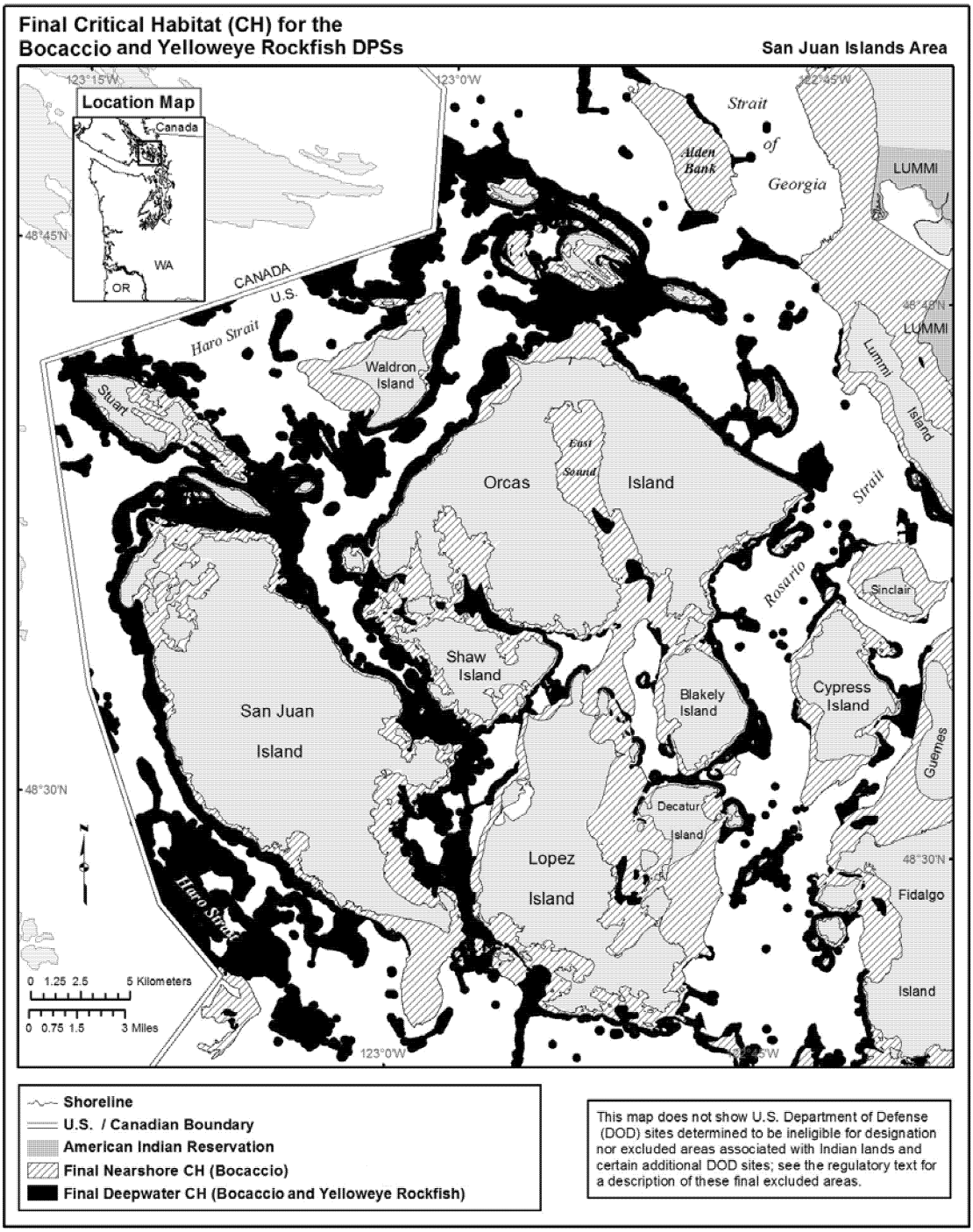
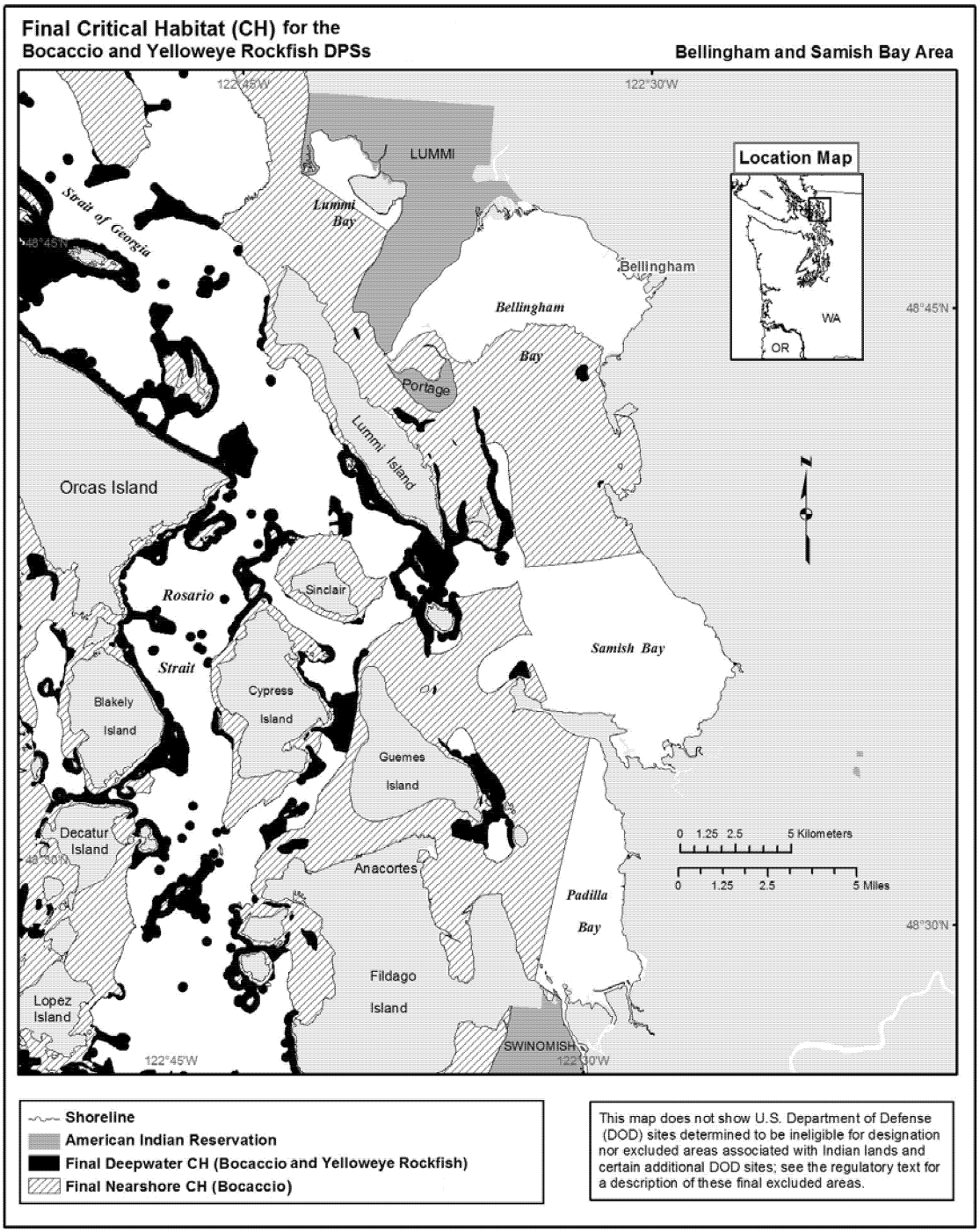
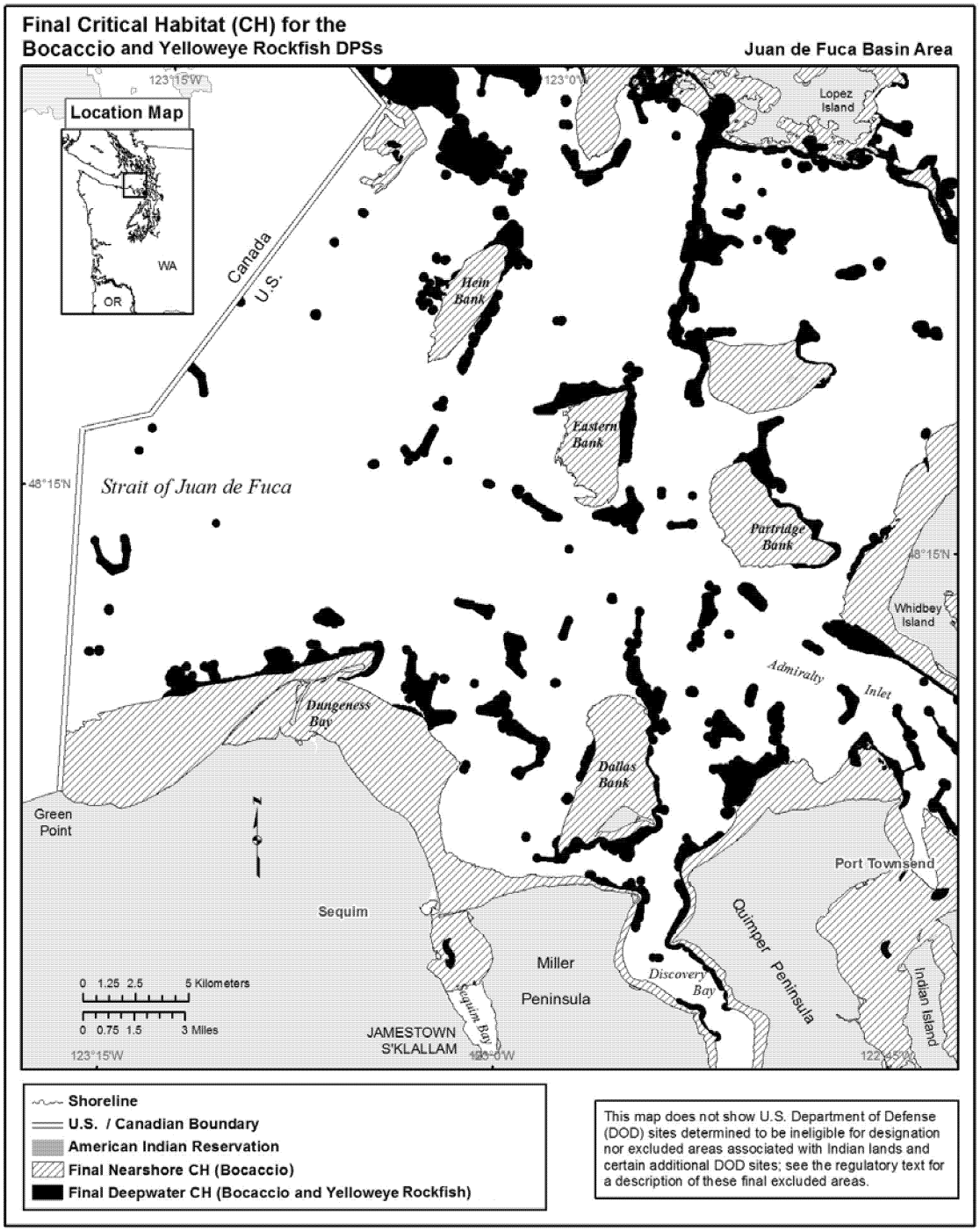
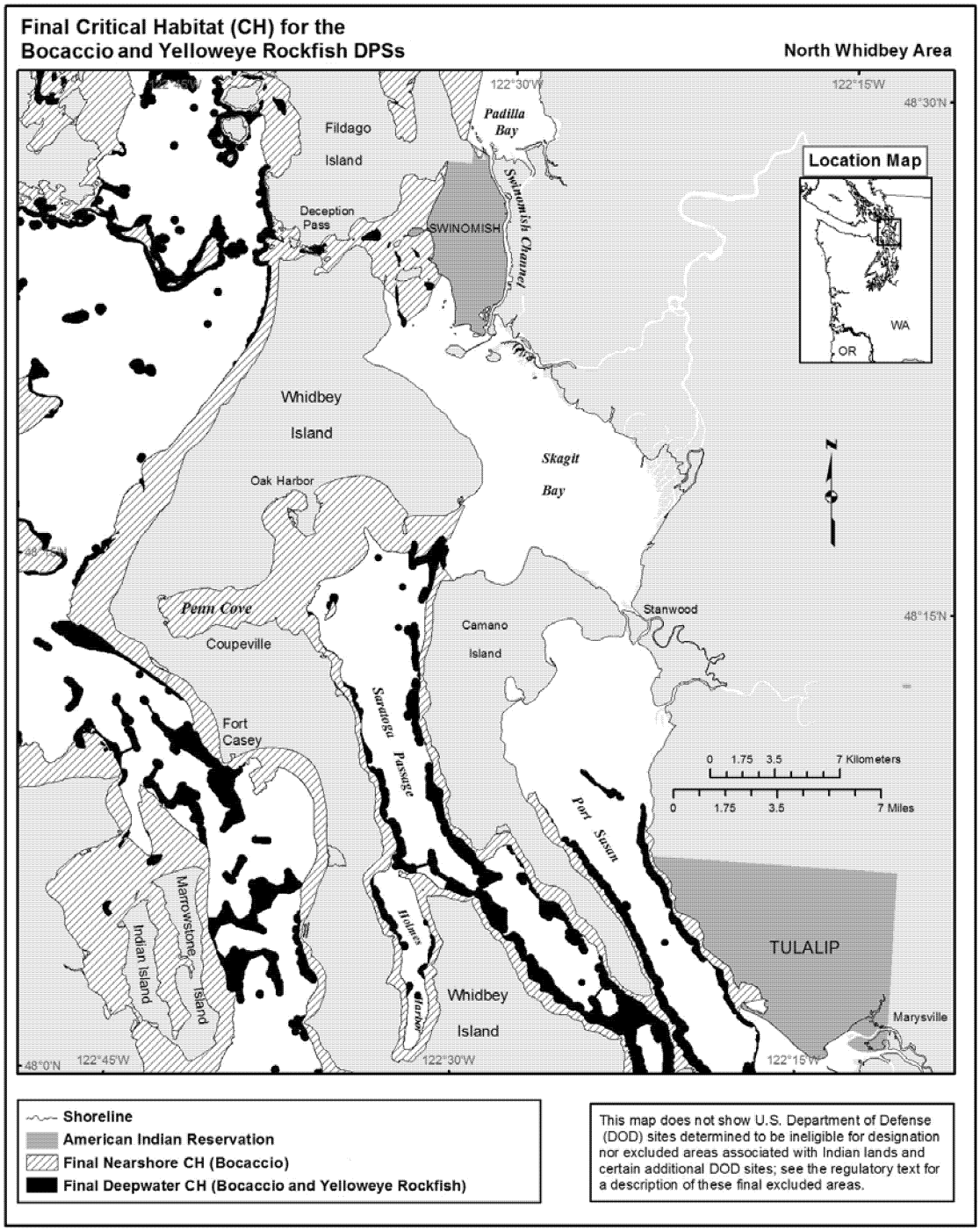
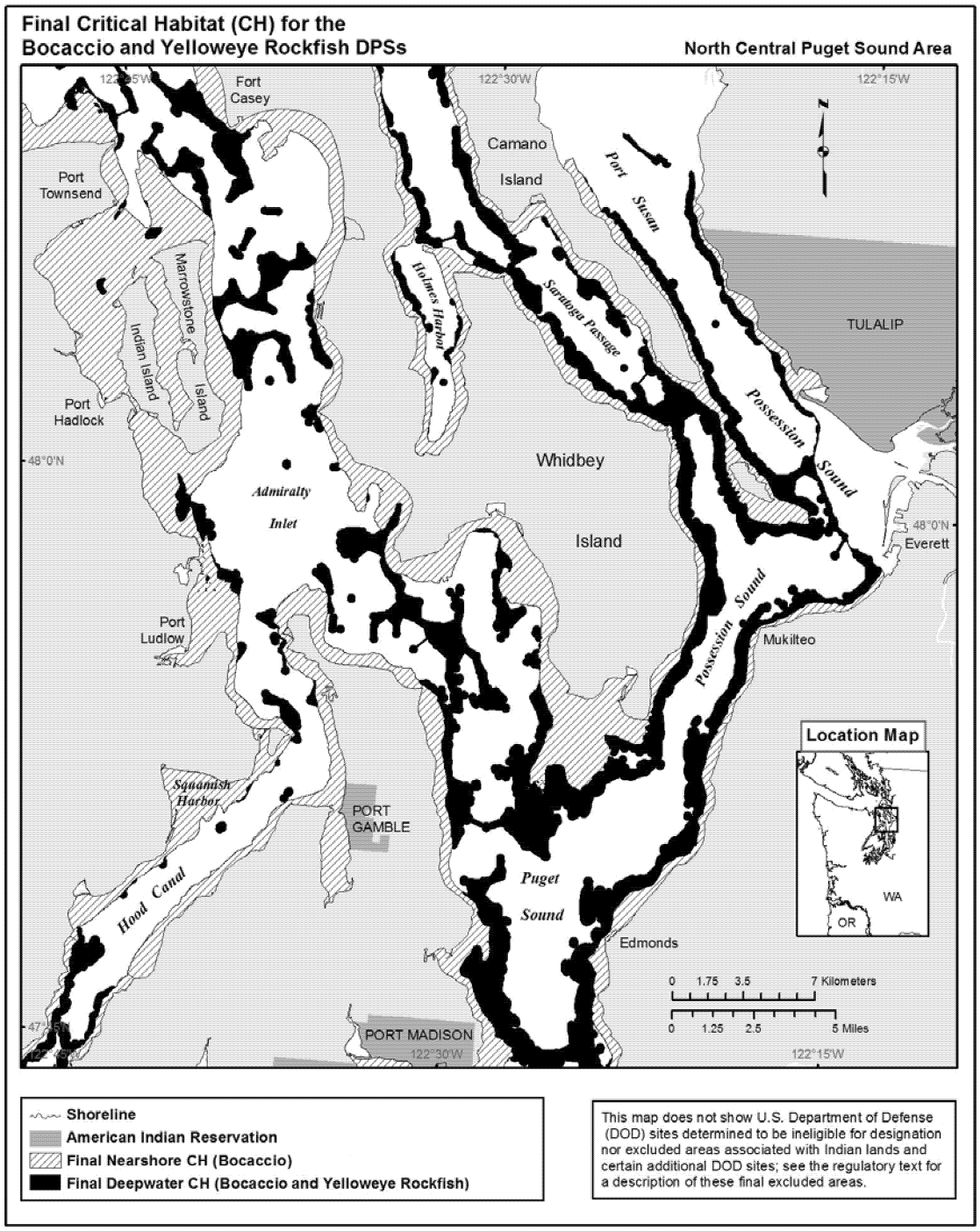

Final Critical Habitat (CH) for the
Bocaccio and Yelloweye Rockfish DPSs
Strait of Georgia Area
49°0'N
123°0'W
Location Map
WA
OR
Point Roberts
CANADA
Blaine
49°0'N
Drayton Harbor
Strait of Georgia
U.S.
Canada
Birch Bay
0 1.75 3.5 7 Kilometers
0 1 2 4 Miles
Pender Island
Saturna Island
Boundary Pass
Alden Bank
LUMMI
Lummi Bay
Waldron Island
Stuart
East Sound
Orcas Island
Lummi Island
Haro Strait
Rosario Strait
Sinclair
San Juan Island
Shaw Island
Blakely Island
Cypress Island
Shoreline
Final Deepwater CH (Bocaccio and Yelloweye Rockfish)
Final Nearshore CH (Bocaccio)
American Indian Reservation
This map does not show U.S. Department of Defense (DOD) sites determined to be ineligible for designation nor excluded areas associated with Indian lands and certain additional DOD sites; see the regulatory text for a description of these final excluded areas.

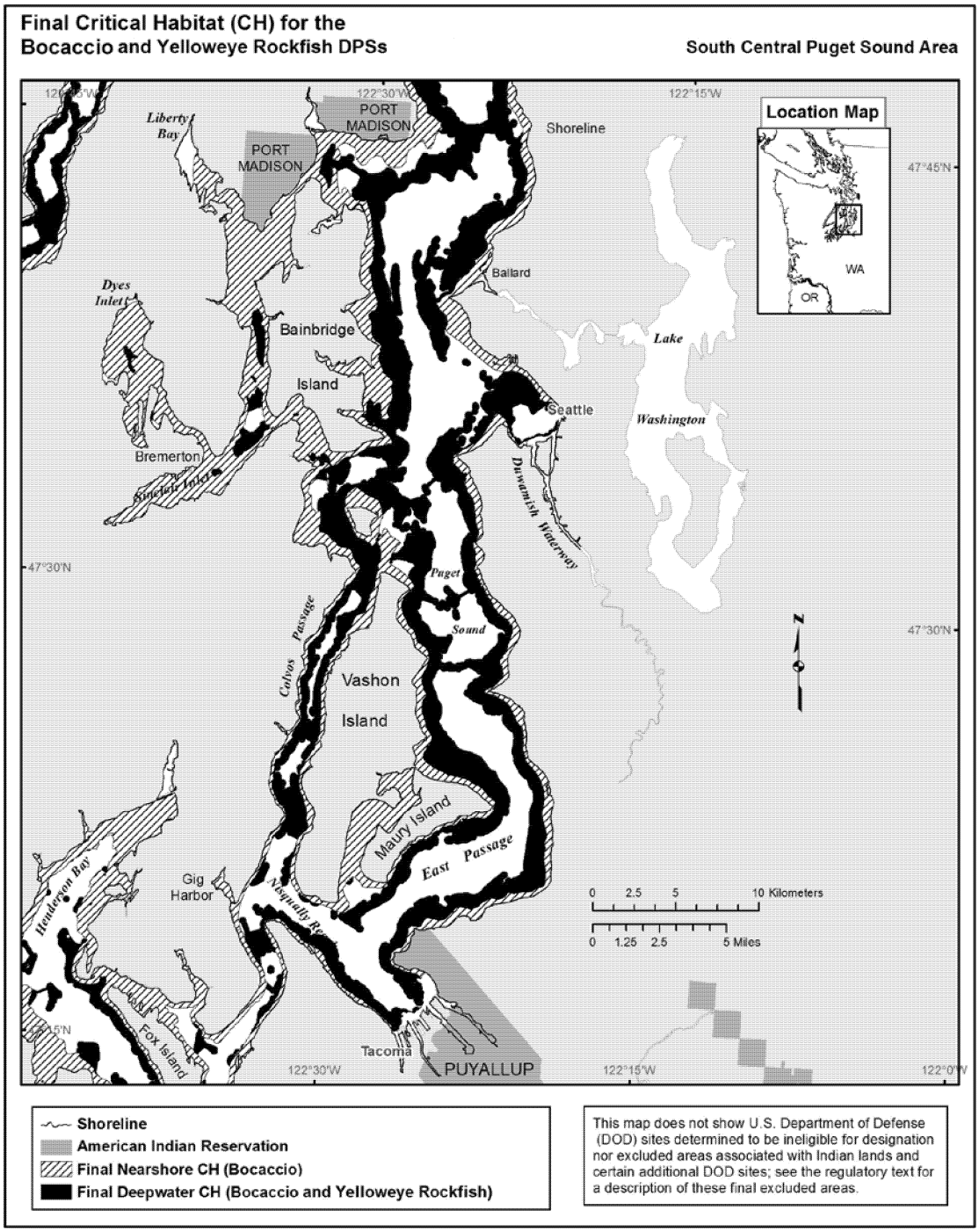

Final Critical Habitat (CH) for the
Bocaccio and Yelloweye Rockfish DPSs
San Juan Islands Area
Location Map
Canada
WA
OR
CANADA
U.S.
Haro Strait
Strait of Georgia
Alden Bank
LUMMI
Waldron Island
Stuart
East Sound
Orcas Island
Lummi Island
Rosario Strait
Sinclair
Shaw Island
San Juan Island
Blakely Island
Cypress Island
Guemes
Decatur Island
Lopez Island
Fidalgo Island
123°15'W
123°0'W
122°45'W
48°45'N
48°30'N
0 1.25 2.5 5 Kilometers
0 0.75 1.5 3 Miles
Shoreline
U.S. / Canadian Boundary
American Indian Reservation
Final Nearshore CH (Bocaccio)
Final Deepwater CH (Bocaccio and Yelloweye Rockfish)
This map does not show U.S. Department of Defense (DOD) sites determined to be ineligible for designation nor excluded areas associated with Indian lands and certain additional DOD sites; see the regulatory text for a description of these final excluded areas.

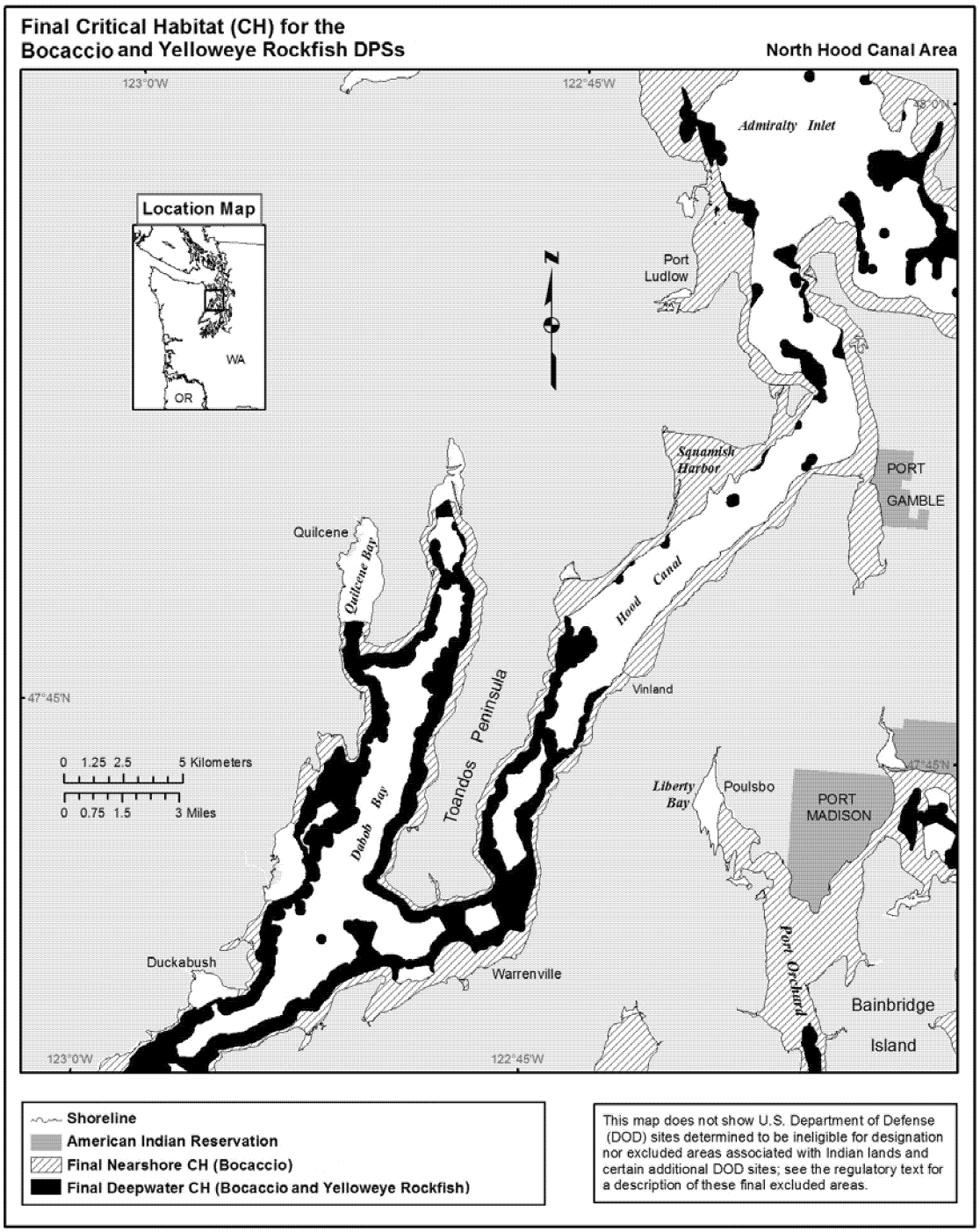

Final Critical Habitat (CH) for the
Bocaccio and Yelloweye Rockfish DPSs
Bellingham and Samish Bay Area
122°45'W
122°30'W
LUMMI
Location Map
Strait of Georgia
Lummi Bay
48°45'N
Bellingham
Bellingham Bay
WA
OR
Portage
Lummi Island
Orcas Island
Rosario Strait
Sinclair
Samish Bay
Blakely Island
Cypress Island
Guemes Island
Decatur Island
48°30'N
Anacortes
Padilla Bay
0 1.25 2.5 5 Kilometers
0 1.25 2.5 5 Miles
Fildago Island
Lopez Island
SWINOMISH
Shoreline
American Indian Reservation
Final Deepwater CH (Bocaccio and Yelloweye Rockfish)
Final Nearshore CH (Bocaccio)
This map does not show U.S. Department of Defense (DOD) sites determined to be ineligible for designation nor excluded areas associated with Indian lands and certain additional DOD sites; see the regulatory text for a description of these final excluded areas.

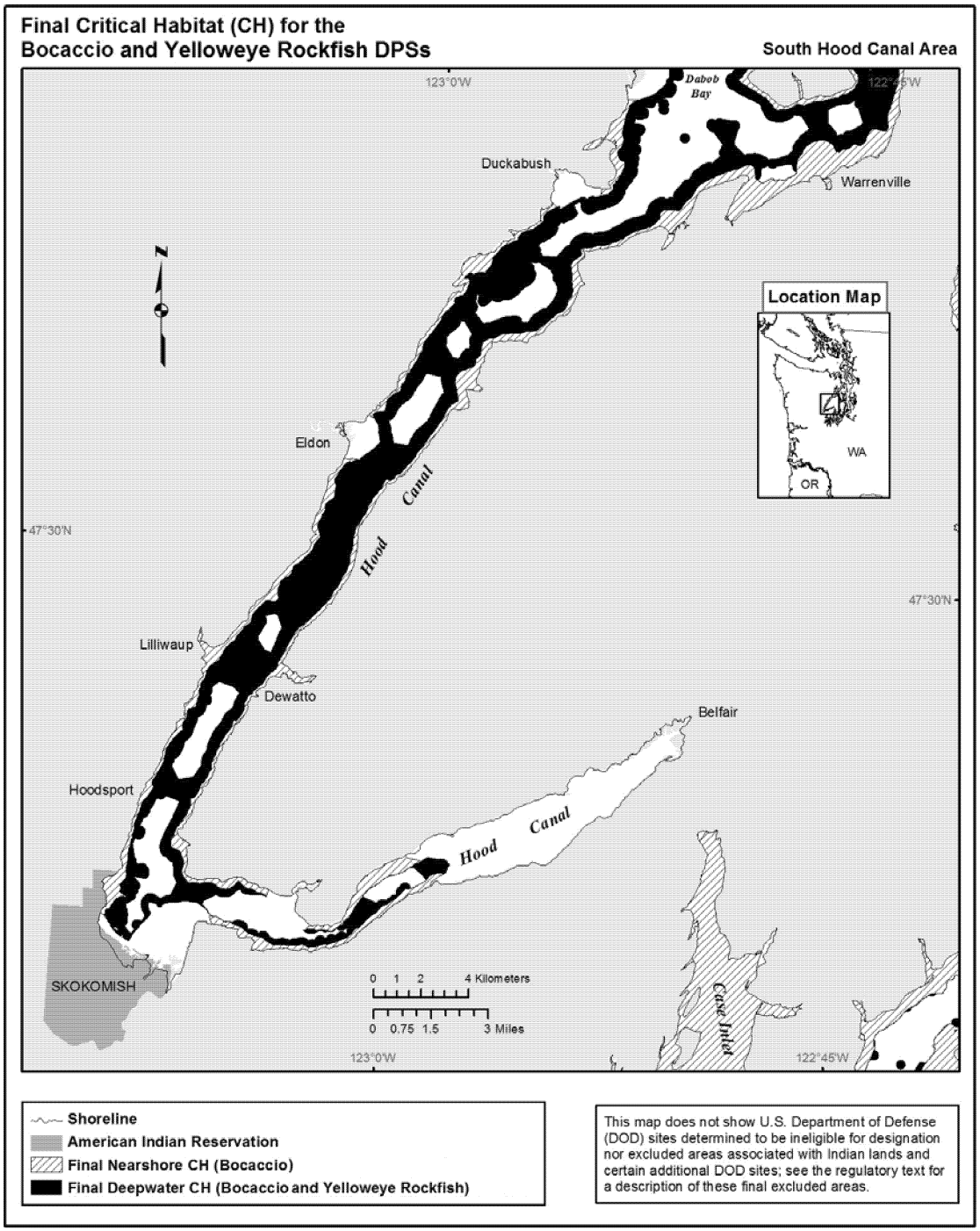

Final Critical Habitat (CH) for the
Bocaccio and Yelloweye Rockfish DPSs
Juan de Fuca Basin Area
Location Map
WA
OR
Canada
U.S.
Strait of Juan de Fuca
Hein Bank
Eastern Bank
Partridge Bank
Dallas Bank
Dungeness Bay
Admiralty Inlet
Whidbey Island
Lopez Island
Green Point
Sequim
Miller Peninsula
Discovery Bay
Quimper Peninsula
Port Townsend
Indian Island
Sequim Bay
JAMESTOWN S'KLALLAM
123°15'W
123°0'W
48°15'N
0 1.25 2.5 5 Kilometers
0 0.75 1.5 3 Miles
Shoreline
U.S. / Canadian Boundary
American Indian Reservation
Final Nearshore CH (Bocaccio)
Final Deepwater CH (Bocaccio and Yelloweye Rockfish)
This map does not show U.S. Department of Defense (DOD) sites determined to be ineligible for designation nor excluded areas associated with Indian lands and certain additional DOD sites; see the regulatory text for a description of these final excluded areas.

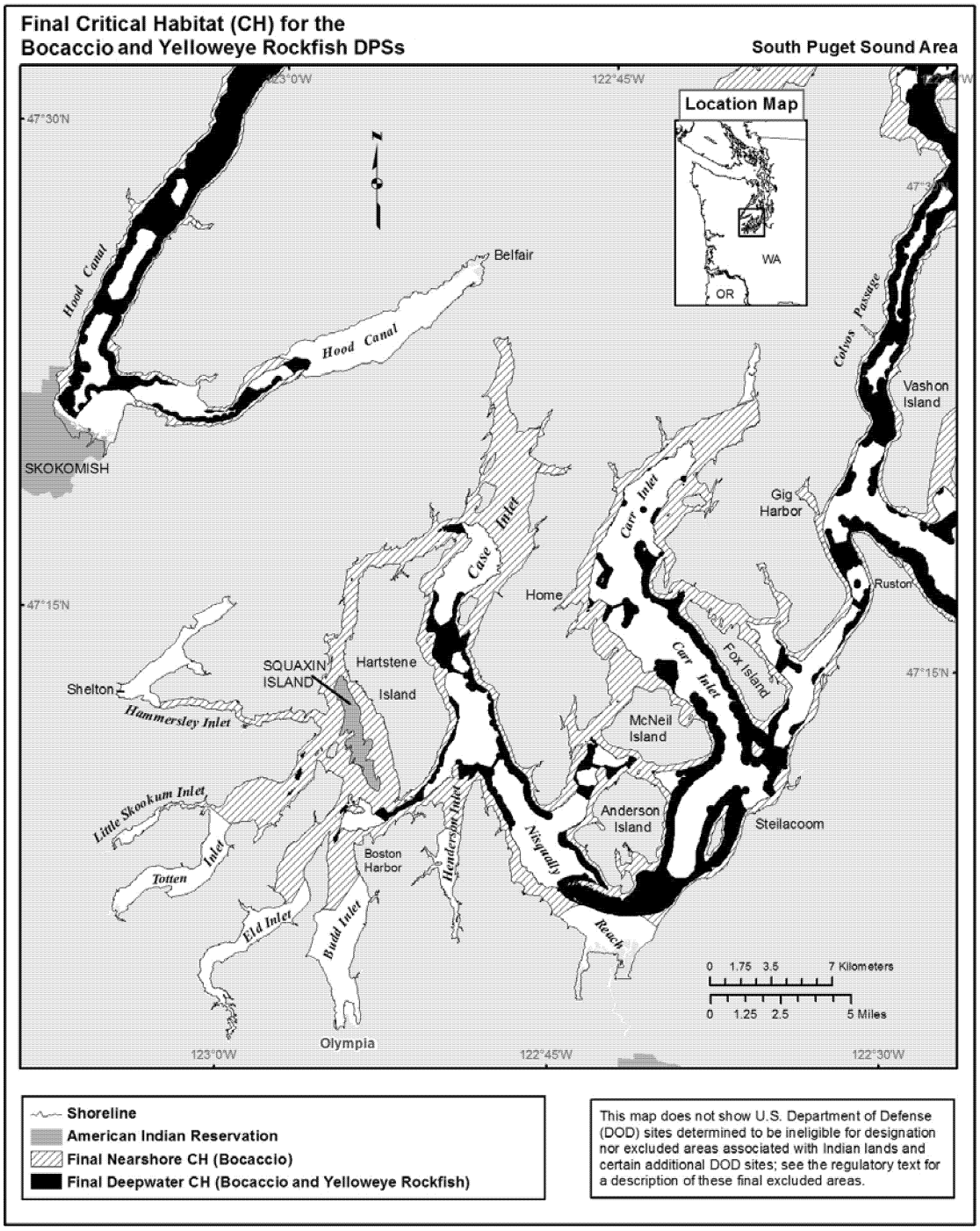

Final Critical Habitat (CH) for the
Bocaccio and Yelloweye Rockfish DPSs
North Whidbey Area
122°30'W
122°15'W
48°30'N
48°15'N
48°0'N
122°45'W
Fildago
Island
Padilla
Bay
Swinomish Channel
Deception
Pass
SWINOMISH
Location Map
WA
OR
Whidbey
Island
Skagit
Bay
Oak Harbor
Penn Cove
Coupeville
Camano
Island
Stanwood
Fort
Casey
Saratoga Passage
Port Susan
0 1.75 3.5 7 Kilometers
0 1.75 3.5 7 Miles
TULALIP
Marrowstone
Island
Indian Island
Holmes
Harbor
Whidbey
Island
Marysville
Shoreline
American Indian Reservation
Final Nearshore CH (Bocaccio)
Final Deepwater CH (Bocaccio and Yelloweye Rockfish)
This map does not show U.S. Department of Defense (DOD) sites determined to be ineligible for designation nor excluded areas associated with Indian lands and certain additional DOD sites; see the regulatory text for a description of these final excluded areas.


Final Critical Habitat (CH) for the
Bocaccio and Yelloweye Rockfish DPSs
North Central Puget Sound Area
122°45'W
122°30'W
122°15'W
Fort Casey
Camano Island
Port Townsend
Port Susan
Marrowstone Island
Indian Island
Holmes Harbor
Saratoga Passage
TULALIP
Port Hadlock
48°0'N
Whidbey Island
Admiralty Inlet
Possession Sound
Everett
Port Ludlow
Mukilteo
Location Map
WA
OR
Squamish Harbor
PORT GAMBLE
Hood Canal
Puget Sound
Edmonds
0 1.75 3.5 7 Kilometers
0 1.25 2.5 5 Miles
47°
PORT MADISON
Shoreline
American Indian Reservation
Final Nearshore CH (Bocaccio)
Final Deepwater CH (Bocaccio and Yelloweye Rockfish)
This map does not show U.S. Department of Defense (DOD) sites determined to be ineligible for designation nor excluded areas associated with Indian lands and certain additional DOD sites; see the regulatory text for a description of these final excluded areas.


Final Critical Habitat (CH) for the
Bocaccio and Yelloweye Rockfish DPSs
South Central Puget Sound Area
Location Map
WA
OR
PORT MADISON
Liberty Bay
Shoreline
Ballard
Dyes Inlet
Bainbridge Island
Lake Washington
Seattle
Bremerton
Sinclair Inlet
Duwamish Waterway
Puget Sound
Colvos Passage
Vashon Island
Maury Island
East Passage
Gig Harbor
Henderson Bay
Fox Island
Tacoma
PUYALLUP
47°45'N
47°30'N
47°15'N
122°30'W
122°15'W
122°0'W
0 2.5 5 10 Kilometers
0 1.25 2.5 5 Miles
Shoreline
American Indian Reservation
Final Nearshore CH (Bocaccio)
Final Deepwater CH (Bocaccio and Yelloweye Rockfish)
This map does not show U.S. Department of Defense (DOD) sites determined to be ineligible for designation nor excluded areas associated with Indian lands and certain additional DOD sites; see the regulatory text for a description of these final excluded areas.


Final Critical Habitat (CH) for the
Bocaccio and Yelloweye Rockfish DPSs
North Hood Canal Area
123°0'W
122°45'W
48°0'N
47°45'N
Admiralty Inlet
Location Map
WA
OR
N
Port Ludlow
Squamish Harbor
PORT GAMBLE
Quilcene
Quilcene Bay
Hood Canal
Toandos Peninsula
Vinland
Dabob Bay
Liberty Bay
Poulsbo
PORT MADISON
Port Orchard
Bainbridge Island
Duckabush
Warrenville
0 1.25 2.5 5 Kilometers
0 0.75 1.5 3 Miles
Shoreline
American Indian Reservation
Final Nearshore CH (Bocaccio)
Final Deepwater CH (Bocaccio and Yelloweye Rockfish)
This map does not show U.S. Department of Defense (DOD) sites determined to be ineligible for designation nor excluded areas associated with Indian lands and certain additional DOD sites; see the regulatory text for a description of these final excluded areas.


Final Critical Habitat (CH) for the
Bocaccio and Yelloweye Rockfish DPSs
South Hood Canal Area
123°0'W
122°45'W
Dabob Bay
Duckabush
Warrenville
Location Map
WA
OR
Eldon
Hood Canal
47°30'N
Lilliwaup
Dewatto
Belfair
Hoodsport
Hood Canal
SKOKOMISH
0 1 2 4 Kilometers
0 0.75 1.5 3 Miles
Case Inlet
Shoreline
American Indian Reservation
Final Nearshore CH (Bocaccio)
Final Deepwater CH (Bocaccio and Yelloweye Rockfish)
This map does not show U.S. Department of Defense (DOD) sites determined to be ineligible for designation nor excluded areas associated with Indian lands and certain additional DOD sites; see the regulatory text for a description of these final excluded areas.



[FR Doc. 2017–00559 Filed 1–19–17; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 665

RIN 0648–XF155

Pacific Island Fisheries; 2017 Northwestern Hawaiian Islands Lobster Harvest Guideline

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

ACTION: Notification of lobster harvest guideline.

SUMMARY: NMFS establishes the annual harvest guideline for the commercial lobster fishery in the Northwestern Hawaiian Islands for calendar year 2017 at zero lobsters.

DATES: January 23, 2017.

FOR FURTHER INFORMATION CONTACT: Bob Harman, NMFS PIR Sustainable Fisheries, telephone: 808–725–5170.

SUPPLEMENTARY INFORMATION: NMFS manages the Northwestern Hawaiian Islands (NWHI) commercial lobster fishery under the Fishery Ecosystem Plan for the Hawaiian Archipelago. The regulations at 50 CFR 665.252(b) require NMFS to publish an annual harvest guideline for lobster Permit Area 1, comprised of Federal waters around the NWHI.

Regulations governing the Papahanaumokuakea Marine National Monument in the NWHI prohibit the unpermitted removal of monument resources (50 CFR 404.7), and establish a zero annual harvest guideline for lobsters (50 CFR 404.10(a)). Accordingly, NMFS establishes the harvest guideline for the NWHI commercial lobster fishery for calendar year 2017 at zero lobsters. Harvest of NWHI lobster resources is not allowed.

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

Dated: January 17, 2017.

Emily H. Menashes,

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

[FR Doc. 2017–01410 Filed 1–19–17; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 82, No. 13
Monday, January 23, 2017

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

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Parts 33 and 35

[Doc. No. AMS–FV–14–0099; FV15–33/35–1 PR]

Regulations Issued Under Authority of the Export Apple Act and Export Grapes and Plums; Changes to Export Reporting Requirements

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: Notice is hereby given that the Agricultural Marketing Service (AMS) is reopening the comment period on the proposed rule to change the reporting of export certificate information under regulations issued pursuant to the Export Apple Act and the Export Grape and Plum Act until March 24, 2017. The proposed rule would require shippers of apples and grapes exported from the United States to electronically enter an Export Form Certificate number or a USDA-defined exemption code into the Automated Export System (AES). This rule would also define ''shipper,'' shift the current file retention requirement from carriers to shippers, and require shippers to provide, upon request, copies of the certificates to AMS. The proposed rule would also remove obsolete regulations and make clarifying changes. It also announced AMS' intention to request revision to a currently approved information collection for exported apples and grapes.

DATES: Comments must be received by March 24, 2017.

ADDRESSES: Interested persons are invited to submit written comments concerning the proposal. Comments must be sent to the Docket Clerk, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW., STOP 0237, Washington, DC 20250–0237; Fax: (202) 720–8938; or Internet: *http://www.regulations.gov.* All comments should reference the document number and the date and page number of this issue and the December 5, 2016, issue of the **Federal Register** and will be made available for public inspection in the Office of the Docket Clerk during regular business hours or can be viewed at: *http://www.regulations.gov.* All comments submitted in response to the proposed rule will be included in the record and will be made available to the public. Please be advised that the identity of the individuals or entities submitting the comments will be made public on the internet at the address provided above.

FOR FURTHER INFORMATION CONTACT: Shannon Ramirez, Compliance and Enforcement Specialist, or Vincent Fusaro, Compliance and Enforcement Branch Chief, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA; Telephone: (202) 720–2491, Fax: (202) 720–8938, or Email: *Shannon.Ramirez@ams.usda.gov* or *VincentJ.Fusaro@ams.usda.gov.*

Small businesses may request information on complying with this regulation by contacting Richard Lower, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW., STOP 0237, Washington, DC 20250–0237; Telephone: (202) 720–2491, Fax: (202) 720–8938, or Email: *Richard.Lower@ams.usda.gov.*

SUPPLEMENTARY INFORMATION: A proposed rule was published in the **Federal Register** on December 5, 2016 (81 FR 87486). The proposed rule would change the reporting of export certificate information under regulations issued pursuant to both the Export Apple Act and the Export Grape and Plum Act (7 CFR part 33, ''Regulations Issued Under Authority of the Export Apple Act,'' and 7 CFR part 35, ''Export Grapes and Plums,'' respectively). Shippers of apples and grapes exported from the United States subject to inspection would be required to enter the certificate number from inspection certificates (*i.e.,* Export Form Certificates) into AES. For apples shipped to Canada in bulk containers, which are exempt from inspection requirements, shippers would be required to enter a special USDA-defined exemption code in lieu of an Export Form Certificate number. Shippers would also be required to maintain paper or electronic copies of the certificates and to provide copies to AMS upon request. The proposed rule would also define ''shipper'' and would remove the requirement that carriers of exported apples and grapes retain certificates on file (because the requirement to retain the certificates would shift to shippers of exported apples and grapes). It would also remove regulations that are no longer applicable to grape exports and add structure and language to clarify the regulations.

Plums are not currently regulated under the Export Grape and Plum Act; therefore, the proposed change would not impact shipments of plums exported from the United States. If plums exported from the United States are regulated in the future under the Export Grape and Plum Act, the reporting of export certificate information similar to what is being proposed for exported grapes and apples would be proposed for plums.

The initial comment period for the proposed rule closed on January 4, 2017. USDA received a comment from a member of the export apple industry requesting that the comment period be extended by 60 days to allow more time to comment on the proposed rule. This individual expressed concern that while the proposed rule provided for a 60-day comment period, additional time was needed beyond the January 4, 2017, deadline to allow interested persons to comment.

After considering the request, USDA is reopening the comment period until March 24, 2017. This will provide interested persons more time to review the proposed rule, perform a complete analysis, and submit written comments.

Authority: This notice is issued pursuant to the Export Apple Act (48 Stat. 124; 7 U.S.C. 581–590) and the Export Grape and Plum Act (74 Stat. 734; 75 Stat. 220; 7 U.S.C. 591–599).

Dated: January 17, 2017.

Elanor Starmer,

Administrator, Agricultural Marketing Service.

[FR Doc. 2017–01417 Filed 1–19–17; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–9490; Directorate Identifier 2016–NE–26–AD]

RIN 2120–AA64

Airworthiness Directives; General Electric Company Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain General Electric Company (GE) CF6–80C2L1F turbofan engines. This proposed AD was prompted by a reduction in the life limit of the affected engines which is the result of a revised operating profile. This proposed AD would require replacement of the high-pressure turbine (HPT) spacer/impeller, part number (P/N) 1539M12P02, at a newer, lower life limit. We are proposing this AD to correct the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by March 9, 2017.

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

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

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–9490; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Herman Mak, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 1200 District Avenue, Burlington, MA 01803; phone: 781–238–7147; fax: 781–238–7199; email: *herman.mak@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2016–9490; Directorate Identifier 2016–NE–26–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

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

Discussion

The United States Air Force revised its operating profile for its GE CF6–80C2L1F engines. As a result of this change in operating profile, GE reduced its life limit for the HPT spacer/impeller from 20,000 to 18,000 cycles. Therefore, we are proposing to require removal of this affected HPT spacer/impeller at the new, lower life limit. This condition, if not corrected, could result in failure of the HPT spacer/impeller, uncontained release of the HPT spacer/impeller, damage to the engine, and damage to the airplane.

FAA's Determination

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

Proposed AD Requirements

This proposed AD would require replacement of the HPT spacer/impeller, P/N 1539M12P02, at a newer, lower life limit.

Costs of Compliance

We estimate that this proposed AD affects 0 engines installed on airplanes of U.S. registry.

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

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Replacement of HPT spacer/impeller at reduced life.	0 work-hours × $85 per hour = $0	$19,320 (pro-rated cost of part)	$19,320	$0

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

(3) Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction, and

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

General Electric Company: Docket No. FAA–2016–9490; Directorate Identifier 2016–NE–26–AD.

(a) Comments Due Date

We must receive comments by March 9, 2017.

(b) Affected ADs

None.

(c) Applicability

This AD applies to General Electric Company (GE) CF6–80C2L1F turbofan engines with a high-pressure turbine (HPT) spacer/impeller, part number (P/N) 1539M12P02, installed.

(d) Subject

Joint Aircraft System Component (JASC) Code 7250, Turbine/Turboprop Engine—Turbine Section.

(e) Unsafe Condition

This AD was prompted by a reduction in the life limit of the affected engines, which is the result of a revised operating profile. We are issuing this AD to prevent failure of the HPT spacer/impeller, uncontained release of the HPT spacer/impeller, damage to the engine, and damage to the airplane.

(f) Compliance

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

After the effective date of this AD, replace the HPT spacer/impeller, P/N 1539M12P02, before it exceeds 18,000 flight cycles since new.

(g) Installation Prohibition

After the effective date of this AD, do not install an HPT spacer/impeller, P/N 1539M12P02, onto any engine, or return to service any engine with an HPT spacer/impeller, P/N 1539M12P02, installed, if the HPT spacer/impeller exceeds 18,000 flight cycles since new.

(h) Alternative Methods of Compliance (AMOCs)

The Manager, Engine Certification Office, FAA, may approve AMOCs for this AD. Use the procedures found in 14 CFR 39.19 to make your request. You may email your request to: *ANE-AD-AMOC@faa.gov.*

(i) Related Information

For more information about this AD, contact Herman Mak, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 1200 District Avenue, Burlington, MA 01803; phone: 781–238–7147; fax: 781–238–7199; email: *herman.mak@faa.gov.*

Issued in Burlington, Massachusetts, on January 12, 2017.

Colleen M. D'Alessandro,

Manager, Engine & Propeller Directorate, Aircraft Certification Service.

[FR Doc. 2017–01227 Filed 1–19–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2016–9355; Airspace Docket No. 16–ANM–8]

Proposed Amendment of Class D and Class E Airspace; Hailey, ID

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to modify Class D airspace, Class E surface area airspace, and Class E airspace extending upward from 700 feet above the surface at Friedman Memorial Airport, Hailey, ID, to support the implementation of new Area Navigation (RNAV) Global Positioning System (GPS) standard instrument approach procedures for Instrument Flight Rules (IFR) at the airport.

DATES: Comments must be received on or before March 9, 2017.

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; telephone: 1–800–647–5527, or (202) 366–9826. You must identify FAA Docket No. FAA–2016–9355; Airspace Docket No. 16–ANM–8, at the beginning of your comments. You may also submit comments through 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 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays.

FAA Order 7400.11A, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *http://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: 202–267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11A at NARA, call 202–741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal-regulations/ibr_locations.html.*

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT: Tom Clark, Federal Aviation Administration, Operations Support Group, Western Service Center, 1601 Lind Avenue SW., Renton, WA 98057; telephone (425) 203–4511.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. 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. 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

amend Class D and Class E airspace at Friedman Memorial Airport, Hailey, ID.

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. Persons 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–2016–9355/Airspace Docket No. 15–ANM–6.'' The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

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/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Northwest Mountain Regional Office of the Federal Aviation Administration, Air Traffic Organization, Western Service Center, Operations Support Group, 1601 Lind Avenue SW., Renton, WA 98057.

Availability and Summary of Documents Proposed for Incorporation by Reference

This document proposes to amend FAA Order 7400.11A, Airspace Designations and Reporting Points, dated August 3, 2016, and effective September 15, 2016. FAA Order 7400.11A is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11A lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) Part 71 by modifying Class D airspace, Class E surface area airspace, and Class E airspace extending upward from 700 feet above the surface at Friedman Memorial Airport, Hailey, ID, to support implementation of new RNAV (GPS) standard instrument approach procedures at the airport. The new RNAV (GPS) procedures require additional Class D airspace in the vicinity of the airport for circling maneuvers, but require less airspace upward from 700 feet above the surface to support IFR arrival and departure aircraft. Class D airspace would be expanded from the surface to and including 7,800 feet MSL to within a 4.9-mile radius (increased from a 4.1-mile radius) of the airport, with an extension from the 4.9-mile radius increased from 6 miles to 6.3 miles southeast.

Class E surface area airspace would be reduced to within a 4.9-mile radius of the airport, with a segment increased from 6 miles to 6.3 miles southeast of the airport to provide controlled airspace when Class D airspace is not in effect.

Class E airspace extending upward from 700 feet above the surface would be reduced to within a 4.9-mile radius of the airport (from the 5.5-mile radius), with the southeast segment reduced from 15.5 miles to 11.3 miles from the radius of the airport. Additionally, the geographic coordinates for the airport listed in the Class D description would be updated to coincide with the FAA's aeronautical database.

Class D and Class E airspace designations are published in paragraph 5000, 6002, and 6005, respectively, of FAA Order 7400.11A, dated August 3, 2016 and effective September 15, 2016, which is incorporated by reference in 14 CFR 71.1. The Class D and Class E airspace designations listed in this document will be published subsequently in the Order.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. 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, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, 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; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR Part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 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 FAA Order 7400.11A, Airspace Designations and Reporting Points, dated August 3, 2016, and effective September 15, 2016, is amended as follows:

Paragraph 5000 Class D Airspace.

* * * * *

ANM ID D Hailey, ID [Modified]

Friedman Memorial Airport, ID
(Lat. 43°30′14″ N., long. 114°17′44″ W.)

That airspace extending upward from the surface to, and including, 7,800 feet MSL within a 4.9-mile radius of Friedman Memorial Airport, and that airspace within 2.1 miles west and 1.4 miles east of the 155° bearing from the airport extending from the airport 4.9-mile radius to 6.3 miles southeast of the airport. This Class D airspace area is effective during the specified dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement (previously called Airport/Facility Directory).

Paragraph 6002 Class E Airspace Designated as Surface Areas.

* * * * *

ANM ID E2 Hailey, ID [Modified]

Friedman Memorial Airport, ID
(Lat. 43°30′14″ N., long. 114°17′44″ W.)

That airspace extending upward from the surface within a 4.9-mile radius of Friedman Memorial Airport, and within 2.1 miles west and 1.4 miles east of the 155° bearing from the airport, extending from the airport 4.9-mile radius to 6.3 miles southeast of the airport.

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ANM ID, E5 Hailey, ID [Modified]

Friedman Memorial Airport, ID
(Lat. 43°30′14″ N., long. 114°17′44″ W.)

That airspace extending upward from 700 feet above the surface within a 4.9-mile radius of Friedman Memorial Airport, and within 2.5 miles each side of the 155° bearing from the airport extending from the airport 4.9-mile radius to 11.3 miles southeast of the airport; and that airspace extending upward from 1,200 feet above the surface bounded by a line beginning at lat. 44°00′00″ N., long. 114°55′00″ W., to lat. 44°00′00″ N., long. 113°53′00″ W., to lat. 43°00′00″ N., long. 113°49′00″ W., to lat. 43°00′00″ N., long. 114°55′00″ W., thence to point of beginning.

Issued in Seattle, Washington, on January 10, 2017.

Richard Roberts,

Acting Manager, Operations Support Group, Western Service Center.

[FR Doc. 2017–01268 Filed 1–19–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2016–8164; Airspace Docket No. 15–ANM–25]

Proposed Establishment of Class E Airspace, Manti, UT

AGENCY: Federal Aviation Administration (FAA), DOT.

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

SUMMARY: This supplemental notice of proposed rulemaking would establish Class E airspace upward from 700 feet above the surface within a 4.7-mile radius of Manti-Ephraim Airport, Manti, UT, with segments extending north and southwest of the airport. In an NPRM published in the **Federal Register** on November 22, 2016, the FAA proposed to establish Class E airspace extending upward from 700 feet above the surface within a 4-mile radius of Manti-Ephraim Airport, with extensions north and southwest. The FAA found additional airspace is necessary for new category D circling Instrument Flight Rules (IFR) operations for standard instrument approach procedures and to support the safety and management of IFR operations at the airport.

DATES: The comment period for the notice of proposed rulemaking published in the **Federal Register** of November 22, 2016 (81 FR 83749), is reopened until February 22, 2017.

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; telephone: 1–800–647–5527, or (202) 366–9826. You must identify FAA Docket No. FAA–2016–8164; Airspace Docket No. 15–ANM–25, at the beginning of your comments. You may also submit comments through the Internet at *http://www.regulations.gov.*

FAA Order 7400.11, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *http://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: 202–267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11A at NARA, call 202–741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal-regulations/ibr_locations.html.*

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT: Tom Clark, Federal Aviation Administration, Operations Support Group, Western Service Center, 1601 Lind Avenue SW., Renton, WA 98057; telephone (425) 203–4511.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. 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. 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 Class E airspace at Manti-Ephraim Airport, Manti, UT.

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. Persons 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–2016–8164/Airspace Docket No. 15–ANM–25.'' The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

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/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Northwest Mountain Regional Office of the Federal Aviation Administration, Air Traffic Organization, Western Service Center, Operations Support Group, 1601 Lind Avenue SW., Renton, WA 98057.

Availability and Summary of Documents Proposed for Incorporation by Reference

This document proposes to amend FAA Order 7400.11A, Airspace Designations and Reporting Points, dated August 3, 2016, and effective September 15, 2016. FAA Order 7400.11A is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11A lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

History

On November 22, 2016, the FAA published in the **Federal Register** an NPRM proposing to establish Class E airspace extending upward from 700 feet above the surface at Manti-Ephraim Airport, Manti, UT (81 FR, 83749) FAA–2016–8164. The FAA has received and concurs with a request by the National Business Aviation Association to develop IFR standard instrument approach circling procedures for category D aircraft for the airport. The additional IFR category D circling procedures would require additional airspace for the safety if IFR aircraft using the new procedure.

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 by establishing Class E airspace extending upward from 700 feet above the surface within a 4.7-mile radius (from a 4-mile radius) of Manti-Ephraim Airport, Manti, UT, with segments extending from the 4.7-mile radius to 11 miles southwest of the airport, and 7.2 miles northeast of the airport. Additional airspace is necessary to support the development of IFR circling procedures for category D aircraft operations in standard instrument approach and departure procedures at the airport.

Class E airspace designations are published in paragraph 6005 of FAA Order 7400.11A, dated August 3, 2016, and effective September 15, 2016, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. 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, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, 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; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 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 FAA Order 7400.11A, Airspace Designations and Reporting Points, dated August 3, 2016, and effective September 15, 2016, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ANM UT E5 Manti, UT [New]

Manti-Ephraim Airport, Utah
(Lat. 39°19′53″ N., long. 111°36′45″ W.)

That airspace extending upward from 700 feet above the surface within a 4.7-mile radius of Manti-Ephraim Airport, and that airspace 2 miles either side of a 225° bearing from the airport extending from the 4.7-mile radius to 11 miles southwest of the airport, and that airspace within 1.8 miles east of the line beginning at lat. 39°17′50″ N., long. 111°39′27″ W., to lat. 39°14′35″ N., long. 111°41′06″ W., and that airspace beginning at the point where a 001° bearing from the airport intersects the 4.7-mile radius to lat. 39°26′54″ N., long. 111°36′20″ W., to lat. 39°26′34″ N., long. 111°31′41″ W., to the point where a 053° bearing from the airport intersects the 4.7-mile radius, thence counter-clockwise along the 4.7-mile radius to the point of beginning.

Issued in Seattle, Washington, on January 10, 2017.

Richard Roberts,

Acting Manager, Operations Support Group, Western Service Center.

[FR Doc. 2017–01039 Filed 1–19–17; 8:45 am]

BILLING CODE 4910–13–P

COMMODITY FUTURES TRADING COMMISSION

17 CFR Parts 3 and 9

RIN 3038–AE15

Technical Amendments to Rules on Registration and Review of Exchange Disciplinary, Access Denial or Other Adverse Actions

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Commodity Futures Trading Commission (''CFTC'' or ''Commission'') is proposing technical amendments to its regulations that govern registration and review of exchange disciplinary, access denial or other adverse actions. The amendments would integrate existing advisory guidance and the amendments to part 9 would also incorporate swap execution facilities (''SEFs'') and update provisions currently applicable to designated contract markets (''DCMs''). The proposal revises existing rules to delete numerous cross-references to previously deleted regulations and adds citations to applicable parallel provisions for SEFs and DCMs.

Additionally, the proposal addresses the publication of final disciplinary and access denial actions taken by the SEFs and DCMs on their exchange Web sites.

DATES: Comments must be received on or before March 24, 2017.

ADDRESSES: You may submit comments, identified by RIN 3038–AE15, by any of the following methods:

- *CFTC Web site: https://comments.cftc.gov.* Follow the instructions for submitting comments through the Comments Online process on the Web site.
- *Mail:* Christopher Kirkpatrick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW., Washington, DC 20581.
- *Hand Delivery/Courier:* Same as Mail, above.
- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Please submit your comments using only one method.

All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to *www.cftc.gov.* You should submit only information that you wish to make available publicly. If you wish the Commission to consider information that you believe is exempt from disclosure under the Freedom of Information Act (''FOIA''), a petition for confidential treatment of the exempt information may be submitted according to the procedures established in Commission regulation 145.9.

The Commission reserves the right, but shall have no obligation, to review, pre-screen, filter, redact, refuse or remove any or all of your submission from *www.cftc.gov* that it may deem to be inappropriate for publication, such as obscene language. All submissions that have been redacted or removed that contain comments on the merits of the rulemaking will be retained in the public comment file and will be considered as required under the Administrative Procedure Act and other applicable laws, and may be accessible under the FOIA.

FOR FURTHER INFORMATION CONTACT: Rachel Berdansky, Deputy Director, Division of Market Oversight, at 202–418–5429 or *rberdansky@cftc.gov;* or David Steinberg, Associate Director, Division of Market Oversight, at 202–418–5102 or *dsteinberg@cftc.gov,* in each case, at the Commodity Futures Trading Commission, Three Lafayette Centre, 1151 21st Street NW., Washington, DC 20581.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background

A. Description of Part 9

On December 20, 1978, the Commission adopted part 9 rules relating to the review of exchange disciplinary, access denial, or other adverse actions.[1] The rules govern the process and procedures by which the Commission may review exchange disciplinary and access denial actions, detailing the appellate process under which such review will be instituted and conducted in cases where a person applies to the Commission for review. In addition to setting forth procedures and standards governing filing and service, motions, and settlement, the rules also cover the process by which exchanges must provide notice of the final disciplinary action to the subject of the disciplinary action and to the Commission, as well as the publication of such notice. As discussed below, DCMs and SEFs are already required to comply with the part 9 regulations.

B. DCM Final Rules and Part 8 Removal

In June 2012, the Commission implemented Core Principles and Other Requirements for Designated Contract Markets (''DCM Final Rules'').[2] Commission regulation 38.2 of the DCM Final Rules provides that DCMs shall comply with all applicable regulations under Title 17 of the Code of Federal Regulations, except for certain exempt provisions.[3] Part 9 is not included in the list of exempt provisions. Furthermore, part 9 applies to DCMs by defining ''exchange'' in Commission regulation 9.2(c) for purposes of the rules as any board of trade which has been designated as a contract market.[4]

Additionally, in the DCM Final Rules, the Commission adopted regulations in ''Subpart N—Disciplinary Procedures'' of part 38 to amend the disciplinary procedures applicable to DCMs.[5] Several of the regulations adopted in subpart N of part 38 are similar to the text of the disciplinary procedures found in former part 8—exchange procedures for disciplinary, summary, and membership denial actions.[6] In order to avoid confusion from the regulations containing two sets of disciplinary procedures for DCMs, the Commission removed part 8 from the regulations.[7] As a result of this removal, the current part 9 rules, which contain cross-references to part 8 throughout, are being updated in this rulemaking (''NPRM'' or ''Proposal'') to instead cite to parallel provisions now contained in part 37 for SEFs and part 38 for DCMs.[8]

C. SEF Final Rules

The Dodd-Frank Wall Street Reform and Consumer Protection Act (''Dodd-Frank Act'') repealed some sections of the Commodity Exchange Act (''CEA'' or ''Act''), amended others, and established new categories of Commission

[1] 43 FR 59343 (Dec. 20, 1978).

[2] 77 FR 36612 (June 19, 2012).

[3] 77 FR 36697 (June 19, 2012); 17 CFR 38.2.

[4] 17 CFR 9.2(c).

[5] 17 CFR 38.700 through 38.712.

[6] 43 FR 41950 (Sept. 19, 1978); 17 CFR 38.700 through 38.712. For example, part 8 contained regulations 8.05 (Enforcement staff); 8.08 (Disciplinary committee); and 8.20 (Final decision). Subpart N of part 38 has corresponding provisions: 38.701 (Enforcement staff); 38.702 (Disciplinary panels); and 38.709 (Final decisions).

[7] Although Commission regulation 38.2 of the DCM Final Rules specifies that DCMs are not required to comply with part 8, the Commission removed part 8 to avoid any confusion resulting from the regulations containing two sets of exchange disciplinary procedures as part of the Adaption of Regulations to Incorporate Swaps Rulemaking. 17 CFR 38.2; and removal of part 8 at 77 FR 66304 (Nov. 2, 2012).

[8] 17 CFR parts 9, 37, and 38. For example, in Commission regulation 9.2(k) the definition of ''summary action'' cites to Commission regulations 8.17(b), 8.25, and 8.27 which were removed along with the entirety of part 8. Proposed Commission regulation 9.2(k) will instead cite to part 37, appendix B, Core Principle 2, paragraphs (a)(10)(vi), (a)(13), and (a)(14) [for SEFs] and part 38, appendix B, Core Principle 13, paragraphs (a)(4), (a)(6), and (a)(7) [for DCMs].

registrants, including SEFs.[9] Pursuant to the Dodd-Frank Act, the Commission adopted new rules in part 37 Core Principles and Other Requirements for Swap Execution Facilities (''SEF Final Rules'').[10] The Commission notes that since the advent of the Dodd-Frank Act's new statutory framework for regulating swaps, it adopted a rulemaking (Adaptation of Regulations to Incorporate Swaps) implementing conforming changes to existing regulations to clarify those pre-Dodd-Frank provisions, including those applicable to SEFs.[11] Part 9, however, which also applies to SEFs, was not addressed in this rulemaking.[12] As such, in regulation 37.2 of the SEF Final Rules, the Commission specified that SEFs shall comply with the requirements of part 9.[13] Accordingly, for clarity purposes, this NPRM amends certain part 9 definitions and language which have not yet been addressed, to better integrate them into the post-Dodd-Frank regulatory regime.

II. Proposed Amendments to Regulations

A. Introduction

This Proposal contains amendments of three different types: Ministerial, accommodating, and substantive. Most of the proposed amendments are purely ministerial—for instance, some of the proposed changes would update definitions in Commission regulation 9.2 to conform them to the CEA as amended by the Dodd-Frank Act as well as other sections of the Commission's regulations. Furthermore, as noted above, the citations to part 8 in the current part 9 rules would be replaced with the appropriate citations to regulations, guidance, and acceptable practices from parts 37 and 38.[14] In a similar vein, one of the proposed amendments to Commission regulation 9.1 would remove the reference to section 5a(a)(11) of the CEA, since this section was eliminated by the passage of the Commodity Futures Modernization Act of 2000 (''CFMA'').[15]

The proposed accommodating amendments do not impose any new obligations on SEFs; rather they clarify that SEFs, in addition to DCMs, must comply with part 9.[16] This clarification would be accomplished by updating part 9's definition of ''exchange'' to include SEFs and to add swaps to language discussing the types of transactions from which an exchange disciplinary action might arise. These amendments are more than ministerial because they require some judgment in drafting. Another example of an accommodating amendment is the proposed formal codification of the part 3 and part 9 advisories and the Commission's delegation to the National Futures Association (''NFA'') of the responsibility to receive notice of final exchange disciplinary and access denial actions, in which the Commission encouraged exchanges to comply with the notice requirements in Commission regulation 9.11 (''9.11 notice'') by filing with the NFA.[17] Additionally, the proposed amendment to Commission regulation 9.11(b)(3)(ii) would codify the clarification contained in the Part 9 Advisory that an exchange indicate in its notice of disciplinary or access denial actions whether the violation underlying the notice resulted in financial harm to any customers.[18]

The remaining proposed amendments are generally substantive in that they include an additional element required to be included in the contents of a 9.11 notice and a material revision to Commission regulation 9.13 which currently requires exchanges to post notice of final exchange disciplinary action on the exchange's premises.[19] First, as part 9 pertains to both DCMs and SEFs which offer a number of varied products for trading, the proposed amendment to Commission regulation 9.11 would require exchanges to include the type of product (as applicable) involved in the adverse action in the contents of the final notice. Second, the proposed amendment to Commission regulation 9.13 would remove the requirement to post notice on the exchange's premises and instead require the exchange to post the notice on the exchange's Web site. Finally, as addressed above in the discussion of accommodating amendments, the Commission is proposing to codify the Part 9 Advisory. By specifying in the rule text that exchanges provide notice of final exchange disciplinary and access denial actions directly to the NFA, the Commission is eliminating the option for exchanges to file notice with the Commission.

B. Part 9

1. Commission Regulation 9.1: Scope of Rules

Commission regulation 9.1 governs the review by the Commission, pursuant to section 8c of the CEA, of any suspension, expulsion, disciplinary or access denial action, or other adverse action by an exchange.[20] As noted above, the Commission is proposing a ministerial amendment to regulation 9.1(b)(1) by removing the reference to section 5a(a)(11) of the CEA, since this section was eliminated by the passage of the CFMA.[21]

Commission regulation 9.1(b)(2) provides an exclusion from the part 9 regulations with respect to the Commission's review of summary actions imposed by an exchange for a minor penalty for the violation of exchange rules relating to decorum, attire, or timely submission of accurate records required for clearing or verifying each day's transactions or similar activities. The Commission proposes to amend regulation 9.1(b)(2) by replacing the reference to regulation 8.27 with a reference to part 37 guidance pertaining to violations of rules regarding timely submission of records and part 38 guidance pertaining to summary fines for violations of rules regarding timely submission of records, decorum, or other similar activities.[22]

Commission regulation 9.1(b)(3) provides an exclusion from the part 9 regulations concerning any exchange action arising from a claim, grievance, or dispute involving cash market transactions which are not a part of, or directly connected with, any transaction for the purchase, sale, delivery or exercise of a commodity for future delivery, or a commodity option. The Commission proposes to amend regulation 9.1(b)(3) by inserting ''swap'' at the end of the paragraph to account

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[9] *See generally* Dodd-Frank Wall Street Reform and Consumer Protection Act, Public Law 111–203, 124 Stat. 1376 (2010) available at *http://www.cftc.gov/LawRegulation/OTCDERIVATIVES/index.htm; see also* Dodd-Frank Act section 721(a)(50), adding CEA section 1a(50), codified at 7 U.S.C. 1a(50).

[10] 78 FR 33476 (June 4, 2013).

[11] 77 FR 66288 (Nov. 2, 2012).

[12] *Id.*

[13] *See* 78 FR 33476, 33479 (June 4, 2013); 17 CFR 37.2.

[14] 17 CFR parts 37 and 38.

[15] Public Law 106–554, 114 Stat. 2763, sec. 110 (2000).

[16] 17 CFR part 9, §§ 37.2 and 38.2.

[17] 64 FR 39913 (July 23, 1999) (''Part 9 Delegation''); 64 FR 39912 (July 23, 1999) (''Part 3 Advisory''); 64 FR 39915 (July 23, 1999) (''Part 9 Advisory''). As discussed more fully below in the preamble, the Part 9 Advisory permits exchanges to file 9.11 notices of final disciplinary or access denial actions with the Commission or with the NFA. The Part 9 Delegation gives the NFA authority to receive and process these notices on behalf of the Commission. Finally, the Part 3 Advisory relieves registrants and registrant applicants from Commission regulation 3.31 Form 3–R reporting obligations in instances when the information to be reported is solely the result of an exchange disciplinary or access denial action.

[18] 64 FR 39917 (July 23, 1999).

[19] 17 CFR 9.11 and 9.13.

[20] 7 U.S.C. 12c.

[21] Public Law 106–554, 114 Stat. 2763, sec. 110 (2000).

[22] The proposed references would be to (i) part 37 guidance, 17 CFR part 37, appendix B, Core Principle 2, paragraph (a)(13); and (ii) part 38 guidance, 17 CFR part 38, appendix B, Core Principle 13, paragraph (a)(6).

for swap transactions on a DCM or on a SEF as a result of the Dodd-Frank Act.[23] As noted above, the addition of ''swap'' language is a conforming amendment as it requires some judgment as to its inclusion.

Commission regulation 9.1(c) provides for the applicability of part 9 rules to matters filed with the Commission after August 6, 1987. In 1987, the part 9 rules in place at the time were superseded and Commission regulation 9.1(c) governed whether an existing matter would be subject to the pre- or post-1987 part 9 rules. Such determination is no longer necessary because no pre-1987 matters are pending before the Commission. As a result, the Proposal seeks to remove text from Commission regulation 9.1(c) that governs whether a matter would be subject to the pre- or post-1987 part 9 rules.

2. Commission Regulation 9.2: Definitions

The Commission proposes to revise the definition of four terms in regulation 9.2. First, the Commission proposes to revise the definition of ''disciplinary action'' in regulation 9.2(b) by deleting the reference to regulation 8.03(i). The Commission also proposes to remove the reference to ''member of an exchange'' and insert ''person'' in its place. The Commission believes it is necessary to expand the ''disciplinary action'' definition to account for instances where an exchange imposes sanctions against a person that is not a member of the exchange. The Commission's proposal to include ''person'' in the ''disciplinary action'' definition is consistent with the statutory language found in Core Principle 2 for DCMs and section 8c(b) of the CEA, as amended by the Dodd-Frank Act.[24]

Second, the Commission proposes to amend the definition of ''exchange'' in regulation 9.2(c) to include SEFs. This change would make clear that the Commission has the discretion to review adverse actions imposed by a SEF and clarify that SEFs are subject to all of the part 9 requirements.[25]

Third, the Commission proposes to amend regulation 9.2(f) to expand the definition of ''member of an exchange'' to include any person who has trading privileges on an exchange. This change is necessary to conform the part 9 definition of ''member'' to the meaning set forth in section 1a(34) of the CEA and in § 1.3(q) of the Commission's regulations.[26]

Fourth, the Commission proposes to amend the definition of ''summary action'' in regulation 9.2(k) by adding references to part 37 for SEFs and replacing the part 8 references with the relevant provisions from part 38.[27]

3. Commission Regulation 9.4: Filing and Service; Official Docket

Commission regulation 9.4(a) describes the procedures for filing any document required by part 9 to be filed with the Commission Procedures Clerk, including proof of filing and proof of service. To ease the burden on parties, the Commission proposes to amend regulation 9.4(a) by replacing the requirement of a formal affidavit of service with the requirement that parties submit a signed ''statement of service'' that: (1) Confirms that service has been made; (2) identifies each person served; (3) sets forth the date of service; and (4) recites the manner of service. The less formal and less burdensome statement of service effectively serves the same purpose as an affidavit of service (*i.e.,* promoting and assuring the full exchange of information among the parties by requiring service of submissions on all of the parties in the proceeding). Additionally, the Commission proposes to amend regulation 9.4(b)(1) to reduce the burden on parties by requiring an original and one copy (instead of two copies) of all documents filed with the Commission.

4. Commission Regulation 9.11: Form, Contents and Delivery of Notice of Disciplinary or Access Denial Action

Commission regulation 9.11(a) requires that whenever an exchange makes a decision, pursuant to which disciplinary action or access denial to be imposed has become final, the exchange must provide written notice of such action to the person against whom the action was taken and to the Commission within 30 days thereafter. In 1999, the Commission delegated authority to the NFA to receive and process exchange disciplinary and access denial information (''Part 9 Delegation'').[28] Consequently, the NFA currently serves as the official custodian of records for exchange disciplinary filings. The Commission intends to again delegate authority to the NFA, via an updated order to be published concurrently with the final rule, to receive and process exchange disciplinary and access denial information. The Commission proposes to issue an updated order that includes specific duties delegated to the NFA, such as: (1) To process exchange disciplinary information; (2) to provide the Commission with access to a report summarizing all recent exchange disciplinary information; (3) to assist the Commission in enforcing exchange compliance with regulation 9.11 filing requirements; and (4) to serve as the official custodian of a database containing records of the exchanges' disciplinary and access denial actions.

In 1999, concurrent with the Part 9 Delegation, the Commission published an advisory permitting exchanges to file 9.11 notices with the Commission or the NFA (''Part 9 Advisory'').[29] While

[23] Section 723(a)(3) of the Dodd-Frank Act added section 2(h)(8) of the CEA to require, among other things, that execution of swaps subject to the clearing requirement of section 2(h)(1) of the CEA must occur on either a DCM or a SEF.

[24] Section 735 of the Dodd-Frank Act amends section 5 of the CEA, including DCM Core Principle 2. Paragraph (B)—Capacity of Contract Market—of Core Principle 2 specifically requires that the board of trade shall have the capacity to detect, investigate, and apply appropriate sanctions to any *person* that violates any rule of the contract market. Section 8c(b) of the CEA, 7 U.S.C. 12c(b), provides that the Commission may, in its discretion and in accordance with such standards and procedures as it deems appropriate, review any decision by an exchange whereby a person is suspended, expelled, disciplined, or denied access to the exchange. In addition, section 8c(b) of the CEA provides that the Commission may, in its discretion and upon application of any person who is adversely affected by any other exchange action, review such action.

[25] *Id.* The Commission notes that regulation 37.2 requires, among other things, that a SEF shall comply with the part 9 regulations. 17 CFR 37.2. Additionally, footnote 40 of the SEF Final Rules states ''the term 'exchange' used in part 9 of the Commission's regulations should be interpreted to include a SEF for purposes of applying the requirements of part 9 to a SEF.'' 78 FR 33476, 33479 (June 4, 2013).

[26] Section 1a(34) of the CEA provides that the term ''member'' means, among other things, an individual, association, partnership, corporation, or trust having trading privileges on the registered entity. *See also* 17 CFR 1.3(q). By amending the definition of ''member of an exchange'' to include all persons with trading privileges, the Commission is clarifying that the appellate process and Commission review, as defined in part 9, would apply to all persons with trading privileges.

[27] Specifically, the proposed definition of ''summary action'' means a disciplinary action resulting in the imposition of a penalty on a person for violation of rules of the exchange permitted under the provisions of part 37, appendix B, Core Principle 2, paragraph (a)(10)(vi) or part 38, appendix B, Core Principle 13, paragraph (a)(4) (penalty for impeding progress of hearing); part 37, appendix B, Core Principle 2, paragraph (a)(14) or part 38, appendix B, Core Principle 13, paragraph (a)(7) (emergency disciplinary actions); part 37, appendix B, Core Principle 2, paragraph (a)(13) (summary fines for violations of rules regarding timely submission of records); or part 38, appendix B, Core Principle 13, paragraph (a)(6) (summary fines for violations of rules regarding timely submission of records, decorum, or other similar activities).

[28] 64 FR 39913 (July 23, 1999). The NFA created the Background Affiliation Status Information Center (''BASIC'') system through which the public can access information pertaining to the types of violations committed, penalties imposed, the effective date of the action, and, in some cases, the text from the exchange's decision.

[29] 64 FR 39915 (July 23, 1999).

permitting filing with the Commission, the Part 9 Advisory encourages exchanges to file the required notice with the NFA and to do so electronically as the Commission believes such filing to be faster and more cost-effective for both the exchanges and the NFA. In an effort to codify the Part 9 Advisory and formally replace the regulation 9.11 requirement that written notice be provided to the Commission, the Commission proposes to amend regulation 9.11 to require that notice be provided to the NFA via the NFA's BASIC system and eliminate the option of filing the notice with the Commission.

Additionally, the Commission proposes to amend regulation 9.11(a) by replacing the reference to regulation 8.27 with a reference to part 38.[30]

Commission regulation 9.11(b) sets forth the content that must be included in the disciplinary notice. The Commission proposes ministerial and conforming amendments to regulation 9.11(b) by inserting references to part 37, replacing the references to part 8 with references to part 38, codifying the Part 9 Advisory clarification that the contents of the notice include whether the violation resulted in customer harm, and specifying the content of notices provided to: (1) The person against whom the action was taken and (2) the NFA. Additionally, for the sake of clarity, the Commission is proposing to renumber regulation 9.11(b) by assigning separate paragraphs 9.11(b)(1) to specify the notice to be provided by DCMs, 9.11(b)(2) to specify the notice to be provided by SEFs, and 9.11(b)(3) to detail the list of items to be included in the contents of the notice.

Furthermore, the Commission is proposing a substantive amendment to regulation 9.11(b)(3)(ii) by adding an additional element required to be included in the contents of the notice. Because part 9 pertains to both DCMs and SEFs, which offer a number of varied products for trading, the Commission believes that requiring exchanges to detail the type of product (as applicable) involved in the adverse action as part of the 9.11 notice will provide the Commission, market participants, the public, and other exchanges with greater transparency concerning where market abuses originate and whether the abuses are concentrated among certain product types.[31] Specifically, proposed Commission regulation 9.11(b) provides that for purposes of part 9, the notice of disciplinary action or access denial action provided to the person against whom the action was taken may be a copy of a decision which accords with part 37 and part 38 regulations and guidance.[32] Alternatively, the notice provided to the person against whom the action was taken must include: (i) The name of the individual against whom the action was taken; (ii) a statement of the reasons for the action, detailing the exchange product which was involved, as applicable, and whether the violation that resulted in the action also resulted in financial harm to any customers together with a list of any rules which the individual was charged with having violated or which otherwise serve as the basis of the action; (iii) a statement of the exchange's conclusions and findings regarding each violation charged or, in the event of a settlement, a statement specifying those rule violations which the exchange believes were committed; (iv) the terms of the action; (v) the date the action was taken and the date the action will become effective; and (vi) a statement informing the party subject to the action of the availability of Commission review pursuant to section 8c of the CEA. Additionally, the Commission proposes to amend regulation 9.11(b) by requiring that notice provided to the NFA include items (i)–(v) immediately above.

Commission regulation 9.11(c) sets forth the delivery process that must be followed when providing notice of disciplinary action or access denial action to the person who was the subject to the action, and the filing process that must be followed when providing notice of the action to the Commission. The Commission proposes to amend regulation 9.11(c) by deleting instructions for filing notice with the Commission and replacing them with instructions for filing notice with the NFA. Specifically, proposed Commission regulation 9.11(c) provides that filing of the notice with the NFA is accomplished when an authorized exchange employee verifies the accuracy of the information entered into BASIC.

Commission regulation 9.11(d) sets forth the effect of delivery and filing by mail. The Commission proposes to amend regulation 9.11(d) by deleting instructions related to filing notices with the Commission by mail since proposed regulation 9.11(c) calls for notice filings be made to the NFA via BASIC instead of with the Commission by mail.

Commission regulation 9.11(e) sets forth the procedures for certifying the notice provided pursuant to Commission regulation 9.11. The Commission proposes to amend regulation 9.11(e) by adding instructions for the certification of notice filed with the NFA. Specifically, proposed Commission regulation 9.11(e) provides that notice filed with the NFA is deemed certified when an authorized exchange employee verifies the accuracy of the information entered into BASIC.

5. Commission Regulation 9.12: Effective Date of Disciplinary or Access Denial Action

Pursuant to Commission regulation 9.12(a), a disciplinary action or access denial imposed by an exchange will not become effective until at least 15 days after the written notice prescribed by Commission regulation 9.11 is delivered to the person disciplined or denied access. However, an exchange may cause a disciplinary action to become effective prior to that time under certain circumstances that are identified in Commission regulation 9.12(a)(1)–(a)(4). The Commission proposes to amend regulation 9.12(a)(1)–(a)(4) by adding references to part 37 and replacing references to part 8 with references to part 38.[33]

[30] Specifically, the reference to Commission regulation 8.27 would be replaced with a reference to part 38, appendix B, Core Principle 13, paragraph (a)(6) (summary fines for violations of rules regarding timely submission of records, decorum, or other similar activities) for DCMs. Under the current rule and in the proposed rule, DCMs would not be required to report summary fines with respect to violations related to decorum or attire. Decorum or attire violations do not apply to SEFs. Accordingly, SEFs are required to report all disciplinary and access denial actions to BASIC.

[31] For example, a product trading on a DCM might be specified as a July 2016 Eurodollar future; while a product trading on a SEF may be a CDX North American High Yield Series 26 5 year.

[32] The notice required by Commission regulation 9.11 may be satisfied by providing a copy of the final decision in accordance with part 37, appendix B, Core Principle 2, paragraph (a)(9) or part 38, appendix B, Core Principle 13, paragraph (a)(3) (settlement offers); Commission regulations 37.206(d) or 38.708 (decisions); or part 37, appendix B, Core Principle 2, paragraph (a)(11)(iv) or part 38, appendix B, Core Principle 13, paragraph (a)(5)(iv) (appeal decisions).

[33] Specifically, the Commission proposes to amend regulation 9.12(a)(1) by adding a reference to part 37, appendix B, Core Principle 2, paragraph (a)(14) (emergency disciplinary actions) and replacing the reference to regulation 8.25 with a reference to Part 38, appendix B, Core Principle 13, paragraph (a)(7) (emergency disciplinary actions). In regulation 9.12(a)(2), the Commission proposes to add a reference to part 37, appendix B, Core Principle 2, paragraph (a)(10)(vi) (hearings) and replace the reference to regulation 8.17(b) with a reference to part 38, appendix B, Core Principle 13, paragraph (a)(4) (hearings). The Commission proposes to amend regulation 9.12(a)(3) by adding a reference to part 37, appendix B, Core Principle 2, paragraph (a)(13) (summary fines for violations of rules regarding timely submission of records) and replacing the reference to regulation 8.27 with a reference to part 38, appendix B, Core Principle 13,

Pursuant to Commission regulation 9.12(b), an exchange that determines that a disciplinary action will become effective prior to the expiration of 15 days after written notice must notify the person disciplined in writing either personally or by telegram or other means of written telecommunication. The exchange must also immediately notify the Commission by telegram or other means of written telecommunication. In order to modernize regulation 9.12(b), the Commission proposes to replace references to ''telegram or other means of written telecommunication'' with the term ''email'' and provide a Commission email address where notice of the early effective date can be sent by the exchange.

6. Commission Regulation 9.13: Publication of Notice

Pursuant to Commission regulation 9.13, whenever an exchange suspends, expels or otherwise disciplines, or denies any person access to the exchange, it must make public its findings by disclosing at least the information contained in the notice required by Commission regulation 9.11(b). An exchange also must make such findings public as soon as the disciplinary action or access denial action becomes effective in accordance with the provisions of Commission regulation 9.12 by posting a notice in a conspicuous place on its premises to which its members and the public regularly have access for a period of five consecutive business days. The exchange must also maintain and make available for public inspection a record of the information contained in the disciplinary or access denial notice.

The Commission notes that regulation 9.13 was published in 1987, at a time when futures trading occurred primarily in person in the exchange's trading pits and on exchange premises. Therefore, posting notice of disciplinary action or access denial action on exchange premises, where it could be readily viewed by market participants, was an effective form of publicizing the disciplinary action. Today, most trading on DCMs and some of the trading on SEFs occurs by electronic execution. While some SEF trading is executed via a voice component, both electronic and voice execution occurs between market participants that are in geographically distinct locations and generally do not set foot on exchange premises. Consequently, posting a notice of disciplinary action on the premises of an exchange does little to publicize a disciplinary action. In an effort to modernize Commission regulation 9.13, and to provide better notice of a disciplinary action or an access denial action, the Commission proposes to amend regulation 9.13 to require such notice be posted on an exchange's Web site to which its members, market participants, and the public regularly have access.[34] In addition, to better inform market participants and maintain a public record of disciplinary action taken by an exchange, the Commission proposes to amend regulation 9.13 to require that such notice of a disciplinary action or an access denial action be maintained and readily available on an exchange's Web site.[35] As a result, the existing requirement to maintain and make available for public inspection a record of the information contained in the disciplinary or access denial notice would be eliminated.

The Commission recognizes that NFA BASIC presently acts as the central repository of all disciplinary action taken by DCMs and SEFs. However, such disciplinary information cannot be queried by a specific exchange. In general, the Commission believes that greater access to exchange disciplinary actions provides valuable guidance and information to market participants and potential market participants. Also, maintaining disciplinary actions on an exchange's public Web site can serve to further deter and prevent future misconduct and to improve overall compliance among market participants. In addition, market participants may use such information to educate themselves as to compliance matters, potential violations and related sanctions, as well as to revise their own compliance procedures involving similar business practices. Further, any market participant facing allegations of rule violations may access an exchange's existing disciplinary decisions to gain greater insight on related facts and sanctions. Finally, in an effort to enhance access to disciplinary information, the Commission anticipates that upon the effective date of the final part 9 rules, it will include links on its SmartCheck Web site to each exchange's Web site for posting notice of disciplinary action or access denial action.[36]

7. Commission Regulation 9.24: Petition for Stay Pending Review

Commission regulation 9.24 provides the procedures that a person disciplined or denied access by an exchange must follow in the event that a person petitions the Commission to stay a disciplinary or access denial action. The Commission proposes to amend regulation 9.24(a)(2) by adding a reference to part 37 and replacing the reference to part 8 with a reference to part 38.[37] In addition, the Commission proposes to remove the reference to regulation 8.26, which provided for emergency action hearing procedures, from regulation 9.24(a)(2), as the part 37 and 38 emergency disciplinary action guidance (cited above) provides for emergency action hearing procedures.

8. Commission Regulation 9.31: Commission Review of Disciplinary or Access Denial Action on Its Own Motion

Commission regulation 9.31(a) permits the specified Divisions at the Commission to request that an exchange file the record of an exchange proceeding and other documents applicable to an exchange proceeding with such Divisions, upon review of the

paragraph (a)(6) (summary fines for violations of rules regarding timely submission of records, decorum, or other similar activities).

[34] The Commission acknowledges that many DCMs have already adopted more modern methods to publicize notices of disciplinary action. For example, the CME Group DCMs (Chicago Board of Trade (''CBOT''), Chicago Mercantile Exchange (''CME''), Commodity Exchange, Inc., (''COMEX''), and New York Mercantile Exchange, Inc. (''NYMEX'')) and ICE Futures U.S. notify subscribers of exchange disciplinary postings via email. The Commission also notes that the proposed amendment generally tracks the Securities and Exchange Commission's (''SEC'') standards for Release of Disciplinary Complaints, Decisions and Other Information in Financial Industry Regulatory Authority, Inc. (''FINRA'') Rule 8313, in which FINRA, with SEC approval, has established its standard for releasing to the public a copy of FINRA issued disciplinary complaints, decisions, and other disciplinary information. *See* FINRA Rule 8313 ''Release of Disciplinary Complaints, Decisions and Other Information,'' available at *http://finra.complinet.com/en/display/display_main.html?rbid=2403&element_id=3892. See also* SEC Release No. 34–69825; File No. SR–FINRA–2013–018 (June 21, 2013).

[35] Some DCMs currently maintain records of disciplinary action on their Web sites. For example, CBOE Futures Exchange, LLC maintains a disciplinary decision database on its Web site that allows the public to review disciplinary decisions dating back to 2012. The Commission notes that in the securities industry, the New York Stock Exchange maintains disciplinary notices as far back as 1972.

[36] In November 2014, the CFTC launched the SmartCheck Web site. It connects investors to tools to check the registration, license, and disciplinary history of certain financial professionals. This collection of tools allows the responsible investor to confirm the credentials of investment professionals, uncover any past disciplinary history, and stay ahead of scam artists with news and alerts.

[37] Specifically, the Commission proposes to add a reference to part 37, appendix B, Core Principle 2, paragraph (a)(14) (emergency disciplinary actions) and replace the reference to regulation 8.25 with a reference to part 38, appendix B, Core Principle 13, paragraph (a)(7) (emergency disciplinary actions).

exchange notice specified in Commission regulation 9.11, in instances where the person disciplined or denied access by the exchange has not appealed the exchange decision to the Commission. The Commission proposes to amend regulation 9.31(a) to delete the reference to the Division of Clearing and Risk from the first sentence. This provision had previously been amended to replace an earlier reference to the Division [of] Clearing and Intermediary Oversight with references to the Division of Swap Dealer and Intermediary Oversight and the Division of Clearing and Risk, as the successors to the Division of Clearing and Intermediary Oversight. Given the current organizational responsibilities of the Divisions, it is not necessary to include the Division of Clearing and Risk in Commission regulation 9.31(a). The Division of Clearing and Risk does not typically review notices of exchange disciplinary or access denial actions filed pursuant to Commission regulation 9.11 but instead reviews reports regarding rule enforcement activities and sanctions imposed against clearing members by registered derivatives clearing organizations pursuant to Commission regulations 39.17(a)(3) and 39.19(c)(4)(xi). The Commission also proposes to amend regulation 9.31(a) by adding language that requires the exchange to provide information to the requesting Division in the manner requested by the Division and to the person who is the subject of the disciplinary or access denial action in the manner prescribed by regulation 9.11(c).

The Commission also proposes to amend regulation 9.31(b) to replace reference to the ''Commission'' with ''NFA'' in the second sentence. Such replacement is necessary to conform Commission regulation 9.31(b) to proposed changes to Commission regulation 9.11 that call for a notice of disciplinary or access denial action to be provided to the NFA.

9. Minor Changes to Commission Regulations 9.3, 9.4, 9.8, and 9.9

The Commission proposes to amend regulation 9.3 by correcting the referenced title of regulation 12.7 to read ''Ex parte communications in reparation proceedings.'' The Commission also proposes to amend regulations 9.4(b)(4) and (c)(3), 9.8(1), and 9.9(b)(3) and (4) to make them gender neutral.

C. Part 3

1. Commission Regulation 3.31: Deficiencies, Inaccuracies, and Changes To Be Reported

Pursuant to Commission regulation 3.31, an applicant or registrant as a futures commission merchant, retail foreign exchange dealer, swap dealer, major swap participant, commodity trading advisor, commodity pool operator, introducing broker, floor trader that is a non-natural person or leverage transaction merchant shall promptly correct any deficiency or inaccuracy in Form 7–R or Form 8–R which has rendered the information contained therein non-current or inaccurate. These corrections must be made on Form 3–R and filed in accordance with the form's instructions (such instructions presently require that Form 3–R be filed with the NFA).

In 1999, concurrent with the Part 9 Delegation and Part 9 Advisory, the Commission issued an advisory pertaining to part 3 of the Commission's regulations (''Part 3 Advisory''). The Part 3 Advisory relieves registrants and applicants for registrant status from filing a Form 3–R, as required under Commission regulation 3.31, if the information to be reported is solely the result of an exchange disciplinary or access denial action.[38] The Part 3 Advisory also explains that the Commission has: (1) Permitted exchanges (via the Part 9 Advisory) to file either electronic or written 9.11 notices with the NFA instead of the Commission and (2) delegated to the NFA (via the Part 9 Delegation) the duty to receive and process exchange disciplinary and access denial action information filed by the exchanges in accordance with Commission regulation 9.11. The Commission further explained that, as a result of the Part 9 Advisory and Part 9 Delegation, the NFA possesses the exchange disciplinary and access denial action information that registrants and applicants for registration status would otherwise be required to include in Form 3–R. Therefore, to avoid duplicative reporting, the Part 3 Advisory advises all individuals and entities subject to Commission regulation 3.31 that they are relieved from Commission regulation 3.31 reporting obligations resulting from an exchange disciplinary or access denial action and reported by an exchange pursuant to a 9.11 notice.

As discussed above, the Commission intends to again delegate authority to the NFA to receive and process exchange disciplinary and access denial information. Additionally, the Commission seeks to replace the Part 9 Advisory by proposing to amend regulation 9.11 to require that notice be provided to the NFA via the NFA's BASIC system. Similarly, the Commission intends to codify the Part 3 Advisory by proposing to amend the end of the first sentence of regulation 3.31(a)(1) with language that relieves the following applicants or registrants from filing a Form 3–R if the information to be reported is solely the result of an exchange disciplinary or access denial action: Futures commission merchants (''FCMs''), retail foreign exchange dealers (''RFEDs''), swap dealers (''SDs''), major swap participants (''MSPs''), commodity trading advisors (''CTAs''), commodity pool operators (''CPOs''), introducing brokers (''IBs''), floor traders (''FTs'') that are non-natural persons or leverage transaction merchants (''LTMs'').

III. Related Matters

A. Regulatory Flexibility Act

The Regulatory Flexibility Act (''RFA'') requires that agencies consider whether the regulations they propose will have a significant economic impact on a substantial number of small entities and, if so, provide a regulatory flexibility analysis respecting the impact.[39] The part 9 rules proposed by the Commission will impact all SEFs and DCMs. The Commission has previously established certain definitions of ''small entities'' to be used by the Commission in evaluating the impact of its regulations on small entities in accordance with the RFA.[40] The Commission has also determined that DCMs and SEFs are not small entities for the purpose of the RFA.[41]

The part 3 rules proposed herein would affect certain applicant or registrant FCMs, RFEDs, SDs, MSPs, CTAs, CPOs, IBs, FTs who are non-natural persons, and LTMs who would no longer have to file a Form 3–R if the information to be reported is solely the result of an exchange disciplinary or access denial action. The Commission has previously determined that FCMs, RFEDS, SDs, MSPs, CPOs, and LTMs are not small entities for purposes of the RFA.[42] Therefore, the requirements of

[38] 64 FR 39912 (July 23, 1999).

[39] 5 U.S.C. 601 *et seq.*

[40] *See* 47 FR 18618 through 18621 (Apr. 30, 1982).

[41] *See* 47 FR 18618, 18619 (Apr. 30, 1982) (DCMs); 78 FR 33548 (June 4, 2013) (SEFs).

[42] *See* Policy Statement and Establishment of Definitions of ''Small Entities'' for Purposes of the Regulatory Flexibility Act, 47 FR 18618 (Apr. 30, 1982) (FCMs and CPOs); Leverage Transactions, 54 FR 41068 (Oct. 5, 1989) (LTMs); Regulation of Off-Exchange Retail Foreign Exchange Transactions and

the RFA do not apply to those entities. With respect to CTAs, FTs, and IBs, the Commission has found it appropriate to consider whether such registrants should be deemed small entities for purposes of the RFA on a case-by-case basis, in the context of the particular Commission regulation at issue.[43] As certain of these registrants may be small entities for purposes of the RFA, the Commission has considered whether this Proposal would have a significant impact on these registrants.

The proposed amendment to Commission regulation 3.31 is technical and not substantive in nature. In 1999, the Commission published the Part 3 Advisory which relieved all applicants and registrants from filing a Form 3–R, as required under Commission regulation 3.31, if the information to be reported is solely the result of an exchange disciplinary or access denial action.[44] As discussed in the preamble, the proposed amendment codifies the filing relief set forth in the Part 3 Advisory and would not impose any new regulatory obligations on any registrant, including CTAs, FTs, and IBs. The Commission does not, therefore, expect small entities to incur any additional costs as a result of this Proposal. Consequently, the Commission finds that no significant economic impact on small entities will result from this Proposal.

Accordingly, the Chairman, on behalf of the Commission pursuant to 5 U.S.C. 605(b), certifies that the proposed rules will not have a significant economic impact on a substantial number of small entities.

B. Paperwork Reduction Act

1. Introduction

The Paperwork Reduction Act of 1995 (''PRA'') imposes certain requirements on Federal agencies, including the Commission, in connection with their conducting or sponsoring any collection of information, as defined by the PRA.[45] 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 control number issued by the Office of Management and Budget (''OMB''). This NPRM contains recordkeeping and reporting requirements that are collections of information within the meaning of the PRA.

The Proposal contains provisions that would qualify as collections of information, for which the Commission has already sought and obtained control numbers from the OMB. The titles for these collections of information are ''Part 38—Core Principles and Other Requirements for Designated Contract Markets'' (OMB Control Number 3038–0052) and ''Part 37—Core Principles and Other Requirements for Swap Execution Facilities'' (OMB Control Number 3038–0074). If adopted, responses to these collections of information would be mandatory.

As discussed below, the Commission is not seeking to amend information collections 3038–0052 or 3038–0074 because the Commission believes that the rule modifications proposed herein will not impose any new information collection requirements that require approval from OMB under the PRA. Accordingly, the Commission invites public comment on the accuracy of its estimate regarding the impact of proposed Commission regulation 9.11 on collections 3038–0052 and 3038–0074 and its determination that no additional recordkeeping or information collection requirements or changes to existing collection requirements would result from the Proposal.[46]

2. Section 9.11 Amendments

As discussed above, the proposed Commission regulation 9.11 amendments are primarily technical and not substantive in nature. Commission regulation 9.11 currently requires that whenever an exchange makes a decision, pursuant to which disciplinary action or access denial to be imposed has become final, the exchange must provide written notice of such action to the person against whom the action was taken and to the Commission within 30 days thereafter. Among the proposed amendments to regulation 9.11, the Commission is clarifying the existing rules to formally incorporate SEFs under the requirements and therefore include references to the part 37 SEF regulations.[47]

Furthermore, the Commission is proposing to add an additional element required to be included in the contents of the notice specifying which product type (as applicable) was involved in the adverse action. The Commission believes that by adding such additional element to the contents of the notice its impact on the burden would be de minimis. For example, to describe a product trading on a DCM, the notice might include the description, ''July 2016 Eurodollar future;'' while a product trading on a SEF may be a ''CDX North American High Yield Series 26 5 year.'' Additionally, as a result of the Commission's removal of part 8, the Commission is proposing to remove all cross-references in regulation 9.11 to the part 8 regulations and replace these references with applicable regulations, guidance, and acceptable practices from parts 37 and 38.[48] Finally, in 1999, the Commission published the Part 9 Advisory permitting exchanges to file 9.11 notices with the Commission or with the NFA.[49] In an effort to codify the Part 9 Advisory and formally replace the regulation 9.11 requirement that written notice be provided to the Commission, the Commission proposes to amend regulation 9.11 to require notice be provided to the NFA via the BASIC system.

3. Clarification of Collections 3038–0052 and 3038–0074

The Commission notes that all DCMs and SEFs are already subject to the part 9 reporting requirements.[50] First, part 9 applies to DCMs, by explicitly defining ''exchange'' in Commission regulation 9.2(c) for purposes of the rules as ''any board of trade which has been designated as a contract market.'' [51] Furthermore, former regulation 38.2, which was adopted by the Commission on August 10, 2001, specifically required DCMs to comply with part 9 (''2001 DCM Rulemaking'').[52] In the 2001 DCM Rulemaking, the Commission requested an OMB control number for part 38 to account for the reporting

Intermediaries, 75 FR 55410, 55416 (Sept. 10, 2010) (RFEDs); and Registration of Swap Dealers and Major Swap Participants, 77 FR 2613, 2620 (Jan. 19, 2012) (SDs and MSPs).

[43] *See* 47 FR 18620 (Apr. 30, 1982) (CTAs); Registration of Floor Traders; Mandatory Ethics Training for Registrants; Suspension of Registrants Charged With Felonies, 58 FR 19575, 19588 (Apr. 15, 1993) (FTs); and Introducing Brokers and Associated Persons of Introducing Brokers, Commodity Trading Advisors and Commodity Pool Operators; Registration and Other Regulatory Requirements, 48 FR 35248, 35276 (Aug. 3, 1983) (IBs).

[44] 64 FR 39912 (July 23, 1999).

[45] 44 U.S.C. 3501 *et seq.*

[46] For collection 3038–0052, *see* OMB Control No. 3038–0052, available at *http://www.reginfo.gov/public/do/PRAOMBHistory?ombControlNumber=3038-0052.* For collection 3038–0074, *see* OMB Control No. 3038–0074, available at *http://www.reginfo.gov/public/do/PRAOMBHistory?ombControlNumber=3038-0074.*

[47] 17 CFR part 37. As explained earlier in the preamble, SEFs are already subject to the part 9 reporting requirements under regulation 37.2, in which the Commission specified that SEFs shall comply with the requirements of part 9.

[48] Removal of part 8 at 77 FR 66288, (Nov. 2, 2012); and 17 CFR parts 37 and 38.

[49] 64 FR 39915 (July 23, 1999).

[50] 17 CFR part 9 and 38.2 [DCMs]; 17 CFR 37.2 [SEFs].

[51] 17 CFR 9.2(c).

[52] 66 FR 42277 (August 10, 2001).

requirements, including part 9.[53] The text of Commission regulation 38.2 that specifically required DCMs to comply with part 9 was amended on June 19, 2012, and currently provides that DCMs shall comply with all applicable regulations under Title 17 of the Code of Federal Regulations, except for certain exempt provisions.[54] Part 9 is not included in the list of exempt provisions. Accordingly, Commission regulation 38.2 still requires that DCMs comply with the part 9 rules, and therefore, the Commission regulation 9.11 reporting requirements. Since the proposed amendments to Commission regulation 9.11 are primarily technical, the Commission believes that these amendments would not impact the current burden estimates in the DCM 3038–0052 collection.

As noted above, SEFs are also subject to the part 9 reporting requirements.[55] The pertinent reporting burden of Commission regulation 9.11 for SEFs is contained in Commission regulation 37.2, which was adopted on June 4, 2013.[56] Among the applicable provisions with which SEFs must comply, Commission regulation 37.2 explicitly lists part 9.[57] Because the proposed amendments to Commission regulation 9.11 are primarily technical, the Commission believes these amendments would not impact the current burden estimates in the SEF 3038–0074 collection.[58]

4. Information Collection Comments

The Commission invites comment on any aspect of the proposed information collection requirements discussed above. Pursuant to 44 U.S.C. 3506(c)(2)(B), the Commission will consider public comments on such proposed requirements in: (1) Evaluating whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have a practical use; (2) evaluating the accuracy of the Commission's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) enhancing the quality, utility, and clarity of the information proposed to be collected; and (4) minimizing the burden of collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological information collection techniques.

Copies of the submission from the Commission to OMB are available from the CFTC Clearance Officer, 1155 21st Street NW., Washington, DC 20581, (202) 418–5160 or from *http://RegInfo.gov*. Persons desiring to submit comments on the proposed information collection requirements should send those comments to: The Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attention: Desk Officer of the Commodity Futures Trading Commission; (202) 395–6566 (fax); or *OIRAsubmissions@omb.eop.gov* (email). Please provide the Commission with a copy of submitted comments so that all comments can be summarized and addressed in the final rulemaking, and please refer to the **ADDRESSES** section of this rulemaking for instructions on submitting comments to the Commission. OMB is required to make a decision concerning the proposed information collection requirements between thirty (30) and sixty (60) days after publication of the Proposal in the **Federal Register**. Therefore, a comment to OMB is best assured of receiving full consideration if OMB (as well as the Commission) receives it within thirty (30) days of publication of the Proposal.

C. Cost-Benefit Considerations

1. Introduction

Section 15(a) of the CEA requires the Commission to consider the costs and benefits of its actions before promulgating a regulation under the CEA or issuing certain orders.[59] Section 15(a) further specifies that the costs and benefits shall be evaluated in light of five broad areas of market and public concern: (1) Protection of market participants and the public; (2) efficiency, competitiveness, and financial integrity of the markets; (3) price discovery; (4) sound risk management practices; and (5) other public interest considerations. The Commission considers the costs and benefits resulting from its discretionary determinations with respect to the section 15(a) factors.

The Commission considers the costs and benefits associated with the proposed amendments, including updating the pre-existing regulatory framework to incorporate SEFs, removing references to part 8 of the Commission's regulations, and revising the reporting and notice requirements for DCMs and SEFs. The Commission compares the costs and benefits of this rulemaking against a baseline of the status quo, the current requirements under part 3 and part 9. As discussed more fully below, the Commission preliminarily believes that the only new cost that would be imposed by the Proposal is the requirement in Commission regulation 9.13 for DCMs and SEFs to publish and maintain disciplinary notices on their respective Web sites.

2. Part 3 and Part 9 Technical Amendments

As explained above, the proposed amendments to part 3 and part 9 are primarily technical in nature. The Commission believes that these technical amendments will not impose any new costs on DCMs, SEFs, or market participants. For example, among the proposed changes, the Commission is clarifying the definition of ''exchange'' to include SEFs and updating the references to part 8, which was removed by the Commission in 2012, to instead cite to parallel provisions now contained in parts 37 and 38.[60] Furthermore, the proposed revisions to Commission regulations 3.31 and 9.11 codify existing reporting procedures which were already authorized by the Commission in the Part 3 Advisory and Part 9 Advisory.[61] These proposed amendments do not substantively change the requirements that the Commission currently imposes on DCMs and SEFs.[62] Rather, instead of providing the 9.11 notices to the Commission, as required under the current part 9 rules, proposed regulation 9.11 will instead instruct exchanges to provide the notices to the NFA, as is permitted as an alternative method of compliance under the Part 9 Advisory.[63]

There is also the ministerial benefit to codifying the Part 3 and Part 9 Advisories. Advisories are staff action and are not rules that have been promulgated by the Commission subject to public notice and comment. Thus, this rulemaking will achieve the benefit

[53] *Id.* at 42268.

[54] 77 FR 36697 (June 19, 2012); 17 CFR 38.2.

[55] 17 CFR 37.2.

[56] 78 FR 33476 (June 4, 2013).

[57] 17 CFR 37.2.

[58] *Supra* note 46.

[59] 7 U.S.C. 19(a).

[60] Removal of part 8 at 77 FR 66288 (Nov. 2, 2012); and 17 CFR parts 37 and 38. *See, e.g.,* 17 CFR part 37 appendix B, Core Principle 2, paragraph (a)(13) and part 38, appendix B, Core Principle 13, paragraph (a)(6).

[61] Part 9 Advisory: 64 FR 39915 (July 23, 1999); Part 3 Advisory: 64 FR 39912 (July 23, 1999).

[62] *Supra* note 46. As noted above in the PRA, the Commission believes the proposed substantive amendment to add an additional element required to be included in the contents of a 9.11 notice will not materially impact the costs imposed by this NPRM.

[63] 17 CFR 9.11.

of codifying the Part 3 Advisory and Part 9 Advisory into rules.

3. Summary of Proposed Amendments to Commission Regulation 9.13—Publication of Notice

As discussed above, proposed Commission regulation 9.13 would require all DCMs and SEFs to maintain and make readily accessible final notices of exchange disciplinary and access denial actions on their Web sites.[64] This new requirement would replace the existing requirement in Commission regulation 9.13 that exchanges publish the notice in a conspicuous place on the exchange's premises.

a. Costs

The Commission believes that posting final disciplinary and access denial notices to exchange Web sites will slightly increase the costs for DCMs and SEFs. The Commission notes that the additional costs incurred by DCMs and SEFs would be offset in part due to the proposed amendment in Commission regulation 9.13 that would remove the requirement of posting disciplinary and access denial notices on the premises of the respective DCM or SEF. In order to estimate the additional costs, the Commission queried the NFA's BASIC to determine the total number of disciplinary and access denial actions filed by DCMs in 2015. Because SEFs did not post any disciplinary or access denial actions to BASIC in 2015, the numbers below reflect the disciplinary and access denial actions filed by the 15 DCMs presently registered with the Commission and provide the basis for estimating the number of disciplinary and access denial actions for SEFs annually.[65]

Total number of reported disciplinary and access denial actions in BASIC by all DCMs in 2015: 452.

In order to estimate the costs for SEFs, the Commission calculated the average number of disciplinary and access denial actions filed by DCMs, excluding the four DCMs with the largest number of reported disciplinary and access denial actions.[66] The Commission notes that SEFs are relatively new entities with significantly less volume and fewer participants than the four DCMs that reported the highest number of disciplinary and access denial actions.[67] Therefore, the Commission preliminary believes that the average number of disciplinary and access denial actions reported by the 11 other DCMs in 2015 provide a more appropriate comparison with respect to estimating the number of disciplinary and access denial actions for SEFs annually. As the SEFs mature, in terms of the number of participants and volume, the Commission anticipates that the number of disciplinary and access denial actions may increase accordingly.

Total number of reported disciplinary and access denial actions in BASIC by DCMs in 2015, excluding the 4 DCMs with the largest number of reported actions: 88.

Average number of reported disciplinary and access denial actions in BASIC per DCM in 2015, excluding the 4 DCMs with the largest number of reported actions: 8.

Currently, there are a total of 23 registered SEFs with the Commission. The Commission estimates that each SEF would report at least eight disciplinary and access denial actions annually in BASIC for an aggregate total of 184 disciplinary and access denial actions for all SEFs per year (eight actions multiplied by 23 SEFs equals 184 actions). Thus, the total number of exchange disciplinary and access denial actions per year for all DCMs and SEFs is estimated to be 636 (184 actions for SEFs plus the 452 actions for DCMs equals 636 total actions per year). The Commission anticipates each DCM and SEF would spend an additional 15 minutes per disciplinary notice to post on the exchange's Web site above the current requirement of posting the notice on the exchange's premises. Accordingly, the aggregate new burden of Commission regulation 9.13 is estimated to be 159 hours per year for the 15 DCMs and 23 SEFs (15 minutes multiplied by 636 anticipated actions per year equals 159 burden hours).

The Commission expects that a compliance officer employed by the exchange will be posting the disciplinary or access denial action notices to the exchange Web site. According to recent Bureau of Labor Statistics National Occupational Employment and Wage Estimates, the mean hourly wage of an employee under occupation code 13–1041, ''Compliance Officers,'' that is employed by the ''Securities and Commodity Exchanges'' industry is $46.01. Because DCMs and SEFs can be large, specialized entities that may engage employees with wages above the mean, the Commission has conservatively chosen to use a mean hourly wage of $50 per hour.[68] Accordingly, the burden associated with posting the disciplinary notices on exchange Web sites will total approximately $7,950 per year for all of the 38 DCMs and SEFs, ($50 multiplied by the anticipated 159 burden hours equals $7,950 per year).[69]

b. Benefits

The Commission preliminarily believes that greater access to information regarding exchange disciplinary and access denial actions provides valuable guidance and information to exchange members, market participants, and the public. Releasing disciplinary information to the public can serve to deter and prevent future misconduct and to improve overall compliance standards in the futures and swaps industry. It also allows customers to consider member firms' and traders' disciplinary histories when considering whether to engage in business with them. In addition, firms may use such information to educate their traders and associated persons as to compliance matters, highlighting potential violations and related sanctions. Further, any firm or individual facing allegations of rule violations may access existing disciplinary decisions to gain greater insight on related facts and sanctions. The Commission believes that the added deterrence of publishing the disciplinary notices on the exchange Web sites and the enhanced investigative and educational benefits of making such information public will ultimately decrease the incidents of wrongdoing and market abuses which will benefit both market participants and the general public.

c. Section 15(a) Factors

As noted above, section 15(a) of the CEA requires the Commission to consider the effects of its actions in light of the following five factors:

(1) *Protection of market participants and the public.* The Commission

[64] 17 CFR 9.13.

[65] As of November 9, 2016, 10 summary fines had been assessed by a total of four SEFs. The notices for such summary fines have been posted to BASIC. Because the Commission did not have a complete year of data for 2016, the Commission used the 2015 numbers of disciplinary and access denial actions to calculate the costs.

[66] The DCMs with largest number of reported disciplinary and access denial actions are: ICE Futures U.S., CME, NYMEX, and CBOT.

[67] 78 FR 33476 (June 4, 2013). The SEF Final Rules implemented the SEF framework enacted by section 733 of the Dodd-Frank Act; 7 U.S.C. 7b–3.

[68] Bureau of Labor Statistics, *Occupational Employment and Wages: 13–1041 Compliance Officers,* (May 2014), available at *http://www.bls.gov/oes/current/oes131041.htm.*

[69] The Commission acknowledges that requiring exchanges to post final notices of disciplinary and access denial actions on their Web sites may necessitate additional bandwidth. The Commission anticipates that any increased costs due to added bandwidth would be insignificant in its calculation of the total annual burden associated with this Proposal.

preliminarily believes that market participants and the public will benefit from the ministerial and conforming amendments proposed herein since they eliminate obsolete, vestigial provisions and references that otherwise could be construed to give rise to confusing inconsistencies between the Commission's regulations and the provisions of the CEA. Furthermore, the Commission preliminarily believes that the proposed substantive amendment to regulation 9.13, which would require exchanges to publish notice of final disciplinary and access denial actions on exchange Web sites, would increase transparency of exchange disciplinary actions and serve as a deterrence of future market abuses. These enhancements allow for operational efficiencies in oversight, increased deterrence from market abuses, and greater transparency of the exchange disciplinary process. Therefore, the Commission anticipates that the amendment to regulation 9.13 would result in improved protection of market participants and the public.

(2) *The efficiency, competitiveness, and financial integrity of the markets.* The requirement that exchanges publish disciplinary notices and access denial actions on their Web site is intended to improve the operational efficiency, competitiveness and financial integrity of the futures and swaps markets by enabling the public and those who access the exchange Web site to be made aware of any disciplinary and access denial actions imposed by the exchange. As discussed above, the vast majority of trading no longer occurs in person on the exchange's premises. The Commission believes that the current requirement in regulation 9.13 of posting disciplinary and access denial actions on the exchange's premises provides little to no public notice of these actions. By publishing the notice on the exchange's Web site, the Commission believes that the efficiency, competitiveness and financial integrity of the markets would be bolstered by the deterrent effect achieved by posting the notice in a publicly accessible medium.

(3) *Price discovery.* The Commission has not identified an impact on price discovery as a result of the proposed regulations, but seeks comment as to any potential impact. Will the proposed regulations impact, positively or negatively, the price discovery process?

(4) *Sound risk management practices.* The Commission has not identified an impact on risk management practices as a result of the proposed regulations, but seeks comment as to any potential impact. Will the proposed regulations impact, positively or negatively, sound risk management practices?

(5) *Other public interest considerations.* The Commission has not identified any other public interest considerations, but welcomes comment on whether this Proposal would promote public confidence in the integrity of derivatives markets by making notice of exchange disciplinary and access denial actions more readily available to the public. Will this Proposal impact, positively or negatively, any unidentified matter of interest to the public?

d. Request for Comments

The Commission seeks additional information regarding the costs and benefits of the Proposal. Beyond the specific questions interspersed throughout its discussion above, the Commission requests comment on all aspects of its consideration of costs and benefits, including: Identification and assessment of any costs and benefits not discussed therein; data and any other information to assist or otherwise inform the Commission's ability to quantify or qualitatively describe the benefits and costs of the proposed rules; and substantiating data, statistics, and any other information to support positions posited by commenters with respect to the Commission's consideration of costs and benefits. Commenters also may suggest other alternatives to the proposed approach where the commenters believe that the alternatives would be appropriate under the CEA and provide a superior cost-benefit profile.

IV. Request for Comments

The Commission requests comment on all aspects of the Proposal. Commenters are specifically encouraged to include any considerations related to the Commission's proposed notice and order delegating regulation 9.11 authority to the NFA.

List of Subjects

17 CFR Part 3

Administrative practice and procedure, Brokers, Commodity futures, Major swap participants, Reporting and recordkeeping requirements, Swap dealers.

17 CFR Part 9

Administrative practice and procedure, Commodity exchanges, Commodity futures.

For the reasons stated in the preamble, the Commodity Futures Trading Commission proposes to amend 17 CFR chapter I as follows:

PART 3—REGISTRATION

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

Authority: 5 U.S.C. 552, 552b; 7 U.S.C. 1a, 2, 6a, 6b, 6b–1, 6c, 6d, 6e, 6f, 6g, 6h, 6*i,* 6k, 6m, 6n, 6*o,* 6p, 6s, 8, 9, 9a, 12, 12a, 13b, 13c, 16a, 18, 19, 21, and 23, as amended by Title VII of Pub. L. 111–203, 124 Stat. 1376.

■ 2. In § 3.31, revise paragraph (a)(1) to read as follows:

§ 3.31 Deficiencies, inaccuracies, and changes, to be reported.

(a)(1) Each applicant or registrant as a futures commission merchant, retail foreign exchange dealer, swap dealer, major swap participant, commodity trading advisor, commodity pool operator, introducing broker, floor trader that is a non-natural person or leverage transaction merchant shall, in accordance with the instructions thereto, promptly correct any deficiency or inaccuracy in Form 7–R or Form 8–R that no longer renders accurate and current the information contained therein, with the exception of any change that requires withdrawal from registration under § 3.33 or any change resulting from an exchange disciplinary or access denial action. Each such correction shall be prepared and filed in accordance with the instructions thereto to create a Form 3–R record of such change.

* * * * *

PART 9—RULES RELATING TO REVIEW OF EXCHANGE DISCIPLINARY, ACCESS DENIAL OR OTHER ADVERSE ACTIONS

■ 3. The authority citation for part 9 is revised to read as follows:

Authority: 7 U.S.C. 1a, 2, 6b–1, 6c, 7, 7a–2, 7b–3, 8, 9, 9a, 12, 12a, 12c, 13b, 16a, 18, 19, 21.

■ 4. In § 9.1, revise paragraphs (b) and (c) to read as follows:

§ 9.1 Scope of rules.

* * * * *

(b) *Matters excluded.* This part does not apply to and the Commission will not accept notices of appeal, or petitions for stay pending review, of:

(1) Any arbitration proceeding, regardless of whether the proceeding involved a controversy between members of an exchange;

(2) Except as provided in §§ 9.11(a), 9.11(b)(3)(i) through (v), 9.11(c), 9.12(a) and 9.13 (concerning the notice, effective date and publication of a disciplinary or access denial action), any summary action permitted under the provisions of part 37, appendix B, Core Principle 2, paragraph (a)(13) of

this chapter or part 38, appendix B, Core Principle 13, paragraph (a)(6) of this chapter imposing a minor penalty for the violation of exchange rules relating to decorum or attire, or relating to the timely submission of accurate records required for clearing or verifying each day's transactions or other similar activities; and

(3) Any exchange action arising from a claim, grievance, or dispute involving cash market transactions which are not a part of, or directly connected with, any transaction for the purchase, sale, delivery or exercise of a commodity for future delivery, a commodity option, or a swap.

(4) The Commission will, upon its own motion or upon motion filed pursuant to § 9.21(b), promptly notify the appellant and the exchange that it will not accept the notice of appeal or petition for stay of matters specified in this paragraph. The determination to decline to accept a notice of appeal will be without prejudice to the appellant's right to seek alternate forms of relief that may be available in any other forum.

(c) *Applicability of these part 9 rules.* Unless otherwise ordered, these rules will apply in their entirety to all appeals, and matters relating thereto.

■ 5. In § 9.2, revise paragraphs (b), (c), (f), and (k) to read as follows:

§ 9.2 Definitions.

* * * * *

(b) *Disciplinary action* means any suspension, expulsion or other penalty imposed on a person by an exchange for violations of rules of the exchange, including summary actions.

(c) *Exchange* means a swap execution facility or any board of trade which has been designated as a contract market.

* * * * *

(f) *Member of an exchange* means

(1) Any person who is admitted to membership or has been granted membership privileges on an exchange; any employee, officer, partner, director or affiliate of such member or person with membership privileges including any associated person; and any other person under the supervision or control of such member or person with membership privileges; or

(2) Any person who has trading privileges on an exchange.

* * * * *

(k) *Summary action* means a disciplinary action resulting in the imposition of a penalty on a person for violation of rules of the exchange permitted under the provisions of part 37, appendix B, Core Principle 2, paragraph (a)(10)(vi) of this chapteror part 38, appendix B, Core Principle 13, paragraph (a)(4) (penalty for impeding progress of hearing); part 37, appendix B, Core Principle 2, paragraph (a)(14) of this chapter or part 38, appendix B, Core Principle 13, paragraph (a)(7) (emergency disciplinary actions) of this chapter; part 37, appendix B, Core Principle 2, paragraph (a)(13) (summary fines for violations of rules regarding timely submission of records) of this chapter; or part 38, appendix B, Core Principle 13, paragraph (a)(6) (summary fines for violations of rules regarding timely submission of records, decorum, or other similar activities) of this chapter.

■ 6. Revise § 9.3 to read as follows:

§ 9.3 Provisions referenced.

Except as otherwise provided in this part, the following provisions of the Commission's rules relating to reparations contained in part 12 of this chapter apply to this part: § 12.3 (Business address; hours); § 12.5 (Computation of time); § 12.6 (Extensions of time; adjournments; postponements); § 12.7 (Ex parte communications in reparation proceedings); and § 12.12 (Signature).

■ 7. In § 9.4, revise paragraphs (a), (b), and (c) to read as follows:

§ 9.4 Filing and service; official docket.

(a) *Filing with the Proceedings Clerk; proof of filing; proof of service.* Any document that is required by this part to be filed with the Proceedings Clerk must be filed by delivering it in person or by mail to: Proceedings Clerk, Office of Proceedings, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW., Washington, DC 20581. To be timely filed under this part, a document must be delivered or mailed to the Proceedings Clerk within the time prescribed for filing. A party must use a means of filing which is at least as expeditious as that used in serving that document upon the other parties. Proof of filing must be made by attaching to the document for filing a statement of service as provided in § 10.12(a)(6) of this chapter.

(b) *Formalities of filing*—(1) *Number of copies.* Unless otherwise specifically provided, an original and one conformed copy of all documents filed with the Commission in accordance with the provisions of this part must be filed with the Proceedings Clerk.

(2) *Title page.* All documents filed with the Proceedings Clerk must include at the head thereof, or on a title page, the name of the Commission, the title of the proceeding, the docket number (if one has been assigned by the Proceedings Clerk), the subject of the particular document and the name of the person on whose behalf the document is being filed.

(3) *Paper, spacing, type.* All documents filed with the Proceedings Clerk must be typewritten, must be on one grade of good white paper no less than 8 or more than 8½ inches wide and no less than 10½ or more than 11½ inches long, and must be bound on the top only. They must be double-spaced, except for long quotations (3 or more lines) and footnotes which should be single-spaced.

(4) *Signature.* The original copy of all papers must be signed in ink by the person filing the same or by his or her duly authorized agent or attorney.

(c) *Service*—(1) *General requirements.* All documents filed with the Proceedings Clerk must, at or before the time of filing, be served upon all parties. A party must use a means of service which is at least as expeditious as that used in filing that document with the Proceedings Clerk. One copy of all motions, petitions or applications made in the course of the proceeding, all notices of appeal, all briefs, and letters to the Commission or an employee thereof must be served by a party upon all other parties.

(2) *Manner of service.* Service may be either personal or by mail. Service by mail is complete upon deposit of the document in the mail. Where service is effected by mail, the time within which the person served may respond thereto will be increased by three days.

(3) *Designation of person to receive service.* The first document filed in a proceeding by or on behalf of any party must state on the first page the name and postal address of the person who is authorized to receive service for the party of all documents filed in the proceeding. Thereafter, service of documents must be made upon the person authorized unless service on a different authorized person or on the party himself or herself is ordered by the Commission, or unless pursuant to § 9.8 the person authorized is changed by the party upon due notice to all other parties. Parties must file and serve notification of any changes in the information provided pursuant to this subparagraph as soon as practicable after the change occurs.

* * * * *

■ 8. In § 9.8, revise paragraph (a)(1) to read as follows:

§ 9.8 Practice before the Commission.

(a) *Practice*—(1) *By non-attorneys.* An individual may appear pro se (on his or her own behalf); a general partner may represent the partnership; a bona fide officer of a corporation, trust or

association may represent the corporation, trust or association.

* * * * *

■ 9. In § 9.9, revise paragraphs (b)(3) and (b)(4) to read as follows:

§ 9.9 Waiver of rules; delegation of authority.

* * * * *

(b) * * *

(3) The General Counsel, or his or her designee, may submit to the Commission for its consideration any matter which has been delegated pursuant to paragraph (b)(1) of this section.

(4) Nothing in this section will be deemed to prohibit the Commission, at its election, from exercising the authority delegated to the General Counsel, or his or her designee, under this section.

■ 10. Revise § 9.11 to read as follows:

§ 9.11 Form, contents and delivery of notice of disciplinary or access denial action.

(a) *When required.* Whenever an exchange decision pursuant to which a disciplinary action or access denial action is to be imposed has become final, the exchange must, within thirty days thereafter, provide written notice of such action to the person against whom the action was taken and notice to the National Futures Association (''NFA'') through the NFA's Background Affiliation Status Information Center (''BASIC'') system: *Provided,* That a designated contract market is not required to notify the NFA of any summary action, as permitted under the provisions of part 38, appendix B, Core Principle 13, paragraph (a)(6) of this chapter, which results in the imposition of minor penalties for the violation of exchange rules relating to decorum or attire. No final disciplinary or access denial action may be made effective by the exchange except as provided in § 9.12.

(b) *Contents of notice.* For purposes of this part:

(1) The written notice of a disciplinary action or access denial action provided to the person against whom the action was taken by a designated contract market must be a copy of a written decision which accords with:

(i) Part 38, appendix B, Core Principle 13, paragraph (a)(3) of this chapter in the case of settlement offers;

(ii) Section 38.708 of this chapter in the case of decisions; or

(iii) Part 38, appendix B, Core Principle 13, paragraph (a)(5)(iv) of this chapter in the case of appeal decisions of this chapter (including copies of any materials incorporated by reference) or other written notice which must include items listed in paragraphs (b)(3)(i)–(vi) of this section.

(2) The written notice of a disciplinary action or access denial action provided to the person against whom the action was taken by a swap execution facility must be a copy of a written decision which accords with:

(i) Part 37, appendix B, Core Principle 2, paragraph (a)(9) of this chapter in the case of settlement offers;

(ii) Section 37.206(d) of this chapter in the case of decisions; or

(iii) Part 37, appendix B, Core Principle 2, paragraph (a)(11)(iv) of this chapter in the case of appeal decisions of this chapter (including copies of any materials incorporated by reference) or other written notice which must include items listed in paragraphs (b)(3)(i) through (vi) of this section.

(3) The notice of a disciplinary action or access denial action provided to the NFA must include only the items listed in the following paragraphs (i) through (v):

(i) The name of the person against whom the disciplinary action or access denial action was taken;

(ii) A statement of the reasons for the disciplinary action or access denial action, detailing the exchange product which was involved, as applicable, and whether the violation that resulted in the action also resulted in financial harm to any customers together with a listing of any rules which the person who was the subject of the disciplinary action or access denial action was charged with having violated or which otherwise serve as the basis of the exchange action;

(iii) A statement of the conclusions and findings made by the exchange with regard to each rule violation charged or, in the event of settlement, a statement specifying those rule violations which the exchange has reason to believe were committed;

(iv) The terms of the disciplinary action or access denial action;

(v) The date on which the action was taken and the date the exchange intends to make the disciplinary or access denial action effective; and

(vi) Except as otherwise provided in § 9.1(b), a statement informing the party subject to the disciplinary action or access denial action of the availability of Commission review of the exchange action pursuant to section 8c of the Act and this part.

(c) *Delivery and filing of the notice.* Delivery of the notice must be made either personally to the person who was the subject of the disciplinary action or access denial action or by mail to such person at that person's last known address. Filing of the notice with the NFA is accomplished when an authorized exchange employee verifies the accuracy of the information entered into BASIC.

(d) *Effect of delivery by mail.* Delivery by mail to the person disciplined or denied access will be complete upon deposit in the mail of a properly addressed and postpaid document. Where delivery to the person disciplined or denied access is effected by such mail, the time within which a notice of appeal or petition for stay may be filed will be increased by three days.

(e) *Certification.* Copies of the notice and the submission of any additional information provided pursuant to this section must be certified as true and correct by a duly authorized officer, agent or employee of the exchange. Notice filed with the NFA is deemed certified when an authorized exchange employee verifies the accuracy of the information entered into BASIC.

■ 11. Revise § 9.12 to read as follows:

§ 9.12 Effective date of disciplinary or access denial action.

(a) *Effective date.* Any disciplinary or access denial action taken by an exchange will not become effective until at least fifteen days after the written notice prescribed by § 9.11 is delivered to the person disciplined or denied access; *Provided, however,* That the exchange may cause a disciplinary action to become effective prior to that time if:

(1) As permitted by part 37, appendix B, Core Principle 2, paragraph (a)(14) of this chapter or part 38, appendix B, Core Principle 13, paragraph (a)(7) (emergency disciplinary actions) of this chapter, the exchange reasonably believes, and so states in its written decision, that immediate action is necessary to protect the best interests of the marketplace; or

(2) As permitted by part 37, appendix B, Core Principle 2, paragraph (a)(10)(vi) of the chapter or part 38, appendix B, Core Principle 13, paragraph (a)(4) (hearings) of this chapter, the exchange determines, and so states in its written decision, that the actions of a person who is within the exchange's jurisdiction has impeded the progress of a disciplinary hearing; or

(3) As permitted by part 37, appendix B, Core Principle 2, paragraph (a)(13) (summary fines for violations of rules regarding timely submission of records) of this chapter or part 38, appendix B, Core Principle 13, paragraph (a)(6) (summary fines for violations of rules regarding timely submission of records, decorum, or other similar activities) of

this chapter, the exchange determines that a person has violated exchange rules relating to decorum or attire, or timely submission of accurate records required for clearing or verifying each day's transactions or other similar activities; or

(4) The person against whom the action is taken has consented to the penalty to be imposed and to the timing of its effectiveness.

(b) *Notice of early effective date.* If the exchange determines in accordance with paragraph (a)(1) of this section that a disciplinary action will become effective prior to the expiration of fifteen days after written notice thereof, it must notify the person disciplined in writing, either personally or by email to the person's last known email address, stating the reasons for the determination. The exchange must also immediately notify the Commission by email to *secretary@cftc.gov.* Where notice is delivered by email, the time within which the person so notified may file a petition for stay pursuant to § 9.24(a)(2) will be increased by one day.

■ 12. Revise § 9.13 to read as follows:

§ 9.13 Publication of notice.

Whenever an exchange suspends, expels or otherwise disciplines, or denies any person access to the exchange, it must make public its findings by disclosing at least the information contained in the notice required by § 9.11(b). An exchange must make such findings public as soon as the disciplinary action or access denial action becomes effective in accordance with the provisions of § 9.12 by posting a notice on its Web site to which its members and the public regularly have access. Such notice must be maintained and readily available on the exchange's Web site.

■ 13. In § 9.24, revise paragraph (a)(2) to read as follows:

§ 9.24 Petition for stay pending review.

(a) * * *

(2) Within ten days after a notice of summary action has been delivered in accordance with § 9.12(b) to a person who is the subject of a summary action permitted by part 37, appendix B, Core Principle 2, paragraph (a)(14) or part 38, appendix B, Core Principle 13, paragraph (a)(7) (emergency disciplinary actions) of this chapter, that person may petition the Commission to stay the effectiveness of the summary action pending completion of the exchange proceeding.

* * * * *

■ 14. Revise § 9.31 to read as follows:

§ 9.31 Commission review of disciplinary or access denial action on its own motion.

(a) *Request for additional information.* Where a person disciplined or denied access has not appealed the exchange decision to the Commission, upon review of the notice specified in § 9.11, the Division of Market Oversight or the Division of Swap Dealer and Intermediary Oversight may request that the exchange file with the Division the record of the exchange proceeding, or designated portions of the record, a brief statement of the evidence and testimony adduced to support the exchange's findings that a rule or rules of the exchange were violated and such recordings, transcripts and other documents applicable to the particular exchange proceeding as the Division may specify. The exchange must promptly advise the person who is the subject of the disciplinary or access denial action of the Division's request. Within thirty days after service of the Division's request, the exchange must file the information requested with the Division in the manner requested by the Division and, upon request, deliver that information to the person who is the subject of the disciplinary or access denial action. Delivery to the person who is the subject of the disciplinary or access denial action must be in the manner prescribed by § 9.11(c). A person subject to the disciplinary action or access denial action requesting a copy of the information furnished to the Division must, if the exchange rules so provide, agree to pay the exchange reasonable fees for printing the copy.

(b) *Review on motion of the Commission.* The Commission may institute review of an exchange disciplinary or access denial action on its own motion. Other than in extraordinary circumstances, such review will be initiated within 180 days after the NFA has received the notice of exchange action provided for in § 9.11. If the Commission should institute review on its own motion, it will issue an order permitting the person who is the subject of the disciplinary or access denial action an opportunity to file an appropriate submission, and the exchange an opportunity to file a reply thereto.

Issued in Washington, DC, on January 13, 2017, by the Commission.

Christopher J. Kirkpatrick,

Secretary of the Commission.

Note: The following appendix will not appear in the Code of Federal Regulations.

Appendix to Amendments to Parts 3 and 9 of the Commodity Futures Trading Commission's Rules—Commission Voting Summary

On this matter, Chairman Massad and Commissioners Bowen and Giancarlo voted in the affirmative. No Commissioner voted in the negative.

[FR Doc. 2017–01232 Filed 1–19–17; 8:45 am]

BILLING CODE 6351–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 11, 16, and 112

[Docket No. FDA–2017–D–0175]

Compliance With and Recommendations for Implementation of the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption for Sprout Operations; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance for industry entitled ''Compliance with and Recommendations for Implementation of the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption for Sprout Operations.'' The draft guidance, when finalized, will help sprout operations subject to FDA's final rule entitled ''Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption'' (the Produce Safety Rule), and primarily focuses on assisting such operations in complying with the sprout-specific requirements in Subpart M (Sprouts) of the Produce Safety Rule. The draft guidance also includes limited discussion on certain other applicable requirements of the Produce Safety Rule. This draft guidance may also be useful to sprout operations that are not subject to the Produce Safety Rule that voluntarily choose to follow the standards established by the rule.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by July 24, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2017–D–0175 for ''Compliance with and Recommendations for Implementation of the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption for Sprout Operations.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Division of Produce Safety, Center for Food Safety and Applied Nutrition (HFS–317), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1600. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Samir Assar, Center for Food Safety and Applied Nutrition (HFS–317), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740–3835, 240–402–1636.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a draft guidance for industry entitled ''Compliance with and Recommendations for Implementation of the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption for Sprout Operations.'' We are issuing the draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent our current thinking on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

The draft guidance for industry is intended to explain our current thinking on how to comply with the requirements for the safe growing, harvesting, packing and holding of produce under 21 CFR part 112, focusing on subparts impacting sprout operations covered by Subpart M. Topics discussed in the draft guidance include:

- General Sprout Production;
- Buildings, Tools, and Equipment;
- Cleaning and Sanitizing;
- Agricultural Water in Sprouting Operations;
- Seeds for Sprouting;
- Sampling and Testing of Spent Sprout Irrigation Water or Sprouts;
- Environmental Monitoring; and
- Recordkeeping.

FDA welcomes comments on any aspect of this draft guidance. We are particularly interested in receiving information about the types of seed or bean treatments that have been used by sprout operations and/or seed suppliers, as well as their feasibility of use, cost, impact on germination; scientific information related to the effectiveness in reducing or eliminating microorganisms of public health significance; and any variability in treatment effectiveness based on seed type.

FDA has developed a risk assessment model to evaluate the public health impact of seed treatment and testing of spent irrigation water in a sprout production system and anticipates making it available in the near future, following peer review.

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the

public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to publish notice in the **Federal Register** soliciting public comment on each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, we will publish a 60-day notice on the proposed collection of information in a future issue of the **Federal Register**.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/FoodGuidances* or *http://www.regulations.gov.* Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: January 12, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–01128 Filed 1–19–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–133353–16]

RIN 1545–BN63

Disclosures of Return Information Reflected on Returns to Officers and Employees of the Department of Commerce for Certain Statistical Purposes and Related Activities; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking by cross-reference to temporary regulation; correction.

SUMMARY: This document contains corrections to a notice of proposed rulemaking by cross-reference to temporary regulation (REG–133353–16) that was published in the **Federal Register** on Friday, December 9, 2016. The proposed regulations authorize the disclosure of specified return information to the Census Bureau (Bureau) for purposes of structuring the censuses and national economic accounts and conducting related statistical activities authorized by title 13.

DATES: Written or electronic comments and request for public hearing for the notice of proposed rulemaking by cross-reference to temporary regulation at 81 FR 89022, December 9, 2016, are still being accepted and must be received by March 9, 2017.

ADDRESSES: Send submissions to CC:PA:LPD:PR (REG–133353–16), Room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (REG–133353–16), Courier's desk, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC 20224, or sent electronically, via the Federal eRulemaking Portal at *www.regulations.gov* (IRS REG–133353–16).

SUPPLEMENTARY INFORMATION:

Background

The notice of proposed rulemaking by cross-reference to temporary regulation that is the subject of this document is under section 6103(j)(1)(A) of the Internal Revenue Code.

Need for Correction

As published, the notice of proposed rulemaking by cross-reference to temporary regulation (REG–133353–16) contains errors that are misleading and are in need of clarification.

Correction to Publication

Accordingly, the notice of proposed rulemaking by cross-reference to temporary regulation, that is the subject of FR Doc. 2016–29490, is corrected as follows:

1. On page 89022, in the preamble, second column, second line from the top of column, the language ''CC:PA:LPD:PR (REG–133533–16), Room'' is corrected to read ''CC:PA:LPD:PR (REG–133353–16), Room''.

2. On page 89022, in the preamble, second column, eighth line from the top of column, the language ''4 p.m. to CC:PA:LPD:PR (REG–133533–'' is corrected to read ''4 p.m. to CC:PA:LPD:PR (REG–133353–''.

3. On page 89022, in the preamble, second column, sixth line from the bottom of **ADDRESSES** caption, the language ''Service, 1111 Constitutional Avenue'' is corrected to read ''Service, 1111 Constitution Avenue''.

§ 301.6103(j)(1)–1 [Corrected]

4. On page 89023, first column, third line of paragraph (e), the language ''(b)(3)(v), (b)(3)(xxv), (b)(3)(xxv) through'' is corrected to read ''(b)(3)(v), (b)(3)(xxv) through''.

Martin V. Franks,

Branch Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administrative).

[FR Doc. 2017–00946 Filed 1–19–17; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

27 CFR Parts 24 and 27

[Docket No. TTB–2016–0014; Notice No. 168; Re: T.D. TTB–147]

RIN 1513–AC31

Implementation of Statutory Amendments Requiring the Modification of the Definition of Hard Cider

AGENCY: Alcohol and Tobacco Tax and Trade Bureau, Treasury.

ACTION: Notice of proposed rulemaking; cross-reference to temporary rule.

SUMMARY: Elsewhere in this issue of the **Federal Register**, by means of a temporary rule, the Alcohol and Tobacco Tax and Trade Bureau (TTB) implements changes made to the definition of ''hard cider'' in the Internal Revenue Code of 1986 by the Protecting Americans from Tax Hikes Act of 2015. The modified definition broadens the range of wines eligible for the hard cider tax rate. TTB is amending its regulations to reflect the modified definition of hard cider effective for products removed on or after January 1, 2017, and to set forth new labeling requirements to identify products to which the hard cider tax rate applies. The new labeling requirements include both a one-year transitional rule and a new labeling requirement that takes effect for products removed on or after January 1, 2018. The text of the regulations in that temporary rule published elsewhere in this issue of the **Federal Register** serves as the text of the proposed regulations.

DATES: Comments must be received on or before March 24, 2017.

ADDRESSES: Please send your comments on this document to one of the following addresses:

- *Internet: https://www.regulations.gov* (via the online comment form for this document as posted within Docket No. TTB–2016–0014 at ''*Regulations.gov,*'' the Federal e-rulemaking portal);

• *U.S. Mail:* Director, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW., Box 12, Washington, DC 20005; or

• *Hand delivery/courier in lieu of mail:* Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW., Suite 400, Washington, DC 20005.

See the Public Participation section of this document for specific instructions and requirements for submitting comments, and for information on how to request a public hearing.

You may view copies of this document, the related temporary rule, and any comments TTB receives about this proposal at *https://www.regulations.gov* within Docket No. TTB–2016–0014. A link to that docket is posted on the TTB Web site at *https://www.ttb.gov/wine/wine-rulemaking.shtml* under Notice No. 168. You also may view copies of this document, the temporary rule, and any comments TTB receives about this proposal by appointment at the TTB Information Resource Center, 1310 G Street, and NW., Washington, DC 20005. Please call (202) 453–2270 to make an appointment.

FOR FURTHER INFORMATION CONTACT: Kara Fontaine, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW., Box 12, Washington, DC 20005; telephone (202) 453–1039, ext. 103.

SUPPLEMENTARY INFORMATION:

Background

On December 18, 2015, the President signed into law the Consolidated Appropriations Act, 2016 (Pub. L. 114–113). Division Q of this Act is titled the Protecting Americans from Tax Hikes Act of 2015 (PATH Act). Section 335(a) of the PATH Act amends the Internal Revenue Code of 1986 (IRC) at 26 U.S.C. 5041 by modifying the definition of hard cider for excise tax classification purposes. Pursuant to section 335(b) of the PATH Act, the amended definition of hard cider applies to such products removed on or after January 1, 2017. The PATH Act does not change the tax rate applicable to wine eligible for the hard cider tax rate; rather, it broadens the range of products to which the hard cider tax rate applies. Among other things, the range of products to which the hard cider tax rate applies will include certain sparkling and carbonated products and certain products that are subject to the requirements of the Federal Alcohol Administration Act (FAA Act).

Elsewhere in this issue of the **Federal Register**, TTB is publishing temporary regulations making amendments to parts 24 and 27 of the TTB regulations (27 CFR parts 24 and 27) to implement the changes made to the definition of ''hard cider'' in the Internal Revenue Code of 1986 by the PATH Act. The text of the temporary regulations serves as the text of these proposed regulations. The preamble to the temporary regulations explains the proposed regulations.

Public Participation

Comments Sought

TTB requests comments from interested members of the public on the proposed changes to our regulations in 27 CFR parts 24 and 27, which are described in detail in the temporary rule issued in conjunction with this notice of proposed rulemaking and published elsewhere in this issue of the **Federal Register**. TTB is particularly interested in comments on the labeling provisions and any alternatives to requiring that ''Tax Class 5041(b)(6)'' appear on the labels of products to which the hard cider tax rate applies. Please provide specific information in support of your comments.

Submitting Comments

You may submit comments on this proposal by using one of the following three methods:

• *Federal e-Rulemaking Portal:* You may send comments via the online comment form posted with this proposed rule within Docket No. TTB–2016–0014 on ''*Regulations.gov,*'' the Federal e-rulemaking portal, at *https://www.regulations.gov.* A direct link to that docket is available under Notice No. 168 on the TTB Web site at *https://www.ttb.gov/wine/wine-rulemaking.shtml.* Supplemental files may be attached to comments submitted via *Regulations.gov.* For complete instructions on how to use *Regulations.gov,* click on the sites ''Help'' tab.

• *U.S. Mail:* You may send comments via postal mail to the Director, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW., Box 12, Washington, DC 20005.

• *Hand Delivery/Courier:* You may hand-carry your comments or have them hand-carried to the Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW., Suite 400, Washington, DC 20005.

Please submit your comments by the closing date shown above in this proposed rule. Your comments must reference Notice No. 168 and include your name and mailing address. Your comments also must be made in English, be legible, and be written in language acceptable for public disclosure. TTB does not acknowledge receipt of comments and considers all comments as originals.

In your comment, please clearly state if you are commenting for yourself or on behalf of an association, business, or other entity. If you are commenting on behalf of an entity, your comment must include the entity's name as well as your name and position title. In your comment via *Regulations.gov*, please enter the entity's name in the ''Organization'' blank of the online comment form. If you comment via postal mail or hand delivery/courier, please submit your entity's comment on letterhead.

You may also write to the Administrator before the comment closing date to ask for a public hearing. The Administrator reserves the right to determine whether to hold a public hearing.

Confidentiality

All submitted comments and attachments are part of the public record and subject to disclosure. Do not enclose any material in your comments that you consider to be confidential or inappropriate for public disclosure.

Public Disclosure

TTB will post, and you may view, copies of this proposed rule, the related temporary rule, and any online or mailed comments received about this proposal within Docket No. TTB–2016–0014 on the Federal e-rulemaking portal. A direct link to that docket is available on the TTB Web site at *https://www.ttb.gov/wine/wine-rulemaking.shtml* under Notice No. 168. You may also reach the relevant docket through the *Regulations.gov* search page at *https://www.regulations.gov.* For information on how to use *Regulations.gov*, click on the site's ''Help'' tab.

All posted comments will display the commenter's name, organization (if any), city, and State, and, in the case of mailed comments, all address information, including email addresses. TTB may omit voluminous attachments or material that it considers unsuitable for posting.

You may view copies of this proposed rule, the related temporary rule, and any electronic or mailed comments TTB receives about this proposal by appointment at the TTB Information Resource Center, 1310 G Street NW., Washington, DC 20005. You may also obtain copies for 20 cents per 8½ x 11-inch page. Contact TTB's information specialist at the above address or by telephone at (202) 453–2270 to schedule

an appointment or to request copies of comments or other materials.

Regulatory Flexibility Act, Paperwork Reduction Act, and Executive Order 12866

Since the regulatory text proposed in this notice of proposed rulemaking is identical to that contained in the companion temporary rule published elsewhere in this issue of the **Federal Register**, the analyses contained in the preamble of the temporary rule concerning the Regulatory Flexibility Act, the Paperwork Reduction Act, and Executive Order 12866 also apply to this proposed rule.

Drafting Information

Dana Register and Kara Fontaine of the Regulations and Rulings Division drafted this document with the assistance of other Alcohol and Tobacco Tax and Trade Bureau personnel.

List of Subjects

27 CFR Part 24

Administrative practice and procedure, Cider, Claims, Electronic funds transfers, Excise taxes, Exports, Food additives, Fruit juices, Hard Cider, Labeling, Liquors, Packaging and containers, Reporting and recordkeeping requirements, Research, Scientific equipment, Spices and flavorings, Surety bonds, Vinegar, Warehouses, Wine.

27 CFR Part 27

Alcohol and alcoholic beverages, Beer, Cosmetics, Customs duties and inspections, Electronic funds transfers, Excise taxes, Imports, Labeling, Liquors, Packaging and containers, Reporting and Recordkeeping requirements, Wine.

Proposed Amendments to the Regulations

For the reasons discussed in the preamble, TTB proposes to amend 27 CFR chapter I, parts 24 and 27 as follows:

PART 24—WINE

■ 1. The authority citation for part 24 continues to read as follows:

Authority: 5 U.S.C. 552(a); 26 U.S.C. 5001, 5008, 5041, 5042, 5044, 5061, 5062, 5121, 5122–5124, 5173, 5206, 5214, 5215, 5351, 5353, 5354, 5356, 5357, 5361, 5362, 5364–5373, 5381–5388, 5391, 5392, 5511, 5551, 5552, 5661, 5662, 5684, 6065, 6091, 6109, 6301, 6302, 6311, 6651, 6676, 7302, 7342, 7502, 7503, 7606, 7805, 7851; 31 U.S.C. 9301, 9303, 9304, 9306.

■ 2. [The proposed amendatory instructions and the proposed regulatory text for part 24 are the same as the amendatory instructions and the amendatory regulatory text set forth in the temporary rule on this subject published in the Rules and Regulations section of this issue of the **Federal Register**].

PART 27—IMPORTATION OF DISTILLED SPIRITS, WINES, AND BEER

■ 3. The authority citation for part 27 continues to read as follows:

Authority: 5 U.S.C. 552(a), 19 U.S.C. 81c, 1202; 26 U.S.C. 5001, 5007, 5008, 5010, 5041, 5051, 5054, 5061, 5121, 5122–5124, 5201, 5205, 5207, 5232, 5273, 5301, 5313, 5382, 5555, 6109, 7805.

■ 4. [The proposed amendatory instructions and the proposed regulatory text for part 27 are the same as the amendatory instructions and the amendatory regulatory text set forth in the temporary rule on this subject published in the Rules and Regulations section of this issue of the **Federal Register**].

Signed: December 7, 2016.

John J. Manfreda,

Administrator.

Approved: January 4, 2017.

Timothy E. Skud,

Deputy Assistant Secretary (Tax, Trade and Tariff Policy).

[FR Doc. 2017–00334 Filed 1–19–17; 8:45 am]

BILLING CODE 4810–31–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

46 CFR Part 4

[Docket No. USCG–2016–0748]

RIN 1625–AC33

Marine Casualty Reporting Property Damage Thresholds

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to amend the monetary property damage threshold amounts for reporting a marine casualty, and for reporting a type of marine casualty called a ''serious marine incident'' (SMI). The initial regulations setting these dollar threshold amounts were promulgated in the early1980s and they have not been updated. Because the monetary thresholds for reporting have not kept pace with inflation, relatively minor casualties must be reported. Additionally, the regulations require mandatory drug and alcohol testing following an SMI; consequently, testing is being conducted for casualties that are less significant than those intended to be captured by the original regulations. Updating the regulations will reduce the burden on vessel owners and operators, and will also reduce the amount of Coast Guard resources expended to investigate these incidents.

DATES: Comments and related material must be submitted to the online docket via *http://www.regulations.gov,* or reach the Docket Management Facility, on or before March 24, 2017.

Comments sent to the Office of Management and Budget (OMB) on collection of information must reach OMB on or before March 24, 2017.

ADDRESSES: Submit comments using one of the listed methods, and see **SUPPLEMENTARY INFORMATION** section below for more information on public comments.

Collection of information. You must submit any comments on the collection of information discussed in Section IV of this preamble both to the Coast Guard's docket and to the Office of Information and Regulatory Affairs (OIRA) in the White House Office of Management and Budget. OIRA submissions can use one of the listed methods.

- *Email* (preferred)—*oira_submission@omb.eop.gov* (include the docket number and ''Attention: Desk Officer for Coast Guard, DHS'' in the subject line of the email).
- *Fax*—202–395–6566.
- *Mail*—Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW., Washington, DC 20503, ATTN: Desk Officer, U.S. Coast Guard.

FOR FURTHER INFORMATION CONTACT: For information about this document, call or email CDR Randy Waddington, CG–INV, Coast Guard; telephone 202–372–1029, email *HQS-PF-fldr-CG-INV@uscg.dhs.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents for Preamble

K. Energy Effects
L. Technical Standards
M. Environment

I. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking, and we will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

We encourage you to submit comments through the Federal eRulemaking Portal at *http://www.regulations.gov.* If your material cannot be submitted using *http://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice of proposed rulemaking (NPRM), and all public comments, are in our online docket at *http://www.regulations.gov* and can be viewed by following that Web site's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

We accept anonymous comments. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

We are not planning to hold a public meeting but will consider doing so if public comments indicate a meeting would be helpful. We would issue a separate **Federal Register** notice to announce the date, time, and location of such a meeting.

II. Abbreviations

BLS Bureau of Labor Statistics
CFR Code of Federal Regulations
CPI-U Consumer Price Index for All Urban Consumers
DHS Department of Homeland Security
E.O. Executive Order
FR *Federal Register*
MISLE Marine Information for Safety and Law Enforcement
NVIC Navigation and Vessel Inspection Circular
OCMI Officer in Charge, Marine Inspection
OMB Office of Management and Budget
SMI Serious marine incident
§ Section symbol
U.S.C. United States Code

III. Background, Basis, and Purpose

Pursuant to 46 U.S.C. 6101, the Coast Guard is required to prescribe regulations on marine casualty reporting and the manner of reporting. Based on this authority, we promulgated regulations in part 4 of Title 46 of the Code of Federal Regulations (CFR) that included, among other criteria, monetary property damage threshold amounts for reporting a ''serious marine incident'' [1] and for reporting a marine casualty.[2] The original regulations setting these property damage threshold amounts were promulgated in the 1980s and they have not since been updated. In this NPRM, the Coast Guard proposes to update the dollar threshold amounts for property damage in 46 CFR 4.03–2(a)(3) and 4.05–1(a)(7) to account for inflation.

In 2013 through 2014, Coast Guard undertook a review of marine casualty reporting requirements during our development of Navigation and Vessel Inspection Circular (NVIC) 01–15, resulting in a **Federal Register** notice [3] requesting public comment on the draft NVIC 01–15. Several commenters from industry and the public noted that property damage threshold amounts for reported marine casualties and serious marine incidents (SMIs) had not been updated to reflect inflation and supported an inflation adjustment to the thresholds. Furthermore, in response to a task to examine the Coast Guard's marine casualty reporting requirements, the Coast Guard's Towing Vessel Safety Advisory Committee recommended that we amend the monetary thresholds in 46 CFR part 4 to account for inflation.[4]

There is Coast Guard and stakeholder consensus that the early 1980s property damage monetary threshold amounts listed in 46 CFR 4.03–2 and 4.05–1 have not kept pace with inflation. Over time, this has resulted in the reporting of a greater number casualties involving relatively minor property damage. As was explained in the 1980 interim final rule, ''the Coast Guard's selection of a monetary value as a reporting criterion is based upon the premise that increased repair costs are indicative of the increased seriousness of a marine casualty [. . .] The monetary damage criterion has been chosen as the most effective method of ensuring that only the more serious casualties are reported.'' (45 FR 77439, 77440). Accordingly, it has never been our intent to require owners or operators to notify us of casualties involving relatively minor property damage; consequently, we are amending the property damage monetary threshold amounts in order to eliminate the reporting of insignificant property damage incidents. The marine casualty reports impacted by this NPRM are those marine casualties where the only outcome was property damage in the amount of $25,000.01 through $72,000. Additionally, because the regulations require mandatory drug and alcohol testing following an SMI, current regulations require chemical testing for casualties that reach a minimum threshold of $100,000 in property damage. Due to cost increases caused by inflation, however, casualties that result in property damage between $100,000 and $200,000 are no longer representative of a ''serious'' casualty. The lack of inflation updates to our marine casualty regulations has resulted in an additional administrative and financial burden on vessel owners and operators, as well as on Coast Guard resources used to investigate these incidents. This NPRM would result in an estimated annual cost savings of $40,809 to industry due to a reduction in the hourly burden of reporting and recordkeeping for both marine casualties and SMIs, and a reduction in an estimated annual cost savings of $4,649 for chemical testing for marine casualties designated as SMIs. This NPRM would result in Coast Guard cost savings by reducing the hourly burden costs to investigate marine casualties as well as the costs associated with processing marine casualty forms.

As a result of updating the dollar amount thresholds to account for inflation, we anticipate there would be a decrease in the number of commercial vessel casualties reported to the Coast Guard. The changes proposed by this NPRM would also likely decrease the number of casualties that fall within the current definition of an SMI, and thereby reduce the amount of chemical tests administered following an SMI that result in property damage of $100,000.01 through $200,000. However mandatory chemical testing would still be required if the property damage meets the revised dollar threshold amount (in excess of $200,000) proposed by this NPRM. The intent of setting a dollar amount threshold in our marine casualty reporting regulation and within the definition of ''serious

[1] 46 CFR 4.03–2.
[2] 46 CFR 4.05–1.
[3] 79 FR 2466 (January 14, 2014).
[4] Towing Safety Advisory Committee, Task 13–09, Recommendations for Improvement of Marine Casualty Reporting Final Report. This report is accessible at *https://homeport.uscg.mil/tsac.*

marine incident'' is to ensure that the Coast Guard is aware of those incidents that could be indicative of more serious problems and that may be averted in the future with timely intervention.

These proposed changes would provide a benefit for both the marine industry and the Coast Guard because they would reduce the hourly burden or eliminate the marine casualty reporting requirements for incidents involving property damage between the existing and proposed thresholds, and reduce SMI chemical testing requirements for incidents involving property damage in the range of $100,000 through $200,000. As a result, the marine industry and Coast Guard resources would be able to focus efforts on higher consequence incidents.

IV. Discussion of Proposed Rule

The Coast Guard proposes to amend 46 CFR 4.03–2 and 4.05–1. The proposed changes would replace the existing reportable marine casualty property damage threshold amount of $25,000 with $72,000 in 46 CFR part 4.05–1(a) (7), and replace the SMI property damage threshold of $100,000 with $200,000 in 46 CFR part 4.03–2(a) (3). These threshold amounts are being updated to account for inflation.

The Coast Guard determined the inflation adjustment factor using the change in the Consumer Price Index for All Urban Consumers (CPI–U) from the original dollar thresholds set in 1980 for marine casualty property damage and 1988 for SMI property damage. The CPI–U is calculated and published by the U.S. Department of Labor, Bureau of Labor Statistics, [5] and uses the period of 1982 to 1984 as the base level where the CPI–U = 100. We calculated the inflation adjustment by comparing the average CPI–U for the base years (82.408 in 1980 and 118.258 in 1988) with the average CPI–U for 2015 (237.017). This resulted in an inflation adjustment factor of 1.876 [6] for the marine casualty dollar threshold and a factor of 1.004 [7] for the SMI dollar threshold.

For the marine casualty reporting threshold, we multiplied the inflation adjustment factor of 1.876 by the current threshold of $25,000 to calculate the raw inflation increment of $46,900, resulting in a total revised threshold of $72,000 (25,000 + $46,900 rounded to the nearest thousand).

For the SMI dollar threshold, we multiplied the inflation adjustment factor of 1.004 by the current threshold of $100,000 to calculate the raw inflation increment of $100,400, resulting in a total revised threshold of $200,000 (100,000 + $100,400 rounded to the nearest thousand).

V. Regulatory Analyses

We developed this NPRM after considering numerous statutes and Executive Orders (E.O.s) related to rulemaking. Below we summarize our analyses based on these statutes or E.O.s.

A. Regulatory Planning and Review

Executive Orders 12866 (''Regulatory Planning and Review'') and 13563 (''Improving Regulation and Regulatory Review'') direct agencies to assess the 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). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This NPRM has not been designated a ''significant regulatory action,'' under section 3(f) of Executive Order 12866. Accordingly, the rule has not been reviewed by the Office of Management and Budget.

This Regulatory Analysis provides an evaluation of the economic impacts associated with this NPRM. The Coast Guard proposes to amend two sections in part 4 of Title 46 of the CFR, 46 CFR 4.03–2 and 4.05–1. Under this NPRM, the Coast Guard proposes to replace the reportable marine casualty dollar threshold of $25,000 with $72,000 in 46 CFR part 4.05–1(a) (7), and replace the SMI dollar threshold of $100,000 with $200,000 in 46 CFR part 4.03–2(a) (3) to update the thresholds to account for inflation, as discussed in Section IV of this NPRM. Table 1 provides a summary of the affected population, costs, and benefits after implementation of this NPRM.

TABLE 1—SUMMARY OF THE IMPACTS OF THE NPRM

Category	Summary
Applicability	Replace the reportable marine casualty dollar threshold of $25,000 with $72,000. Replace the SMI dollar threshold of $100,000 with $200,000. Owners, agents, masters, operators, or persons in charge involved in a marine casualty and crewmembers who are required to undergo chemical testing.
Affected Population	Annual average of 316 vessel owners, operators, or their representatives reporting a marine casualty, 21 marine employers reporting an SMI, and average of 32 vessel crewmembers completing chemical testing would no longer be required to report these incidents to the Coast Guard.
Costs	No quantitative costs.
Benefits	$45,458 annualized and $319,281 10-year present value monetized industry benefits (cost savings) (7% discount rate). $637,688 annualized and $4,478,854 10-year present value monetized Government benefits (cost savings) (7% discount rate). Total of industry and Government benefits: $683,146 annualized and $4,798,134 10-year present value monetized combined benefits (cost savings) (7% discount rate).

Affected Population

We expect that this NPRM would affect the owners, agents, masters, operators, or persons in charge of a commercial vessel who, pursuant to 46 CFR 4.05–1, are required to notify the nearest Sector Office whenever a vessel is involved in a marine casualty. Specifically, the proposed regulations in this NPRM would affect those individuals who would have completed the necessary forms (CG–2692 series) to report a marine casualty where the only outcome was property damage of $25,000.01 through $72,000, or an SMI

[5] CPI Detailed Report December 2015, Table 24. *http://www.bls.gov/cpi/cpid1512.pdf.*

[6] (237.017 – 82.408)/82.408 = 1.876.

[7] (237.017 – 118.258)/118.258 = 1.004.

with property damage of $100,000.01 through $200,000 (CG–2692 series, supplemented with an appended SMI written report (CG–2692B).[8]

We used incident investigation data from the Coast Guard's Marine Information for Safety and Law Enforcement (MISLE) system from 2012 through 2014 [9] to estimate the average number of vessel crewmembers affected by this NPRM. From 2012 through 2014, we found there was an average of 5,967 reports of a marine casualty per year, with one individual per vessel who we assume to be a vessel crewmember completing each report. An average of 271, or 4.5 percent of the annual 5,967 marine casualty reports, involved an SMI.

Of the 5,967 marine casualty reports, approximately 5.3 percent were for a reportable marine casualty where the only outcome was property damage of $25,000.01 through $72,000. Therefore, we expect that an average of approximately 316 fewer reports of marine casualties would be required per year. Vessel owners and operators would benefit from a reduction in the time burden associated with a crewmember no longer having to prepare and submit the required marine casualty reporting paperwork.

Of the 271 casualty reports that involved an SMI, approximately 7.9 percent (21 out of 271) were ones in which the sole outcome of the SMI was property damage of $100,000.01 through $200,000. Based on that annual average, the amendments proposed in this NPRM would likely result in a reduction of about 21 SMI written reports (CG–2692B) per year due to the proposed change to the monetary threshold amount for an SMI involving property damage. Because property damage of $100,000.01 through $200,000 exceeds the threshold for a reportable marine casualty, the forms for a marine casualty report (CG–2692 series) would still need to be completed. However, marine employers would no longer be required to complete the additional paperwork required for an SMI written report (CG–2692B). Consequently, marine employers would benefit from a reduction in the time burden associated with an SMI written report (CG–2692B) as well as cost savings associated with chemical savings.

Benefits or Cost Savings to Industry

The benefit or cost savings to industry is the difference between the current baseline cost to industry and the cost to industry after implementation of this NPRM.

Current Reporting Cost to Industry for CG–2692 and CG–2692B

To estimate the benefit to industry, we first estimate the current cost to industry. The cost to industry includes costs for reporting and recordkeeping for a reportable marine casualty and the costs for chemical testing for marine casualties designated as SMIs. The reporting and recordkeeping costs for marine casualties include the time to complete the forms (CG–2692 series) for a marine casualty, the time for approximately 10 percent of the forms to be internally reviewed before submission, and the time to complete the additional SMI written report (CG–2692B) pursuant to 46 CFR 4.06–60(a) if a marine casualty is designated as an SMI. The time estimates and wage rates for reporting and recordkeeping are taken from the existing Collection of Information, entitled ''Report of Marine Casualty & Chemical Testing of Commercial Vessel Personnel,'' which has OMB Control Number 1625–0001.[10] We use the same time estimates and wage rates in this analysis to maintain consistency and to capture the changes due to this NPRM.

An average of 5,967 marine casualty reports are submitted annually by vessel owners or operators. For each reportable marine casualty, the existing Collection of Information estimates that it takes about 1 hour for a vessel crewmember to complete the necessary forms (CG–2692 series). The existing Collection of Information also estimates that the position of vessel crewmember is analogous to a government employee at the grade level of a GS–03. The fully loaded wage rate for a GS–03 is $26 per hour, according to Commandant Instruction 7310.1P, ''Reimbursable Standard Rates.'' [11] The annual baseline cost to complete the current 5,967 CG–2692 series forms would be $155,142 (5,967 marine casualty reports × $26).

We estimate that it takes, on average, 1 hour to complete the CG–2692 series forms. However, we received public comments in 2011 on existing COI number 1625–0001 stating that completing the CG–2692 form takes more than one hour and one commenter stated that it can take up to 8 to 12 hours to complete the form.[12] The reason for this difference is that some entities choose to have the forms reviewed by shore-side personnel, such as an attorney prior to submission to the Coast Guard. We adjusted our burden estimate to account for the additional layer of review. To account for this additional time, 10 percent of the forms submitted would have 10 hours of additional burden. The additional time reflects internal review by individuals employed by the owner or operator in addition to the vessel crewmember who completes the form. The additional reviewers may be shoreside representatives, port engineers, and attorneys, among others. We estimate the wage rate for this added review is done by personnel analogous to a government employee at the grade level of a GS–14. The fully loaded wage rate for a GS–14 is $101 per hour, per Commandant Instruction 7310.1P. The total annual cost of this additional time is $602,970 (597 marine casualty reports × 10 additional burden hours × $101).

When a marine casualty is designated as an SMI, the marine employer must also complete an SMI written report (CG–2692B). (See 46 CFR 4.06–60.) We estimate that it takes about 0.5 hours for a marine employer analogous to a government employee at the grade level of a GS–03 to complete this form. The annual cost to complete an SMI written report (CG–2692B) is about $3,523 (271 SMI reports × 0.5 hours × $26 per hour wage rate).

Table 2 shows a summary of the current industry costs for reporting and recordkeeping.

[8] ''Report of Required Chemical Drug and Alcohol Testing Following a Serious Marine Incident.'' See, 46 CFR 4.05–10.

[9] This 3-year time period was used to be consistent with the existing Collection of Information, entitled ''Report of Marine Casualty & Chemical Testing of Commercial Vessel Personnel,'' which has OMB Control Number 1625–0001.

[10] Existing Collection of Information, ''Report of Marine Casualty & Chemical Testing of Commercial Vessel Personnel'', OMB Control Number 1625–0001, Docket Number USCG–2015–0910, can be found at *https://www.federalregister.gov/documents/2015/10/23/2015-27019/information-collection-request-to-office-of-management-and-budget-omb-control-number-1625-0001.*

[11] Out of Government Rate for GS–03. Hourly Rates for Personnel ($), Enclosure (2) to Commandant Instruction 7310.1P. We use this version to maintain consistency with the existing COI 1625–0001.

[12] Docket ID: USCG–2011–0710. Comments can be found at *https://www.regulations.gov/docket?D=USCG-2011-0710.*

TABLE 2—CURRENT ANNUAL INDUSTRY COSTS FOR REPORTING AND RECORDKEEPING

Requirement	Crewmembers/ responses	Burden hours per response	Annual hour burden	Wage rate	Annual cost burden
Written report of marine casualty	5,967	1	5,967	$26	$155,142
Additional Burden for 10% of Respondents	597	10	5,970	101	602,970
SMI written report	271	0.5	136	26	3,523
Totals			12,073		761,635

* Estimates may not sum due to independent rounding.

As mentioned earlier in this NPRM, when a marine casualty is designated as an SMI, the crewmembers involved are required to take a chemical test pursuant to 46 CFR 4.06–3. The marine employer incurs costs for the actual costs of the chemical test and the time it takes for a crewmember to take the chemical test. The actual cost of the chemical test includes the costs of the chemical test collection kits, collector fees, Coast Guard alcohol-testing swabs, and costs of overnight mailing. These costs can vary, but on average, the actual chemical test costs approximately $100 per test.[13] Each vessel crewmember involved in an SMI is required to take a chemical test. The number of vessel crewmembers required to take a chemical test can vary depending on the circumstances of the SMI. We analyzed the casualty reports that involved an SMI from MISLE and found an average of 1.5 crewmembers per SMI were required to take a chemical test. We used an estimate of 1.5 crewmembers to estimate the costs of chemical testing to account for the variation in crewmembers involved in SMIs. With an average of 271 SMIs per year, the current annual cost for the actual chemical tests is $40,650 (271 SMIs × average of 1.5 crewmembers × $100 per test).

In addition to the cost of the chemical tests, there is a cost associated with the time it takes a vessel crewmember to complete the chemical test. We estimate that it takes 1 hour for a crewmember to complete the chemical test.[14] We obtained the wage rate of the crewmember from the U.S. Bureau of Labor Statistics (BLS), using Occupational Series 53–5000, Water Transportation Workers (May 2015). The BLS reports that the mean hourly wage rate for a water transportation worker is $31.11.[15] To account for employee benefits, we use a load factor of 1.53, which we calculated from 2016 first quarter BLS data.[16] The loaded wage for a crewmember is estimated at $47.60 ($31.11 wage rate × 1.53 load factor). The cost of the time for a crewmember to take the chemical test is $19,349 (271 SMIs × average of 1.5 crewmembers × 1 hour burden × $47.60 wage rate). Therefore, the current annual cost to industry for chemical testing is $59,999 (see Table 3). Adding the costs for chemical testing of $59,999 to the cost for reporting and recordkeeping of $761,635 (see Table 2), brings the current total annual cost to industry to $821,634.

TABLE 3—CURRENT ANNUAL INDUSTRY COSTS FOR CHEMICAL TESTING

SMIs per year	Average crewmembers tested per SMI	Cost of testing procedures	Hours to take test	Wage rate	Total cost of testing procedures
271	1.5	$100	1	$47.60	$59,999

Total Reporting Costs to Industry After Implementation of the NPRM

Increasing the dollar threshold amount for a reportable marine casualty involving property damage, as well as the dollar threshold amount for property damage within the definition of a ''serious marine incident,'' would reduce the number of marine casualty responses by 5.3 percent, and the number of SMIs by 7.9 percent, annually. The burden hours per response would remain the same, but we estimate that the total number of responses would decrease to 5,651 for marine casualties and 250 for SMIs, resulting in 316 fewer reported marine casualties and 21 fewer SMIs. The following sections replicate the calculation of marine casualty reporting and chemical testing, but reflect the reduced number of reports and testing under the revised thresholds.

For each reportable marine casualty, we estimate that it takes about 1 hour for a vessel crewmember to complete all parts of the necessary forms at a wage rate of $26. We estimate that the cost to complete the reduced number of marine casualty forms would be $146,926 (5,651 marine casualty reports × $26).

In addition to the time to complete the forms, some of the marine casualty forms would require additional processing time. The additional processing time reflects internal review by individuals employed by the owner or operator, in addition to the time needed by the vessel crewmember who completes the form. The additional reviewers may be shoreside representatives, port engineers, or attorneys, among others. To account for

[13] Most marine employers use a consortium that simplifies and reduces the costs per test and also assists in managing a company's drug-testing program. There are variables associated with the cost of testing, as costs can vary depending on the number of personnel included in a plan and the type of testing plan adopted by a particular company. Based on discussions with industry and Coast Guard medical testing contract data that is not publically available, we estimated testing costs of $79 and $114. We are, therefore, using an average cost of $100 for this analysis [($79+$114)/2, rounded].

[14] Hourly estimate is from Coast Guard subject matter experts, and takes into account that these are not planned tests, but instead are emergent tests—required as a result of accidents—that must be taken no later than 32 hours after the incident.

[15] Mean wage, *http://www.bls.gov/oes/2015/may/oes_nat.htm*

[16] Employer Costs for Employee Compensation provides information on the employer compensation and can be found at *http://data.bls.gov/data/*. The loaded wage factor is equal to the total compensation of $27.61 divided by the wages and salary of $18.05. Values for the total compensation and wages and salary are for all private industry workers in the transportation and material moving occupations, 2016 1st quarter.

this time, 10 percent [17] of the forms submitted (565 forms) would have 10 hours of additional burden, and the wage rate for this added review would be done by personnel analogous to a government employee at the grade level of a GS–14. We estimate that the total cost of this additional time after the implementation of this NPRM would be $570,650 (565 marine casualty reports × 10 additional burden hours × $101).

As mentioned earlier in this NPRM, when a marine casualty is designated as an SMI, the marine employer must complete an SMI written report (CG–2692B). We estimate that it takes about 0.5 hours for a marine employer analogous to a government employee at a grade level of a GS–03 to complete this form.[18] We estimate that the cost to complete the additional forms for an SMI after implementation of this NPRM would be $3,250 (250 SMI reports × 0.5 hours × $26 per hour wage rate).

Table 4 shows a summary of the industry costs after implementation of this NPRM.

TABLE 4—ANNUAL INDUSTRY COSTS FOR REPORTING AND RECORDKEEPING WITH REVISED REPORTING THRESHOLDS

Requirement	Crewmembers/ responses	Burden hours per response	Annual hour burden	Wage rate	Annual cost burden
Written report of marine casualty	5,651	1	5,651	$26	$146,926
Additional Burden for 10% of Respondents	565	10	5,650	101	570,650
SMI written report	250	0.5	125	26	3,250
Totals			11,426		720,826

Note: Estimates may not sum due to independent rounding.

The marine employer incurs the actual costs of the chemical test as well as the wage burden it takes for a crewmember to complete the chemical test. On average, each chemical test costs approximately $100. We use an estimate of 1.5 crewmembers to estimate the costs of chemical testing to account for the variation in crewmembers involved in SMIs. With an average of 250 SMIs per year, the annual cost after implementation of this NPRM for the actual chemical tests is $37,500 (250 SMIs × average of 1.5 crewmembers × $100 per test).

In addition to the cost of the chemical tests, there is a cost associated with the time it takes a vessel crewmember to complete the chemical test. We estimate that it takes 1 hour for a crewmember to complete the chemical test at a loaded wage rate of $47.60 per hour. We estimate that the cost of the time for a crewmember to take the chemical test under the NPRM would be $17,850 (250 SMIs × average of 1.5 crewmembers × 1 hour burden × $47.60 wage rate). Therefore, the annual cost to industry for chemical testing after implementation of this NPRM would be $55,350 (see Table 5). Adding the costs for chemical testing of $55,350 to the cost for reporting and recordkeeping of $720,826 (see Table 4) brings the estimated total annual cost to industry to $776,176, if this NPRM is implemented.

TABLE 5—ANNUAL INDUSTRY COSTS FOR CHEMICAL TESTING AFTER IMPLEMENTATION OF THE NPRM

SMIs per year	Average Crewmembers tested per SMI	Cost of testing procedures	Hours to take test	Wage Rate	Total cost of testing procedures
250	1.5	$100	1	$47.60	$55,350

The current annual burden of reporting marine casualties and SMIs under the current dollar amount thresholds is $821,634. The annual burden of reporting under the proposed new thresholds would be $776,176. Therefore, we estimate that the annual cost savings or benefit to industry after implementation of this NPRM would be $45,458. Table 6 shows a summary of the annual current industry cost burden, the annual industry cost burden after implementation of the NPRM, and the annual cost savings resulting from implementation of this NPRM.

TABLE 6—TOTAL ANNUAL COST SAVINGS TO INDUSTRY BY REQUIREMENT AFTER IMPLEMENTATION OF THE NPRM

Requirement	Current annual industry cost burden	Annual industry cost burden after implementation of NPRM	Annual industry cost savings after implementation of NPRM
Written report of marine casualty	$155,142	$146,926	$8,216
Additional burden for 10% of respondents	602,970	570,650	32,320
SMI written report	3,523	3,250	273
Testing procedures	59,999	55,350	4,649
Total	821,634	776,176	45,458

[17] Docket ID: USCG–2011–0710, *https://www.regulations.gov/docket?D=USCG-2011-0710.*

[18] The wage rate for a marine employer to complete the form CG–2692B and to report chemical test results to the OCMI is taken from existing COI number 1625–0001.

The total 10-year undiscounted industry cost savings of this NPRM would be $454,584. Table 7 shows the 10-year estimated discounted cost savings to industry to be about $319,281 with an annualized cost savings of approximately $45,458 using a 7-percent discount rate.

TABLE 7—TOTAL ESTIMATED COST SAVINGS OR INDUSTRY BENEFITS OF THE NPRM OVER A 10-YEAR PERIOD OF ANALYSIS

[Discounted Costs at 7 and 3 Percent]

Year	Total undiscounted costs	Total, discounted	
		7%	3%
1	$45,458	$42,484	$44,134
2	45,458	39,705	42,849
3	45,458	37,108	41,601
4	45,458	34,680	40,389
5	45,458	32,411	39,213
6	45,458	30,291	38,071
7	45,458	28,309	36,962
8	45,458	26,457	35,885
9	45,458	24,726	34,840
10	45,458	23,109	33,825
Total	454,584	319,281	387,769
Annualized		45,458	45,458

Benefits or Cost Savings to Government

The benefit to the Federal Government is the difference between the baseline current cost to the Coast Guard and the cost to the Coast Guard after implementation of this NPRM.

Current Costs to Government

We first estimated the current costs to the Coast Guard, which include the cost to investigate a marine casualty and the cost of processing marine casualty forms. Because an SMI is a type of marine casualty, the estimate for the cost of the investigation and the processing of the casualty forms includes those incidents that constitute an SMI. Reportable marine casualties are investigated by the Coast Guard. Some investigations may be more complex than others, depending on the incident. The Coast Guard reviewed the CG–741 (Coast Guard Office of Shore Forces) Sector Staffing Model to estimate the average number of hours per investigation across all incident types. The Sector Staffing Mode assigns a total hourly effort for the type of incident (*e.g.,* allision, grounding, collision) that is matched against MISLE data, which then provides the resource needs for each sector. The Coast Guard estimates that, across all types of incidents, these investigations take an average of 25 hours for a Lieutenant (LT; O–3) to complete. There is an average of 5,967 marine casualty cases per year. The fully loaded wage rate for an O–3 is $78 per hour, per Commandant Instruction 7310.1P. As shown in Table 8, the current annual cost of investigations is $11,635,650 (5,967 reportable marine casualties × 25 burden hours × $78 wage rate).

The Coast Guard must process the forms submitted for each reportable marine casualty. The Coast Guard currently processes an average of 5,967 marine casualty reports per year. To maintain consistency and capture the changes to this NPRM, the time estimates and wage rates for processing the forms are taken from the existing COI 1625–0001. For each reportable marine casualty, we estimate that it takes about 1 hour by a Lieutenant Junior Grade (LTJG; O–2) to process the forms (CG–2692 series), including auditing at a local field investigation office and the entry of pertinent information into Coast Guard's MISLE system. The fully loaded wage rate for an O–2 is $68 per hour, per Commandant Instruction 7310.1P. As shown in Table 8, the current annual cost for the Coast Guard to process reportable marine casualties is $405,756 (5,967 reportable marine casualties × 1 burden hour × $68 wage rate). We estimate that the total current annual cost to the Federal Government would be $12,041,406.

TABLE 8—CURRENT ANNUAL GOVERNMENT COSTS

Cost category	Reportable marine casualties	Burden hours per response	Annual hours	Wage rate	Annual cost
Investigation	5,967	25	149,175	$78	$11,635,650
Processing marine casualty reports	5,967	1	5,967	68	405,756
Total					12,041,406

Under this NPRM, increasing the dollar amount threshold for property damage would reduce the number of reportable marine casualties by 5.3 percent, resulting in 316 fewer reportable marine casualties. The burden hours per response for investigations and processing marine casualty reports would remain the same, but the average number of reportable marine casualties would decrease to 5,651 per year. We estimate that it takes an average of 25 hours for an O–3 to complete and investigate and about 1 hour for an O–2 to process the forms for each reportable marine casualty. As shown in Table 9, the annual cost for the Coast Guard to complete

investigations under the NPRM would be approximately $11,019,450 (5,651 reportable marine casualties × 25 hour burden × $78). The annual cost to process reportable marine casualties after implementation of this NPRM would be approximately $384,268 (5,651 reportable marine casualties × 1 hour burden × $68). We estimate that the total annual cost to the Federal Government would be approximately $11,403,718 after implementation of this NPRM.

TABLE 9—ESTIMATED ANNUAL GOVERNMENT COSTS AFTER IMPLEMENTATION OF THE NPRM

Cost category	Reportable marine casualties	Burden hours per response	Annual hours	Wage rate	Annual cost
Investigation	5,651	25	141,275	$78	$11,019,450
Processing marine casualty report	5,651	1	5,651	68	384,268
Total					11,403,718

The current annual cost to the Coast Guard to process marine casualty reports is $12,041,406. The annual cost to the Coast Guard after implementation of this NPRM would be approximately $11,403,718. Therefore, the annual Federal Government benefit of reducing those reportable marine casualties that involve property damage alone would be $637,688. Though this reduction does not result in a need for fewer Coast Guard investigators, the existing investigators would be able to focus on higher priority investigations. We estimate the total undiscounted cost savings or benefit of this NPRM to the Federal Government to be $6,376,880 over the 10-year period of analysis. Table 10 shows the total estimated 10-year discounted cost savings to the Federal Government to be $4,478,854, with an annualized cost savings of $637,688 using a 7-percent discount rate.

TABLE 10—TOTAL ESTIMATED COST SAVINGS OR GOVERNMENT BENEFITS OF THE NPRM OVER A 10-YEAR PERIOD OF ANALYSIS

[Discounted costs at 7 and 3 percent]

Year	Total undiscounted costs	Total, discounted	
		7%	3%
1	$637,688	$595,970	$619,115
2	637,688	556,981	601,082
3	637,688	520,543	583,575
4	637,688	486,489	566,578
5	637,688	454,663	550,075
6	637,688	424,918	534,054
7	637,688	397,120	518,499
8	637,688	371,140	503,397
9	637,688	346,860	488,735
10	637,688	324,168	474,500
Total	6,376,880	4,478,854	5,439,608
Annualized		637,688	637,688

Total Benefits of the NPRM

Table 11 presents the total estimated benefits or cost savings of the NPRM using 7- and 3-percent discount rates. We estimate the total 10-year (industry and Federal Government) undiscounted cost savings of this NPRM to be about $6,831,464. We estimate the total 10-year discounted cost savings of this NPRM to be about $4,798,134 and the annualized benefit to be about $683,146 using a 7-percent discount rate.

TABLE 11—TOTAL ESTIMATED BENEFITS OF THE NPRM OVER A 10-YEAR PERIOD OF ANALYSIS

[Discounted benefits at 7 and 3 percent]

Year	Total undiscounted costs	Total, discounted	
		7%	3%
1	$683,146	$638,455	$663,249
2	683,146	596,687	643,931
3	683,146	557,651	625,176
4	683,146	521,169	606,967
5	683,146	487,074	589,288
6	683,146	455,209	572,124
7	683,146	425,429	555,461
8	683,146	397,597	539,282

TABLE 11—TOTAL ESTIMATED BENEFITS OF THE NPRM OVER A 10-YEAR PERIOD OF ANALYSIS—Continued

[Discounted benefits at 7 and 3 percent]

Year	Total undiscounted costs	Total, discounted	
		7%	3%
9	683,146	371,586	523,575
10	683,146	347,277	508,325
Total	6,831,464	4,798,134	5,827,377
Annualized	.....	683,146	683,146

B. Small Entities

Under the Regulatory Flexibility Act, 5 U.S.C. 601–612, we have considered whether this NPRM 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.

This NPRM reduces the burden on industry by increasing the monetized threshold amounts for reporting a marine casualty incident and an SMI. There is no effect on any crewmember, owner, or operator of a vessel that does not have a reportable marine casualty or serious marine incident. There is no effect on any crewmember, owner, or operator of a vessel that has a marine casualty with property damage less than or equal to $25,000, or an SMI with damage less than or equal to $100,000, as these individuals currently do not have to report the casualty and would not have to do so under this NPRM. There is no effect on any crewmember, owner, or operator of a vessel that has a marine casualty with property damage greater than $72,000, or an SMI with property damage greater than $200,000, as these individuals must currently report such casualties and perform chemical testing, and would continue to be required to do so under this NPRM.

This NPRM would not impose any direct costs on any specific industry. The only affected individuals are owners or operators of those vessels that would be involved in a marine casualty where the only outcome is property damage of $25,000.01 through $72,000, or an SMI where the only outcome is property damage of $100,000.01 through $200,000. These entities, which would have incurred costs to report these casualties or conduct chemical testing, would be positively impacted from this NPRM because of the increase in the monetized threshold amounts.

As discussed in Section V of this NPRM, we expect that an average of approximately 316 fewer reports of marine casualties would be required per year, with one individual per vessel who we assume to be a vessel crewmember completing each report. We assume the 316 marine casualty reports occur on 316 separate vessels. It is possible a vessel could have multiple incidents in one year, resulting in multiple marine casualty reports, but for this analysis we assume the 316 fewer reports are ascribed to 316 separate vessels. We compared this affected population to the total population that could have a marine casualty and be required to prepare and submit marine casualty reporting paperwork. We used the MISLE Vessel Population data to estimate the total population that could be impacted. We found the current total population of vessels that could have a marine casualty and be required to submit paperwork is 209,475.[19] Therefore, the 316 fewer vessels preparing marine casualty paperwork represents 0.15 percent of the total population.

The owners or operators of these 316 vessels would benefit from a reduction in time burden associated with a crewmember no longer having to prepare and submit the required marine casualty reporting paperwork. Table 6 in Section V summarizes the annual cost savings to industry by requirement. Table 13 below shows these annual cost savings, as well as the vessel population we estimated would benefit from each reduction in paperwork or testing requirement.

TABLE 13—MAXIMUM POTENTIAL COST SAVINGS PER VESSEL PER INCIDENT

Requirement	Total annual cost savings	Vessel population	Maximum potential cost savings per vessel
Written report of marine casualty	$8,216	316	$26
Additional Burden for 10% of Respondents	32,320	32	1,010
SMI written report	273	21	13
Testing Procedures	4,649	21	221
Totals	45,458	.....	1,270

The total cost savings per vessel for the population of 316 vessels benefiting from this NPRM will vary depending on the requirements. For example, we estimate that 32 of the vessels (10 percent of population, rounded) would have savings due to a reduction in marine casualty reports ($26) and an additional savings for the additional

[19] Population data was pulled from MISLE on 9/28/2016. The population is for commercial vessels that are active and in-service. The population includes commercial fishing vessels, fish processing vessels, freight barges, industrial vessels, mobile offshore drilling units, offshore supply vessels, oil recovery, passenger (inspected and uninspected), passenger barges (inspected and uninspected), public freights, public tankship/barges, unclassified public vessels, research vessels, school ships, tank barges, tank ships, and towing vessels.

burden of reviewing the paperwork ($1,010) in any given year. Therefore, a one-time savings could be $1,036 for a vessel with only these two requirements. The minimum savings would be $26 for a vessel that only had the requirement of preparing and submitting the marine casualty report. If a vessel would have had to complete all the requirements in Table 13, the maximum cost savings would be $1,270. This maximum cost savings would be for a vessel with a marine casualty designated as an SMI that completed additional paperwork and reported the chemical test results to the OCMI. Therefore, the owner or operator of the 316 vessels impacted by this NPRM would have to have maximum annual revenues of $2,600 to $127,000 for this NPRM to have a positive impact greater than 1 percent.

Therefore, pursuant to section 605(b) of the Regulatory Flexibility Act, 5 U.S.C. 605(b), the Coast Guard certifies that this NPRM would not have a significant economic impact on a substantial number of small entities because the increase in the monetized property damage threshold amounts reduces the reporting burden on crewmembers or vessel owners or operators who complete the marine casualty reports or perform the required chemical testing, as described above. This NPRM would reduce the hour burden associated with marine casualty reporting and chemical testing and would not adversely impact small entities as defined by the SBA in 13 CFR. 121.201. If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this NPRM would have a significant economic impact on it, please submit a comment to the Docket Management Facility at the address under the **ADDRESSES** section of this NPRM. In your comment, explain why you think it qualifies and how and to what degree this NPRM would economically affect it.

C. Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996, Public Law 104–121, we want to assist small entities in understanding this NPRM so that they can better evaluate its effects on them and participate in the rulemaking. If you think that the NPRM would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please consult with the Coast Guard personnel listed under the **FOR FURTHER INFORMATION CONTACT** section of this NPRM. 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.

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).

D. Collection of Information

This NPRM would call for a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). As defined in 5 CFR 1320.3(c), ''collection of information'' comprises reporting, recordkeeping, monitoring, posting, labeling, and other similar actions. The title and description of the information collection, a description of those who must collect the information, and an estimate of the total annual burden follow.

Under the provisions of the NPRM, the Coast Guard would collect information from ship personnel who are involved in marine casualties resulting in more than $72,000 in property damage, and serious marine incidents resulting in more than $200,000 in property damage. This proposed requirement would amend an existing collection of information by effectively reducing the number of instances requiring information to be collected under OMB control number 1625–0001.

Title: Report of Marine Casualty & Chemical Testing of Commercial Vessel Personnel.

OMB Control Number: 1625–0001.

Summary of the Collection of Information: This NPRM would require responses such as the preparation of written notification in the form of CG–2692 (series), and the processing of records. We use this information to identify pertinent safety lessons and to initiate appropriate steps for reducing the likelihood of similar accidents in the future. The collection of information would aid the regulated public in assuring safe practices.

Need for Information: These reporting requirements permit the Coast Guard to initiate the immediate investigation of marine casualties as required by 46 U.S.C. 6301, in order to determine the causes of casualties and whether existing safety standards are adequate, or whether new laws or regulations need to be developed. Receipt of a marine casualty report is often the only way in which the Coast Guard becomes aware of a marine casualty. It is therefore a necessary first step that provides the Coast Guard with the opportunity to determine the extent to which a casualty will be investigated.

Proposed Use of Information: In the short term, the information provided in the report may also trigger corrective safety actions addressing immediate hazards or defective conditions, further investigations of mariner conduct or professional competence, or civil or criminal enforcement actions by the Coast Guard, other Federal agencies, or state and local authorities. In the long term, information contained in the report becomes part of the MISLE marine casualty database at Coast Guard Headquarters. The Coast Guard uses this information in MISLE to identify safety problems and long term trends, publish casualty summaries and annual statistics for public use, establish whether additional safety oversight or regulation is needed, measure the effectiveness of existing regulatory programs, and better focus limited Coast Guard marine safety resources.

Description of the Respondents: The respondents are those owners, agents, masters, operators, or persons in charge that notify the nearest Sector Office, Marine Inspection Office, or Coast Guard Group Office whenever a vessel is involved in a marine casualty. Specifically, this NPRM would affect those vessel crewmembers and marine employers who completed the necessary forms to report a marine casualty where the only outcome was property damage of $25,000.01 through $72,000, or an SMI with property damage of $100,000.01 through $200,000 (CG–2692 series).

Number of Respondents: We estimate the number of respondents would be 5,651 per year. This is a decrease of 316 respondents from an OMB-approved number of respondents of 5,967 per year. We estimate 250 of these marine casualty respondents would fall under the category of SMI respondents and be required to fill out an additional SMI written report (CG–2692B). This is a decrease of 21 respondents per year from 271 respondents.

Frequency of Response: The notification response would be required only if a marine casualty occurs as defined in 46 CFR 4.03–2 and 46 CFR 4.05–1.

Burden of Response: For each response, we estimate that it takes about 1 hour for a vessel crewmember to complete all of the necessary forms

(CG–2692 series). In addition, some marine casualty forms may undergo additional processing by the respondents. To account for this additional time, 10 percent of the forms submitted would have 10 hours of additional burden.[20] When a marine casualty is designated as an SMI, the marine employer must also complete an SMI written report (CG–2692B). We estimate that it takes about 0.5 hours for a respondent to complete an SMI written report (CG–2692B).

Estimate of Total Annual Burden: We estimate that the number of responses would decrease by 316 per year. At 1 hour per response, the reduced burden for submitting the responses would be 316 hours. In addition, 10 percent of these responses would have required additional processing of 10 hours per response, for a reduction of an additional 320 burden hours.[21] We estimate 21 of the responses would have been designated as an SMI. At 0.5 hours per SMI, the burden would be reduced by 11 hours (rounded). Therefore, this NPRM would decrease the total annual burden by 647 hours.[22]

As required by 44 U.S.C. 3507(d), we will submit a copy of this NPRM to OMB for its review of the collection of information.

We ask for public comment on the proposed collection of information to help us determine how useful the information is, whether it can help us perform our functions better, whether it is readily available elsewhere, how accurate our estimate of the burden of collection is' how valid our methods for determining burden are, how we can improve the quality, usefulness, and clarity of the information, and how we can minimize the burden of collection.

If you submit comments on the collection of information, submit them both to OMB and to the Docket Management Facility where indicated under the **ADDRESSES** section of this NPRM, by the date under the **DATES** section.

You are not required to respond to a collection of information unless it displays a currently valid control number from OMB. Before the Coast Guard could enforce the collection of information requirements in this NPRM, OMB would need to approve the Coast Guard's request to collect this information.

E. Federalism

A rule has implications for federalism under E.O. 13132 (''Federalism'') if it has a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this NPRM under E.O. 13132 and have determined that it is consistent with the fundamental federalism principles and preemption requirements as described in E.O.13132. Our analysis follows.

It is well settled that States may not regulate in categories reserved for regulation by the Coast Guard. It is also well settled that Coast Guard regulations promulgated under the authority of 46 U.S.C. 6101 are within a field foreclosed from regulation by the States. *See U.S.* v. *Locke,* 529 U.S. 89, 115–16 (2000) (stating ''Congress intended that the Coast Guard regulations be the sole source of a vessel's [marine casualty] reporting obligations.'').

This NPRM would change the property damage threshold amounts for reporting marine casualties and serious marine incidents, which is within the sole purview of the Coast Guard to regulate pursuant to 46 U.S.C. 6101 and the principles discussed in *Locke.* Thus, the proposed regulations are consistent with the principles of federalism and preemption requirements in E.O. 13132.

While it is settled that States may not regulate in categories in which Congress intended the Coast Guard to be the sole source of a vessel's obligations, we recognize the key role that State and local governments may have in making regulatory determinations. Additionally, for rules with federalism implications and preemptive effect, E.O 13132 specifically directs agencies to consult with State and local governments during the rulemaking process. If you believe this NPRM has implications for federalism under E.O. 13132, please contact the person listed in the **FOR FURTHER INFORMATION** section of this preamble.

F. Unfunded Mandates Reform Act

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

G. Taking of Private Property

This NPRM would not cause a taking of private property or otherwise have taking implications under E.O. 12630 (''Governmental Actions and Interference with Constitutionally Protected Property Rights'').

H. Civil Justice Reform

This NPRM meets applicable standards in sections 3(a) and 3(b)(2) of E.O. 12988, (''Civil Justice Reform''), to minimize litigation, eliminate ambiguity, and reduce burden.

I. Protection of Children

We have analyzed this NPRM under E.O. 13045 (''Protection of Children from Environmental Health Risks and Safety Risks''). This NPRM is not an economically significant rule and would not create an environmental risk to health or risk to safety that might disproportionately affect children.

J. Indian Tribal Governments

This NPRM does not have tribal implications under E.O. 13175 (''Consultation and Coordination with Indian Tribal Governments''), because it would 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.

K. Energy Effects

We have analyzed this NPRM under E.O. 13211 (''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use''). We have determined that this NPRM is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under E.O. 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

L. Technical Standards

The National Technology Transfer and Advancement Act, codified as a

[20] The Coast Guard estimates that it takes up to 1 hour to complete Form CG–2692 (series). However, we received public comments in 2013 on COI number 1625–0001 stating that some submitters take more time—up to 8 to 12 hours—to complete the form. Docket ID: USCG–2011–0710, *https://www.regulations.gov/docket?D=USCG-2011-0710.* The reason for this difference is that some entities have the form(s) reviewed by shore-side personnel, such as an attorney, prior to submission to the Coast Guard. The practice of having a form reviewed by an attorney is not required by Coast Guard regulation. While we believe that this does not typically occur, we adjusted our burden estimate to account for the added review.

[21] Due to rounding in the estimates, the current burden for the additional review is 5,970 hours. The burden under this NPRM is 5,650 hours, which is a reduction of 320 hours.

[22] The current annual burden in COI 1625–0001 for completing the marine casualty forms, the additional processing for some respondents, and the time to complete the SMI forms is 12,073 hours. The annual burden under this NPRM is 11,426 hours, a reduction of 647 hours.

note to 15 U.S.C. 272, directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through OMB, 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 NPRM does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

M. Environment

We have analyzed this NPRM under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.1D, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969, 42 U.S.C. 4321–4370f, and we have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. A preliminary environmental analysis checklist supporting this categorical exclusion determination is available in the docket where indicated under the ''Public Participation and Request for Comments'' section of this preamble.

This NPRM involves regulations concerning marine casualties and proposes to update the monetary threshold amounts for a reportable marine casualty as well as the definition of an SMI relative to property damage. Thus, we expect that this NPRM would likely be categorically excluded under Section 2.b.2 and figure 2–1, paragraph 34(d) of the Instruction. We seek any comments or information that may lead to the discovery of a significant environmental impact from this NPRM.

List of Subjects in 46 CFR Part 4

Administrative practice and procedure, Drug testing, Investigations, Marine safety, National Transportation Safety Board, Nuclear vessels, Radiation protection, Reporting and recordkeeping requirements, Safety, Transportation.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 46 CFR part 4 as follows:

TITLE 46—SHIPPING

PART 4—MARINE CASUALTIES AND INVESTIGATIONS

■ 1. The authority citation for part 4 continues to read as follows:

Authority: 33 U.S.C. 1231; 43 U.S.C. 1333; 46 U.S.C. 2103, 2303a, 2306, 6101, 6301, and 6305; 50 U.S.C. 198; Department of Homeland Security Delegation No. 0170.1. Subpart 4.40 issued under 49 U.S.C. 1903(a)(1)(E).

■ 2. In § 4.03–2, revise paragraph (a) (3) to read as follows:

§ 4.03–2 Serious marine incident.

(a) * * *

(3) Damage to property, as defined in § 4.05–1(a)(7) of this part, in excess of $200,000;

* * * * *

■ 3. In § 4.05–1, revise paragraph (a)(7) to read as follows:

§ 4.05–1 Notice of marine casualty.

(a) * * *

(7) An occurrence causing property-damage in excess of $72,000, this damage including the cost of labor and material to restore the property to its condition before the occurrence, but not including the cost of salvage, cleaning, gas-freeing, drydocking, or demurrage.

* * * * *

Dated: January 13, 2017.

V.B. Gifford,

Captain, U.S. Coast Guard, Director of Inspections and Compliance.

[FR Doc. 2017–01323 Filed 1–19–17; 8:45 am]

BILLING CODE 9110–04–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 6, 7, 14, 64, and 67

[CG Docket No. 16–145 and GN Docket No. 15–178; FCC 16–169]

Transition From TTY to Real-Time Text Technology

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In this document, the Commission seeks comment on further actions the Commission could undertake to continue the transition from outdated text telephony (TTY) technology to a reliable and interoperable means of providing real-time text (RTT) communication over Internet Protocol (IP) enabled networks and services for people who are deaf, hard of hearing, deaf-blind, or have a speech disability.

DATES: Comments are due February 22, 2017. Reply Comments are due March 24, 2017.

ADDRESSES: You may submit comments, identified by CG Docket No. 16–145 and GN Docket No. 15–178, by any of the following methods:

- *Electronic Filers:* Comments may be filed electronically using the Internet by accessing the Commission's Electronic Comment Filing System (ECFS), through the Commission's Web site *http://apps.fcc.gov/ecfs/.* Filers should follow the instructions provided on the Web site for submitting comments. For ECFS filers, in completing the transmittal screen, filers should include their full name, U.S. Postal service mailing address, and CG Docket No. 16–145 and GN Docket No. 15–178.
- *Paper Filers:* Parties who choose to file by paper must file an original and one copy of each filing. If more than one docket or rulemaking number appears in the caption of this proceeding, filers must submit two additional copies for each additional docket or rulemaking number. Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.

For detailed instructions for submitting comments and additional information on the rulemaking process, *see* the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Michael Scott, Consumer and Governmental Affairs Bureau, at (202) 418–1264 or email *Michael.Scott@fcc.gov,* or Suzy Rosen Singleton, Consumer and Governmental Affairs Bureau at (202) 510–9446 or email *Suzanne.Singleton@fcc.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to 47 CFR 1.415, 1.419, interested parties may file comments and reply comments on or before the dates indicated in the **DATES** section. Comments may be filed using the Commission's ECFS. *See Electronic Filing of Documents in Rulemaking Proceedings,* 63 FR 24121 (1998).

- All hand-delivered or messenger-delivered paper filings for the Commission's Secretary must be delivered to FCC Headquarters at 445 12th Street SW., Room TW–A325, Washington, DC 20554. The filing hours are 8:00 a.m. to 7:00 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes must be disposed of before entering the building.

• Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743.

• U.S. Postal Service first-class, Express, and Priority mail must be addressed to 445 12th Street SW., Washington DC 20554.

This is a summary of the Commission's document FCC 16–169, *Transition from TTY to Real-Time Text Technology,* Further Notice of Proposed Rulemaking, adopted December 15, 2016, and released December 16, 2016, in CG Docket No. 16–145 and GN Docket No. 15–178. The Report and Order, FCC 16–169, adopted on December 15, 2016, and released on December 16, 2016, is published elsewhere in this issue. The full text of document FCC 16–169 will be available for public inspection and copying via ECFS, and during regular business hours at the FCC Reference Information Center, Portals II, 445 12th Street SW., Room CY–A257, Washington, DC 20554. This proceeding shall be treated as a ''permit-but-disclose'' proceeding in accordance with the Commission's ex parte rules. 47 CFR 1.1200 *et seq.* Persons making ex parte presentations must file a copy of any written presentation or a memorandum summarizing any oral presentation within two business days after the presentation (unless a different deadline applicable to the Sunshine period applies). Persons making oral ex parte presentations are reminded that memoranda summarizing the presentation must (1) list all persons attending or otherwise participating in the meeting at which the ex parte presentation was made, and (2) summarize all data presented and arguments made during the presentation. If the presentation consisted in whole or in part of the presentation of data or arguments already reflected in the presenter's written comments, memoranda or other filings in the proceeding, the presenter may provide citations to such data or arguments in his or her prior comments, memoranda, or other filings (specifying the relevant page and/or paragraph numbers where such data or arguments can be found) in lieu of summarizing them in the memorandum. Documents shown or given to Commission staff during ex parte meetings are deemed to be written ex parte presentations and must be filed consistent with 47 CFR 1.1206(b). In proceedings governed by 47 CFR 1.49(f) or for which the Commission has made available a method of electronic filing, written ex parte presentations and memoranda summarizing oral ex parte presentations, and all attachments thereto, must be filed through the electronic comment filing system available for that proceeding, and must be filed in their native format (*e.g.,* .doc, .xml, .ppt, searchable .pdf). Participants in this proceeding should familiarize themselves with the Commission's ex parte rules.

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

Initial Paperwork Reduction Act of 1995 Analysis

Document FCC 16–169 seeks comment on proposed rule amendments that may result in modified information collection requirements. If the Commission adopts any modified information collection requirements, the Commission will publish another notice in the **Federal Register** inviting the public to comment on the requirements, as required by the Paperwork Reduction Act. Public Law 104–13; 44 U.S.C. 3501–3520. In addition, pursuant to the Small Business Paperwork Relief Act of 2002, the Commission seeks comment on how it might further reduce the information collection burden for small business concerns with fewer than 25 employees. Public Law 107–198; 44 U.S.C. 3506(c)(4).

Synopsis

1. Real-time text is a mode of communication that permits text to be sent immediately as it is being created. The Commission's proposed action seeks to further ensure that people who are deaf, hard of hearing, deaf-blind, or have a speech disability can fully utilize and benefit from twenty-first century communications technologies as the United States migrates from legacy circuit-switched systems to IP-based networks and services.

2. In document FCC 16–169, the Commission seeks further comment on:

• Setting an appropriate timeline or trigger for the sunset of service providers' obligation to ensure backward compatibility between real-time text (RTT) and text telephone (TTY) technology, and a proposed date of 2021 for this purpose;

• Integrating RTT into the provision of telecommunications relay services (TRS);

• Addressing the RTT needs of people with cognitive disabilities and people who are deaf-blind through the provision of block mode and connectivity with refreshable Braille displays.

Establishing a Deadline To Sunset the Obligation To Ensure RTT Is Backward Compatible With TTY Technology

3. In document FCC 16–169, the Commission concludes that it is premature to establish a deadline to sunset the obligation to ensure that services and equipment that support RTT is backward compatible with TTY technology, until the Commission has gathered additional information about the deployment and effectiveness of the transition from TTY to RTT technology. The Commission believes that collecting such information will be useful for a Commission determination as to when TTY users have transitioned to RTT to a point that warrants elimination of the backward compatibility requirement. To this end, the Commission seeks comment on the type of data and metrics that can be used to monitor the availability, adoption, and acceptance of RTT services and devices. For example, would it be useful to gather data on the total number of end user devices supporting RTT that are made available for sale? Would it also be helpful to track the adoption of RTT on services and devices used by public safety answering points (PSAPs), government entities, and businesses? To assess the impact of RTT on PSAPs without IP connectivity, should the Commission track the frequency of RTT-to-TTY 911 calls, and how should the Commission address contingencies if there is an adverse impact? To what extent can service providers also gather data on RTT usage by consumers? Next, the Commission seeks input on when and how such data should be reported. The Commission currently requires wireless service providers who have been granted waivers of the TTY obligations to report to the Commission semi-annually on the progress of their RTT implementation efforts. Should the Commission require similar reports of wireless and wireline service providers and manufacturers? Should certain actions, such as the grant of a waiver, trigger a reporting requirement? Alternatively, should any reporting requirement be postponed until after the requirements for the wireline transition have been adopted? Are there other reports collected by the Commission through which it should collect this or similar information on RTT?

4. The Commission notes that by 2021, Tier I wireless service providers will have had the opportunity to support RTT on their IP-based networks for three years, manufacturers will have been producing RTT-compliant

equipment for two years, and smaller wireless service providers will have supported RTT on their network for at least 18 months. For these reasons, and because by such date, the Commission expects to have data sufficient to assess adoption of RTT technology, the Commission proposes to set a sunset date for RTT–TTY backward compatibility of 2021 unless the Commission finds a reason to extend this deadline. The Commission seeks comment on this proposal, and whether there is a different point in time when it would be appropriate for the Commission to reassess the need for covered entities to continue supporting TTY technology via backward compatibility on their IP-based voice service networks. For example, should the Commission's reassessment be tied in any way to the implementation of the deployment of RTT technology over wireline networks, or should this reassessment take place after the sunset of the public switched telecommunications network (PSTN) and the transition of all consumers to IP-based wireless *and* wireline networks?

Requirements for TRS Providers

5. In document FCC 16–169, the Commission allows wireless service providers to support TRS access through RTT technology, including via 711 abbreviated dialing access, in lieu of supporting TRS through TTY technology. The Commission further clarifies that wireless service providers transmitting such calls may comply with these RTT support requirements by ensuring that such communications are backward compatible with the TTY technology currently used in such call centers. This approach is designed to ensure that RTT users can place and receive TRS calls through state TRS program call centers even when such centers are not equipped to receive RTT calls.

6. Some forms of TRS are provided over the PSTN, while others are made available via IP networks. In the Notice of Proposed Rulemaking (*NPRM*), published at 81 FR 33170, May 25, 2016, preceding document FCC 16–169, the Commission sought comment on whether and how it should amend the Commission's TRS rules to authorize or require other forms of TRS to incorporate RTT capabilities into platforms and terminal equipment used with these services.

7. Comments in the record express a variety of views as to the manner in which RTT should be integrated into TRS operations. The record in this proceeding also contains extensive information about the benefits of RTT. It would appear, therefore, that integrating RTT into TRS operations similarly would benefit text-reliant users, and would fulfill a congressional directive to the Commission to ensure that TRS regulations ''encourage . . . the use of existing technology and do not discourage or impair the development of improved technology.'' In other words, taking this action will ensure that TRS users are able to benefit from evolving technologies in what will eventually be an all-IP environment.

8. However, before adopting rules governing the provision of RTT as an integrated component of TRS, the Commission seeks additional comment on the costs, benefits, and technical feasibility of enabling this feature for various forms of TRS, for both TRS providers and TRS users. For example, what changes would be needed in TRS equipment (*e.g.,* hardware, software, or applications) to support RTT between an IP-based TRS user and the communications assistant (CA) or between the parties to the call? Will adoption of an RTT mandate require TRS providers or users to purchase new TRS equipment or updates to TRS equipment software? To what extent will providers have to modify their call routing and handling features?

9. Additionally, the Commission seeks comment on whether the incorporation of RTT into the provision of TRS operations should be mandated or only allowed. Along these lines, the Commission seeks comment on the appropriate regulatory treatment for RTT in the TRS context. Specifically, given that RTT is a text-based form of communication—as is TTY-based TRS and IP Relay—should this feature be subject to the same regulatory treatment that applies to TTY-based TRS, or would it be more appropriate to consider this akin to IP Relay for purposes of the Commission's TRS rules? For example, should the Commission require RTT-based TRS providers to meet the same mandatory minimum standards as currently applied to TTY-based TRS, such as call release functionality? To what extent should such providers be required to handle emergency calls, and should they adhere to the Commission's rules for TTY-based TRS or IP Relay TRS for this purpose? Are there certain mandatory minimum standards that should not be applicable to RTT technology?

10. Given that TTY-based TRS is a mandated service for common carriers, if the Commission requires the provision of RTT–TRS, at what point in the future should providers be relieved of their obligations to provide and support TTY-based TRS? Should wireline IP-based voice service providers and equipment manufacturers be required to support RTT before TRS providers are required to support RTT?

11. At the same time that the Commission recognizes that RTT has the potential to improve TRS for certain RTT users who choose to communicate directly in text with another party, the Commission agrees with commenters that RTT should augment and complement rather than supplant TRS, and seeks comment on this belief. Specifically, the Commission acknowledges that some forms of TRS, such as video relay service and speech-to-speech service, may fulfill the needs of people with disabilities who are not text-reliant users. The Commission therefore believes that the addition of RTT as a TRS option should not diminish the ability of individuals who are reliant on these other forms of TRS to continue having access to those services. The Commission seeks comment on this assumption.

12. Finally, the Commission seeks input on the mechanisms that are needed to ensure that the provision of RTT–TRS by IP-based providers effectively meets the communication needs of TRS users. Should the Commission require TRS providers to support RTT to enable text-based communication between the CA and the text-reliant user; between the CA and the other party to the call; or between both parties to the call? Are there technical challenges associated with supporting RTT in situations where the parties to the call are connected through an IP-based TRS provider? Should the Commission require IP captioned telephone service (IP CTS) providers to support RTT transmission in any voice channels they provide and in any off-the-shelf equipment provided to IP CTS users? Would the use of conversation windows help an IP CTS user distinguish between a direct RTT communication received from the other party and text generated by an IP CTS relay operator? Are there technical standards the Commission should adopt for the provision of RTT by IP-based TRS providers? The Commission seeks comment specifically on the costs, benefits, and feasibility of requiring IP-based TRS providers to incorporate RTT capability into the provision of their services and on other related matters. Finally, the Commission seeks comment on the appropriate timeline for adopting RTT requirements for IP-based TRS providers.

13. *Impact of RTT on TRS.* In the *NPRM,* the Commission assumed that

because RTT will provide greater opportunities for direct, point-to-point text communications and can enable text to be intermixed with voice, it can reduce reliance on relay services to the extent RTT capabilities in end user devices become ubiquitous as a universal text solution. The Commission similarly noted that RTT could enhance the ability of TRS to provide functionally equivalent telephone service for those individuals who continue to rely on TRS as their communication method. AT&T agrees that it is important to review the potential impacts of RTT on TRS, and specifically to assess the need to adjust the TRS Fund supporting these services as this impact becomes clearer. The Commission seeks comment on the best methodology to determine the extent to which RTT reduces reliance on TRS. Additionally, how can the Commission best determine the extent to which the introduction of RTT increases TRS use among some consumers because it enhances the ability of TRS to provide functionally equivalent telephone service? Should any data collected on the effect that RTT has on TRS wait until wireline networks transition from TTY technology to RTT? What other information should the Commission consider in determining whether the availability and use of RTT necessitates changes to the TRS program or its funding?

Other RTT Features

14. In the *NPRM,* the Commission sought comment on whether it is possible to identify certain RTT features or functional capabilities that are necessary to meet the communication needs of individuals who are deaf-blind, people with cognitive disabilities, or other specific segments of the disability community. Some commenters suggest that slowing down an RTT text display is necessary for refreshable Braille displays. They also suggest enabling Braille display users to suspend incoming text when the user is typing, because receiving text while typing on a Braille keyboard could cause confusion. The Commission seeks comment on whether these and similar features can enhance service providers' and manufacturers' ability to meet performance objectives under 47 CFR parts 6, 7, and 14 for individuals who use refreshable Braille displays, including people who are deaf-blind. The Commission also seeks further comment on the technical and practical challenges of supporting compatibility with refreshable Braille displays and similar assistive technologies. What current steps are being taken to examine these issues? Is there a potential timeline for resolving concerns to support the use of refreshable Braille displays with RTT?

15. Block mode allows the user to hold onto a text communication while it is being composed, and then send it in its entirety, in a manner akin to short message service (SMS) or text messaging. This enables the user to edit individual characters and groups of words before sending a message. Some commenters agree that block mode is a desirable option that would enhance effective communication for certain individuals and in certain situations. The Commission seeks further comment on the extent to which offering a block mode option will enhance service providers' and manufacturers' ability to meet part 6, 7, and 14 performance objectives for people with certain types of disabilities.

Initial Regulatory Flexibility Analysis

16. As required by the Regulatory Flexibility Act, as amended (RFA), the Commission has prepared this Initial Regulatory Flexibility Analysis (IRFA) of the possible significant economic impact on a substantial number of small entities by the policies and rules proposed in document FCC 16–169. Written public comments are requested on this IRFA. Comments must be identified as responses to the IRFA and must be filed by the deadlines for comments specified in the **DATES** section. The Commission will send a copy of document FCC 16–169, to the Chief Counsel for Advocacy of the Small Business Administration (SBA).

Need for, and Objectives of, the Proposed Rules

17. In document FCC 16–169, the Commission seeks comment on:

- Setting an appropriate timeline or trigger for the sunset of service providers' obligation to ensure backward compatibility between RTT and TTY technology, and a proposal of a date of 2021 for this purpose;
- Integrating RTT into the provision of TRS; and
- Addressing the RTT needs of people with cognitive disabilities and people who are deaf-blind through the provision of block mode transmission and through connectivity with refreshable Braille displays.

Legal Basis

18. The proposed action is authorized under sections 1, 2, 4(i), 225, 251, 255, 303, 316, and 716 of the Communications Act of 1934, as amended, section 6 of the Wireless Communications and Public Safety Act of 1999, and section 106 of the CVAA; 47 U.S.C. 151, 152, 154(i), 225, 255, 303, 316, 615a–1, 615c, 617.

Listing of Small Entities to Which the Proposed Rules Will Apply

19. The majority of the proposals in document FCC 16–169 will affect obligations on telecommunications carriers and providers, VoIP service providers, wireline and wireless service providers, advanced communications services (ACS) providers, and telecommunications equipment and software manufacturers. Other entities, however, that choose to object to the substitution of RTT for TTY technology under the Commission's amended rules may be economically impacted by document FCC 16–169.

- *Wired Telecommunications Carriers;*
- *Local Exchange Carriers (LECs);*
- *Incumbent Local Exchange Carriers (Incumbent LECs);*
- *Competitive Local Exchange Carriers (Competitive LECs), Competitive Access Providers (CAPs), Shared-Tenant Service Providers, and Other Local Service Providers;*
- *Interexchange Carriers;*
- *Other Toll Carriers;*
- *Wireless Telecommunications Carriers (except Satellite);*
- *Cable Companies and Systems (Rate Regulation);*
- *All Other Telecommunications;*
- *TRS Providers;*
- *Electronic Computer Manufacturing;*
- *Telephone Apparatus Manufacturing (wireline);*
- *Computer Terminal and Other Computer Peripheral Equipment Manufacturing;*
- *Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing;*
- *Other Communications Equipment Manufacturing; and*
- *Software Publishers*

Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements

20. In document FCC 16–169, the Commission seeks comment on integrating RTT into the provision of TRS, requiring certain additional features and capabilities of RTT, and the appropriate timeline to sunset the requirement for backward compatibility of RTT with TTY technology. With the following exception, these proposals do not include new or modified reporting, recordkeeping, and other compliance requirements. Specifically, in document 16–169, the Commission seeks comment on the type of data that should be

collected to help determine the extent to which RTT reduces reliance on TRS or alternatively the extent to which the introduction of RTT increases TRS use among some consumers because it has enhanced the ability of TRS to provide functionally equivalent telephone service.

Steps Taken To Minimize Significant Economic Impact on Small Entities, and Significant Alternatives Considered

21. The RFA requires an agency to describe any significant, specifically small business, alternatives that it has considered in reaching its proposed approach, which may include the following four alternatives (among others): ''(1) the establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance or reporting requirements under the rule for small entities; (3) the use of performance, rather than design, standards; and (4) an exemption from coverage of the rule, or any part thereof, for small entities.''

22. In document FCC 16–169, the Commission seeks comment on the type of data and metrics that can be used to monitor the availability, adoption, and acceptance of RTT services and devices. This information is intended to help the Commission determine when TTY users have transitioned to RTT to a point that would warrant elimination of the requirement for RTT to be backward compatible with TTY. While the collection of data may initially burden small businesses, the eventual sunset of the obligation to ensure that RTT is backward compatible with TTY will in the long run reduce the burden for small entities and emergency call centers to maintain TTY technology and backward compatibility capability.

23. The Commission also seeks comments on the costs, benefits, feasibility, and appropriate timeline for requiring IP-based TRS providers to incorporate RTT capability into the provision of their services. The information requested will inform the Commission of concerns with the transition and appropriate timelines for all entities, which will allow the Commission to consider rules and implementation deadlines that minimize burdens and relieve possible adverse economic impact on small entities. The Commission's gathering of information to determine the effect of RTT on TRS services and the TRS Fund will allow the Commission to consider changes to the rules that may minimize burdens and relieve possible adverse economic impact on small entities.

24. In document FCC 16–169, the Commission also seeks comment on identifying certain RTT features or functional capabilities, such as compatibility with refreshable braille displays and block mode transmission, that are necessary to meet the communication needs of individuals who are deaf-blind, people with cognitive disabilities, or other specific segments of the disability community. In seeking comments on feasibility, the Commission seeks to integrate flexibility into the requirements to take into consideration the limitations of small businesses. Because the Commission will require implementation of these features only if achievable, the Commission anticipates that there will be little to no impact on small entities that would claim the requirement is not achievable.

Federal Rules That May Duplicate, Overlap, or Conflict With the Commission's Proposals

25. None.

Ordering Clauses

Pursuant to sections 4(i), 225, 255, 301, 303(r), 316, 403, 715, and 716 of the Communications Act of 1934, as amended, and section 106 of the CVAA, 47 U.S.C. 154(i), 225, 255, 301, 303(r), 316, 403, 615c, 616, 617, document FCC 16–169 is adopted.

The Commission's Consumer Information Bureau, Reference Information Center, shall send a copy of document FCC 16–169, including the Initial Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the Small Business Administration.

Federal Communications Commission.

Katura Howard,

Federal Register Liaison Officer, Office of the Secretary.

[FR Doc. 2017–01382 Filed 1–19–17; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Part 1

[FAR Case 2016–005; Docket No. 2016–0005; Sequence No. 1]

RIN 9000–AN29

Federal Acquisition Regulation; Effective Communication Between Government and Industry; Extension of Time for Comments

AGENCY: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Proposed rule; extension of comment period.

SUMMARY: DoD, GSA, and NASA issued a proposed rule (FAR Case 2016–005) on November 29, 2016, amending the Federal Acquisition Regulation (FAR) to implement a section of the National Defense Authorization Act for Fiscal Year 2016. This rule clarifies that agency acquisition personnel are permitted and encouraged to engage in responsible and constructive exchanges with industry, so long as those exchanges are consistent with existing law and regulation and do not promote an unfair competitive advantage to particular firms. The deadline for submitting comments is being extended from January 30, 2017 to March 2, 2017 to provide additional time for interested parties to provide comments on the FAR case.

DATES: For the proposed rule published on November 29, 2016 (81 FR 85914), submit comments by March 2, 2017.

ADDRESSES: Submit comments in response to FAR Case 2016–005 by any of the following methods:

- *Regulations.gov: http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by searching for ''FAR Case 2016–005''. Select the link ''Comment Now'' that corresponds with ''FAR Case 2016–005.'' Follow the instructions provided at the ''Comment Now'' screen. Please include your name, company name (if any), and ''FAR Case 2016–005'' on your attached document.
- *Mail:* General Services Administration, Regulatory Secretariat Division (MVCB), ATTN: Ms. Flowers, 1800 F Street NW., 2nd Floor, Washington, DC 20405.

Instructions: Please submit comments only and cite FAR Case 2016–005, in all

correspondence related to this case. All comments received will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided.

FOR FURTHER INFORMATION CONTACT: Mr. Michael O. Jackson, Procurement Analyst, at 202–208–4949, for clarification of content. For information pertaining to status or publication schedules, contact the Regulatory Secretariat Division at 202–501–4755. Please cite FAR Case 2016–005.

SUPPLEMENTARY INFORMATION:

I. Background

DoD, GSA, and NASA published a proposed rule in the **Federal Register** at 81 FR 85914, on November 29, 2016. The comment period is extended to provide additional time for interested parties to submit comments on the FAR case until March 2, 2017.

List of Subjects in 48 CFR Part 1

Government procurement.

Dated: January 17, 2017.

William F. Clark,

Director, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2017–01405 Filed 1–19–17; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

49 CFR Part 40

[Docket DOT–OST–2016–0189]

RIN 2105–AE58

Procedures for Transportation Workplace Drug and Alcohol Testing Programs: Addition of Certain Schedule II Drugs to the Department of Transportation's Drug-Testing Panel and Certain Minor Amendments

AGENCY: Office of the Secretary of Transportation (OST), U.S. Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department of Transportation is proposing to amend its drug-testing program regulation to add four opioids (hydrocodone, hydromorphone, oxymorphone, and oxycodone) to its drug-testing panel; add methylenedioxyamphetamine (MDA) as an initial test analyte; and remove methylenedioxyethylamphetamine, (MDEA) as a confirmatory test analyte. The proposed revision of the drug-testing panel is intended to harmonize with the revised Mandatory Guidelines established by the U.S. Department of Health and Human Services for Federal drug-testing programs for urine testing. This proposal also adds clarification to certain drug-testing program provisions where necessary, removes outdated information in the regulations that is no longer needed, and proposes to remove the requirement for employers and Consortium/Third Party Administrators to submit blind specimens.

DATES: Comments to the notice of proposed rulemaking should be submitted by March 24, 2017. Late-filed comments will be considered to the extent practicable.

ADDRESSES: To ensure that you do not duplicate your docket submissions, please submit them by only one of the following means:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for submitting comments.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Ave. SE., West Building Ground Floor Room W12–140, Washington, DC 20590–0001.
- *Hand delivery:* West Building Ground Floor, Room W–12–140, 1200 New Jersey Ave. SE., between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

Instructions: To ensure proper docketing of your comment, please include the agency name and docket number DOT–OST–2016–0189 or the Regulatory Identification Number (RIN), 2105–AE58, for the rulemaking at the beginning of your comments. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Patrice M. Kelly, Acting Director, Office of Drug and Alcohol Policy and Compliance, 1200 New Jersey Avenue SE., Washington, DC 20590; telephone number 202–366–3784; *ODAPCWebMail@dot.gov.*

SUPPLEMENTARY INFORMATION:

I. Purpose

The Department of Transportation (DOT or the Department) is issuing this notice of proposed rulemaking (NPRM) to revise Part 40 of Title 49 of the Code of Federal Regulations to harmonize with the revised Department of Health and Human Services (HHS) Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine (HHS Mandatory Guidelines) published on January 23, 2017, effective October 1, 2017. DOT currently requires urine testing for safety-sensitive transportation industry employees subject to drug testing under Part 40.

There are two changes to the HHS Mandatory Guidelines to which this notice proposes to harmonize Part 40. First, the revised HHS Mandatory Guidelines, in part, allow Federal agencies with drug-testing responsibilities to test for four additional Schedule II (of the Controlled Substances Act) prescription medications: Hydrocodone, hydromorphone, oxycodone, and oxymorphone. Second, the HHS Mandatory Guidelines remove methylenedioxyethylamphetamine, (MDEA) as a confirmatory test analyte from the existing drug-testing panel and add methylenedioxyamphetamine (MDA) as an initial test analyte.

In addition to harmonizing with pertinent sections of the HHS Mandatory Guidelines for urine testing, we also propose in this NPRM to modify (for clarification) certain existing Part 40 provisions that cover the handling of urine specimens; to remove provisions that no longer are necessary (such as obsolete compliance dates); and to add clarifying language to other provisions (such as updated definitions and web links where necessary.) The Department also proposes to remove existing Part 40 requirements related to blind specimen testing.

II. Authority for This Rulemaking

This rulemaking is promulgated pursuant to the Omnibus Transportation Employee Testing Act (OTETA) of 1991 (Pub. L. 102–143, tit. V, 105 Stat. 952). OTETA sets forth DOT reliance on the HHS Mandatory Guidelines for scientific testing issues. Section 503 of the Supplemental Appropriations Act, 1987 (Pub. L. 100–71, 101 Stat 391, 468), 5 U.S.C. 7301, and Executive Order 12564 establish HHS as the agency that directs scientific and technical guidelines for Federal workplace drug-testing programs and standards for certification of laboratories engaged in such drug testing. While DOT has discretion concerning many aspects of the regulations governing testing in the transportation industries' regulated programs, we must follow the HHS Mandatory Guidelines for the categories of drugs for which we will require testing.

III. Background

Relevant History of the DOT Drug-Testing Program Regulation

The Department first published its drug-testing program regulation (49 CFR part 40) on November 21, 1988 as an interim final rule (53 FR 47002). We based the rule on HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs (See 53 FR 11970), which, in part, required cocaine and marijuana to be screened by Federal agencies. HHS based this requirement on the incidence and prevalence of the abuse of these two substances in the general population and on the experiences, at the time, of the Departments of Defense and Transportation in screening their workforces (53 FR 11973–11974). Agencies also were authorized under the 1988 HHS Mandatory Guidelines to test for phencyclidine, amphetamines, and opiates. Among other provisions from those guidelines, DOT incorporated a 5-panel test to include all of the drugs HHS authorized and published a final rule on December 1, 1989 (54 FR 49854).

We made the last comprehensive revisions to Part 40, on August 16, 2010 (See 75 FR 49850). This 2010 revision once again harmonized our DOT drug-testing program, where necessary, with the HHS Mandatory Guidelines effective October 1, 2010 (See 73 FR 7185; 75 FR 22809). Specifically, to harmonize we required initial and confirmatory testing for methylenedioxymethamphetamine (MDMA); confirmatory testing for MDA and MDEA; and initial testing for 6-acetylmorphine (6–AM). We also lowered the initial and confirmatory test cutoff concentrations for amphetamines and cocaine.

Just as we have revised Part 40 in the past, we propose to revise Part 40 now to harmonize, in pertinent part, with the most recently revised HHS Mandatory Guidelines issued on January 23, 2017. HHS has set an effective date of October 1, 2017, for compliance with its final revision.

Relevant Changes to the HHS Mandatory Guidelines

HHS monitors drug abuse trends and reviews information on new drugs of abuse from sources such as Federal regulators, researchers, the drug-testing industry, and public and private sector employers. In its May 15, 2015 ''Notice of Proposed Revisions'' (See 80 FR 28103), HHS indicated that, since its original Guidelines were published in 1988, a number of recommendations have been made for additional drugs to be included in Federal workplace drug-testing programs. According to HHS, recommendations for the four added semi-synthetic drugs were based on a review of scientific information and on input from the Drug Testing Advisory Board (DTAB) [1] on the methods necessary to detect the analytes of drugs and on drug abuse trends. With the DTAB recommendations, private sector experience findings, and analysis of current drug abuse trends, HHS concluded that the additional opioids, oxycodone, oxymorphone, hydrocodone, and hydromorphone, should be added in the Federal program.

In its ''Final Notice of Revisions'' HHS acknowledged that, while it had proposed MDA and MDEA as initial test analytes, three commenters disagreed with the addition of MDA and MDEA as target analytes. HHS indicated that the commenters stated that this change would require modification of current immunoassay reagents, laboratory processes, or both. The commenters noted that this imposes an unnecessary burden for compounds with such low incidence in workplace testing. HHS agreed and, based on comment, removed MDEA from its Mandatory Guidelines. HHS determined that the number of positive MDEA specimens reported by HHS-certified laboratories does not support testing all specimens for MDEA in Federal workplace drug testing programs. HHS indicated that it understands that MDA and some other analytes also have a low incidence, but believes that continued testing for these analytes is warranted in a deterrent program. In particular, inclusion of MDA as an initial and confirmatory test analyte is warranted according to HHS because, in addition to being a drug of abuse, it is a metabolite of MDEA and MDMA.

Harmonizing Changes to the DOT Drug-Testing Program Regulation

In keeping with our obligations under OTETA to follow the HHS Mandatory Guidelines for the drugs for which we test, we propose to add and remove the drugs adopted in the revised HHS Mandatory Guidelines for urine. Adding the four semi-synthetic opioids, which are already tested for in many transportation employers' non-DOT testing programs, would allow the DOT to detect a broader range of potentially impairing drugs and thereby enhance the safety of the transportation industry and the public they serve.

[1] The Drug Testing Advisory Board provides advice to HHS (the Administrator of SAMHSA) based on an ongoing review of the direction, scope, balance, and emphasis of the Agency's drug-testing activities and the drug testing laboratory certification program. See *http://www.samhsa.gov/about-us/advisory-councils/drug-testing-advisory-board-dtab/board-charter.*

IV. Discussion of the Proposal

In this NPRM, in addition to proposing to add and remove drugs on the DOT drug-testing panel, we are using this opportunity to make some necessary modifications to Part 40. Specifically, we are proposing to amend certain provisions related to the testing of urine specimens. For example, we would add a new section to Part 40 to emphasize that only urine specimens screened and confirmed at HHS certified laboratories are currently authorized to be used for drug testing. We also have determined, based on a focused analysis of historical drug-testing program data, that the burdens associated with blind specimen testing may not be cost-beneficial. Therefore, in the interest of reducing burden on program participants who are affected by blind specimen testing requirements, we propose to remove this requirement from our program. We propose other, mainly editorial, revisions to improve the efficiency of our program, such as removing compliance dates that are no longer needed and updating program web links to reflect those currently being used on the DOT Web site.

Here is a more detailed summary of our specific proposals. We propose to:

1. Amend our drug-testing panel and Medical Review Officer (MRO) test result verification procedures to add hydrocodone, hydromorphone, oxycodone, and oxymorphone (and their corresponding test cutoff concentrations), add MDA as an initial test analyte, and remove MDEA.

2. Remove, modify, and add some definitions to further clarify our program and also to make certain definitions consistent with the revised HHS Mandatory Guidelines.

3. Modify three provisions related to urine specimens. We propose to: Add a new provision to indicate that only urine specimens are authorized to be used for drug testing under Part 40; revise an existing provision to describe the procedure for discarding an original urine specimen under certain circumstances; and align our regulations with the revised National Laboratory Certification Program (NLCP) manual by adding three new ''fatal flaws'' to the existing list of four ''fatal flaws'' currently found in Part 40.

4. Remove Part 40 provisions that reference blind specimen testing.

5. Add emphasis to an existing Part 40 provision that prohibits DNA testing of urine specimens.

6. Amend § 40.141, which refers to how an MRO obtains information for the

verification decision. We would amend this section to add a clarification that a ''prescription'' means a ''valid prescription under the Controlled Substances Act,'' which is language that already exists in Part 40 and add a new paragraph that would harmonize this section with Section 3.5 of the HHS Mandatory Guidelines, which allows MROs to request additional testing of a specimen in certain circumstances.

7. Modify §§ 40.137 and 40.139, the sections that address how the MRO must verify test results, by proposing to make minor modifications to the section headings and regulatory text to incorporate the addition of the four new semi-synthetic opioids.

8. Include a provision that would require collectors, Substance Abuse Professionals (SAPs), MROs, Screening Test Technicians (STTs), and Breath Alcohol Technicians (BATs) to subscribe to the DOT Office of Drug and Alcohol Policy and Compliance (ODAPC) list-serve.

9. Remove the list of SAP certification organizations from the list of qualifying SAP credentials in Part 40. Instead, we would maintain the list of certifying organizations on our Web site.

10. Provide a provision to prohibit program participants from using DOT- (or other Federal agency) branded items (such as logos, titles, emblems, etc.) on their Web sites, publications, etc.

11. Remove certain compliance dates that are now obsolete because they are more than 5 years old.

12. Correct two typos, in §§ 40.233(c)(4) and 40.162(c), that reference incorrect paragraph sections and make an editorial correction in § 40.67(n) that would delete erroneous wording.

13. Update the following appendices to Part 40: Appendices B and C, to add the four new drugs to the drugs listed and remove MDEA; Appendix D, to update a web link; and Appendix H, to remove the instruction sheet for the Management Information System Data Collection from our regulations and move it to our guidance material located on our Web site.

14. Update web links referenced in the current rule that have changed on our DOT Web site.

Detailed Discussion of the Proposals

1. *Modification of the Drug-Testing Panel*—We propose to modify the existing drug-testing panel in § 40.87(a) and the MRO test result verification procedures in §§ 40.137 and 40.139, to include hydrocodone, hydromorphone, oxycodone, and oxymorphone. We also propose to remove MDEA from § 40.87(a) and add MDA as an initial test analyte as discussed previously in this document. As indicated above in the section of this preamble entitled ''II. Authority for this Rulemaking,'' OTETA mandates that the DOT drug-testing panel must correspond to HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs. As such, since the inception of our drug-testing program, the DOT has never deviated from HHS on the drugs for which we test, the type of specimens which we test, specimen testing validity values, or initial and confirmatory cutoff values. This proposal is no different. We propose to fully adhere to the revised HHS guidelines regarding the drugs for which we propose to require testing.

Currently, DOT regulations mandate urine testing under a five-panel test. We propose to maintain the current five-panel test, but would rename the existing opiates category in § 40.85 from ''opiates'' to ''opioids'' to include the new HHS-mandated drugs.

Opiates are derived from opium poppy plant alkaloid compounds, and include codeine and morphine. Heroin is produced by acetylation of morphine. Opioids is a broader term but, for purposes of Part 40, includes only opiate and semi-synthetic compounds (*i.e.,* hydrocodone, hydromorphone, oxycodone, and oxymorphone). Semi-synthetic opioids interact with the body's chemical system in the same way as natural opiates (*e.g.* codeine, morphine, and heroin) and produce similar effects. Misuse, abuse, opioid use disorder (addiction), and overdose are potential dangers related to prescription opioids.

The following is a representative sampling of information provided by various organizations who have reported on prescription opioid use trends over the past few years:

- CDC data from 2012 indicates that 259 million prescriptions were written for prescription opioids, which is more than enough to give every American adult their own bottle of pills.[2]
- According to the SAMHSA National Survey on Drug Use and Health 2014 data, almost 2 million Americans misused or were dependent on prescription opioids.[3]
- As posted by the Office of National Drug Control Policy, according to the National Center for Health Statistics, the number of overdose deaths involving opioids rose from 28,647 in 2014 to 33,091 in 2015.[4]
- National Center for Health Statistics[5] data indicates that every year since 2002 more than 40 percent of the total number of overdose deaths in the United States have been related to prescription opioids.

In light of this compelling information regarding opioid use (and the national attention being focused on this issue), we propose to modify the DOT drug-testing regimen not only to meet our statutory obligation under OTETA to do so, but also to raise the level of safety for the transportation industry and the public.

2. *Definitions*—We propose to revise § 40.3 to make the following modifications:

- *Blind specimen or blind performance test specimen* would be removed. Because we are proposing to remove the requirement for blind specimen testing, we no longer would need to define this term in Part 40. In addition, Part 40 provisions do not refer to ''blind performance test specimen,'' so we propose to remove it as well.
- *DOT, the Department, DOT agency* would be revised to make a clarification with respect to the status of the U.S. Coast Guard. The Coast Guard transferred to the Department of Homeland Security (DHS) in 2003, and as such, is not part of the DOT. The Coast Guard, however, has continued to use Part 40 for most of its drug and alcohol testing procedures. This amendment would clarify that, when Part 40 mentions DOT agencies, the Coast Guard is included under that heading even though it resides in DHS.
- *Drugs* would be revised (for reasons discussed in detail earlier in this preamble) to reflect the addition of hydrocodone, hydromorphone, oxycodone, and oxymorphone to the existing DOT drug-testing panel. Specifically, we would expand the reference to ''opiates'' in the existing definition to ''opioids.''

3. *Clarification/modifications related to urine specimens*—We propose the following three amendments relating to the testing of urine specimens:

- We propose to add a new § 40.210 entitled: ''Are drug tests other than urine permitted under the regulations?'' to indicate that *only* urine specimens are currently authorized for drug testing. Adding new § 40.210 would establish

[2] Centers for Disease Control and Prevention (2014). Opioid Painkiller and Prescribing, Where You Live Makes a Difference. Available at: *http://www.cdc.gov/vitalsigns/opioid-prescribing/.*

[3] Substance Abuse and Mental Health Services Administration, National Survey on Drug Use and Health, 2014. Available at: *http://www.samhsa.gov/data/sites/default/files/NSDUH-FRR1-2014/NSDUH-FRR1-2014.pdf.*

[4] *https://www.whitehouse.gov/the-press-office/2016/12/08/continued-rise-opioid-overdose-deaths-2015-shows-urgent-need-treatment.*

[5] *https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates.*

parity with an existing Part 40 alcohol testing section, § 40.277, entitled: ''Are alcohol tests other than saliva or breath permitted under these regulations?'' which indicates (for alcohol testing) that only saliva and breath are authorized.

• We propose to amend existing § 40.83 and § 40.199 to include revisions made to the ''fatal flaws'' listing found in the latest revision of the NLCP Manual which became effective September 21, 2016. Existing paragraph (b) of § 40.199 provides for four ''fatal flaws'' but would be amended to include three additional fatal flaws included in the revised NLCP Manual for a total of seven fatal flaws that MROs must consider during the review and verification process.

• We propose to amend paragraph § 40.193(b)(4) to address what a collector does when the employee provides a ''questionable'' specimen (due to signs of tampering or when the temperature is out of range), and then the employee does not provide a second sufficient specimen under direct observation even after being provided with a wait period of up to three hours.

Currently, Part 40 requires the collector to package and send the questionable specimen (*i.e.,* out of temperature range specimen or specimen with signs of tampering) to the laboratory along with a second sufficient specimen assuming a second specimen was collected (§§ 40.65(b)(7) & 40.65(c)(2), respectively). Part 40 does not, however, instruct the collector on what to do with the questionable specimen when the employee does not provide a sufficient specimen after a ''shy bladder'' wait period. The instructions in § 40.193(b)(1) direct the collector not to discard a questionable specimen; however, these instructions are rooted on the assumption that a second specimen will be collected. So absent a second sufficient specimen, § 40.193 does not tell the collector what to do with the questionable specimen.

Furthermore, we found the following inconsistencies in our guidance documents related to questionable specimens. In the July 2008 Q&A on § 40.193, the collector is instructed to ''. . . discard any specimen the employee previously provided . . .'' However, the Urine Specimen Collection Guidelines state that the collector is to send the questionable specimen to the laboratory and to immediately initiate another collection under direct observation.

If the employee did not provide a second specimen during the shy bladder period, and the collector sends the questionable specimen to the laboratory, the MRO must verify the employee's laboratory-reported questionable sample. The MRO would also conduct an evaluation to determine if a medical condition has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of urine.

The intent of the shy bladder evaluation is to provide the employee with an opportunity to provide an explanation for his/her inability to provide a sufficient specimen. This rationale becomes clouded when it's coupled with a verified drug test result from the same collection event. If an employee provides a questionable specimen, the employee may have tampered with or substituted his/her specimen. Following this logic, the employee should be able to provide a sufficient specimen immediately after providing the questionable specimen. If the employee cannot provide a sufficient specimen, the employee would have the opportunity to provide an explanation for his/her shy bladder via an evaluation (§ 40.193(c)). Absent a supported medical condition, an employee's inability to provide a sufficient specimen indicates that the employee chose not to provide a specimen in an effort to avoid a positive drug test result. As such, the MRO would report the result as a ''refusal to test'' to the employer, further ensuring the safety of the traveling public.

Therefore, we are proposing to require the collector to discard any specimen previously collected, thereby leaving the MRO to report only the outcome of the required evaluation. The Department seeks comment as to whether the proposed amendment to § 40.193 (b)(4) is a reasonable approach or whether there may be an alternate solution to the proposal.

4. *Removal of blind specimen testing*—We are proposing to remove existing Part 40 provisions (from §§ 40.3, 40.29, 40.103, 40.105, 40.123, 40.169, and 40.189) that reference blind specimen testing. We propose this as a burden-relieving measure for affected entities (*e.g.* employers, C/TPAs, etc.).

Existing Part 40 defines a blind specimen as ''a specimen submitted to a laboratory for quality control testing purposes, with a fictitious identifier, so that the laboratory cannot distinguish it from an employee specimen.'' Blind specimens are intended to test the accuracy and integrity of the laboratory testing system. As part of an overall quality control effort, employers have been required, since 1990 (54 FR 49857), to send blind urine specimens for drug testing to the laboratories they use. These samples are made to look like normal samples, are packaged in the same manner, and arrive unannounced at the laboratory. Only the senders know if the results of the blind specimens are negative, positive, adulterated, or substituted.

Initially, in 1990 (54 FR 49854), the Department required three blind test specimens for each 100 employee test specimens. For employers with 2000 or more covered employees, approximately 80 percent of the samples were required to be negative, with the remaining samples positive for one or more of the drugs per sample in a distribution such that all the drugs to be tested were included in approximately equal frequencies of challenge. The positive samples were required to contain only those drugs for which the employer was testing.

DOT has always been concerned about the burdens associated with imposing blind specimen procedures in its drug-testing program and has attempted to reduce such burdens incrementally over time. For example, in an attempt to simplify the process and reduce burden, in 2001, (65 FR 79462; December 19, 2000), the Department revised Part 40 blind specimen requirements by reducing the number of quarterly blind specimens sent to a laboratory from three percent to one percent with a maximum number of 50 blinds per quarter.

In light of this rulemaking and the requirement in Executive Order 13563 to conduct retrospective analyses, we have once again reviewed the impact of blind specimen testing. Upon review, we found that, since the 2000 final rule, we did not identify any laboratory problems regarding false positives. Any discrepancies that have been brought to our attention were problems with the manufacturer of the blinds and not the laboratory testing procedures.

It is also important to remember that the laboratories are rigorously inspected through the HHS National Laboratory Certification Program (NLCP). After a thorough initial inspection, laboratories are inspected semi-annually and receive performance test ''PT'' samples every quarter. If there are any discrepancies, NLCP thoroughly investigates the matter that requires corrective action as necessary.

Finally, another important ''check and balance'' already in place is the employee's split specimen or the ''B'' bottle. If the employee believes that the primary laboratory erred in reporting his/her result of the ''A'' bottle, the employee, via the MRO, can request to have his/her split (''B'') specimen sent to another laboratory.

Blind specimen testing requirements have been diligently followed over the

history of our program resulting in no cause for concern regarding laboratory accuracy. After 25 years, blind specimen testing has served its purpose and is now redundant in urine testing. Therefore, the Department seeks comment on any concerns, or unforeseen or unintended consequences, associated with our proposal to remove blind specimen requirements.

5. *DNA testing*—We propose to amend existing § 40.331 to add language that would further clarify that Deoxyribonucleic Acid (DNA) testing is not allowed for DOT-regulated urine specimens. To add further emphasis to this section, we would amend paragraph (f) to add the following sentence: *DNA testing or other types of identity testing are not authorized.* Identity testing, to include (DNA) testing, is prohibited in Section 3.3 of the HHS Mandatory Guidelines and in Part 40. The Department's main reason for imposing this prohibition (*See* 65 FR 79484, 79530) was to provide a safeguard against employees who would attempt to undermine the collection process by substituting a sample and, subsequently, request identity testing so that their sample would not be a match. If an employee believes there has been an error with his/her sample, the employee can request the Bottle B of the specimen to be drug tested (but not DNA tested) at a second HHS certified laboratory.

As the Court of Appeals recently validated in *Swaters* v. *Department of Transportation,* No. 14–1277 (D.C. Cir. June 24, 2016), the procedures described in the HHS Mandatory Guidelines and a properly completed Federal Drug Testing Custody and Control Form ensure that the specimen provided by the donor is the same specimen tested by a laboratory. Permitting DNA testing would undermine the integrity of the urine testing program because it would legitimize a donor's substitution of urine during an unobserved collection. The Court also indicated that ''neither the DOT's general rule against releasing urine samples for DNA testing, nor its refusal to release the sample in this case, is arbitrary, capricious, or contrary to the Omnibus Transportation Employee Testing Act of 1991.''

6. *MRO Verification*—We propose to amend existing § 40.141 (b) to add a parenthetical ''*i.e.*'' that would indicate that ''prescription'' is intended to mean (as currently provided in § 40.135 (e)), ''a legally valid prescription under the Controlled Substances Act (CSA).''

We understand that there may be various definitions for ''prescription'' under Federal law (*e.g.,* the Controlled Substances Act Pub. L. 91–513, tit. II, 84 Stat. 1242 (1970) and the Patient Protection and Affordable Care Act, Pub. L. 111–148, 124 Stat. 119 (2010)). As such, we propose to amend existing § 40.141 (b) to add language to indicate that, in the DOT drug-testing program, prescription means ''a legally valid prescription under the Controlled Substances Act (CSA).'' Doing so will clarify what prescription an MRO can accept when verifying an employee's claim that his/her use of a prescribed medication was the reason for the laboratory-confirmed positive drug result. This clarification does not create a new standard because this language is identical to the language used in § 40.135(e).

We also propose to modify § 40.141(b) to harmonize, in part, with Section 3.5 of the HHS Mandatory Guidelines. Specifically, we propose to allow MROs to conduct additional testing (*i.e.,* D, L stereoisomers and tetrahydrocannabivarin (THC–V)) of a DOT urine specimen, if the MRO determines such testing is necessary for the purpose of verifying the drug test result. For example, the MRO could request a D, L stereoisomer test of a laboratory confirmed methamphetamine result to help rule out whether the result was possibly due to the use of an over-the-counter product. Another example would be for the MRO to request a THC–V test when verifying a positive marijuana test result after a dronabinol (Marinol) [6] prescription is provided by the donor. THC–V testing provides useful information to the MRO when determining whether the laboratory-reported positive result for marijuana resulted from the employee's use of marijuana. As proposed, the MRO would not need to obtain DOT consent prior to requesting the D, L stereoisomer testing and/or the THC–V testing. Furthermore, the HHS-certified laboratory could only conduct these additional tests if its testing meets the appropriate validation and quality control requirements through the NLCP.

7. *Revision of certain Part 40 provisions to incorporate references to the new drugs*—We would revise the existing section headings and some regulatory text in §§ 40.137 and 40.139 to incorporate the proposed addition of the new opioids to the drug-testing panel. We would revise the section headings, and corresponding regulatory language where appropriate in these sections, to clarify our intent regarding how the MRO must verify test results. We would revise the § 40.137 section heading to add the text ''semi-synthetic opioids'' and the § 40.139 section heading so that it would refer to ''6-acetylmorphine, codeine, and morphine'' specifically. The Department also proposes to clarify the example used in § 40.139(c)(3) regarding an employee's admission of an unauthorized use of a substance when use of that substance is not confirmed by their drug test.

8. *Subscription to ODAPC list-serve*—We would amend §§ 40.33, 40.121, 40.213, and 40.281 to require collectors, MROs, STTs and BATs, and SAPs to subscribe to the ODAPC list-serve, found on our Web site at *https://www.transportation.gov/odapc/get-odapc-email-updates.* The ODAPC list-serve provides an additional means for these individuals to meet existing requirements in the referenced sections to ''be knowledgeable about'' and to ''keep current on any changes to'' materials used in our program. In addition to all of the information (web links) available on the ODAPC Web site, the ODAPC list-serve is the vehicle that allows us to communicate all program matters of importance to our constituency in the most timely manner possible and, by extension, enables us to keep our program responsive. The list-serve is free of charge to list-serve subscribers.

9. *Nationally Recognized Training Organizations*—We propose to remove the list of approved certification organizations and their respective certified drug and alcohol counselors found in § 40.281, paragraph (a)(6) and to display that list on the ODAPC Web site. Currently, when a certification organization requests to be added to the list of acceptable credentials for a SAP, that organization needs to petition the DOT for inclusion. The DOT reviews the petition. If the DOT approves the petition, we must initiate a rulemaking process to add the SAP certification organization to Part 40. Each time a new certification organization is added, the DOT must initiate a separate rulemaking action. Because this is a time-consuming process, we are proposing to display the list on the ODAPC Web site and update it when necessary instead of including all qualified SAP certification organizations in the rule language. Any SAP certification organization seeking to be added to the web-based list would still need to petition the DOT and meet the criteria set forth in Appendix E of Part 40. Although this process would remove the public comment requirement of rulemaking, DOT would

[6] Generically known as dronabinol, Marinol is a Schedule III drug product formulated in sesame oil in soft gelatin capsules, containing synthetic delta-9–THC. FDA has approved Marinol for the treatment of nausea and vomiting associated with cancer chemotherapy and for anorexia. (For further information *see* 81 FR 53691.)

fully vet the organization before deciding to add it to the list. Therefore, as a burden-relieving measure, the Department proposes to remove § 40.281 (a)(6) entirely and henceforth maintain the listing of nationally-recognized training or professional organizations in guidance material at *https://www.transportation.gov/odapc/sap.* In this manner, we would be able to maintain a more responsive list of organizations under which an individual may certify as a SAP and update it as needed without undertaking rulemaking action.

10. *Prohibition against use of federal branding*—We would amend § 40.365 to permit the public interest exclusion of a service agent for that agent's use of a DOT, or a DOT Agency's, logo on a Web site, in printed materials, or in any other manner that represents that the Department has approved, endorsed, or certified the service agent or its activities. The use of the DOT or DOT Agency's logo on materials generated by the DOT or the DOT Agency are permitted as long as the logo was on the original material being reprinted.

11. *Removal of Outdated Compliance Dates*—We would remove existing compliance dates from several Part 40 sections. Five Part 40 sections provide for training with compliance dates dating back to the early 2000s: § 40.33—A training schedule for collectors for qualification training and initial proficiency demonstration; § 40.121—a training schedule for MROs for qualification training; § 40.203—a specific timeframe relating to Federal Drug Testing Custody and Control Forms that has now expired; § 40.213—a training schedule for STTs and BATs for qualification training, initial proficiency training, and refresher training; § 40. 281—a training schedule for qualification for SAPs. These compliance dates are no longer applicable, thus we propose to remove them from these sections where they occur.

12. *Editorial corrections*—Section 40.162 entitled ''What must MROs do with multiple verified results for the same testing event?'' contains an incorrect reference to § 40.159(f) in paragraph (c). Existing § 40.162(c) refers to how an MRO must handle multiple verified non-negative test results and is intended to conform to a § 40.159(g) provision that directs the MRO to act on the verified non-negative result and not report the invalid result unless the split specimen fails to reconfirm the results of the primary specimen. Section 40.162(c), however, inadvertently refers to § 40.159(f) rather than § 40.159(g) requirements because of a typographical error. We would like this 40.162(c) provision to reference § 40.159(g) which is the correct reference.

Section 40.233 entitled ''What are the requirements for proper use and care of EBTs?'' contains an incorrect reference to § 40.333(a)(2) in paragraph (c)(4). Existing § 40.233(c)(4) refers to maintaining records of the inspection, maintenance, and calibration of Evidential Breath Testing devices and is intended to conform to a § 40.333(a)(3) provision related to the specific timeframe for keeping such records. Section 40.233(c)(4), however, inadvertently refers to § 40.333(a)(2) rather § 40.333(a)(3) requirements because of a typographical error. We would like this § 40.233(c)(4) provision to reference § 40.333(a)(3) which is the correct reference.

Section 40.67 entitled ''When and how is a directly observed collection conducted?'' would be revised to remove the words ''As the collector'' to clarify that *any* service agent participating in the testing process (not just the collector) who discovers a direct observation should have taken place, but did not, would inform the employer.

13. *Appendix Items*—We propose amendments to four appendices. At Appendices B and C, we propose to add to the listing of the new drugs to conform with the revised drug testing list in proposed § 40.87 and also remove references to MDEA in those appendices. These revisions are needed to conform with the newly adopted HHS Guidelines that add these drugs. At Appendix D, we propose to modify existing web links from *http://www.dot.gov/ost/odapc* to *https://www.transportation.gov/odapc.* We propose to remove Appendix H in its entirety and relocate it to our Web page. This would remove the instruction sheet entitled ''U.S. Department of Transportation Drug and Alcohol Testing MIS Data Collection Form Instruction Sheet'' and the actual MIS Data Collection Form. With this change made, we would be able to keep the instruction sheet and MIS Data Collection Form updated as necessary without a rulemaking action.

14. *Web links/electronic submissions*—We would update references to web links that have been revised. Periodically our Departmental webmaster must update DOT Web sites for any number of reasons. The ODAPC Web site ''*http://www.dot.gov/ost/odapc*'' currently referenced in our regulation is now linked at ''*https://www.transportation.gov/odapc.*'' Therefore, we propose to update the regulation to replace *http://www.dot.gov/ost/odapc* with *https://www.transportation.gov/odapc* where the link occurs in the following sections: §§ 40.33, 40.45, 40.105, 40.121, 40.213, 40.225, and 40.401.

V. Regulatory Analyses and Notices

Changes to Federal regulations must undergo several analyses. First, Executive Orders 12866 and 13563 direct that each Federal agency shall propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. Second, the Regulatory Flexibility Act of 1980 (Pub. L. 96–354), as codified in 5 U.S.C. 601 *et seq.,* requires agencies to analyze the economic impact of regulatory changes on small entities. The Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*) requires that DOT consider the impact of paperwork and other information collection burdens imposed on the public and, under the provisions of PRA section 3507(d), obtain approval from OMB for each collection of information it conducts, sponsors, or requires through regulations. Section (a)(5) of division H of the Fiscal Year 2005 Omnibus Appropriations Act, Public Law 108–447, 118 Stat. 3268 (Dec. 8, 2004) and section 208 of the E-Government Act of 2002, Public Law 107–347, 116 Stat. 2889 (Dec. 17, 2002) requires DOT to conduct a Privacy Impact Assessment (PIA) of a regulation that will affect the privacy of individuals. Finally, the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 *et seq.*) requires DOT to analyze this action to determine whether it will have an effect on the quality of the environment. This portion of the preamble summarizes the DOT's analyses of these impacts with respect to this notice.

Executive Order 12866 and 13563 and DOT's Regulatory Policies and Procedures

This proposal is not a significant regulatory action under Executive Order 12866 and 13563, as well as the Department's Regulatory Policies and Procedures (44 FR 11034). It proposes to harmonize specific Part 40 procedures with recently mandated HHS Guidelines and, in the interest of improving efficiency, make certain program modifications. As such, this proposal would not impose any major policy changes and would not impose any significant new costs or burdens. Actually, DOT estimates a cost-savings of at least $3.1 million per year for the proposed elimination of the requirement for employers to submit blind specimen testing to laboratories.

Costs

The HHS Mandatory Guidelines addressed the burdens associated with the addition of new drugs to the drug-testing panel. The cost impact of drug testing for oxycodone, oxymorphone, hydrocodone, and hydromorphone would be minimal because HHS has determined that all HHS laboratories testing specimens from Federal agencies are currently conducting tests for one or more of these analytes on non-regulated urine specimens. HHS further indicated in its analysis that laboratory personnel currently are trained to test for the additional drugs and test methods already have been implemented. Many HHS-certified laboratories conduct non-regulated tests for transportation employers who already include the four proposed drugs in their non-regulated testing programs. For those employers, therefore, shifting the four drugs from non-regulated tests to regulated tests would not increase testing costs.

HHS determined that the costs associated with implementation of testing for the four additional drugs would be approximately $0.11–$0.30 per test. Once the testing has been implemented, the cost per specimen for initial testing for the added analytes would range from $.06 to $0.20 due to reagent costs. Current costs for each confirmatory test range from $5.00 to $10.00 for each specimen reported as positive due to costs of sample preparation and analysis. HHS indicated that based on information from non-regulated workplace drug testing for these analytes in 2012 and testing performed on de-identified federally regulated specimens in 2011, approximately 1% of the submitted specimens is expected to be confirmed as positive for the added analytes. Therefore, HHS indicates that the added cost for confirmatory testing will be $0.05 to $0.10 per submitted specimen.

Approximately 6.3 million DOT-regulated tests occur per year. DOT considered the maximum ranges HHS provided in its analysis. Therefore, with the projected maximum implementation cost per specimen of $0.30, the maximum cost per specimen of initial testing at $0.20, and the maximum cost per specimen of confirmation testing at $0.10, the additional cost per urine test would be an additional $0.60. Under the new HHS Mandatory Guidelines, and based on an estimated 6.3 million DOT tests conducted annually, a cost of approximately $3,800,000 would be realized by employers subject to DOT-regulated testing ($0.60 × 6,300,000 DOT tests annually = $3,780,000).

HHS indicated that there will be minimal costs associated with adding MDA as an initial test analyte because the current immunoassays can be adapted to test for this analyte. According to HHS, before a lab is allowed to test regulated specimens for MDA, HHS must test three groups of performance test, or ''PT'' samples. HHS provides the PT samples at no cost to its certified laboratories but HHS estimates that the laboratory costs to conduct the PT testing would range from $900 to $1800 for each certified laboratory. There are approximately 27 HHS-certified laboratories who process DOT drug tests. With the maximum cost estimate of $1800 for each certified laboratory, a cost of approximately $48,600 would be realized for DOT ($1800 × 27 laboratories = $48,600.)

Testing for additional drugs would result in MRO cost as MROs would have additional review and verification to conduct. Based on the positivity rates from non-regulated workplace drug testing and the additional review of specimens confirmed positive for prescription medications, HHS estimates that MRO costs would increase by approximately 3%. The additional costs for testing and MRO review would be incorporated into the overall cost for the Federal agency submitting the specimen to the laboratory. HHS bases the estimation of costs incurred on overall cost to the Federal agency affected because cost is usually based on all specimens submitted from an agency, rather than individual specimen testing costs or MRO review of positive specimens. Based on this analysis, therefore, DOT would project an additional MRO cost of $189,000 (.03 projected increase × 6,300,000 DOT tests annually).

Cost-Savings

DOT estimates a cost-savings of at least $3.1 million per year from the proposed elimination of the requirement for employers to submit blind specimen testing to laboratories (estimated at approximately $50 per test). This estimate of cost-savings is based on the regulatory analysis performed when DOT reduced blind specimen testing in 2000, [*see* 65 FR 79462, 79517 (Dec 19, 2000)] adjusted for inflation. Based on the blind specimen requirements made effective in 2000 for employers to submit 1% of 6,300,000 DOT tests for blind testing conducted annually at a cost of approximately $50 per test yields a cost-savings of $3,150,000 (63,000 × $50).

Net Economic Impact

The DOT believes the projected cost-savings realized would, for the most part, offset the projected cost to the DOT of implementing testing for the additional drugs being added to the drug-testing regimen. The projected $3,848,600 for the four opioid drugs (and MDA) as well as the $189,000 projected MRO costs would result in a total projected cost of $4,037,600. The estimated cost impact of this proposal, therefore, would be negligible, an estimated $887,600 ($4,037,600 − $3,150,000). If identifying illicit drug use by safety-sensitive transportation employees subjected to drug testing prevents a single serious accident, then the benefits of this proposal outweigh its minimal cost. This proposal would not have a major impact under Executive Order 12866 because it would not have an annual effect on the economy of $100 million or more, nor would it adversely affect any sector of the economy.

Regulatory Flexibility Analysis

The Regulatory Flexibility Act of 1980 (Pub. L. 96–354, ''RFA''), 5 U.S.C. 601 *et seq.,* establishes ''as a principle of regulatory issuance that agencies shall endeavor, consistent with the objectives of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation. To achieve this principle, agencies are required to solicit and consider flexible regulatory proposals and to explain the rationale for their actions to assure that such proposals are given serious consideration.'' The RFA covers a wide-range of small entities, including small businesses, not-for-profit organizations, and small governmental jurisdictions.

Agencies must perform a review to determine whether a proposed rule would have a significant economic impact on a substantial number of small entities. If the agency determines that it would, the agency must prepare a regulatory flexibility analysis. However, if an agency determines that it is not expected to have a significant economic impact on a substantial number of small entities, section 605(b) provides that the head of the agency may so certify, and a regulatory flexibility analysis would not be required. The certification must include a statement providing the factual basis for this determination, and the reasoning should be clear.

This rulemaking proposes to conform the existing DOT drug-testing panel to recently issued HHS Mandatory

Guidelines and, with certain minor amendments (mostly editorial), to improve the efficiency of the DOT drug-testing program. As noted above, any costs due to this rule are, for the most part, offset by the cost savings from the proposed elimination of the requirement for employers to submit blind specimen testing to laboratories. The net costs of this rule are negligible overall and would not constitute a significant burden to any entity, small or otherwise. Consequently, the DOT certifies, under the RFA, that this proposal would not have a significant economic impact on a substantial number of small entities.

Federalism

This proposal has been analyzed in accordance with the principles and criteria contained in Executive Order 13132 (''Federalism''). This proposal does not include requirements that (1) have substantial direct effects on the States, the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government, (2) impose substantial direct compliance costs on State and local governments, or (3) preempt State law. Therefore, the consultation and funding requirements of Executive Order 13132 do not apply.

Paperwork Reduction Act/Privacy Act

The Paperwork Reduction Act requires that the DOT consider the impact of paperwork and other information collection burdens imposed on the public. Information collections for Part 40 currently are approved under OMB Control No. 2105–0529. The Privacy Act provides safeguards against invasion of personal privacy through the misuse of records by Federal Agencies. It establishes controls over what personal information is collected, maintained, used and disseminated by agencies in the executive branch of the Federal government. This proposal would not create any new paperwork or other information collection burdens needing approval, nor would it require any further protections under the Privacy Act.

National Environmental Policy Act

The Department has analyzed the environmental impacts of this proposed action pursuant to the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 *et seq.*) and has determined that it is categorically excluded pursuant to DOT Order 5610.1C, Procedures for Considering Environmental Impacts (44 FR 56420, Oct. 1, 1979). Categorical exclusions are actions identified in an agency's NEPA implementing procedures that do not normally have a significant impact on the environment and therefore do not require either an environmental assessment (EA) or environmental impact statement (EIS). See 40 CFR 1508.4. In analyzing the applicability of a categorical exclusion, Federal agencies also must consider whether extraordinary circumstances are present that would warrant the preparation of an EA or EIS. This proposal does not meet any of these criteria. Paragraph 3.c.5 of DOT Order 5610.1C incorporates by reference the categorical exclusions for all DOT Operating Administrations. This action is covered by the categorical exclusion listed in the Federal Highway Administration's implementing procedures, ''[p]romulgation of rules, regulations, and directives.'' 23 CFR 771.117(c)(20). The agency does not anticipate any environmental impacts, and there are no extraordinary circumstances present in connection with this rulemaking.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) does not require a written statement for this final rule because the rule does not include a Federal mandate that may result in the expenditure in any one year of $155,000,000 or more by State, local, and tribal governments, or the private sector.

List of Subjects in 49 CFR Part 40

Administrative practice and procedures, Alcohol abuse, Alcohol testing, Drug abuse, Drug testing, Laboratories, Reporting and recordkeeping requirements, Safety, Transportation.

The Proposal

For reasons discussed in the preamble, the Department of Transportation proposes to amend part 40 of Title 49 Code of Federal Regulations, as follows:

PART 40—PROCEDURES FOR TRANSPORTATION WORKPLACE DRUG AND ALCOHOL TESTING PROGRAMS

■ 1. The authority citation for 49 CFR part 40 continues to read as follows:

Authority: 40 U.S.C. 102, 301, 322, 5331, 20140, 31306, and 54101 *et seq.*

■ 2. Amend § 40.3 as follows:

■ a. Remove the definition ''*Blind specimen or blind performance test specimen*''*;* and

■ b. Revise and reorder (in correct alphabetical order) the definitions ''*DOT, the Department, DOT Agency*'' and ''*Drugs*'' to read as follows:

§ 40.3 What do the terms used in this part mean?

* * * * *

DOT, The Department, DOT Agency. These terms encompass all DOT agencies, including, but not limited to the Federal Aviation Administration (FAA), the Federal Railroad Administration (FRA), the Federal Motor Carrier Safety Administration (FMCSA), the Federal Transit Administration (FTA), the National Highway Traffic Safety Administration (NHTSA), the Pipeline and Hazardous Materials Safety Administration (PHMSA), and the Office of the Secretary (OST). For purposes of this part, the United States Coast Guard (USCG), in the Department of Homeland Security, is considered to be a DOT agency. These terms include any designee of a DOT agency.

* * * * *

Drugs. The drugs for which tests are required under this part and DOT agency regulations are marijuana, cocaine, amphetamines, phencyclidine (PCP), and opioids.

* * * * *

■ 3. Revise § 40.26 to read as follows:

§ 40.26 What form must an employer use to report Management Information System data to a DOT agency?

As an employer, when you are required to report MIS data to a DOT agency, you must use the U.S. Department of Transportation Drug and Alcohol Testing MIS Data Collection Form to report that data. You may view and download this form and its instructions on the Department's Web site (*https://www.transportation.gov/odapc*). You must submit the MIS report in accordance with rule requirements (*e.g.,* dates for submission, selection of companies required to submit, and method of reporting) established by the DOT agency regulating your operation.

§ 40.29 [Amended]

■ 4. Amend § 40.29 by removing the entry ''§§ 40.103–40.105—Blind specimen requirements.''

■ 5. Amend § 40.33 by revising paragraphs (a) and (d) to read as follows:

§ 40.33 What training requirements must a collector meet?

* * * * *

(a) *Basic information.* You must be knowledgeable about this part, the current ''DOT Urine Specimen Collection Procedures Guidelines,'' and DOT agency regulations applicable to the employers for whom you perform

collections. The DOT Urine Specimen Collection Procedures Guidelines document is available from ODAPC (Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590, 202–366–3784, or on the ODAPC Web site (*https://www.transportation.gov/odapc*). DOT agency regulations are available at each agency's Web site, on the DOT Web site (*http://www.transportation.dot.gov*), or at *www.ecfr.gov.* You must keep current on any changes to these materials. You must subscribe to the ODAPC list-serve (*https://www.transportation.gov/odapc/get-odapc-email-updates*).

* * * * *

(d) You must meet the requirements of paragraphs (b) and (c) of this section before you begin to perform collector functions.

* * * * *

■ 6. Amend § 40.67 by revising paragraph (n) to read as follows:

§ 40.67 When and how is a directly observed collection conducted?

* * * * *

(n) As a service agent, when you learn that a directly observed collection should have been collected but was not, you must inform the employer that it must direct the employee to have an immediate recollection under observation.

■ 7. Amend § 40.83 by revising paragraph (c) to read as follows:

§ 40.83 How do laboratories process incoming specimens?

* * * * *

(c) You must inspect each specimen and CCF for the following ''fatal flaws:''

(1) There is no CCF;

(2) There is no specimen submitted with the CCF;

(3) There is no printed collector's name and no collector's signature;

(4) Two separate collections are performed using one CCF;

(5) The specimen ID numbers on the specimen bottle and the CCF do not match;

(6) The specimen bottle seal is broken or shows evidence of tampering, unless a split specimen can be redesignated (see paragraph (h) of this section);

(7) There is an insufficient amount of urine in the primary bottle for analysis, unless the specimens can be redesignated (see paragraph (h) of this section).

* * * * *

■ 8. Revise § 40.85 to read as follows:

§ 40.85 What drugs do laboratories test for?

As a laboratory, you must test for the following five drugs or classes of drugs in a DOT drug test. You must not test ''DOT specimens'' for any other drugs.

(a) Marijuana metabolites.

(b) Cocaine metabolites.

(c) Amphetamines.

(d) Opioids.

(e) Phencyclidine (PCP).

■ 9. Amend § 40.87 by revising paragraph (a) to read as follows:

§ 40.87 What are the cutoff concentrations for drug tests?

(a) As a laboratory, you must use the cutoff concentrations displayed in the following table for initial and confirmatory drug tests. All cutoff concentrations are expressed in nanograms per milliliter (ng/mL). The table follows:

Initial test analyte	Initial test cutoff [1]	Confirmatory test analyte	Confirmatory test cutoff concentration
Marijuana metabolites (THCA) [2]	50 ng/mL [3]	THCA	15 ng/mL.
Cocaine metabolite (Benzoylecgonine)	150 ng/mL [3]	Benzoylecgonine	100 ng/mL.
Codeine/Morphine	2000 ng/mL	Codeine	2000 ng/mL.
		Morphine	2000 ng/mL.
Hydrocodone/Hydromorphone	300 ng/mL	Hydrocodone	100 ng/mL.
		Hydromorphone	100 ng/mL.
Oxycodone/Oxymorphone	100 ng/mL	Oxycodone	100 ng/mL.
		Oxymorphone	100 ng/mL.
6-Acetylmorphine	10 ng/mL	6-Acetylmorphine	10 ng/mL.
Phencyclidine	25 ng/mL	Phencyclidine	25 ng/mL.
Amphetamine/Methamphetamine	500 ng/mL	Amphetamine	250 ng/mL
		Methamphetamine	250 ng/mL.
MDMA [4]/MDA [5]	500 ng/mL	MDMA	250 ng/mL.
		MDA	250 ng/mL.

[1] For grouped analytes (*i.e.,* two or more analytes that are in the same drug class and have the same initial test cutoff):

Immunoassay: The test must be calibrated with one analyte from the group identified as the target analyte. The cross-reactivity of the immunoassay to the other analyte(s) within the group must be 80 percent or greater; if not, separate immunoassays must be used for the analytes within the group.

Alternate technology: Either one analyte or all analytes from the group must be used for calibration, depending on the technology. At least one analyte within the group must have a concentration equal to or greater than the initial test cutoff or, alternatively, the sum of the analytes present (i.e., equal to or greater than the laboratory's validated limit of quantification) must be equal to or greater than the initial test cutoff.

[2] An immunoassay must be calibrated with the target analyte, Δ-9-tetrahydrocannabinol-9-carboxylic acid (THCA).

[3] *Alternate technology (THCA and benzoylecgonine):* When using alternate technology to test for THCA and Benzoylecgonine, the screening and confirmatory test cutoff concentrations must be the same respectively (i.e., 15 ng/mL for THCA and 100 ng/mL for Benzoylecgnine).''

[4] Methylenedioxymethamphetamine (MDMA).

[5] Methylenedioxyamphetamine (MDA).

* * * * *

§ 40.103 [Removed]

■ 10. Remove § 40.103.

■ 11. Remove § 40.105.

■ 12. Amend § 40.121 by revising paragraphs (b)(3) and (c)(3), and the paragraph (d) introductory text to read as follows:

§ 40.121 Who is qualified to act as an MRO?

* * * * *

(b) * * *

(3) You must be knowledgeable about this part, the DOT MRO Guidelines, and the DOT agency regulations applicable to the employers for whom you evaluate drug test results, and you must keep current on any changes to these materials. You must subscribe to the ODAPC list-serve at *https://www.transportation.gov/odapc/get-odapc-email-updates.* DOT agency regulations, DOT MRO Guidelines, and other materials are available from ODAPC (Department of Transportation, 1200 New Jersey Avenue SE.,

Washington, DC 20590, 202–366–3784, or on the ODAPC Web site (*http://www.transportation.gov/odapc*).

(c) * * *

(3) You must meet the requirements of paragraphs (a), (b), and (c) of this section before you begin to perform MRO functions.

(d) *Requalification training.* During each five-year period from the date on which you satisfactorily completed the examination under paragraph (c) (2) of this section or have successfully completed the required continuing education requirements, you must complete requalification training.

* * * * *

■ 13. Amend § 40.123 by revising paragraph (e) to read as follows:

§ 40.123 What are the MRO's responsibilities in the DOT drug testing program?

* * * * *

(e) You must act to investigate and correct problems where possible and notify appropriate parties (*e.g.,* HHS, DOT, employers, service agents) where assistance is needed (*e.g.,* cancelled or problematic tests, incorrect results).

* * * * *

■ 14. Amend § 40.137 by revising the section heading and paragraph (a) to read as follows:

§ 40.137 On what basis does the MRO verify test results involving marijuana, cocaine, amphetamines, semi-synthetic opioids, or PCP?

(a) As the MRO, you must verify a confirmed positive test result for marijuana, cocaine, amphetamines, semi-synthetic opioids (*i.e.,* hydrocodone, hydromorphone, oxycodone, and oxymorphone), and/or PCP unless the employee presents a legitimate medical explanation for the presence of the drug(s)/metabolite(s) in his or her system.

* * * * *

■ 15. Amend § 40.139 by revising the section heading and paragraphs (c) introductory text and (c)(3) to read as follows:

§ 40.139 On what basis does the MRO verify test results involving 6-acetylmorphine, codeine, and morphine?

* * * * *

(c) For all other codeine and morphine positive results, you must verify a confirmed positive test result only if you determine that there is clinical evidence, in addition to the urine test, of unauthorized use of any opium, opiate, or opium derivative (*i.e.,* morphine, codeine, or heroin).

(1) * * *

(2) * * *

(3) To be the basis of a verified positive result for codeine or morphine, the clinical evidence you find must concern a drug that the laboratory found in the specimen. (For example, if the test confirmed the presence of codeine, and the employee admits to unauthorized use of hydrocodone, you must verify the test positive for codeine. The admission must be for the substance that was found through the actual drug test).

* * * * *

■ 16. Amend § 40.141 by revising paragraph (b) to read as follows:

§ 40.141 How does the MRO obtain information for the verification decision?

* * * * *

(b) If the employee asserts that the presence of a drug or drug metabolite in his or her specimen results from taking prescription medication (*i.e.,* a legally valid prescription under the Controlled Substances Act), you must review and take all reasonable and necessary steps to verify the authenticity of all medical records the employee provides. You may contact the employee's physician or other relevant medical personnel for further information. You may request an HHS-certified laboratory with validated protocols (see § 40.81(c)) to conduct D, Lstereoisomer testing or tetrahydrocannabivarin (THC–V) testing when verifying lab results, as you determine necessary.

■ 17. Amend § 40.162 by revising paragraph (c) to read as follows:

§ 40.162 What must MROs do with multiple verified results for the same testing event?

* * * * *

(c) As an exception to paragraphs (a) and (b) of this section, as the MRO, you must follow procedures at § 40.159(g) when any verified non-negative result is also invalid.

§ 40.169 [Amended]

■ 18. Amend § 40.169 by removing the entry ''§ 40.105—Notification of discrepancies in blind specimen results.''

§ 40.189 [Amended]

■ 19. Amend § 40.189 by removing the entry ''§ 40.103—Blind split specimens.''

■ 20. Amend § 40.193 by revising paragraph (b)(4) to read as follows:

§ 40.193 What happens when an employee does not provide a sufficient amount of urine for a drug test?

* * * * *

(b) * * *

(4) If the employee has not provided a sufficient specimen within three hours of the first unsuccessful attempt to provide the specimen, you must discontinue the collection, note the fact on the ''Remarks'' line of the CCF (Step 2), and immediately notify the DER. You must also discard any specimen the employee previously provided to include any specimen that is 'out of temperature range' or shows signs of tampering. In the remarks section of the CCF that you will distribute to the MRO and DER, you must note the fact that the employee provided an 'out of temperature range specimen' or 'specimen that shows signs of tampering' and that it was discarded because the employee did not provide a second sufficient specimen.

* * * * *

■ 21. Amend § 40.199 by revising paragraph (b) to read as follows:

§ 40.199 What problems always cause a drug test to be cancelled?

(a) * * *

(b) The following are ''fatal flaws'':

(1) There is no CCF;

(2) There is no specimen submitted with the CCF;

(3) There is no printed collector's name and no collector's signature;

(4) Two separate collections are performed using one CCF;

(5) The specimen ID numbers on the specimen bottle and the CCF do not match;

(6) The specimen bottle seal is broken or shows evidence of tampering (and a split specimen cannot be re-designated, see § 40.83(h)); and

(7) Because of leakage or other causes, there is an insufficient amount of urine in the primary specimen bottle for analysis and the specimens cannot be re-designated (see § 40.83(h)).

* * * * *

■ 22. Amend § 40.203 by revising paragraph (d)(3) to read as follows:

§ 40.203 What problems cause a drug test to be cancelled unless they are corrected?

* * * * *

(d) * * *

(3) The collector uses a non-Federal form or an expired CCF for the test. This flaw may be corrected through the procedure set forth in § 40.205(b)(2), provided that the collection testing process has been conducted in accordance with the procedures in this part in an HHS-certified laboratory.

■ 23. Add § 40.210 in subpart I to read as follows:

§ 40.210 Are drug tests other than urine permitted under the regulations?

No. Drug tests other than on urine specimens are not authorized for testing under this part. Only urine specimens screened and confirmed at HHS

certified laboratories (see § 40.81) are allowed for drug testing under this part. Point-of-collection urine testing or instant tests are not authorized.

■ 24. Amend § 40.213 by revising paragraphs (a), (d), and (e) to read as follows:

§ 40.213 What training requirements must STTs and BATs meet?

* * * * *

(a) You must be knowledgeable about the alcohol testing procedures in this part and the current DOT guidance. Procedures and guidance are available from ODAPC (Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590, 202–366–3784, or on the ODAPC Web site, *https://www.transportation.gov/odapc*). You must keep current on any changes to these materials. You must subscribe to the ODAPC list-serve at (*https://www.transportation.gov/odapc/get-odapc-email-updates*).

* * * * *

(d) You must meet the requirements of paragraphs (b) and (c) of this section before you begin to perform STT or BAT functions.

(e) *Refresher training.* No less frequently than every five years from the date on which you satisfactorily complete the requirements of paragraphs (b) and (c) of this section, you must complete refresher training that meets all the requirements of paragraphs (b) and (c) of this section.

* * * * *

■ 25. Amend § 40.233 by revising paragraph (c)(4) to read as follows:

§ 40.233 What are the requirements for proper use and care of EBTs?

* * * * *

(c) * * *

(4) You must maintain records of the inspection, maintenance, and calibration of EBTs as provided in § 40.333(a)(3).

* * * * *

■ 26. Amend § 40.281 by revising paragraphs (a)(6), (b)(3), and (c)(3) to read as follows:

§ 40.281 Who is qualified to act as a SAP?

* * * * *

(a) * * *

(6) You are a drug and alcohol counselor certified by an organization listed at *https://www.transportation.gov/odapc/sap.*

(b) * * *

(3) You must be knowledgeable about this part, the DOT agency regulations applicable to the employers for whom you evaluate employees, and the DOT SAP Guidelines. You must keep current on any changes to these materials. You must subscribe to the ODAPC list-serve at *https://www.transportation.gov/odapc/get-odapc-email-updates.* DOT agency regulations, DOT SAP Guidelines, and other materials are available from ODAPC (Department of Transportation, 1200 New Jersey Avenue SE., Washington DC, 20590 (202–366–3784), or on the ODAPC Web site (*http://www.transportation.gov/odapc*).

(c) * * *

(3) You must meet the requirements of paragraphs (a), (b), and (c) of this section before you begin to perform SAP functions.

* * * * *

■ 27. Amend § 40.331 by revising paragraph (f) to read as follows:

§ 40.331 To what additional parties must employers and service agents release information?

* * * * *

(f) Except as otherwise provided in this part, as a laboratory you must not release or provide a specimen or a part of a specimen to a requesting party, without first obtaining written consent from ODAPC. DNA testing and other types of identity testing are not authorized and ODAPC will not give permission for such testing. If a party seeks a court order directing you to release a specimen or part of a specimen contrary to any provision of this part, you must take necessary legal steps to contest the issuance of the order (*e.g.,* seek to quash a subpoena, citing the requirements of § 40.13). This part does not require you to disobey a court order, however.

* * * * *

■ 28. Amend § 40.365 by revising paragraph (b)(10) to read as follows:

§ 40.365 What is the Department's policy concerning starting a PIE proceeding?

* * * * *

(b) * * *

(10) For any service agent, representing falsely that the service agent or its activities is approved or certified by the Department or a DOT agency (such representation includes, but is not limited to, the use of a Department or DOT agency logo, title, or emblem).

* * * * *

■ 29. Revise appendix B to part 40 to read as follows:

Appendix B to Part 40—DOT Drug-Testing Semi-Annual Laboratory Report to Employers

The following items are required on each laboratory report:

Reporting Period: (inclusive dates)
Laboratory Identification: (name and address)
Employer Identification: (name; may include Billing Code or ID code)
C/TPA Identification: (where applicable; name and address)
Specimen Results Reported (total number)
By Test Reason
- (a) Pre-employment (number)
- (b) Post-Accident (number)
- (c) Random (number)
- (d) Reasonable Suspicion/Cause (number)
- (e) Return-to-Duty (number)
- (f) Follow-up (number)
- (g) Type of Test Not Noted on CCF (number)

2. Specimens Reported
- (a) Negative (number)
- (b) Negative and Dilute (number)

3. Specimens Reported as Rejected for Testing (total number)
- By Reason
- (a) Fatal flaw (number)
- (b) Uncorrected Flaw (number)

4. Specimens Reported as Positive (total number) By Drug
- (a) Marijuana Metabolite (number)
- (b) Cocaine Metabolite (number)
- (c) Opioids (number)
- (1) Codeine (number)
- (2) Morphine (number)
- (3) 6–AM (number)
- (4) Hydrocodone (number)
- (5) Hydromorphone (number)
- (6) Oxycodone (number)
- (7) Oxymorphone (number)
- (d) Phencyclidine (number)
- (e) Amphetamines (number)
- (1) Amphetamine (number)
- (2) Methamphetamine (number)
- (3) MDMA (number)
- (4) MDA (number)

5. Adulterated (number)
6. Substituted (number)
7. Invalid Result (number)

■ 30. Revise appendix C to part 40 to read as follows:

Appendix C to Part 40—DOT Drug-Testing Semi-Annual Laboratory Report to DOT

Mail, fax, or email to:

U.S. Department of Transportation, Office of Drug and Alcohol Policy and Compliance, W62–300, 1200 New Jersey Avenue SE., Washington, DC 20590, *Fax:* (202) 366–3897, *Email: ODAPCWebMail@dot.gov*.

The following items are required on each report:

Reporting Period: (inclusive dates)
Laboratory Identification: (name and address)
DOT Specimen Results Reported (total number)
2. Negative Results Reported (total number)
- Negative (number)
- Negative-Dilute (number)

3. Rejected for Testing Results Reported (total number)
- By Reason
- (a) Fatal flaw (number)
- (b) Uncorrected Flaw (number)

4. Positive Results Reported (total number)
- By Drug
- (a) Marijuana Metabolite (number)
- (b) Cocaine Metabolite (number)
- (c) Opioids (number)

(1) Codeine (number)
(2) Morphine (number)
(3) 6–AM (number)
(4) Hydrocodone (number)
(5) Hydromorphone (number)
(6) Oxycodone (number)
(7) Oxymorphone (number)
(d) Phencyclidine (number)
(e) Amphetamines (number)
(1) Amphetamine (number)
(2) Methamphetamine (number)
(3) MDMA (number)
(4) MDA (number)
5. Adulterated Results Reported (total number)
By Reason (number)
6. Substituted Results Reported (total number)
7. Invalid Results Reported (total number)
By Reason (number)

■ 31. Revise appendix D to part 40 to read as follows:

Appendix D to Part 40—Report Format: Split Specimen Failure To Reconfirm

Mail, fax, or submit electronically to: U.S. Department of Transportation, Office of Drug and Alcohol Policy and Compliance, W62–300, 1200 New Jersey Avenue SE., Washington, DC 20590, *Fax:* (202) 366–3897.

Submit Electronically: *https://www.transportation.gov/content/split-specimen-cancellation-notification-49-cfr-part-40187-appendix-d*

The following items are required on each report:

MRO name, address, phone number, and fax number.
2. Collection site name, address, and phone number.
3. Date of collection.
4. Specimen I.D. number.
5. Laboratory accession number.
6. Primary specimen laboratory name, address, and phone number.
7. Date result reported or certified by primary laboratory.
8. Split specimen laboratory name, address, and phone number.
9. Date split specimen result reported or certified by split specimen laboratory.
10. Primary specimen results (*e.g.,* name of drug, adulterant) in the primary specimen.
11. Reason for split specimen failure-to-reconfirm result (*e.g.,* drug or adulterant not present, specimen invalid, split not collected, insufficient volume).
12. Actions taken by the MRO (*e.g.,* notified employer of failure to reconfirm and requirement for recollection).
13. Additional information explaining the reason for cancellation.
14. Name of individual submitting the report (if not the MRO).

Appendix H to Part 40 [Removed]

■ 32. Remove appendix H to part 40.

Dated: January 12, 2017.

Anthony R. Foxx,

Secretary of Transportation.

[FR Doc. 2017–01131 Filed 1–19–17; 8:45 am]

BILLING CODE P

Notices

Federal Register
Vol. 82, No. 13
Monday, January 23, 2017

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.

UNITED STATES AFRICAN DEVELOPMENT FOUNDATION

Public Quarterly Meeting of the Board of Directors

AGENCY: United States African Development Foundation.

ACTION: Notice of meeting.

SUMMARY: The U.S. African Development Foundation (USADF) will hold its quarterly meeting of the Board of Directors to discuss the agency's programs and administration.

DATES: The meeting date is Tuesday, January 31, 2017, 9:00 a.m. to 12:00 p.m.

ADDRESSES: The meeting location is 1400 I St. NW., Suite 1000, Washington, DC 20005.

FOR FURTHER INFORMATION CONTACT: June Brown, 202–233–8882.

Authority: Public Law 96–533 (22 U.S.C. 290h).

Dated: January 13, 2017.

June Brown,

Interim General Counsel.

[FR Doc. 2017–01312 Filed 1–19–17; 8:45 am]

BILLING CODE 6117–01–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Docket No. AMS–LPS–16–0114]

U.S. Standards for Grades of Catfish and Catfish Products

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice.

SUMMARY: This Notice informs the public that the Agricultural Marketing Service (AMS) will not proceed with the development of voluntary U.S. Standards for Grades of Catfish and Catfish Products at this time.

DATES: January 23, 2017.

ADDRESSES: USDA, AMS, Quality Assessment Division (QAD); 1400 Independence Avenue SW., Stop 0258, Room 3932–S, Washington, DC 20250.

FOR FURTHER INFORMATION CONTACT: David Bowden, Chief, Standardization Branch; USDA, AMS, QAD; 1400 Independence Avenue SW., Stop 0258, Room 3932–S, Washington, DC 20250; phone (202) 690–3148; or via email at *David.Bowden@ams.usda.gov.* Alternately, Bucky Gwartney, Marketing Specialist, Standardization Branch; USDA, AMS, QAD; 1400 Independence Avenue SW., Stop 0258, Room 3932–S, Washington, DC 20250; phone (202) 720–1424; or via email at *Bucky.Gwartney@ams.usda.gov.*

SUPPLEMENTARY INFORMATION: Under section 203(c) of the Agricultural Marketing Act of 1946 (7 U.S.C. 1621–1627), the Secretary of Agriculture is directed to ''develop and improve standards of quality, condition, quantity, grade, and packaging, and recommend and demonstrate such standards in order to encourage uniformity and consistency in commercial practices.'' USDA is committed to carrying out this authority in a manner that facilitates the marketing of agricultural products. One method of achieving this objective is through the development and maintenance of standards by AMS. Currently, AMS maintains standards for a wide variety of commodities and in many cases applies those standards to commodities on a fee-for-service basis.

The Food, Conservation, and Energy Act of 2008 (2008 Farm Bill) and the Agricultural Act of 2014 (2014 Farm Bill) directed the Secretary of Agriculture to establish within USDA a voluntary, fee-based grading program for catfish. Since passage of the 2008 and 2014 Farm Bills, and particularly since the publication of the Food Safety and Inspection Service (FSIS) final rule, ''Mandatory Inspection of Fish of the Order Siluriformes and Products Derived From Such Fish,'' which defined catfish (80 FR 75589), AMS has engaged the U.S. catfish industry and other stakeholders to seek input on requirements for voluntary U.S. standards for grades of catfish. This culminated in a Notice published in the **Federal Register** (81 FR 45449) on July 14, 2016, inviting the public to submit information, background, comments, and data to assist in the development of voluntary U.S. Standards for Grades of Catfish and Catfish Products.

During the 60-day comment period, four responses were submitted—two from catfish importers, one from an industry institution, and one from a U.S. catfish producer/processor. One importer stated support for a USDA grading program if it included all Siluriformes species (currently, imported products of many varieties of Siluriformes are not eligible to be graded under the U.S. Department of Commerce's National Marine Fisheries Service (NMFS) Standard). Two additional responses did not support USDA's development of voluntary U.S. standards or a grading program. One pointed out the duplicity of creating these under AMS when they already exist under NFMS, noting the unnecessary use of resources to develop a program ''and market to a consuming [public] that is not demanding a new U.S. Grade Standard;'' the other recommended the use of the NMFS standards and grading program, as these are already familiar to the industry and their customers. The final response was outside the scope of the Notice, as it objected to the mandatory inspection of fish of the order Siluriformes by FSIS but did not address development by USDA of voluntary U.S. standards or a grading program. These comments are available at the following Web site: *https://www.regulations.gov/document?D=AMS-LPS-16-0006.*

Based on the responses received from the Notice as well as additional feedback from stakeholders through other avenues, including two industry workshops coordinated by AMS and academia and an industry-wide conference call held by AMS in May 2016, AMS has concluded that there is not sufficient interest in USDA–AMS standards for catfish or an AMS-administered grading program at this time.

It is important to note that a standard for catfish, and associated voluntary grading services, are currently available to the industry through NMFS. NMFS maintains the ''United States Standards for Grades of North American Freshwater Catfish and Products Made Therefrom'' and provides grading and certification services on a fee-for-service basis. Graded catfish and catfish products may bear official marks, including 'U.S. Grade A,' 'Processed

Under Federal Inspection,' and 'Lot Inspection.' Additional services provided by NMFS include system and process audits, product inspection, and export certification.

In light of the response from industry stakeholders indicating there is no current need for USDA–AMS standards nor a subsequent AMS-administered grading program for catfish, AMS will discontinue the initiative to establish either at this time. AMS stands ready to assist agricultural industries in establishing voluntary standards and grading programs for commodities for which it has authority to do so; the catfish industry retains this option should the need arise.

Dated: January 17, 2017.

Elanor Starmer,

Administrator, Agricultural Marketing Service.

[FR Doc. 2017–01413 Filed 1–19–17; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2016–0114]

Notice of Request for Extension of Approval of an Information Collection; Plum Pox Compensation

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Extension of approval of an information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to request an extension of approval of an information collection associated with the regulations that provide for the payment of compensation to owners of commercial stone fruit orchards and fruit tree nurseries whose trees or nursery stock were destroyed to eradicate plum pox virus.

DATES: We will consider all comments that we receive on or before March 24, 2017.

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

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2016-0114.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2016–0114, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2016-0114* or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: For information on the regulations for plum pox compensation, contact Dr. Robert Baca, Assistant Director, Permitting and Compliance Coordination, Compliance and Environmental Coordination Branch, PPQ, APHIS, 4700 River Road Unit 150, Riverdale, MD 20737; (301) 851–2292. For copies of more detailed information on the information collection, contact Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851–2483.

SUPPLEMENTARY INFORMATION:

Title: Plum Pox Compensation.

OMB Control Number: 0579–0159.

Type of Request: Extension of approval of an information collection.

Abstract: The Plant Protection Act (PPA, 7 U.S.C. 7701 *et seq.*) authorizes the Secretary of Agriculture, either independently or in cooperation with the States, to carry out operations or measures to detect, eradicate, suppress, control, prevent, or retard the spread of plant pests, such as plum pox virus (PPV), that are new to or not widely distributed within the United States.

Plum pox is an extremely serious viral disease of plants that can affect many *Prunus* (stone fruit) species, including plum, peach, apricot, almond, nectarine, and sweet and tart cherry. A number of wild and ornamental *Prunus* species may also be susceptible to this disease. Infection eventually results in severely reduced fruit production, and the fruit that is produced is often misshapen and blemished. PPV is transmitted under natural conditions by several species of aphids. The long distance spread of PPV occurs by budding and grafting with infected plant material and by farm tools/equipment, and through movement of infected budwood, nursery stock, and other plant parts. There are no known effective methods for treating trees or other plant material infected with PPV, nor are there any known effective preventive treatments. Without effective treatments, the only option for preventing the spread of the disease is the destruction of infected and exposed trees and other infected plant material.

The regulations in ''Subpart–Plum Pox'' (7 CFR 301.74–301.74–5) quarantine areas of the United States where PPV has been detected, restrict the interstate movement of host material from quarantined areas, and when the Secretary of Agriculture declares an extraordinary emergency, provides for compensation to owners of commercial stone fruit orchards and fruit tree nurseries whose trees or nursery stock were destroyed to eradicate PPV. The regulations require applicants for the payment of compensation to complete required documentation.

We are asking the Office of Management and Budget (OMB) to approve our use of this information collection activity for an additional 3 years.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our information collection. These comments will help us:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies; *e.g.,* permitting electronic submission of responses.

Estimate of burden: The public reporting burden for this collection of information is estimated to average 0.04 hours per response.

Respondents: Owners and affiliates of stone fruit orchards and fruit tree nurseries.

Estimated annual number of respondents: 2,524.

Estimated annual number of responses per respondent: 1.

Estimated annual number of responses: 2,548.

Estimated total annual burden on respondents: 107 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Done in Washington, DC, this 13th day of January 2017.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2017–01388 Filed 1–19–17; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2016–0112]

Notice of Request for Revision to and Extension of Approval of an Information Collection; Importation of Unshu Oranges

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Revision to and extension of approval of an information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to request a revision to and extension of approval of an information collection associated with the regulations for the importation of Unshu oranges.

DATES: We will consider all comments that we receive on or before March 24, 2017.

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

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2016-0112.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2016–0112, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2016-0112* or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: For information on the regulations for the importation of Unshu oranges, contact Dr. Robert Baca, Assistant Director, Permitting and Compliance Coordination, Compliance and Environmental Coordination Branch, PPQ, APHIS, 4700 River Road Unit 150, Riverdale, MD 20737; (301) 851–2292. For copies of more detailed information on the information collection, contact Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851–2483.

SUPPLEMENTARY INFORMATION:

Title: Importation of Unshu Oranges.

OMB Control Number: 0579–0173.

Type of Request: Revision to and extension of approval of an information collection.

Abstract: The Plant Protection Act (PPA, 7 U.S.C. 7701 *et seq.*) authorizes the Secretary of Agriculture to restrict the importation, entry, or interstate movement of plants, plant products, and other articles to prevent the introduction of plant pests into the United States or their dissemination within the United States. As authorized by the PPA, the United States Department of Agriculture, Animal and Plant Health Inspection Service (APHIS) regulates the importation of citrus fruit from certain parts of the world as provided in ''Subpart—Citrus Fruit'' (7 CFR 319.28).

In accordance with these regulations, APHIS allows the importation of Unshu oranges from certain regions into the United States under certain conditions to prevent the introduction of plant pests into the United States. These conditions involve the use of information collection activities, including markings, registrations, permits, and certificates.

The information collection requirements above are currently approved by the Office of Management and Budget (OMB) under OMB Control Number 0579–0173, Importation of Unshu Oranges, and OMB Control Number 0579–0418, Importation of Fresh Unshu Oranges From Japan into the United States. After OMB approves this combined information collection package (0579–0173), APHIS will retire OMB Control Number 0579–0418.

We are asking OMB to approve our use of these information collection activities, as described, for an additional 3 years.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our information collection. These comments will help us:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies; *e.g.,* permitting electronic submission of responses.

Estimate of burden: The public reporting burden for this collection of information is estimated to average 0.08 hours per response.

Respondents: Growers and packinghouses of Unshu oranges, and the national plant protection organization of the exporting region.

Estimated annual number of respondents: 27.

Estimated annual number of responses per respondent: 2,469.

Estimated annual number of responses: 66,663.

Estimated total annual burden on respondents: 5,585 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Done in Washington, DC, this 13th day of January 2017.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2017–01389 Filed 1–19–17; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2016–0048]

Addition of the Republic of Korea to the List of Regions Affected by Contagious Equine Metritis

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that we have added the Republic of Korea to the Animal and Plant Health Inspection Service (APHIS) list maintained on the APHIS Web site of regions considered affected with contagious equine metritis (CEM). We took this action because of the confirmation of CEM in the Republic of Korea.

DATES: *Effective Date:* The addition of the Republic of Korea to the APHIS list of regions considered affected with CEM is effective retroactively to May 7, 2015.

FOR FURTHER INFORMATION CONTACT: Mr. Javier Vargas, Import Risk Analyst, National Import Export Services, VS, APHIS, 4700 River Road, Unit 38, Riverdale, MD 20737; (301) 851–3300; *Javier.Vargas@aphis.usda.gov.*

SUPPLEMENTARY INFORMATION: The regulations in 9 CFR part 93 (referred to below as the regulations) prohibit or restrict the importation of certain animals into the United States to prevent the introduction of communicable diseases of livestock. Subpart C—Horses, §§ 93.300 through 93.326, pertains to the importation of horses into the United States. Sections 93.301 and 93.304 of the regulations contain specific provisions for the importation of horses from regions affected with contagious equine metritis (CEM), which is a highly contagious venereal disease of horses and other equines caused by an infection with the bacterium *Taylorella equigenitalis.* A list of regions that the Animal and Plant Health Inspection Service (APHIS) considers to be affected with CEM or that trade horses freely with a region in which CEM exists without testing for CEM is maintained on the APHIS Web site at *https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/ct_animal_disease_status.*

APHIS receives notice of CEM outbreaks from veterinary officials of the exporting country, from the World Organization for Animal Health (OIE), or from other sources the Administrator determines to be reliable. On June 19, 2015, the veterinary authorities of the Republic of Korea reported to the OIE that subclinical infections of *T. equigenitalis* had been confirmed in 17 horses held in 7 locations in Jejudo on May 7, 2015.

In response to this outbreak, APHIS added the Republic of Korea to the list of regions where CEM exists or is reasonably believed to exist. As a result, horses and other equines from the Republic of Korea are subject to APHIS import restrictions designed to mitigate risk of CEM introduction into the United States. These restrictions are effective retroactively to May 7, 2015.

Authority: 7 U.S.C. 1622 and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

Done in Washington, DC, this 13th day of January 2017.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2017–01394 Filed 1–19–17; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2016–0092]

Concurrence With OIE Risk Designations for Bovine Spongiform Encephalopathy

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public of our preliminary concurrence with the World Organization for Animal Health's (OIE) bovine spongiform encephalopathy (BSE) risk designations for seven regions. The OIE recognizes these regions as being of negligible risk for BSE. We are taking this action based on our review of information supporting the OIE's risk designations for these regions.

DATES: We will consider all comments that we receive on or before March 24, 2017.

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

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2016-0092.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2016–0092, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road, Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2016-0092* or in our reading room, which is located in Room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: Dr. Roberta Morales, Senior Staff Veterinarian, Regionalization Evaluation Services, National Import Export Services, VS, APHIS, 920 Main Campus Drive, Suite 200, Raleigh, NC 27606; (919) 855–7735.

SUPPLEMENTARY INFORMATION: The regulations in 9 CFR part 92 subpart B, ''Importation of Animals and Animal Products; Procedures for Requesting BSE Risk Status Classification With Regard To Bovines'' (referred to below as the regulations), set forth the process by which the Animal and Plant Health Inspection Service (APHIS) classifies regions for bovine spongiform encephalopathy (BSE) risk. Section 92.5 of the regulations provides that all countries of the world are considered by APHIS to be in one of three BSE risk categories: Negligible risk, controlled risk, or undetermined risk. These risk categories are defined in § 92.1. Any region that is not classified by APHIS as presenting either negligible risk or controlled risk for BSE is considered to present an undetermined risk. The list of those regions classified by APHIS as having either negligible risk or controlled risk can be accessed on the APHIS Web site at *https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/import-live-animals/ct_bovine_spongiform_encephalopathy.* The list can also be obtained by writing to APHIS at National Import Export Services, 4700 River Road, Unit 38, Riverdale, MD 20737.

Under the regulations, APHIS may classify a region for BSE in one of two ways. One way is for countries that have not received a risk classification from the World Organization for Animal Health (OIE) to request classification by APHIS. The other way is for APHIS to concur with the classification given to a country by the OIE.

If the OIE has classified a country as either BSE negligible risk or BSE controlled risk, APHIS will seek information to support concurrence with the OIE classification. This information may be publicly available information, or APHIS may request that countries supply the same information given to the OIE. APHIS will announce in the **Federal Register**, subject to public comment, its intent to concur with an OIE classification.

In accordance with this process, we are giving notice in this document that APHIS intends to concur with the OIE risk classifications of the following countries:

- *Regions of negligible risk for BSE:* Costa Rica, Germany, Lithuania, Mexico, Namibia, Romania, and Spain.

The OIE recommendations regarding each of the above countries can be viewed at *http://www.oie.int/animal-health-in-the-world/official-disease-status/bse/list-of-bse-risk-status/.*

The conclusions of the OIE scientific commission for these countries can be viewed at:

Costa Rica: http://www.oie.int/fileadmin/Home/eng/Internationa_Standard_Setting/docs/pdf/SCAD/A_SCAD_Feb2016.pdf (page 92).

Germany: http://www.oie.int/fileadmin/Home/eng/Internationa_Standard_Setting/docs/pdf/SCAD/A_SCAD_Feb2016.pdf (page 93).

Lithuania: http://www.oie.int/fileadmin/Home/eng/Internationa_Standard_Setting/docs/pdf/SCAD/A_SCAD_Feb2016.pdf (page 95).

Mexico: http://www.oie.int/fileadmin/Home/eng/Internationa_Standard_Setting/docs/pdf/SCAD/A_SCAD_Feb2016.pdf (page 96).

Namibia: http://www.oie.int/fileadmin/Home/eng/Internationa_Standard_Setting/docs/pdf/SCAD/A_SCAD_Feb2016.pdf (page 98).

Romania: http://www.oie.int/fileadmin/Home/eng/Internationa_Standard_Setting/docs/pdf/SCAD/A_SCAD_Feb2016.pdf (page 101).

Spain: http://www.oie.int/fileadmin/Home/eng/Internationa_Standard_Setting/docs/pdf/SCAD/A_SCAD_Feb2016.pdf (page 99).

After reviewing any comments we receive, we will announce our final determination regarding the BSE classification of these countries in the **Federal Register**, along with a discussion of and response to pertinent issues raised by commenters. If APHIS recognizes a country as either negligible risk or controlled risk for BSE, the Agency will include that country on the list of regions of negligible risk or controlled risk for BSE, as applicable, that is available to the public on the Agency's Web site at *https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/import-live-animals/ct_bovine_spongiform_encephalopathy.*

Authority: 7 U.S.C. 1622 and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

Done in Washington, DC, this 13th day of January 2017.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2017–01390 Filed 1–19–17; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2016–0072]

Addition of Lebanon to the List of Regions Affected by Highly Pathogenic Avian Influenza

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that we added Lebanon to the Animal and Plant Health Inspection Service (APHIS) list maintained on the APHIS Web site of regions considered affected with highly pathogenic avian influenza (HPAI). We are taking this action because of the confirmation of HPAI detection in Lebanon.

DATES: *Effective Date:* The addition of Lebanon to the APHIS list of regions considered affected with HPAI is effective retroactively to April 22, 2016.

FOR FURTHER INFORMATION CONTACT: Mr. Javier Vargas, Import Risk Analyst, National Import Export Services, VS, APHIS, 4700 River Road, Unit 38, Riverdale, MD 20737; (301) 851–3300; *Javier.Vargas@aphis.usda.gov.*

SUPPLEMENTARY INFORMATION: The regulations in 9 CFR part 94 (referred to below as the regulations) govern the importation of certain animals and animal products into the United States to prevent the introduction of various animal diseases, including Newcastle disease and highly pathogenic avian influenza (HPAI). The regulations prohibit or restrict the importation of live poultry, poultry meat, and other poultry products from regions where these diseases are considered to exist.

Section 94.6 of part 94 of the regulations contain requirements governing the importation into the United States of carcasses, meat, parts or products of carcasses, and eggs (other than hatching eggs) of poultry, game birds, or other birds from regions of the world where HPAI exists or is reasonably believed to exist. HPAI is an extremely infectious and potentially fatal form of avian influenza in birds and poultry that, once established, can spread rapidly from flock to flock. A list of regions that the Animal and Plant Health Inspection Service (APHIS) considers affected with HPAI of any subtype is maintained on the APHIS Web site at *https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/ct_animal_disease_status.*

APHIS receives notice of HPAI outbreaks from veterinary officials of the exporting country, from the World Organization for Animal Health (OIE), or from other sources the Administrator determines to be reliable. On April 23, 2016, the veterinary authorities of Lebanon reported to the OIE that an HPAI outbreak had been confirmed in the Bekaa region on April 22, 2016. The outbreak affected a farm of approximately 20,000 birds.

In response to this outbreak, APHIS added Lebanon to the list of regions where HPAI exists or is reasonably believed to exist. As a result, live poultry, poultry meat, and other poultry products from Lebanon are subject to APHIS import restrictions designed to mitigate risk of HPAI introduction into the United States. These restrictions are effective retroactively to April 22, 2016.

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

Done in Washington, DC, this 13th day of January 2017.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2017–01392 Filed 1–19–17; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2016–0101]

Notice of Request for Reinstatement of an Information Collection; National Veterinary Accreditation Program Application Form

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Reinstatement of an information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to request a reinstatement of an information collection associated with the National Veterinary Accreditation Program application form.

DATES: We will consider all comments that we receive on or before March 24, 2017.

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

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2016-0101.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2016–0101, Regulatory Analysis

and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2016-0101* or in our reading room, which is located in Room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: For information on the National Veterinary Accreditation Program application form, contact Dr. Todd Behre, Veterinary Medical Officer, National Veterinary Accreditation Program, VS, APHIS, 4700 River Road Unit 64, Riverdale, MD 20737; (301) 851–3401. For copies of more detailed information on the information collection, contact Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851–2483.

SUPPLEMENTARY INFORMATION:

Title: National Veterinary Accreditation Program Application Form.

OMB Control Number: 0579–0297.

Type of Request: Reinstatement of an information collection.

Abstract: Under the Animal Health Protection Act (7 U.S.C. 8301 *et seq.*), the Secretary of Agriculture is authorized to protect the health of U.S. livestock by preventing the introduction and interstate spread of serious diseases and pests of livestock and for eradicating such diseases from the United States when feasible. This authority has been delegated to the Animal and Plant Health Inspection Service (APHIS). In connection with this mission, the U.S. Department of Agriculture established the National Veterinary Accreditation Program (NVAP) so that accredited private practitioners can assist Federal veterinarians in controlling animal diseases and facilitating the movement of animals. Regulations concerning the accreditation of veterinarians and the suspension and revocation of accreditation are in 9 CFR, chapter I, subchapter J (parts 160 through 162).

NVAP is a voluntary program that is administered by APHIS. As part of this program, APHIS uses an NVAP application form to collect information regarding an applicant's eligibility for accreditation and, among other things, to update an individual's contact information and renew or revise his or her accreditation status.

We are asking the Office of Management and Budget (OMB) to approve our use of this information collection activity for 3 years.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our information collection. These comments will help us:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies; *e.g.,* permitting electronic submission of responses.

Estimate of burden: The public reporting burden for this collection of information is estimated to average 0.50 hours per response.

Respondents: Veterinarians.

Estimated annual number of respondents: 23,800.

Estimated annual number of responses per respondent: 1.

Estimated annual number of responses: 23,801.

Estimated total annual burden on respondents: 11,901 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Done in Washington, DC, this 13th day of January 2017.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2017–01387 Filed 1–19–17; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2016–0102]

Notice of Request for Reinstatement of an Information Collection; National Veterinary Services Laboratories; Bovine Spongiform Encephalopathy Surveillance Program

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Reinstatement of an information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to request the reinstatement of an information collection associated with National Veterinary Services Laboratories diagnostic support for the bovine spongiform encephalopathy surveillance program.

DATES: We will consider all comments that we receive on or before March 24, 2017.

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

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2016-0102.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2016–0102, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road, Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2016-0102* or in our reading room, which is located in Room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: For information collection activities associated with the bovine spongiform encephalopathy surveillance program, contact Dr. Tyler McAlpin, Staff Veterinarian, Surveillance, Preparedness, and Response, Veterinary Services, APHIS, 4700 River Road Unit 46, Riverdale, MD 20737; (301) 851–3458. For copies of more detailed information on the information collection, contact Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851–2483.

SUPPLEMENTARY INFORMATION:

Title: National Veterinary Services Laboratories; Bovine Spongiform Encephalopathy Surveillance Program.

OMB Control Number: 0579–0409.

Type of Request: Reinstatement of an information collection.

Abstract: Under the Animal Health Protection Act (7 U.S.C. 8301 *et seq.*), the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture (USDA) is authorized, among other things, to carry out activities to detect, control, and eradicate pests and diseases of livestock within the United States. APHIS' National Veterinary Services Laboratories (NVSL) safeguard U.S. animal health and contribute to public health by ensuring that timely and accurate laboratory support is provided by their nationwide animal health diagnostic system.

USDA complies with the standard set by the World Organization for Animal Health (OIE) for bovine spongiform encephalopathy (BSE) surveillance. This compliance is critical for maintaining our BSE-risk status with the OIE. Our BSE surveillance program requires information collection activities, such as completing the USDA BSE Surveillance Submission form and the USDA BSE Surveillance Data Collection form.

We are asking the Office of Management and Budget (OMB) to approve our use of these information collection activities for 3 years.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our information collection. These comments will help us:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies; *e.g.,* permitting electronic submission of responses.

Estimate of burden: The public reporting burden for this collection of information is estimated to average 0.1 hours per response.

Respondents: Slaughter establishments, offsite collection facilities for condemned slaughter cattle, rendering 3D/4D facilities, State animal health personnel, veterinary diagnostic laboratories, and accredited veterinarians.

Estimated annual number of respondents: 1,035.

Estimated annual number of responses per respondent: 29.23.

Estimated annual number of responses: 30,248.

Estimated total annual burden on respondents: 3,026 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Done in Washington, DC, this 13th day of January 2017.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2017–01386 Filed 1–19–17; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2016–0104]

Notice of Request for an Extension of Approval of an Information Collection; Highly Pathogenic Avian Influenza, All Subtypes, and Newcastle Disease; Additional Restrictions

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Extension of approval of an information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to request an extension of approval of an information collection associated with the regulations to prevent the introduction of highly pathogenic avian influenza, all subtypes, and Newcastle disease into the United States through the importation of birds, poultry, and unprocessed bird and poultry products.

DATES: We will consider all comments that we receive on or before March 24, 2017.

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

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2016-0104.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2016–0104, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2016-0104* or in our reading room, which is located in Room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: For information on the regulations to prevent the introduction of highly pathogenic avian influenza and Newcastle disease, contact Dr. Bettina Helm, Senior Staff Veterinary Medical Officer, Live Animal Imports, National Import Export Services, VS, APHIS, 4700 River Road Unit 40, Riverdale, MD 20737; (301) 851–3300. For copies of more detailed information on the information collection, contact Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851–2483.

SUPPLEMENTARY INFORMATION:

Title: Highly Pathogenic Avian Influenza, All Subtypes, and Newcastle Disease; Additional Restrictions.

OMB Control Number: 0579–0245.

Type of Request: Extension of approval of an information collection.

Abstract: Under the Animal Health Protection Act (7 U.S.C. 8301 *et seq.*), the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) is authorized, among other things, to prohibit or restrict the importation and interstate movement of animals and animal products to prevent the introduction into and dissemination within the United States of livestock diseases and pests. To carry out this mission, APHIS regulates the importation of animals and animal products into the United States. The regulations for the importation of animals and animal products are contained in 9 CFR parts 92 through 98.

The regulations in 9 CFR parts 93, 94, and 95 govern the importation of specified animals and animal products and byproducts to prevent the introduction of various animal diseases, including highly pathogenic avian influenza (HPAI), all subtypes, and Newcastle disease.

HPAI, as defined in § 94.0, is an infectious and fatal disease of poultry.

HPAI can strike poultry quickly without any warning signs of infection and, once established, can spread rapidly from flock to flock. HPAI viruses can be spread by manure, equipment, vehicles, egg flats, crates, and people whose clothing or shoes have come in contact with the viruses. In addition, HPAI viruses can remain viable at moderate temperatures for long periods in the environment and can survive indefinitely in frozen material. One gram of contaminated manure can contain enough virus to infect 1 million poultry.

Newcastle disease is a contagious disease of birds and poultry caused by a paramyxovirus. Newcastle disease, as defined in § 94.0, is one of most infectious diseases of poultry in the world. A death rate of almost 100 percent can occur in unvaccinated poultry flocks. Newcastle disease can also infect and cause death even in vaccinated birds and poultry.

APHIS' regulations prohibit or restrict the importation of unprocessed bird and poultry products and byproducts from regions that have reported the presence of HPAI or Newcastle disease, and contain permit and quarantine requirements for pet birds and U.S. performing or theatrical birds and poultry returning to the United States. In addition, there are also restrictions concerning importation of live poultry and birds that have been vaccinated for certain types of Newcastle disease, or that have moved through or originate from regions where HPAI or Newcastle disease is considered to exist. These regulations require the use of a number of information collection activities, including various APHIS forms, application of seals, agreements, notarized declarations or affirmations, notification of signs of disease in a recently imported bird, cooperative service agreements, and recordkeeping by processing establishments.

We are asking OMB to approve our use of these information collection activities for an additional 3 years.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our information collection. These comments will help us:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies; *e.g.,* permitting electronic submission of responses.

Estimate of burden: The public reporting burden for this collection of information is estimated to average 0.55 hours per response.

Respondents: Foreign federal government officials and owners of U.S.-origin pet birds and performing or theatrical birds or poultry returning to the United States, and U.S. importers of bird and poultry carcasses, parts, products and byproducts (bird blood, bird tissues, etc.) of birds and poultry and eggs (other than hatching eggs) from certain regions.

Estimated annual number of respondents: 973.

Estimated annual number of responses per respondent: 3.81.

Estimated annual number of responses: 3,707.

Estimated total annual burden on respondents: 2,041 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Done in Washington, DC, this 13th day of January 2017.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2017–01393 Filed 1–19–17; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2016–0044]

Notice of Availability of an Evaluation of the Classical Swine Fever, Foot-and-Mouth Disease, Swine Vesicular Disease, and Rinderpest Status of Cyprus

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of availability.

SUMMARY: We are advising the public that we are proposing to recognize Cyprus as being free of foot-and-mouth disease, rinderpest, and swine vesicular disease, and as low risk for classical swine fever. This proposed recognition is based on evaluations we have prepared in connection with this action, which we are making available for review and comment.

DATES: We will consider all comments that we receive on or before March 24, 2017.

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

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2016-0044.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2016–0044, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road, Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2016-0044* or in our reading room, which is located in Room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: Dr. Ingrid Kotowski, Regionalization Evaluation Services, National Import Export Services, Veterinary Services, APHIS, 920 Main Campus Drive, Suite 200, Raleigh, NC 27606; (919) 855–7732; *Ingrid.Kotowski@aphis.usda.gov.*

SUPPLEMENTARY INFORMATION: The regulations in 9 CFR part 94 (referred to below as the regulations) govern the importation of certain animals and animal products into the United States to prevent the introduction of various animal diseases, including classical swine fever (CSF), foot-and-mouth disease (FMD), swine vesicular disease (SVD), and rinderpest.[1] The regulations prohibit or restrict the importation of live ruminants and swine, and products from these animals, from regions where these diseases are considered to exist.

Within part 94, § 94.1 contains requirements governing the importation of ruminants and swine from regions where rinderpest or FMD exists and the

[1] The World Organization for Animal Health (OIE) recognizes rinderpest as having been globally eradicated, and recommends that countries not impose any rinderpest-related conditions on import or transit of livestock and livestock products. In addition, the OIE recently delisted SVD as a disease of concern for international trade. However, APHIS continues to regulate for rinderpest and SVD through its import regulations for animals and animal products.

importation of the meat of any ruminants or swine from regions where rinderpest or FMD exists to prevent the introduction of either disease into the United States. We consider rinderpest and FMD to exist in all regions except those listed in accordance with paragraph (a) of that section as free of rinderpest and FMD.

Section 94.9 contains requirements governing the importation of pork and pork products from regions where CSF exists. Section 94.10 contains importation requirements for swine from regions where CSF is considered to exist and designates the Animal and Plant Health Inspection Service (APHIS)-defined European CSF region as a single region of low-risk for CSF. Section 94.31 contains requirements governing the importation of pork, pork products, and swine from the APHIS-defined European CSF region. We consider CSF to exist in all regions of the world except those listed in accordance with paragraph (a) of § 94.9 as free of the disease.

Section 94.11 of the regulations contains requirements governing the importation of meat of any ruminants or swine from regions that have been determined to be free of rinderpest and FMD, but that are subject to certain restrictions because of their proximity to or trading relationships with rinderpest- or FMD-affected regions. Such regions are listed in accordance with paragraph (a) of that section.

Section 94.12 of the regulations contains requirements governing the importation of pork or pork products from regions where SVD exists. We consider SVD to exist in all regions of the world except those listed in accordance with paragraph (a) of that section as free of SVD.

Section 94.13 contains importation requirements governing the importation of pork or pork products from regions that have been declared free of SVD as provided in § 94.12(a) but supplement their national pork supply by the importation of fresh (chilled or frozen) meat of animals from regions where SVD is considered to exist, or have a common border with such regions, or have trade practices that are less restrictive than are acceptable to the United States. Such regions are listed in accordance with paragraph (a) of § 94.13.

Section 94.14 states that no swine which are moved from or transit any region in which SVD is known to exist may be imported into the United States except wild swine imported in accordance with § 94.14(b).

The regulations in 9 CFR part 92, § 92.2, contain requirements for requesting the recognition of the animal health status of a region (as well as for the approval of the export of a particular type of animal or animal product to the United States from a foreign region). If, after review and evaluation of the information submitted in support of the request, APHIS believes the request can be safely granted, APHIS will make its evaluation available for public comment through a document published in the **Federal Register**. Following the close of the comment period, APHIS will review all comments received and will make a final determination regarding the request that will be detailed in another document published in the **Federal Register**.

The Republic of Cyprus [2] submitted a request to APHIS to evaluate the CSF, FMD, SVD, and rinderpest status of the country. In response to this request, APHIS conducted a qualitative risk assessment to evaluate Cyprus with respect to these diseases. Based on this evaluation, APHIS recognizes Cyprus to be free of FMD, SVD, and rinderpest, and low risk for CSF. APHIS has also determined that the surveillance, prevention, and control measures implemented by the European Union (EU) and Cyprus, an EU Member State, are sufficient to minimize the likelihood of introducing CSF, FMD, SVD, and rinderpest into the United States via imports of species susceptible to these diseases or products of those species. Our determinations support adding Cyprus to the Web-based list of regions comprising the APHIS-defined European CSF region, which APHIS considers to be low risk for CSF, and to the respective Web-based lists of regions APHIS considers free of FMD, SVD, and rinderpest.

Therefore, in accordance with § 92.2(e), we are announcing the availability of our risk assessment of the CSF, FMD, SVD, and rinderpest status of Cyprus for public review and comment. We are also announcing the availability of four environmental assessments (EAs) and a finding of no significant impact (FONSI) [3] which has been prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provision of NEPA (40 CFR parts 1500–1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372). The evaluation, EAs, and FONSI may be viewed on the *Regulations.gov* Web site or in our reading room. (Instructions for accessing *Regulations.gov* and information on the location and hours of the reading room are provided under the heading **ADDRESSES** at the beginning of this notice.) The documents are also available by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

Information submitted in support of Cyprus' original request is available by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

After reviewing any comments we receive, we will announce our decision regarding the disease status of Cyprus under consideration with respect to CSF, FMD, SVD, and rinderpest and the import status of susceptible animals and products of such animals in a subsequent notice.

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

Done in Washington, DC, this 13th day of January 2017.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2017–01396 Filed 1–19–17; 8:45 am]

BILLING CODE 3410–34–P

[2] The geographic scope of the action is limited to the Republic of Cyprus excluding those areas of the Republic of Cyprus in which the Government of the Republic of Cyprus does not exercise effective control.

[3] The FONSI for Cyprus incorporates by reference EAs prepared for Slovakia, Slovenia, Estonia, and Hungary that addresses the potential environmental impacts of CSF, FMD, SVD, and rinderpest for EU Member States. We are making these EAs available for review with this document.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2016–0105]

Notice of Request for Extension of Approval of an Information Collection; Importation of Horses, Ruminants, Swine, and Dogs; Inspection and Treatment for Screwworm

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Extension of approval of an information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to request an extension of approval of an information collection associated with the regulations for the importation of horses, ruminants, swine, and dogs from

regions of the world where screwworm is considered to exist.

DATES: We will consider all comments that we receive on or before March 24, 2017.

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

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2016-0105.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2016–0105, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road, Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2016-0105* or in our reading room, which is located in Room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: For information on the regulations for the importation of horses, ruminants, swine, and dogs from regions of the world where screwworm is considered to exist, contact Dr. Betsy Lopez, Senior Staff Veterinarian, Live Animal Imports, National Import Export Services, VS, APHIS, 4700 River Road, Unit 39, Riverdale, MD 20737; (301) 851–3300. For copies of more detailed information on the information collection, contact Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851–2483.

SUPPLEMENTARY INFORMATION:

Title: Importation of Horses, Ruminants, Swine, and Dogs; Inspection and Treatment for Screwworm.

OMB Control Number: 0579–0165.

Type of Request: Extension of approval of an information collection.

Abstract: Under the Animal Health Protection Act (7 U.S.C. 8301 *et seq.*), the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture (USDA) is authorized, among other things, to prohibit or restrict the importation and interstate movement of animals and animal products to prevent the introduction into and dissemination within the United States of livestock diseases and pests.

The regulations in 9 CFR part 93 prohibit or restrict the importation of certain animals into the United States to prevent the introduction of communicable diseases of livestock and poultry. Subparts C, D, E, and F of part 93 govern the importation of horses, ruminants, swine, and dogs, respectively, and include provisions for the inspection and treatment of these animals if imported from any region of the world where screwworm is considered to exist. Screwworm is a pest native to tropical areas of South America, the Indian subcontinent, Southeast Asia, tropical and sub-Saharan Africa, and the Arabian peninsula. Screwworm causes extensive damage to livestock and other warmblooded animals.

The regulations in subparts C, D, E, and F involve the use of information collection activities, such as quarantine reservations, an Application for Import or In Transit Permit (Animals, Animal Semen, Animal Embryos, Birds, Poultry, or Hatching Eggs) form, and a Declaration of Importation of Animals, Animal Semen, Animal Embryos, Birds, Poultry, or Hatching Eggs form. An additional requirement is a request for and issuance of health certificates for horses, ruminants, swine, and dogs signed by a full-time salaried veterinary official of the exporting region stating that the animal has been inspected, under certain conditions, and found free of screwworm and, as appropriate, that the animal was treated for screwworm.

We are asking the Office of Management and Budget (OMB) to approve our use of these information collection activities for an additional 3 years.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our information collection. These comments will help us:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies; *e.g.,* permitting electronic submission of responses.

Estimate of burden: The public reporting burden for this collection of information is estimated to average 0.15 hours per response.

Respondents: Full-timed salaried veterinary officials of exporting regions and importers of horses, ruminants, swine, and dogs from regions where screwworm is considered to exist.

Estimated annual number of respondents: 92.

Estimated annual number of responses per respondent: 58.25.

Estimated annual number of responses: 5,359.

Estimated total annual burden on respondents: 827 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Done in Washington, DC, this 13th day of January 2017.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2017–01391 Filed 1–19–17; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Forest Service

Alabama Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Alabama Resource Advisory Committee (RAC) will meet in Montgomery, Alabama. The committee is authorized under the Secure Rural Schools and Community Self-Determination Act (the Act) and operates in compliance with the Federal Advisory Committee Act. The purpose of the committee is to improve collaborative relationships and to provide advice and recommendations to the Forest Service concerning projects and funding consistent with Title II of the Act.

DATES: The meeting will be held Tuesday, February 28, 2017, at 1:00 p.m. to 4:00 p.m.

All RAC meetings are subject to cancellation. For status of meeting prior to attendance, please contact the person listed under *For Further Information Contact.*

ADDRESSES: The meeting will be held at the USDA Forest Service Supervisor's Office, Downstairs Conference Room, 2946 Chestnut Street, Montgomery, Alabama. If you would like to attend by telephone, please contact the person

listed under **FOR FURTHER INFORMATION CONTACT.**

Written comments may be submitted as described under **SUPPLEMENTARY INFORMATION.** All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at the USDA Forest Service Supervisor's Office. Please call ahead to facilitate entry into the building.

FOR FURTHER INFORMATION CONTACT: Lisa Kamnikar, RAC Coordinator, by phone at 334–241–8114 or via email at *lkamnikar@fs.fed.us;* or Tammy Freeman Brown, Designated Federal Officer, by phone 334–241–8144 or via email at *tfreemanbrown@fs.fed.us.*

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8:00 a.m. and 8:00 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to:

1. Introduce new RAC Members,

2. Discuss purpose of RAC, operating guidelines and responsiblities;

3. Elect a RAC Chairperson, and

4. Discuss potential projects and processes.

The meeting is open to the public. The agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should request in writing by close-of business, February 17, 2017, to be scheduled on the agenda. Anyone who would like to bring related matters to the attention of the committee may file written statements with the committee staff before or after the meeting. Written comments and requests for time to make oral comments must be sent to Lisa Kamnikar, Alabama RAC Coordinator, 2946 Chestnut Street Montgomery, Alabama 36107; by email to *lkamnikar@fs.fed.us,* or via facsimile to 334–241–8111.

Meeting Accommodations: If you are a person requiring reasonable accommodation, please make requests in advance for sign language interpreting, assistive listening devices, or other reasonable accommodation. For access to the facility or proceedings, pleases contact the person listed in the section titled **FOR FURTHER INFORMATION CONTACT.** All reasonable accommodation requests are managed on a case by case basis.

Dated: January 13, 2017.

Tammy Freeman Brown,

Designated Federal Officer.

[FR Doc. 2017–01347 Filed 1–19–17; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Forest Service

Willamette National Forest, Sweet Home Ranger District; Oregon; Trout Creek Project

AGENCY: Forest Service, USDA.

ACTION: Notice of intent to prepare an environmental impact statement.

SUMMARY: The Trout Creek Project is proposed to encourage stand health, vigor, species diversity and structural complexity in the Matrix, Adaptive Management Area (AMA), and Riparian Reserves; contribute a variety of sustainable forest products to local markets; increase spatial heterogeneity, including complex early seral habitat, at a landscape scale by mimicking mixed severity fire; improve fire resiliency and strategically manage hazardous fuels in high risk areas that could adversely affect the integrity of adjacent privately owned lands, Late Successional Reserves (LSR), Matrix, AMA, and Riparian Reserve lands and to enhance hardwood habitat and diversity. Proposed activities to achieve the purpose of the project inculde forest management treatments across approximately 1,670 acres (about 4.5% of the analyzed landscape). Treatments include approximately 733 acres of variable forest thinning (including 109 acres of Riparian Reserve thinning) and approximately 101 acres of regeneration harvesting that would include aggregate retention. Additionally, approximately 370 acres of non-commercial treatments are proposed including fall and leave treatments, snag creation, underplanting of native conifers, the planting of special forest products, and the restoration of a 2-acre meadow. Road work would also be part of the actions associated with the proposed activities and would include road maintenance/reconstruction (48.5 miles), temporary road construction (4 miles), new road construction (less than 1 mile), road decommissioning (7 miles) and the expansion or establishment of 2 new rock pits.

DATES: Comments concerning the scope of the analysis must be received by February 15, 2017. The draft environmental impact statement is expected July 2017 and the final environmental impact statement is expected May 2018.

ADDRESSES: Send written comments to 4431 Highway 20, Sweet Home, OR 97386. Comments may also be submitted online at *https://cara.ecosystem-management.org/Public//CommentInput?Project=46279.*

FOR FURTHER INFORMATION CONTACT: Joanie Schmidgall at *jschmidgall02@fs.fed.us* or at 541–367–3809

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday.

SUPPLEMENTARY INFORMATION:

Purpose and Need for Action

The Trout Creek project is approximately 37,344 acres in size and located approximately 20 miles east of the town of Sweet Home, Oregon. The project encompasses an area both to the north and south of Highway 20. The purposes of the project are to encourage stand health, vigor, species diversity and structural complexity in the Matrix, Adaptive Management Area (AMA), and Riparian Reserves; contribute a variety of sustainable forest products to local markets; increase spatial heterogeneity, including complex early seral habitat, at a landscape scale by mimicking mixed severity fire; improve fire resiliency and strategically manage hazardous fuels in high risk areas that could adversely affect the integrity of adjacent privately owned lands, Late Successional Reserves (LSR), Matrix, AMA, and Riparian Reserve lands; enhance and create hardwood habitat and diversity.

The district resource specialists reviewed this landscape and identified it to have the greatest need across the Sweet Home Ranger District for work that would benefit forest health and diversity. Many of the forested stands in the project area are overstocked from a silviculture perspective. There is opportunity to thin, reduce the number of trees and increase the diversity and structure of the remaining forest over time. Additionally, the project area includes a portion of the Menagerie Wilderness and is adjacent to a large swath of private land. This interface of public and private ownership has resulted in neighboring parcels of land with differing management objectives and fuel loads. This project presents an opportunity to reduce the risk of fires spreading across these landscapes through strategically-placed fuel treatments. No management activities are proposed within the wilderness boundary.

Proposed Action

We propose to thin approximately 733 acres (about 2% of the project area) and regenerate approximately 101 acres (less than 1% of the project area). Thinning treatments will be prescribed at varying frequencies and incorporate some untreated areas (skips) and create gaps up to 2 acres in size with variable spacing of remaining trees. We would design the regeneration harvest using an aggregate retention prescription to increase forest-age diversity and structural complexity across the project area.

There are two categories of stands proposed for treatment: Managed stands that are about 40–60 years old and fire origin stands that range from 100–150 years old. Approximately 576 acres of thinning and 52 acres of regeneration would take place in managed stands and 157 of thinning and 49 acres of regeneration acres in fire origin stands. These actions will provide roughly 12 MMBF of timber products to the local community. Cedar, sugar pine and other minor species would be under planted on about 300 acres across the project area. Additionally, about 38 acres would be planted with desirable conifer bough species for future bough harvest. There would be 109 acres thinned in the Riparian Reserves in the managed stands. The older fire origin stands would see no thinning in the Riparian Reserves. We propose thinning harvests in managed stands within the Riparian Reserves to increase in-stream productivity by increasing hardwood species and light availability. About 8 acres of fall and leave treatments are also proposed to improve hardwood diversity and structure in the Riparian Reserve.

This project also aims to increase spatial heterogeneity and complex early seral habitat by mimicking mixed severity fire on a landscape scale. On 309 acres of managed stands a combination of thinning, aggregate retention harvest, gap creation and controlled burn would result in a diverse landscape of green trees and openings. The treatments will vary by unit. In the fire origin stands, 47 acres would be treated to mimic high severity fire using a combination of commercial thinning, underburning and varying levels of tree girdling. An unburned area or low severity fire patch would be simulated by a proposed 65 acres of untreated skips.

Hardwood fuel breaks, where conifers are thinned heavily and hardwood species are planted, are proposed on about 35 acres in managed stands and 76 acres of fire origin stands. This will help curb the volume of hazardous fuels in these stands, provide a long term option for managing wildfires in the area, and further improve fire resiliency in and adjacent to the project area. A 14 acre managed stand in Late Successional Reserve is also proposed to be treated in this way to help protect an Oregon Department of Transportation facility.

Additionally, approximately 370 acres of non-commerical treatments are proposed across the project area. These include the fall and leave treatments, snag creation for oak and madrone restoration, underplanting of native conifers such as sugar pine and cedar, the planting of special forest products, and the restoration of a 2-acre meadow. While not adding commerical value, these actions will restore and maintain hardwood populations, increase forest diversity and structure, and contribute to over all landscape health in the project area.

The removal of forest products would include associated road work across the project area. The project would propose approximately 50 miles of road maintenance or reconstruction that would include the installation of approximately 260 culverts (primarily replacements). There would be less than 1 mile of new road construction. Construction or reconstruction of temporary road access would be approxiately 4 miles. These temporary roads would be decommissioned and returned to their original condition at the conclusion of project activities. Also proposed would be to decommission and hydrologically stabilize approximately 7 miles of road. The impacted roads for decommissioning would be existing Forest Sevice roads 2000–011, 2000–600, 632, 636, 641, and 643, 2000–308, 2000–017, 2032–419, and 2027–830. Most of these roads or sections of road are currently inaccessible to vehicle traffic. A rock pit would be developed near the 2027–825 road junction and an existing rock pit would be expanded at the end of the 2027–730 road.

Responsible Official

Nikki Swanson, Sweet Home District Ranger

Nature of Decision To Be Made

Given the purpose and need, the scope of the decision to be made by the responsible official will be as follows:

- Do the proposed actions comply with all applicable laws governing Forest Service actions?
- Do the proposed actions comply with the applicable Standards and Guidelines found in the Willamette Land and Resource Management plan (LRMP)?
  - If not, will the action ammend the LRMP?
- Does the environmental impact statement have suffcient site-specific environmental analysis to make an informed decesion?
- Do the proposed actions meet the purpose and need for action?

With these assurances, the responsible official must decide:

- Whether or not to select the proposed action or one of any other potential alternatives that may be developed, and what, if any, additional actions should be required.

Scoping Process

This Notice of Intent initiates the scoping process, which guides the development of the environmental impact statement. We are interested in your comments on the following questions:

- Are there alternative ways to meet the purpose and need of the project other than the proposed action we offer, which you would like the Forest Service to consider and analyze?
- Is there any information about the project area, which you believe is important in the context of the proposed activities that you would like the Forest Service to consider?
- What specifically are the potential effects of this proposed action that you are particularly concerned about? For example: Rather that simply stating that you would like a change in a proposed activity or that you would like an activity to not occur, it is more helpful to understand why you desire this. What are your underlying concerns with an activity or action; what are the effects from the activity that concern you?

It is important that reviewers provide their comments at such times and in such manner that they are useful to the agency's preparation of the environmental impact statement. Therefore, comments should be provided prior to the close of the comment period and should clearly articulate the reviewer's concerns and contentions.

Comments received in response to this solicitation, including names and addresses of those who comment, will be part of the public record for this proposed action. Comments submitted anonymously will also be accepted and considered.

Dated: January 12, 2017.

Nikki Swanson,

District Ranger.

[FR Doc. 2017–01343 Filed 1–19–17; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF AGRICULTURE

Office of Inspector General

Privacy Act of 1974; System of Records

AGENCY: Office of Inspector General, USDA.

ACTION: Notice of a modified system of records.

SUMMARY: In accordance with the Privacy Act, the United States Department of Agriculture, Office of Inspector General (USDA OIG) publishes this records notice to modify an existing system of records, USDA/OIG–8, the Research Aggregated Data Analysis Repository (RADAR) System, in order to update certain system information, including the system owner, and to clarify the records contained in the system and the purpose of the system.

DATES: The modified system of records established in this notice is effective upon publication in the **Federal Register**.

ADDRESSES: You may submit comments, identified by docket number OIG–2017–XXXX by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: Comments@oig.usda.gov.*
- *Fax:* (202) 690–1528.
- *Mail:* Christy A. Slamowitz, Counsel to the Inspector General, U.S. Department of Agriculture, 1400 Independence Avenue SW., STOP 2308, Washington, DC 20250–2308.
- *Instructions:* All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.
- *Docket:* For access to the docket or to read background documents or comments received go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Cherry W. Tolliver, Assistant Counsel to the Inspector General, USDA OIG, (202) 720–9110.

SUPPLEMENTARY INFORMATION: The Privacy Act of 1974 requires a notice to be published in the **Federal Register** when an agency revises a system of records, and that a report be filed with Congress when an agency makes a change to a system of records. 5 U.S.C. 552a(e)(4) and (r). USDA OIG updated and published its system of records notices in their entirety on August 13, 2015. 80 FR 48476. System of Records USDA/OIG–8 ''Office of Audit's Research Aggregated Data Analysis Repository (RADAR) System,'' originally established on March 5, 2009 (74 FR 9584), was included and updated in that consolidated notice. Since August 13, 2015, OIG has reorganized to establish a permanent Office of Data Sciences (ODS).

ODS will be conducting data mining and data analysis, predictive data analysis, statistical sampling, data modeling, computer matching, and data warehousing in support of OIG's audits, investigations, and other activities. ODS will be helping to fulfill OIG's mission of overseeing more than $100 billion managed by USDA agencies across numerous programs. Under the Inspector General Act of 1978, as amended, the USDA OIG is responsible for conducting, supervising, and coordinating audits and investigations related to programs and operations of the USDA. This system of records facilitates OIG's performance of this statutory duty by identifying leads and assessing vulnerabilities for OIG's Office of Audit or Office of Investigations.

RADAR, USDA/OIG–8, was established to house USDA data in order to detect fraud, waste, and abuse by utilizing software to match, merge, and analyze the data associated with USDA programs and activities, program participants, and other USDA information. Specifically, OIG is revising RADAR, USDA/OIG–8, in order to (1) reflect a new system manager, the newly created ODS (the prior owner was OIG's Office of Audit), and related system information regarding safeguards and storage; (2) clarify that the contents of USDA/OIG–8 will also include (a) OIG generated records and products that are the result of OIG's ODS data analysis work, and (b) information on USDA employees, as well as program participants; and (3) clarify the purpose of RADAR to include its use in support of OIG investigations and other activities, as well as OIG audits. The routine uses for RADAR are unchanged. The complete list of applicable USDA OIG routine uses can be found at 80 FR 48476 (Aug. 13, 2015).

A report on the modified system of records has been sent to Congress and the Office of Management and Budget in accordance with 5 U.S.C. 552a(r).

Dated: January 17, 2017.

Phyllis K. Fong,

Inspector General, Department of Agriculture.

Accordingly, we are republishing the notice for the modified RADAR system of records, USDA/OIG–8, in its entirety, as follows:

USDA/OIG–8

SYSTEM NAME AND NUMBER:

Office of Data Sciences (ODS) Research Aggregated Data Analysis Repository (RADAR) System, USDA/OIG–8.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

U.S. Department of Agriculture, National Information Technology Center, 8930 Ward Parkway, Kansas City, Missouri 64114.

SYSTEM MANAGER:

Assistant Inspector General for Data Sciences, OIG, U.S. Department of Agriculture, 1400 Independence Avenue SW., Washington, DC 20250.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Inspector General Act of 1978, 5 U.S.C. app 3; 5 U.S.C. 301.

PURPOSE OF THE SYSTEM:

The records maintained in this system are used by the U.S. Department of Agriculture (USDA), Office of Inspector General (OIG) to fulfill its statutory mission under the Inspector General Act, as amended, to conduct, supervise, and coordinate audits and investigations relating to the programs and operations of USDA; and to promote economy, efficiency, and effectiveness in the administration of, and prevent and detect fraud and abuse in, the programs and operations of USDA. The results of these data analysis activities, including fraud leads and vulnerability assessments, may be used in the conduct of OIG audits, investigations, and other activities.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

(1) Individuals who participate in programs funded, monitored, and administered by USDA and their parents, siblings, spouse, children, and members of their household;

(2) employees, principals or business associates of organizations, or firms who participate in programs funded, monitored, and administered by USDA participating entities

(3) Subjects of USDA OIG audits and investigations; and

(4) USDA temporary and permanent employees, and former employees of USDA.

CATEGORIES OF RECORDS IN THE SYSTEM:

RADAR will house USDA data from numerous USDA agency systems of records, including data associated with USDA programs and activities, USDA

program participants (including recipients, borrowers, grantees, and contractors), USDA employees, and other USDA information. RADAR will also contain records OIG ODS generates that are the result of its data analysis and data analytics work.

RECORD SOURCE CATEGORIES:

Information contained in this system is obtained from systems of records maintained by USDA and other Government agencies; individuals; non-Government, commercial, public, and private agencies and organizations; media, including periodicals, newspapers, and broadcast transcripts; and publicly-available databases.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSE OF SUCH USES:

Routine Uses 1 through 16, 19, 20, and 21 apply. 80 FR 48476 (Aug. 13, 2015).

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

The RADAR System, USDA/OIG–8, consists of computerized and paper records.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

The records are retrieved by names, addresses, Social Security Numbers, and tax identification numbers of USDA program participants or employees, or by case numbers. Records are retrieved by USDA OIG's Office of Data Sciences employees.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

The records contained in this system are currently unscheduled. A record retention schedule will be developed and submitted to NARA for approval. No records will be destroyed until a NARA approved record retention schedule is in place.

Any records contained in the system before the creation of the Office of Data Sciences, are retained and disposed of in compliance with OIG's record disposition authority approved by NARA for Inspector General Audit and Evaluation Case Files.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

OIG has adopted appropriate administrative, technical, and physical controls in accordance with OIG's information security policies to protect the security, integrity, and availability of the information, and to ensure that records are not disclosed to or accessed by unauthorized individuals.

Computerized records are maintained in a secure, password protected computer system. The computer server is maintained in a secure, access-controlled area within an access-controlled building. Paper records are kept in limited access areas during duty hours and in locked offices during nonduty hours.

RECORD ACCESS PROCEDURES:

An individual may request access to a record in this system that pertains to him/her by submitting a written request to the Counsel to the Inspector General, Office of Inspector General, U.S. Department of Agriculture, 1400 Independence Avenue SW., Stop 2308, Washington, DC 20250–2308.

CONTESTING RECORD PROCEDURES:

An individual may contest information in this system that pertains to him/her by submitting a written request to the Counsel to the Inspector General, Office of Inspector General, U.S. Department of Agriculture, 1400 Independence Avenue SW., Stop 2308, Washington, DC 20250–2308. This system may contain records originated by USDA agencies and contained in USDA's other systems of records. Where appropriate, coordination will be effected with the appropriate USDA agency regarding individuals contesting records in the relevant system of records.

NOTIFICATION PROCEDURES:

Any individual may request information regarding this system of records, or information as to whether the system contains records pertaining to him/her, from the Counsel to the Inspector General, Office of Inspector General, U.S. Department of Agriculture, 1400 Independence Avenue SW., Stop 2308, Washington, DC 20250–2308.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

No exemptions are applicable to records created by OIG ODS in the RADAR System, USDA/OIG–8. For individual records originating within a USDA system of records, OIG will continue to apply any applicable Privacy Act exemptions to those individual records.

HISTORY:

USDA OIG updated and published its system of records notices in their entirety on August 13, 2015. 80 FR 48476. System of Records USDA/OIG–8, originally established on March 5, 2009 (74 FR 9584), was included and updated in that consolidated notice.

[FR Doc. 2017–01412 Filed 1–19–17; 8:45 am]

BILLING CODE 3410–23–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request Information Collection for Self-Certification to the EU-U.S. Privacy Shield Framework

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: International Trade Administration (ITA).

Title: Information Collection for Self-Certification to the EU-U.S. Privacy Shield Framework.

OMB Control Number: 0625–0276.

Form Number(s): None.

Type of Request: Regular submission.

Number of Respondents: 3,600.

Average Hours per Response: 38 minutes.

Burden Hours: 2,954.

Needs and Uses: The United States and the European Union (EU) share the goal of enhancing privacy protection for their citizens, but take different approaches to protecting personal data. Given those differences, the Department of Commerce (DOC) developed the EU-U.S. Privacy Shield Framework (Privacy Shield) in consultation with the European Commission, as well as with industry and other stakeholders, to provide organizations in the United States with a reliable mechanism for personal data transfers to the United States from the European Union while ensuring the protection of the data as required by EU law.

On July 12, 2016, the European Commission deemed the Privacy Shield Framework adequate to enable data transfers under EU law, and the DOC began accepting self-certification submissions from organizations on August 1, 2016. More information on the Privacy Shield is available at: *https://www.privacyshield.gov/welcome*.

The DOC has issued the Privacy Shield Principles under its statutory authority to foster, promote, and develop international commerce (15 U.S.C. 1512). The International Trade Administration (ITA) administers and supervises the Privacy Shield, including by maintaining and making publicly available an authoritative list of U.S. organizations that have self-certified to the DOC. U.S. organizations submit information to ITA to self-certify their compliance with Privacy Shield.

U.S. organizations considering self-certifying to the Privacy Shield should review the Privacy Shield Framework.

In summary, in order to enter the Privacy Shield, an organization must (a) be subject to the investigatory and enforcement powers of the Federal Trade Commission (FTC), the Department of Transportation, or another statutory body that will effectively ensure compliance with the Principles; (b) publicly declare its commitment to comply with the Principles; (c) publicly disclose its privacy policies in line with the Principles; and (d) fully implement them.

Self-certification to the DOC is voluntary; however, an organization's failure to comply with the Principles after its self-certification is enforceable under Section 5 of the Federal Trade Commission Act prohibiting unfair and deceptive acts in or affecting commerce (15 U.S.C. 45(a)) or other laws or regulations prohibiting such acts.

In order to rely on the Privacy Shield for transfers of personal data from the EU, an organization must self-certify its adherence to the Principles to the DOC, be placed by ITA on the Privacy Shield List, and remain on the Privacy Shield List. To self-certify for the Privacy Shield, an organization must provide to the DOC a self-certification submission that contains the information specified in the Privacy Shield Principles. The Privacy Shield self-certification form would be the means by which an organization would provide the relevant information to ITA.

ITA has committed to follow up with organizations that have been removed from the Privacy Shield List. ITA will send questionnaires to organizations that fail to complete the annual certification or who have withdrawn from the Privacy Shield to verify whether they will return, delete, or continue to apply the Principles to the personal information that they received while they participated in the Privacy Shield, and if personal information will be retained, verify who within the organization will serve as an ongoing point of contact for Privacy Shield-related questions.

In addition, ITA has committed to conduct compliance reviews on an ongoing basis, including through sending detailed questionnaires to participating organizations. In particular, such compliance reviews shall take place when: (a) The DOC has received specific non-frivolous complaints about an organization's compliance with the Principles, (b) an organization does not respond satisfactorily to inquiries by the DOC for information relating to the Privacy Shield, or (c) there is credible evidence that an organization does not comply with its commitments under the Privacy Shield.

Affected Public: Primarily businesses or other for-profit organizations.

Frequency: Annual and periodic.

Respondent's Obligation: Voluntary.

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view the Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to OIRA *Submission@omb.eop.gov* or fax to (202) 975–5806.

Sheleen Dumas,

PRA Departmental Lead, Office of the Chief Information Officer.

[FR Doc. 2017–01334 Filed 1–19–17; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Information Systems Technical Advisory Committee; Notice of Partially Closed Meeting

The Information Systems Technical Advisory Committee (ISTAC) will meet on January 25 and 26, 2017, 9:00 a.m., in the Herbert C. Hoover Building, Room 3884, 14th Street between Constitution and Pennsylvania Avenues NW., Washington, DC. The Committee advises the Office of the Assistant Secretary for Export Administration on technical questions that affect the level of export controls applicable to information systems equipment and technology.

Wednesday, January 25

Open Session

1. Welcome and Introductions
2. Working Group Reports
3. Old Business
4. Industry Presentations: Quantum Computing
5. New business

Thursday, January 26

Closed Session

6. Discussion of matters determined to be exempt from the provisions relating to public meetings found in 5 U.S.C. app. 2 §§ 10(a)(1) and 10(a)(3).

The open session will be accessible via teleconference to 20 participants on a first come, first serve basis. To join the conference, submit inquiries to Ms. Yvette Springer at *Yvette.Springer@bis.doc.gov,* no later than January 18, 2017.

A limited number of seats will be available for the public session. Reservations are not accepted. To the extent time permits, members of the public may present oral statements to the Committee. The public may submit written statements at any time before or after the meeting. However, to facilitate distribution of public presentation materials to Committee members, the Committee suggests that public presentation materials or comments be forwarded before the meeting to Ms. Springer.

The Assistant Secretary for Administration, with the concurrence of the delegate of the General Counsel, formally determined on January 12, 2017, pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. app. 2 § 10(d)), that the portion of the meeting concerning trade secrets and commercial or financial information deemed privileged or confidential as described in 5 U.S.C. 552b(c)(4) and the portion of the meeting concerning matters the disclosure of which would be likely to frustrate significantly implementation of an agency action as described in 5 U.S.C. 552b(c)(9)(B) shall be exempt from the provisions relating to public meetings found in 5 U.S.C. app. 2 §§ 10(a)(1) and 10(a)(3). The remaining portions of the meeting will be open to the public.

For more information, call Yvette Springer at (202) 482–2813.

Dated: January 17, 2017.

Yvette Springer,

Committee Liaison Officer.

[FR Doc. 2017–01423 Filed 1–19–17; 8:45 am]

BILLING CODE 3510–JT–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Sensors and Instrumentation Technical Advisory Committee; Notice of Partially Closed Meeting

The Sensors and Instrumentation Technical Advisory Committee (SITAC) will meet on February 1, 2017, 9:30 a.m., (Pacific Standard Time) at the SPIE Photonics West, The Moscone Center South, 747 Howard Street, Room 102 South Hall (Exhibit Level), San Francisco, CA 94103. Registration for an exhibit-only pass is required and is available for free. Attendees can register for an exhibit-only pass in advance at *https://spie.org/conferences-and-exhibitions/photonics-west/registration* or sign up onsite at the registration booth. The Committee advises the Office of the Assistant Secretary for Export

Administration on technical questions that affect the level of export controls applicable to sensors and instrumentation equipment and technology.

Agenda

Public Session

1. Welcome and Introductions.
2. Remarks from the Bureau of Industry and Security Management.
3. Industry Presentations.
4. New Business.

Closed Session

5. Discussion of matters determined to be exempt from the provisions relating to public meetings found in 5 U.S.C. app. 2 §§ 10(a)(1) and 10(a)(3).

The open session will be accessible via teleconference to 20 participants on a first come, first serve basis. To join the conference, submit inquiries to Ms. Yvette Springer at *Yvette.Springer@bis.doc.gov* no later than January 25, 2017.

A limited number of seats will be available during the public session of the meeting. Reservations are not accepted. To the extent that time permits, members of the public may present oral statements to the Committee. The public may submit written statements at any time before or after the meeting. However, to facilitate distribution of public presentation materials to the Committee members, the Committee suggests that the materials be forwarded before the meeting to Ms. Springer.

The Assistant Secretary for Administration, with the concurrence of the General Counsel, formally determined on January 12, 2017 pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. app. 2 § 10(d), that the portion of this meeting dealing with pre-decisional changes to the Commerce Control List and U.S. export control policies shall be exempt from the provisions relating to public meetings found in 5 U.S.C. app. 2 §§ 10(a)(1) and 10(a)(3). The remaining portions of the meeting will be open to the public.

For more information contact Yvette Springer on (202) 482–2813.

Dated: January 17, 2017.

Yvette Springer,

Committee Liaison Officer.

[FR Doc. 2017–01425 Filed 1–19–17; 8:45 am]

BILLING CODE –P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–580–879]

Certain Corrosion-Resistant Steel Products From the Republic of Korea: Rescission of Countervailing Duty Expedited Review; 2014

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce is rescinding the expedited review of the countervailing duty order on certain corrosion-resistant steel products (CORE) from the Republic of Korea (Korea) for the period of review January 1, 2014, through December 31, 2014, based on the timely withdrawal of requests for review.

DATES: Effective January 23, 2017.

FOR FURTHER INFORMATION CONTACT: Myrna Lobo, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–2371.

SUPPLEMENTARY INFORMATION:

Background

On July 25, 2016, the Department published the countervailing duty order on CORE from Korea.[1] On August 24, 2016, POSCO and Hyundai Steel Company (Hyundai) each submitted a request to conduct an expedited review of this countervailing duty order.[2] POSCO and Hyundai were not selected for individual examination during the investigation and made these requests pursuant to 19 CFR 351.214(k). On October 4, 2016, the Department published in the **Federal Register** a notice of initiation with respect to POSCO and Hyundai.[3] On October 11 and 17, 2016, POSCO and Hyundai, respectively, timely withdrew their review requests.[4]

Rescission of Review

Pursuant to 19 CFR 351.214(k)(3), expedited countervailing duty reviews will be conducted in accordance with the new shipper review regulations. Pursuant to 19 CFR 351.214(f)(1), the Department will rescind a new shipper review, in whole or in part, if a party that requested a review withdraws the request within 60 days of the date of publication of notice of initiation of the requested review. The date of publication of notice of initiation of the requested review was October 4, 2016, and POSCO and Hyundai each withdrew its request for review on October 11 and 17, 2016, respectively, within the 60-day deadline. No other parties requested an expedited review of the order. Therefore, we are rescinding the expedited review of the countervailing duty order on CORE from Korea covering the period January 1, 2014, through December 31, 2014.

Notification Regarding Administrative Protective Order

This notice 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 in accordance with 19 CFR 351.305(a)(3). Timely written notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

This notice is published in accordance with section 751 of the Act and 19 CFR 351.213(d)(4).

Dated: January 12, 2017.

Gary Taverman,

Associate Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2017–01272 Filed 1–19–17; 8:45 am]

BILLING CODE 3510–DS–P

[1] *See Certain Corrosion-Resistant Steel Products from India, Italy, Republic of Korea and the People's Republic of China: Countervailing Duty Order,* 81 FR 48387 (July 25, 2016).

[2] *See* letter from POSCO, ''Corrosion-Resistant Steel Products from South Korea, Case No. C–580–879: Request for Expedited Review Pursuant to 19 CFR 351.214(k),'' (August 24, 2016). *See also* letter from Hyundai, ''Corrosion-Resistant Steel Products from South Korea, Case No. C–580–879: Request for Expedited Review Pursuant to 19 CFR 351.214(k),'' (August 24, 2016).

[3] *See Certain Corrosion-Resistant Steel Products From the Republic of Korea: Initiation of Expedited Review of the Countervailing Duty Order,* 81 FR 68404 (October 4, 2016).

[4] *See* letter from POSCO, ''Certain Corrosion-Resistant Steel Products from the Republic of Korea, Countervailing Duty Expedited Review, Case No. C–580–879: Withdrawal of POSCO's Request for Review,'' (October 11, 2016). *See also* letter from Hyundai, ''Certain Corrosion-Resistant Steel Products from the Republic of Korea, Countervailing Duty Expedited Review, Case No. C–580–879: Withdrawal of Hyundai Steel's Request for Review,'' (October 17, 2016).

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[Docket Number: 170111066–7066–01]

RIN 0648–XF167

Notice of Availability of and Request for Public Comment on White Paper on Improving the Space Weather Forecasting Research to Operations (R2O)—Operations to Research (O2R) Capability

AGENCY: National Weather Service, National Oceanic and Atmospheric Administration, U.S. Department of Commerce.

ACTION: Notice of Availability of White Paper on Improving the Space Weather Forecasting Research to Operations (R2O)—Operations to Research (O2R) Capability and request for public comment.

SUMMARY: The National Weather Service on behalf of the National Science and Technology Council; Committee on Environment, Natural Resources, and Sustainability; Space Weather Operations, Research, and Mitigation Subcommittee announces the availability of and requests public comments on the draft white paper on Improving the Space Weather Forecasting Research to Operations (R2O)—Operations to Research (O2R) Capability (Draft R2O–O2R white paper).

DATES: Comments must be received by March 20, 2017 to be considered.

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

- *Email: swxo2rplan@noaa.gov.* Include [Improving Space Weather Forecasting R2O–O2R] in the subject line of the message.
- *Fax:* (301) 713–7144, Attn: Michael Bonadonna.
- *Mail:* Attn: Michael Bonadonna, Office of the Federal Coordinator for Meteorology, 1325 East-West Highway (SSMC2), Suite 7130, Silver Spring, MD 20910.

Instructions: The Draft R2O–O2R white paper is available for public comment at *http://www.ofcm.gov/publications/spacewx/DRAFT_O2R_plan.pdf.* Responses exceeding 2000 words will not be considered; please reference page and line numbers of the Draft R2O–O2R white paper in your response, as appropriate. Please be aware that your comments may be posted online. The NOAA National Weather Service therefore requests that no business proprietary information, copyrighted information, confidential, or personally identifiable information be submitted in response to this request. Please note that the U.S. Government will not pay for response preparation or for the use of any information contained in the response.

FOR FURTHER INFORMATION CONTACT: For more information on the Draft R2O–O2R white paper, contact Michael Bonadonna, (301) 628–0058, *michael.bonadonna@noaa.gov,* Office of the Federal Coordinator for Meteorology.

SUPPLEMENTARY INFORMATION: Space weather refers to the dynamic conditions of the space environment that arise from interactions with emissions from the sun, including solar flares, solar energetic particles, and coronal mass ejections. These emissions can affect Earth and its surrounding space, potentially causing disruption to electric power transmission; satellite, aircraft, and spacecraft operations; telecommunications; position, navigation, and timing services; and other technology and infrastructure. Given the growing importance and reliance of the Nation on these services and infrastructures, it is critical that the Nation prepare for the effects of space weather events.

In October 2016, the Space Weather Operations, Research, and Mitigation (SWORM) Subcommittee was established by the National Science and Technology Council (NSTC) Committee on Environment, Natural Resources, and Sustainability, pursuant to Executive Order 13744 on Coordinating Efforts to Prepare the Nation for Space Weather Events. The Executive Order directed the SWORM Subcommittee to coordinate the implementation of the activities specified in the 2015 National Space Weather Action Plan (SWAP), among them the development of a plan that will ensure the improvement, testing, and maintenance of operational forecasting models. This plan is described in the draft white paper Improving the Space Weather Forecasting Research to Operations (R2O)—Operations to Research (O2R) Capability, and this notice solicits public inputs to inform its development.

Dated: January 17, 2017.

Louis Uccellini,

Director.

[FR Doc. 2017–01331 Filed 1–19–17; 8:45 am]

BILLING CODE 3270–F4–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: West Coast Saltwater Fishing Survey.

OMB Control Number: 0648-xxxx.

Form Number(s): None.

Type of Request: Regular (request for a new information collection)

Number of Respondents: 3,767.

Average Hours Per Response: Saltwater angler survey, 25 minutes; non-saltwater angler survey, 10 minutes; screening survey 3 minutes.

Burden Hours: 408.

Needs and Uses: This request is for a new information collection.

The Northwest Fisheries Science Center and Southwest Fisheries Science Center are undertaking an economics research project to assess the behavior of saltwater recreational anglers in response to catch rates, bag limits, and the timing and length of the season, and how these actions affect the value of saltwater recreational fishing. The West Coast Saltwater Fishing Survey (WCSFS) will provide critical economic data related to saltwater recreational fishing on the Pacific West Coast. More specifically, the WCSFS will collect data needed to (1) assess the socioeconomic characteristics of recreational saltwater fishing participants; (2) assess the economic value of saltwater recreational fishing trips through statistical estimation of models; and (3) assess the change in these values associated with possible changes in management policies related to catch rates, bag limits, season timing and length, time and area closures, and changes in economic or fishery conditions.

All of the protocols that will be used in the final survey will be tested prior to the full survey administration. If the survey needs revision based on this pretest, we will submit the revised instruments as part of a non-substantive change request.

Affected Public: Individuals or households.

Frequency: One time.

Respondent's Obligation: Voluntary.

This information collection request may be viewed at reginfo.gov. Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov* or fax to (202) 395–5806.

Dated: January 13, 2017.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2017–01286 Filed 1–19–17; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XF171

Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice; public meeting.

SUMMARY: The Pacific Fishery Management Council's (Pacific Council) trawl catch share five-year review Community Advisory Board (CAB), will hold a webinar, which is open to the public.

DATES: The CAB webinar will be on Tuesday, February 7, 2017, from 10 a.m. to 12 p.m. Pacific Time, or when business for the day is complete.

ADDRESSES: To attend the CAB webinar, visit this link: *http://www.gotomeeting.com/online/webinar/join-webinar.* Enter the Webinar ID: 363–170–539. Please enter your name and email address (required). After logging into the webinar, dial this TOLL number +1 (631) 992–3221 (not a toll-free number), enter the attendee phone audio access code 981–429–294, then enter your audio phone PIN (shown after joining the webinar). NOTE: We have disabled Mic/Speakers as on option and require all participants to use a telephone or cell phone to participate. You may send an email to Mr. Kris Kleinschmidt (*kris.kleinschmidt@noaa.gov*) or contact him at (503) 820–2280, extension 425 for technical assistance. A listening station will also be provided at the Pacific Council office.

Council address: Pacific Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220–1384.

FOR FURTHER INFORMATION CONTACT: Jim Seger, Pacific Council; telephone: (503) 820–2416.

SUPPLEMENTARY INFORMATION: The CAB will hold a webinar to review the Council actions from the November 2016 Pacific Council meeting, continue preliminary discussions of actions that might follow-on from the five year review of the trawl catch share program, and make plans for its May/June 2017 meeting.

Although nonemergency issues not contained in the meeting agenda may be discussed, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this document and any issues arising after publication of this document that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Technical Information and System Requirements

PC-based attendees: Windows® 7, Vista, or XP operating system required. Mac®-based attendees: Mac OS® X 10.5 or newer required. Mobile attendees: iPhone®, iPad®, Android™ phone or Android tablet required (use GoToMeeting Webinar Apps).

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Mr. Kris Kleinschmidt at (503) 820–2280 at least 10 days prior to the meeting date.

Dated: January 13, 2017.

Jeffrey N. Lonergan,

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

[FR Doc. 2017–01307 Filed 1–19–17; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Science Advisory Board (SAB); Notice of Public Meeting

AGENCY: Office of Oceanic and Atmospheric Research (OAR), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Notice of public meeting.

SUMMARY: This notice sets forth the schedule and proposed agenda of a forthcoming meeting of the NOAA Science Advisory Board. The members will discuss and provide advice on issues outlined in the section on Matters to be considered.

TIME AND DATE: The meeting is scheduled for February 10, 2017 from 4:00 p.m. to 5:30 p.m. Eastern Standard Time.

ADDRESSES: Conference call. Public access is available at: NOAA, SSMC 3, Room 11836, 1315 East-West Highway, Silver Spring, MD. Members of the public will not be able to dial in to this meeting.

Status: The meeting will be open to public participation with a 5-minute public comment period at 5:20 p.m. Eastern Standard Time. The SAB expects that public statements presented at its meetings will not be repetitive of previously submitted verbal or written statements. In general, each individual or group making a verbal presentation will be limited to a total time of one minute. Written comments should be received in the SAB Executive Director's Office by February 3 to provide sufficient time for SAB review. Written comments received by the SAB Executive Director after February 3, will be distributed to the SAB, but may not be reviewed prior to the meeting date.

Special Accommodations: These meetings are physically accessible to people with disabilities. Requests for special accommodations may be directed no later than 12 p.m. on February 3, Dr. Cynthia Decker, SAB Executive Director, SSMC3, Room 11230, 1315 East-West Hwy., Silver Spring, MD 20910; Email: *Cynthia.Decker@noaa.gov.*

SUPPLEMENTARY INFORMATION: The NOAA Science Advisory Board (SAB) was established by a Decision Memorandum dated September 25, 1997, and is the only Federal Advisory Committee with responsibility to advise the Under Secretary of Commerce for Oceans and Atmosphere on strategies for research, education, and application of science to operations and information services. SAB activities and advice provide necessary input to ensure that National Oceanic and Atmospheric Administration (NOAA) science programs are of the highest quality and provide optimal support to resource management.

Matters To Be Considered: The meeting will include the following topics: (1) NOAA Update; (2) Discussion of SAB Transition Activities; (3) Update on Final SAB Subcommittee Concept of Operations and Processes and (4) Framing the SAB Work Plan for the Future. For the latest agenda, please

visit the SAB Web site at *http://www.sab.noaa.gov.*

FOR FURTHER INFORMATION CONTACT: Dr. Cynthia Decker, SAB Executive Director, SSMC3, Room 11230, 1315 East-West Hwy., Silver Spring, MD 20910; Email: *Cynthia.Decker@noaa.gov* or visit the NOAA SAB Web site at *http://www.sab.noaa.gov.*

Dated: January 13, 2017.

Jason Donaldson,

Chief Financial Officer and Chief Administrative Officer, Office of Oceanic and Atmospheric Research, National Oceanic and Atmospheric Administration.

[FR Doc. 2017–01439 Filed 1–19–17; 8:45 am]

BILLING CODE 3510–KD–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: West Coast Fisheries Participation Survey.

OMB Control Number: 0648–xxxx.

Form Number(s): None.

Type of Request: Regular (request for a new information collection).

Number of Respondents: 3,543.

Average Hours per Response: 20 minutes.

Burden Hours: 1,181.

Needs and Uses: Northwest Fisheries Science Center (NWFSC) seeks to conduct fisheries participation analyses which involve a survey of United States (U.S.) West Coast commercial fishing participants. A U.S. mail survey will be conducted. The survey will be voluntary, and contacted individuals may decline to participate. Respondents will be asked to answer questions about their motivations for fishing and other factors that affect participation in the suite of West Coast commercial fisheries. Demographic and employment information will be collected so that responses can be organized based on a respondent typology. This survey is essential because data on smaller scale fishing practices, values, participation decisions and beliefs about fishing livelihoods are sparse; yet, they are critical to the development of usable fishery ecosystem models that account for non-pecuniary benefits of fishing, as well as the ways in which fishing practices shape individual and community well-being.

Affected Public: Individuals or households.

Frequency: One time.

Respondent's Obligation: Voluntary.

This information collection request may be viewed at *reginfo.gov.* Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov* or fax to (202) 395–5806.

Dated: January 17, 2017.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2017–01322 Filed 1–19–17; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XF173

Taking and Importing of Marine Mammals

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

ACTION: Notice; effectiveness of requirement for observer statements to accompany certain tuna products.

SUMMARY: On November 18, 2016, the Office of Management and Budget (OMB) approved, under the Paperwork Reduction Act, changes to the collection-of-information under Control Number 0648–0335 necessary to require observer statements to support shipments of tuna harvested in fisheries with regular and significant mortality and serious injury of marine mammals. With notice of this approval, the new requirements for observer statements described in the **Federal Register** notice published on September 28, 2016, are hereby effective.

DATES: Effective January 23, 2017.

FOR FURTHER INFORMATION CONTACT: Bill Jacobson, National Marine Fisheries Service, 501 West Ocean Blvd., Long Beach, CA 90802–4213. Phone: 562–980–4035. Email: *bill.jacobson@noaa.gov.* More information on this final action can be found on the NMFS Web site at *http://www.nmfs.noaa.gov/pr/dolphinsafe/.*

SUPPLEMENTARY INFORMATION: In accordance with a determination of NMFS under 50 CFR 216.91(a)(3)(v), implementing the Dolphin Protection Consumer Information Act, 16 U.S.C. 1385, that certain fisheries have a regular and significant mortality and serious injury of marine mammals, observer statements are required to accompany tuna product from tuna harvested in those fisheries (observer statements). *See* the **Federal Register** notice ''Taking and Importing of Marine Mammals and Dolphin-Safe Tuna Products'' published by NMFS on September 28, 2016 (81 FR 66625). NMFS' authority to require these observer statements was subject to approval by the Office of Management and Budget (OMB) because the statements are considered a ''collection of information'' subject to the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* Under the terms of the September 28, 2016, **Federal Register** notice, the observer statements would be required only upon publication of an additional notice in the **Federal Register** of OMB approval under the Paperwork Reduction Act. On November 18, 2016, pursuant to the Paperwork Reduction Act, OMB approved the observer statements under Control Number 0648–0335.

Therefore, the observer statements are required beginning on January 23, 2017.

Dated: January 17, 2017.

John Henderschedt,

Director, Office for International Affairs and Seafood Inspection, National Marine Fisheries Service.

[FR Doc. 2017–01356 Filed 1–19–17; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[Docket Number: 170111055–7055–01]

RIN 0648–XF162

Notice of Availability of and Request for Public Comment on Space Weather Phase 1 Benchmarks

AGENCY: National Weather Service, National Oceanic and Atmospheric Administration, U.S. Department of Commerce.

ACTION: Notice of availability of Space Weather Phase 1 Benchmarks and request for public comment.

SUMMARY: The National Weather Service on behalf of the National Science and Technology Council; Committee on Environment, Natural Resources, and

Sustainability; Space Weather Operations, Research, and Mitigation Subcommittee announces the availability of and requests public comments on the draft 2017 Space Weather Phase 1 Benchmarks (Draft Benchmarks).

DATES: Comments must be received by March 20, 2017 to be considered.

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

- *Email: spwxbenchmarks@noaa.gov.* Include [Space Weather Phase 1 Benchmarks] in the subject line of the message.
- *Fax:* (301) 713–7144, Attn: Michael Bonadonna.
- *Mail:* Attn: Michael Bonadonna, Office of the Federal Coordinator for Meteorology, 1325 East-West Highway (SSMC2), Suite 7130, Silver Spring, MD 20910.

Instructions: The Draft Benchmarks are available for download at *http://www.ofcm.gov/publications/spacewx/DRAFT_SWx_Phase_1_Benchmarks.pdf.* Response to this request for public comment is voluntary. Responses exceeding 2,000 words will not be considered; please reference page and line numbers of the Draft Benchmarks in your response, as appropriate. Please be aware that your comments may be posted online. The NOAA National Weather Service therefore requests that no business proprietary information, copyrighted information, confidential, or personally identifiable information be submitted in response to this request. Please note that the U.S. Government will not pay for response preparation or for the use of any information contained in the response.

FOR FURTHER INFORMATION CONTACT: For more information on the Draft Benchmarks, contact Michael Bonadonna, (301) 628–0058, *michael.bonadonna@noaa.gov,* Office of the Federal Coordinator of Meteorology.

SUPPLEMENTARY INFORMATION: Space weather refers to the dynamic conditions of the space environment that arise from interactions with emissions from the sun, including solar flares, solar energetic particles, and coronal mass ejections. These emissions can affect Earth and its surrounding space, potentially causing disruption to electric power transmission; satellite, aircraft, and spacecraft operations; telecommunications; position, navigation, and timing services; and other technology and infrastructure. Given the growing importance and reliance of the Nation on these services and infrastructures, it is critical that the Nation prepare for the effects of space weather events.

In October 2016, the Space Weather Operations, Research, and Mitigation (SWORM) Subcommittee was established by the National Science and Technology Council (NSTC) Committee on Environment, Natural Resources, and Sustainability, pursuant to Executive Order 13744 on Coordinating Efforts to Prepare the Nation for Space Weather Events. The Executive Order directed the SWORM Subcommittee to coordinate the implementation of the activities specified in the 2015 National Space Weather Action Plan, among them the development of space weather benchmarks, sets of physical characteristics and conditions against which a space-weather event can be measured. The Phase 1 benchmarks were developed by the interagency through a quick-turnaround analysis, using existing data sets and studies where available, whereas Phase 2 benchmarks will be developed through more rigorous analyses. This notice solicits public input on a draft of the Phase 1 benchmarks to inform their completion and the development of the Phase 2 benchmarks.

Dated: January 17, 2016.

Louis Uccellini,

Director.

[FR Doc. 2017–01333 Filed 1–19–17; 8:45 am]

BILLING CODE 3270–F4–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Additions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed additions to the Procurement List.

SUMMARY: The Committee is proposing to add products and a service to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

Comments Must Be Received on or Before: February 19, 2017.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S. Clark Street, Suite 715, Arlington, Virginia 22202–4149.

FOR FURTHER INFORMATION OR TO SUBMIT COMMENTS CONTACT: Amy B. Jensen, Telephone: (703) 603–2132, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 8503 (a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Additions

If the Committee approves the proposed additions, the entities of the Federal Government identified in this notice will be required to provide the products and service listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

The following products and service are proposed for addition to the Procurement List for production by the nonprofit agencies listed:

Products

NSN(s)—Product Name(s): 6515–01–656–6191—Tourniquet, Tactical Mechanical
Mandatory Source(s) of Supply: Alphapointe, Kansas City, MO
Mandatory for: 100% of the requirements of the Department of Defense
Contracting Activity: Defense Logistics Agency Troop Support
Distribution: C-List

NSN(s)—Product Name(s):
MR 1172—Sweeper Set, Wet and Dry
MR 1173—Refill, Sweeper Set, Dry Cloths, 16 Count
MR 1174—Refill, Sweeper Set, Dry Cloths, 30 Count
MR 1175—Refill, Sweeper Set, Wet Cloths, 24 Count
Mandatory Source(s) of Supply: LC Industries, Durham, NC
Mandatory for: The requirements of military commissaries and exchanges in accordance with the Code of Federal Regulations, Chapter 51, 51–6.4
Contracting Activity: Defense Commissary Agency
Distribution: C-List

Service

Service Type: Transcription Service
Mandatory Source(s) of Supply: Lighthouse for the Blind of Houston, Houston, TX
Mandatory for: US Navy, Office of the Inspector General, SPAWARSYSCEN ATLANTIC CHARLESTON, North Charleston, SC
Contracting Activity: US Navy SPAWARSYSCEN ATLANTIC CHARLESTON North Charleston, SC

Patricia Briscoe,

Deputy Director, Business Operations Pricing and Information Management.

[FR Doc. 2017–01399 Filed 1–19–17; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Additions And Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Additions to and deletions from the Procurement List.

SUMMARY: This action adds products to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and deletes products from the Procurement List previously furnished by such agencies.

DATES: Effective February 19, 2017.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S. Clark Street, Suite 715, Arlington, Virginia 22202–4149.

FOR FURTHER INFORMATION CONTACT: Amy B. Jensen, Telephone: (703) 603–2132, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION:

Additions

On 12/16/2016 (81 FR 91140–91141), the Committee for Purchase From People Who Are Blind or Severely Disabled published notice of proposed additions to the Procurement List.

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the products and impact of the addition on the current or most recent contractors, the Committee has determined that the products listed below are suitable for procurement by the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the products to the Government.

2. The action will result in authorizing small entities to furnish the products to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the products proposed for addition to the Procurement List.

End of Certification

Accordingly, the following products are added to the Procurement List:

Products

NSN(s)—Product Name(s): 6645–01–NIB–0153—Clock, LCD Digital Display, Radio-Controlled, Silver, 9.75″ x 7.25″ x 1″

Mandatory Source(s) of Supply: Chicago Lighthouse Industries, Chicago, IL

Mandatory for: Total Government Requirement

Contracting Activity: General Services Administration, New York, NY

Distribution: A-List

NSN(s)—Product Name(s): MR 357—Tumblers, Red, White and Blue, Includes Shipper 10357

Mandatory Source(s) of Supply: Industries for the Blind, Inc., West Allis, WI

Mandatory for: Military commissaries and exchanges in accordance with the Code of Federal Regulations, Chapter 51, 51–6.4

Contracting Activity: Defense Commissary Agency

Distribution: C-List

Deletions

On 12/16/2016 (81 FR 91140–91141), the Committee for Purchase From People Who Are Blind or Severely Disabled published notice of proposed deletions from the Procurement List.

After consideration of the relevant matter presented, the Committee has determined that the products listed below are no longer suitable for procurement by the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in additional reporting, recordkeeping or other compliance requirements for small entities.

2. The action may result in authorizing small entities to furnish the products to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the products deleted from the Procurement List.

End of Certification

Accordingly, the following products are deleted from the Procurement List:

Products

NSN(s)—Product Name(s): 8520–00–NIB–0116—PURELL/SKILCRAFT Instant Hand Sanitzer, Gel, 1200ml

Mandatory Source(s) of Supply: Travis Association for the Blind, Austin, TX

Contracting Activity: Department of Veterans Affairs, Strategic Acquisition Center

NSN(s)—Product Name(s): 8950–01–E60–5752—Garlic Powder, 160 oz. Container, 5 lb. per container, 3/CS

Mandatory Source(s) of Supply: CDS Monarch, Webster, NY

Contracting Activities: Department of Veterans Affairs, Defense Logistics Agency Troop Support

NSN(s)—Product Name(s): 5340–01–527–6885—Clamp, Loop, CRES, 1/2″ loop x 1/2″ wide

Mandatory Source(s) of Supply: Provail, Seattle, WA

Contracting Activity: Defense Logistics Agency Troop Support

Patricia Briscoe,

Deputy Director, Business Operations Pricing and Information Management.

[FR Doc. 2017–01400 Filed 1–19–17; 8:45 am]

BILLING CODE 6353–01–P

CONSUMER PRODUCT SAFETY COMMISSION

Sunshine Act Meetings Notice

TIME AND DATE: Wednesday, January 25, 2017, 10:00 a.m.–12:00 p.m.

PLACE: Hearing Room 420, Bethesda Towers, 4330 East West Highway, Bethesda, Maryland.

STATUS: Commission Meeting—Open to the Public.

Matters To Be Considered

1. Decisional Matter: Recreational Off-Highway Vehicles (ROVs)—Termination of Rulemaking (10:00 a.m.–11:00 a.m.)

2. Decisional Matter: Proposed Rule: Amendments to Fireworks Regulations (11:00 a.m.–12:00 p.m.)

A live webcast of the Meeting can be viewed at *www.cpsc.gov/live.*

CONTACT PERSON FOR MORE INFORMATION: Todd A. Stevenson, Office of the Secretary, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814, (301) 504–7923.

Dated: January 17, 2017.

Todd A. Stevenson,

Secretary.

[FR Doc. 2017–01497 Filed 1–18–17; 11:15 am]

BILLING CODE 6355–01–P

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Proposed Information Collection; Comment Request

AGENCY: Corporation for National and Community Service.

ACTION: Notice.

SUMMARY: The Corporation for National and Community Service (CNCS), as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) (44 U.S.C. Sec. 3506(c)(2)(A)). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirement on respondents can be properly assessed.

Currently, CNCS is soliciting comments concerning its proposed renewal of AmeriCorps Application Instructions: State Commissions; State and National Competitive, Professional Corps; Indian Tribes; States and Territories without Commissions, and State and National Planning Grants Applicants. Applicants will respond to the questions in this ICR in order to apply for funding through these grant competitions.

Copies of the information collection request can be obtained by contacting the office listed in the Addresses section of this Notice.

DATES: Written comments must be submitted to the individual and office listed in the **ADDRESSES** section by March 24, 2017.

ADDRESSES: You may submit comments, identified by the title of the information collection activity, by any of the following methods:

(1) By mail sent to: Corporation for National and Community Service, Attention: Jill Graham, Senior Program and Project Specialist, Room 3219B, 250 E Street SW., Washington, DC, 20525.

(2) By hand delivery or by courier to the CNCS mailroom at Room 4300 at the mail address given in paragraph (1) above, between 9:00 a.m. and 4:00 p.m. Eastern Time, Monday through Friday, except Federal holidays.

(3) Electronically through the CNCS email system: *jgraham@cns.gov.*

Individuals who use a telecommunications device for the deaf (TTY–TDD) may call 1–800–833–3722 between 8:00 a.m. and 8:00 p.m. Eastern Time, Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Jill Graham, 202–606–6905, *jgraham@cns.gov*

SUPPLEMENTARY INFORMATION: CNCS is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of CNCS, 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 expected to respond, including 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).

Background

These application instructions will be used by applicants for funding through AmeriCorps State and National Grant Competitions.

Current Action

CNCS seeks to renew the current AmeriCorps State and National Application Instructions. The information collection will be used in the same manner as the existing Instructions. CNCS also seeks to continue using the current application until the revised application is approved by OMB. The current application is due to expire on January 31, 2017.

Type of Review: Renewal

Agency: Corporation for National and Community Service.

Title: AmeriCorps Application Instructions: State Commissions, State and National Competitive; Professional Corps; Indian Tribes; States and Territories without Commissions; and State and National Planning.

OMB Number: 3045–0047.

Agency Number: None.

Affected Public: Nonprofit organizations, State, Local, and Tribal.

Total Respondents: 1159.

Frequency: Annually.

Average Time Per Response: Averages 80 hours.

Estimated Total Burden Hours: 92720.

Total Burden Cost (capital/startup): None.

Total Burden Cost (operating/maintenance): None.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Dated: January 13, 2017.

Jennifer Bastress Tahmasebi,

Acting Director, AmeriCorps State and National.

[FR Doc. 2017–01292 Filed 1–19–17; 8:45 am]

BILLING CODE 6050–28–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 (CNCS) has submitted a public information collection request (ICR) entitled AmeriCorps NCCC Project Completion Report 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, Jacob Sgambati, at 202–606–6839 or email to *jsgambati@cns.gov.* Individuals who use a telecommunications device for the deaf (TTY–TDD) may call 1–800–833–3722 between 8:00 a.m. and 8:00 p.m. Eastern Time, Monday through Friday.

DATES: Comments may be submitted, identified by the title of the information collection activity, within February 22, 2017.

ADDRESSES: Comments may be submitted, identified by the title of the information collection activity, to the Office of Information and Regulatory Affairs, Attn: Ms. Sharon Mar, 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 the **Federal Register:**

(1) By fax to: 202–395–6974, Attention: Ms. Sharon Mar, OMB Desk Officer for the Corporation for National and Community Service; or

(2) By email to: *smar@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 CNCS, 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.

Comments

A 60-day Notice requesting public comment was published in the **Federal Register** on Tuesday, October 4, 2016, at Vol 81, No. 192 FR 68408. This comment period ended December 5, 2016. No public comments were received from this Notice.

Description: The AmeriCorps NCCC Project Completion Report is distributed to organizations that sponsor an AmeriCorps NCCC team in order to report on the project's implementation and assess the project's scope and community impact.

Type of Review: Renewal.

Agency: Corporation for National and Community Service.

Title: AmeriCorps NCCC Project Completion Report.

OMB Number: None.

Agency Number: None.

Affected Public: AmeriCorps NCCC Project Sponsoring Organizations.

Total Respondents: Approximately 1,000 per year.

Frequency: Once per project.

Average Time Per Response: Averages 15 minutes.

Estimated Total Burden Hours: Approximately 300 hours.

Total Burden Cost (capital/startup): None.

Total Burden Cost (operating/maintenance): None.

Dated: January 13, 2017.

Jacob Sgambati,

Director of Operations, AmeriCorps NCCC.

[FR Doc. 2017–01291 Filed 1–19–17; 8:45 am]

BILLING CODE 6050–28–P

DEPARTMENT OF DEFENSE

Department of the Army

[Docket ID: USA–2015–0010]

Submission for OMB Review; Comment Request

ACTION: Notice.

SUMMARY: The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by February 22, 2017.

FOR FURTHER INFORMATION CONTACT: Fred Licari, 571–372–0493.

SUPPLEMENTARY INFORMATION:

Title, Associated Form and OMB Number: Army Military Auxiliary Radio System Membership Application; Army MARS Form AM–1; OMB Control Number 0702–XXXX.

Type of Request: New.

Number of Respondents: 550.

Responses per Respondent: 1.

Annual Responses: 550.

Average Burden per Response: 15 minutes.

Annual Burden Hours: 138.

Needs and Uses: Army Military Auxiliary Radio System (MARS), provides contingency communications support to the Army and Department of Defense. Membership in Army MARS is voluntary and open to all FCC licenses amateur radio operators. In order to join, an individual must submit an application to join. The applicant is requested to provide basic information so their membership can be tracked in the membership database for the purpose of headquarters knowing who are members of MARS.

Affected Public: Individuals or households.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Seehra.

Comments and recommendations on the proposed information collection should be emailed to Ms. Jasmeet Seehra, DoD Desk Officer, at *Oira_submission@omb.eop.gov.* Please identify the proposed information collection by DoD Desk Officer and the Docket ID number and title of the information collection.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, Docket ID 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.

DOD Clearance Officer: Mr. Frederick Licari.

Written requests for copies of the information collection proposal should be sent to Mr. Licari at WHS/ESD Directives Division, 4800 Mark Center Drive, East Tower, Suite 03F09, Alexandria, VA 22350–3100.

Dated: January 17, 2017.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2017–01376 Filed 1–19–17; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Defense Health Board; Notice of Federal Advisory Committee Meeting

AGENCY: Department of Defense (DoD).

ACTION: Notice of Federal Advisory Committee meeting.

SUMMARY: The Department of Defense is publishing this notice to announce that the following Federal Advisory Committee meeting of the Defense Health Board (DHB) will take place.

DATES:

Thursday, February 9, 2017

9:00 a.m.–12:15 p.m. (Open Session)
12:15 p.m.–1:15 p.m. (Administrative Session)
1:15 p.m.–5:15 p.m. (Open Session)

ADDRESSES: Gatehouse, 8111 Gatehouse Road, second floor meeting room-252AB, Falls Church, Virginia 22042 (registration required; see guidance in **SUPPLEMENTARY INFORMATION**, ''Public's Accessibility to the Meeting'').

FOR FURTHER INFORMATION CONTACT: The Executive Director (Acting) of the Defense Health Board is CAPT Juliann Althoff, 7700 Arlington Boulevard, Suite 5101, Falls Church, Virginia 22042, (703) 681–6653, Fax: (703) 681–9539, *juliann.m.althoff.mil@mail.mil.* For meeting information, please contact Ms. Kendal Brown, 7700 Arlington Boulevard, Suite 5101, Falls Church, Virginia 22042, *kendal.l.brown2.ctr@*

mail.mil, (703) 681–6670, Fax: (703) 681–9539.

SUPPLEMENTARY INFORMATION: This meeting is being held under the provisions of the Federal Advisory Committee Act of 1972 (5 U.S.C., Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102–3.150.

Additional information, including the agenda and electronic registration, is available at the DHB Web site, *http://www.health.mil/About-MHS/Defense-Health-Agency/Special-Staff/Defense-Health-Board/Meetings.*

Purpose of the Meeting

The purpose of the meeting is to provide progress updates on specific taskings before the DHB. In addition, the DHB will receive information briefings on current issues or lessons learned related to military medicine, health policy, health research, disease/injury prevention, health promotion, and health care delivery.

Agenda

Pursuant to 5 U.S.C. 552b and 41 CFR 102–3.140 through 102–3.165 and subject to availability of space, the Defense Health Board meeting is open to the public from 9:00 a.m. to 12:15 p.m. and 1:15 p.m. to 5:15 p.m. on February 9, 2017. The DHB anticipates receiving a decision brief from the Public Health Subcommittee on its review of improving Defense Health Program medical research processes, as well as progress updates from the Health Care Delivery and Neurological/Behavioral Health subcommittees on the pediatric health care services tasking and from a subset of the Board on the Deployment Health Centers review. In addition, the DHB anticipates receiving overview briefings from Army Medicine, Navy Medicine, Air Force Medical Services, Coast Guard Health Services, and the Defense Health Agency. Any changes to the agenda can be found at the link provided in this **SUPPLEMENTARY INFORMATION** section.

Public's Accessibility to the Meeting

Pursuant to 5 U.S.C. 552b, and 41 CFR 102–3.140 through 102–3.165 and subject to availability of space, this meeting is open to the public. Seating is limited and is on a first-come basis. All members of the public who wish to attend the public meeting must contact Ms. Kendal Brown at the number listed in the section **FOR FURTHER INFORMATION CONTACT** no later than 12:00 p.m. on Wednesday, February 1, 2017 to register. Additional details will be provided to all registrants.

Special Accommodations

Individuals requiring special accommodations to access the public meeting should contact Ms. Kendal Brown at least five (5) business days prior to the meeting so that appropriate arrangements can be made.

Written Statements

Any member of the public wishing to provide comments to the DHB may do so in accordance with section 10(a)(3) of the Federal Advisory Committee Act, 41 CFR 102–3.105(j) and 102–3.140, and the procedures described in this notice.

Individuals desiring to provide comments to the DHB may do so by submitting a written statement to the DHB Designated Federal Officer (DFO) (see **FOR FURTHER INFORMATION CONTACT**). Written statements should not be longer than two type-written pages and address the following details: The issue, discussion, and a recommended course of action. Supporting documentation may also be included, as needed, to establish the appropriate historical context and to provide any necessary background information.

If the written statement is not received at least five (5) business days prior to the meeting, the DFO may choose to postpone consideration of the statement until the next open meeting.

The DFO will review all timely submissions with the DHB President and ensure they are provided to members of the DHB before the meeting that is subject to this notice. After reviewing the written comments, the President and the DFO may choose to invite the submitter to orally present their issue during an open portion of this meeting or at a future meeting. The DFO, in consultation with the DHB President, may allot time for members of the public to present their issues for review and discussion by the Defense Health Board.

Dated: January 17, 2017.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2017–01395 Filed 1–19–17; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Department of Defense Military Family Readiness Council (MFRC); Notice of Federal Advisory Committee Meeting; Cancellation

AGENCY: Department of Defense.

ACTION: Notice; cancellation.

SUMMARY: On Friday, December 16, 2016 (81 FR 91147–91148), the Department of Defense published a notice announcing a meeting of the Military Family Readiness Council (MFRC) that was to take place on Thursday, January 26, 2017. Due to schedule conflicts, the MFRC is unable to assemble a quorum of members for this meeting. Therefore, the Department of Defense is cancelling the January 26, 2017 meeting.

FOR FURTHER INFORMATION CONTACT: Ms. Melody McDonald or Dr. Randy Eltringham, Office of the Deputy Assistant Secretary of Defense (Military Community & Family Policy), Office of Family Readiness Policy, 4800 Mark Center Drive, Alexandria, VA 22350–2300, Room 3G15. Telephones (571) 372–0880; (571) 372–5315 and/or email: OSD Pentagon OUSD P–R Mailbox Family Readiness Council, *osd.pentagon.ousd-p-r.mbx.family-readiness-council@mail.mil.*

SUPPLEMENTARY INFORMATION: Due to circumstances beyond the control of the Designated Federal Officer and the Department of Defense, the Military Family Readiness Council was unable to provide public notification cancelling its meeting of January 26, 2017, as required by 41 CFR 102–3.150(a). Accordingly, the Advisory Committee Management Officer for the Department of Defense, pursuant to 41 CFR 102–3.150(b), waives the 15-calendar day notification requirement.

Dated: January 17, 2017.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2017–01360 Filed 1–19–17; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Department of Defense Military Family Readiness Council (MFRC); Notice of Federal Advisory Committee Meeting

AGENCY: Department of Defense.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing this notice to announce a Federal Advisory Committee meeting of the Department of Defense Military Family Readiness Council (MFRC). This meeting will be open to the public.

DATES: Wednesday, February 15, 2017, from 1:00 p.m. to 3:00 p.m.

ADDRESSES: Pentagon Library & Conference Center, Room B6. Escorts will be provided from the Pentagon Visitors Center waiting area (Pentagon Metro entrance) upon request.

FOR FURTHER INFORMATION CONTACT: Ms. Melody McDonald or Dr. Randy Eltringham, Office of the Deputy Assistant Secretary of Defense (Military Community & Family Policy), Office of Family Readiness Policy, 4800 Mark Center Drive, Alexandria, VA 22350–2300, Room 3G15. Telephones (571) 372–0880; (571) 372–5315 or email: OSD Pentagon OUSD P–R Mailbox Family Readiness Council, *osd.pentagon.ousd-p-r.mbx.family-readiness-council@mail.mil.*

SUPPLEMENTARY INFORMATION: This meeting is being held under the provisions of the Federal Advisory Committee Act of 1972 (5 U.S.C. Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102–3.150.

Pursuant to 5 U.S.C. 552b and 41 CFR 102–3.140 through 102–3.165, this meeting is open to the public, subject to the availability of space. Members of the public who are entering the Pentagon should arrive at the Pentagon Visitors Center (Pentagon Metro entrance) by 12:00 p.m. on the day of the meeting to allow time to pass through the security check points and to be escorted to the meeting location. Members of the public need to email their RSVP to the Council at *osd.pentagon.ousd-p-rmbx.family-readiness-council@mail.mil* no later than 5:00 p.m. on Wednesday, February 8, 2017 to confirm seating availability and to request an escort if needed.

Pursuant to 41 CFR 102–3.105(j) and 102–3.140, and section 10(a)(3) of the Federal Advisory Committee Act of 1972, interested persons may submit a written statement for review and consideration by the Council. Persons desiring to submit a written statement to the Council must submit to the email address *osd.pentagon.ousd-p-r.mbx.family-readiness-council@mail.mil* no later than 5:00 p.m. on Friday, February 3, 2017.

The purpose of this meeting is to receive information related to programs and services for DoD Family Members with Special Needs, including healthcare and the Exceptional Family Member Program.

Wednesday, February 15, 2017 Meeting Agenda

Welcome & Administrative Remarks.

Healthcare Update for Children Using the Military Medical System, including those with Special Needs.

Exceptional Family Member Program Update.

Defense State Liaison Office (DSLO) Initiatives Review.

Closing Remarks.

Note: Exact order may vary.

Dated: January 17, 2017.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2017–01361 Filed 1–19–17; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

[Docket ID ED–2016–FSA–0011]

Privacy Act of 1974; System of Records

AGENCY: Federal Student Aid, Department of Education.

ACTION: Notice of an altered system of records.

SUMMARY: In accordance with the Privacy Act of 1974, as amended (Privacy Act), the Chief Operating Officer for Federal Student Aid (FSA) of the U.S. Department of Education (the Department) publishes this notice to revise the system of records entitled ''Health Education Assistance Loan (HEAL) program'' (18–11–20).

The Department publishes this notice to propose to revise programmatic routine use (18) (routine use (15) in the system of records notice published in the **Federal Register** on June 26, 2014 (79 FR 36299, 36301)) to include the **Federal Register**, and a Defaulted Borrowers Web site (should the Department elect to reestablish this or a similar Web site), as locations where the Department may publish the names of defaulted HEAL program borrowers (and any other fields the Department intends to publish, *e.g.,* area of practice).

DATES: Submit your comments on this altered system of records notice on or before February 22, 2017.

The Department has filed a report describing the altered system of records covered by this notice with the Chair of the Senate Committee on Homeland Security and Governmental Affairs, the Chair of the House Committee on Oversight and Government Reform, and the Administrator of the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) on January 6, 2017. This altered system of records will become effective on the later date of: (1) The expiration of the 40-day period for OMB review on February 16, 2017, unless OMB waives 10 days of the 40–day review period for compelling reasons shown by the Department; or (2) February 22, 2017, unless the altered system of records notice needs to be changed as a result of public comment or OMB review. The Department will publish any changes to the altered system of records notice that result from public comment or OMB review.

ADDRESSES: Submit your comments through the Federal eRulemaking Portal or via postal mail, commercial delivery, or hand delivery. We will not accept comments submitted by fax or by email or those submitted after the comment period. To ensure that we do not receive duplicate copies, please submit your comments only once. In addition, please include the Docket ID at the top of your comments.

- *Federal eRulemaking Portal:* Go to *www.regulations.gov* to submit your comments electronically. Information on using *Regulations.gov*, including instructions for accessing agency documents, submitting comments, and viewing the docket, is available on the site under the ''help'' tab.
- *Postal Mail, Commercial Delivery, or Hand Delivery:* If you mail or deliver your comments about this altered system of records, address them to: Valerie Sherrer, Director, Systems Integration Division, Systems Operations and Aid Delivery Management Services, Business Operations, Federal Student Aid, U.S. Department of Education, 830 First Street, NE., Union Center Plaza (UCP), room 44F1, Washington, DC 20202–5454.

Privacy Note: The Department's policy is to make all comments received from members of the public available for public viewing in their entirety on the Federal eRulemaking Portal at *www.regulations.gov.* Therefore, commenters should be careful to include in their comments only information that they wish to make publicly available.

Assistance to Individuals with Disabilities in Reviewing the Rulemaking Record: On request, we will supply an appropriate accommodation or auxiliary aid to an individual with a disability who needs assistance to review the comments or other documents in the public rulemaking record for this notice. If you want to schedule an appointment for this type of accommodation or auxiliary aid, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

FOR FURTHER INFORMATION CONTACT: Valerie Sherrer, Director, Systems Integration Division, Systems Operations and Aid Delivery Management Services, Business Operations, Federal Student Aid, U.S. Department of Education, UCP, 830 First Street, NE., room 44F1, Washington, DC 20202–5454. Telephone number: (202) 377–3547.

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), you may call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

Introduction

Under division H, title V, section 525 of the Consolidated Appropriations Act, 2014 (Pub. L. 113–76) and title VII, part A, subpart I of the Public Health Service Act, the authority to administer the HEAL program, including servicing, collecting, and enforcing any loans made under the program that remain outstanding, was transferred from the Secretary of Health and Human Services to the Secretary of Education on July 1, 2014, the date of the enactment of the Consolidated Appropriations Act, 2014.

The HEAL program system of records covers records for all activities that the Department carries out with regard to servicing, collecting, and enforcing Federal student loans made under title VII, part A, subpart I of the Public Health Service Act that remain outstanding. The HEAL program system also contains records of transactions performed by the Department to carry out the purposes of this system of records. The Privacy Act (5 U.S.C. 552a(e)(4) and (11)) requires Federal agencies to publish in the **Federal Register** this notice of an altered system of records. The Department's regulations implementing the Privacy Act are contained in part 5b of title 34 of the Code of Federal Regulations (CFR).

The Privacy Act applies to records about individuals that contain individually identifying information and that are retrieved by a unique identifier associated with each individual, such as a name or Social Security number. The information about each individual is called a ''record,'' and the system, whether manual or computer-based, is called a ''system of records.''

Whenever the Department makes a significant change to an established system of records, the Privacy Act requires the Department to publish a notice of an altered system of records in the **Federal Register** and to prepare and send a report to the Chair of the Committee on Oversight and Government Reform of the House of Representatives, the Chair of the Committee on Homeland Security and Governmental Affairs of the Senate, and the Administrator of the Office of Information and Regulatory Affairs, OMB. These reports are intended to permit an evaluation of the probable effect of the proposal on the privacy rights of individuals.

A change to a system of records is considered to be a significant change that must be reported whenever an agency expands the types or categories of information maintained, significantly expands the number, types, or categories of individuals about whom records are maintained, changes the purpose for which the information is used, changes the equipment configuration in a way that creates substantially greater access to the records, or adds a routine use disclosure to the system.

The Department of Education previously published the HEAL program system of records in the **Federal Register** on June 26, 2014 (79 FR 36299). This notice will revise programmatic routine use (18) (formerly routine use (15)) to include the **Federal Register**, and a Defaulted Borrowers Web site, should the Department elect to reestablish this or a similar Web site, as locations where the Department may publish the names of defaulted HEAL program borrowers (and any other fields the Department intends to publish, *e.g.,* area of practice). Former programmatic routine use (15) included only the Defaulted Borrowers Web site as the location for this information to be published.

Accessible Format: Individuals with disabilities can obtain this document in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc) on request to the person listed under **FOR FURTHER INFORMATION CONTACT**.

Electronic Access to This Document: 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 via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of the Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: January 17, 2017.

James W. Runcie,

Chief Operating Officer, Federal Student Aid.

For the reasons discussed in the preamble, the Chief Operating Officer of Federal Student Aid (FSA), U.S. Department of Education (Department or ED), publishes a notice of an altered system of records to read as follows:

SYSTEM NUMBER:

18–11–20

SYSTEM NAME:

Health Education Assistance Loan (HEAL) program.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Office of Information Technology Parklawn Data Center, Health Resources and Services Administration, U.S. Department of Health and Human Services (HHS), 5600 Fishers Lane, Room 9–105, Rockville, MD 20857 (HEAL program data center).

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The HEAL program system covers recipients of HEAL program loans that remain outstanding. This system also contains records on HEAL program loans that are paid in full.

CATEGORIES OF RECORDS IN THE SYSTEM:

Each HEAL recipient record contains the borrower's name, contact information (such as email address and telephone number), area of practice, Social Security number (SSN) or other identifying number, birth date, demographic background, educational status, loan location and status, and financial information about the individual for whom the record is maintained. Each loan record contains lender and school identification information.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The authority for maintenance of the system includes sections 701 and 702 of the Public Health Service Act, as amended (PHS Act) (42 U.S.C. 292 and 292a), which authorize the establishment of a Federal program of student loan insurance; section 715 of the PHS Act (42 U.S.C. 292n), which directs the Secretary of Education to require institutions to provide information for each student who has a loan; section 709(c) of the PHS Act (42 U.S.C. 292h(c)), which authorizes disclosure and publication of HEAL defaulters; the Debt Collection Improvement Act (31 U.S.C. 3701 and 3711–3720E); and the Consolidated Appropriations Act, 2014, Div. H, title V, section 525 of Public Law 113–76, which transferred the authority to administer the HEAL program from the Secretary of HHS to the Secretary of Education.

PURPOSES:

The information maintained in this system of records is used for the following purposes:

(1) To verify the identity of an individual;

(2) To determine program benefits;

(3) To enforce the conditions or terms of a loan;

(4) To service, collect, assign, adjust, transfer, refer, or discharge a loan;

(5) To counsel a debtor in repayment efforts;

(6) To investigate possible fraud or abuse or verify compliance with program regulations;

(7) To locate a delinquent or defaulted borrower or an individual obligated to repay a loan;

(8) To prepare a debt for litigation, provide support services for litigation on a debt, litigate a debt, or audit the results of litigation on a debt;

(9) To prepare for, conduct, enforce, or assist in the conduct or enforcement of a Medicare Exclusion of the individual in default on a HEAL loan;

(10) To ensure that program requirements are met by HEAL program participants;

(11) To verify whether a debt qualifies for discharge, cancellation, or forgiveness;

(12) To conduct credit checks or respond to inquiries or disputes arising from information on the debt already furnished to a credit-reporting agency;

(13) To investigate complaints, update information, or correct errors contained in Department records;

(14) To refund credit balances to the individual or loan holder;

(15) To allow HEAL program participants to report information to the Department on all aspects of HEAL loans in uniform formats;

(16) To report to the Internal Revenue Service (IRS) information required by law to be reported, including, but not limited to, reports required by 26 U.S.C. 6050P and 6050S;

(17) To compile and generate managerial and statistical reports; and

(18) To carry out the statutory requirement to compile and publish a list of the HEAL program borrowers who are in default.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

The Department may disclose information contained in a record in this system of records under the routine uses listed in this system of records without the consent of the individual if the disclosure is compatible with the purposes for which the information in the record was collected. These disclosures may be made on a case-by-case basis, or, if the Department has complied with the computer matching requirements of the Privacy Act of 1974, as amended (Privacy Act), under a computer matching agreement. Return information that the Department obtains from the Internal Revenue Service (IRS) (*i.e.,* taxpayer mailing address) under the authority in 26 U.S.C. 6103(m)(2) or (m)(4) may be disclosed only as authorized by 26 U.S.C. 6103.

(1) Program Disclosures. The Department may disclose records for the following program purposes:

(a) To verify the identity of the individual whom records indicate has received the loan, disclosures may be made to HEAL program participants, and their authorized representatives; Federal, State, or local agencies, and their authorized representatives; private parties, such as relatives, business and personal associates; educational and financial institutions; present and former employers; collection agencies; creditors; consumer reporting agencies; adjudicative bodies; and the individual whom the records identify as the party obligated to repay the debt;

(b) To determine program benefits, disclosures may be made to HEAL program participants, and their authorized representatives; Federal, State, or local agencies, and their authorized representatives; private parties, such as relatives, business and personal associates; educational and financial institutions; present and former employers; to creditors; consumer reporting agencies; and adjudicative bodies;

(c) To enforce the conditions or terms of the loan, disclosures may be made to HEAL program participants; educational and financial institutions, and their authorized representatives; Federal, State, or local agencies, and their authorized representatives; private parties, such as relatives, business and personal associates, and present and former employers; creditors; consumer reporting agencies; and adjudicative bodies;

(d) To permit servicing, collecting, assigning, adjusting, transferring, referring, or discharging a loan, disclosures may be made to HEAL program participants; educational institutions, or financial institutions that made, held, serviced, or have been assigned the debt, and their authorized representatives; a party identified by the debtor as willing to advance funds to repay the debt; Federal, State, or local agencies, and their authorized representatives; private parties, such as relatives, business and personal associates, and present and former employers; creditors; consumer reporting agencies; and adjudicative bodies;

(e) To counsel a debtor in repayment efforts, disclosures may be made to HEAL program participants; educational and financial institutions, and their authorized representatives; and Federal, State, or local agencies, and their authorized representatives;

(f) To investigate possible fraud or abuse or verify compliance with any applicable statutory, regulatory, or legally binding requirement, disclosures may be made to HEAL program participants; educational and financial institutions, and their authorized representatives; Federal, State, or local agencies, and their authorized representatives; private parties, such as relatives, present and former employers, and business and personal associates; creditors; consumer reporting agencies; and adjudicative bodies;

(g) To locate a delinquent or defaulted borrower, or an individual obligated to repay a loan, disclosures may be made to HEAL program participants; educational and financial institutions, and their authorized representatives; Federal, State, or local agencies, and their authorized representatives; private parties, such as relatives, business and personal associates, and present and former employers; creditors; consumer reporting agencies; and adjudicative bodies;

(h) To prepare a debt for litigation, to provide support services for litigation on a debt, to litigate a debt, or to audit the results of litigation on a debt, disclosures may be made to HEAL program participants, and their authorized representatives; Federal, State, or local agencies, and their authorized representatives; and adjudicative bodies;

(i) To prepare for, conduct, enforce, or assist in the conduct or enforcement of a Medicare exclusion action, disclosures may be made to HEAL program participants; educational or financial institutions, and their authorized representatives; Federal, State, or local agencies, and their authorized representatives; and adjudicative bodies;

(j) To ensure that HEAL program requirements are met by HEAL program participants, disclosures may be made to HEAL program participants; educational or financial institutions, and their authorized representatives; auditors engaged to conduct an audit of a HEAL program participant or of an educational or financial institution; Federal, State, or local agencies, and their authorized representatives;

accrediting agencies; and adjudicative bodies;

(k) To verify whether a debt qualifies for discharge, forgiveness, or cancellation, disclosures may be made to HEAL program participants; educational and financial institutions, and their authorized representatives; Federal, State, or local agencies, and their authorized representatives; private parties, such as relatives, present and former employers, and business and personal associates; creditors; consumer reporting agencies; and adjudicative bodies;

(l) To conduct credit checks or to respond to inquiries or disputes arising from information on the debt already furnished to a credit reporting agency, disclosures may be made to credit reporting agencies; HEAL program participants; educational and financial institutions, and their authorized representatives; Federal, State, or local agencies, and their authorized representatives; private parties, such as relatives, present and former employers, and business and personal associates; creditors; and adjudicative bodies;

(m) To investigate complaints or to update information or correct errors contained in Department records, disclosures may be made to HEAL program participants; educational and financial institutions, and their authorized representatives; Federal, State, or local agencies, and their authorized representatives; private parties, such as relatives, present and former employers, and business and personal associates; creditors; credit reporting agencies; and adjudicative bodies;

(n) To refund credit balances that are processed through the Department's systems, as well as the U.S. Department of the Treasury's (Treasury's) payment applications, to the individual or loan holder, disclosures may be made to HEAL program participants; educational and financial institutions, and their authorized representatives; Federal, State, or local agencies, and their authorized representatives; private parties, such as relatives, present and former employers, and business and personal associates; and creditors;

(o) To allow the reporting of information to the Department on all aspects of loans made under the HEAL program in uniform formats and to permit the Department directly to compare data submitted to the Department by HEAL program participants, educational and financial institutions, or third-party servicers, disclosures may be made to HEAL program participants and to educational and financial institutions;

(p) To report information required by law to be reported, including, but not limited to, reports required by 26 U.S.C. 6050P and 6050S, disclosures may be made to the IRS; and

(q) To allow the Department to make disclosures to governmental entities at the Federal, State, local, or tribal levels regarding the practices of Department contractors who have been provided with access to the HEAL program system with regards to all aspects of loans made under the HEAL program, in order to permit these governmental entities to verify the contractor's compliance with debt collection, financial, and other applicable statutory, regulatory, or local requirements. Before making a disclosure to these Federal, State, local or tribal governmental entities, the Department will require them to maintain Privacy Act safeguards to protect the security and confidentiality of the disclosed records.

(2) Feasibility Study Disclosure. The Department may disclose information from this system of records to other Federal agencies, and to guaranty agencies and to their authorized representatives, to determine whether computer matching programs should be conducted by the Department for purposes such as to locate a delinquent or defaulted debtor or to verify compliance with program regulations.

(3) Disclosure for Use by Other Law Enforcement Agencies. The Department may disclose information to any Federal, State, local, tribal, or foreign agency or other public authority responsible for enforcing, investigating, or prosecuting violations of administrative, civil, or criminal law or regulation if that information is relevant to any enforcement, regulatory, investigative, or prosecutorial responsibility within the receiving entity's jurisdiction.

(4) Enforcement Disclosure. In the event that information in this system of records indicates, either alone or in connection with other information, a violation or potential violation of any applicable statutory, regulatory, or legally binding requirement, the Department may disclose the relevant records to an entity charged with the responsibility for investigating or enforcing those violations or potential violations.

(5) Litigation and Alternative Dispute Resolution (ADR) Disclosure.

(a) Introduction. In the event that one of the parties listed below is involved in judicial or administrative litigation or ADR, or has an interest in such litigation or ADR, the Department may disclose certain records to the parties described in paragraphs (b), (c), and (d) of this routine use under the conditions specified in those paragraphs:

(i) The Department or any of its components;

(ii) Any Department employee in his or her official capacity;

(iii) Any Department employee in his or her individual capacity where the Department of Justice (DOJ) has been requested to or agrees to provide or arrange for representation for the employee;

(iv) Any Department employee in his or her individual capacity where the Department has agreed to represent the employee; and

(v) The United States, where the Department determines that the litigation is likely to affect the Department or any of its components.

(b) Disclosure to the DOJ. If the Department determines that disclosure of certain records to the DOJ is relevant and necessary to the judicial or administrative litigation or ADR, the Department may disclose those records as a routine use to the DOJ.

(c) Adjudicative Disclosure. If the Department determines that disclosure of certain records to an adjudicative body before which the Department is authorized to appear or to an individual or an entity designated by the Department or otherwise empowered to resolve or mediate disputes is relevant and necessary to the judicial or administrative litigation or ADR, the Department may disclose those records as a routine use to the adjudicative body, individual, or entity.

(d) Parties, Counsel, Representatives, and Witnesses. If the Department determines that disclosure of certain records to a party, counsel, representative, or witness is relevant and necessary to the judicial or administrative litigation or ADR, the Department may disclose those records as a routine use to the party, counsel, representative, or witness.

(6) Employment, Benefit, and Contracting Disclosure.

(a) For Decisions by the Department. The Department may disclose a record to a Federal, State, or local agency maintaining civil, criminal, or other relevant enforcement or other pertinent records, or to another public authority or professional organization, if necessary to obtain information relevant to a Department decision concerning the hiring or retention of an employee or other personnel action, the issuance of a security clearance, the letting of a contract, or the issuance of a license, grant, or other benefit.

(b) For Decisions by Other Public Agencies and Professional Organizations. The Department may

disclose a record to a Federal, State, local, or other public authority or professional organization, in connection with the hiring or retention of an employee or other personnel action, the issuance of a security clearance, the reporting of an investigation of an employee, the letting of a contract, or the issuance of a license, grant, or other benefit, to the extent that the record is relevant and necessary to the receiving entity's decision on the matter.

(7) Employee Grievance, Complaint, or Conduct Disclosure. If a record is relevant and necessary to an employee grievance, complaint, or disciplinary action, the Department may disclose the record in this system of records in the course of investigation, fact-finding, or adjudication to any witness, designated fact-finder, mediator, or other person designated to resolve issues or decide the matter.

(8) Labor Organization Disclosure. The Department may disclose a record from this system of records to an arbitrator to resolve disputes under a negotiated grievance procedure or to officials of a labor organization recognized under 5 U.S.C. chapter 71 when relevant and necessary to their duties of exclusive representation.

(9) Freedom of Information Act (FOIA) and Privacy Act Advice Disclosure. The Department may disclose records to the DOJ or to the Office of Management and Budget (OMB) if the Department determines that disclosure is desirable or necessary in determining whether particular records are required to be disclosed under the FOIA or the Privacy Act.

(10) Disclosure to the DOJ. The Department may disclose records to the DOJ, or the authorized representative of DOJ, to the extent necessary for obtaining DOJ advice on any matter relevant to an audit, inspection, or other inquiry related to the programs covered by this system.

(11) Contracting Disclosure. If the Department contracts with an entity for the purposes of performing any function that requires disclosure of records in this system to employees of the contractor, the Department may disclose the records to those employees. Before entering into such a contract, the Department shall require the contractor to maintain Privacy Act safeguards as required under 5 U.S.C. 552a(m) of the Privacy Act with respect to the records in the system.

(12) Research Disclosure. The Department may disclose records to a researcher if the Department determines that the individual or organization to which the disclosure would be made is qualified to carry out specific research related to functions or purposes of this system of records. The Department may disclose records from this system of records to that researcher solely for the purpose of carrying out that research related to the functions or purposes of this system of records. The researcher shall be required to maintain Privacy Act safeguards with respect to the disclosed records.

(13) Congressional Member Disclosure. The Department may disclose the records of an individual to a Member of Congress in response to an inquiry from the Member made at the written request of that individual whose records are being disclosed. The Member's right to the information is no greater than the right of the individual who requested the inquiry.

(14) Disclosure to OMB for Credit Reform Act (CRA) Support. The Department may disclose records to OMB as necessary to fulfill CRA requirements. These requirements currently include transfer of data on lender interest benefits and special allowance payments, defaulted loan balances, and supplemental pre-claims assistance payments information.

(15) Disclosure in the Course of Responding to a Breach of Data. The Department may disclose records to appropriate agencies, entities, and persons when (a) the Department suspects or has confirmed that the security or confidentiality of information in a system covered by this system of records notice has been compromised; (b) 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 system or programs (whether maintained by the Department or another agency or entity) that rely upon the compromised information; and (c) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the Department's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm.

(16) Disclosure to Third Parties through Computer Matching Programs. Unless otherwise prohibited by other laws, any information from this system of records, including personal information obtained from other agencies through computer matching programs, may be disclosed to any third party through a computer matching program, which is conducted under a Computer Matching Agreement between the Department and the third party, and requires that the matching be conducted in compliance with the requirements of the Privacy Act. Purposes of these disclosures may be: (a) To establish or verify program eligibility and benefits, (b) to establish or verify compliance with program regulations or statutory requirements, such as to investigate possible fraud or abuse; and (c) to recoup payments or delinquent debts under any Federal benefit programs, such as to locate or take legal action against a delinquent or defaulted debtor. At the time of the publication of this notice, the Department is not engaged in a computer matching program for the HEAL program.

(17) Disclosure of Information to Treasury. The Department may disclose records of this system to (a) a Federal or State agency, its employees, agents (including contractors of its agents), or contractors, or (b) a fiscal or financial agent designated by the Treasury, including employees, agents, or contractors of such agent, for the purpose of identifying, preventing, or recouping improper payments to an applicant for, or recipient of, Federal funds, including funds disbursed by a State in a State-administered, Federally funded program; and disclosure may be made to conduct computerized comparisons for this purpose.

(18) Disclosure of Defaulted Debtors in **Federal Register** Publication or on Designated Web sites. In accordance with the directive in 42 U.S.C. 292h(c), ED must publish in the **Federal Register** a list of borrowers who are in default on a HEAL loan. FSA intends to publish the names of the defaulted borrowers, last known city and state, area of practice, and amount of HEAL loan in default. FSA intends to publish the additional information about the borrower, as well as the names, in order to correctly identify the person in default and to provide relevant information to the intended recipients of this information, such as State licensing boards and hospitals. Additionally, this information may be published on a Defaulted Borrowers Web site, should the Department elect to reestablish this, or a similar, Web site. The Department may do this in order to provide the information to the intended recipients in a timely and effective way.

(19) Disclosure of Defaulted Debtors to Other Authorized Parties. In accordance with the directive in 42 U.S.C. 292h(c)(2), disclosure of borrowers who are in default on a HEAL loan may be made to relevant Federal agencies, schools, school associations, professional and specialty associations, State licensing boards, hospitals with which a HEAL loan defaulter may be

associated, or other similar organizations.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

Disclosures pursuant to 5 U.S.C. 552a(b)(12) (as set forth in 31 U.S.C. 3711(e)): Disclosures may be made from this system to ''consumer reporting agencies,'' as defined in the Fair Credit Reporting Act (15 U.S.C. 1681a(f)) or the Debt Collection Improvement Act (31 U.S.C. 3701(a)(3)). The purpose of these disclosures is to provide an incentive for debtors to repay delinquent Federal Government debts by making these debts part of their credit records.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained in database servers, file folders, CDs, DVDs, and magnetic tapes.

RETRIEVABILITY:

Records are retrieved by SSN or other identifying number.

SAFEGUARDS:

Authorized users: Access to the system is limited to authorized HEAL program personnel and contractors responsible for administering the HEAL program. Authorized personnel include ED employees and officials, financial and fiscal management personnel, computer personnel and program managers who have responsibilities for implementing the HEAL program. Read-only users: Read-only access is given to servicers, holders, and financial/fiscal management personnel.

Physical safeguards: Magnetic tapes, disc packs, computer equipment, and other forms of personal data are stored in areas where fire and life safety codes are strictly enforced. All documents are protected during lunch hours and nonworking hours in locked file cabinets or locked storage areas. Security guards are staffed 24 hours a day, seven days a week, to perform random checks on the physical security of the records storage areas.

Procedural safeguards: A password is required to access the terminal and a data set name controls the release of data to only authorized users. All users of personal information in connection with the performance of their jobs protect information from public view and from unauthorized personnel entering an unsupervised office. In addition, all sensitive data is encrypted using Oracle Transparent Data Encryption functionality. Access to records is strictly limited to those staff members trained in accordance with the Privacy Act and automatic data processing (ADP) security procedures. Contractors are required to maintain, and are also required to ensure that subcontractors maintain, confidentiality safeguards with respect to these records. Contractors and subcontractors are instructed to make no further disclosure of the records except as authorized by the System Manager and permitted by the Privacy Act. All individuals who have access to these records receive the appropriate ADP security clearances. ED personnel make site visits to ADP facilities for the purpose of ensuring that ADP security procedures continue to be met. Privacy Act and ADP system security requirements are specifically included in contracts. The HEAL program project directors, project officers, and the system manager oversee compliance with these requirements.

Implementing guidelines: The safeguards described above were established in accordance with HHS Chapter 45–13 and supplementary Chapter PHS.hf: 45–13 of HHS' General Administration Manual.

RETENTION AND DISPOSAL:

In accordance with the Department's record retention and disposition schedule, records for HEAL program awards are retained for seven years after final payment or discharge of the loan, whichever is sooner, and thereafter destroyed.

SYSTEM MANAGER AND ADDRESS:

Valerie Sherrer, Director, Systems Integration Division, Systems Operations and Aid Delivery Management Services, Business Operations, Federal Student Aid, U.S. Department of Education, 830 First Street NE., Room 44F1, UCP, Washington, DC 20202–5454. Telephone: (202) 377–3547.

NOTIFICATION PROCEDURE:

If you wish to determine whether a record exists about you in the system of records, provide the System Manager with your name, date of birth, and SSN. Your request must meet the requirements of the regulations in 34 CFR 5b.5, including proof of identity.

RECORD ACCESS PROCEDURES:

If you wish to gain access to your record in the system of records, provide the System Manager with your name, date of birth, and SSN. Requests by an individual for access to a record must meet the requirements of the regulations in 34 CFR 5b.5, including proof of identity.

CONTESTING RECORD PROCEDURE:

If you wish to contest the content of your record in the system of records, provide the System Manager with your name, date of birth, and SSN as well as a reasonable description of the record, specify the information being contested, the corrective action sought, and the reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant. Requests by an individual to amend a record must meet the requirements of the regulations in 34 CFR 5b.7.

RECORD SOURCE CATEGORIES:

Record source categories include individual loan recipients, HEAL schools, lenders, holders of HEAL loans and their agents, HHS, and other Federal agencies.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. 2017–01434 Filed 1–19–17; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2017–ICCD–0005]

Agency Information Collection Activities; Comment Request; Loan Discharge Application: Forgery

AGENCY: Federal Student Aid (FSA), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing a new information collection.

DATES: Interested persons are invited to submit comments on or before March 24, 2017.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2017–ICCD–0005. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Room 224–84, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Beth Grebeldinger, 202–377–4018.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Loan Discharge Application: Forgery.

OMB Control Number: 1845—NEW.

Type of Review: A new information collection.

Respondents/Affected Public: Individuals or Households.

Total Estimated Number of Annual Responses: 2,786.

Total Estimated Number of Annual Burden Hours: 2,786.

Abstract: This requests is for a new information collection to approve a form to be used to obtain information from federal student loan borrowers who allege that the loan(s) in their name were the result of a forgery. This information will be used by the Secretary to make a determination of forgery for the Direct Loans, FFEL Program Loans, and Federal Perkins Loans held by the Department. This information collection stems from the common law legal principal of forgery, which is not reflected specifically in the Department's statute or regulations, but with which the Department must comply.

Dated: January 17, 2017.

Kate Mullan,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2017–01329 Filed 1–19–17; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2017–ICCD–0004]

Agency Information Collection Activities; Comment Request; Study of Weighted Student Funding Systems

AGENCY: Office of Planning, Evaluation and Policy Development (OPEPD), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing a new information collection.

DATES: Interested persons are invited to submit comments on or before March 24, 2017.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2017–ICCD–0004. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Room 224–84, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Jacob Schak, 202–453–5643.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Study of Weighted Student Funding Systems.

OMB Control Number: 1875—NEW.

Type of Review: A new information collection.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 125.

Total Estimated Number of Annual Burden Hours: 189.

Abstract: The purpose of this study is to examine districts that have implemented weighted student funding (WSF) systems. In doing so, the study team will investigate how these systems for funding schools have been implemented, the benefits in terms of enhanced school funding equity and improved resource allocation practices through more equitable distributions of funding to schools and increased principal autonomy, and the challenges each district may have faced in undertaking such a reform. To this end, the study team will conduct site visits to a set of nine case study districts that will involve in-person interviews with district officials and school staff involved in WSF system administration. In addition, the study team will collect and review relevant extant data (budget and audited expenditure files) and administer surveys to a nationally representative sample of principals and school district administrators.

Dated: January 17, 2017.

Kate Mullan,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2017–01328 Filed 1–19–17; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Methane Hydrate Advisory Committee

AGENCY: Office of Fossil Energy, Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Methane Hydrate Advisory Committee. The Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat.770) requires that notice of these meetings be announced in the **Federal Register**.

DATES: Wednesday, February 15, 2017; 1:45 p.m. to 2:00 p.m. (EST)—Registration; 2:00 p.m. to 4:00 p.m. (EST)—Meeting.

ADDRESSES: U.S. Department of Energy, Forrestal Building, Room 3G–043, 1000 Independence Ave. SW., Washington, DC 20585.

FOR FURTHER INFORMATION CONTACT: Lou Capitanio, U.S. Department of Energy, Office of Oil and Natural Gas, 1000 Independence Avenue SW., Washington, DC 20585. *Phone:* (202) 586–5098.

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's Methane Hydrate Research and Development Program.

Tentative Agenda: The agenda will include: Welcome and Introduction by the Designated Federal Officer; Discussion of Committee Issues and Recommendations for Topics Requiring In-Depth Examination; and Public Comments, if any.

Public Participation: The meeting is open to the public. The Designated Federal Officer and the Chair 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 Lou Capitanio at the phone number listed above and provide your name, organization, citizenship, and contact information. Anyone attending the meeting will be required to present government issued identification. Space is limited. 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 three-minute rule.

Minutes: The minutes of this meeting will be available for public review and copying within 60 days at the following Web site: *http://energy.gov/fe/services/advisory-committees/methane-hydrate-advisory-committee*.

Issued at Washington, DC, on January 13, 2017.

LaTanya R. Butler,

Deputy Committee Management Officer.

[FR Doc. 2017–01330 Filed 1–19–17; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Office of Energy Efficiency and Renewable Energy

External Peer Review Meeting

AGENCY: Water Power Technologies Office; Office of Energy Efficiency and Renewable Energy; Department of Energy.

ACTION: Notice of external peer review meeting.

SUMMARY: All programs within the U.S. Department of Energy's (DOE) Office of Energy Efficiency and Renewable Energy are required to undertake rigorous, objective peer review of their funded projects on a regular basis in order to ensure and enhance the management, relevance, effectiveness, and productivity of those projects. The Water Power Technologies Office intends to hold an External Peer Review in Arlington, VA, on February 14–16, 2017. An External Peer Review Panel will review current and recently completed projects and provide feedback on technical, scientific, and business merit; the actual or anticipated results; and the productivity and management effectiveness of projects. The review panel will also assess the potential impact of projects on the water power industry and identify additional research initiatives and resources that may prove to be advantageous in the future.

Principal Investigators, expert reviewers, Water Power Technologies Office staff, and contract support staff will be in attendance during the review meeting. *The event is open to the public based upon space availability.*

DATES: The meeting is open to industry, academia, government, and the general public beginning at 8:30 a.m. on Tuesday, February 14, 2017, and ending on Thursday, February 16, 2017, at 5:00 p.m., based on availability. See pre-registration information below.

ADDRESSES: The External Peer Review will be held at the Sheraton Pentagon City Hotel, 900 S. Orme Street, Arlington, VA 22204. The Water Power Technologies Office Peer Review will be co-located with the Wind Energy Technologies Office Peer Review.

Pre-Registration: To pre-register, please contact Ms. Jenn ZiBerna via email at *jziberna@aetherquest.com* or via telephone at (571) 297–4018, or visit the meeting registration Web page: *https://ww2.eventrebels.com/er/Registration/StepRegInfo.jsp?ActivityID=19344&StepNumber=1.* Participants interested in attending should indicate the research area or areas they would like to observe, their name, company name or organization (if applicable), telephone number, and email no later than the close of business on January 30, 2017.

Comments: Comments may be submitted by the following methods:

- Email: *Matthew.Grosso@ee.doe.gov.* Include ''Water Power Peer Review'' in the subject line of the message.
- Postal Mail: Matthew Grosso, EE–4WP, U.S. Department of Energy, 1000 Independence Avenue SW., Washington, DC 20585. Due to the potential delays in DOE's receipt and processing of mail sent through the U.S. Postal Service, DOE encourages respondents to submit comments electronically to ensure timely receipt.

SUPPLEMENTARY INFORMATION:

Objectives

The objectives of the meeting are to:

- Review and evaluate the strategy and goals of the Water Power Technologies Office;
- Review and evaluate the progress and accomplishments of the Program's projects funded from FY2014 through FY2016; and
- Foster interactions among the DOE's national laboratories, industry, and academic institutions conducting research and development on behalf of the Office.

Research Areas

The Water Power Technologies Peer Review meeting will review projects sponsored by the Water Power Program in the following research areas:

- Marine Hydrokinetics
  - Environmental Research, Siting, and Resource Assessment
  - Market and Industry Development, Analysis and Data Dissemination
  - Component-level Research and Development
  - System-level Innovation and Design Iterations
  - Demonstrations for Performance

Evaluation and Installation, Operations, and Maintenance Improvements
- Testing Infrastructure and Instrumentation

- Hydropower
  - Growth
  - Optimization
  - Sustainability

Agenda

Presentations from Principal Investigators representing industry, academia, and DOE's national laboratories will have time limits. Depending on the type of project, Principal Investigators will have 20–30 minutes to present. This includes time for question and answer sessions between the Principal Investigators and the expert reviewers.

Public Participation

The event is open to the public based upon space availability. DOE will also accept public comments as for purposes of developing the Water Power Program portfolio, but will not respond individually to comments received. Following the meeting, a summary will be compiled by DOE and posted for public comment.

Information on Services for Individuals With Disabilities

Individuals requiring special accommodations at the meeting should contact Ms. ZiBerna no later than the close of business on January 30, 2017.

Issued in Washington, DC, on January 17, 2017.

James Ahlgrimm,

Acting Director, Water Power Technologies Office, U.S. Department of Energy.

[FR Doc. 2017–01437 Filed 1–19–17; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Office of Energy Efficiency and Renewable Energy

External Peer Review Meeting

AGENCY: Wind Energy Technologies Office; Office of Energy Efficiency and Renewable Energy; Department of Energy.

ACTION: Notice of external peer review meeting.

SUMMARY: All programs within the U.S. Department of Energy's (DOE) Office of Energy Efficiency and Renewable Energy are required to undertake rigorous, objective peer review of their funded projects on a regular basis in order to ensure and enhance the management, relevance, effectiveness, and productivity of those projects. The Wind Energy Technologies Office intends to hold an External Peer Review in Arlington, VA, on February 14–16, 2017. An External Peer Review Panel will review current and recently completed projects and provide feedback on technical, scientific, and business merit; the actual or anticipated results; and the productivity and management effectiveness of projects. The review panel will also assess the potential impact of projects on the wind power industry and identify additional research initiatives and resources that may prove to be advantageous in the future.

Principal Investigators, expert reviewers, Wind Energy Technologies Office staff, and contract support staff will be in attendance during the review meeting. *The event is open to the public based upon space availability.*

DATES: The meeting is open to industry, academia, government, and the general public beginning at 8:30 a.m. on Tuesday, February 14, 2017, and ending on Thursday, February 16, 2017, at 5:00 p.m., based on availability. See pre-registration information below.

ADDRESSES: The External Peer Review will be held at the Sheraton Pentagon City Hotel, 900 S. Orme Street, Arlington, VA 22204. The Wind Energy Technologies Office Peer Review will be co-located with the Water Power Technologies Office Peer Review.

Pre-Registration: To pre-register, please contact Ms. Jenn ZiBerna via email at *jziberna@aetherquest.com* or via telephone at (571) 297–4018, or visit the meeting registration Web page: *https://ww2.eventrebels.com/er/Registration/StepRegInfo.jsp?ActivityID=19344&StepNumber=1.* Participants interested in attending should indicate the research area or areas they would like to observe, their name, company name or organization (if applicable), telephone number, and email no later than the close of business on January 30, 2017.

Comments: Comments may be submitted by the following methods:

- *Email: Jose.Zayas@ee.doe.gov.* Include ''Wind Energy Peer Review'' in the subject line of the message.
- *Postal Mail:* Jose Zayas, EE–4WE, U.S. Department of Energy, 1000 Independence Avenue SW., Washington, DC 20585. Due to the potential delays in DOE's receipt and processing of mail sent through the U.S. Postal Service, DOE encourages respondents to submit comments electronically to ensure timely receipt.

SUPPLEMENTARY INFORMATION:

Objectives

The objectives of the meeting are to:

- Review and evaluate the strategy and goals of the Wind Energy Technologies Office;
- Review and evaluate the progress and accomplishments of the Program's projects funded from FY2014 through FY2016; and
- Foster interactions among the DOE's national laboratories, industry, and academic institutions conducting research and development on behalf of the Office.

Research Areas

The Wind Energy Technologies Peer Review meeting will review projects sponsored by the Wind Program in the following research areas:

- Analysis, Modeling, Cost of Energy, and Policy Impact
- Grid Systems Planning and Operation
- Siting, Radar and Environmental
- Stakeholder Engagement, Outreach, and Workforce Development
- Atmosphere to Electrons, High Performance Computing, Resource Characterization, Flow Field Analysis and Testing
- Standards Development
- Distributed Wind Research, Development, and Testing
- Innovation, Manufacturing, Reliability, Advanced Components, and Testing
- Utility-scale Wind Unique Research, Development, and Testing

Agenda

Presentations from Principal Investigators representing industry, academia, and DOE's national laboratories will have time limits. Depending on the type of project, Principal Investigators will have 20–30 minutes to present. This includes time for question and answer sessions between the Principal Investigators and the expert reviewers.

Public Participation

The event is open to the public based upon space availability. DOE will also accept public comments as for purposes of developing the Wind Power Program portfolio, but will not respond individually to comments received. Following the meeting, a summary will be compiled by DOE and posted for public comment.

Information on Services for Individuals With Disabilities

Individuals requiring special accommodations at the meeting should contact Ms. ZiBerna no later than the close of business on January 30, 2017.

Issued in Washington, DC, on January 17, 2017.

Jose Zayas,

Director, Wind Energy Technologies Office, U.S. Department of Energy.

[FR Doc. 2017–01438 Filed 1–19–17; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER17–790–000]

Cimarron Bend Wind Project II, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Cimarron Bend Wind Project II, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is February 2, 2017.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: January 13, 2017.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2017–01354 Filed 1–19–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER17–786–000]

Luz Solar Partners Ltd., IV; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Luz Solar Partners Ltd., IV's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is February 2, 2017.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: January 13, 2017.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2017–01353 Filed 1–19–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP17–30–000]

Columbia Gas Transmission, LLC; Notice of Request Under Blanket Authorization

Take notice that on January 6, 2017 Columbia Gas Transmission, LLC (Columbia), 5151 San Felipe, Suite 2500, Houston, TX 77056, filed in Docket No. CP17–30–000 a prior notice request pursuant to sections 157.205 and 157.213(b) of the Commission's regulations under the Natural Gas Act (NGA) and Columbia's authorization in Docket No. CP83–76–000, 22 FERC ¶ 62,029 (1983), requesting authorization to (i) construct two wells located in Vinton County, Ohio, and (ii) construct two well lines to tie the wells into existing pipelines, all as more fully set forth in the application which is on file with the Commission and open to public inspection. The filing may also be viewed on the web at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@*

ferc.gov or toll free at (866) 208–3676, or TTY, contact (202) 502–8659.

Any questions concerning this application may be directed to Robert D. Jackson, Manager, Certificates & Regulatory Administration, Columbia Gas Transmission, LLC, 700 Louisiana Street, Suite 700, Houston, TX, 77002–2700, at (832) 320–5487 or fax (832) 320–6487 or *robert_jackson@transcanada.com.*

Any person or the Commission's staff may, within 60 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to section 157.205 of the regulations under the NGA (18 CFR 157.205), a protest to the request. If no protest is filed within the time allowed therefore, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the allowed time for filing a protest, the instant request shall be treated as an application for authorization pursuant to section 7 of the NGA.

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.

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 commenter's 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 commenter's will not be required to serve copies of filed documents on all other parties. However, the non-party commentary, 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 strongly encourages electronic filings of comments, protests, and interventions via the internet in lieu of paper. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site (*www.ferc.gov*) under the ''e-Filing'' link. Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

Dated: January 13, 2017.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2017–01352 Filed 1–19–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER11–47–008; ER12–1540–006; ER12–1541–006; ER12–1542–006; ER12–1544–006; ER10–2981–008; ER14–2475–005; ER14–2476–005; ER14–2477–005; ER14–594–010; ER11–46–011; ER11–41–008; ER12–2343–006; ER13–1896–012.

Applicants: Appalachian Power Company, Indiana Michigan Power Company, Kentucky Power Company, Kingsport Power Company, Wheeling Power Company, AEP Texas Central Company, AEP Texas North Company, Public Service Company of Oklahoma, Southwestern Electric Power Company, Ohio Power Company, AEP Energy Partners, Inc., AEP Retail Energy Partners LLC, AEP Energy, Inc., AEP Generation Resources Inc.

Description: Notice of Non-material Change of Status of the AEP Companies.

Filed Date: 1/13/17.

Accession Number: 20170113–5094.

Comments Due: 5 p.m. ET 2/3/17.

Docket Numbers: ER16–2227–002

Applicants: Kelly Creek Wind, LLC.

Description: Notice of Non-Material Change in Status of Kelly Creek Wind, LLC.

Filed Date: 1/13/17.

Accession Number: 20170113–5113.

Comments Due: 5 p.m. ET 2/3/17.

Docket Numbers: ER16–2240–003.

Applicants: Rush Springs Wind Energy, LLC.

Description: Notice of Non-material Change in Status of Rush Springs Wind Energy, LLC.

Filed Date: 1/12/17.

Accession Number: 20170112–5181.

Comments Due: 5 p.m. ET 2/2/17.

Docket Numbers: ER17–135–002.

Applicants: DesertLink, LLC.

Description: Tariff Amendment: Amendment to 2 to be effective 12/19/2016.

Filed Date: 1/12/17.

Accession Number: 20170112–5147, 20170112–5168.

Comments Due: 5 p.m. ET 2/2/17.

Docket Numbers: ER17–786–000.

Applicants: Luz Solar Partners Ltd., IV.

Description: Baseline eTariff Filing: Luz Solar Partners Ltd., IV Application for Market-Based Rates to be effective 1/31/2017.

Filed Date: 1/12/17.

Accession Number: 20170112–5174.

Comments Due: 5 p.m. ET 2/2/17.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: January 13, 2017.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2017–01350 Filed 1–19–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER16–2293–003.
Applicants: Drift Sand Wind Project, LLC.
Description: Notice of Non-Material Change in Status of Drift Sand Wind Project, LLC.
Filed Date: 1/13/17.
Accession Number: 20170113–5175.
Comments Due: 5 p.m. ET 2/3/17.
Docket Numbers: ER17–787–000.
Applicants: Southern California Edison Company.
Description: Tariff Cancellation: Termination of 3 DSAs with ECOS Energy, LLC to be effective 3/15/2017.
Filed Date: 1/13/17.
Accession Number: 20170113–5127.
Comments Due: 5 p.m. ET 2/3/17.
Docket Numbers: ER17–788–000.
Applicants: Southern California Edison Company.
Description: § 205(d) Rate Filing: DSA Wildomar Solar Project SA No. 939 to be effective 3/15/2017.
Filed Date: 1/13/17.
Accession Number: 20170113–5128.
Comments Due: 5 p.m. ET 2/3/17.
Docket Numbers: ER17–789–000.
Applicants: Southern California Edison Company.
Description: § 205(d) Rate Filing: GIA and Distribution Service Agmt Richard Moss to be effective 1/17/2017.
Filed Date: 1/13/17.
Accession Number: 20170113–5129.
Comments Due: 5 p.m. ET 2/3/17.
Docket Numbers: ER17–790–000.
Applicants: Cimarron Bend Wind Project II, LLC.
Description: Baseline eTariff Filing: MBR Tariff to be effective 3/1/2017.
Filed Date: 1/13/17.
Accession Number: 20170113–5133.
Comments Due: 5 p.m. ET 2/3/17.
Docket Numbers: ER17–791–000.
Applicants: Duke Energy Florida, LLC.
Description: § 205(d) Rate Filing: DEF-U.S. EcoGen Polk LGIA SA No. 180 to be effective 3/14/2017.
Filed Date: 1/13/17.
Accession Number: 20170113–5152.
Comments Due: 5 p.m. ET 2/3/17.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: January 13, 2017.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2017–01351 Filed 1–19–17; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2013–0329; FRL–9956–14–OEI]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; NSPS for Rubber Tire Manufacturing (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency has submitted an information collection request (ICR), ''NSPS for Rubber Tire Manufacturing (40 CFR part 60, subpart BBB) (Renewal)'' (EPA ICR No. 1158.12, OMB Control No. 2060–0156), to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). This is a proposed extension of the ICR, which is currently approved through January 31, 2017. Public comments were previously requested via the **Federal Register** (81 FR 26546) on May 3, 2016 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An Agency may neither conduct nor sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before February 22, 2017.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OECA–2013–0329, to: (1) EPA online using *www.regulations.gov* (our preferred method), or by email to *docket.oeca@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460; and (2) OMB via email to *oira_submission@omb.eop.gov.* Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Patrick Yellin, Monitoring, Assistance, and Media Programs Division, Office of Compliance, Mail Code 2227A, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: (202) 564–2970; fax number: (202) 564–0050; email address: *yellin.patrick@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit: *http://www.epa.gov/dockets.*

Abstract: Owners and operators of affected facilities are required to comply with reporting and record keeping requirements for the General Provisions (40 CFR part 60, subpart A), as well as for the specific requirements at 40 CFR part 60, subpart BBB. This includes submitting initial notifications, performance tests and periodic reports and results, and maintaining records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. These reports are used by EPA to determine compliance with the standards.

Form Numbers: None.

Respondents/affected entities: Rubber tire manufacturing plants that commenced construction or modification after January 20, 1983.

Respondent's obligation to respond: Mandatory (40 CFR part 60, subpart BBB).

Estimated number of respondents: 41 (total).

Frequency of response: Initially, occasionally, semiannually, and annually.

Total estimated burden: 17,700 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $1,850,000 (per year), which includes $16,400 in either annualized capital/startup or operation & maintenance costs.

Changes in the Estimates: There is an adjustment increase in the total estimated burden and cost as currently identified in the OMB Inventory of Approved Burdens. This increase is not due to any program changes. The change in the respondent labor hour estimates occurred because of a change in assumption. This ICR assumes all existing respondents will have to familiarize with the regulatory requirements each year.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2017–01279 Filed 1–19–17; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OLEM–2016–0182; FRL–9958–66–OEI]

Information Collection Request to OMB for Review and Approval; Comment Request; 2017 Hazardous Waste Report, Notification of Regulated Waste Activity, and Part A Hazardous Waste Permit Application and Modification (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency has submitted an information collection request (ICR), ''2017 Hazardous Waste Report, Notification of Regulated Waste Activity, and Part A Hazardous Waste Permit Application and Modification (Renewal)'' (EPA ICR No. 0976.18, OMB Control No. 2050–0024) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). This is a proposed extension of the ICR, which is currently approved through January 31, 2017. Public comments were previously requested via the **Federal Register** (81 FR 25398) on April 28, 2016 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. 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.

DATES: Additional comments may be submitted on or before February 22, 2017.

ADDRESSES: Submit your comments, referencing Docket ID No. EPA–HQ–OLEM–2016–0182, to (1) EPA, online using *www.regulations.gov* (our preferred method), by email to *rcra-docket@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460, and (2) OMB via email to *oira_submission@omb.eop.gov.* Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Peggy Vyas, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: 703–308–5477; fax number: 703–308–8433; email address: *vyas.peggy@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Abstract: Section 3002 of RCRA requires hazardous waste generators to report, at least every 2 years, the quantity and nature of hazardous waste generated and managed during that reporting cycle. Section 3004 requires treatment, storage, and disposal facilities (TSDFs) to report any waste received. This is mandatory reporting. The information is collected via the Hazardous Waste Report (EPA Form 8700–13 A/B). This form is also known as the ''Biennial Report'' form.

Section 3010 of RCRA requires any person who generates or transports regulated waste or who owns or operates a facility for the treatment, storage, or disposal of regulated waste to notify the EPA of their activities, including the location and general description of activities and the regulated wastes handled. The entity is then issued an EPA Identification number. Entities use the Notification Form (EPA Form 8700–12) to notify EPA of their hazardous waste activities. This form is also known as the ''Notification'' form. On January 13, 2015, EPA published the Definition of Solid Waste (DSW) final rule (80 FR 1694), which revised the regulations related to certain exclusions from solid and hazardous waste regulation. Changes have been made to the Notification form to reflect this final rule.

Section 3005 of RCRA requires TSDFs to obtain a permit. To obtain the permit, the TSDF must submit an application describing the facility's operation. The RCRA Hazardous Waste Part A Permit Application form (EPA Form 8700–23) defines the processes to be used for treatment, storage, and disposal of hazardous wastes; the design capacity of such processes; and the specific hazardous wastes to be handled at the facility.

Form Numbers: EPA form numbers 8700–12, 8700–13A/B, and 8700–23.

Respondents/affected entities: Business or other for-profit as well as State, Local, or Tribal governments.

Respondent's obligation to respond: Mandatory (RCRA Sections 3002, 3304, 3005, 3010).

Estimated number of respondents: 64,005.

Frequency of response: Biennially and on occasion.

Total estimated burden: 647,425 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $28,488,775 (per year), includes $323,817 annualized capital or operation & maintenance costs.

Changes in the Estimates: There is an increase of 27,936 hours in the total estimated respondent burden compared with the ICR currently approved by OMB. This increase is due to an increase in the number of projected respondents to the 2017 Hazardous Waste Report vs the 2015 Hazardous Waste Report.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2017–01281 Filed 1–19–17; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OGC–2017–0016; FRL 9958–74–OGC]

Proposed Consent Decree, Clean Air Act Citizen Suit

AGENCY: Environmental Protection Agency.

ACTION: Notice of proposed consent decree; request for public comment.

SUMMARY: In accordance with section 113(g) of the Clean Air Act, as amended (''CAA'' or the ''Act''), notice is hereby given of a proposed consent decree to address a lawsuit filed by Sierra Club (''Plaintiffs'') in the United States District Court for the District of Columbia: *Sierra Club* v. *McCarthy,* Civil Action No. 1:16–cf–01895–KBJ (D.D.C). On September 23, 2016, Plaintiffs filed a complaint alleging that the Administrator of the United States Environmental Protection Agency (''EPA'') failed to perform a non-discretionary duty to grant or deny within 60 days a petition submitted by Plaintiffs on April 11, 2016 requesting that EPA object to a CAA Title V permit issued by the Utah Department of Air Quality, to PacifiCorp Energy, authorizing the operation of the coal-fired Hunter Plant in Castle Dale, Utah. The proposed consent decree would establish a deadline for EPA to take such action.

DATES: Written comments on the proposed consent decree must be received by February 22, 2017.

ADDRESSES: Submit your comments, identified by Docket ID number EPA–HQ–OGC–2017–0016, online at *www.regulations.gov* (EPA's preferred method). For comments submitted at *www.regulations.gov,* follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *www.regulations.gov.* The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: John Krallman, Air and Radiation Law Office (2344A), Office of General Counsel, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone: (202) 564–0904; email address: *krallman.john@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Additional Information About the Proposed Consent Decree

The proposed consent decree would resolve a lawsuit filed by the Plaintiffs seeking to compel the Administrator to take actions under CAA section 505(b)(2). Under the terms of the proposed consent decree, EPA would agree to sign its response granting or denying the petition filed by Plaintiffs regarding PacifiCorp Energy's Hunter Plant located in Castle Dale, Utah, pursuant to section 505(b)(2) of the CAA, on or before August 31, 2017.

Under the terms of the proposed consent decree, EPA would expeditiously deliver notice of EPA's response to the Office of the Federal Register for review and publication following signature of such response. In addition, the proposed consent decree outlines the settlement in regard to Petitioner's attorney fees.

For a period of thirty (30) days following the date of publication of this notice, the Agency will accept written comments relating to the proposed consent decree from persons who are not named as parties or intervenors to the litigation in question. EPA or the Department of Justice may withdraw or withhold consent to the proposed consent decree if the comments disclose facts or considerations that indicate that such consent is inappropriate, improper, inadequate, or inconsistent with the requirements of the Act. Unless EPA or the Department of Justice determines that consent to this consent decree should be withdrawn, the terms of the consent decree will be affirmed.

II. Additional Information About Commenting on the Proposed Consent Decree

A. How can I get a copy of the consent decree?

The official public docket for this action (identified by Docket ID No. EPA–HQ–OGC–2017–0016) contains a copy of the proposed consent decree. The official public docket is available for public viewing at the Office of Environmental Information (OEI) Docket in the EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OEI Docket is (202) 566–1752.

An electronic version of the public docket is available through *www.regulations.gov.* You may use *www.regulations.gov* to submit or view public comments, access the index listing of the contents of the official public docket, and access those documents in the public docket that are available electronically. Once in the system, key in the appropriate docket identification number then select ''search.''

It is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing online at *www.regulations.gov* without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. Information claimed as CBI and other information whose disclosure is restricted by statute is not included in the official public docket or in the electronic public docket. EPA's policy is that copyrighted material, including copyrighted material contained in a public comment, will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the EPA Docket Center.

B. How and to whom do I submit comments?

You may submit comments as provided in the **ADDRESSES** section. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments.

If you submit an electronic comment, EPA recommends that you include your name, mailing address, and an email address or other contact information in the body of your comment and with any disk or CD ROM you submit. This ensures that you can be identified as the submitter of the comment and allows

EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. Any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. 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.

Use of the *www.regulations.gov* Web site to submit comments to EPA electronically is EPA's preferred method for receiving comments. The electronic public docket system is an ''anonymous access'' system, which means EPA will not know your identity, email address, or other contact information unless you provide it in the body of your comment. In contrast to EPA's electronic public docket, EPA's electronic mail (email) system is not an ''anonymous access'' system. If you send an email comment directly to the Docket without going through *www.regulations.gov,* your email address is automatically captured and included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

Dated: January 6, 2017.

Lorie J. Schmidt,

Associate General Counsel.

[FR Doc. 2017–01419 Filed 1–19–17; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2013–0301; FRL—9955–39–OEI]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; NESHAP for Beryllium (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency has submitted an information collection request (ICR), ''NESHAP for Beryllium (40 CFR part 61, subpart C) (Renewal)'' (EPA ICR No. 0193.12, OMB Control No. 2060–0092), to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). This is a proposed extension of the ICR, which is currently approved through January 31, 2017. Public comments were previously requested via the **Federal Register** (81 FR 26546) on May 3, 2016 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An Agency may neither conduct nor sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before February 22, 2017

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OECA–2013–0301, to: (1) EPA online using *www.regulations.gov* (our preferred method), or by email to *docket.oeca@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460; and (2) OMB via email to *oira_submission@omb.eop.gov.* Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Patrick Yellin, Monitoring, Assistance, and Media Programs Division, Office of Compliance, Mail Code 2227A, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: (202) 564–2970; fax number: (202) 564–0050; email address: *yellin.patrick@epa.gov.*

SUPPLEMENTARY INFORMATION:

Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit: *http://www.epa.gov/dockets.*

Abstract: Owners and operators of affected facilities are required to comply with reporting and record keeping requirements for the general provisions of 40 CFR part 61, subpart A, as well as the specific requirements at 40 CFR part 61, subpart C. This includes submitting initial notifications, performance tests and periodic reports and results, and maintaining records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. These reports are used by EPA to determine compliance with these standards.

Form Numbers: None.

Respondents/affected entities: Facilities processing beryllium and its derivatives.

Respondent's obligation to respond: Mandatory (40 CFR part 61, subpart C).

Estimated number of respondents: 33 (total).

Frequency of response: Initially, occasionally, and monthly.

Total estimated burden: 2,670 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $310,000 (per year), which includes $35,000 in either annualized capital/startup or operation & maintenance costs.

Changes in the Estimates: There is an adjustment increase in the respondent burden as currently identified in the OMB Inventory of Approved Burdens. This increase is not due to any program changes. The change in labor hour and cost estimates occurred because of a change in assumption. This ICR assumes all existing sources will have to re-familiarize with the regulatory requirements each year.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2017–01273 Filed 1–19–17; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9958–58–OAR]

Minor Revisions to AP–42 Section 13.5: Industrial Flares

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of final action.

SUMMARY: On December 14, 2016, the Environmental Protection Agency (EPA) issued minor revisions to AP–42 Section 13.5: Industrial Flares. AP–42 is the primary compilation of the EPA's emissions factor information. The EPA finalized these revisions in compliance with a settlement agreement entered into with Air Alliance Houston, Community In-Power and Development Association, Inc., Louisiana Bucket Brigade, and Texas Environmental Justice Advocacy Services (''Plaintiffs'').

ADDRESSES: You may view this final action and the supporting information

electronically at: *https://www.epa.gov/air-emissions-factors-and-quantification/new-and-revised-emissions-factors-flares-and-new-emissions.*

FOR FURTHER INFORMATION CONTACT: Ms. Gerri Garwood, Measurement Policy Group (MPG), Sector Policies and Programs Division (D243–05), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, telephone number: (919) 541–2406; fax number: (919) 541–1039; and email address: *garwood.gerri@epa.gov.*

SUPPLEMENTARY INFORMATION: As described above, the EPA finalized these actions to fulfill its obligations under a settlement agreement, which resolves a petition for judicial review on actions the EPA took on April 20, 2015. On April 20, 2015, the EPA issued new and revised emissions factors for flares and other refinery process units and issued its final determination that revisions to existing emissions factors for tanks and wastewater treatment systems were not necessary in order to fulfill its obligations under a consent decree. Plaintiffs alleged that the EPA failed to perform nondiscretionary duties pursuant to Clean Air Act (CAA) section 130 to review, and, if necessary, revise the emissions factors for volatile organic compounds (VOC) for flares, liquid storage tanks (''tanks''), and wastewater collection, treatment and storage systems (''wastewater treatment systems'') at least once every 3 years. See *Air Alliance Houston, et al.* v. *EPA,* Case No. 15–1210 (D.C. Cir.) and *Air Alliance Houston, et al.* v. *McCarthy,* No. 1:13–cv–00621–KBJ (D.D.C.).

The settlement agreement outlined 20 specific Source Classification Codes (SCCs) that Plaintiffs argued should be included in Tables 13.5–1 and 13.5–2 of AP–42, *Compilation of Air Pollutant Emission Factors.* AP–42 is the primary compilation of EPA's emissions factor information. Additionally, Plaintiffs sought minor clarifications to the text in Section 13.5 of AP–42, as well as an update to the VOC emissions factor due to errors in the original calculation.

Per the requirements of the settlement agreement, this final action was issued by December 16, 2016. To support this action, we developed a memorandum to document our determinations in regards to the 20 SCCs specified in the settlement agreement. We also revised section 13.5 of AP–42, the supporting background documentation, and the previously issued report, *Review of Emissions Test Reports for Emissions Factors Development for Flares and Certain Refinery Operations.* The SCC determination memorandum and the revised report, along with a link to the updated section in AP–42 and supporting background documentation, were posted on the Web site listed in the **ADDRESSES** section of this document on December 14, 2016.

These actions constitute final agency action of national applicability for purposes of section 307(b)(1) of the CAA. Pursuant to CAA section 307(b)(1), judicial review of these final agency actions may be sought only in the United States Court of Appeals for the District of Columbia Circuit. Petitions for review must be filed by March 24, 2017. Judicial review of these final agency actions may not be obtained in subsequent proceedings, pursuant to CAA section 307(b)(2). These actions are not a rulemaking and are not subject to the various statutory and other provisions applicable to a rulemaking.

Dated: January 13, 2017.

Stephen Page,

Director, Office of Air Quality Planning and Standards.

[FR Doc. 2017–01263 Filed 1–19–17; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–9031–4]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564–7146 or *http://www.epa.gov/nepa.*

Weekly receipt of Environmental Impact Statements

Filed 01/09/2017 Through 01/13/2017 Pursuant to 40 CFR 1506.9.

Notice

Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *http://www.epa.gov/compliance/nepa/eisdata.html.*

EIS No. 20170011, Draft, APHIS, Other, Revisions to USDA–APHIS 7 CFR part 340 Regulations Governing the Importation, Interstate Movement, and Environmental Release of Genetically Engineered Organisms, Comment Period Ends: 05/22/2017, Contact: Cindy Eck 301–851–3892.

EIS No. 20170012, Final, TVA, TN, Bull Run Fossil Plant Landfill, Review Period Ends: 02/21/2017, Contact: Anita E. Masters 423–751–8697.

EIS No. 20170013, Final, NPS, CA, Alcatraz Ferry Embarkation, Review Period Ends: 02/21/2017, Contact: Brian Aviles 415–561–4942.

EIS No. 20170014, Draft, APHIS, Other, Regulation of the Importation, Interstate Movement, and Intrastate Movement of Plant Pests, Comment Period Ends: 03/20/2017, Contact: Tracy Willard 301–851–3101.

EIS No. 20170015, Final, USFS, AZ, Camp Tatiyee Land Exchange, Review Period Ends: 02/21/2017, Contact: Randall Chavez 928–368–2106.

Amended Notices

EIS No. 20160263, Draft, USN, WA, EA–18G ''Growler'' Airfield Operations at the NAS Whidbey Island Complex, Comment Period Ends: 02/24/2017, Contact: Sarah Stallings 757–322–4733.

Revision to FR Notice Published 11/10/2016; Extending Comment Period from 01/25/2017 to 02/24/2017.

EIS No. 20160274, Draft, FHWA, NY, NYS Route 198 (Scajaquada Expressway) Corridor Project, Comment Period Ends: 01/25/2017, Contact: Peter Osborn 518–431–4127.

Revision to FR Notice Published 11/25/2016; Extending Comment Period from 01/25/2017 to 02/08/2017.

EIS No. 20160319, Draft, BLM, CA, Central Coast Field Office Draft Resource Management Plan Amendment for the Oil and Gas Leasing and Development, Comment Period Ends: 04/06/2017, Contact: Melinda Moffitt 916–978–4376.

Revision to FR Notice Published 01/06/2017; Extending Comment Period from 02/21/2017 to 04/06/2017.

Dated: January 17, 2017.

Dawn Roberts,

Management Analyst, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2017–01426 Filed 1–19–17; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2013–0310; FRL–9955–64–OEI]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; NSPS for Sewage Sludge Treatment Plants (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency has submitted an information

collection request (ICR), ''NSPS for Sewage Sludge Treatment Plants (40 CFR part 60, subpart O) (Renewal)'' (EPA ICR No 1063.13, OMB Control No. 2060–0035), to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). This is a proposed extension of the ICR, which is currently approved through January 31, 2017. Public comments were previously requested via the **Federal Register** (81 FR 26546) on May 3, 2016, during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An Agency may neither conduct nor sponsor, and a person is not required to respond to, a collection of information unless it displays a currently-valid OMB control number.

DATES: Additional comments may be submitted on or before February 22, 2017.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OECA–2013–0310, to: (1) EPA online using *www.regulations.gov* (our preferred method), or by email to *docket.oeca@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460; and (2) OMB via email to *oira_submission@omb.eop.gov.* Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the public docket without change, including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Patrick Yellin, Monitoring, Assistance, and Media Programs Division, Office of Compliance, Mail Code 2227A, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: (202) 564–2970; fax number: (202) 564–0050; email address: *yellin.patrick@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov,* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit: *http://www.epa.gov/dockets.*

Abstract: Owners and operators of affected facilities are required to comply with reporting and record keeping requirements for the General Provisions (40 CFR part 60, subpart A), as well as for the specific requirements at 40 CFR part 60, subpart O. This includes submitting initial notifications, performance tests and periodic reports and results, and maintaining records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. These reports are used by EPA to determine compliance with these standards.

Form Numbers: None.

Respondents/affected entities: Sewage sludge treatment plants.

Respondent's obligation to respond: Mandatory (40 CFR part 60 Subpart O).

Estimated number of respondents: 86 (total).

Frequency of response: Initially, occasionally and semiannually.

Total estimated burden: 9,690 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $4,050,000 (per year), which includes $3,050,000 for both annualized capital/startup and operation & maintenance costs.

Changes in the Estimates: There is an adjustment decrease in the total estimated burden and O&M costs as currently identified in the OMB Inventory of Approved Burdens. This decrease is not due to any program changes. The change in the burden and cost estimates occurred because the number of respondents has decreased as compared to the most-recently approved ICR.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2017–01274 Filed 1–19–17; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2013–0314; FRL—9956–06–OEI]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; NSPS for Phosphate Rock Plants (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency has submitted an information collection request (ICR), ''NSPS for Phosphate Rock Plants (40 CFR part 60, subpart NN)'' (EPA ICR No. 1078.11, OMB Control No. 2060–0111), to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). This is a proposed extension of the ICR, which is currently approved through January 31, 2017. Public comments were previously requested via the **Federal Register** (81 FR 26546) on May 3, 2016 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An Agency may neither conduct nor sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before February 22, 2017.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OECA–2013–0314, to: (1) EPA online using *www.regulations.gov* (our preferred method), or by email to *docket.oeca@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460; and (2) OMB via email to *oira_submission@omb.eop.gov.* Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Patrick Yellin, Monitoring, Assistance, and Media Programs Division, Office of Compliance, Mail Code 2227A, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: (202) 564–2970; fax number: (202) 564–0050; email address: *yellin.patrick@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW., Washington,

DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit: *http://www.epa.gov/dockets.*

Abstract: The affected entities are subject to the General Provisions of the NSPS (40 CFR part 60, subpart A, and any changes, or additions to these Provisions are specified at 40 CFR part 60, subpart NN. Owners or operators of the affected facilities must submit a one-time report of any physical or operational changes, initial performance tests, and periodic reports and results. Owners or operators are also required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. Reports are required semiannually at a minimum.

Form Numbers: None.

Respondents/affected entities: Owners and operators of phosphate rock plants.

Respondent's obligation to respond: Mandatory (40 CFR part 60, subpart NN).

Estimated number of respondents: 15 (total).

Frequency of response: Initially and semiannually.

Total estimated burden: 1,860 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $333,000 (per year), includes $141,000 in both annualized capitalstartup and operation & maintenance costs.

Changes in the Estimates: The adjustment increase in burden from the most recently approved ICR is due to an increase in the number of new sources. This ICR assumes one additional source becomes subject to the regulation over the three-year ICR period. This ICR also uses updated labor rates from the Bureau of Labor Statistics to calculate burden costs.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2017–01275 Filed 1–19–17; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2013–0342; FRL–9956–16–OEI]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; NESHAP for Lime Manufacturing (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency has submitted an information collection request (ICR), ''NESHAP for Lime Manufacturing (40 CFR part 63, subpart AAAAA)'' (EPA ICR No. 2072.06, OMB Control No. 2060–0544), to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). This is a proposed extension of the ICR, which is currently approved through January 31, 2017. Public comments were previously requested via the **Federal Register** (81 FR 26546) on May 3, 2016 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An Agency may neither conduct nor sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before February 22, 2017.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OECA–2013–0342, to: (1) EPA online using *www.regulations.gov* (our preferred method), or by email to *docket.oeca@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460; and (2) OMB via email to *oira_submission@omb.eop.gov.* Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Patrick Yellin, Monitoring, Assistance, and Media Programs Division, Office of Compliance, Mail Code 2227A, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: (202) 564–2970; fax number: (202) 564–0050; email address: *yellin.patrick@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit: *http://www.epa.gov/dockets.*

Abstract: The affected entities are subject to the General Provisions of the NESHAP (40 CFR part 63, subpart A), and any changes, or additions to the General Provisions are specified at 40 CFR part 63, subpart AAAAA. Owners or operators of the affected facilities must submit a one-time-only report of any physical or operational changes, initial performance tests, and periodic reports and results. Owners or operators are also required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. Reports, at a minimum, are required semiannually.

Form Numbers: None.

Respondents/affected entities: Lime manufacturing plants.

Respondent's obligation to respond: Mandatory (40 CFR part 63, subpart AAAAA).

Estimated number of respondents: 68 (total).

Frequency of response: Initially, occasionally, and semiannually.

Total estimated burden: 16,300 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $2,010,000 (per year), includes $325,000 in both annualized capital/startup or operation & maintenance costs.

Changes in the Estimates: There is an adjustment increase in the respondent burden and cost due to an increase in the estimated number of sources subject to the regulation. This ICR assumes an industry growth rate of one respondent per year, which results in an average increase of three respondents since the last ICR renewal period.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2017–01280 Filed 1–19–17; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OW–2006–0369; FRL–9958–67–OW]

Proposed Information Collection Request; Comment Request; National Estuary Program (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency is planning to submit an information collection request (ICR), ''National Estuary Program (Renewal)'' (EPA ICR No. 1500.08, OMB Control No. 2040–0138) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. Before doing so, EPA is soliciting public comments on specific aspects of the proposed information collection as described below. This is a proposed extension of the ICR, which is currently approved through June 30, 2017. 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.

DATES: Comments must be submitted on or before March 24, 2017.

ADDRESSES: Submit your comments, referencing Docket ID No. EPA–HQ–OW–2006–0369, online using *www.regulations.gov* (our preferred method), by email to *OW-Docket@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Vince Bacalan, Oceans and Coastal Protection Division, Office of Wetlands, Oceans, and Watersheds, (Mail Code 4504T), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: 202–566–0930; fax number: 202–566–1336; email address: *bacalan.vince@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Pursuant to section 3506(c)(2)(A) of the PRA, EPA is soliciting comments and information to enable it to: (i) 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; (ii) 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; (iii) enhance the quality, utility, and clarity of the information to be collected; and (iv) 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. EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval. At that time, EPA will issue another **Federal Register** notice to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB.

Abstract: The National Estuary Program (NEP) involves collecting information from the state or local agency or nongovernmental organizations that receive funds under Sec. 320 of the Clean Water Act (CWA). The regulation requiring this information is found at 40 CFR part 35.

Prospective grant recipients seek funding to develop or oversee and coordinate implementation of Comprehensive Conservation Management Plans (CCMPs) for estuaries of national significance. In order to receive funds, grantees must submit an annual workplan to EPA which are used to track performance of each of the 28 estuary programs currently in the NEP. EPA provides funding to NEPs to support long-term implementation of CCMPs if such programs pass a program evaluation process. The primary purpose of the program evaluation process is to help EPA determine whether the 28 programs included in the National Estuary Program (NEP) are making adequate progress implementing their CCMPs and therefore merit continued funding under Sec. 320 of the Clean Water Act. EPA also requests that each of the 28 NEPs receiving Sec. 320 funds report information that can be used in the GPRA reporting process. This reporting is done on an annual basis and is used to show environmental results that are being achieved within the overall National Estuary Program. This information is ultimately submitted to Congress along with GPRA information from other EPA programs.

Form Numbers: None.

Respondents/affected entities: Entities potentially affected by this action are those state or local agencies or nongovernmental organizations in the National Estuary Program (NEP) who receive grants under Section 320 of the Clean Water Act.

Respondent's obligation to respond: Required to obtain or retain a benefit (Section 320 of the Clean Water Act).

Estimated number of respondents: 28 (total).

Frequency of response: Annual.

Total estimated burden: 5,460 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $247,338 (per year), includes $0 annualized capital or operation & maintenance costs.

Changes in Estimates: There will likely be an increase in the total estimated respondent burden compared with the ICR currently approved by OMB. This increase is due to program evaluations taking place in the next three years, compared to only two years in the currently approved ICR. Note that these numbers will be updated in the final FR Notice.

Dated: January 12, 2017.

Marcus Zobrist,

Acting Director, Oceans and Coastal Protection Division.

[FR Doc. 2017–01422 Filed 1–19–17; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[PS Docket No. 16–353; DA16–1282]

Fifth Generation Wireless Network and Device Security

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: In this document, the Commission seeks comment on new security issues that implementation of the fifth generation (5G) wireless network and device security presents to the general public, and on the current state of planning to address these issues. The inquiry, focusing on cybersecurity for 5G, raises fundamental questions about scope and responsibilities for such security. The goal of this proceeding is to begin a conversation on the state of 5G wireless network and device security and to foster a dialogue on the best methods for ensuring that the 5G wireless networks and devices used by service providers in their

operations are secure from the beginning.

DATES: Comments are due on or before April 24, 2017; reply comments are due on or before May 23, 2017.

ADDRESSES: You may submit comments, identified by PS Docket No. 16–353, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions comments.
- *Federal Communications Commission's Web site: http://fjallfoss.fcc.gov/ecfs2/.* Follow the instructions for submitting comments.
- *Mail:* Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.
- *People with Disabilities:* Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by email: *FCC504@fcc.gov* or phone: (202) 418–0530 or TTY: (202) 418–0432.

For detailed instructions for submitting comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: For further information, contact Gregory Intoccia of the Public Safety and Homeland Security Bureau, Communications Cybersecurity and Reliability Division, at (202) 418–1470 or at *Gregory.Intoccia@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Notice of Inquiry,* DA 16–1282, adopted and released on December 16, 2016. The full text is available for public inspection and copying during regular business hours in the FCC Reference Center, Federal Communications Commission, 445 12th Street SW., Room CY–A257, Washington, DC 20554. This document will also be available via ECFS at *http://transition.fcc.gov/Daily_Releases/Daily_Business/2016/db1216/DA-16-1282A1.pdf.* Documents will be available electronically in ASCII, Microsoft Word, and/or Adobe Acrobat. The complete text may be purchased from the Commission's copy contractor, 445 12th Street SW., Roomy CY–B402, Washington, DC 20554. Alternative formats are available for people with disabilities (Braille, large print, electronic files, audio format), by sending an email to *fcc504@fcc.gov* or calling the Commission's Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 481–0432 (TTY).

Synopsis

I. Introduction and Background

1. Fifth generation (5G) wireless technologies represent the next evolutionary step in wireless communications. These networks promise to enable or support a diverse range of new applications, and will provide for a vast array of user requirements, traffic types, and connected devices. 5G communications technology could be particularly useful in enabling the growing number of high-capacity networks necessary for transformative business and consumer services, as well as backhaul, and communications related to the ''Internet of Things'' (IoT) technology.

2. 5G has the potential to be an enormous driver of economic activity. It is a national priority to foster an environment in which 5G can be developed and deployed across the country. That means both ensuring that networks are secure and that the regulatory obligations are measured. The Federal Communications Commission (FCC) has an opportunity at this stage to ensure that these new technologies and networks are secure by design. Therefore, while the FCC is moving quickly to make the spectrum needed for 5G available in the near term, it is also seeking to accelerate the dialogue around the critical importance of the early incorporation of cybersecurity protections in 5G networks, services, and devices.

3. In its July 2016 *Spectrum Frontiers Report and Order,* the FCC reiterated its view that communications providers are generally in the best position to evaluate and address security risks to network operations. Toward this end, the FCC adopted a rule requiring Upper Microwave Flexible Use Service licensees to submit general statements of their network security plans. The statements are designed to encourage licensees to consider security in their new 5G networks. The Public Safety and Homeland Security Bureau (PSHSB) issues this Notice of Inquiry (NOI) to seek input on the new issues raised by 5G security in order to foster dialogue between relevant standards bodies and prospective 5G providers on the best methods for ensuring that networks and devices are secure from the beginning.

4. PSHSB intends this inquiry to complement the important work on cybersecurity that is already taking place within the government and private sector. The FCC, these other groups, and the wireless industry all have a significant interest in ensuring that these new networks consider security risk and mitigation techniques from the outset. This NOI, and the record it seeks to develop, will help in that effort.

5. PSHSB recognizes that the inquiry, focusing on cybersecurity for 5G, raises fundamental questions relative to scope and responsibilities. Security of network infrastructure, such as protecting software and hardware that are essential to signaling and control of Radio Access Networks and to ensure the proper operation of the network, creates one perspective. Another perspective, however, is the end-to-end security of both the network and the devices that connect to commercial network services. Devices and other network elements may be furnished by the service provider, third parties, and consumers themselves. Who should be responsible for cyber protections for a device, or should responsibility be shared in some recognizable manner across the 5G ecosystem? PSHSB also appreciates that 5G is not apt to be a separate network, but rather will be integrated with existing previous generation networks, perhaps indefinitely. Do questions about the cyber protections of 5G networks inherently implicate the other networks associated with them? Where should the lines between networks be drawn relative to responsibility for 5G cybersecurity?

II. Inquiry

6. This NOI looks holistically at the security implications arising through the provision of a wide variety of services to various market sectors and users in the future 5G network environment. The NOI also explores 5G security threats, solutions, and best practices. As used in this NOI, ''security'' and ''information security'' refer to protecting data, networks, and systems from unauthorized access, use, disclosure, disruption, modification, or destruction, in order to protect confidentiality, integrity, and availability with respect to such networks, systems, and defined user communities. The terms ''confidentiality,'' ''integrity,'' and ''availability,'' or ''CIA,'' are meant to refer to those three interrelated, and dynamic principles (''that collectively guide security practices and illustrate the various considerations that must be applied when developing a security posture for communications technologies and services. Confidentiality'' refers to protecting data from unauthorized access and

disclosure. ''Integrity'' refers to protecting data from unauthorized modification or destruction, both at rest and in transit. Finally, ''availability'' refers to whether a network provides timely, reliable access to data and information services for authorized users. All three of these principles are fundamental to any security framework and are dynamically interrelated, and thus no particular principle should be addressed in isolation if 5G security is to be achieved.

7. As an initial matter, the NOI seeks to understand the current state of security planning for 5G networks. Please comment on the current efforts across industry to study 5G security, develop security protocols and solutions, and triage 5G security issues when they arise. How are equipment developers considering security in the design of 5G equipment? How are service providers considering security in the planning of 5G networks and ensuring end-to-end security where 5G technology is integrated with prior generation technology in heterogeneous networks? How can the FCC support and enhance this work? What known vulnerabilities require increased study? How should 5G differ in terms of cybersecurity needs from its widely-deployed predecessor generation, 4G LTE? What cybersecurity lessons can be learned from 4G deployment and operational experience that are applicable to the 5G security environment? What should be different, if anything, between LTE pre-5G deployment and post-5G deployment?

8. The Commission encourages commenters to consider this common thread throughout the NOI: how can the FCC, working together with other stakeholders, ensure the rapid deployment of secure 5G networks, services, and technologies?

A. Protecting Confidentiality, Integrity, and Availability

9. The FCC seeks to promote 5G security through a ''security-by-design'' approach to 5G development. The NOI seeks comment on the premise that, by utilizing the ''confidentiality,'' ''integrity,'' and ''availability'' (CIA) principles, a firm may avoid or mitigate 5G network and device data security risk through strong, adaptive, protections against unauthorized use, disclosure, and access. What are the benefits and limitation of a security-by-design approach and of employing CIA principles?

10. Please comment on how the CIA principles are being considered for 5G networks, systems, and devices. In particular, the NOI examines below how CIA principles are being taken into consideration with respect to authentication, encryption, physical security, device security, protecting 5G networks from cyber attacks, patch management, and risk segmentation of networks. This is a non-exclusive list, and comment is requested on other areas that are potential vulnerabilities for 5G.

1. Authentication

11. Preserving the confidentiality and integrity of networks, systems, and data depends on limiting access to authorized users. This is typically accomplished through effective, and sometimes mutual, authentication. Mutual authentication generally requires that both entities involved in a transaction verify each other's identity at the same time. The NOI seeks comment on the use of authentication in networks today and whether existing authentication practices will be applicable to the 5G environment. The NOI further seeks comment on the effective use of mutual authentication, in particular, for protecting 5G networks against unauthorized access and end-user devices against attaching to malicious network components, as well as the perceived limitations and drawbacks of those uses. Are there specific considerations that would apply to 5G devices? Under what circumstances would mutual authentication be considered essential to ensure or bolster security? Are there any circumstances where mutual authentication would not be beneficial? If a communications provider did not invest in mutual authentication, how would that likely affect its relative overall security risk? What other authentications methodologies might be effective for 5G security? Would the mass deployment of high-volume, low-cost 5G devices in IoT networks present particular authentication challenges? How can providers effectively authenticate the communications of high-volume, low-cost 5G devices—device to device, device to network, and network to device? How can providers effectively address these challenges? Would it be appropriate for 5G architects to consider identity credentialing and access management, in addition to authentication?

2. Encryption

12. Encryption can be an important aspect of protecting confidentiality, integrity and availability in communications environments. The NOI seeks comment on the planned deployment and use of encryption to promote 5G security, as well as on the perceived challenges, costs, and benefits of encryption at both the network and device levels.

13. Please comment on whether currently available encryption protocols are effective in securing devices and are likely to be effective in a 5G environment in which innumerable, low-cost devices are expected to operate, as well as ways that 5G participants can address encryption key management and distribution mechanism challenges. Additionally comment is requested on stakeholder responsibilities with respect to objective encryption key management for 5G.

14. Please also comment on whether encryption is necessary for all 5G communications, and whether the decisions made by the 3rd Generation Partnership Project (3GPP) standards body that resulted in non-encryption for such systems are rooted in increased latency, degraded performance due to added signaling or computational requirements, an interest in minimizing changes to LTE standards as 5G is standardized, or other factors. Please comment on what lessons, if any, can be learned from the underlying rationale of these decisions as they pertain to encryption for 5G communications.

15. Finally, the NOI seeks comment on whether 5G service providers should distinguish between the application of encryption to products that would operate primarily on the 5G control plane and those that would be part of the user plane. If such a distinction is desirable, how should such a distinction be made?

3. Physical Security

16. Physical security aims to protect networks and critical components of end-user devices, even where those devices are in the possession of unauthorized users. Please comment on physical security objectives and needs in the 5G environment, and on any other considerations the FCC should take into account in its examination of physical security of 5G networks and devices.

17. What device- and network-based physical security methods would be most effective if applied to 5G devices? To what extent does lack of physical security pose a threat to, or introduce risk from unsupervised 5G devices? To what extent does lack of physical security pose a threat to, or introduce risk from unsupervised 5G devices? Will the 5G environment present any new or unique challenges? What other issues and factors should the FCC consider on the question of preserving confidentiality, integrity and availability through physical security?

18. What aspects or uses of 5G networks should be considered ''mission critical'' and, as such, do they warrant special consideration with respect to physical security? What ''mission critical'' activities distinguish these networks and how can they be physically secured in the 5G environment? Should certain 5G networks be physically diverse at the network level as a result of the ''mission-critical'' aspects they support or enable? If so, how should that diversity be achieved?

4. Device Security

19. Ensuring the provision of confidentiality, integrity, and availability requires that devices are secure and capable of authenticating on the network. What methodologies will be used to protect the variety of devices connected to 5G networks? Is current SIM technology robust enough to ensure security without posing threats to consumers, service providers, or the underlying infrastructure? Will SIM technology be leveraged for 5G? Do standards for next generation SIM cards effectively address security and integrity concerns? What new security benefits or challenges are created by the use of eSIMs? Are there non-SIM methods that should be considered for high-volume, low-cost devices, and if so, are standards bodies currently developing standards for such methods? What other issues and factors should the FCC consider on the question of preserving CIA through device security?

5. Protecting 5G Networks From DoS and DDoS Attacks

20. A security exploit that targets network resources, such as a Denial-of-Service (DoS) or Distributed Denial of Service (DDoS) attack, could have an impact on availability of service by causing a total or partial disruption of service. The NOI seeks comment and supporting data on the mechanisms most likely to be effective at preserving confidentiality, integrity and availability through mitigation of DoS and DDoS attack risks in the planned 5G environment, including techniques for protecting both the network control and data planes. Which methods of defense against DoS and DDoS attacks are the most cost-effective?

21. Please comment on whether additional standards are needed to assist in mitigating DoS and DDoS attacks. What anti-spoofing technologies are most likely to be effective in the 5G environment, and what are the challenges to their deployment?

6. Patch Management

22. For more than a decade, communications security authorities and expert bodies, such as the FCC's Federal Advisory Committee for communications security policy development The FCC seeks comment and supporting data on patch management's role as part of a service provider's overall security risk management strategy in the 5G environment.

23. Please also comment on which 5G network elements can be successfully maintained by service providers through patch management. There are generally four types of patches that are pushed to devices with service provider involvement: (1) Patches from service providers to their own infrastructure; (2) patches service providers require and push on to subscriber devices; (3) patches to third-party infrastructure that are leased by service providers but owned by a third party; (4) patches to subscriber devices that are sent by device manufactures under the direction of service providers. For each type of patch, please comment on processes that service providers and mobile device manufacturers should adopt to sustain an effective patch management program in the 5G environment. How do service providers and mobile device manufacturers routinely make themselves aware of new vulnerabilities that need to be patched? How soon after a vulnerability is discovered is the corresponding patch pushed to devices? What other mechanisms might preclude unauthenticated code from running on 5G devices that are connected to their networks?

24. Please comment on how 5G service providers and equipment manufacturers can ensure that critical security software updates are installed on their subscriber devices in a timely fashion. How can 5G service providers effectively ensure firmware and software patch management related to security through their customer relationships? How common is it for manufacturers or service providers to rely on consumers to become aware of and install patches to their software and/or hardware? What do 5G service providers plan to do to help ensure that a subscriber's devices remain ''patchable'' and/or ''discoverable'' for purposes of device updates? How can consumers determine whether an older device or service, no longer being sold at retail, is still receiving security-related patches and whether it is still safe to use?

25. Finally, please comment on whether relevant standards have been produced that present a common approach, or describe a best practice, to facilitate patch management procedures that can be applied regardless of the underlying device operating system in a 5G ecosystem. In the absence of any deployed standard, should this effort be explored, and if so, which standards body or forum would be the best candidate to address this issue? What other issues and factors should the FCC consider on the question of preserving CIA through patch management?

7. Risk Segmentation

26. Risk segmentation involves splitting network elements into separate components to help isolate security breaches and minimize overall risk. Risk segmentation or network slicing might allow greater resiliency, more effective cyber threat monitoring and analysis and stronger security for network service supporting critical infrastructure communications (to include ICS and SCADA). Please comment on the use of segmentation in 5G networks and how segmentation can reduce risk in such networks.

27. Please provide comments and supporting data on ways that segmentation could be achieved throughout the 5G ecosystem to ensure service providers have greater situational awareness and ability to respond to, and contain, security threats. What lessons have service providers and other enterprises learned about the application of segmentation in older networks that can be applied to 5G networks? To what extent can service providers use network segmentation technologies, such as a virtual private network (VPN) or other cryptographic separation, to help ensure that no device operating on their network's control plane is directly and immediately accessible via the Internet? Could VPNs or a similar mechanism be scaled in such a way that 5G providers could implement segmentation across their entire ecosystem? Please comment on the technologies used for network segmentation, and on how to ensure that future networks employing these new architectures use security-by-design principles to minimize security risk.

28. Should segmentation in the 5G environment be based on geography or region, on type of function or device, or by community of interest? To what extent are service providers segmenting physical, logical and virtual risks? Please comment on what 5G service providers plan to do to establish logical and physical separation of different bands and/or receive antennas in order to improve integrated device security.

29. Please comment on whether certain network elements or activities merit special consideration with respect to risk segmentation. To what extent are such segmentation strategies effective in reducing security risk?

30. Risk segmentation can also be applied to devices in terms of firmware, software, and data. In some cases, configuration data may be set as read-only by the device, but can only be changed by the service provider. Please comment on whether privacy features and requirements have been standardized in organizations like 3GPP (and to what extent they will be standardized for 5G) to support confidentiality and integrity of information. What other issues and factors should the FCC consider on the question of preserving CIA through segmentation?

31. Finally, with respect to each of the topics discussed above, the FCC seeks information regarding which standards bodies are involved and the state of standards development to protect CIA in the 5G environment. Is there a need for additional standards body involvement?

B. Additional 5G Security Considerations

1. Overview

32. It is widely expected that 5G networks will be used to connect the myriad devices, sensors and other elements that will form the Internet of Things (IoT). The anticipated diversity and complexity of these networks, how they interconnect, and the sheer number of discrete elements they will comprise raise concerns about the effective management of cyber threats. How can holistic security objectives for 5G be established? What roles can service providers and device manufacturers play to reduce security risk for various communities of interest? How should service providers, device manufacturers, standards bodies and the FCC coordinate their efforts? Are there particular standards being developed for 5G IoT applications? Finally, please comment on benefits and costs associated with effective hardware, firmware, software, and application security for 5G.

33. Please provide comments on the extent to which IoT devices could place 5G networks at unique risk. For example, are there particular vulnerabilities that arise from, or are increased by, the fact that 5G communications have relatively short range and rely on multiple access points? It is possible that some of IoT devices will have limited security features. Could this have a negative effect on overall 5G network security? If so, what roles can network equipment providers, ISPs and device manufacturers play, by themselves and in coordination, to mitigate the risks? Are any lessons being learned from the October 2016 DDoS attacks relevant to 5G? Where risk externalities exist? How will the 5G marketplace address cybersecurity risk in the commons?

34. Please comment on whether and how security needs for 5G IoT devices might differ from other infrastructures, including, in particular, each of the critical infrastructure sectors. What expectations would various critical infrastructure sectors likely have for the security capabilities and features of 5G services? Does the government have a role where residual risk unduly threatens critical infrastructure or national security, and if so, what should it be?

35. Given the likely unprecedented diversity of connected devices and their manufacturers, comment is sought on whether 5G security could be challenged by hardware issues, including threats from a compromised supply chain. How are service providers and equipment manufacturers currently assessing supply chain risks? Are they assessing risks consistent with NIST guidelines? The FCC seeks comment on whether, and if so, how 5G service providers should ensure the provenance of the hardware, firmware, software, and applications operating in their environments. What special considerations, if any, should be applied relative to 5G supply chain risks?

36. Please comment on benefits and costs associated with effective hardware, firmware, software, and application security for 5G. What are the costs associated with updating existing hardware, firmware, software, and applications versus the costs of adding entirely new elements for a totally new security posture? Is there a role for 5G-specific third party security entities? Do benefits and costs vary depending on the use of open-source software compared to proprietary software? What are the costs of adding security-specific features to 5G network hardware, firmware, software and applications? Are there scale economies observed across local, regional, and nationwide 5G networks? Finally, what other issues or factors should the FCC consider with respect to the preservation of confidentiality, integrity and availability in the 5G environment?

2. Roles and Responsibilities

37. Because of the anticipated proliferation of 5G networks and the devices that will be deployed on them, there is a chance that the cyber integrity of the network as a whole could be overlooked on the assumption that another network participant would be responsible. Is this a valid concern? Please provide comments on who should be responsible for assuring cyber security across the 5G ecosystem, what principles should guide the management of cyber risk, and how cyber risk should be managed within companies. How should providers work together across the 5G ecosystem to achieve desirable outcomes in cyber risk management?

38. Relatedly, please provide information on how the 5G ecosystem will share information about cyber threats and concerns. Please comment on whether an Information Sharing and Analysis Organization (ISAO) construct could be or should be applied to the 5G ecosystem. Would it be appropriate to develop a 5G-specific ISAO? Should 5G networks be instrumented to support automated cybersecurity threat indicators and network anomaly information sharing and analysis? Is an ISAO or multiple ISAOs the right focal point for automated cyber information sharing and analysis? Should it address IoT concerns more broadly or focus on network-based considerations? Who should be involved? Should work of ISAOs dealing with related topics be formally coordinated? If so, how? What are the proper roles of standards bodies, advisory committees such as the North American Numbering Council (NANC), industry authorities, numbering and data services and the FCC?

39. The NIST Framework for Improving Critical Infrastructure Cybersecurity Framework (NIST CSF) has been voluntarily used by members of the critical infrastructure community, including the communications sector, for several years to help manage cybersecurity risk. Please comment on whether, and if so how, the NIST CSF can be used to manage risk for 5G service providers and networks. The NIST CSF includes several top level organizational functions that can be performed concurrently and continuously to form an operational culture that addresses dynamic security risk, namely, Identify, Detect, Protect, Respond, and Recover (IPDRR). Please comment on unique factors with respect to these functions that should guide 5G design, standards development and operations.

3. Other Considerations

40. Are there additional functions that should be considered in the 5G environment? How should addressing

and naming be accommodated for 5G? Are stakeholders working to evolve any of today's numbering schemas to encompass 5G? What practical steps should 5G planners take in order to ensure that the functions discussed in this NOI, and any other relevant functions, are properly considered and implemented within their respective organizations?

4. Benefits and Costs

41. Please comment on the public harm expected to result from failure to integrate confidentiality, integrity and availability into 5G networks through authentication, encryption, physical and device security, protecting against DoS attacks, patch management and risk segmentation. Could failure to implement these measures decrease broadband adoption and detract from its productive economic use? Could it reduce the risk of loss of competitively sensitive information for businesses? Could it prevent the loss of consumers' personally identifiable information? Could it play a role in preventing the unnecessary loss of life or property by, for example, preventing malicious intrusion into critical infrastructure? How should the FCC quantify these benefits in terms of their economic impact? What other benefits would likely stem from an appropriately secure 5G network?

42. Please comment on the costs associated with the implementation of the measures discussed above as investments early in the design and build plans of networks, as opposed to ''bolt-on'' security after deployment. Are there opportunities for 5G implementation that would only be realized if networks are perceived to be secure? Are there some security elements that, by plan, should be ''just in time'' or reactive investments, based on realized threats, after 5G implementation? Would these costs include those associated with updating existing hardware, firmware, software, and applications? How would the costs of system updates compare to the costs of adding entirely new elements for a totally new security posture? Do benefits and costs vary depending on the use of open-source software compared to proprietary software? If so, to what extent are open-source solutions available that could reduce costs? Are there scale economies observed across local, regional and nationwide 5G networks? Please comment on specific costs associated with authentication, encryption, physical and device security, protecting against DDoS attacks, patch management and risk segmentation in the 5G environment.

C. 5G Implications for Public Safety

43. Many public safety services and technologies are undergoing radical change as underlying networks transition from legacy to IP-based modes. Will any new categories of public safety sensors or other machine-based tools become an included part of 5G public safety communications architecture? The development of 5G networks will potentially contribute new capabilities to these IP-based public safety platforms while also creating new challenges, including security challenges, for public safety entities.

44. Please comment on the security implications of linking or integrating 5G networks with IP-based public safety communications platforms. Could this create new security risks or vulnerabilities for NG911, first responder communications, or emergency alerting? What responsibility should 5G service providers have for mitigating and managing these risks? Conversely, could 5G networks help reduce security risks that public safety faces in migrating from legacy to IP-based technologies? Could 5G services support ICAM in a manner that reduces these security risks? Should public safety anticipate a need for unmanned, unattended device ICAM? Are there special considerations for standards development for public safety services and technologies for 5G, and if so, are standards bodies addressing these issues? Is there a need for additional standards body involvement?

III. Procedural Matters

A. Ex Parte Rules

45. This proceeding shall be treated as a ''permit-but-disclose'' proceeding in accordance with the Commission's *ex parte* rules. Persons making *ex parte* presentations must file a copy of any written presentation or a memorandum summarizing any oral presentation within two business days after the presentation (unless a different deadline applicable to the Sunshine period applies). Persons making oral *ex parte* presentations are reminded that memoranda summarizing the presentation must (1) list all persons attending or otherwise participating in the meeting at which the *ex parte* presentation was made, and (2) summarize all data presented and arguments made during the presentation. If the presentation consisted in whole or in part of the presentation of data or arguments already reflected in the presenter's written comments, memoranda or other filings in the proceeding, the presenter may provide citations to such data or arguments in his or her prior comments, memoranda, or other filings (specifying the relevant page and/or paragraph numbers where such data or arguments can be found) in lieu of summarizing them in the memorandum. Documents shown or given to Commission staff during *ex parte* meetings are deemed to be written *ex parte* presentations and must be filed consistent with rule 1.1206(b). In proceedings governed by rule 1.49(f) or for which the Commission has made available a method of electronic filing, written *ex parte* presentations and memoranda summarizing oral *ex parte* presentations, and all attachments thereto, must be filed through the electronic comment filing system available for that proceeding, and must be filed in their native format (*e.g.,* .doc, .xml, .ppt, searchable .pdf). Participants in this proceeding should familiarize themselves with the Commission's *ex parte* rules.

Federal Communications Commission.

David Grey Simpson,

Chief, Public Safety & Homeland Security Bureau.

[FR Doc. 2017–01325 Filed 1–19–17; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Sunshine Act Meeting

Pursuant to the provisions of the ''Government in the Sunshine Act'' (5 U.S.C. 552b), notice is hereby given that at 10:01 a.m. on Wednesday, January 18, 2017, the Board of Directors of the Federal Deposit Insurance Corporation met in closed session to consider matters related to the Corporation's supervision, corporate, and resolution activities.

In calling the meeting, the Board determined, on motion of Vice Chairman Thomas M. Hoenig, seconded by Director Thomas J. Curry (Comptroller of the Currency), concurred in by Director Richard Cordray (Director, Consumer Financial Protection Bureau), and Chairman Martin J. Gruenberg, that Corporation business required its consideration of the matters which were to be the subject of this meeting on less than seven days' notice to the public; that no earlier notice of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting by authority of

subsections (c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), and (c)(9)(B) of the ''Government in the Sunshine Act'' (5 U.S.C. 552b(c)(4), (c)(6), (c)(8), (c)(9)(A)(ii) and (c)(9)(B).

Dated: January 18, 2017.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2017–01523 Filed 1–18–17; 4:15 pm]

BILLING CODE P

FEDERAL ELECTION COMMISSION

Sunshine Act Meetings

AGENCY: Federal Election Commission

DATE AND TIME: Wednesday, January 25, 2017 at 11:00 a.m.

PLACE: 999 E Street NW., Washington, DC (Ninth Floor).

STATUS: This meeting will be open to the public.

ITEMS TO BE DISCUSSED:

Correction and Approval of Minutes for December 1, 2016
Draft Advisory Opinion 2016–26: Green Party of Florida
Draft Advisory Opinion 2016–25: Mike Pence for Indiana
Management and Administrative Matters

Individuals who plan to attend and require special assistance, such as sign language interpretation or other reasonable accommodations, should contact Dayna C. Brown, Acting Secretary and Clerk, at (202) 694–1040, at least 72 hours prior to the meeting date.

PERSON TO CONTACT FOR INFORMATION: Judith Ingram, Press Officer, Telephone: (202) 694–1220.

Dayna C. Brown,

Acting Secretary and Clerk of the Commission.

[FR Doc. 2017–01576 Filed 1–18–17; 4:15 pm]

BILLING CODE 6715–01–P

FEDERAL RETIREMENT THRIFT INVESTMENT BOARD

Sunshine Act; Notice of Meeting

AGENDA Federal Retirement Thrift Investment Board Member Meeting, 77 K Street NE., 10th Floor Board Meeting Room, Washington, DC 20002, January 23, 2017, In-Person, 8:30 a.m.

OPEN SESSION

1. Approval of the minutes for the December 19, 2016 Board Member Meeting
2. Monthly Reports
   (a) Participant Activity Report
   (b) Legislative Report
3. Quarterly Reports
   (c) Investment Policy
   (d) Budget Review
4. Annual Expense Ratio Review
5. Blended Retirement Update

CLOSED SESSION

Information covered under 5 U.S.C. 552b(c)(4) and (c)(9)(B).

ADJOURN

CONTACT PERSON FOR MORE INFORMATION: Kimberly Weaver, Director, Office of External Affairs, (202) 942–1640.

Dated: January 17, 2017.

Megan Grumbine,

General Counsel, Federal Retirement Thrift Investment Board.

[FR Doc. 2017–01505 Filed 1–18–17; 11:15 am]

BILLING CODE 6760–01–P

GENERAL SERVICES ADMINISTRATION

[Notice-PBS–2016–02; Docket No. 2016–0002; Sequence No. 27]

Notice of Intent To Prepare an Environmental Impact Statement for the Proposed Department of Labor Headquarters Consolidation and Exchange of the Frances Perkins Building

AGENCY: Public Building Service (PBS), General Services Administration (GSA).

ACTION: Notice of intent to prepare an environmental impact statement and public meeting.

SUMMARY: Pursuant to the requirements of the National Environmental Policy Act of 1969 (NEPA), GSA plans to prepare an Environmental Impact Statement (EIS) for the proposed Department of Labor Headquarters (DOL HQ) Consolidation to guide the evaluation of alternatives for a new permanent location for the DOL HQ, and to look at the impacts from the exchange of the Frances Perkins Building. GSA also will be initiating related consultation under Section 106 of the National Historic Preservation Act (NHPA) for the project.

DATES: *Effective:* January 23, 2017.

The public scoping meeting dates and location addresses are:

1. *NoMa Site:* Tuesday, February 7, 2017 from 6:30 p.m. until 8:30 p.m. Eastern Standard Time. Address: 1200 First Street NE., Washington, DC 20402.

2. *Capitol Riverfront and Poplar Point Sites:* Wednesday, February 8, 2017 from 6:30 p.m. until 8:30 p.m. Eastern Standard Time. Address: Southwest Neighborhood Library, 900 Wesley Place SW., Washington, DC 20024.

3. *Frances Perkins Building location:* Thursday, February 9, 2017 from 6:30 p.m. until 8:30 p.m. eastern standard time. Address: Martin Luther King Jr. Memorial Library, 901 G Street NW., Washington, DC 20001.

FOR FURTHER INFORMATION CONTACT: Alexis Gray, NEPA Compliance Specialist, GSA, National Capital Region, at 202–260–6895. Also, please call this number if special assistance is needed to attend and participate in the scoping meeting.

SUPPLEMENTARY INFORMATION: Pursuant to the requirements of the National Environmental Policy Act of 1969 (NEPA), 42 United States Code (U.S.C.) 4321–4347; the Council on Environmental Quality Regulations (Code of Federal Regulations (CFR), Title 40, chapter V, parts 1500–1508); and the GSA Public Buildings Service NEPA Desk Guide, dated October 1999, GSA plans to prepare an Environmental Impact Statement (EIS) for the proposed DOL HQ Consolidation to guide the evaluation of alternatives for a new permanent location for the DOL HQ. GSA also will be initiating related consultation under Section 106 of the National Historic Preservation Act (NHPA), 36 CFR part 800 (Protection of Historic Properties) for the project.

GSA intends to prepare an EIS to analyze the potential impacts resulting from the proposed action, which encompasses two parts: (1) Acquisition of a consolidated DOL HQ at a new permanent location; and (2) exchange of the Frances Perkins Building parcel.

Background

The purpose of the proposed action is to: (1) Consolidate the existing DOL HQ offices and divisions into one location in Washington, DC; and (2) provide the DOL with a headquarters facility that meets the Interagency Security Council (ISC) Level III security standards.

A consolidated DOL HQ is needed to consolidate approximately 4,400 DOL personnel currently scattered in both federally-owned and leased locations into one federally-owned building. Currently, the Frances Perkins building is outdated with inefficient floor plates and support spaces that impede more than aid the agency in performing its missions. In addition to the age of the property and the building's inefficiencies, there are significant costs for repair and replacement of major building systems.

GSA is the lead agency for the DOL HQ consolidation and exchange of Frances Perkins, and associated NEPA and NHPA compliance. DOL and the National Capital Planning Commission

are cooperating agencies for NEPA and signatories for NHPA.

Frances Perkins Building Exchange

The new DOL HQ would be built by a developer, on one of the acceptable sites identified by GSA and DOL through a site selection process that concluded with an announcement of shortlisted sites on November 29, 2016. Following construction of the new DOL HQ and acceptance of the DOL HQ by GSA, the title to Frances Perkins will be transferred to the developer to offset the cost of the new DOL HQ.

Alternatives Under Consideration

As part of the EIS, GSA will study the impacts of developing approximately 1 million rentable square feet consolidated DOL HQ on three site alternatives. These sites are:

- Site 1 NoMa—this site is located at the intersection of North Capitol Street and New York Avenue in the Northeast quadrant of Washington, DC.
- Site 2 Capitol Riverfront—this site is located at the intersection of M Street and South Capitol Street in the Southwest quadrant of Washington, DC.
- Site 3 Poplar Point—this site is located in Anacostia and bordered by interstate 295, Howard Road and Suitland Parkway in the Southeast quadrant of Washington, DC.

Additionally, GSA will study potential indirect impacts related to the exchange of the Frances Perkins parcel. GSA also will evaluate a ''No Action Alternative'', in which DOL would remain in its current locations without consolidation at a new permanent location.

Resource areas to be addressed in the EIS will include, but not be limited to: air quality, noise, land use, socioeconomics, traffic and transportation, infrastructure and community services, natural resources, biological resources, cultural resources, and safety and environmental hazards. The analysis will evaluate direct, indirect, and cumulative impacts. Relevant and reasonable measures that could avoid or mitigate environmental effects will also be analyzed. In conjunction with the NEPA process, GSA will undertake any consultations required by applicable laws or regulations, including NHPA.

Scoping Process

In accordance with NEPA, a scoping process will be conducted to: (1) Aid in determining the alternatives to be considered and the scope of issues to be addressed; and (2) identify the significant environmental issues related to the proposed DOL HQ consolidation that should be addressed during the preparation of the Draft EIS. Scoping will be accomplished through a series of public scoping meetings; mail and email correspondence to potentially interested persons, agencies, and organizations; social media and other web-based communications; and meetings with agencies having an interest in the DOL HQ consolidation. GSA is also using the NEPA scoping process to facilitate consultation with the public under Section 106 of the NHPA (36 CFR part 800). GSA welcomes comments from the public to ensure that the agency takes into account the effects of the proposed action on historic and cultural resources.

GSA will publish announcement notices in the Washington Post and the Washington Business Journal approximately one to two weeks prior to the public scoping meetings. After receiving scoping comments, GSA will respond to them in the EIS and through the Section 106 consultation process. GSA will make available to the public a comment/response matrix summarizing the scoping and Section 106 comments in the Draft and Final EIS.

Written Comments: Agencies and the public are encouraged to provide written comments on the scoping issues related to the EIS for the proposed DOL HQ consolidation in addition to, or in lieu of, providing comments at the public scoping meeting. Written comments must be postmarked no later than March 1, 2017, and sent to the General Services Administration, Attention: Alexis Gray, NEPA Compliance Specialist, 301 7th Street SW., Room 4004, Washington, DC 20407. Email: *alexis.gray@gsa.gov* using the subject line: DOL NEPA Scoping Comment. Comments may also be submitted via the Web site: *www.gsa.gov/dolhqexchange.*

Dated: January 13, 2017.

Mina Wright,

Director, Office of Planning and Design Quality, National Capital Region, Public Buildings Service, General Services Administration.

[FR Doc. 2017–01380 Filed 1–19–17; 8:45 am]

BILLING CODE 6820–Y1–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Safety and Occupational Health Study Section (SOHSS), National Institute for Occupational Safety and Health (NIOSH or Institute)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following committee meetings.

Times and Dates:

8:00 a.m.–5:00 p.m., EST, February 14, 2017 (Closed).

8:00 a.m.–5:00 p.m., EST, February 15, 2017 (Closed).

8:00 a.m.–5:00 p.m., EST, February 16, 2017 (Closed).

Place: Embassy Suites, 1900 Diagonal Road, Alexandria, Virginia 22314, Telephone: 703–684–5900, Fax: 703–684–0653.

Purpose: The Safety and Occupational Health Study Section will review, discuss, and evaluate grant application(s) received in response to the Institute's standard grants review and funding cycles pertaining to research issues in occupational safety and health, and allied areas.

It is the intent of NIOSH to support broad-based research endeavors in keeping with the Institute's program goals. This will lead to improved understanding and appreciation for the magnitude of the aggregate health burden associated with occupational injuries and illnesses, as well as to support more focused research projects, which will lead to improvements in the delivery of occupational safety and health services, and the prevention of work-related injury and illness. It is anticipated that research funded will promote these program goals.

Matters for Dicussion: The meeting will convene to address matters related to the conduct of Study Section business and for the study section to consider safety and occupational health-related grant applications.

These portions of the meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, Centers for Disease Control and Prevention, pursuant to Section 10(d) Public Law 92–463.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Price Connor, Ph.D., NIOSH Health

Scientist, CDC, 2400 Executive Parkway, Mailstop E–20, Atlanta, Georgia 30345; Telephone: 404–498–2511; Fax: 404–498–2571.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2017–01403 Filed 1–19–17; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, National Center for Health Statistics: Notice of Charter Renewal

This gives notice under the Federal Advisory Committee Act (Pub. L. 92–463) of October 6, 1972, that the Board of Scientific Counselors, National Center for Health Statistics, Department of Health and Human Services, has been renewed for a 2-year period through January 19, 2019.

For information, contact Virginia Cain, Ph.D., Designated Federal Officer, Board of Scientific Counselors, National Center for Health Statistics, Department of Health and Human Services, 3311 Toledo Road, Room 2627, Mailstop P08, Hyattsville, Maryland 20782, telephone 301/458–4395 or fax 301/458–4020.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 2017–01402 Filed 1–19–17; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–R–262]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by February 22, 2017.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–5806 *OR*, Email: *OIRA_submission@omb.eop.gov.*

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786–1326.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Contract Year 2018 Plan Benefit Package (PBP) Software and Formulary Submission; *Use:* We require that Medicare Advantage and Prescription Drug Plan organizations submit a completed PBP and formulary as part of the annual bidding process. During this process, organizations prepare their proposed plan benefit packages for the upcoming contract year and submit them to us for review and approval. We publish beneficiary education information using a variety of formats. The specific education initiatives that utilize PBP and formulary data include web application tools on *www.medicare.gov* and the plan benefit insert in the Medicare & You handbook. In addition, organizations utilize the PBP data to generate their Summary of Benefits marketing information. *Form Number:* CMS–R–262 (OMB control number 0938–0763); *Frequency:* Yearly; *Affected Public:* Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 524; *Total Annual Responses:* 5,185; *Total Annual Hours:* 50,619. (For policy questions regarding this collection contact Kristy Holtje at 410–786–2209.)

Dated: January 17, 2017.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2017–01378 Filed 1–19–17; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[CFDA Numbers: 93.581, 93.587, 93.612]

Request for Public Comment on the Proposed Adoption of Administration for Native Americans Program Policies and Procedures

AGENCY: Administration for Native Americans, ACF, HHS.

ACTION: Notice for public comment.

SUMMARY: Pursuant to Section 814 of the Native American Programs Act of 1974 (NAPA), as amended, the Administration for Native Americans (ANA) is required to provide members of the public an opportunity to comment on proposed changes in interpretive rules and general statements of policy and to give notice of the final adoption of such changes no less than 30 days before such changes become effective. In accordance with notice requirements of NAPA, ANA herein describes proposed interpretive rules and general statements of policy that relate to ANA's funding opportunities beginning in fiscal year (FY) 2017 related to the following programs: Environmental Regulatory Enhancement (HHS–2017–ACF–ANA–NR–1221), Sustainable Employment and Economic Development Strategies (HHS–2017–ACF–ANA–NE–1225), Native American Language Preservation and Maintenance-Esther Martinez Immersion (HHS–2017–ACF–ANA–NB–1226), Native American Language Preservation and Maintenance (HHS–2017–ACF–ANA–NL–1235), Social and Economic Development Strategies (HHS–2017–ACF–ANA–NA–1236), and Economic Development Strategies-Alaska (HHS–2015–ACF–ANA–NK–0960), and Native Youth Initiative for Leadership, Empowerment, and Development (HHS–2017–ACF–ANA–NC–1263). This notice of public comment also provides additional information about ANA's plan for administering grant programs.

DATES: The deadline for receipt of comments is 30 days from the date of publication in the **Federal Register**. No Funding Opportunity Announcement (FOA) will be published prior to 30 days from publication of this Notice.

ADDRESSES: Comments in response to this notice should be addressed to Camille Loya, Director of Policy, Administration for Native Americans, 330 C Street SW., Washington, DC 20201. Delays may occur in mail delivery to federal offices; therefore, a copy of comments should be emailed to *ANAComments@acf.hhs.gov.* Comments will be available for inspection by members of the public at the Administration for Native Americans, 330 C Street SW., Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Camille Loya, Director, Division of Policy, Administration for Native Americans, (877) 922–9262.

SUPPLEMENTARY INFORMATION: Section 814 of NAPA, as amended, incorporates provisions of the Administrative Procedure Act that require ANA to provide notice of its proposed interpretive rules and statements of policy and to seek public comment on such proposals. ANA has also decided to provide notice and seek comments on proposed new rules of agency organization, procedure, or practice. The proposed interpretive rules, statements of policy, and rules of ANA procedure and practice reflected in clarifications, modifications, and new text will appear in the seven FY 2017 FOAs: Environmental Regulatory Enhancement (ERE), Sustainable Employment and Economic Development Strategies (SEEDS), Native American Language Preservation and Maintenance-Esther Martinez Immersion (EMI), Native American Language Preservation and Maintenance (P&M), Social and Economic Development Strategies (SEDS), Social and Economic Development Strategies-Alaska (SEDS–AK), and Native Youth Initiative for Leadership, Empowerment, and Development (I–LEAD). This notice serves to fulfill the statutory notice and public comment requirement.

A. Funding Opportunity Announcements

For information on the types of projects funded by ANA, please refer to the following for information on current and previously funded ANA grants at *http://www.acf.hhs.gov/ana/grants.*

B. Interpretive Rules, Statements of Policy, Procedures, and Practice

1. The following is applicable to all ANA FOAs published beginning in FY 2017:

a. Pre-application trainings, teleconferences, or webinars. It is government-wide policy and practice that each FOA contain all of the detail needed for an applicant to fully understand the funding opportunity and submit a complete and compliant application. ANA has historically conducted in-person pre-application trainings through its Regional Technical Assistance (TA) Centers and now proposes possible additional pre-application teleconferences or webinars related to its FOAs beginning in FY 2017. Joining and participating in any pre-application in-person training, teleconference, or webinar is voluntary and only information provided in published FOAs will be presented. ACF policy requires that no additional information that is not already provided in the FOA can be disseminated after FOAs have been published. Participation in any of the pre-application training or informational opportunities is voluntary and will not affect award selection. Participants will remain anonymous and, in the case of in-person training, names of participants will not be retained after the training. Opting not to participate in a pre-application in-person training, teleconference, or webinar will not affect eligibility, application scoring, or the selection process. Applicants unable to attend pre-application teleconferences or webinars will be able to access materials, recordings, or transcripts on the ANA Web site at on the Events section of the ANA Web site at *http://www.acf.hhs.gov/ana/events* after the teleconference or webinar has concluded and no later than 30 days prior to the application due date. ANA has historically posted its *Pre-Application Guide to Developing and Writing Your ANA Application* that is used in in-person pre-application meetings and will continue to do so. This resource can be found at *http://www.acf.hhs.gov/ana/resource/pre-application-training-manual.* For the dates, times, registration, and other information for scheduled pre-application in-person trainings applicants should contact the appropriate regional Training and Technical Assistance Provider at *http://www.acf.hhs.gov/ana/t-ta-regions-map.* This proposed policy and practice will be reflected in *Section I. Program Description—Pre-Application Teleconferences or Webinars* of the FOAs.

b. Application periods. ANA proposes to reduce from 90 to 60 days the time period applicants have to respond to all FY 2017 FOAs because we have determined, based on experience and feedback provided by prior applicants

and TA providers, that a 60-day period to prepare, finalize, and submit applications responsive to the FOAs is a sufficient period of time. In addition, a 60-day application period will help ANA to ensure grants are awarded timely given the time required for competitive panel review, internal review, award decisions, and administrative processing of grant awards. This proposed policy and practice will be reflected in the *Overview Section* of the FOAs.

c. Application Toolkit. ANA proposes to add a link in all FOAs to allow applicants to access ANA's newly established ANA Application Toolkit. The purpose of the Application Toolkit is to provide examples and templates to assist eligible applicants to navigate the application requirements detailed in FOAs. As a collection of otherwise available tools, use of the ANA Application Toolkit is voluntary. This proposed practice will be reflected in *Section VIII. Other Information, Reference Web sites* in the FOAs.

2. The following is applicable to Social and Economic Development Strategies (SEDS) FOA (HHS–2017–ACF–ANA–NA–1236), including Social and Economic Development Strategies for Alaska (SEDS–AK) (HHS–2015–ACF–ANA–NK–0960), beginning in FY 2017:

New Program Area of Interest. In response to the enactment of the Native American Tourism and Improving Visitor Experience Act (NATIVE Act), Public Law 114–221, in September 2016, ANA proposes to include a new economic development program area of interest under the SEDS and SEDS–AK FOAs. The new program area of interest is proposed as:

> Tourism—Planning or developing resources, services, and businesses that promote travel, recreation and tourism, or branding to tell the story of Native Americans as the First Peoples of the United States. Projects may use the arts or other cultural resources to help revitalize Native communities, promote economic development, increase livability, and present the uniqueness of the Native communities to visitors in a way that celebrates the diversity of the United States

Even though ANA has previously funded economic and social development projects broadly falling under tourism, the new program area of interest is proposed in response to new specific statutory authority under the NATIVE Act. This proposed policy will be reflected in *Section I. Program Description, Program Areas of Interest* in the SEDS and SEDS–AK FOAs.

3. The following is applicable to Native Youth Initiative for Leadership, Empowerment, and Development (I–LEAD) (HHS–2017–ACF–ANA–NC–1263) FOA beginning in FY 2017:

a. Application due dates. ANA proposes to modify the application due dates for I–LEAD applications because ANA anticipates earlier publication than in FY 2016. In addition, ANA proposes a 60-day application period for all FY 2017 FOAs. These two factors combine to result in earlier I–LEAD application deadlines.

b. Grants as the instruments of I–LEAD financial assistance. In 2016, ANA awarded I–LEAD financial assistance as cooperative agreements. We propose, beginning in FY 2017, to award I–LEAD financial assistance as grants instead of cooperative agreements because we do not believe the level of substantial federal involvement associated with cooperative agreements is necessary for successful future I–LEAD projects. Both cooperative agreements and grants are legal instruments of financial assistance, but cooperative agreements are distinguished from grants in that cooperative agreements provide for substantial federal involvement between the federal awarding agency (ANA) and the non-federal entity (I–LEAD awardee) in carrying out the activity(ies) contemplated by the federal award. In general terms, ''substantial federal involvement'' refers to the degree to which federal employees (or technical assistance providers) are directly performing, implementing, or directing parts of the funded program. In a cooperative agreement, federal employees and their agents participate more closely in performance under the financial assistance award including mandated collaborations and activities with other entities. In contrast, with grants, the federal government is limited to an oversight and monitoring role but does not direct grant performance. ANA has determined that I–LEAD projects do not require the level of ''substantial federal involvement'' contemplated by cooperative agreements. While ANA intends to continue to develop and refine technical assistance resources, materials, and opportunities for all recipients of I–LEAD awards and to encourage and facilitate communities of practice across funded projects serving Native youth, we have determined that the oversight and monitoring role is sufficient to ensure the purposes of I–LEAD projects are adequately supported while, at the same time, allowing I–LEAD grant recipients to determine how to implement their grants within the terms and conditions of their grant awards.

c. Length of project periods. ANA proposes to shorten the project period for I–LEAD awards beginning in FY 2017 from no more than 60 months to no more than 48 months because we have determined that project periods of up to 48 months better position I–LEAD projects for long-term success. Based on ANA's experience with the first recipients of I–LEAD financial assistance, we believe slightly more compressed I–LEAD project periods will facilitate greater emphasis by I–LEAD grantees, at the beginning their projects, on the efficient implementation of culturally relevant evidence-based programming as well as a greater emphasis at end of I–LEAD project periods on activities to ensure financial and programmatic sustainability of project outcomes. We believe there is an inherent momentum in 48-month project periods that will carry I–LEAD projects forward from planning, implementation, and continuous quality improvement to long term sustainability at the end of 48-month I–LEAD project periods. This proposed policy will be reflected in the *Executive Summary* of the I–LEAD FOA.

d. Project Description—

i. Objective Work Plan. ANA proposes requiring submission of the Objective Work Plan (OWP) as part of the initial application submission and reflecting the entire project period of up to 48 months. When I–LEAD projects were funded as cooperative agreements, part of ANA's substantial federal involvement included post-award development of the OWP in partnership with I–LEAD recipients. Since ANA proposes to award I–LEAD financial assistance as grants, without the substantial federal involvement entailed by joint development of OWPs, submission of the OWP as an application requirement beginning in FY 2017 has been determined necessary to support adequate project planning and post-award monitoring. This proposed policy will be reflected in *Section IV.2. Content and Form of Application Submission—Project Description—Objective Work Plan* in the I–LEAD FOA.

ii. Outcome oriented project objectives. ANA proposes outcome oriented objectives that are Specific, Measurable, Achievable, Relevant, and Time-bound (S.M.A.R.T.) be included in funding applications because it is our experience that objectives that are S.M.A.R.T. are more likely to be achieved and are more likely to be useful to gauge project progress. This change for I–LEAD projects would also make the requirements for I–LEAD applications consistent with the

application requirements for ANA's other funding opportunities. This proposed policy will be reflected in *Section IV.2. Content and Form of Application Submission—Project Description—Expected Outcomes—Objectives and V.1. Criteria—Outcomes Expected* in the I–LEAD FOA.

iii. Impact Indicator. ANA proposes applications for I–LEAD financial assistance include at least one impact indicator: a qualitative measure that defines factor(s) the project needs to benchmark and monitor. Impact indicators also provide the means for measuring and evaluating an I–LEAD project's progress and impact. This proposed policy will be reflected in the *Section IV.2. Content and Form of Application Submission—Project Description—Expected Outcomes—Impact* in the I–LEAD FOA.

e. Project Budget and Budget Justification. I–LEAD applicants are required to attend ANA's annual grantee meeting. We propose to add a new requirement of attendance for an additional day to convene with I–LEAD projects funded by ANA and the youth involved in project implementation. This proposed policy will be reflected in *Section IV.2. Content and Form of Application Submission—Project Description—Project Budget and Budget Justification* in the I–LEAD FOA and will also reflect suggested travel costs increased by $500 per region for additional estimated lodging and per diem.

f. Review Criteria—

i. Elimination of Bonus Points. ANA proposes to remove the bonus points that were authorized in FY 2016 I–LEAD FOAs because our experience with the prior year's application review demonstrated the allocation of up to 5 bonus points for letters of support from youth is not necessary to ensure applications reflect support from youth involved in the development of the project proposal as well as in project implementation. The proposed application point allocation reflecting the discontinued use of bonus points is found at *Section V.1. Criteria* of the I–LEAD FOA.

ii. Allocation of points across I–LEAD application evaluation criteria. ANA proposes to modify the point allocation across I–LEAD application review criteria to account for the proposed elimination of bonus points as well as the proposed OWP application requirement. We propose, beginning in FY 2017, the following evaluation criteria point allocations: Needs for Assistance up to 10 points; Outcomes Expected up to 25 points; Approach up to 35 points; OWP up to 20 points; and the Budget and Budget Justification up to10 points. The proposed modification to the point allocation can be found at *Section V.1. Criteria* for the I–LEAD FOA.

Statutory Authority: Section 814 of the Native American Programs Act of 1974 (NAPA), as amended.

Kimberly Romine,

Deputy Commissioner, Administration for Native Americans.

[FR Doc. 2017–01418 Filed 1–19–17; 8:45 am]

BILLING CODE 4184–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Project: Performance Reporting for the Tribal Maternal, Infant, and Early Childhood Home Visiting Grant Program.

Title: Tribal Maternal, Infant, and Early Childhood Home Visiting Program Performance Reporting Form 2.

OMB No.: New Collection.

Description: Social Security Act, Title V, Section 511 (42 U.S.C. 711), as added by § 2951 of the Patient Protection and Affordable Care Act (Pub. L. 111–148), created the Maternal, Infant, and Early Childhood Home Visiting Program (MIECHV) and authorized the Secretary of HHS (in Section 511(h)(2)(A)) to award grants to Indian tribes (or a consortium of Indian tribes), tribal organizations, or urban Indian organizations to conduct an early childhood home visiting program. The legislation set aside 3 percent of the total MIECHV program appropriation (authorized in Section 511(j)) for grants to tribal entities. The implementation of the program is a collaborative endeavor between Health Resources Services Administration (HRSA) and the Administration for Children and Families (ACF). HRSA administers the State MIECHV program while ACF administers the Tribal MIECHV program. The goal of the Tribal MIECHV program is to support the development of happy, healthy, and successful American Indian and Alaska Native children and families through a coordinated home visiting system. Tribal MIECHV grants, to the greatest extent practicable, are to be consistent with the requirements of the MIECHV grants to states and jurisdictions (authorized in Section 511(c)), and include conducting a needs assessment and establishing quantifiable, measurable benchmarks.

Specifically, the MIECHV legislation requires that State and Tribal MIECHV grantees collect data to measure improvements for eligible families in six specified areas (referred to as ''benchmark areas'') that encompass the major goals for the program and are listed below:

1. Improved maternal and newborn health;
2. Prevention of child injuries, child abuse, neglect, or maltreatment, and reduction in emergency department visits;
3. Improvement in school readiness and achievement;
4. Reduction in crime or domestic violence;
5. Improvement in family economic self-sufficiency;
6. Improvement in the coordination and referrals for other community resources and supports.

Tribal Home Visiting (HV) Form 2—Tribal Grantees Performance Reporting

The proposed Tribal HV Form 2 will be used by two new cohorts of Tribal MIECHV grantees that were funded in FY2016 to report their benchmark performance measures. As stipulated in the MIECHV legislation, the Tribal MIECHV grantees, like their State counterparts, must meet the required reporting of benchmark areas. Tribal MIECHV grantees are required to propose a plan for meeting the benchmark requirements specified in the legislation and must report on improvement at the end of Year 4 and Year 5 of their 5-year grants, (*i.e.* after 3 years of implementation and at the end of their 5-year grant).

The Tribal HV Form 2 will be used by Tribal MIECHV grantees beginning in October 2018 pending OMB approval. The Tribal HV Form 2 is new to the MIECHV Program information system and is remotely similar to the currently-approved Tribal HV Form 3 (OMB #0915–0357). The creation of Tribal HV Form 2 is due to the added level of specificity and revised performance reporting requirements for grantees to report benchmarks data.

Specifically, ACF will use the proposed Tribal HV Form 2 to:

- Track and improve the quality of benchmark measure data submitted by the Tribal grantees;
- Improve program monitoring and oversight;
- Improve rigorous data analyses that help to assess the effectiveness of the programs and enable ACF to better monitor projects; and

• Ensure adequate and timely reporting of program data to relevant federal agencies and stakeholders including the Congress, and members of the public.

Tribal HV Form 2 will provide a template for Tribal MIECHV grantees to report data on their progress under the six benchmark areas as stipulated in legislation.

Respondents: Tribal Maternal, Infant, and Early Childhood Home Visiting Program Grantees.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Tribal Maternal, Infant, and Early Childhood Home Visiting Performance Reporting Form	20	1	500	10,000

Estimated Total Annual Burden Hours: 10,000.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C St. SW., Washington, DC 20201, Attn: OPRE Reports Clearance Officer. Email address: *OPREinfocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments 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 collection of information; (c) 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 within 60 days of this publication.

Mary Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2017–01276 Filed 1–19–17; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–P–0377]

Determination That ACTHAR GEL SYNTHETIC (Seractide Acetate) Injection, 80 Units/Milliliter and 40 Units/Milliliter, Was Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) has determined that ACTHAR GEL SYNTHETIC (seractide acetate) injection, 80 units/milliliter (mL) and 40 units/mL, was withdrawn from sale for reasons of safety or effectiveness. The Agency will not accept or approve abbreviated new drug applications (ANDAs) for seractide acetate injection, 80 units/mL and 40 units/mL.

FOR FURTHER INFORMATION CONTACT: David E. Markert, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6222, Silver Spring, MD 20993–0002, 301–796–0752.

SUPPLEMENTARY INFORMATION:

I. Background

In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (21 CFR 314.161). FDA may not approve an ANDA that does not refer to a listed drug.

ACTHAR GEL SYNTHETIC (seractide acetate) injection, 80 units/mL and 40 units/mL was the subject of NDA 017861, which was held by Armour Pharmaceutical Co. (Armour), and initially approved on February 21, 1978. ACTHAR GEL SYNTHETIC is indicated for diagnostic testing of adrenocortical function. The labeling also provides that ACTHAR GEL SYNTHETIC may be employed in the following disorders:

Endocrine Disorders: Nonsuppurative thyroiditis; Hypercalcemia associated with cancer.

Nervous System Diseases: Acute exacerbations of multiple sclerosis.

Rheumatic Disorders: As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in: Psoriatic arthritis; rheumatoid arthritis, including juvenile

rheumatoid arthritis (selected cases may require low-dose maintenance therapy); ankylosing spondylitis; acute and subacute bursitis; acute non-specific tenosynovitis; acute gouty arthritis; post-traumatic arthritis; synovitis of osteoarthritis; epicondylitis.

Collagen Diseases: During an exacerbation or as maintenance therapy in selected cases of: Systemic lupus erythematosus; systemic dermatomyositis (polymyositis); acute rheumatic carditis.

Dermatologic Diseases: Pemphigus; bullous dermatitis herpetiformis; severe erythema multiforme (Stevens-Johnson syndrome); exfoliative dermatitis; severe psoriasis; severe seborrheic dermatitis; mycosis fungoides.

Allergic States: Control of severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment—seasonal or perennial allergic rhinitis; bronchial asthma; contact dermatitis; atopic dermatitis; serum sickness.

Ophthalmic Diseases: Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as: Allergic conjunctivitis; keratitis; herpes zoster ophthalmicus; iritis and iridocyclitis; diffuse posterior uveitis and choroiditis; optic neuritis; sympathetic ophthalmia; chorioretinitis; anterior segment inflammation; allergic corneal marginal ulcers.

Respiratory Diseases: Symptomatic sarcoidosis; Loeffler's syndrome not manageable by other means; berylliosis; fulminating or disseminated pulmonary tuberculosis when used concurrently with anti-tuberculous chemotherapy; aspiration pneumonitis.

Hematologic Disorders: Acquired (autoimmune) hemolytic anemia; secondary thrombocytopenia in adults; erythroblastopenia (RBC anemia); congenital (erythroid) hypoplastic anemia.

Neoplastic Diseases: For palliative management of: Leukemias and lymphomas in adults; acute leukemia of childhood.

Edematous State: To induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus.

Gastrointestinal Diseases: To tide the patient over a critical period of the disease in: Ulcerative colitis; regional enteritis.

Miscellaneous: Tuberculous meningitis with subarachnoid block or impending block when concurrently accompanied by appropriate anti-tuberculous chemotherapy; trichinosis with neurologic or myocardial involvement.

Armour never marketed ACTHAR GEL SYNTHETIC (seractide acetate) injection, 80 units/mL and 40 units/mL. In previous instances (see, *e.g.,* 72 FR 9763, March 5, 2007 and 61 FR 25497, May 21, 1996), the Agency has determined that for purposes of §§ 314.161 and 314.162, never marketing an approved drug product is equivalent to withdrawing the drug from sale. FDA withdrew approval of the NDA for ACTHAR GEL SYNTHETIC in 2014 because Armour had repeatedly failed to file annual reports for the application (79 FR 68454, November 17, 2014).

Hyman, Phelps & McNamara, P.C., submitted a citizen petition dated April 1, 2014 (Docket No. FDA–2014–P–0377), under 21 CFR 10.30, requesting that the Agency determine whether ACTHAR GEL SYNTHETIC (seractide acetate) injection, 80 units/mL and 40 units/mL, was withdrawn from sale for reasons of safety or effectiveness.

II. Response to Citizen Petition

We have carefully reviewed the citizen petition (and comments submitted to the docket); our records for ACTHAR GEL SYNTHETIC (seractide acetate) injection, 80 units/mL and 40 units/mL; the scientific literature on seractide acetate; and other relevant information. Based on that review, and for the reasons set forth in this section, we have concluded that additional studies of safety would be necessary before ACTHAR GEL SYNTHETIC could be considered for introduction to the market today. Consequently, FDA has determined under § 314.161 that ACTHAR GEL SYNTHETIC (seractide acetate) injection, 80 units/mL and 40 units/mL, was withdrawn for reasons of safety.[1]

The labeling for ACTHAR GEL SYNTHETIC describes the product as ''a highly purified synthetic polypeptide containing thirty-nine amino acids in the sequence described for human corticotropin by Lee, T.H.; Lerner, A.B.; and Buettner-Janusch, Vina (J. Biol Chem, 236:2970–2974, Nov. 1961)'' (Refs. 1 and 2). At the time of ACTHAR GEL SYNTHETIC's approval, FDA believed the amino acid sequence described by Lee et al. was the correct sequence for human corticotropin and, therefore, that ACTHAR GEL SYNTHETIC was identical to human corticotropin.[2] However, since approval, the Agency has learned that ACTHAR GEL SYNTHETIC is not identical to the human corticotropin sequence. We now know that the amino acid sequence described by Lee et al. is a deamidated version of human corticotropin that differs from full length human corticotropin at four positions.[3]

The fact that ACTHAR GEL SYNTHETIC has a different amino acid sequence from human corticotropin raises significant safety concerns. Due to its different amino acid sequence, ACTHAR GEL SYNTHETIC might have a structure or function that is not recognized as endogenous by the immune system. ACTHAR GEL SYNTHETIC thus poses a higher risk of immunogenicity than a synthetic peptide product that is, in fact, identical to human corticotropin. The health consequences of immunogenicity range from subacute, minor reactions to severe, even deadly, reactions (*e.g.,* anaphylaxis). In addition, frequent stimulation of the immune system could produce antibodies that cross-react with human corticotropin and other closely related endogenous peptides, resulting in the loss of those peptides' physiological functions. Such an effect could last long after treatment with ACTHAR GEL SYNTHETIC has stopped.

The safety concerns noted in this section have not been adequately investigated. ACTHAR GEL SYNTHETIC was studied in two clinical trials in 51 healthy adult men between 21 and 54 years old. Although no unusual adverse effects were reported during these trials, the trials did not assess the impact of immunogenicity on safety. Nor were they designed to assess immunogenicity. Moreover, because ACTHAR GEL SYNTHETIC was never marketed, the Agency has no postmarketing safety data or information confirming that the product is safe for human use, notwithstanding the differences between ACTHAR GEL SYNTHETIC's amino acid sequence and that of human corticotropin. Given the lack of any premarket or postmarket

[1] In light of this conclusion, it is unnecessary for us to determine whether ACTHAR GEL SYNTHETIC was also withdrawn from sale for reasons of effectiveness. This notice does not address the effectiveness of ACTHAR GEL SYNTHETIC for its labeled indications.

[2] The Agency's Institutional Summary of Basis of Approval (Ref. 3) describes ACTHAR GEL SYNTHETIC as ''a synthetic peptide of 39 amino acids identical with that of natural human'' corticotropin.

[3] The record for human pro-opiomelanocortin preproprotein in the National Center for Biotechnology Information's ''Protein'' database (Reference Sequence NP_000930.1) contains the correct amino acid sequence for human corticotropin. The record is available at the following URL: *https://www.ncbi.nlm.nih.gov/protein/NP_000930.1.* The sequence described by Lee et al. differs from the correct sequence at positions 25–27 and 30.

immunogenicity safety data, FDA cannot conclude that ACTHAR GEL SYNTHETIC would be safe for human use if it were introduced to the market today.

Accordingly, the Agency will remove ACTHAR GEL SYNTHETIC (seractide acetate) injection, 80 units/mL and 40 units/mL, from the list of drug products published in the Orange Book. FDA will not accept or approve ANDAs that refer to this drug product.

III. References

The following references have been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.*

1. Armour Pharmaceutical Co., ''ACTHAR® Gel Synthetic (SERACTIDE ACETATE), Synthetic Corticotropin,'' Product Labeling, 1979.
2. Lee, T. H., A. B. Lerner, and V. Buettner-Janusch, ''On the Structure of Human Corticotropin (Adrenocorticotropic Hormone),'' *The Journal of Biological Chemistry,* vol. 236, pp. 2970–2974, 1961.
3. FDA, ''Seractide Acetate: Institutional Summary of Basis of Approval,'' August 22, 1977.

Dated: January 13, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–01249 Filed 1–19–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0825]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Premarket Approval of Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by February 22, 2017.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0231. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North 10A63, 11601 Landsdown St., North Bethesda, MD 20852, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Premarket Approval of Medical Devices—OMB Control Number 0910–0231—Extension

Under section 515 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360e) all devices placed into class III by FDA are subject to premarket approval (PMA) requirements. PMA is the process of scientific and regulatory review to ensure the safety and effectiveness of class III devices. An approved PMA is, in effect, a private license granted to the applicant for marketing a particular medical device. A class III device that fails to meet PMA requirements is considered to be adulterated under section 501(f) of the FD&C Act (21 U.S.C. 351(f)) and cannot be marketed. PMA requirements apply differently to preamendments devices, postamendments devices, and transitional class III devices.

Manufacturers of class III preamendments devices, devices that were in commercial distribution before May 28, 1976, are not required to submit a PMA until 30 months after the issuance of a final classification regulation or until 90 days after the publication of a final regulation requiring the submission of a PMA, whichever period is later. FDA may allow more than 90 days after issuance of a final rule for submission of a PMA.

A postamendments device is one that was first distributed commercially on or after May 28, 1976. Postamendments devices determined by FDA to be substantially equivalent to preamendments class III devices are subject to the same requirements as the preamendments devices. FDA determines substantial equivalence after reviewing an applicant's premarket notification submitted in accordance with section 510(k) of the FD&C Act (21 U.S.C. 360(k)). Postamendments devices determined by FDA to be not substantially equivalent to either preamendments devices or postamendments devices classified into class I or II are ''new'' devices and fall automatically into class III. Before such devices can be marketed, they must have an approved PMA application or be must reclassified into class I or class II.

The Food and Drug Modernization Act of 1997 (FDAMA) (Pub. L. 105–115) was enacted on November 21, 1997, to implement revisions to the FD&C Act by streamlining the process of bringing safe and effective drugs, medical devices, and other therapies to the U.S. market. FDAMA added section 515(d)(6) to the FD&C Act (21 U.S.C. 360e(d)(6)), which provided that PMA supplements were required for all device changes that affect safety and effectiveness unless such changes are modifications to manufacturing procedures or method of manufacture. That type of manufacturing change will require a 30-day notice, or where FDA finds such notice inadequate, a 135-day PMA supplement.

The implementing regulations, contained in part 814 (21 CFR part 814), further specify the contents of a PMA for a medical device and the criteria FDA will employ in approving, denying, or withdrawing approval of a PMA and supplements to PMAs. The regulations' purpose is to establish an efficient and thorough procedure for FDA's review of PMAs and supplements to PMAs for class III medical devices. The regulations facilitate the approval of PMAs and supplements to PMAs for devices that have been shown to be reasonably safe and effective and otherwise meet the statutory criteria for approval. The regulations also ensure the denial of PMAs and supplements to PMAs for devices that have not been shown to be reasonably safe and effective and that do not otherwise meet the statutory criteria for approval.

The industry-wide burden estimate for PMAs is based on an FDA average fiscal year (FY) annual rate of receipt of PMA submissions data FYs 2013 through 2015 and our expectation of submissions to come in the next few years. The burden data for PMAs is based on data provided by applicants by device type and cost element in an earlier study.

Reporting Burden: The reporting burden can be broken out by certain

sections of the PMA regulations and the FD&C Act as follows:

§ 814.15(b)—Research Conducted Outside the United States. Each foreign study should be performed in accordance with the ''Declaration of Helsinki'' or the laws and regulations of the country in which the study was conducted. If the study was conducted in accordance with the laws of the country, the PMA applicant is required to explain to FDA in detail the differences between the laws of the country and the ''Declaration of Helsinki.'' Based on the number of PMAs received that contained studies from overseas, FDA estimates that the burden estimate necessary to meet this requirement is 50 hours.

§ 814.20—Application. Included in this requirement is the conduct of laboratory and clinical trials, as well as the analysis, review, and physical preparation of the PMA application. FDA estimates that 35 applicants, including hospital remanufacturers of single-use devices, will be affected by these requirements which are based on the actual average of FDA receipt of new PMA applications in FYs 2013 through 2015. FDA's estimate of the hours per response (668) was derived through FDA's experience and consultation with industry and trade associations. In addition, FDA also based its estimate on the results of an earlier study that accounts for the bulk of the hourly burden for this requirement, which is identified by applicants.

§ 814.37(a) through (c) and (e)—PMA Amendments and Resubmitted PMAs. As part of the review process, FDA often requests the PMA applicant to submit additional information regarding the device necessary for FDA to file the PMA or to complete its review and make a final decision. The PMA applicant may, also on their own initiative, submit additional information to FDA during the review process. These amendments contain information ranging from additional test results and re-analysis of the original data set to revised device labeling. Almost all PMAs received by the Agency have amendments submitted during the review process.

§ 814.39(a)—PMA Supplements. This information collection includes the requirements for the range of PMA supplements (panel track, 180-day fee-based, 180-day non fee-based, and real-time supplements).

§ 814.39(d)—Special PMA Supplements—Changes Being Affected. This type of supplement is intended to enhance the safety of the device or the safe use of the device. The number of PMA supplements received that fit this category averaged 88 per year based on the numbers received from FYs 2013 through 2015. Because of the minimal data required to be included in this type of supplement, FDA estimates that the number of burden hours necessary to satisfy this requirement is 528.

§ 814.39(f)—30-Day Notice. Under section 515(d) of the FD&C Act, modifications to manufacturing procedures or methods of manufacture that affect the safety and effectiveness of a device subject to an approved PMA do not require submission of a PMA supplement under paragraph (a) of this section and are eligible to be the subject of a 30-day notice. A 30-day notice shall describe in detail the change, summarize the data or information supporting the change, and state that the change has been made in accordance with the requirements of part 820 (21 CFR part 820). The applicant may distribute the device 30 days after the date on which FDA receives the 30-day notice, unless FDA notifies the applicant within 30 days from receipt of the notice that it is not adequate.

§ 814.82(a)(9)—Postapproval Requirements. Postapproval requirements concerns approved PMAs that were not reclassified and require a periodic report. After approval, all PMAs require a submission of an annual report. A majority of the submitted PMAs require associated post-approval studies, *i.e.,* followup of patients used in clinical trials to support the PMA or additional preclinical information that is labor-intensive to compile and complete; the remaining PMAs require minimal information.

§ 814.84(b)—Periodic Reports. Postapproval requirements described in § 814.82(a)(7) require submission of an annual report for each approved PMA. FDA estimates that respondents will average about 10 hours in preparing their reports to meet this requirement. This estimate is based on FDA's experience and consultation with industry.

Expedited or Priority Review—Section 515(d)(5) of the FD&C Act. FDA will provide special review, which can include expedited processing of a PMA application, for certain devices intended to treat or diagnose life threatening or irreversibly debilitating diseases or conditions. To receive special review, the devices must meet one of the following criteria:

- The device represents a breakthrough technology;
- There are no approved alternatives;
- The use of the device offers significant advantages over existing approved alternatives; or
- Availability is in the best interest of the patients.

Agreement Meeting—Section 520(g)(7) of the FD&C Act (21 U.S.C. 360j(g)(7)). Applicants planning to submit a PMA may submit a written request to reach agreement with FDA on the key parameters of the investigational plan.

Determination Meeting—Section 513(a)(3)(D) of the FD&C Act (21 U.S.C. 360c(a)(3)(D)). Applicants planning to submit a PMA may submit a written request to FDA for a meeting to determine the type of information (valid scientific evidence) necessary to support the effectiveness of their device.

Panel of Experts—Section 515(c)(3) of the FD&C Act. An original PMA or panel track PMA supplement is taken to an advisory panel of experts unless FDA determines that the information in the application substantially duplicates information which has previously been reviewed by the panel.

Day 100 Meeting—Section 515(d)(3) of the FD&C Act. FDA must, upon the written request of the applicant, meet with that party within 100 days of receipt of the filed PMA application to discuss the review status of the application. With the concurrence of the applicant, a different schedule may be established. Prior to this meeting, FDA must inform the applicant in writing of any identified deficiencies and what information is required to correct those deficiencies. FDA must also promptly notify the applicant if FDA identifies additional deficiencies or of any additional information required to complete Agency review.

Recordkeeping

§ 814.82(a)(5) and (a)(6)—Maintenance of Records. The recordkeeping burden under this section requires the maintenance of records, used to trace patients and the organization and indexing of records into identifiable files to ensure the device's continued safety and effectiveness. These records are required of all applicants who have an approved PMA.

PMAs have been required since 1976, and there are 725 active PMAs that could be subject to these requirements, based on actual FDA data, and approximately 30 new PMAs are approved every year. The aggregate burden for the estimated 422 PMA holders of approved original PMAs for the next few years is estimated to be 7,174 hours.

The applicant determines which records should be maintained during product development to document and/or substantiate the device's safety and effectiveness. Records required by the

current good manufacturing practices for medical devices regulation (21 CFR part 820) may be relevant to a PMA review and may be submitted as part of an application. In individual instances, records may be required as conditions of approval to ensure the device's continuing safety and effectiveness.

In the **Federal Register** of October 19, 2016 (81 FR 72063), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity/21 CFR or FD&C Act section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Research conducted outside the United States (814.15(b))	25	1	25	2	50
PMA application (814.20)	35	1	35	668	23,380
PMA amendments and resubmitted PMAs (814.37(a)–(c) and (e))	1,222	1	1,222	167	204,074
PMA supplements (814.39(a))	695	1	695	60	41,700
Special PMA supplement—changes being affected (814.39(d))	88	1	88	6	528
30-day notice (814.39(f))	1,710	1	1,710	16	27,360
Postapproval requirements (814.82(a)(9))	340	1	340	135	45,900
Periodic reports (814.84(b))	695	1	695	10	6,950
Agreement meeting (520(g)(7))	1	1	1	50	50
Expedited review request (515(d)(5) of the FD&C Act)	6	1	6	10	60
Determination Meeting (513(1)(3)(D) of the FD&C Act)	1	1	1	50	50
Panel meeting (515(c)(3) of the FD&C Act)	9	1	9	30	270
Day 100 meeting (515(d)(3) of the FD&C Act)	19	1	19	10	190
Total					350,562

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity/21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual responses	Average burden per response	Total hours
Maintenance of records (814.82(a)(5) and (a)(6))	422	1	422	17	7,174

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: January 13, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–01188 Filed 1–19–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; Virtual Reality Tools to Enhance Evidence-Based Treatment of Substance Use Disorders (5583).

Date: February 1, 2017.

Time: 8:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Gerald L. McLaughlin, Ph.D., Scientific Review Officer, Office of Extramural Policy and Review, National Institute on Drug Abuse, NIH, DHHS, 6001 Executive Blvd., Room 4238, MSC 9550, Bethesda, MD 20892–9550, 301–827–5819, *gm145a@nih.gov.*

(Catalogue of Federal Domestic Assistance Program No.: 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: January 13, 2017.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–01253 Filed 1–19–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning

individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel; P41 BTRC Review (2017/05).

Date: March 16, 2017.

Time: 08:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, Suite 920, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Dennis Hlasta, Ph.D., Scientific Review Officer, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, 6707 Democracy Blvd., Bethesda, MD 20892, (301) 451–4794, *dennis.hlasta@nih.gov.*

Dated: January 12, 2016.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–01252 Filed 1–19–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; SBIB Clinical Pediatric and Fetal Applications.

Date: February 15, 2017.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Songtao Liu, M.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5108, Bethesda, MD 20817, 301–435–3578, *songtao.liu@nih.gov.*

Name of Committee: Musculoskeletal, Oral and Skin Sciences Integrated Review Group; Oral, Dental and Craniofacial Sciences Study Section.

Date: February 16–17, 2017.

Time: 7:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree by Hilton Los Angeles Westside Hotel, 6161 W. Centinela Avenue, Culver City, CA 90230.

Contact Person: Yi-Hsin Liu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4214, MSC 7814, Bethesda, MD 20892, 301–435–1781, *liuyh@csr.nih.gov.*

Name of Committee: Biological Chemistry and Macromolecular Biophysics Integrated Review Group; Macromolecular Structure and Function A Study Section.

Date: February 16–17, 2017.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Pier 2620 Hotel, 2620 Jones Street, San Francisco, CA 94133.

Contact Person: Nitsa Rosenzweig, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4152, MSC 7760, Bethesda, MD 20892, (301) 404–7419, *rosenzweign@csr.nih.gov.*

Name of Committee: Immunology Integrated Review Group; Innate Immunity and Inflammation Study Section.

Date: February 16–17, 2017.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The Ritz-Carlton, Pentagon City, 1250 South Hayes St., Arlington, VA 22202.

Contact Person: Tina McIntyre, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4202, MSC 7812, Bethesda, MD 20892, 301–594–6375, *mcintyrt@csr.nih.gov.*

Name of Committee: Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group; Cellular, Molecular and Integrative Reproduction Study Section.

Date: February 16–17, 2017.

Time: 8:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The Westgate Hotel, 1055 Second Avenue, San Diego, CA 92101.

Contact Person: Gary Hunnicutt, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6164, MSC 7892, Bethesda, MD 20892, 301–435–0229, *hunnicuttgr@csr.nih.gov.*

Name of Committee: Cardiovascular and Respiratory Sciences Integrated Review Group; Myocardial Ischemia and Metabolism Study Section.

Date: February 16–17, 2017.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The Fairmont Washington, DC, 2401 M Street NW., Washington, DC 20037.

Contact Person: Kimm Hamann, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4118A, MSC 7814, Bethesda, MD 20892, 301–435–5575, *hamannkj@csr.nih.gov.*

Name of Committee: Genes, Genomes, and Genetics Integrated Review Group; Genetic Variation and Evolution Study Section.

Date: February 16–17, 2017.

Time: 8:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Renaissance M Street Hotel, 1143 New Hampshire Avenue NW., Washington, DC 20037.

Contact Person: Ronald Adkins, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2206, MSC 7890, Bethesda, MD 20892, 301–435–4511, *ronald.adkins@nih.gov.*

Name of Committee: Emerging Technologies and Training Neurosciences Integrated Review Group; Molecular Neurogenetics Study Section.

Date: February 16–17, 2017.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Mary G Schueler, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5214, MSC 7846, Bethesda, MD 20892, 301–915–6301, *marygs@csr.nih.gov.*

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group, Diseases and Pathophysiology of the Visual System Study Section.

Date: February 16–17, 2017.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bahia Resort Hotel, 998 West Mission Bay Drive, San Diego, CA 92109.

Contact Person: Nataliya Gordiyenko, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5202, MSC 7846, Bethesda, MD 20892, 301.435.1265, *gordiyenkon@csr.nih.gov.*

Name of Committee: Biobehavioral and Behavioral Processes Integrated Review Group; Child Psychopathology and Developmental Disabilities Study Section.

Date: February 16–17, 2017.

Time: 8:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Ritz-Carlton Hotel, 1700 Tysons Boulevard, McLean, VA 22102.

Contact Person: Jane A Doussard-Roosevelt, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3184, MSC 7848, Bethesda, MD 20892, (301) 435–4445, *doussarj@csr.nih.gov.*

Name of Committee: Healthcare Delivery and Methodologies Integrated Review Group, Community Influences on Health Behavior Study Section.

Date: February 16–17, 2017.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Serrano Hotel, 405 Taylor Street, San Francisco, CA 94102.

Contact Person: Tasmeen Weik, DRPH, MPH, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3141, Bethesda, MD 20892, *weikts@mail.nih.gov.*

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group; Neural Oxidative Metabolism and Death Study Section.

Date: February 16–17, 2017.

Time: 8:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: JW Marriott New Orleans, 614 Canal St., New Orleans, LA 70130.

Contact Person: Carol Hamelink, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4192, MSC 7850, Bethesda, MD 20892, (301) 213–9887, *hamelinc@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Ocular Surface, Cornea, Anterior Segment Glaucoma and Refractive Error.

Date: February 16–17, 2017.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The Dupont Hotel, 1500 New Hampshire Avenue NW., Washington, DC 20036.

Contact Person: Kristin Kramer, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5205, MSC 7846, Bethesda, MD 20892, (301) 437–0911, *kramerkm@csr.nih.gov.*

Name of Committee: Emerging Technologies and Training Neurosciences Integrated Review Group; Neuroscience and Ophthalmic Imaging Technologies Study Section.

Date: February 16–17, 2017.

Time: 8:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The St. Regis Washington DC, 923 16th Street NW., Washington, DC 20006.

Contact Person: Yvonne Bennett, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5199, MSC 7846, Bethesda, MD 20892, 301–379–3793, *bennetty@csr.nih.gov.*

Name of Committee: Integrative, Functional and Cognitive Neuroscience Integrated Review Group; Neurobiology of Motivated Behavior Study Section.

Date: February 16–17, 2017.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites DC Convention Center, 900 10th Street NW., Washington, DC 20001.

Contact Person: Jasenka Borzan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4214, MSC 7814, Bethesda, MD 20892, 301–435–1787, *borzanj@csr.nih.gov.*

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group; Cellular and Molecular Biology of Glia Study Section.

Date: February 16–17, 2017.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Ritz-Carlton Hotel, 1700 Tysons Boulevard, McLean, VA 22102.

Contact Person: Linda MacArthur, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4187, Bethesda, MD 20892, 301–537–9986, *macarthurlh@csr.nih.gov.*

Name of Committee: Infectious Diseases and Microbiology Integrated Review Group; Pathogenic Eukaryotes Study Section.

Date: February 16–17, 2017.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Torrance Marriott Redondo Beach, 3635 Fashion Way, Torrance, CA 90503.

Contact Person: Tera Bounds, DVM, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3198, MSC 7808, Bethesda, MD 20892, 301–435–2306, *boundst@csr.nih.gov.*

Name of Committee: Population Sciences and Epidemiology Integrated Review Group; Social Sciences and Population Studies A Study Section.

Date: February 16, 2017.

Time: 8:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Courtyard Riverwalk Marriott, 207 N. St Mary's Street, San Antonio, TX 78205.

Contact Person: Suzanne Ryan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3139, MSC 7770, Bethesda, MD 20892, (301) 435–1712, *ryansj@csr.nih.gov.*

Name of Committee: Population Sciences and Epidemiology Integrated Review Group; Social Sciences and Population Studies B Study Section.

Date: February 16, 2017.

Time: 8:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: JW Marriott New Orleans, 614 Canal St., New Orleans, LA 70130.

Contact Person: Kate Fothergill, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3142, Bethesda, MD 20892, 301–435–2309, *fothergillke@mail.nih.gov.*

Name of Committee: Immunology Integrated Review Group; Vaccines Against Microbial Diseases Study Section.

Date: February 16–17, 2017.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Marriott Courtyard Pioneer Square, 612 2nd Avenue, Seattle, WA 981042.

Contact Person: Jian Wang, M.D, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4218, MSC 7812, Bethesda, MD 20892, (301) 435–2778, *wangjia@csr.nih.gov.*

Name of Committee: Infectious Diseases and Microbiology Integrated Review Group; Clinical Research and Field Studies of Infectious Diseases Study Section.

Date: February 16–17, 2017.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Garden Inn Bethesda, 7301 Waverly Street, Bethesda, MD 20814.

Contact Person: Soheyla Saadi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3211, MSC 7808, Bethesda, MD 20892, 301–435–0903, *saadisoh@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Musculoskeletal, Oral and Skin Sciences AREA (R15) Review.

Date: February 16, 2017.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Aftab A Ansari, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4108, MSC 7814, Bethesda, MD 20892, 301–237–9931, *ansaria@csr.nih.gov.*

Name of Committee: Bioengineering Sciences & Technologies Integrated Review Group; Gene and Drug Delivery Systems Study Section.

Date: February 16–17, 2017.

Time: 8:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Courtyard by Marriott, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Contact Person: Kee Hyang Pyon, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5148, MSC 7806, Bethesda, MD 20892, *pyonkh2@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Retinal Development, Signaling and Circuitry.

Date: February 16, 2017.

Time: 12:00 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Afia Sultana, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 827–7083, *sultanaa@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Topics in Infectious Diseases.

Date: February 17, 2017.

Time: 11:15 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Neerja Kaushik-Basu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3198, MSC 7808, Bethesda, MD 20892, (301) 435–2306, *kaushikbasun@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: BTSS and SAT.

Date: February 17, 2017.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Guo Feng Xu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5122, MSC 7854, Bethesda, MD 20892, 301–237–9870, *xuguofen@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Collaborative Applications: Child Psychopathology.

Date: February 17, 2017.

Time: 3:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Ritz-Carlton Hotel, 1700 Tysons Boulevard, McLean, VA 22102.

Contact Person: Jane A Doussard-Roosevelt, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3184, MSC 7848, Bethesda, MD 20892, (301) 435–4445, *doussarj@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR 16–242: Bioengineering Research.

Date: February 17, 2017.

Time: 4:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The St. Regis Washington, DC, 923 16th Street NW., Washington, DC 20006.

Contact Person: Yvonne Bennett, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5199, MSC 7846, Bethesda, MD 20892, 301–379–3793, *bennetty@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Glycoscience Data Analysis Methods Glycoscience Data Analysis Methods.

Date: February 17, 2017.

Time: 12:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Raj K Krishnaraju, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6190, Bethesda, MD 20892, 301–435–1047, *kkrishna@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 13, 2017.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–01250 Filed 1–19–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Council on Drug Abuse.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and/or contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council on Drug Abuse.

Date: February 15, 2017.

Closed: 9:00 a.m. to 10:30 a.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852.

Open: 10:45 a.m. to 5:00 p.m.

Agenda: This portion of the meeting will be open to the public for announcements and reports of administrative, legislative, and program developments in the drug abuse field.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852.

Contact Person: Susan R.B. Weiss, Ph.D., Director, Division of Extramural Research, Office of the Director, National Institute on Drug Abuse, NIH, DHHS, 6001 Executive Boulevard, NSC, Room 5274, MSC 9591, Rockville, MD 20892, 301–443–6487, *sweiss@nida.nih.gov.*

Any member of the public interested in presenting oral comments to the committee may notify the Contact Person listed on this notice at least 10 days in advance of the meeting. Interested individuals and representatives of organizations may submit a letter of intent, a brief description of the organization represented, and a short description of the oral presentation. Only one representative of an organization may be allowed to present oral comments and if accepted by the committee, presentations may be limited to five minutes. Both printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the committee by forwarding their statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *www.drugabuse.gov/NACDA/NACDAHome.html,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos.: 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: January 13, 2017.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–01254 Filed 1–19–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Peer Review Meeting.

Date: February 10, 2017.

Time: 11:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Chelsea D. Boyd, Ph.D., Scientific Review Officer, Scientific Review Program, DEA/NIAID/NIH/DHHS, 5601 Fishers Lane, MSC–9823, Rockville, MD 20852–9834, 240–669–2081, *chelsea.boyd@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: January 13, 2017.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–01251 Filed 1–19–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2016–1050]

Towing Safety Advisory Committee; Vacancies

AGENCY: Coast Guard, Department of Homeland Security.

ACTION: Request for applications.

SUMMARY: The Coast Guard seeks applications for membership on the Towing Safety Advisory Committee. This Committee advises the Secretary of the Department of Homeland Security on matters relating to shallow draft inland and coastal waterway navigation and towing safety.

DATES: Completed applications should reach the Coast Guard on or before March 9, 2017.

ADDRESSES: Applicants should send a cover letter expressing interest in an appointment to the Towing Safety Advisory Committee that also identifies which membership category the applicant is applying under, along with a resume detailing the applicant's experience via one of the following methods:

- *By Email: William.J.Abernathy@uscg.mil*
- *By Fax:* 202–372–8379 ATTN: William Abernathy
- *By Mail:* William J. Abernathy, Alternate Designated Federal Officer, Commandant (CG–OES–2), U.S. Coast Guard Stop 7509, 2703 Martin Luther King Jr Ave SE., Washington, DC 20593–7509

FOR FURTHER INFORMATION CONTACT: William J. Abernathy, Alternate Designated Federal Officer of the Towing Safety Advisory Committee; Telephone 202–372–1363; or Email at *William.J.Abernathy@uscg.mil*.

SUPPLEMENTARY INFORMATION: The Towing Safety Advisory Committee is a federal advisory committee which operates under the provisions of the Federal Advisory Committee Act, (Title 5, United States Code, Appendix). It was established under authority of the Act to establish a Towing Safety Advisory Committee in the Department of Transportation, (Pub. L. 96–380), which was recently amended by section 621 of the Coast Guard Authorization Act of 2010, (Pub. L. 111–281). The Committee advises the Secretary of Homeland Security on matters relating to shallow-draft inland and coastal waterway navigation and towing safety. This advice also assists the Coast Guard in formulating the position of the United States regarding the towing industry in advance of International Maritime Organization meetings.

It is expected that the committee will meet at least twice a year either in the Washington, DC, area or in cities with large towing centers of commerce and populated by high concentrations of towing industry and related businesses. It may also meet for extraordinary purposes. Its subcommittees may also meet to consider specific tasks as required. The Committee and its subcommittees may conduct intercessional telephonic meetings when necessary, in response to specific U.S. Coast Guard tasking.

Each Towing Safety Advisory Committee member serves a term of office of up to 3 years. Members may be considered to serve an additional consecutive term. All members serve without compensation from the Federal Government; however, upon request, they may receive travel reimbursement and per diem.

We will consider applications for the following seven positions. The first position listed is currently vacant, and the rest will become vacant on September 30, 2017:

1. One position representing the holders of active licensed Masters of towing vessels in offshore service;
2. Two positions representing the Barge and Towing Industry (reflecting a regional geographical balance);
3. One position representing port districts, port authorities or terminal operators;
4. One position representing holders of active licensed Masters or Pilots of towing vessels with experience on the Western Rivers and the Gulf Intracoastal Waterway;
5. One position representing active Masters of ship-docking or harbor towing vessels; and,
6. One position drawn from the general public.

To be eligible, applicants should have particular expertise, knowledge, and experience regarding shallow-draft inland, coastal waterway navigation, offshore navigation, and towing safety.

Registered lobbyists are not eligible to serve on federal advisory committees in an individual capacity. See ''Revised Guidance on Appointment of Lobbyists to Federal Advisory Committees, Boards and Commissions'' (79 FR 47482, August 13, 2014). The position we list for a member from the general public would be someone appointed in their individual capacity and would be designated as a Special Government Employee as defined in 202(a), Title 18, U.S.C. Registered lobbyists are lobbyists as defined in 2 U.S.C. 1602 who are required by 2 U.S.C. 1603 to register with the Secretary of the Senate and the Clerk of the House of Representatives.

If you are selected as a member drawn from the general public, you will be appointed and serve as a Special Government Employee as defined in section 202(a) of Title 18, United States Code. As a candidate for appointment as a Special Government Employee, applicants are required to complete a Confidential Financial Disclosure Report (OGE Form 450). The Coast Guard may not release the reports or the information in them to the public except under an order issued by a Federal court or as otherwise provided under the Privacy Act (5 U.S.C. 552a). Only the Designated Coast Guard Ethics Official or his or her designee may release a Confidential Financial Disclosure Report. Applicants can obtain this form by going to the Web site of the Office of Government Ethics (*www.oge.gov*), or by contacting the individual listed above in **FOR FURTHER INFORMATION CONTACT**. Applications for a member drawn from the general public that are not accompanied by a completed OGE Form 450 will not be considered.

In an effort to maintain a geographic balance of membership, we are encouraging representatives from tug and barge companies operating on the Western Rivers to apply for representation on the Committee.

The Department of Homeland Security does not discriminate in selection of Committee members on the basis of race, color, religion, sex, national origin, political affiliation, sexual orientation, gender identity, marital status, disabilities and genetic information, age, membership in an employee organization, or any other non-merit factor. The Department of Homeland Security strives to achieve a

widely diverse candidate pool for all of its recruitment selections.

If you are interested in applying to become a member of the Committee, send your cover letter and resume to William J. Abernathy, Alternate Designated Federal Officer of the Towing Safety Advisory Committee via one of the transmittal methods in the **ADDRESSES** section by the deadline in the **DATES** section of this notice. All email submittals will receive email receipt confirmation.

Dated: December 19, 2016.

J.G. Lantz,

Director of Commercial Regulations and Standards.

[FR Doc. 2017–01324 Filed 1–19–17; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2016–0002]

Final Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final notice.

SUMMARY: Flood hazard determinations, which may include additions or modifications of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or regulatory floodways on the Flood Insurance Rate Maps (FIRMs) and where applicable, in the supporting Flood Insurance Study (FIS) reports have been made final for the communities listed in the table below.

The FIRM and FIS report are the basis of the floodplain management measures that a community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the Federal Emergency Management Agency's (FEMA's) National Flood Insurance Program (NFIP). In addition, the FIRM and FIS report are used by insurance agents and others to calculate appropriate flood insurance premium rates for buildings and the contents of those buildings.

DATES: The effective date of April 5, 2017 which has been established for the FIRM and, where applicable, the supporting FIS report showing the new or modified flood hazard information for each community.

ADDRESSES: The FIRM, and if applicable, the FIS report containing the final flood hazard information for each community is available for inspection at the respective Community Map Repository address listed in the tables below and will be available online through the FEMA Map Service Center at *www.msc.fema.gov* by the effective date indicated above.

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW., Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final determinations listed below for the new or modified flood hazard information for each community listed. Notification of these changes has been published in newspapers of local circulation and 90 days have elapsed since that publication. The Deputy Associate Administrator for Insurance and Mitigation has resolved any appeals resulting from this notification.

This final notice is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR part 67. FEMA has developed criteria for floodplain management in floodprone areas in accordance with 44 CFR part 60.

Interested lessees and owners of real property are encouraged to review the new or revised FIRM and FIS report available at the address cited below for each community or online through the FEMA Map Service Center at *www.msc.fema.gov.*

The flood hazard determinations are made final in the watersheds and/or communities listed in the table below.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Dated: December 21, 2016.

Roy E. Wright,

Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

Community	Community map repository address
Adair County, Iowa and Incorporated Areas Docket No.: FEMA–B–1540	
City of Bridgewater	City Hall, 105 North Main Street, Bridgewater, IA 50837.
City of Fontanelle	City Hall, 313 Washington Street, Fontanelle, IA 50846.
City of Stuart	City Hall, 119 East Front Street, Stuart, IA 50250.
Unincorporated Areas of Adair County	Adair County Courthouse, 400 Public Square, Suite 5, Greenfield, IA 50849.
Adams County, Iowa and Incorporated Areas Docket No.: FEMA–B–1540	
City of Carbon	City Hall, 300 B Street, Carbon, IA 50839.
City of Corning	City Hall, 601 6th Street, Corning, IA 50841.
City of Nodaway	Community Building, 300 7th Avenue, Nodaway, IA 50857.
City of Prescott	City Hall, 607 2nd Street, Prescott, IA 50859.
Unincorporated Areas of Adams County	Adams County Courthouse, 500 9th Street, Corning, IA 50841.
Guthrie County, Iowa and Incorporated Areas Docket No.: FEMA–B–1540	
City of Bagley	City Hall, 207 Main Street, Bagley, IA 50026.
City of Bayard	City Hall, 403 Main Street, Bayard, IA 50029.
City of Casey	City Hall, 503 McPherson Street, Casey, IA 50048.
City of Guthrie Center	City Hall, 102 North 1st Street, Guthrie Center, IA 50115.
City of Jamaica	City Hall, Clerk's Office, 202 Van Nest Street, Jamaica, IA 50128.

Community	Community map repository address
City of Panora	City Hall, 102 Northwest 2nd Street, Panora, IA 50216.
Unincorporated Areas of Guthrie County	Guthrie County Courthouse, 200 North 5th Street, Guthrie Center, IA 50115.
Taylor County, Iowa and Incorporated Areas Docket No.: FEMA–B–1540	
City of Bedford	City Hall, 625 Court Avenue, Bedford, IA 50833.
City of Blockton	City Hall, 405 Division Street, Blockton, IA 50836.
City of Conway	City Hall, 308 Broad Street, Conway, IA 50833.
City of Gravity	City Hall, 304 Main Street, Gravity, IA 50848.
City of Lenox	City Hall, 200 South Main Street, Lenox, IA 50851.
Unincorporated Areas of Taylor County	Taylor County Courthouse, 405 Jefferson Street, Bedford, IA 50833.
Jackson County, Oregon and Incorporated Areas Docket No.: FEMA–B–1542	
City of Ashland	City of Ashland, 51 Winburn Way, Ashland, OR 97520.
Unincorporated Areas of Jackson County	Jackson County Development Services, 10 South Oakdale Avenue, Room 100, Medford, OR 97501.
Metropolitan Government of Nashville and Davidson County, Tennessee and Incorporated Areas Docket No.: FEMA–B–1404	
City of Belle Meade	Belle Meade City Hall, 4705 Harding Road, Nashville, TN 37205.
City of Berry Hill	Berry Hill City Hall, 698 Thompson Lane, Nashville, TN 37204.
City of Forest Hills	Forest Hills City Hall, 6300 Hillsboro Pike, Nashville, TN 37215.
City of Goodlettsville	City Hall, 105 South Main Street, Goodlettsville, TN 37072.
City of Oak Hill	Oak Hill City Hall, 5548 Franklin Pike, Suite 101, Nashville, TN 37220.
Metropolitan Government of Nashville and Davidson County..	Metro Nashville Public Works Department, 800 Second Avenue South, Nashville, TN 37219.
Willacy County, Texas and Incorporated Areas Docket No.: FEMA–B–1546	
Unincorporated Areas of Willacy County	Willacy County Courthouse, 576 West Main Avenue, Raymondville, TX 78580.

[FR Doc. 2017–01374 Filed 1–19–17; 8:45 am]
BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2016–0002; Internal Agency Docket No. FEMA–B–1661]

Proposed Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: Comments are requested on proposed flood hazard determinations, which may include additions or modifications of any Base Flood Elevation (BFE), base flood depth, Special Flood Hazard Area (SFHA) boundary or zone designation, or regulatory floodway on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports for the communities listed in the table below. The purpose of this notice is to seek general information and comment regarding the preliminary FIRM, and where applicable, the FIS report that the Federal Emergency Management Agency (FEMA) has provided to the affected communities. The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP). In addition, the FIRM and FIS report, once effective, will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents of those buildings.

DATES: Comments are to be submitted on or before April 24, 2017.

ADDRESSES: The Preliminary FIRM, and where applicable, the FIS report for each community are available for inspection at both the online location and the respective Community Map Repository address listed in the tables below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *www.msc.fema.gov* for comparison.

You may submit comments, identified by Docket No. FEMA–B–1661, to Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW., Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov.*

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW., Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov*; or visit the FEMA Map Information eXchange (FMIX) online at *www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: FEMA proposes to make flood hazard determinations for each community listed below, in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed flood hazard determinations, together with the floodplain management criteria required

by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. These flood hazard determinations are used to meet the floodplain management requirements of the NFIP and also are used to calculate the appropriate flood insurance premium rates for new buildings built after the FIRM and FIS report become effective.

The communities affected by the flood hazard determinations are provided in the tables below. Any request for reconsideration of the revised flood hazard information shown on the Preliminary FIRM and FIS report that satisfies the data requirements outlined in 44 CFR 67.6(b) is considered an appeal. Comments unrelated to the flood hazard determinations also will be considered before the FIRM and FIS report become effective.

Use of a Scientific Resolution Panel (SRP) is available to communities in support of the appeal resolution process. SRPs are independent panels of experts in hydrology, hydraulics, and other pertinent sciences established to review conflicting scientific and technical data and provide recommendations for resolution. Use of the SRP only may be exercised after FEMA and local communities have been engaged in a collaborative consultation process for at least 60 days without a mutually acceptable resolution of an appeal. Additional information regarding the SRP process can be found online at *http://floodsrp.org/pdfs/srp_fact_sheet.pdf.*

The watersheds and/or communities affected are listed in the tables below. The Preliminary FIRM, and where applicable, FIS report for each community are available for inspection at both the online location and the respective Community Map Repository address listed in the tables. For communities with multiple ongoing Preliminary studies, the studies can be identified by the unique project number and Preliminary FIRM date listed in the tables. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *www.msc.fema.gov* for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

February 27, 2017

Dated: December 21, 2016.

Roy E. Wright,

Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

Community	Community map repository address
Berkeley County, South Carolina and Incorporated Areas	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
Project: 10–04–4851S Preliminary Date: February 12, 2016	
City of Charleston	Engineering Department, 2 George Street, Suite 2100, Charleston, SC 29401.
City of Goose Creek	City Hall, 519 North Goose Creek Boulevard, Goose Creek, SC 29445.
City of Hanahan	City Hall, 1255 Yeamans Hall Road, Hanahan, SC 29410.
Town of Bonneau	Town Hall, 420 Municipal Lane, Bonneau, SC 29431.
Town of Jamestown	Municipal Complex, 7604 State Highway 41, Jamestown, SC 29453.
Town of Moncks Corner	Municipal Complex, 118 Carolina Avenue, Moncks Corner, SC 29461.
Unincorporated Areas of Berkeley County	Berkeley County Office Building, 1003 U.S. Highway 52, Moncks Corner, SC 29461.

[FR Doc. 2017–01375 Filed 1–19–17; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2016–0002; Internal Agency Docket No. FEMA–B–1664]

Proposed Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: Comments are requested on proposed flood hazard determinations, which may include additions or modifications of any Base Flood Elevation (BFE), base flood depth, Special Flood Hazard Area (SFHA) boundary or zone designation, or regulatory floodway on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports for the communities listed in the table below. The purpose of this notice is to seek general information and comment regarding the preliminary FIRM, and where applicable, the FIS report that the Federal Emergency Management Agency (FEMA) has provided to the affected communities. The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP). In addition, the FIRM and FIS report, once effective, will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents of those buildings.

DATES: Comments are to be submitted on or before April 24, 2017.

ADDRESSES: The Preliminary FIRM, and where applicable, the FIS report for each community are available for inspection at both the online location and the respective Community Map Repository address listed in the tables below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *www.msc.fema.gov* for comparison.

You may submit comments, identified by Docket No. FEMA–B–1664, to Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW., Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov.*

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and

Mitigation Administration, FEMA, 400 C Street SW., Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: FEMA proposes to make flood hazard determinations for each community listed below, in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. These flood hazard determinations are used to meet the floodplain management requirements of the NFIP and also are used to calculate the appropriate flood insurance premium rates for new buildings built after the FIRM and FIS report become effective.

The communities affected by the flood hazard determinations are provided in the tables below. Any request for reconsideration of the revised flood hazard information shown on the Preliminary FIRM and FIS report that satisfies the data requirements outlined in 44 CFR 67.6(b) is considered an appeal. Comments unrelated to the flood hazard determinations also will be considered before the FIRM and FIS report become effective.

Use of a Scientific Resolution Panel (SRP) is available to communities in support of the appeal resolution process. SRPs are independent panels of experts in hydrology, hydraulics, and other pertinent sciences established to review conflicting scientific and technical data and provide recommendations for resolution. Use of the SRP only may be exercised after FEMA and local communities have been engaged in a collaborative consultation process for at least 60 days without a mutually acceptable resolution of an appeal. Additional information regarding the SRP process can be found online at *http://floodsrp.org/pdfs/srp_fact_sheet.pdf.*

The watersheds and/or communities affected are listed in the tables below. The Preliminary FIRM, and where applicable, FIS report for each community are available for inspection at both the online location and the respective Community Map Repository address listed in the tables. For communities with multiple ongoing Preliminary studies, the studies can be identified by the unique project number and Preliminary FIRM date listed in the tables. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *www.msc.fema.gov* for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Dated: December 21, 2016.

Roy E. Wright,

Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

I. Non-watershed-based studies:

Community	Community map repository address
Los Angeles County, California and Incorporated Areas	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
Project: 15–09–2881S Preliminary Date: March 9, 2016	
City of Los Angeles	Department of Public Works, Bureau of Engineering, Street Improvement and Stormwater Division, 1149 South Broadway, Suite 810, Los Angeles, CA 90015.
City of Malibu	City Hall, 23825 Stuart Ranch Road, Malibu, CA 90265.
Unincorporated Areas of Los Angeles County	Public Works Headquarters, Watershed Management Division, 900 South Fremont Avenue, Alhambra, CA 91803.
Adams County, Illinois and Incorporated Areas	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
Project: 12–05–8943S Preliminary Date: January 29, 2016	
Unincorporated Areas of Adams County	Adams County Highway Department, 101 North 54th Street, Quincy, IL 62305.
Camden County, Missouri and Incorporated Areas	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
Project: 15–07–1668S Preliminary Date: June 30, 2016	
City of Camdenton	City Hall, 437 West US Highway 54, Camdenton, MO 65020.
City of Linn Creek	Camden County Courthouse, 1 Court Circle, Suite 15, Camdenton, MO 65020.
Unincorporated Areas of Camden County	Camden County Courthouse, 1 Court Circle, Suite 15, Camdenton, MO 65020.

Community	Community map repository address
Miller County, Missouri and Incorporated Areas	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
Project: 15–07–1669S Preliminary Date: June 30, 2016	
Unincorporated Areas of Miller County	Miller County Courthouse, 2001 Highway 52, Tuscumbia, MO 65082.
Morgan County, Missouri and Incorporated Areas	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
Project: 15–07–1671S Preliminary Date: June 30, 2016	
Town of Gravois Mills	City Office, 154 Highway 5, Gravois Mills, MO 65037.
Unincorporated Areas of Morgan County	Morgan County Courthouse, 100 East Newton, Versailles, MO 65084.

[FR Doc. 2017–01373 Filed 1–19–17; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2016–0002]

Final Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final Notice.

SUMMARY: Flood hazard determinations, which may include additions or modifications of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or regulatory floodways on the Flood Insurance Rate Maps (FIRMs) and where applicable, in the supporting Flood Insurance Study (FIS) reports have been made final for the communities listed in the table below.

The FIRM and FIS report are the basis of the floodplain management measures that a community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the Federal Emergency Management Agency's (FEMA's) National Flood Insurance Program (NFIP). In addition, the FIRM and FIS report are used by insurance agents and others to calculate appropriate flood insurance premium rates for buildings and the contents of those buildings.

DATES: The effective date of April 19, 2017 which has been established for the FIRM and, where applicable, the supporting FIS report showing the new or modified flood hazard information for each community.

ADDRESSES: The FIRM, and if applicable, the FIS report containing the final flood hazard information for each community is available for inspection at the respective Community Map Repository address listed in the tables below and will be available online through the FEMA Map Service Center at *www.msc.fema.gov* by the effective date indicated above.

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW., Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final determinations listed below for the new or modified flood hazard information for each community listed. Notification of these changes has been published in newspapers of local circulation and 90 days have elapsed since that publication. The Deputy Associate Administrator for Insurance and Mitigation has resolved any appeals resulting from this notification.

This final notice is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR part 67. FEMA has developed criteria for floodplain management in floodprone areas in accordance with 44 CFR part 60.

Interested lessees and owners of real property are encouraged to review the new or revised FIRM and FIS report available at the address cited below for each community or online through the FEMA Map Service Center at *www.msc.fema.gov.*

The flood hazard determinations are made final in the watersheds and/or communities listed in the table below.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Dated: December 21, 2016.

Roy E. Wright,

Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

I. Watershed-based studies:

Community	Community map repository address
Middle Chattahoochee-Lake Harding Watershed	
Carroll County, Georgia and Incorporated Areas Docket No.: FEMA–B–1551	
City of Whitesburg	City Hall, 60 Booster Field Drive, Whitesburg, GA 30185.
Unincorporated Areas of Carroll County	Carroll County Administration Building, Community Development Office, 423 College Street, Carrollton, GA 30117.

Community	Community map repository address
Columbus Consolidated Government, Georgia Docket No.: FEMA–B–1551	
Columbus Consolidated Government	Department of Engineering, Storm Water Division, 420 10th Street, 2nd Floor, Columbus, GA 31901.
Harris County, Georgia and Incorporated Areas Docket No.: FEMA–B–1551	
Unincorporated Areas of Harris County	Harris County Commissioners' Office, 104 North College Street, Hamilton, GA 31811.
Heard County, Georgia and Incorporated Areas Docket No.: FEMA–B–1551	
City of Franklin	City Hall, 150 Davis Street, Franklin, GA 30217.
Unincorporated Areas of Heard County	Heard County Building and Zoning Department, 215 East Court Square, Room 19, Franklin, GA 30217.
Troup County, Georgia and Incorporated Areas Docket No.: FEMA–B–1551	
City of LaGrange	City Hall, 200 Ridley Avenue, LaGrange, GA 30240.
City of West Point	City Hall, 730 1st Avenue, West Point, GA 31833.
Unincorporated Areas of Troup County	Troup County Government Center, 100 Ridley Avenue, LaGrange, GA 30240.
Lower Missouri-Moreau Watershed	
Boone County, Missouri and Incorporated Areas Docket No.: FEMA–B–1604	
City of Columbia	City Hall, 701 East Broadway, Columbia, MO 65205.
City of Rocheport	City Hall, 703 1st Street, Rocheport, MO 65279.
Town of McBaine	Boone County Government Center, Assessor's Office, 801 East Walnut Street, 1st Floor, Columbia, MO 65201.
Unincorporated Areas of Boone County	Boone County Government Center, Assessor's Office, 801 East Walnut Street, 1st Floor, Columbia, MO 65201.
Village of Hartsburg	Boone County Government Center, Assessor's Office, 801 East Walnut Street, 1st Floor, Columbia, MO 65201.
Village of Huntsdale	Boone County Government Center, Assessor's Office, 801 East Walnut Street, 1st Floor, Columbia, MO 65201.

II. Non-watershed-based studies:

Community	Community map repository address
Riverside County, California and Incorporated Areas Docket No.: FEMA–B–1532	
City of La Quinta	City Hall, Community Development Department, 78–495 Calle Tampico, La Quinta, CA 92253.
City of San Jacinto	Tri-Lake Consultants, 166 East Main Street, Suite 2, San Jacinto, CA 92583.
Unincorporated Areas of Riverside County	Riverside County Flood Control and Water Conservation District, 1995 Market Street, Riverside, CA 92501.
Marion County, Florida and Incorporated Areas Docket No.: FEMA–B–1523	
City of Ocala	Department of Public Works, 1805 Northeast 30th Avenue, Ocala, FL 34470.
Unincorporated Areas of Marion County	Marion County Growth Services, 2710 East Silver Springs Boulevard, Ocala, FL 34470.
Page County, Iowa and Incorporated Areas Docket No.: FEMA–B–1548	
City of Blanchard	City Hall, 104 Main Street, Blanchard, IA 51630.
City of Braddyville	City Hall, 208 East Main Street, Braddyville, IA 51631.
City of Clarinda	City Hall, 200 South 15th Street, Clarinda, IA 51632.
City of Coin	City Hall, 506 Depot Street, Coin, IA 51636.
City of Essex	City Hall, 412 Iowa Avenue, Essex, IA 51638.

Community	Community map repository address
City of Hepburn	Hepburn City Office, 501 Railroad Street, Clarinda, IA 51632.
City of Northboro	Clarinda City Building, 200 South 15th Street, Clarinda, IA 51632.
City of Shambaugh	City Hall, 307 Main Street, Shambaugh, IA 51651.
City of Shenandoah	City Hall, 500 West Clarinda Avenue, Shenandoah, IA 51601.
City of Yorktown	Clarinda City Building, 200 South 15th Street, Clarinda, IA 51632.
Unincorporated Areas of Page County	Clarinda City Building, 200 South 15th Street, Clarinda, IA 51632.
St. Mary Parish, Louisiana and Incorporated Areas Docket No.: FEMA–B–1543	
Chitimacha Tribe of Louisiana	Chitimacha Tribe of Louisiana, St. Mary Parish Courthouse, Planning and Zoning Office, 500 Main Street, 5th Floor, Franklin, LA 70538.
City of Franklin	City Hall, 300 Iberia Street, Franklin, LA 70538.
City of Morgan City	Planning and Zoning Department, 509 2nd Street, Morgan City, LA 70380.
City of Patterson	City Hall, 1314 Main Street, Patterson, LA 70392.
Town of Baldwin	Town Hall, 800 Main Street, Baldwin, LA 70514.
Town of Berwick	Town Hall, 3225 3rd Street, Berwick, LA 70342.
Unincorporated Areas of St. Mary Parish	St. Mary Parish Courthouse, Planning and Zoning Office, 500 Main Street, 5th Floor, Franklin, LA 70538.
Olmsted County, Minnesota and Incorporated Areas Docket Nos.: FEMA–B–1329 and FEMA–B–1557	
City of Chatfield	Municipal Offices, 21 Southeast 2nd Street, Chatfield, MN 55923.
City of Dover	City Hall, 218 North Chatfield Street, Dover, MN 55929.
City of Eyota	City Hall, 38 South Front Street Southwest, Eyota, MN 55934.
City of Pine Island	City Hall, 250 South Main Street, Pine Island, MN 55963.
City of Rochester	City Hall, 201 4th Street Southeast, Rochester, MN 55904.
City of Stewartville	City Hall, 105 East 1st Street, Stewartville, MN 55976.
Unincorporated Areas of Olmsted County	Olmsted County Government Center, 151 4th Street Southeast, Rochester, MN 55904.
Roseau County, Minnesota and Incorporated Areas Docket Nos.: FEMA–B–1310 and FEMA–B–1548	
City of Badger	City Hall, 111 North Main Street, Badger, MN 56714.
City of Greenbush	City Hall, 244 Main Street North, Greenbush, MN 56726.
City of Roseau	City Center, 121 Center Street East, Suite 202, Roseau, MN 56751.
City of Warroad	City Office, 121 Main Avenue Northeast, Warroad, MN 56763.
Unincorporated Areas of Roseau County	Roseau County Courthouse, 606 5th Avenue Southwest, Room 130, Roseau, MN 56751.

[FR Doc. 2017–01372 Filed 1–19–17; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R6–MB–2017–N008; FF06M00000–XXX–FRMB48720660090]

Availability of Record of Decision for Eagle Take Permits for the Chokecherry and Sierra Madre Phase I Wind Energy Project

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service or USFWS), have prepared a record of decision (ROD) on the final environmental impact statement (Final EIS) for Eagle Take Permits for the Chokecherry and Sierra Madre Phase I Wind Energy Project (CCSM Phase I Project). The ROD and Final EIS were prepared under the National Environmental Policy Act of 1969 (NEPA), as amended, in response to an application from Power Company of Wyoming LLC (PCW) for eagle take permits (ETPs) pursuant to the Bald and Golden Eagle Protection Act (BGEPA) and its implementing regulations. PCW has applied for both a standard and a programmatic ETP for the CCSM Phase I Project in Carbon County, Wyoming. The ROD is a concise statement of the purpose and need for the action, description of the project, the action alternatives considered, decisions made, and acceptable mitigation measures identified and committed to for avoiding or minimizing environmental impacts. The ROD also summarizes potential effects of the selected alternative, the public involvement process, and comments on the Final EIS.

ADDRESSES: Copies of the ROD are available at the Carbon County Library System at 215 West Buffalo Street, Rawlins, Wyoming; the Saratoga Public Library at 503 West Elm Street, Saratoga, Wyoming; the USFWS Wyoming Ecological Services Office at 5353 Yellowstone Road, Suite 308A, Cheyenne, Wyoming (contact Nathan Darnall to coordinate access, at *nathan_darnall@fws.gov* or 307–772–2374 ext. 246); and the USFWS Region 6 Office at 134 South Union Boulevard, Lakewood, Colorado (contact Louise Galiher to coordinate access, at *louise_galiher@fws.gov* or 303–236–8677). The ROD, the Final EIS, the permit application and the supporting eagle conservation plan are also available electronically on the USFWS Web site at *https://www.fws.gov/mountain-prairie/wind/ChokecherrySierraMadre/index.html.*

You may contact us regarding the ROD via the following methods:

- *Email: CCSM_EIS@fws.gov.*
- *U.S. Mail:* Chokecherry and Sierra Madre EIS, U.S. Fish and Wildlife Service, Mountain-Prairie Region,

Attention: Louise Galiher, P.O. Box 25486 DFC, Denver, CO 80225.

• *Hand-Delivery/Courier:* Chokecherry and Sierra Madre EIS, U.S. Fish and Wildlife Service, Mountain-Prairie Region, Attention: Louise Galiher, 134 Union Blvd., Lakewood, CO 80228.

FOR FURTHER INFORMATION CONTACT: Louise Galiher, at 303–236–8677 (phone) or *louise_galiher@fws.gov* (email); or Clint Riley, at 303–236–5231 (phone) or *clint_riley@fws.gov* (email). Persons who use a telecommunications device for the deaf may call the Federal Relay Service at 1–800–877–8339 to contact the above individuals. The Federal Relay Service is available 24 hours a day, 7 days a week, for you to leave a message or question with the above individuals. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: We, the U.S. Fish and Wildlife Service (Service), have prepared a ROD on the Final EIS under NEPA, as amended (42 U.S.C. 4321 *et seq.*), in response to an application from PCW for ETPs pursuant to BGEPA, (16 U.S.C. 668–668c) and its implementing regulations. PCW has applied for both a standard and programmatic ETP for the CCSM Phase I Project in Carbon County, Wyoming.

Public Coordination

As noted in the notice of availability for the Final EIS (81 FR 89133, December 9, 2016), the public was notified of the intent to prepare an EIS, and was earlier notified of the availability of the Draft EIS for review and comment. The alternatives analyzed in the Draft EIS were carried forward for full analysis in the Final EIS. Agencies, tribes, organizations, and interested parties provided comments on the Draft EIS via mail, email, and public meetings, and the Final EIS via mail and email.

The Selected Alternative

In the Final EIS, the Service analyzed four alternatives as described below. The Service identified the proposed action as the preferred alternative. In the ROD, the proposed action was identified as the selected alternative for implementation.

Alternative 1: Proposed Action. Alternative 1 is for the Service to issue ETPs for the construction of the Phase I wind turbines and infrastructure components and for the operation of the Phase I CCSM project, based on the ETP applications submitted by PCW. The proposed action includes avoidance and minimization measures, best management practices, and compensatory mitigation described in detail in the EIS and in PCW's application and ECP. As compensatory mitigation PCW has proposed to retrofit existing high-risk power poles, thereby reducing ongoing eagle mortality from electrocution.

Other Alternatives Considered

Four alternatives, including the proposed action, were analyzed in the Final EIS. The other three alternatives analyzed included:

Alternative 2: Proposed Action with Different Mitigation. Under Alternative 2, the Service would issue ETPs for the construction and operation of the Phase I CCSM Project as under Alternative 1, but would require PCW to implement a different form of compensatory mitigation than proposed in its ETP applications. We considered mitigation of older wind facilities, lead abatement, carcass removal, carcass avoidance, wind conservation easements, habitat enhancement (focusing on prey habitat), and rehabilitation of injured eagles as possible alternative forms of compensatory mitigation.

Alternative 3: Issue ETPs for Only the Phase I of Sierra Madre Wind Development Area. The Service received numerous comments during the scoping process requesting that we examine a different development scenario from that proposed by PCW. However, to issue an ETP, we must analyze a specific project and ECP to determine if it meets the requirements for an ETP. Alternative 3 represented an example of a different development scenario PCW could present in a new application if the Service were to determine that the Phase I CCSM Project would meet all the criteria for issuing an ETP, but not at the scale proposed. Alternative 3 was for the Service to issue ETPs for the construction of Phase I infrastructure and the construction and operation of wind turbines only in the Sierra Madre Wind Development Area (WDA) (298 turbines total). This alternative included avoidance and minimization measures, best management practices, and compensatory mitigation described in PCW's application as they apply to the Sierra Madre WDA.

Alternative 4: No Action. Under Alternative 4, the Service would deny PCW standard and programmatic ETPs for construction and operation of the Phase I CCSM Project. In addition to being a potential outcome of the permit review process, analysis of the No Action alternative is required by Council on Environmental Quality (CEQ) regulations (40 CFR 1502.14) and provides a baseline against which to compare the environmental impacts of the proposed action and other reasonable alternatives. ETPs are not required in order for PCW to construct and operate the project; therefore, if we deny the ETPs, PCW may choose to construct and operate the Phase I CCSM Project without ETPs and without adhering to an ECP. Alternative 4 analyzed both a ''No Build'' scenario and a ''Build Without ETPs'' scenario.

Environmentally Preferable Alternative

After review of the programmatic ETP application and completion of the NEPA process, we determined that Alternative 3 (Issue ETPs for Only Phase I of Sierra Madre Wind Development Area) and the No Build option of Alternative 4 (No Action: Denial of ETPs) are the Environmentally Preferable Alternatives. Although Alternative 3 would result in lower eagle take and fewer environmental impacts than Alternative 1, we have not received a permit application for this or any other smaller subset of the CCSM Phase I Project. As described in the Final EIS, we considered Alternative 3 as an example of a different development scenario and stated that Alternative 3 would have been eligible for selection only if we were to determine that Alternative 1 did not meet regulatory criteria for a standard ETP and programmatic ETP. Because Alternative 1 did meet regulatory criteria, we did not select Alternative 3 for implementation.

Because the Alternative 4 No Build option would result in no construction or operation impacts from developing the proposed CCSM Phase I Project, including no take of eagles, we have identified the No Build option as an Environmentally Preferred Alternative. However, because we find that Alternative 1 meets permitting regulatory criteria, and have identified no other basis for denying the ETP applications, we are not selecting Alternative 4. In addition, the No Build option of Alternative 4 would be inconsistent with Secretarial Order 3285, which encourages development of renewable energy generation projects in the United States. We also note that Alternative 4 would deny the ETP applications, but would not necessarily result in the No Build scenario, and that if Alternative 4 would result in the CCSM Phase I Project being built without conservation measures that would otherwise be required by an ETP, it would not constitute an environmentally preferred alternative.

Minimization of Impacts

The Final EIS addresses public concerns, potential impacts, and methods to minimize impacts. The Service considered that all identified practicable means to avoid or minimize environmental impacts associated with implementing the selected alternative will be utilized.

Decision

The Service's decision is to implement Alternative 1: Proposed Action, and issue a standard and a programmatic eagle take permit for the CCSM Phase I Project.

This decision is based on the information contained in the Final EIS for Eagle Take Permits for the CCSM Phase I Project, which updated and supplemented the information contained in the Draft EIS.

National Environmental Policy Act Compliance

Our decision of whether to issue standard and programmatic ETPs to PCW triggered compliance with NEPA. NEPA required the Service to analyze the direct, indirect, and cumulative impacts of the CCSM Phase I Project before we made our decision, and to make our analysis available to the public. We prepared the Final EIS to inform the public of our proposed permit action, alternatives to that action, the environmental impacts of the alternatives, and measures to minimize adverse environmental effects.

Authorities

This notice is published in accordance with NEPA; the CEQ's regulations for implementing NEPA, 40 CFR parts 1500 through 1508; and the Department of the Interior's NEPA regulations, 43 CFR part 46.

Noreen Walsh,

Regional Director, USFWS Mountain-Prairie Region.

[FR Doc. 2017–01346 Filed 1–19–17; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

[FWS–R4–FHC–2017–N003; FVHC98220410150–XXX–FF04G01000]

Deepwater Horizon Oil Spill; Louisiana Trustee Implementation Group Final Restoration Plan #1: Restoration of Wetlands, Coastal, and Nearshore Habitats; Habitat Projects on Federally Managed Lands; and Birds

AGENCY: Department of the Interior.

ACTION: Notice of availability.

SUMMARY: In accordance with the Oil Pollution Act of 1990 (OPA), the National Environmental Policy Act (NEPA), the Consent Decree, and the Final Programmatic Damage Assessment Restoration Plan and Final Programmatic Environmental Impact Statement, the Federal and State natural resource trustee agencies for the Louisiana Trustee Implementation Group (Trustees) have approved the ''Louisiana Trustee Implementation Group Final Restoration Plan #1: Restoration of Wetlands, Coastal, and Nearshore Habitats; Habitat Projects on Federally Managed Lands; and Birds'' (Restoration Plan #1). The Trustees have selected to fund engineering and design activities for six projects intended to continue the process of restoring natural resources and services injured or lost as a result of the *Deepwater Horizon* oil spill, which occurred on or about April 20, 2010, in the Gulf of Mexico.

ADDRESSES: Obtaining Documents: You may download the ''Louisiana Trustee Implementation Group Final Restoration Plan #1: Restoration of Wetlands, Coastal, and Nearshore Habitats, Habitat Projects on Federally Managed Lands; and Birds'' at any of the following sites:

- *http://www.gulfspillrestoration.noaa.gov*.
- *http://www.doi.gov/deepwaterhorizon*.
- *http://la-dwh.com*.

Alternatively, you may request a CD of the Final Restoration Plan # 1 (see **FOR FURTHER INFORMATION CONTACT**). You may also view the document at any of the public facilities listed at *http://www.gulfspillrestoration.noaa.gov.*

FOR FURTHER INFORMATION CONTACT: Liz Williams, at *LATIG@la.gov.*

SUPPLEMENTARY INFORMATION:

Introduction

On or about April 20, 2010, the mobile offshore drilling unit *Deepwater Horizon,* which was being used to drill a well for BP Exploration and Production, Inc. (BP), in the Macondo prospect (Mississippi Canyon 252–MC252), experienced a significant explosion, fire, and subsequent sinking in the Gulf of Mexico, resulting in an unprecedented volume of oil and other discharges from the rig and from the wellhead on the seabed. The *Deepwater Horizon* oil spill is the largest oil spill in U.S. history, discharging millions of barrels of oil over a period of 87 days. In addition, well over 1 million gallons of dispersants were applied to the waters of the spill area in an attempt to disperse the spilled oil. An undetermined amount of natural gas was also released into the environment as a result of the spill.

The *Deepwater Horizon* State and Federal natural resource trustees (Trustees) conducted the natural resource damage assessment (NRDA) for the *Deepwater Horizon* oil spill under the Oil Pollution Act 1990 (OPA; 33 U.S.C. 2701 *et seq.*). Pursuant to OPA, Federal and State agencies act as trustees on behalf of the public to assess natural resource injuries and losses and determine actions required to compensate the public for those injuries and losses. OPA further instructs the designated trustees to develop and implement a plan for the restoration, rehabilitation, replacement, or acquisition of the equivalent of the injured natural resources under their trusteeship, including the loss of use and services from those resources from the time of injury until the time of restoration to baseline (the resource quality and conditions that would exist if the spill had not occurred) is complete.

The Trustees are:

- U.S. Department of the Interior (DOI), as represented by the National Park Service, U.S. Fish and Wildlife Service, and Bureau of Land Management;
- National Oceanic and Atmospheric Administration (NOAA), on behalf of the U.S. Department of Commerce;
- U.S. Department of Agriculture (USDA);
- U.S. Environmental Protection Agency (EPA);
- State of Louisiana Coastal Protection and Restoration Authority (CPRA), Oil Spill Coordinator's Office (LOSCO), Department of Environmental Quality (LDEQ), Department of Wildlife and Fisheries (LDWF), and Department of Natural Resources (LDNR);
- State of Mississippi Department of Environmental Quality;
- State of Alabama Department of Conservation and Natural Resources and Geological Survey of Alabama;
- State of Florida Department of Environmental Protection and Fish and Wildlife Conservation Commission; and
- For the State of Texas: Texas Parks and Wildlife Department, Texas General Land Office, and Texas Commission on Environmental Quality.

Upon completion of the NRDA, the Trustees reached and finalized a settlement of their natural resource damage claims with BP in a Consent Decree approved by the United States District Court for the Eastern District of Louisiana. Pursuant to that Consent Decree, restoration projects in Louisiana are now chosen and managed by the

Louisiana Trustee Implementation Group (TIG). The TIG Trustees are:

- U.S. Department of the Interior (DOI), as represented by the National Park Service, U.S. Fish and Wildlife Service, and Bureau of Land Management;
- National Oceanic and Atmospheric Administration (NOAA), on behalf of the U.S. Department of Commerce;
- U.S. Department of Agriculture (USDA);
- U.S. Environmental Protection Agency (EPA);
- Louisiana Coastal Protection and Restoration Authority (CPRA);
- Louisiana Department of Natural Resources (LDNR);
- Louisiana Department of Environmental Quality (LDEQ);
- Louisiana Oil Spill Coordinator's Office (LOSCO); and
- Louisiana Department of Wildlife and Fisheries (LDWF).

A notice of availability of the Draft Restoration Plan #1: Restoration of Wetlands, Coastal, and Nearshore Habitats; Habitat Projects on Federally Managed Lands; and Birds was published in the **Federal Register** on November 1, 2016 (81 FR 75840). The public was provided with a period to review and comment on the Draft Restoration Plan, from October 20 through December 9, 2016, and a public meeting was held on November 30, 2016, in Baton Rouge, Louisiana. The Louisiana TIG considered the public comments received, which informed the TIG's analyses and selection of the restoration alternatives in the Restoration Plan #1. A summary of the public comments received, and the Louisiana TIG's responses to those comments, are addressed in chapter 5 of the Restoration Plan #1.

Overview of the ''Louisiana Trustee Implementation Group Final Restoration Plan #1: Restoration of Wetlands, Coastal, and Nearshore Habitats; Habitat Projects on Federally Managed Lands; and Birds'' (Restoration Plan #1)

For selected restoration alternatives in this Restoration Plan #1, the Louisiana TIG may, after completion of the engineering and design process discussed in this plan, propose some or all of those projects for construction using *Deepwater Horizon* NRDA funds. Projects selected for construction funding would then be evaluated further under NEPA and OPA in a future Draft Restoration Plan, which would be provided to the public for review and comment in accordance with the appropriate Louisiana and Federal laws.

The total estimated cost for the engineering and design activities for the six restoration projects is $22,300,000. Details on the engineering and design activities for these projects are provided in the Restoration Plan #1.

Administrative Record

The documents comprising the Administrative Record for this Restoration Plan can be viewed electronically at *https://www.doi.gov/deepwaterhorizon.*

Authority

The authority of this action is the Oil Pollution Act of 1990 (33 U.S.C. 2701 *et seq.*) and the implementing Natural Resource Damage Assessment regulations found at 15 CFR 990.

Kevin D. Reynolds,

Deepwater Horizon NRDAR Case Manager, Department of the Interior.

[FR Doc. 2017–00999 Filed 1–19–17; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLCAD01000 L12100000.MD0000 17XL1109AF]

Meeting of the California Desert District Advisory Council

AGENCY: Bureau of Land Management.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act of 1976 (FLPMA), and the Federal Advisory Committee Act of 1972 (FACA), the U.S. Department of the Interior, Bureau of Land Management (BLM) California Desert District Advisory Council (DAC) will meet as indicated below.

DATES: The next meeting of the BLM's California DAC will be held February 24–25, 2017. The council will participate in a field tour of BLM-administered public lands on Friday, February 24, 2017, from 10:00 a.m. to 5:00 p.m. and will meet in formal session on Saturday, February 25, 2017, from 8:00 a.m. to 5:00 p.m. in Needles, California. Members of the public are welcome. They must provide their own transportation, meals and beverages. Final agendas for the Friday field trip and the Saturday public meeting, along with the Saturday meeting location, will be posted on the BLM Web page when finalized.

FOR FURTHER INFORMATION CONTACT: Stephen Razo, BLM California Desert District External Affairs, 1–951–697–5217. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individuals. You will receive a reply during normal hours.

SUPPLEMENTARY INFORMATION: All DAC meetings are open to the public. The 15-member council advises the Secretary of the Interior, through the BLM, on a variety of planning and management issues associated with public land management on BLM-administered lands in the California desert. The agenda will include time for public comment at the beginning and end of the meeting, as well as during various presentations. While the Saturday meeting is tentatively scheduled from 8:00 a.m. to 5:00 p.m., the meeting could conclude prior to 5:00 p.m. should the council conclude its presentations and discussions. Therefore, members of the public interested in a particular agenda item or discussion should schedule their arrival accordingly. The agenda for the Saturday meeting will include updates by council members, the BLM California Desert District manager, five field managers, and council subgroups. Written comments may be filed in advance of the meeting for the California Desert District Advisory Council, c/o Bureau of Land Management, External Affairs, 22835 Calle San Juan de Los Lagos, Moreno Valley, CA 92553. Written comments will also be accepted at the time of the meeting and, if copies are provided to the recorder, will be incorporated into the minutes.

Dated: January 9, 2017.

Beth Ransel,

California Desert District Manager.

[FR Doc. 2017–01340 Filed 1–19–17; 8:45 am]

BILLING CODE 4310–40–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–968]

Certain Radiotherapy Systems and Treatment Planning Software, and Components Thereof; Commission Determination To Review a Final Initial Determination in Part and, on Review, To Affirm in Part, Vacate in Part and Remand Some Issues to the Administrative Law Judge, and Maintain Certain Issues Under Review

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission (''the Commission'') has determined to review in part the final initial determination (the ''Final ID'') issued by the presiding administrative law judge (''ALJ'') on October 27, 2016. As to one issue under review, the Commission has determined to affirm. As to other issues, the Commission has determined to vacate and remand the investigation to the ALJ for additional findings. Other issues remain under review.

FOR FURTHER INFORMATION CONTACT: Ron Traud, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–3427. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone 202–205–2000. General information concerning the Commission may also be obtained by accessing its Internet server (*https://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202–205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on October 30, 2015, based on a complaint filed by Varian Medical Systems, Inc. of Palo Alto, California; and Varian Medical Systems International AG of ZG, Switzerland (collectively, ''Varian''). 80 FR 66934 (Oct. 30, 2015). The complaint alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain radiotherapy systems and treatment planning software, and components thereof by reason of infringement of certain claims of U.S. Patent Nos. 7,945,021 (''the '021 patent''); 8,116,430 (''the '430 patent''); 8,867,703 (''the '703 patent''); 7,880,154 (''the '154 patent''); 7,906,770 (''the '770 patent''); and 8,696,538 (''the '538 patent''). *Id.* The notice of investigation named as respondents Elekta AB of Stockholm, Sweden; Elekta Ltd. of Crawley, United Kingdom; Elekta GmbH of Hamburg, Germany; Elekta Inc. of Atlanta, Georgia; IMPAC Medical Systems, Inc. of Sunnyvale, California; Elekta Instrument (Shanghai) Limited of Shanghai, China; and Elekta Beijing Medical Systems Co. Ltd. of Beijing, China (collectively, ''Elekta''). The Office of Unfair Import Investigations (''OUII'') also was named as a party to the investigation. *Id.*

Prior to the evidentiary hearing, Varian withdrew its allegations as to certain patent claims and also added additional claims. *See* Notice of Commission Determination Not to Review an Initial Determination Granting a Motion to Amend the Complaint and Notice of Investigation (Apr. 4, 2016). Varian proceeded at the evidentiary hearing on the following patents and claims: Claims 1, 4, 9, and 15 of the '021 patent; claims 6 and 18 of the '430 patent; claim 1 of the '703 patent; claims 23 and 26 of the '154 patent; claims 61, 67, and 68 of the '770 patent; and claims 26 and 41 of the '538 patent.

On October 27, 2016, the ALJ issued his Final ID, which finds a violation of section 337 by Elekta as to claims 23 and 26 of the '154 patent; claims 26 and 41 of the '538 patent; and claim 67 of the '770 patent. The Final ID found no violation of section 337 in connection with claim 61 of the '770 patent; claims 1, 4, 9, and 15 of the '021 patent; claims 6 and 18 of the '430 patent; and claim 1 of the '703 patent. The ALJ recommended that the Commission issue a limited exclusion orders directed to Elekta's accused products that infringe the claims for which a violation was found. The ALJ further recommended that cease and desist orders issue.

Having examined the record in this investigation, including the Final ID, the petitions for review, and the responses thereto, the Commission has determined to review the Final ID in part and, on review, to take certain actions. In particular, the Commission has determined as follows:

(1) To review the Final ID's conclusions that the claims asserted for infringement and/or domestic industry of the '154 patent, the '770 patent, and the '538 patent are not invalid as obvious due to Elekta's witness's failure to analyze Varian's evidence of secondary considerations of nonobviousness. On review, the Commission has determined to vacate this determination and to remand the investigation to the ALJ with respect to this issue. The ALJ shall analyze Varian's evidence of secondary considerations and (1) make findings as to that evidence, including whether Varian has demonstrated that there is a nexus between the claims and the evidence of secondary considerations, and any other finding necessary to determine the effect of that evidence on whether those claims are obvious; (2) make findings as to whether and to what extent that evidence of secondary considerations supports Varian's arguments that Elekta has not shown that the asserted claims are obvious; and (3) reconsider the ultimate conclusion of whether the claims are obvious in light of the foregoing.

(2) To review the Final ID's determination regarding the obviousness of the asserted claims of the '021 patent, the '430 patent, and the '703 patent. This issue remains under review.

(3) To review the claim construction in the Final ID of the claim term ''communications network,'' as found in the asserted claims of the '021 and '430 patents. *See, e.g.,* Final ID at 46–54. This issue remains under review.

(4) To review the Final ID's conclusions regarding the anticipation of claim 18 of the '430 patent by the Jaffray MICCAI 2001 reference, and on review, the Commission affirms that this claim is not anticipated and clarifies that the indication otherwise on page 152 of the Final ID is a typographical error.

(5) To review the Final ID's discussion, interpretation, and application of *Certain Electronic Devices with Image Processing Systems, Components Thereof, and Associated Software,* 337–TA–724, Comm'n Op. (Nov. 21, 2011), in analyzing the infringement of claim 18 of the '430 patent and the asserted claims of the '154, '538, and '770 patents, and to review the Final ID's conclusions regarding infringement of the aforementioned claims. *See, e.g.,* Final ID at 133–39, 253–57, 327, 394. This issue remains under review.

The Commission has determined to not review the remainder of the Final

ID. The Commission does not seek further briefing at this time.

In light of the remand, the ALJ shall set a new target date within thirty days of the date of this notice consistent with the Remand Order. The current target date for this investigation is March 16, 2017.

Any briefing on reviewed and remanded issues, and on remedy, bonding, and the public interest will follow Commission consideration of the remand ID.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.
Issued: January 13, 2017.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2017–01315 Filed 1–19–17; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 332–560]

Generalized System of Preferences: Possible Modifications, 2016 Review

AGENCY: United States International Trade Commission.

ACTION: Notice of institution of investigation and scheduling of public hearing.

SUMMARY: Following receipt of a request on January 5, 2017, from the United States Trade Representative (USTR), the U.S. International Trade Commission (Commission) instituted investigation No. 332–560, *Generalized System of Preferences: Possible Modifications, 2016 Review,* for the purpose of providing advice and information relating to the possible designation of additional articles, removal of articles, and waiver of competitive need limitations.

DATES:

February 3, 2017: Deadline for filing requests to appear at the public hearing.

February 8, 2017: Deadline for filing pre-hearing briefs and statements.

February 21, 2017: Public hearing.

February 27, 2017: Deadline for filing post-hearing briefs and statements.

March 3, 2017: Deadline for filing all other written submissions.

May 5, 2017: Transmittal of Commission report to the USTR.

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 *https://edis.usitc.gov.*

FOR FURTHER INFORMATION CONTACT: Information specific to this investigation may be obtained from Renee Berry, Project Leader, Office of Industries (202–205–3498 or *renee.berry@usitc.gov*) or Sabina Neumann, Deputy Project Leader, Office of Industries (202–205–3000 or *sabina.neumann@usitc.gov*), or Marin Weaver, Technical Advisor, Office of Industries (202–205–3461 or *marin.weaver@usitc.gov*). 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*). The media should contact Margaret O'Laughlin, Office of External Relations (202–205–1819 or *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 Web 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: In his letter, the USTR requested the advice and information described below.

(1) Advice concerning the probable economic effect of elimination of U.S. import duties on certain articles from all beneficiary developing countries under the GSP program. In accordance with sections 503(a)(1)(A), 503(e), and 131(a) of the Trade Act of 1974, as amended (''the 1974 Act'') (19 U.S.C. 2463(a)(1)(A), 2463(e), and 2151(a)), and pursuant to the authority of the President delegated to the USTR by sections 4(c) and 8(c) and (d) of Executive Order 11846 of March 31, 1975, as amended, and pursuant to section 332(g) of the Tariff Act of 1930 (19 U.S.C. 1332(g)), the USTR notified the Commission that the articles identified in Table A of the Annex to the USTR request letter are being considered for designation as eligible articles for purposes of the GSP program. The USTR requested that the Commission provide its advice as to the probable economic effect on total U.S. imports, U.S. industries producing like or directly competitive articles, and on U.S. consumers of the elimination of U.S. import duties on the articles identified in Table A of the Annex to the USTR request letter for all beneficiary developing countries under the GSP program (see Table A below).

TABLE A—POSSIBLE ADDITIONS TO THE LIST OF PRODUCTS ELIGIBLE FOR THE GSP ELIGIBLE PRODUCTS

HTS subheading	Brief description	Countries
1104.19.90	Rolled or flaked grains of cereals, other than of barley or oats	Beneficiary Developing Countries.
2008.20.00	Pineapples, otherwise prepared or preserved, nesoi	Beneficiary Developing Countries.
2915.90.18	Saturated acyclic monocarboxylic acids, nesoi	Beneficiary Developing Countries.
3809.93.50	Finishing agents, dye carriers and other preparations used in leather and like industries, <5% by weight aromatic (mod.) substance(s).	Beneficiary Developing Countries.
3912.20.00	Cellulose nitrates (including collodions), in primary forms	Beneficiary Developing Countries.

(2) Advice concerning the probable economic effect of removal of certain articles from specified countries from eligibility for duty-free treatment. The USTR notified the Commission that one article is being considered for removal from eligibility for duty free treatment under the GSP program from all countries. Under authority delegated by the President, pursuant to section 332(g) of the Tariff Act of 1930, with respect to the article listed in Table B of the Annex to the USTR request letter, the USTR requested that the Commission provide its advice as to the probable economic effect of the removal from eligibility for duty-free treatment under the GSP program for this article from all countries on total U.S. imports, U.S. industries producing like or directly

competitive articles, and on U.S. consumers (see Table B below).

TABLE B—POSSIBLE REMOVAL FROM DUTY-FREE STATUS FROM ALL COUNTRIES FOR A PRODUCT ON THE LIST OF ELIGIBLE ARTICLES FOR THE GSP

HTS subheading	Brief description	Country
2922.49.40.20	Glycine—part of 2922.49.40, ''Amino acids''	All.

(3) Advice concerning waiver of certain competitive need limitations. Under authority delegated by the President, pursuant to section 332(g) of the Tariff Act of 1930, and in accordance with section 503(d)(1)(A) of the 1974 Act, the USTR requested that the Commission provide advice on whether any industry in the United States is likely to be adversely affected by a waiver of the competitive need limitations specified in section 503(c)(2)(A) of the 1974 Act for the countries and articles specified in Table C of the attached Annex to the request letter (see Table C below). Further, in accordance with section 503(c)(2)(E) of the 1974 Act, the USTR requested that the Commission provide its advice with respect to whether like or directly competitive products were being produced in the United States on January 1, 1995. The USTR also requested that the Commission provide its advice as to the probable economic effect on total U.S. imports, as well as on consumers, of the requested waivers. With respect to the competitive need limit in section 503(c)(2)(A)(i)(I) of the 1974 Act, the USTR requested that the Commission use the dollar value limit of $175,000,000.

TABLE C—POSSIBLE WAIVERS OF THE CNL FROM A SPECIFIC COUNTRY

HTS subheading	Brief description	Country
0410.00.00	Edible products of animal origin, nesoi	Indonesia.
0714.90.10	Fresh or chilled dasheens, whether or not sliced or in the form of pellets	Ecuador.
4011.20.10	New pneumatic radial tires, of rubber, of a kind used on buses or trucks	Indonesia.
4409.10.05	Coniferous wood continuously shaped along any of its ends, whether or not also continuously shaped along any {of} its edges or faces.	Brazil.
6802.99.00	Monumental or building stone & arts. thereof, nesoi, further worked than simply cut/sawn, nesoi.	Brazil.
8525.80.30	Television cameras, nesoi	Thailand.
9001.50.00	Spectacle lenses of materials other than glass, unmounted	Thailand.

Time for reporting, HTS detail, portions of report to be classified. As requested by the USTR, the Commission will provide the requested advice and information by May 5, 2017. The USTR asked that the Commission issue, as soon as possible thereafter, a public version of the report containing only the unclassified information, with any confidential business information deleted. As requested, the Commission will provide its economic effect advice and statistics (profile of the U.S. industry and market and U.S. import and export data) and any other relevant information or advice separately and individually for each U.S. Harmonized Tariff Schedule subheading for all products subject to the request. The USTR indicated that those sections of the Commission's report and working papers that contain the Commission's advice and assessment will be classified as ''confidential.'' The USTR also stated that his office considers the Commission's report to be an inter-agency memorandum that will contain pre-decisional advice and be subject to the deliberative process privilege.

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 February 21, 2017. Requests to appear at the public hearing should be filed with the Secretary no later than 5:15 p.m., February 3, 2017. All pre-hearing briefs and statements should be filed no later than 5:15 p.m., February 8, 2017; and all post-hearing briefs and statements should be filed no later than 5:15 p.m., February 27, 2017. All requests to appear, and pre- and post-hearing briefs and statements should be filed in accordance with the requirements of the ''written submissions'' section below.

Written Submissions: In lieu of or in addition to appearing at the hearing, interested parties are invited to file written submissions concerning this investigation. All written submissions should be addressed to the Secretary, and should be received not later than 5:15 p.m., March 3, 2017. All written submissions must conform to the provisions of section 201.8 of the Commission's Rules of Practice and Procedure (19 CFR 201.8). Section 201.8 and the Commission's Handbook on Filing Procedures require that interested parties file documents electronically on or before the filing deadline and submit eight (8) true paper copies by 12:00 p.m. eastern time on the next business day. In the event that confidential treatment of a document is requested, interested parties must file, at the same time as the eight paper copies, at least four (4) additional true paper copies in which the confidential information must be deleted (see the following paragraph for further information regarding confidential business information). Persons with questions regarding electronic filing should contact the Office of the Secretary, Docket Services Division (202–205–1802).

Confidential Business Information: Any submissions that contain 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 is clearly identified by means of brackets. All

written submissions, except for confidential business information, will be made available for inspection by interested parties.

The Commission may include some or all of the confidential business information submitted in the course of this investigation in the report it sends to the USTR. Additionally, all information, including confidential business information, submitted in this investigation may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel (a) for cybersecurity purposes or (b) in monitoring user activity on U.S. government classified networks. The Commission will not otherwise disclose any confidential business information in a manner that would reveal the operations of the firm supplying the information.

Summaries of Written Submissions: The Commission intends to publish summaries of the positions of interested persons. Persons wishing to have a summary of their position included in the report should include a summary with their written submission. The summary may not exceed 500 words, should be in MSWord format or a format that can be easily converted to MSWord, and should not include any confidential business information. The summary will be published as provided if it meets these requirements and is germane to the subject matter of the investigation. The Commission will identify the name of the organization furnishing the summary and will include a link to the Commission's Electronic Document Information System (EDIS) where the full written submission can be found.

By order of the Commission.

Issued: January 17, 2017.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2017–01401 Filed 1–19–17; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Importer of Controlled Substances Application: Mylan Technologies, Inc.

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration in accordance with 21 CFR 1301.34(a) on or before February 22, 2017. Such persons may also file a written request for a hearing on the application pursuant to 21 CFR 1301.43 on or before February 22, 2017.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DRW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for hearing must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for hearing should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/LJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DRW, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: The Attorney General has delegated her authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Assistant Administrator of the DEA Diversion Control Division (''Assistant Administrator'') pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.34(a), this is notice that on October 31, 2016, Mylan Technologies, Inc., 110 Lake Street, Saint Albans, Vermont 05478 applied to be registered as an importer of the following basic classes of controlled substances:

Controlled substance	Drug code	Schedule
Methylphenidate	1724	II
Fentanyl	9801	II

The company plans to import the listed controlled substances in finished dosage form (FDF) from foreign sources for analytical testing and clinical trials in which the foreign FDF will be compared to the company's own domestically-manufactured FDF. This analysis is required to allow the company to export domestically-manufactured FDF to foreign markets.

Dated: October 22, 2016.

Louis J. Milione,

Assistant Administrator.

[FR Doc. 2017–01305 Filed 1–19–17; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Resource Conservation and Recovery Act

On January 12, 2017, the Department of Justice and the State of Louisiana on behalf of the Louisiana Department of Environmental Quality (''LDEQ'') filed a Complaint and lodged a proposed Consent Decree with the United States District Court for the Middle District of Louisiana in the matter of *United States of America and Louisiana Department of Environmental Quality* vs. *Innophos, Inc.,* Civil Action No. 17–26–SDD–RLB (M.D. La.).

In the Complaint filed in this action, the United States and LDEQ sought injunctive relief and civil penalties against Innophos, Inc. (''Innophos'') for violations of the Resource Conservation and Recovery Act (''RCRA''), 42 U.S.C. 6901–6992k, at Innophos's purified phosphoric acid manufacturing facility near Geismar, Louisiana. The Complaint alleged that Innophos routinely generated two hazardous wastes, Raffinate and RP Pondwater, and sent them to an adjacent facility for disposal; the receiving facility was not authorized to dispose of hazardous waste. LDEQ is a co-plaintiff and has brought its own claims under state law.

The proposed Consent Decree memorializes that Innophos has already corrected the violations related to RP Pondwater. Innophos also agrees in the Consent Decree to handle Raffinate appropriately, either by disposing of it in a permitted hazardous waste Underground Injection Control well system, by treating it on-site, or by shipping it to a permitted hazardous waste treatment, storage, and disposal

facility. The Consent Decree also provides that Innophos will pay a $1,398,000 civil penalty, half of which will be payable to the United States and half to LDEQ.

The publication of this notice opens a period for public comment on the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States of America and Louisiana Department of Environmental Quality vs. Innophos, Inc..,* D.J. Ref. No. 90–7–1–08688. All comments must be submitted no later than forty-five (45) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By e-mail	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the Consent Decree may be examined and downloaded at this Justice Department Web site: *https://www.usdoj.gov/enrd/consent-decrees.* We will provide a paper copy of the Consent Decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $11.25 (25 cents per page reproduction cost) for the Consent Decree, payable to the United States Treasury.

Thomas P. Carroll,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2017–01348 Filed 1–19–17; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

[Attorney General Order No. 3824–2017]

Judicial Redress Act of 2015; Attorney General Designations

AGENCY: Office of the Attorney General; United States Department of Justice.

ACTION: Notice of designation by the Attorney General of ''covered countries'' and ''designated Federal agencies or components''.

SUMMARY: In accordance with the Judicial Redress Act of 2015, relating to the extension of certain Privacy Act remedies to citizens of designated countries, notice is given that the Attorney General has designated 26 countries and 1 regional economic integration organization, as set forth below, as ''covered countries.'' Notice is also given that the United States anticipates designating additional EU member countries as soon as practicable. In addition, notice is given that the Attorney General has designated four Federal agencies and nine components of other Federal agencies, as set forth below, as ''designated Federal agencies or components.''

DATES: The designations herein are effective on February 1, 2017, the date of entry into force of the U.S.-EU Data Protection and Privacy Agreement.

FOR FURTHER INFORMATION CONTACT: Kenneth Harris, Acting Deputy Director, Office of International Affairs, Criminal Division, United States Department of Justice, 1301 New York Avenue, Suite 900, Washington, DC 20005, 202–514–0080.

SUPPLEMENTARY INFORMATION: On December 2, 2016, the European Union (the ''EU'') undertook the final steps necessary under EU law to approve an executive agreement between the United States (the ''U.S.'') and the EU (the ''Parties'') relating to privacy protections for personal information transferred between the U.S., the EU, and the EU Member States for the prevention, detection, investigation, or prosecution of criminal offenses. The Agreement, commonly known in the United States as the Data Protection and Privacy Agreement (the ''DPPA''), establishes a set of protections that the Parties are to apply to personal information exchanged for the purpose of preventing, detecting, investigating, or prosecuting criminal offenses. Article 19 of the DPPA establishes an obligation for the Parties to provide, in their domestic law, specific judicial redress rights to each other's citizens. The Judicial Redress Act, Public Law 114–126, 130 Stat. 282 (5 U.S.C. 552a note), is implementing legislation for Article 19.

Determinations and Designations Pursuant to Section 2(d)(1)

For purposes of implementing section 2(d)(1) of the Judicial Redress Act:

(1) The Attorney General has determined that the countries and the regional economic integration organization listed below have entered into an agreement with the United States that provides for appropriate privacy protections for information shared for the purpose of preventing, investigating, detecting, or prosecuting criminal offenses; to wit, the DPPA;

(2) The Attorney General has determined that the country or regional economic integration organization, or member country of such organization, permits the transfer of personal data for commercial purposes between the territory of that country or regional economic organization and the territory of the United States, through an agreement with the United States or otherwise;

(3) The Attorney General has certified that the policies regarding the transfer of personal data for commercial purposes and related actions of the countries and the regional economic integration organization, or member countries of such organization, listed below, do not materially impede the national security interests of the United States; and

(4) The Attorney General has obtained the concurrence of the Secretary of State, the Secretary of the Treasury, and the Secretary of Homeland Security to designate the following regional economic integration organization and countries as a ''covered country'':

(a) Designation as a ''covered country.'' The following regional economic integration organization and countries have each been designated as a ''covered country,'' effective on February 1, 2017, the date of the DPPA's entry into force:

1. European Union;
2. Austria;
3. Belgium;
4. Bulgaria;
5. Croatia;
6. Republic of Cyprus;
7. Czech Republic;
8. Estonia;
9. Finland;
10. France;
11. Germany;
12. Greece;
13. Hungary;
14. Ireland;
15. Italy;
16. Latvia;
17. Lithuania;
18. Luxembourg;
19. Malta;
20. Netherlands;
21. Poland;
22. Portugal;
23. Romania;
24. Slovakia;
25. Slovenia;
26. Spain; and
27. Sweden.

(b) *Anticipated designation as a ''covered country'' as soon as practicable.* With respect to three

countries, Denmark, Ireland, and the United Kingdom, Article 27 of the DPPA excludes them from coverage unless the European Commission notifies the United States that Denmark, Ireland, or the United Kingdom has decided that the DPPA applies to its State. The EU has notified the United States that Ireland has agreed that the DPPA applies to it, and Ireland has been designated as a ''covered country'' above. With respect to Denmark and the United Kingdom, the Department of Justice intends to move promptly to designate each of those countries as a ''covered country'' on receiving notice, in accordance with the provisions of Article 27 of the DPPA, that the country has decided that the DPPA applies to it.

Determinations and Designations Pursuant to Section 2(e)(1)

For purposes of implementing section 2(e) of the Judicial Redress Act:

(1) The Attorney General has determined that information exchanged by the Federal agencies or components listed below with the above-designated countries and regional economic integration organization is within the scope of the DPPA;

(2) The Attorney General has obtained the concurrence of the head of the relevant agency, or of the head of the agency to which the component belongs, as needed, for the following ''designated Federal agency or component'' designations:

(a) Designation of Federal agencies as a ''designated Federal agency or component.'' The following Federal agencies, and all of their respective components, have each been designated as a ''designated Federal agency or component,'' effective on February 1, 2017, the date of the DPPA's entry into force:

1. United States Department of Justice;
2. United States Department of Homeland Security;
3. United States Securities and Exchange Commission; and
4. United States Commodity Futures Trading Commission.

(b) Designation of individual components of Federal agencies as a ''designated Federal agency or component.'' The following components of a Federal agency have each been designated as a ''designated Federal agency or component,'' effective on February 1, 2017, the date of the DPPA's entry into force:

1. Bureau of Diplomatic Security, United States Department of State;
2. Office of the Inspector General, United States Department of State;
3. Alcohol and Tobacco Tax and Trade Bureau, United States Department of the Treasury;
4. Financial Crimes Enforcement Network, Department of the Treasury;
5. Internal Revenue Service, Division of Criminal Investigation, Department of the Treasury;
6. Office of Foreign Assets Control, United States Department of the Treasury;
7. Office of the Inspector General, United States Department of the Treasury;
8. Office of the Treasury Inspector General for Tax Administration, United States Department of the Treasury; and
9. Special Inspector General for the Troubled Asset Relief Program, United States Department of the Treasury.

Scope of EU Designation

Designation of the European Union as a ''covered country'' is intended to ensure that records transferred by European Union institutional components, such as Europol, Eurojust, and OLAF (the European Antifraud Office), are treated as ''covered records'' pursuant to section 2(h)(4) of the Judicial Redress Act. Designation of the European Union as a ''covered country'' is not intended to, and does not, constitute designation of its member states as covered countries.

Non-Retroactivity

It is intended that no cause of action shall be afforded by the Judicial Redress Act retroactively with respect to any record transferred prior to the date of the DPPA's entry into force on February 1, 2017.

Non-Reviewable Determination

In accordance with section 2(f) of the Judicial Redress Act, the determinations by the Attorney General described in this notice shall not be subject to judicial or administrative review.

Dated: January 17, 2017.

Loretta E. Lynch,

Attorney General.

[FR Doc. 2017–01381 Filed 1–19–17; 8:45 am]

BILLING CODE 4410–14–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Clean Water Act

On January 13, 2017, the Department of Justice lodged a Consent Decree with the United States District Court for the District of Columbia to resolve a claim under Section 309(b) and (d) of the Clean Water Act, 33 U.S.C. 1319(b) and (d) filed against Potomac Electric Power Company (Pepco) in *United States et al.* v. *Pepco,* Civil Action No. 1:15-cv-01845, in which the United States alleged violations of the effluent limitations for metals and total suspended solids in Pepco's National Pollutant Discharge Elimination System (''NPDES'') permit for Pepco's Benning Street facility. The proposed consent decree obligates Pepco to put into place best management practices to address its stormwater discharges, including stormwater control devices to be inserted into drains and inlets; regular inspections and housekeeping; maintenance; training, and similar measures. Pepco also will design and install in-pipe treatment systems in targeted areas, to be put into place no later than December 31, 2017. Under the consent decree, Pepco also will pay a civil penalty of $1.6 million, and design and perform a mitigation project to eliminate discharges from Outfall 101. If Pepco fails to implement the mitigation project, it must pay a stipulated penalty of $500,000.

The publication of this notice opens a period for public comment on the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States et al.* v. *Pepco,* Civil Action No. 1:15-cv-01845, DOJ number 90–5–1–1–11336. All comments must be submitted no later than 30 days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By email	pubcomment-ees.enrd@usdoj.gov.
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, D.C. 20044–7611.

During the public comment period, the Consent Decree may be examined and downloaded at this Justice Department Web site: *https://www.justice.gov/enrd/consent-decrees.* We will provide a paper copy of the Consent Decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $ 16.00 (25 cents per page reproduction cost) payable to the United States Treasury. For a paper copy

without the exhibits and signature pages, the cost is $15.00.

Robert Brook,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2017–01255 Filed 1–19–17; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Comprehensive Environmental Response, Compensation, and Liability Act

On January 17, 2017, the Department of Justice lodged a proposed Consent Decree with the United States District Court for the Eastern District of Wisconsin in the lawsuit entitled *United States and the State of Wisconsin* v. *NCR Corp., et al.,* Civil Action No. 10–cv–910.

In 2010, the United States and the State of Wisconsin filed this action under the Comprehensive Environmental Response, Compensation, and Liability Act, 42 U.S.C. 9601 *et seq.* (''CERCLA''). The United States and the State brought claims against NCR Corporation (''NCR''), Appvion, Inc. (''Appvion''), and other defendants for recovery of response costs and natural resource damages, as well as enforcement of an administrative cleanup order issued by the U.S. Environmental Protection Agency (''EPA''), concerning polychlorinated biphenyl contamination in sediment at the Lower Fox River and Green Bay Superfund Site in northeastern Wisconsin (the ''Site''). Most of the original defendants entered into earlier, court-approved settlements with the United States and the State.

The proposed Consent Decree with two remaining defendants—NCR and Appvion—would require NCR to continue and complete the ongoing sediment remediation work at the Site, which is currently being performed under EPA's cleanup order. The settlement requires NCR to finish most of that work by the end of 2018, including the dredging and off-Site disposal of contaminated sediment located in the last few miles of the Lower Fox River and Green Bay. In return, the United States and the State agree not to continue pursuing their claims for the Site against NCR and Appvion under sections 106 and 107 of CERCLA. Under EPA's cleanup order and prior court orders in the litigation, other defendants will have primary responsibility for long-term monitoring and maintenance of specially-engineered sediment containment caps installed in some portions of the river. The United States and the State also will continue their pursuit of cost recovery claims against one non-settling defendant, P.H. Glatfelter Company.

The publication of this notice opens a period for public comment on the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States and the State of Wisconsin* v. *NCR Corp., et al.,* D.J. Ref. No. 90–11–2–1045/3. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By email	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the Consent Decree may be examined and downloaded at this Justice Department Web site: *https://www.justice.gov/enrd/consent-decrees.* We will provide a paper copy of the Consent Decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $17.50 (25 cents per page reproduction cost) payable to the United States Treasury.

Randall M. Stone,

Acting Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2017–01416 Filed 1–19–17; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Safe Drinking Water Act

On January 13, 2017, the Department of Justice filed a complaint and lodged a proposed Consent Decree with the United States District Court for the District of Kansas in the lawsuit entitled *United States* v. *The City of Pretty Prairie, Kansas,* Civil Action No. 17–cv–01014.

In this action under 42 U.S.C. 300f *et seq.* of the Safe Drinking Water Act (''SDWA'') and the regulations promulgated thereunder at 40 CFR part 141, the United States sought civil penalties for violations of the Maximum Contaminant Level for nitrate of 10 milligrams per Liter. The proposed Decree requires Defendants to perform injunctive relief and pay to the United States civil penalties of $1,500.00 within thirty (30) days of the entry of the Decree.

The publication of this notice opens a period for public comment on the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States* v. *The City of Pretty Prairie, Kansas,* D.J. Ref. No. 90–5–1–1–11526. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By email	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the Consent Decree may be examined and downloaded at this Justice Department Web site: *http://www.usdoj.gov/enrd/Consent_Decrees.html.* We will provide a paper copy of the Consent Decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $11.75 (25 cents per page reproduction cost) payable to the United States Treasury.

Susan Akers,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2017–01427 Filed 1–19–17; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Energy Employees Occupational Illness Compensation Program Act Forms

ACTION: Notice.

SUMMARY: The Department of Labor is submitting the Office of Workers' Compensation Programs (OWCP) sponsored information collection request (ICR) titled, ''Energy Employees Occupational Illness Compensation Program Act Forms,'' to the Office of Management and Budget (OMB) for review and approval for continued use, without change, in accordance with the Paperwork Reduction Act (PRA) of 1995. Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before February 22, 2017.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the *RegInfo.gov* Web site at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201610-1240-003* or by contacting Michel Smyth by telephone at 202–693–4129 (this is not a toll-free number) or sending an email to *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–OWCP, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503, Fax: 202–395–6881 (this is not a toll-free number), email: *OIRA_submission@omb.eop.gov.* Commenters are encouraged, but not required, to send a courtesy copy of any comments to the U.S. Department of Labor-OASAM, Office of the Chief Information Officer, Attn: Information Management Program, Room N1301, 200 Constitution Avenue NW., Washington, DC 20210, email: *DOL_PRA_PUBLIC@dol.gov.*

FOR FURTHER INFORMATION CONTACT: Michel Smyth by telephone at 202–693–4129 (this is not a toll-free number) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Authority: 44 U.S.C. 3507(a)(1)(D).

SUPPLEMENTARY INFORMATION: This ICR seeks to maintain PRA authorization for the Energy Employees Occupational Illness Compensation Program Act Forms information collection. The OWCP is the primary agency responsible for administering the Energy Employees Occupational Illness Compensation Program Act of 2000, as amended (EEOICPA) (42 U.S.C. 7384 *et seq.*). The EEOICPA provides for timely payment of compensation to covered employees who sustained either occupational or otherwise covered illnesses incurred in the performance of duty for the Department of Energy (DOE) and certain of its contractors and subcontractors and, where applicable, survivors of such employees. The EEOICPA sets forth eligibility criteria for claimants for compensation under EEOICPA parts B and E and outlines the various elements of compensation payable from the Energy Employees Occupational Illness Compensation Fund.

Regulations 20 CFR 30.100, –.101, –.102, –.103, –.111, –.112, –.113, –.114, –.206, –.207, –.212, –.213, –.214, –.215, –.221, –.222, –.226, –.231, –.232, –.415, –.416, –.417, –.505, –.620, –.806, –.905, and –.907 implementing the EEOICPA contain information collection requirements covered by this ICR. The OWCP also uses this ICR to obtain PRA authorization to implement the information collection requirement found at 42 U.S.C. 7385s–11.

More specifically, the OWCP uses forms covered by this ICR to determine a claimant's eligibility for EEOICPA compensation and responses are required to obtain or retain benefits. The information collections in this ICR collect demographic, factual, and medical information needed to determine entitlement to EEOICPA benefits. Before the OWCP can pay benefits, the case file must contain medical and employment evidence showing the claimant's eligibility. The various collections covered by this ICR and the purpose of each are as follows:

Form EE–1—A living current or former employee completes the form to file a claim under parts B and/or E. The form requests information about the illness or illnesses being claimed and information about tort suits, settlements, or awards in litigation; State workers' compensation benefits; and fraud convictions that affect entitlement. This form is also available in Spanish. (20 CFR 30.100, –.103, –.505, and –.620.)

Form EE–2—The survivor of a deceased employee uses the form to file a claim under parts B and/or E. The form requests information regarding both the survivor and the deceased employee. The form also requests information about illnesses, tort suits, settlements, or awards in litigation; State workers' compensation benefits; and fraud convictions that affect entitlement. This form is also available in Spanish. (20 CFR 30.101, –.103, –.505, and –.620.)

Form EE–3—The form gathers information about the employee's work history. This form is also available in Spanish. (20 CFR 30.103, –.111, –.113, –.114, –.206, –.212, –.214, –.221, and –.231.)

Form EE–4—The employee or survivor uses the form to support the claimed employment history by affidavit. This form is also available in Spanish. (20 CFR 30.103, –.111, –.113, –.114, –.206, –.212, –.214, –.221, and –.231.)

Form EE–5A—A claimant must provide supplemental employment evidence to substantiate periods of unverified employment. There is no standard form or format for the submission of this information. For purposes of identification only, this requirement has been designated Form EE–5A. (20 CFR 30.112.)

Form EE–5B—A current or former DOE contractor provides information to substantiate periods of unverified employment. There is no standard form or format for the submission of the information. For purposes of identification only, this requirement has been designated Form EE–5B. (20 CFR 30.106.)

Form EE–7—The OWCP uses this form to inform an employee, survivor, or physician of the medical evidence needed to establish a diagnosis of an occupational illness under part B or a covered illness under part E. This form is also available in Spanish. (20 CFR 30.103, –.207, –.215, –.222, –.232(a) and (b), –.415, –.416, and –.417.)

Form EE–7A—A claimant is required to provide information about when an injury, illness, or disability is sustained because of an occupational illness under part B or a covered illness under part E. There is no standard form or format for the submission of this medical information. For purposes of identification only, this requirement has been designated Form EE–7A. (20 CFR 30.207, –.215, –.222, –.226, and –.232(c).)

Form EE–8—The OWCP sends this letter with enclosure EN–8 to a claimant to obtain information about an employee's smoking history when lung cancer due to radiation is claimed. Department of Health and Human Services (HHS) guidelines require the OWCP to ask for information regarding the employee's smoking history before the OWCP can determine the probability of causation for radiogenic lung cancer. (20 CFR 30.213.)

Form EE–9—The OWCP sends this letter with enclosure EN–9 to a claimant

to obtain information concerning the race or ethnicity of the employee when radiogenic skin cancer is claimed. HHS guidelines require the OWCP to ask for this particular information regarding the employee's race/ethnicity before the OWCP can determine the probability of causation for radiogenic skin cancer. (20 CFR 30.213.)

Form EE–10—A covered part E employee who has received an award for wage-loss and/or impairment due to a covered illness uses this form to provide information needed to support a claim for an additional award for a subsequent calendar year of wage-loss and/or any additional impairment. (20 CFR 30.102, –.103, and –.505.)

Form EE–11A—The OWCP sends this letter about impairment benefits under part E with enclosure EN–11A to a claimant to obtain medical evidence needed to support an initial award for permanent impairment due to an accepted covered illness. (20 CFR 30.905 and –.907.)

Form EE–11B—The OWCP sends this letter with enclosure EE–11B to a part E claimant to obtain the factual and medical evidence necessary to support an initial award for wage-loss benefits due to an accepted covered illness. (20 CFR 30.806.)

Form EE–12—The OWCP sends this letter with enclosure EN–12 to a covered part B or E employee receiving medical benefits to collect updated information about settlements or awards in litigation and State workers' compensation benefits that affect continuing entitlement. (20 CFR 30.100 and –.505.)

Form EE–13—The OWCP sends this letter with enclosure EN–13 to a State workers' compensation authority to identify covered part E employees receiving medical benefits who have also been awarded State workers' compensation for their covered illnesses. (42 U.S.C. 7385s–11.)

Form EE–16—The OWCP sends this letter with enclosure EN–16 to a claimant to verify/obtain updated information about tort suits, settlements, or awards in litigation; State workers' compensation benefits; and fraud convictions that affect entitlement immediately prior to issuance of a recommended decision on the claim. (20 CFR 30.505 and –.620.)

Form EE–20—The OWCP sends this letter with enclosure EN–20 to a claimant to obtain financial information necessary to pay approved claims under part B or E. (20 CFR 30.505 and –.620.)

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1240–0002. The DOL notes that existing information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on October 28, 2016 (81 FR 75163).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within 30 days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1240–0002. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Agency: DOL–OWCP.

Title of Collection: Energy Employees Occupational Illness Compensation Program Act Forms.

OMB Control Number: 1240–0002.

Affected Public: Individuals or households; Private Sector—businesses or other for-profits.

Total Estimated Number of Respondents: 57,277.

Total Estimated Number of Responses: 60,621.

Total Estimated Time Burden: 20,539 hours.

Total Estimated Annual Other Costs Burden: $27,800.

Dated: January 13, 2017.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2017–01404 Filed 1–19–17; 8:45 am]

BILLING CODE 4510–CR–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2007–0039]

Intertek Testing Services NA, Inc.: Grant of Expansion of Recognition

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice.

SUMMARY: In this notice, OSHA announces its final decision to expand the scope of recognition for Intertek Testing Service NA, Inc., as a Nationally Recognized Testing Laboratory (NRTL).

DATES: The expansion of the scope of recognition becomes effective on January 23, 2017.

FOR FURTHER INFORMATION CONTACT: Information regarding this notice is available from the following sources:

Press inquiries: Contact Mr. Frank Meilinger, Director, OSHA Office of Communications, U.S. Department of Labor, 200 Constitution Avenue NW., Room N–3508, Washington, DC 20210; telephone: (202) 693–1999; email: *meilinger.francis2@dol.gov.*

General and technical information: Contact Mr. Kevin Robinson, Director, Office of Technical Programs and Coordination Activities, Directorate of Technical Support and Emergency Management, Occupational Safety and Health Administration, U.S. Department of Labor, 200 Constitution Avenue NW., Room N–3655, Washington, DC 20210; telephone: (202) 693–2110; email: *robinson.kevin@dol.gov.* OSHA's Web page includes information about the NRTL Program (see *http://www.osha.gov/dts/otpca/nrtl/index.html*).

SUPPLEMENTARY INFORMATION:

I. Notice of Final Decision

OSHA hereby gives notice of the expansion of the scope of recognition of Intertek Testing Services NA, Inc. (ITSNA), as an NRTL. ITSNA's expansion covers the addition of twenty-three (23) test standards to its scope of recognition.

OSHA recognition of an NRTL signifies that the organization meets the requirements specified by 29 CFR

1910.7. Recognition is an acknowledgment that the organization can perform independent safety testing and certification of the specific products covered within its scope of recognition, and is not a delegation or grant of government authority. As a result of recognition, employers may use products properly approved by the NRTL to meet OSHA standards that require testing and certification of the products.

The Agency processes applications by an NRTL for initial recognition, or for expansion or renewal of this recognition, following requirements in Appendix A to 29 CFR 1910.7. This appendix requires that the Agency publish two notices in the **Federal Register** in processing an application. In the first notice, OSHA announces the application and provides its preliminary finding and, in the second notice, the Agency provides its final decision on the application. These notices set forth the NRTL's scope of recognition or modifications of that scope. OSHA maintains an informational Web page for each NRTL that details its scope of recognition. These pages are available from the Agency's Web site at *http://www.osha.gov/dts/otpca/nrtl/index.html.*

ITSNA submitted an application, dated April 21, 2015, (OSHA–2007–0039–0022) to expand its recognition to include 23 additional test standards. OSHA staff performed a detailed analysis of the application packet and reviewed other pertinent information. OSHA did not perform any on-site reviews in relation to this application.

OSHA published the preliminary notice announcing ITSNA's expansion application in the **Federal Register** on October 31, 2016 (81 FR 75442). The Agency requested comments by November 15, 2016, but it received no comments in response to this notice. OSHA now is proceeding with this final notice to grant expansion of ITSNA's scope of recognition.

To obtain or review copies of all public documents pertaining to ITSNA's application, go to *www.regulations.gov* or contact the Docket Office, Occupational Safety and Health Administration, U.S. Department of Labor, 200 Constitution Avenue NW., Room N–3508, Washington, DC 20210. Docket No. OSHA–2007–0039 contains all materials in the record concerning ITSNA's recognition.

II. Final Decision and Order

OSHA staff examined ITSNA's expansion application, its capability to meet the requirements of the test standards, and other pertinent information. Based on its review of this evidence, OSHA finds that ITSNA meets the requirements of 29 CFR 1910.7 for expansion of its recognition, subject to the limitation and conditions listed below. OSHA, therefore, is proceeding with this final notice to grant ITSNA's scope of recognition. OSHA limits the expansion of ITSNA's recognition to testing and certification of products for demonstration of conformance to the test standards listed in Table 1 below.

TABLE 1—LIST OF APPROPRIATE TEST STANDARDS FOR INCLUSION IN ITSNA'S NRTL SCOPE OF RECOGNITION

Test standard	Test standard title
UL 5C	Standard for Surface Raceways and Fittings for Use with Data, Signal, and Control Circuits.
UL 50E	Enclosures for Electrical Equipment, Environmental Considerations.
UL 565	Standard for Liquid-Level Gauges for Anhydrous Ammonia and LP-Gas.
UL 60745–2–1	Hand-Held Motor-Operated Electric Tools—Safety—Part 2–1: Particular Requirements for Drills and Impact Drills.
UL 60745–2–14	Hand-Held Motor-Operated Electric Tools—Safety—Part 2–14: Particular Requirements for Planers.
UL 60745–2–17	Hand-Held Motor-Operated Electric Tools—Safety—Part 2–17: Particular Requirements for Routers and Trimmers.
UL 60745–2–3	Hand-Held Motor-Operated Electric Tools—Safety—Part 2–3: Particular Requirements for Grinders, Polishers and Disk-Type Sanders.
UL 962A	Standard for Furniture Power Distribution Units.
UL 1769	Standard for Cylinder Valves.
UL 2061	Standard for Adapters and Cylinder Connection Devices for Portable LP-Gas Cylinder Assemblies.
UL 2108	Standard for Low Voltage Lighting Systems.
UL 2238	Standard for Cable Assemblies and Fittings for Industrial Control and Signal Distribution.
UL 2305	Standard for Exhibition Display Units, Fabrication and Installation.
UL 2438	Standard for Outdoor Seasonal-Use Cord-Connected Wiring Devices.
UL 5085–2	Low Voltage Transformers—Part 2: General Purpose Transformers.
UL 61010–2–031	Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use—Part 031: Safety requirements for hand-held probe assemblies for electrical measurement and test.
UL 61010–2–030	Safety requirements for electrical equipment for measurement, control, and laboratory use—Part 2–030: Particular requirements for testing and measuring circuits.
UL 60730–2–2	Standard for Automatic Electrical Controls for Household and Similar Use; Part 2: Particular Requirements for Thermal Motor Protectors.
UL 60745–2–5	Hand-Held Motor-Operated Electric Tools—Safety—Part 2–5: Particular Requirements for Circular Saws.
UL 60745–2–21	Hand-Held Motor-Operated Electric Tools—Safety—Part 2–21: Particular Requirements for Drain Cleaners.
UL 60950–23	Information Technology Equipment—Safety—Part 23: Large Data Storage Equipment.
UL 62368–1	Audio/video, information and communication technology equipment—Part 1: Safety requirements.
UL 1691	Single Pole Locking-Type Separable Connectors.

OSHA's recognition of any NRTL for a particular test standard is limited to equipment or materials for which OSHA standards require third-party testing and certification before using them in the workplace. Consequently, if a test standard also covers any products for which OSHA does not require such testing and certification, an NRTL's scope of recognition does not include these products.

The American National Standards Institute (ANSI) may approve the test standards listed above as American National Standards. However, for convenience, we may use the designation of the standards-developing organization for the standard as opposed to the ANSI designation. Under the NRTL Program's policy (see OSHA Instruction CPL 1–0.3, Appendix C, paragraph XIV), any NRTL recognized for a particular test standard may use either the proprietary version of the test standard or the ANSI version of that standard. Contact ANSI to determine whether a test standard is currently ANSI-approved.

A. Conditions

In addition to those conditions already required by 29 CFR 1910.7, ITSNA must abide by the following conditions of the recognition:

1. ITSNA must inform OSHA as soon as possible, in writing, of any change of ownership, facilities, or key personnel, and of any major change in its operations as an NRTL, and provide details of the change(s);

2. ITSNA must meet all the terms of its recognition and comply with all OSHA policies pertaining to this recognition; and

3. ITSNA must continue to meet the requirements for recognition, including all previously published conditions on ITSNA's scope of recognition, in all areas for which it has recognition.

Pursuant to the authority in 29 CFR 1910.7, OSHA hereby expands the scope of recognition of ITSNA, subject to the limitation and conditions specified above.

III. Authority and Signature

Jordan Barab, Acting Assistant Secretary of Labor for Occupational Safety and Health, 200 Constitution Avenue NW., Washington, DC 20210, authorized the preparation of this notice. Accordingly, the Agency is issuing this notice pursuant to 29 U.S.C. 657(g)(2), Secretary of Labor's Order No. 1–2012 (77 FR 3912, Jan. 25, 2012), and 29 CFR 1910.7.

Dated: January 17, 2017.

Jordan Barab,

Acting Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2017–01408 Filed 1–19–17; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2007–0042]

TUV Rheinland of North America, Inc.: Grant of Expansion of Recognition and Modification to the NRTL Program's List of Appropriate Test Standards

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice.

SUMMARY: In this notice, OSHA announces its final decision to expand the scope of recognition for TUV Rheinland of North America, Inc. as a Nationally Recognized Testing Laboratory (NRTL) and to add one new standard to the NRTL Program's List of Appropriate Test Standards.

DATES: The expansion of the scope of recognition becomes effective on January 23, 2017.

FOR FURTHER INFORMATION CONTACT: Information regarding this notice is available from the following sources:

Press inquiries: Contact Mr. Frank Meilinger, Director, OSHA Office of Communications, U.S. Department of Labor, 200 Constitution Avenue NW., Room N–3647, Washington, DC 20210; telephone: (202) 693–1999; email: *meilinger.francis2@dol.gov.*

General and technical information: Contact Mr. Kevin Robinson, Director, Office of Technical Programs and Coordination Activities, Directorate of Technical Support and Emergency Management, Occupational Safety and Health Administration, U.S. Department of Labor, 200 Constitution Avenue NW., Room N–3655, Washington, DC 20210; telephone: (202) 693–2110; email: *robinson.kevin@dol.gov.* OSHA's Web page includes information about the NRTL Program (see *http://www.osha.gov/dts/otpca/nrtl/index.html*).

SUPPLEMENTARY INFORMATION:

I. Notice of Final Decision

OSHA hereby gives notice of the expansion of the scope of recognition of TUV Rheinland of North America, Inc. (TUVRNA) as an NRTL. TUVRNA's expansion covers the addition of three recognized testing standards and two recognized testing and certification sites to its NRTL scope of recognition. Additionally, OSHA announces a modification to the NRTL Program's List of Appropriate Test Standards to include one additional test standard.

OSHA recognition of an NRTL signifies that the organization meets the requirements specified in 29 CFR 1910.7. Recognition is an acknowledgment that the organization can perform independent safety testing and certification of the specific products covered within its scope of recognition, and is not a delegation or grant of government authority. As a result of recognition, employers may use products properly approved by the NRTL to meet OSHA standards that require testing and certification.

The Agency processes applications by an NRTL for initial recognition, or for expansion or renewal of this recognition, following requirements in Appendix A to 29 CFR 1910.7. This appendix requires that the Agency publish two notices in the **Federal Register** in processing an application. In the first notice, OSHA announces the application and provides its preliminary finding and, in the second notice, the Agency provides its final decision on the application. These notices set forth the NRTL's scope of recognition or modifications of that scope. OSHA maintains an informational Web page for each NRTL that details its scope of recognition. These pages are available from the Agency's Web site at *http://www.osha.gov/dts/otpca/nrtl/index.html.*

TUVRNA submitted five applications, dated April 1, 2015 (OSHA–2007–0042–0016), May 6, 2015 (OSHA–2007–0042–0017), August 20, 2015 (OSHA–2007–0042–0018), December 7, 2015 (OSHA–2007–0042–0019) and March 2, 2016 (OSHA–2007–0042–0020), to expand its recognition to include three additional recognized test standards and two additional recognized sites. The two recognized testing sites are located at: TUV Rheinland Japan Ltd., Global Technology Assessment Center, 4–25–2 Kita-Yamata, Tsuzuki-ku, Yokohama, Kanagawa, 224–0021 JAPAN and TUV Rheinland LGA Products GmbH, Am Grauen Stein 29, Koln, NRW 51105 GERMANY. OSHA staff performed a detailed analysis of the applications and other pertinent information. OSHA staff also performed on-site reviews of TUV Yokohama on February 16–17, 2016, and TUV Cologne on June 9–10, 2016, and recommended expansion of TUVRNA's recognition to include these two sites. Further, OSHA staff recommended expansion of TUVRNA's recognition to include three test standards, including one OSHA has added to the NRTL Program's List of Appropriate Test Standards.

OSHA published the preliminary notice announcing TUVRNA's expansion application and modification to the NRTL Program's List of Appropriate Test Standards in the **Federal Register** on October 31, 2016 (81 FR 75444). The Agency requested comments by November 15, 2016, but it received no comments in response to this notice. OSHA now is proceeding with this final notice to grant expansion of TUVRNA's scope of recognition and to modify the NRTL Program's List of Appropriate Test Standards.

To obtain or review copies of all public documents pertaining to the TUVRNA's application, go to *www.regulations.gov* or contact the Docket Office, Occupational Safety and Health Administration, U.S. Department of Labor, 200 Constitution Avenue NW., Room N–2625, Washington, DC 20210. Docket No. OSHA–2007–0042 contains all materials in the record concerning TUVRNA's recognition.

II. Final Decision and Order

OSHA staff examined TUVRNA's expansion application, conducted a detailed on-site assessment, and examined other pertinent information. Based on its review of this evidence, OSHA finds that TUVRNA meets the requirements of 29 CFR 1910.7 for expansion of its recognition, subject to the limitations and conditions listed below. OSHA, therefore, is proceeding with this final notice to grant TUVRNA's scope of recognition. OSHA limits the expansion of TUVRNA's recognition to include the sites at TUV Cologne, Germany and TUV Yokohama, Japan as listed above. OSHA's recognition of these sites limits TUVRNA to performing product testing and certifications only to the test standards for which the site has the proper capability and programs, and for test standards in TUVRNA's scope of recognition. This limitation is consistent with the recognition that OSHA grants to other NRTLs that operate multiple sites. OSHA further limits the expansion of TUVRNA's recognition to testing and certification of products for demonstration of conformance to the test standards listed in Table 1 below.

Additionally, Table 2, below, lists the test standard new to the NRTL Program's List of Appropriate Test Standards. The Agency evaluated the standard to (1) verify it represents a product category for which OSHA requires certification by an NRTL, (2) verify the document represents an end product and not a component, and (3) verify the document defines safety test specifications (not installation or operational performance specifications). Based on this evaluation, OSHA finds that it is an appropriate test standard and has added the standard to the NRTL Program's List of Appropriate Test Standards.

TABLE 1—LIST OF APPROPRIATE TEST STANDARDS FOR INCLUSION IN TUVRNA'S NRTL SCOPE OF RECOGNITION

Test standard	Test standard title
UL 62368–1	Audio/video, information and technology equipment—Part 1: Safety Requirements.
UL 1004–1	Standard for Rotating Electrical Machines—General Requirements.
UL 62109–1 *	Standard for Safety of power converters for use in photovoltaic power systems—Part 1: General requirements.

* Represents the standard that OSHA will add to the NRTL List of Appropriate Test Standards.

TABLE 2—TEST STANDARD OSHA IS ADDING TO THE NRTL PROGRAM'S LIST OF APPROPRIATE TEST STANDARDS

Test standard	Test standard title
UL 62109–1	Standard for Safety of power converters for use in photovoltaic power systems—Part 1: General requirements.

OSHA's recognition of any NRTL for a particular test standard is limited to equipment or materials for which OSHA standards require third-party testing and certification before using them in the workplace. Consequently, if a test standard also covers any products for which OSHA does not require such testing and certification, an NRTL's scope of recognition does not include these products.

The American National Standards Institute (ANSI) may approve the test standards listed above as American National Standards. However, for convenience, we may use the designation of the standards-developing organization for the standard as opposed to the ANSI designation. Under the NRTL Program's policy (see OSHA Instruction CPL 1–0.3, Appendix C, paragraph XIV), any NRTL recognized for a particular test standard may use either the proprietary version of the test standard or the ANSI version of that standard. Contact ANSI to determine whether a test standard is currently ANSI-approved.

A. Conditions

In addition to those conditions already required by 29 CFR 1910.7, TUVRNA also must abide by the following conditions of the recognition:

1. TUVRNA must inform OSHA as soon as possible, in writing, of any change of ownership, facilities, or key personnel, and of any major change in its operations as an NRTL, and provide details of the change(s);

2. TUVRNA must meet all the terms of its recognition and comply with all OSHA policies pertaining to this recognition; and

3. TUVRNA must continue to meet the requirements for recognition, including all previously published conditions on TUVRNA's scope of recognition, in all areas for which it has recognition.

Pursuant to the authority in 29 CFR 1910.7, OSHA hereby expands the recognition of TUVRNA, subject to the limitations and conditions specified above.

III. Authority and Signature

David Michaels, Ph.D., MPH, Assistant Secretary of Labor for Occupational Safety and Health, 200 Constitution Avenue NW., Washington, DC 20210, authorized the preparation of this notice. Accordingly, the Agency is issuing this notice pursuant to 29 U.S.C. 657(g)(2), Secretary of Labor's Order No. 1–2012 (77 FR 3912, Jan. 25, 2012), and 29 CFR 1910.7.

Signed at Washington, DC, on January 11, 2017.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2017–01409 Filed 1–19–17; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2017–0003]

Michigan State Plan; Change in Level of Federal Enforcement: Marine Construction

AGENCY: Occupational Safety and Health Administration (OSHA), Department of Labor.

ACTION: Notice.

SUMMARY: This document gives notice of OSHA's approval of a change to the State of Michigan's Occupational Safety and Health State Plan that clarifies that marine construction is included in its State Plan. Therefore, OSHA announces an amendment to the Operational Status

Agreement between OSHA and the Michigan State Plan to clarify Michigan's coverage of marine construction.

DATES: *Effective Date:* January 23, 2017.

FOR FURTHER INFORMATION CONTACT:

For press inquiries, contact Francis Meilinger, Director, Office of Communications, Room N–3647, OSHA, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone: (202) 693–1999; email: *meilinger.francis2@dol.gov.*

For general and technical information, contact Douglas J. Kalinowski, Director, Directorate of Cooperative and State Programs, Room N–3700, OSHA, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone: (202) 693–2200; email: *kalinowski.doug@dol.gov.*

SUPPLEMENTARY INFORMATION: Section 18 of the Occupational Safety and Health Act of 1970, 29 U.S.C. 667 (OSH Act), provides that states that wish to assume responsibility for developing and enforcing their own occupational safety and health standards may do so by submitting and obtaining federal approval of a State Plan. State Plan approval occurs in stages that include initial approval under Section 18(c) of the Act and, ultimately, final approval under Section 18(e).

The Michigan State Plan was initially approved under Section 18(b) of the OSH Act and 29 CFR part 1902 on September 24, 1973 (38 FR 27388, October 3, 1973). The Michigan State Plan is administered by the Michigan Department of Licensing and Regulatory Affairs, Michigan Occupational Safety and Health Administration (MIOSHA). On January 6, 1977, an Operational Status Agreement was entered into between OSHA and the Michigan State Plan agency whereby concurrent federal enforcement authority was suspended with regard to most federal occupational safety and health standards in issues covered by the state's OSHA-approved occupational safety and health plan. Federal OSHA retained its authority over safety and health in private sector maritime employment, with regard to federal government employers and employees, and employees of the U.S. Postal Services (effective June 9, 2000), and employers who are enrolled members of Indian tribes and who own or operate businesses located within the boundaries of Indian reservations.

MIOSHA has covered construction since the Plan's inception. A legal issue has arisen as to whether employees engaged in marine construction are covered by the Longshore and Harbor Workers' Compensation Act (33 U.S.C. 901 *et seq.*) and thus were included in Federal OSHA's coverage of maritime employment. MIOSHA requested that its coverage be clarified to explicitly include coverage over marine construction. OSHA and MIOSHA have agreed to amendments to the State Plan's Operational Status Agreement (OSA) that clarify that the exclusion of private sector maritime employment from the State Plan does not include marine construction, and the State Plan's coverage of construction includes marine construction. The amendment was signed on July 25, 2016. All other terms of the OSA remain in effect.

Authority and Signature

David Michaels, Ph.D., MPH, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, authorized the preparation of this notice. OSHA is issuing this notice under the authority specified by Section 18 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 667), Secretary of Labor's Order No. 1–2012 (77 FR 3912), and 29 CFR parts 1902 and 1953.

Dated: January 9, 2017.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health

[FR Doc. 2017–01414 Filed 1–19–17; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2009–0026]

Curtis-Strauss LLC: Grant of Expansion of Recognition

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice.

SUMMARY: In this notice, OSHA announces its final decision to expand the scope of recognition for Curtis-Strauss LLC, as a Nationally Recognized Testing Laboratory (NRTL).

DATES: The expansion of the scope of recognition becomes effective on January 23, 2017.

FOR FURTHER INFORMATION CONTACT: Information regarding this notice is available from the following sources:

Press inquiries: Contact Mr. Frank Meilinger, Director, OSHA Office of Communications, U.S. Department of Labor, 200 Constitution Avenue NW., Room N–3647, Washington, DC 20210; telephone: (202) 693–1999; email: *meilinger.francis2@dol.gov.*

General and technical information: Contact Mr. Kevin Robinson, Director, Office of Technical Programs and Coordination Activities, Directorate of Technical Support and Emergency Management, Occupational Safety and Health Administration, U.S. Department of Labor, 200 Constitution Avenue NW., Room N–3655, Washington, DC 20210; telephone: (202) 693–2110; email: *robinson.kevin@dol.gov.* OSHA's Web page includes information about the NRTL Program (see *http://www.osha.gov/dts/otpca/nrtl/index.html*).

SUPPLEMENTARY INFORMATION:

I. Notice of Final Decision

OSHA hereby gives notice of the expansion of the scope of recognition of Curtis-Strauss LLC (CSL), as an NRTL. CSL's expansion covers the addition of sixteen (16) test standards to its scope of recognition.

OSHA recognition of an NRTL signifies that the organization meets the requirements specified by 29 CFR 1910.7. Recognition is an acknowledgment that the organization can perform independent safety testing and certification of the specific products covered within its scope of recognition and is not a delegation or grant of government authority. As a result of recognition, employers may use products properly approved by the NRTL to meet OSHA standards that require testing and certification of the products.

The Agency processes applications by an NRTL for initial recognition, or for expansion or renewal of this recognition, following requirements in Appendix A to 29 CFR 1910.7. This appendix requires that the Agency publish two notices in the **Federal Register** in processing an application. In the first notice, OSHA announces the application and provides its preliminary finding and, in the second notice, the Agency provides its final decision on the application. These notices set forth the NRTL's scope of recognition or modifications of that scope. OSHA maintains an informational Web page for each NRTL that details its scope of recognition. These pages are available from the Agency's Web site at *http://www.osha.gov/dts/otpca/nrtl/index.html.*

CSL submitted four applications, each dated December 29, 2015 (OSHA–2009–0026–0065; OSHA–2009–0026–0066; OSHA–2009–0026–0069; OSHA–2009–0026–0068), to expand its recognition to include 16 additional test standards. OSHA staff performed a comparability analysis and reviewed other pertinent

information. OSHA did not perform any on-site reviews in relation to this application.

OSHA published the preliminary notice announcing CSL's expansion application in the **Federal Register** on October 31, 2016 (81 FR 75446). The Agency requested comments by November 15, 2016, but it received no comments in response to this notice. OSHA now is proceeding with this final notice to grant expansion of CSL's scope of recognition.

To obtain or review copies of all public documents pertaining to the CSL's application, go to *www.regulations.gov* or contact the Docket Office, Occupational Safety and Health Administration, U.S. Department of Labor, 200 Constitution Avenue NW., Room N–3508, Washington, DC 20210. Docket No. OSHA–2009–0026 contains all materials in the record concerning CSL's recognition.

II. Final Decision and Order

OSHA staff examined CSL's expansion application, its capability to meet the requirements of the test standards, and other pertinent information. Based on its review of this evidence, OSHA finds that CSL meets the requirements of 29 CFR 1910.7 for expansion of its recognition, subject to the limitation and conditions listed below. OSHA, therefore, is proceeding with this final notice to grant CSL's scope of recognition. OSHA limits the expansion of CSL's recognition to testing and certification of products for demonstration of conformance to the test standards listed in Table 1 below.

TABLE 1—LIST OF APPROPRIATE TEST STANDARDS FOR INCLUSION IN CSL'S NRTL SCOPE OF RECOGNITION

Test standard	Test standard title
UL 60745–1	Hand-Held Motor-Operated Electric Tools—Safety—Part 1: General Requirements.
UL 60745–2–1	Hand-Held Motor-Operated Electric Tools—Safety—Part 2–1: Particular Requirements for Drills and Impact Drills.
UL 60745–2–11	Hand-Held Motor-Operated Electric Tools—Safety—Part 2–11: Particular Requirements for Reciprocating Saws.
UL 60745–2–2	Hand-Held Motor-Operated Electric Tools—Safety—Part 2–2: Particular Requirements for Screwdrivers and Impact Wrenches.
UL 60745–2–3	Hand-Held Motor-Operated Electric Tools—Safety—Part 2–3: Particular Requirements for Grinders, Polishers and Disk-Type Sanders.
UL 60745–2–4	Hand-Held Motor-Operated Electric Tools—Safety—Part 2–4: Particular Requirements for Sanders and Polishers Other Than Disk Type.
UL 60745–2–5	Hand-Held Motor-Operated Electric Tools—Safety—Part 2–5: Particular Requirements for Circular Saws.
UL 60745–2–6	Hand-Held Motor-Operated Electric Tools—Safety—Part 2–6: Particular Requirements for Hammers.
UL 1741	Standard for Inverters, Converters, Controllers and Interconnection System Equipment for Use With Distributed Energy Resources.
UL 1778	Uninterruptable Power Systems.
UL 1083	Household Electric Skillets and Frying-Type Appliances.
UL 153	Standard for Portable Electric Lights.
UL 1598	Luminaires.
UL 1993	Self-Ballasted Lamps and Lamp Adapters.
UL 8750	Standard for Light Emitting Diode (LED) Equipment for Use in Lighting Products.
UL 935	Fluorescent-Lamp Ballasts.

OSHA's recognition of any NRTL for a particular test standard is limited to equipment or materials for which OSHA standards require third-party testing and certification before using them in the workplace. Consequently, if a test standard also covers any products for which OSHA does not require such testing and certification, an NRTL's scope of recognition does not include these products.

The American National Standards Institute (ANSI) may approve the test standards listed above as American National Standards. However, for convenience, we may use the designation of the standards-developing organization for the standard as opposed to the ANSI designation. Under the NRTL Program's policy (see OSHA Instruction CPL 1–0.3, Appendix C, paragraph XIV), any NRTL recognized for a particular test standard may use either the proprietary version of the test standard or the ANSI version of that standard. Contact ANSI to determine whether a test standard is currently ANSI-approved.

A. Conditions

In addition to those conditions already required by 29 CFR 1910.7, CSL must abide by the following conditions of the recognition:

1. CSL must inform OSHA as soon as possible, in writing, of any change of ownership, facilities, or key personnel, and of any major change in its operations as an NRTL, and provide details of the change(s);

2. CSL must meet all the terms of its recognition and comply with all OSHA policies pertaining to this recognition; and

3. CSL must continue to meet the requirements for recognition, including all previously published conditions on CSL's scope of recognition, in all areas for which it has recognition.

Pursuant to the authority in 29 CFR 1910.7, OSHA hereby expands the scope of recognition of CSL, subject to the limitation and conditions specified above.

III. Authority and Signature

David Michaels, Ph.D., MPH, Assistant Secretary of Labor for Occupational Safety and Health, 200 Constitution Avenue NW., Washington, DC 20210, authorized the preparation of this notice. Accordingly, the Agency is issuing this notice pursuant to 29 U.S.C. 657(g)(2), Secretary of Labor's Order No. 1–2012 (77 FR 3912, Jan. 25, 2012), and 29 CFR 1910.7.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2017–01411 Filed 1–19–17; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF LABOR

[Docket No. OSHA–2017–0004]

Occupational Safety and Health Administration Maritime Advisory Committee for Occupational Safety and Health (MACOSH)

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice of renewal of the MACOSH charter.

SUMMARY: In accordance with the provisions of the Federal Advisory Committee Act (FACA), and after consultation with the General Services Administration, the Secretary of Labor is renewing the charter for the Maritime Advisory Committee for Occupational Safety and Health. The Committee will better enable OSHA to perform its duties under the Occupational Safety and Health Act (the OSH Act) of 1970. The Committee is diverse and balanced, both in terms of segments of the maritime industry represented (*e.g.,* shipyard employment, longshoring, and marine terminal industries), and in the views and interests represented by the members.

FOR FURTHER INFORMATION CONTACT: Amy Wangdahl, Director, Office of Maritime and Agriculture, Directorate of Standards and Guidance, U.S. Department of Labor, Occupational Safety and Health Administration, Room N–3609, 200 Constitution Avenue NW., Washington, DC 20210; telephone: (202) 693–2066.

SUPPLEMENTARY INFORMATION: The Committee will advise OSHA on matters relevant to the safety and health of employees in the maritime industry. This includes advice on maritime issues that will result in more effective enforcement, training, and outreach programs, and streamlined regulatory efforts. The maritime industry includes shipyard employment, longshoring, marine terminal, and other related industries, *e.g.,* commercial fishing and shipbreaking. The Committee will function solely as an advisory body in compliance with the provisions of FACA and OSHA's regulations covering advisory committees (29 CFR part 1912).

Authority and Signature

Jordan Barab, Acting Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210, authorized the preparation of this notice pursuant to Sections 6(b)(1), and 7(b) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 655(b)(1), 656(b)), the Federal Advisory Committee Act (5 U.S.C. App. 2), Section 41 of the Longshore and Harbor Workers' Compensation Act (33 U.S.C. 941), Secretary of Labor's Order 1–2012 (77 FR 3912, Jan. 25, 2012), and 29 CFR part 1912.

Signed at Washington, DC, on January 13, 2017.

Jordan Barab,

Acting Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2017–01407 Filed 1–19–17; 8:45 am]

BILLING CODE 4510–26–P

LIBRARY OF CONGRESS

U.S. Copyright Office

[Docket No. 2017–2]

Study on the Moral Rights of Attribution and Integrity

AGENCY: U.S. Copyright Office, Library of Congress.

ACTION: Notice of inquiry.

SUMMARY: The United States Copyright Office is undertaking a public study to assess the current state of U.S. law recognizing and protecting moral rights for authors, specifically the rights of attribution and integrity. As part of this study, the Office will review existing law on the moral rights of attribution and integrity, including provisions found in title 17 of the U.S. Code as well as other federal and state laws, and whether any additional protection is advisable in this area. To support this effort and provide thorough assistance to Congress, the Office is seeking public input on a number of questions.

DATES: Written comments must be received no later than 11:59 p.m. Eastern Time on March 9, 2017. Written reply comments must be received no later than 11:59 p.m. Eastern Time on April 24, 2017. The Office may announce one or more public meetings, to take place after written comments are received, by separate notice in the future.

ADDRESSES: For reasons of government efficiency, the Copyright Office is using the *regulations.gov* system for the submission and posting of public comments in this proceeding. All comments must be submitted electronically. Specific instructions for submitting comments will be posted on the Copyright Office Web site at *https://www.copyright.gov/policy/moralrights/comment-submission/*. To meet accessibility standards, all comments must be provided in a single file not to exceed six megabytes (MB) in one of the following formats: Portable Document File (PDF) format containing searchable, accessible text (not an image); Microsoft Word; WordPerfect; Rich Text Format (RTF); or ASCII text file format (not a scanned document). All comments must include the name of the submitter and any organization the submitter represents. The Office will post all comments publicly in the form that they are received. If electronic submission of comments is not feasible due to lack of access to a computer and/or the Internet, please contact the Office, using the contact information below, for special instructions.

FOR FURTHER INFORMATION CONTACT: Kimberley Isbell, Senior Counsel for Policy and International Affairs, by email at *kisb@loc.gov* or by telephone at 202–707–8350; or Maria Strong, Deputy Director for Policy and International Affairs, by email at *mstrong@loc.gov* or by telephone at 202–707–8350.

SUPPLEMENTARY INFORMATION:

I. Background

The term ''moral rights'' is taken from the French phrase *droit moral,* and generally refers to certain non-economic rights that are considered personal to an author.[1] Chief among these are the right of an author to be credited as the author of his or her work (the right of attribution), and the right of an author to prevent prejudicial distortions of the work (the right of integrity). These rights have a long history in international copyright law, dating back to the turn of the 20th century when several European countries included provisions on moral rights in their copyright laws.[2] A provision on moral rights was first adopted at the international level through the Berne Convention for the Protection of Literary and Artistic Works (''Berne Convention'') during its Rome revision in 1928.[3] The current text of article 6*bis*(1) of the Berne Convention states: ''Independently of the author's economic rights, and even after the transfer of the said rights, the author shall have the right to claim authorship of the work and to object to any distortion, mutilation or other modification of, or other derogatory action in relation to, the said work, which would be prejudicial to his honor or reputation.'' [4]

In contrast to the early adoption of strong moral rights protections in

[1] In this Notice, we use the general term ''author'' to include all creators, including visual artists and performers.

[2] *See* Sam Ricketson & Jane C. Ginsburg, International Copyright and Neighboring Rights: The Berne Convention and Beyond ¶¶ 10.03–.04, at 587–89 (2d ed. 2006).

[3] *See* Mihály Ficsor, World Intellectual Property Organization, Guide to the Copyright and Related Rights Treaties Administered by WIPO and Glossary of Copyright and Related Rights Terms ¶ BC-6*bis,* at 44 (2003).

[4] Berne Convention for the Protection of Literary and Artistic Works art. 6*bis*(1), Sept. 9, 1886, *as revised* July 24, 1971, *and as amended* Sept. 28, 1979, S. Treaty Doc. No. 99–27 (1986).

Europe, the United States' experience with the concept of moral rights is more recent. The United States did not adopt the Berne Convention right away, only joining the Convention in 1989.[5] At that time, the United States elected not to adopt broad moral rights provisions in its copyright law, but instead relied on a combination of various state and federal statutes to comply with its Berne obligations.[6]

In July 2014, the Subcommittee on Courts, Intellectual Property, and the Internet of the House Judiciary Committee held a hearing that focused in part on moral rights for authors in the United States as part of its broader review of the nation's copyright laws.[7] At that hearing, the Chairman of the House Judiciary Committee, Representative Bob Goodlatte, noted that ''we should consider whether current law is sufficient to satisfy the moral rights of our creators or, whether something more explicit is required.'' [8] The Ranking Member of the Subcommittee, Representative Jerrold Nadler, also indicated his interest in a further evaluation of the status of moral rights in the United States, asking ''how our current laws are working and what, if any, changes might be necessary and appropriate.'' [9] Register of Copyrights Maria Pallante recommended further study of moral rights in her testimony before Congress at the end of the two-year copyright review hearings process,[10] at which time the Ranking Member of the House Judiciary Committee requested that the Office undertake this study.[11] As part of the preparation for this study, the Copyright Office co-hosted a day-long symposium on moral rights in April 2016 in order to hear views about current issues in this area. The Office is now commencing a formal study on moral rights and soliciting public input.

[5] Berne Convention Implementation Act of 1988, Public Law 100–568, 102 Stat. 2853 (''BCIA'').

[6] *See* discussion on the BCIA *infra* notes 15–23 and accompanying text.

[7] *See Moral Rights, Termination Rights, Resale Royalty, and Copyright Term: Hearing Before the Subcomm. on Courts, Intellectual Prop., & the Internet of the H. Comm. on the Judiciary,* 113th Cong. (2014) (''*Moral Rights Hearing*'').

[8] *Moral Rights Hearing* at 4.

[9] *Id.*

[10] *Register's Perspective on Copyright Review: Hearing Before the H. Comm. on the Judiciary,* 114th Cong. 34–35 (2015) (written statement of Maria A. Pallante, Register of Copyrights and Dir., U.S. Copyright Office) (''*Register's Perspective Hearing*'').

[11] *Register's Perspective Hearing* at 49 (statement of Rep. John Conyers, Ranking Member, H. Comm. on the Judiciary).

A. Moral Rights in the United States Prior to Implementation of the Berne Convention in 1989

In the late 1950s, the Copyright Office and Congress reviewed the issue of moral rights as part of the larger, comprehensive review of the copyright laws leading to a general revision of the 1909 Copyright Act.[12] In support of the review, William Strauss completed a study for the Office entitled ''The Moral Right of the Author'' in 1959.[13] The report found that U.S. common law principles, such as those governing tort and contract actions, ''afford an adequate basis for protection of [moral] rights'' and can provide the same protection given abroad under the doctrine of moral rights.[14]

Later, Congress considered the specific question of ''whether the current law of the United States is sufficient, or whether additional laws are needed, to satisfy [Berne article 6*bis*'s] requirements.'' [15] The majority of those who testified before Congress argued against any change to U.S. law concerning an artist's right to control attribution or any alteration to his creation, stating that current U.S. law was sufficient.[16] Indeed, WIPO Director General Dr. Árpád Bogsch explained to Congress that the United States did not need to make any changes to U.S. law to meet the obligations of article 6*bis*.[17]

Both the House and Senate Judiciary Committees accepted this conclusion,[18] finding that U.S. law met the requirements outlined in the Berne Convention's article 6*bis* based on the existing patchwork of laws in the United States, including:

- Section 43(a) of the Lanham Act relating to false designations of origin and false descriptions, which could be applied in some instances to attribution of copyright-protected work.[19]
- The Copyright Act's provisions regarding protection of an author's exclusive rights in derivatives of his or her works; [20] limits on a mechanical licensee's rights to arrange an author's musical composition; [21] and termination of transfers and licenses.[22]
- State and local laws relating to publicity, contractual violations, fraud and misrepresentation, unfair competition, defamation, and invasion of privacy.[23]

B. Subsequent Developments After the U.S. Implementation of the Berne Convention

Since the United States' implementation of the Berne Convention over 25 years ago, there have been a number of legal and technological developments affecting the scope and protection of moral rights. In 1990, Congress passed the Visual Artists Rights Act (VARA), codified at section 106A of the Copyright Act, [24]

[12] As part of the consideration for possible accession to the Berne Convention, the general review of the 1909 Act took more than 20 years and resulted in the 1976 Copyright Act.

[13] *See* William Strauss, *Study No. 4: The Moral Right of the Author* (1959), *in* Staff of S. Comm. on the Judiciary, 86th Cong., Copyright Law Revision: Studies Prepared for the Subcomm. on Patents, Trademarks, and Copyrights of the Comm. on the Judiciary, United States Senate: Studies 1–4, at 109 (Comm. Print 1960).

[14] Strauss at 142. The report rejected the idea of an ''irreconcilable breach between European and American concepts of protection of authors' personal rights,'' instead concluding that U.S. and European courts generally arrived at the same results in upholding the same rights or limitations on those rights, just in different ways. *Id.* at 141–42.

[15] H.R. Rep. No. 100–609, at 33 (1988).

[16] *See* S. Rep. No. 100–352, at 6 (1988); H.R. Rep. No. 100–609, at 33 (1988).

[17] *See* H.R. Rep. No. 100–609, at 37 (1988); S. Rep. No. 100–352, at 10 (1988); *see also* Letter from Dr. Árpád Bogsch, Dir. Gen., World Intellectual Prop. Org., to Irwin Karp, Esq. (June 16, 1987), *reprinted in Berne Convention Implementation Act of 1987: Hearing on H.R. 1623 Before the Subcomm. on Courts, Civil Liberties & the Admin. of Justice of the H. Comm. on the Judiciary,* 100th Cong. 213 (1987) (''In my view, it is not necessary for the United States of America to enact statutory provisions on moral rights in order to comply with Article 6*bis* of the Berne Convention. The requirements under this Article can be fulfilled not only by statutory provisions in a copyright statute but also by common law and other statutes.'').

[18] *See* S. Rep. No. 100–352, at 9–10 (1988); H.R. Rep. No. 100–609, at 37–38 (1988); *see also S. Exec. Rep. No.* 100–17, at 55 (1988) (to accompany S. Treaty Doc. No. 99–27 (1986)) (statement of John K. Uilkema on behalf of Am. Bar Ass'n before the S. Comm. on Foreign Relations) (''Whether greater or lesser moral rights per se should be the subject of legislative consideration in the United States is a question that is separate and apart from the Berne adherence compatibility question.'').

[19] *See* 15 U.S.C. 1125(a).

[20] *See* 17 U.S.C. 106(2).

[21] *See* 17 U.S.C. 115(a)(2).

[22] *See* 17 U.S.C. 203.

[23] *See* H.R. Rep. No. 100–609, at 34 (1988). Contract law is particularly important for authors to control aspects of their economic and moral rights. For example, the collective bargaining agreements that govern the creation of major motion pictures often contain explicit requirements with regards to attribution for actors, writers, directors, and other guilds. Many copyright sectors that involve numerous authors and participants in the creative process, such as filmed entertainment, business and entertainment software, music production, and book publishing, also rely on both employment agreements and the work-for-hire doctrine to determine ownership issues, which in turn may include elements related to attribution and integrity.

[24] Visual Artists Rights Act (VARA) of 1990, Public Law 101–650, 104 Stat. 5128–29 (codified at 17 U.S.C. 106A). In the Report accompanying H.R. 2690 (Visual Artists Rights Act of 1990), the House Judiciary provided background information on the Berne Convention and moral rights, noting that the

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which guarantees to authors of works of ''visual arts'' the right to claim or disclaim authorship in a work and limited rights to prevent distortion, mutilation, or modification of a work.[25] In contrast to how moral rights were often adopted elsewhere, with VARA, Congress identified specific instances in which the limited rights could be waived.[26] As part of the legislation, Congress also directed the Copyright Office to conduct studies on the VARA waiver provision and also on resale royalties.[27]

In its 1996 report on the waiver provision, the Office concluded it could not make an accurate assessment of the impact of VARA's waiver provisions because artists and art consumers were generally unaware of moral rights and recommended that in order for artists to take advantage of their legal rights under VARA, further education about moral rights in the United States would be necessary.[28] The Office also made observations about the implementation of moral rights obligations in other countries, finding that, of the laws reviewed by the Office, only the moral rights laws of the United Kingdom and Canada contained express waiver provisions.[29]

The Supreme Court's 2003 Decision in Dastar

In 2003, some scholars began to question the strength of the U.S. patchwork of protection as a result of the U.S. Supreme Court's ruling in *Dastar Corp.* v. *Twentieth Century Fox Film Corp.* (''*Dastar*''), which foreclosed some attribution claims under section 43(a) of the Lanham Act.[30] The Court unanimously rejected an interpretation of section 43(a) that would ''require attribution of uncopyrighted materials.'' [31] Citing VARA, the Court said that when Congress has wanted to provide an attribution right under copyright law, ''it has done so with much more specificity than the Lanham Act's ambiguous use of 'origin.' '' [32] The Court found that ''origin of goods'' is most naturally understood as referring to the source of a physical product, not the person or entity that originated the underlying creative content.[33] In a well-known sentence, Justice Scalia, writing for the Court, stated that permitting a section 43(a) claim for such misattribution ''would create a species of mutant copyright law that limits the public's 'federal right to copy and to use' expired copyrights.'' [34]

Some lower courts have read *Dastar* as a broad prohibition on applying federal trademark and unfair competition laws in the realm of copyright, regardless of whether the copyrighted work remains under the term of protection or has fallen into the public domain.[35] In contrast, some scholars have argued that the Court did not write federal trademark and unfair competition law out of the patchwork entirely.[36]

Rights Management Information and Moral Rights for Performers

Since implementation of the Berne Convention, the United States has joined two additional international treaties that address moral rights—the WIPO Copyright Treaty (WCT) and the WIPO Performances and Phonograms Treaty (WPPT). The WCT incorporates the substantive provisions of Berne, including those of article 6*bis*.[37] Article 5 of the WPPT expands the obligations of Contracting Parties to recognize the moral rights of attribution and integrity for performers with respect to their live performances and performances fixed in phonograms.[38] Furthermore, both the WCT and the WPPT include new obligations concerning rights management information (RMI).[39] These provisions protect new means of identifying and protecting works while also helping protect the rights of attribution and integrity.[40]

The United States implemented its WCT and WPPT obligations via enactment of the 1998 Digital Millennium Copyright Act (''DMCA''),[41] and signed as a contracting party to both treaties in 1999, three years before the

Congress at the time of the BCIA agreed that existing federal and state laws were sufficient to comply with the Berne Convention requirements, but that ''adherence to the Berne Convention did not end the debate about whether the United States should adopt artists' rights laws, and the Subcommittee on Courts, Intellectual Property, and the Administration of Justice continued its review of the issue in [hearings held] in June.'' H.R. Rep. No. 101–514, at 8 (1990). Congress cited the ''critical factual and legal differences in the way visual arts and audiovisual works are created and disseminated'' in support of providing additional protections for visual artists. H.R. Rep. No. 101–514, at 9 (1990).

[25] *See* 17 U.S.C. 101 (definition of a ''work of visual art''); § 106A(a)(1) (providing for the right of attribution); § 106A(a)(3) (providing for the right of integrity). Section 604 of VARA, codified at 17 U.S.C. 113, created special rules for removal of works visual art incorporated into buildings. Unlike Berne's article 6*bis,* VARA's protections only apply to works of visual art.

[26] *See* H.R. Rep. No. 101–514, at 18 (1990). VARA permits authors to waive these rights only if expressly agreed in a written instrument signed by the author. *See* 17 U.S.C. 106A(e).

[27] *See* Visual Artists Rights Act of 1990, Public Law 101–650, 608, 104 Stat. 5128, 5132 (1990). The Copyright Office's 1992 study concluded there was insufficient economic and copyright policy justification to establish *droit de suite* in the United States. *See* U.S. Copyright Office, Droit De Suite: The Artist's Resale Royalty xv (1992), *http://www.copyright.gov/history/droit_de_suite.pdf.* In 2013, the Copyright Office responded to a congressional request and issued a second report which examined the changes in law and practice regarding resale royalties, in both the United States and abroad, since the 1992 report. *See U.S. Copyright Office, Resale Royalties: An Updated Analysis* (2013), *http://www.copyright.gov/docs/resaleroyalty/usco-resaleroyalty.pdf.*

[28] *See* U. S. Copyright Office, Waiver of Moral Rights in Visual Artworks: Final Report of the Register of Copyrights xiii, 186 (1996), *https://www.copyright.gov/reports/waiver-moral-rights-visual-artworks.pdf* (''Waiver of Moral Rights'').

[29] Waiver of Moral Rights at 183.

[30] 539 U.S. 23 (2003). *Dastar* involved the distribution of an edited version of a 1949 broadcast to which Twentieth Century Fox had owned the copyright but which it failed to renew, placing the work in the public domain. Dastar distributed copies of the edited series listing Dastar and its subsidiary as the producer and distributor of the edited work, rather than Fox. Fox sued for reverse passing off, claiming Dastar violated section 43(a) of the Lanham Act's prohibition against false designation of origin.

[31] *Id.* at 35.

[32] *Id.*at 34.

[33] *See id.* at 31–32.

[34] *Id.* at 34 (internal quote marks omitted). The Supreme Court left open the possibility of a Lanham Act claim under section 43(a)(1)(B) where, in advertising for a copied work of authorship, the copier ''misrepresents the nature, characteristics [or] qualities'' of the work. *Id.* at 38.

[35] *See, e.g., Kehoe Component Sales Inc.* v. *Best Lighting Prods., Inc.,* 796 F.3d 576, 587 (6th Cir. 2015); *Gen. Universal Sys., Inc.* v. *Lee,* 379 F.3d 131, 148–49 (5th Cir. 2004); *Zyla* v. *Wadsworth,* 360 F.3d 243, 251–52 (1st Cir. 2004); *Carroll* v. *Kahn,* No. 03–CV–0656, 2003 WL 22327299, at *5–6 (N.D.N.Y. Oct. 9, 2003).

[36] *See, e.g.,* Jane C. Ginsburg, *Moral Rights in the U.S.: Still in Need of a* Guardian Ad Litem, 30 Cardozo Arts & Ent. L.J. 73, 83–87 (2012); Justin Hughes, *American Moral Rights and Fixing the* Dastar ''*Gap,*'' 2007 Utah L. Rev. 659 (2007). At least one commenter has argued that not only do section 43(a)(1)(B) claims survive *Dastar,* but so do some section 43(a)(1)(A) claims. *See* Hughes at 692–95.

[37] *See* WIPO Copyright Treaty art. 1(4), Dec. 20, 1996, 2186 U.N.T.S. 121 (''WCT''); *see also Summary of the WIPO Copyright Treaty (WCT) (1996),* WIPO, *http://www.wipo.int/treaties/en/ip/wct/summary_wct.html.*

[38] *See* WIPO Performances and Phonograms Treaty art. 5(1), Dec. 20, 1996, 2186 U.N.T.S. 203 (''WPPT''). Like the Berne Convention, the WPPT provides that the duration of protection shall be at least for the term of economic rights and shall be governed by national law. WPPT arts. 5(2)–(3).

[39] *See* WCT art. 12; WPPT art. 19. WCT article 12 and WPPT article 19 define rights management information to include identification of the author and owner and terms of use of the work or sound recording.

[40] *See* J. Carlos Fernández-Molina & Eduardo Peis, *The Moral Rights of Authors in the Age of Digital Information,* 52 J. Am. Soc'y for Info. Sci. & Tech. 109, 112 (2001) (explaining how the WIPO Internet Treaties' rights management information provisions fit within the treaties and also are useful in protecting moral rights).

[41] Digital Millennium Copyright Act (DMCA), Public Law 105–304, 103 122 Stat. 2860, 2863–76 (1998) (codified as amended at 17 U.S.C. 1201–1205). The WIPO Internet Treaties were submitted to Congress for advice and consent the previous year, and the Senate voted to approve the Treaties shortly before passage of the DMCA. *See* S. Treaty Doc. No. 105-17 (1997); 105 Cong. Rec. S12,972–73 (daily ed. Oct. 21, 1998).

treaties entered into force.[42] Congress added a new chapter 12 to title 17, which contained two new provisions to implement the treaties—section 1201, which addresses technological protection measures, and section 1202, which protects rights management information (called copyright management information in U.S. law)[43]—but did not make any additional changes, finding that ''[t]he treaties do not require any change in the substance of copyright rights or exceptions in U.S. law.''[44]

Section 1202 includes prohibitions on both providing false copyright management information (''CMI''), and removing or altering CMI.[45] In addition to facilitating the administration of an author's or right holder's economic rights, the CMI protections afforded by section 1202 may have implications for authors' protection and enforcement of their moral rights.[46] However, two aspects of section 1202 may limit its usefulness as a mechanism to protect an author's moral rights. First, to be liable under section 1202, a person who removes copyright management information must know both that they have caused its removal and that such removal is likely to cause others to infringe the work.[47] Second, while most courts recognize section 1202 as protecting against any removal of attribution from works, a minority of courts have limited section 1202 to protect only against removal of attribution that is digital or part of an ''automated copyright protection or management system.''[48]

Recent International Developments

There have also been changes to the landscape of moral rights protection internationally since the U.S. acceded to the Berne Convention in 1989. The Copyright Office noted in its 1996 report *Waiver of Moral Rights in Visual Artworks* that, while statutory recognition of the commonly recognized moral rights—*i.e.,* attribution and integrity—is the norm internationally, the strength of the moral rights laws varied among Berne members, even among those with the same basic legal systems.[49] For example, at the time of the Report the United Kingdom required an author or her heirs, in some cases, to assert the right of paternity and was generally considered to have adopted one of the more restrictive approaches to implementing moral rights.[50] However, ten years later, in 2006, the United Kingdom amended its moral rights provision by extending to qualifying performances the right to attribution and the right to object to derogatory treatment of a work.[51]

The most recent international development on CMI and moral rights occurred four years ago at a Diplomatic Conference in Beijing where WIPO and its member states concluded a new treaty on audiovisual performances.[52] Similar to the approach of the WPPT, the Beijing Treaty on Audiovisual Performances also contains provisions on CMI and moral rights for audiovisual performers.[53]

Availability and Use of Licenses, Contracts, and State Laws

Another part of the patchwork upon which moral rights protection in the United States relies is state contract law, which allows authors to negotiate for protection of their rights of attribution and integrity through private ordering. Since the United States' accession to the Berne Convention, a major change to this area has been the emergence of Creative Commons and its various licenses that have simplified licensing for all kinds of authors and users, large and small. The CC license suites have served to facilitate private ordering, including for individual authors that would not previously have been able to afford the services of a lawyer to create licenses to govern use of their works.[54]

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[42] *See WCT Notification No. 10: WIPO Copyright Treaty: Ratification by the United States of America,* WIPO (Sept. 14, 1999), *available at http://www.wipo.int/treaties/en/notifications/wct/treaty_wct_10.html; WPPT Notification No. 8: WIPO Performances and Phonograms Treaty: Ratification by the United States of America,* WIPO (Sept. 14, 1999), *available at http://www.wipo.int/treaties/en/notifications/wppt/treaty_wppt_8.html.*

[43] The other sections of chapter 12 include sections 1203 and 1204, which set forth available civil remedies and criminal sanctions for violation of sections 1201 and 1202, and section 1205, which explicitly carves out federal and state laws affecting Internet privacy. 17 U.S.C. §§ 1203–1205.

[44] H.R. Rep. No. 105-551, pt. 1, at 9 (1998).

[45] The term ''copyright management information'' in the Copyright Act is seen as a synonymous term for ''rights management information'' as used in the WCT and WPPT. *See* S. Rep. No. 105–190, at 11 n.18 (1998) (''Rights management information is more commonly referred to in the U.S. as copyright management information (CMI).'').

[46] Section 1202 makes it an offense to ''intentionally remove or alter any copyright management information,'' which includes the name of a work's author. 17 U.S.C. §§ 1202(b)(1), (c)(2). *See* Jane C. Ginsburg, *Have Moral Rights Come of (Digital) Age in the United States?,* 19 Cardozo Arts & Ent. L.J. 9, 11 (2001) (''The DMCA may contain the seeds of a more general attribution right. . . .''); *see also* Greg Lastowka, *Digital Attribution: Copyright and the Right to Credit,* 87 B.U. L. Rev. 41, 69–73 (2007).

[47] *See* 17 U.S.C. 1202(a)–(b); *see also Stevens* v. *Corelogic,* No. 14-cv-1158, 2016 WL 4371549, at *5, 6 (S.D. Cal. July 1, 2016) (''Under § 1202(b)(1), Plaintiffs must present evidence that [defendant] intentionally removed or altered CMI. . . . '' and ''[a]lthough Plaintiffs need not show actual infringement, the fact that there was none is relevant to Plaintiffs' burden to show that [defendant] had a reasonable ground to believe it was likely to happen.'').

[48] *Compare Murphy* v. *Millennium Radio Grp. LLC,* 650 F.3d 295, 305 (3d Cir. 2011) (rejecting argument that the definition of CMI under section 1202 is ''restricted to the context of 'automated copyright protection or management systems'''), *and Williams* v. *Cavalli S.p.A.,* No. CV 14–06659–AB (JEMx), 2015 WL 1247065, at *3 (C.D. Cal. Feb. 12, 2015) (holding that ''[t]he plain meaning of § 1202 indicates that CMI can include non-digital copyright information''), *and Leveyfilm, Inc.* v. *Fox Sports Interactive Media, LLC,* 999 F. Supp. 2d 1098, 1101–02 (N.D. Ill. 2014) (noting that the majority of courts have rejected a requirement for CMI to be digital under section 1202), *and Fox* v. *Hildebrand,* No. CV 09–2085 DSF (VBKx), 2009 WL 1977996, at *3 (C.D. Cal. July 1, 2009) (''The plain language of the statute indicates that the DMCA provision at issue is not limited to copyright notices that are digitally placed on a work.''), *with Textile Secrets Int'l Inc.* v. *Ya-Ya Brand Inc.,* 524 F. Supp. 2d 1184, 1201 (C.D. Cal. 2007) (''[T]he Court [] cannot find that the provision was intended to apply to circumstances that have no relation to the Internet, electronic commerce, automated copyright protections or management systems, public registers, or other technological measures or processes as contemplated in the DMCA as a whole.''), *and IQ Grp., Ltd.* v. *Wiesner Publ'g, LLC,* 409 F. Supp. 2d 587, 597 (D.N.J. 2006) (holding that ''[t]o come within § 1202, the information removed must function as a component of an automated copyright protection or management system''). The majority position seems to accord with statements from the legislative history. *See, e.g.,* S. Rep. No. 105–190, at 16 (1998) (''CMI need not be in digital form, but CMI in digital form is expressly included.'').

[49] *See* Waiver of Moral Rights at 53.

[50] *See* Waiver of Moral Rights at 47–51, 53.

[51] *See* Performances (Moral Rights, etc.) Regulations 2006, SI 2006/18, arts. 5–6 (UK).

[52] *See* Beijing Treaty on Audiovisual Performances, June 24, 2012, 51 I.L.M. 1214 (2012) (''Beijing Treaty'').

[53] *See* Beijing Treaty art. 5 (''Moral Rights''), art. 16 (''Obligations Concerning Rights Management Information''). Negotiations to conclude this treaty took more than a decade, with a major point of contention involving the provision on contractual transfers. *See* Beijing Treaty art. 12; *see also* Press Release, WIPO, WIPO Diplomatic Conference Opens in Beijing to Conclude Treaty on Performers' Rights in Audiovisual Productions, WIPO Press Release PR/2012/713 (June 20, 2012), *available at http://www.wipo.int/pressroom/en/articles/2012/article_0012.html* (noting that as far back as the year 2000 negotiators could not agree on the issue involving transfer of rights, and a breakthrough compromise occurred in June 2011). This treaty has not yet entered into force, and the United States has not yet ratified it. The Obama Administration has submitted a legislative package to Congress in support of U.S. implementation of the Beijing Treaty. *See* Letter from Michelle K. Lee, Under Sec'y Commerce for Intellectual Prop. & Dir., U.S. Patent & Trademark Office, to Joseph R. Biden, President of the Senate (Feb. 26, 2016), *available at http://www.uspto.gov/sites/default/files/documents/Beijing-treaty-package.pdf* (treaty implementation package for the Beijing Treaty on Audiovisual Performances which includes a transmittal letter, Beijing Treaty Implementation Act of 2016, and Statement of Purpose and Need and Sectional Analysis).

[54] Founded in 2001, Creative Commons offers various open source content licenses. *Creative Commons Project,* Cover Pages (Aug. 22, 2008), *http://xml.coverpages.org/creativeCommons.html.* These types of licenses were held to be governed by copyright law rather than contract law in

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Currently there are over one billion works licensed under Creative Commons licenses, most of which require attribution of the author.[55]

Changes in Technology to Deliver Content and Identify Content

The evolution of technology in the past few decades has also impacted the availability of moral rights protections for modern authors. Technology can facilitate improved identification and licensing of works with persistent identifiers,[56] while, at the same time, it can also make it easier to remove attribution elements and distribute the unattributed works widely.[57]

II. Congressional Copyright Review and This Study

As part of its effort to begin a dialogue about moral rights protections in the United States, the Copyright Office organized a symposium entitled ''Authors, Attribution, and Integrity: Examining Moral Rights in the United States,'' which was held on April 18, 2016.[58] The symposium served as a launching point for the issuance of this Notice of Inquiry.

Seven sessions covered the historical development of moral rights, the value authors place on moral rights, the various ways current law provides for these rights, and new considerations for the digital age. Participants, including professional authors, artists, musicians, and performers, discussed the importance that copyright law generally, and attribution specifically, plays in supporting their creative process and their livelihood.[59] Leading academics provided an overview of the scope of moral rights and how countries, including the United States, approach these concepts. [60]

Many participants identified the right of attribution as particularly important to authors, both from a personal and from an economic perspective. For example, participants cited the role of copyright management information for purposes of attribution, and discussed the perceived strengths and limitations of section 1202.[61] Keynote speaker Professor Jane Ginsburg posited ways to strengthen the right of attribution.[62] Others discussed the possibilities of using non-copyright laws post-*Dastar,*[63] as well as expressing concerns about how potential moral rights-like causes of action might interact with First Amendment protections.[64]

Some participants asserted that the current patchwork of laws, particularly the availability of contract law, the work for hire doctrine, and collective bargaining agreements (available in some industry sectors), provides sufficient protection for moral rights concerns.[65] In contrast, several voices criticized the limited scope of existing law, ranging from upset that a right of publicity is not a federal right[66] to disappointment with VARA's under-inclusiveness and strict standards.[67]

Discussion also addressed the role of technology, both in creation and in dissemination of authorized and unauthorized works. For example, a photographer noted the importance of attribution that stays with images,[68] and a photo company described the technology they use to persistently connect authorship information to images.[69]

Looking at what lessons might be gleaned from the experiences of other countries, one panelist commented that there is ''tremendous diversity in how different countries have implemented moral rights,'' [70] and another confirmed that moral rights litigation constitutes only a small percentage of the copyright cases on those countries' litigation documents.[71]

III. Subjects of Inquiry

The Copyright Office seeks public comments addressing how existing law, including provisions found in title 17 of the U.S. Code as well as other federal and state laws, affords authors with effective protection of their rights, equivalent to those of moral rights of attribution and integrity.

The Office invites written comments in particular on the subjects below. A party choosing to respond to this Notice of Inquiry need not address every subject, but the Office requests that responding parties clearly identify and

Jacobsen v. *Katzer,* 535 F.3d 1373, 1380–83 (Fed. Cir. 2008).

[55] Creative Commons, *https://creativecommons.org/* (last visited Jan. 5, 2017) (''1.1 billion works and counting.'').

[56] For example, the PLUS Coalition has created an image rights language to allow for global communication of image rights information, and it is currently developing an image registry that will function as a hub connecting registries worldwide and providing both literal and image-based searches. PLUS Coalition, Comments Submitted in Response to U.S. Copyright Office's Apr. 24, 2015 Notice of Inquiry (Visual Works Study) at 1 (July 22, 2015) (noting that the Coalition's unique image rights language is meant to address the ''challenges [arising] from a present inability to ensure that any person or machine encountering a visual work has ready access to rights information sufficient to allow the work to be identified, and sufficient to facilitate an informed decision regarding the display, reproduction and distribution of the work'').

[57] Indeed, CMI is of particular interest to visual artists who embed copyright information in their works only to find it unlawfully stripped from digital copies. This makes it difficult for potential users to identify and contact the copyright owner to obtain a license to use a work found online. *See* Columbia University Libraries, Comments Submitted in Response to U.S. Office's Apr. 24, 2015 Notice of Inquiry (Visual Works Study) at 2 (July 23, 2015) (''Rights metadata that includes author attribution and source information would [ ] facilitate subsequent re-uses of visual works while at the same time support the interests of legitimate copyright owners.'').

[58] The Office co-hosted this symposium with the George Mason University School of Law and its Center for the Protection of Intellectual Property. Videos of the proceedings can be accessed on the U.S. Copyright Office Web site event page at *http://www.copyright.gov/events/moralrights/.* The official transcript has been published by the *George Mason Journal of International Commercial Law. See* Symposium, *Authors, Attribution, and Integrity: Examining Moral Rights in the United States,* 8 Geo. Mason J. Int'l Com. L. 1 (2016), available at *http://www.georgemasonjicl.org/wp-content/uploads/2016/08/Summer-Issue-2016.pdf.*

[59] *See Session 4: The Importance of Moral Rights to Authors,* 8 Geo. Mason J. Int'l Com. L. 87, 90 (2016).

[60] *See Session 1: Overview of Moral Rights,* 8 Geo. Mason J. Int'l Com. L. 7 (2016).

[61] *See, e.g.,* Jane C. Ginsburg, Keynote Address, *The Most Moral of Rights: The Right to be Recognized as the Author of One's Work,* 8 Geo. Mason J. Int'l Com. L. 44, 48, 60–72 (2016); *Session 4: The Importance of Moral Rights to Authors,* 8 Geo. Mason J. Int'l Com. L. 87, 91–93 (2016) (comments of Yoko Miyashita, Getty Images).

[62] *See* Jane C. Ginsburg, *Keynote Address: The Most Moral of Rights: The Right to be Recognized as the Author of One's Work,* 8 Geo. Mason J. Int'l Com. L. 44, 72–81 (2016).

[63] *See, e.g., Session 2: The U.S. Perspective,* 8 Geo. Mason J. Int'l Com. L. 26, 30–34 (2016) (remarks of Duncan Crabtree-Ireland, SAG–AFTRA, & Peter K. Yu, Tex. A&M Univ. Sch. of Law); *Session 6: New Ways to Disseminate Content and the Impact on Moral Rights,* 8 Geo. Mason J. Int'l Com. L. 125, 139 (2016) (remarks of Stanley Pierre-Louis, Entm't Software Ass'n).

[64] *See Session 5: The Intersection of Moral Rights and Other Laws,* 8 Geo. Mason J. Int'l Com. L. 106, 119–20 (2016) (remarks of Paul Alan Levy, Pub. Citizen).

[65] *See Session 2: The U.S. Perspective,* 8 Geo. Mason J. Int'l Com. L. 26, 27–29 (2016) (remarks of Allan Adler, Ass'n of Am. Publishers (''AAP'')) (noting that the testimony of AAP at the 2014 hearing ''raise[d] the threshold policy question of 'whether to superimpose vague, subjective, and wholly unpredictable new rights upon a longstanding balanced and successful copyright system.'''').

[66] *See Session 2: The U.S. Perspective,* 8 Geo. Mason J. Int'l Com. L. 26, 30 (2016) (remarks of Duncan Crabtree-Ireland, SAG–AFTRA).

[67] *See, e.g.,* Jane C. Ginsburg, Keynote Address, *The Most Moral of Rights: The Right to be Recognized as the Author of One's Work,* 8 Geo. Mason J. Int'l Com. L. 44, 53 (2016); *Session 5: The Intersection of Moral Rights and Other Laws,* 8 Geo. Mason J. Int'l Com. L. 106, 107–10, 113–14 (2016) (remarks of Sonya G. Bonneau, Geo. Univ. Law Ctr.; Eugene Mopsik, Am. Photographic Artists; & Nancy E. Wolff, Cowan, DeBaets, Abrahams & Sheppard LLP).

[68] *See Session 5: The Intersection of Moral Rights and Other Laws,* 8 Geo. Mason J. Int'l Com. L. 106, 110 (2016) (remarks of Eugene Mopsik, Am. Photographic Artists).

[69] *See Session 4: The Importance of Moral Rights to Authors,* 8 Geo. Mason J. Int'l Com. L. 87, 92 (2016) (remarks of Yoko Miyashita, Getty Images).

[70] *Session 7: Where Do We Go From Here?,* 8 Geo. Mason J. Int'l Com. L. 142, 147 (2016) (remarks of Mira Sundara Rajan, Univ. of Glasgow Sch. of Law).

[71] *See Session 1: Overview of Moral Rights,* 8 Geo. Mason J. Int'l Com. L. 7, 15 (2016) (remarks of Daniel Gervais, Vand. Law Sch.).

separately address each numbered subject for which a response is submitted.

General Questions Regarding Availability of Moral Rights in the United States

1. Please comment on the means by which the United States protects the moral rights of authors, specifically the rights of integrity and attribution. Should additional moral rights protection be considered? If so, what specific changes should be considered by Congress?

Title 17

2. How effective has section 106A (VARA) been in promoting and protecting the moral rights of authors of visual works? What, if any, legislative solutions to improve VARA might be advisable?

3. How have section 1202's provisions on copyright management information been used to support authors' moral rights? Should Congress consider updates to section 1202 to strengthen moral rights protections? If so, in what ways?

4. Would stronger protections for either the right of attribution or the right of integrity implicate the First Amendment? If so, how should they be reconciled?

5. If a more explicit provision on moral rights were to be added to the Copyright Act, what exceptions or limitations should be considered? What limitations on remedies should be considered?

Other Federal and State Laws

6. How has the *Dastar* decision affected moral rights protections in the United States? Should Congress consider legislation to address the impact of the *Dastar* decision on moral rights protection? If so, how?

7. What impact has contract law and collective bargaining had on an author's ability to enforce his or her moral rights? How does the issue of waiver of moral rights affect transactions and other commercial, as well as non-commercial, dealings?

Insights From Other Countries' Implementation of Moral Rights Obligations

8. How have foreign countries protected the moral rights of authors, including the rights of attribution and integrity? How well would such an approach to protecting moral rights work in the U.S. context?

Technological Developments

9. How does, or could, technology be used to address, facilitate, or resolve challenges and problems faced by authors who want to protect the attribution and integrity of their works?

Other Issues

10. Are there any voluntary initiatives that could be developed and taken by interested parties in the private sector to improve authors' means to secure and enforce their rights of attribution and integrity? If so, how could the government facilitate these initiatives?

11. Please identify any pertinent issues not referenced above that the Copyright Office should consider in conducting its study

Dated: January 13, 2017.

Karyn Temple Claggett,

Acting Register of Copyrights and Director of the U.S. Copyright Office.

[FR Doc. 2017–01294 Filed 1–19–17; 8:45 am]

BILLING CODE 1410–30–P

LIBRARY OF CONGRESS

Copyright Royalty Board

[Docket Nos. 17–0008–CRB–AU and 17–0009–CRB–AU]

Notice of Intent To Audit

AGENCY: Copyright Royalty Board, Library of Congress.

ACTION: Public notice.

SUMMARY: The Copyright Royalty Judges announce receipt of two notices of intent to audit the 2013, 2014, and 2015 statements of account submitted by broadcasters Cox Radio (Docket No. 17–CRB–0009–AU) and Hubbard Broadcasting (Docket No. 17–CRB–0008–AU) concerning royalty payments each made pursuant to two statutory licenses.

FOR FURTHER INFORMATION CONTACT: Anita Brown, Program Specialist, by telephone at (202) 707–7658 or by email at *crb@loc.gov.*

SUMMARY INFORMATION: The Copyright Act, title 17 of the United States Code, grants to copyright owners of sound recordings the exclusive right to publicly perform sound recordings by means of certain digital audio transmissions, subject to limitations. Specifically, the right is limited by the statutory license in section 114 which allows nonexempt noninteractive digital subscription services, eligible nonsubscription services, and preexisting satellite digital audio radio services to perform publicly sound recordings by means of digital audio transmissions. 17 U.S.C. 114(f). In addition, a statutory license in section 112 allows a service to make necessary ephemeral reproductions to facilitate the digital transmission of the sound recording. 17 U.S.C. 112(e).

Licensees may operate under these licenses provided they pay the royalty fees and comply with the terms set by the Copyright Royalty Judges. The rates and terms for the section 112 and 114 licenses are set forth in 37 CFR parts 380 and 382–84.

As part of the terms set for these licenses, the Judges designated SoundExchange, Inc., as the Collective, *i.e.,* the organization charged with collecting the royalty payments and statements of account submitted by eligible nonsubscription services such as broadcasters and with distributing the royalties to copyright owners and performers entitled to receive them. *See* 37 CFR 380.33(b)(1).

As the designated Collective, SoundExchange may, once during a calendar year, conduct an audit of a licensee for any or all of the prior three years in order to verify royalty payments. SoundExchange must first file with the Judges a notice of intent to audit a licensee and deliver the notice to the licensee. *See* 37 CFR 380.35.

On December 22, 2016, SoundExchange filed with the Judges notices of intent to audit licensee broadcasters Cox Radio, Inc., and Hubbard Broadcasting, Inc., for 2013–15. The Judges must publish notice in the **Federal Register** within 30 days of receipt of a notice announcing the Collective's intent to conduct an audit. *See* 37 CFR 380.35(c). Today's notice fulfills this requirement with respect to SoundExchange's December 22, 2016 notices of intent to audit.

Dated: January 13, 2017.

Suzanne M. Barnett,

Chief Copyright Royalty Judge.

[FR Doc. 2017–01319 Filed 1–19–17; 8:45 am]

BILLING CODE 1410–72–P

LIBRARY OF CONGRESS

Copyright Royalty Board

[Docket No. 17–0004–CRB–AU, 17–0007–CRB–AU, and 17–0010–CRB–AU]

Notice of Intent To Audit

AGENCY: Copyright Royalty Board, Library of Congress.

ACTION: Public notice.

SUMMARY: The Copyright Royalty Judges announce receipt of three notices of intent to audit the 2013, 2014, and 2015 statements of account submitted by commercial webcasters Radionomy (Docket No. 17–CRB–0004–AU), IMVU, Inc. (Docket No. 17–CRB–0007–AU),

and Slacker, Inc. (Docket No. 17–CRB–0010–AU), concerning the royalty payments each made pursuant to two statutory licenses.

FOR FURTHER INFORMATION CONTACT: Anita Brown, Program Specialist, by telephone at (202) 707–7658 or by email at *crb@loc.gov.*

SUMMARY INFORMATION: The Copyright Act, title 17 of the United States Code, grants to sound recordings copyright owners the exclusive right to publicly perform sound recordings by means of certain digital audio transmissions, subject to limitations. Specifically, the right is limited by the statutory license in section 114 which allows nonexempt noninteractive digital subscription services, eligible nonsubscription services, and preexisting satellite digital audio radio services to perform publicly sound recordings by means of digital audio transmissions. 17 U.S.C. 114(f). In addition, a statutory license in section 112 allows a service to make necessary ephemeral reproductions to facilitate the digital transmission of the sound recording. 17 U.S.C. 112(e).

Licensees may operate under these licenses provided they pay the royalty fees and comply with the terms set by the Copyright Royalty Judges. The rates and terms for the section 112 and 114 licenses are set forth in 37 CFR parts 380 and 382–84.

As part of the terms set for these licenses, the Judges designated SoundExchange, Inc., as the Collective, *i.e.,* the organization charged with collecting the royalty payments and statements of account submitted by eligible nonexempt noninteractive digital subscription services such as Commercial Webcasters and with distributing the royalties to the copyright owners and performers entitled to receive them under the section 112 and 114 licenses. *See* 37 CFR 380.4(d).

As the Collective, SoundExchange may, only once a year, conduct an audit of a licensee for any or all of the prior three calendar years in order to verify royalty payments. SoundExchange must first file with the Judges a notice of intent to audit a licensee and deliver the notice to the licensee. *See* 37 CFR 380.6.

On December 22, 2016, SoundExchange filed with the Judges notices of intent to audit Radionomy, IMVU, Inc., and Slacker, Inc., for the years 2013, 2014, and 2015. The Judges must publish notice in the **Federal Register** within 30 days of receipt of a notice announcing the Collective's intent to conduct an audit. *See* 37 CFR 380.6(c). Today's notice fulfills this requirement with respect to SoundExchange's December 22, 2016, notices of intent to audit.

Dated: January 13, 2017.

Suzanne M. Barnett,

Chief Copyright Royalty Judge.

[FR Doc. 2017–01320 Filed 1–19–17; 8:45 am]

BILLING CODE 1410–72–P

LIBRARY OF CONGRESS

Copyright Royalty Board

[Docket No. 17–0006–CRB–AU]

Notice of Intent To Audit

AGENCY: Copyright Royalty Board, Library of Congress.

ACTION: Public notice.

SUMMARY INFORMATION: The Copyright Royalty Judges announce receipt of a notice of intent to audit the 2013, 2014, and 2015 statements of account of Sirius XM Radio, Inc., concerning royalty payments its Commercial Webcaster service, Preexisting Satellite Digital Audio Radio Service, New Subscription Service, and Business Establishment Service made pursuant to two statutory licenses.

FOR FURTHER INFORMATION CONTACT: Anita Brown, Program Specialist, by telephone at (202) 707–7658 or by email at *crb@loc.gov.*

SUMMARY INFORMATION: The Copyright Act, title 17 of the United States Code, grants to copyright owners of sound recordings the exclusive right to publicly perform sound recordings by means of certain digital audio transmissions, subject to limitations. Specifically, the right is limited by the statutory license in section 114 which allows nonexempt noninteractive digital subscription services, eligible nonsubscription services, and preexisting satellite digital audio radio services to perform publicly sound recordings by means of digital audio transmissions. 17 U.S.C. 114(f).

In addition, a statutory license in section 112 allows a service to make necessary ephemeral reproductions to facilitate the digital transmission of the sound recording, including transmissions to business establishments.[1] 17 U.S.C. 112(e).

Licensees may operate under these licenses provided they pay the royalty fees and comply with the terms set by the Copyright Royalty Judges. The rates and terms for the section 112 and 114 licenses are set forth in 37 CFR parts 380 and 382–84.

As part of the terms set for these licenses, the Judges designated SoundExchange, Inc. as the Collective, *i.e.,* the organization charged with collecting the royalty payments and statements of account submitted by licensees, including those that operate commercial webcaster services, preexisting satellite digital audio radio services, new subscription services, and those that make ephemeral copies for transmission to business establishments. The Collective is also charged with distributing the royalties to the copyright owners and performers entitled to receive them under the section 112 and 114 licenses. *See* 37 CFR 380.4(d), 382.13(b)(1), 383.4(a), 384.4(b)(1).

As the Collective,t, SoundExchange may, once during a calendar year, conduct an audit of a licensee for any or all of the prior three years in order to verify royalty payments. SoundExchange must first file with the Judges a notice of intent to audit a licensee and deliver the notice to the licensee. *See* 37 CFR 380.6, 382.15, 383.4(a), and 384.6.

On December 22, 2016, SoundExchange filed with the Judges a notice of intent to audit Sirius XM Radio, Inc.'s Commercial Webcaster service, Preexisting Satellite Digital Audio Radio Service, New Subscription Service, and Business Establishment Service for the years 2013, 2014, and 2015. The Judges must publish notice in the **Federal Register** within 30 days of receipt of a notice announcing the Collective's intent to conduct an audit. *See* 37 CFR 380.6(c), 382.15(c), 383.4(a), and 384.6(c). Today's notice fulfills this requirement with respect to SoundExchange's December 22, 2016, notice of intent to audit.

Dated: January 13, 2017.

Suzanne M. Barnett,

Chief Copyright Royalty Judge.

[FR Doc. 2017–01321 Filed 1–19–17; 8:45 am]

BILLING CODE 1410–72–P

LIBRARY OF CONGRESS

Copyright Royalty Board

[Consolidated Docket No. 14–CRB–0010–CD (2010–13)]

Distribution of 2010–13 Cable Royalty Funds

AGENCY: Copyright Royalty Board, Library of Congress.

ACTION: Notice requesting comments.

SUMMARY: The Copyright Royalty Judges announce settlement of controversies and requests for partial distribution of

[1] Subject to the limitations set forth in section 114(d)(1)(C)(iv).

cable television distant retransmission royalties claimed by National Public Radio (NPR) and Music Claimants. National Public Radio appeared in this proceeding on its own behalf and on behalf of its NPR Members retransmitted as distant signals by cable television operators. Music Claimants include Broadcast Music, Inc. (BMI) and the American Society of Composers, Authors, and Publishers (ASCAP), as well as SESAC, Inc.

DATES: Comments are due on or before February 22, 2017.

ADDRESSES: Submit electronic comments via email to *crb@loc.gov.* Those who choose not to submit comments electronically should see ''How to Submit Comments'' in the Supplementary Information section below for physical addresses and further instructions. This notice and request is also posted on the agency's Web site (*www.loc.gov/crb*) and on *Regulations.gov* (*www.regulations.gov*).

FOR FURTHER INFORMATION CONTACT: Kimberly Whittle, Attorney-Advisor, by telephone at (202) 707–7658 or email at *crb@loc.gov.*

SUPPLEMENTARY INFORMATION: Each year cable systems must submit royalty payments to the Register of Copyrights as required by the statutory license set forth in section 111 of the Copyright Act for the distant retransmission to cable subscribers of over-the-air television and radio broadcast signals. *See* 17 U.S.C. 111(d). The Copyright Royalty Judges (Judges) oversee distribution of royalties to copyright owners whose works were included in a qualifying retransmission and who timely filed a claim for royalties. Allocation of the royalties collected occurs in one of two ways. In the first instance, the Judges may authorize distribution in accordance with a negotiated settlement among all claiming parties. 17 U.S.C. 111(d)(4)(A). If all claimants do not reach agreement with respect to the royalties, the Judges must conduct a proceeding to determine the distribution of any royalties that remain in controversy. 17 U.S.C. 111(d)(4)(B). Alternatively, the Judges may, on motion of claimants and on notice to all interested parties, authorize a partial distribution of royalties, reserving on deposit sufficient funds to resolve identified disputes. 17 U.S.C. 111(d)(4)(C), 801(b)(3)(C).

National Public Radio

On December 6, 2016, the Judges received a joint motion [1] seeking distribution by stipulation to NPR of 0.16% of all cable royalty funds on deposit for royalty years 2010 through 2013, inclusive (2010–13 Funds) (NPR Motion). The Moving Parties confirm that no other claimant or category of claimants asserts a controversy regarding the funds allocated to NPR. The Moving Parties further agree that the distribution of royalties to NPR shall equal the value of its 0.16% settlement share minus the dollar value of partial distributions NPR has received to date for each of the 2010–13 Funds.[2] The stated amounts reflect a 0.16% share of the total funds on deposit as of the date of the final distribution to NPR for each of the years included in the 2010–13 Funds; [3] the dollar amounts might vary as of the date of distribution, depending upon costs incurred for managing the funds and interest accrued on the funds. The Parties further stipulate and agree that these sums, once distributed, shall not be subject to repayment and that no additional sums shall be distributed to NPR in the future with respect to the 2010–13 Funds, and that NPR need not participate further in royalty distribution proceedings related to the 2010–13 Funds.

[2] The amounts that NPR received in partial distribution for each of the 2010–13 Funds can be found at *http://www.copyright.gov/licensing/distribution-fund.pdf.* To date, NPR has received a total of $846,675.38 in partial distributions, as follows:

2010: $179,048.31 (distributed October 25, 2012)
2011: $187,871.22 (distributed April 25, 2013)
2012: $236,077.95 (distributed January 15, 2015)
2013: $243,677.90 (distributed June 18, 2015)

[3] The total funds for each of the years included in the 2010–13 Funds as of September 30, 2016, can be found at page 6 of *http://www.copyright.gov/licensing/financial-statements/operating/sep2016.pdf* (chart tracking cable royalties entitled ''Growth in the Copyright Royalty Funds As of September 30, 2016''). Recognizing that the amount of NPR's 0.16% settlement share will be determined as of the date of the final distribution to NPR, at least as of September 30, 2016, the total funds attributable for each of the years included in the 2010–13 Funds (calculated by adding the amounts already distributed and the ''Funds Available for Distribution'' as of September 30, 2016) were reported as follows:

Cable	Distributed	Funds available for distribution	Fund total	Percent growth
2013	$135,376,610.47	$90,865,875.68	$226,242,486.15	3.363
2012	131,154,417.29	87,726,471.99	218,880,889.28	4.699
2011	104,372,898.09	104,683,702.75	209,056,600.84	4.919
2010	99,471,281.18	99,783,533.64	199,254,814.82	15.577

Music Claimants

On December 15, 2016, the Judges received a joint motion seeking distribution by stipulation to the Music Claimants from the cable royalty funds on deposit for royalty years 2010 through 2013, inclusive (2010–13 Funds) (Music Motion). The Moving Parties consist of all participants in this consolidated proceeding. In the Music Motion, the Moving Parties notified the Judges that they stipulate and agree that Music Claimants shall receive a share of each of the 2010–13 Funds as follows (the Music Claimants' Share):

Year	Basic fund (percent)	3.75% fund (percent)	Syndex fund (percent)
2010	3.50	3.50	3.50
2011	3.50	3.50	3.50
2012	3.55	3.55	3.55
2013	3.55	3.55	3.55

[1] The Moving Parties included all other participants in this consolidated proceeding: Motion Picture Association of America, Joint Sports Claimants, National Association of Broadcasters and the Commercial Television Claimants, Music Claimants, Canadian Claimants Group, Settling Devotional Claimants, National Public Radio, Public Broadcasting Service and the Public Television Claimants, and Multigroup Claimants (collectively, the Moving Parties).

The Moving Parties stipulate that the value of the Music Claimants' Share is as listed as above, minus the dollar value of partial distributions of the 2010–13 Funds that Music Claimants have received to date.[4] The Licensing Office will calculate the Music Claimants' Share of the total funds as of the date of the distribution to Music Claimants for each of the years included in the 2010–13 Funds, including interest accrued to the date of distribution and excluding (1) the distribution to NPR of its 0.16% share as specified in the December 6, 2016, NPR Motion and (2) taxable costs incurred by the Department of Licensing.

The Moving Parties represent that there are no outstanding inter- or intra-category controversies regarding the claims in the Music Claimant category. The Parties further stipulate and agree that these sums shall not be subject to repayment once distributed, that Music Claimants need not participate further in royalty distribution proceedings related to the 2010–13 Funds, and that no additional sums shall be distributed to Music Claimants in the future with respect to the 2010–13 Funds, provided that Music Claimants shall be entitled to receive the Music Claimants' Share of any additional royalties deposited into any of the 2010–13 Funds due to any audit of any cable system operator's Statement of Account pursuant to 37 CFR 201.16 that Music Claimants joined as participating copyright owners.

The Moving Parties' further stipulate that the terms described in the Music Motion represent a compromise and settlement and apply to the 2010, 2011, 2012, and 2013 Cable Royalty Distribution Proceedings only; no party accepts the requested allocation as precedent and no party admits to any principle underlying stipulated amounts of the Music Claimants' Share.

Partial Distribution

The Moving Parties therefore request the Judges to order a partial distribution of royalties to NPR in the agreed amounts and a partial distribution to Music Claimants in the agreed amounts pursuant to section 801(b)(3)(C) of the Copyright Act.[5] 17 U.S.C. 801(b)(3)(C). That section requires that, before ruling on the motion, the Judges publish a notice in the **Federal Register** seeking responses to the motion for partial distribution to ascertain whether any claimant entitled to receive the subject royalties has a reasonable objection to the requested distribution. Accordingly, this Notice seeks comments from interested claimants on whether any reasonable objection exists that would preclude the distributions to NPR or Music Claimants described in this Notice. Parties making objection to the partial distribution must advise the Judges of the existence and details of all objections by the end of the comment period. The Judges will not consider any objections with respect to the partial distribution motion that come to their attention after the close of the comment period.

The Judges have caused the joint motion regarding NPR and the joint motion regarding Music Claimants to be posted on the Copyright Royalty Board Web site at *http://www.loc.gov/crb.*

How To Submit Comments

Interested members of the public must submit comments to only one of the following addresses. If not commenting by email or online, commenters must submit an original of their comments, five paper copies, and an electronic version on a CD.

Email: crb@loc.gov; or

Online: www.regulations.gov; or

U.S. mail: Copyright Royalty Board, P.O. Box 70977, Washington, DC 20024–0977; or

Overnight service (only USPS Express Mail is acceptable): Copyright Royalty Board, P.O. Box 70977, Washington, DC 20024–0977; or

Commercial courier: Address package to: Copyright Royalty Board, Library of Congress, James Madison Memorial Building, LM–403, 101 Independence Avenue SE., Washington, DC 20559–6000. Deliver to: Congressional Courier Acceptance Site, 2nd Street NE. and D Street NE., Washington, DC; or

Hand delivery: Library of Congress, James Madison Memorial Building, LM–401, 101 Independence Avenue SE., Washington, DC 20559–6000.

Dated: January 17, 2017.

Suzanne M. Barnett,

Chief U.S. Copyright Royalty Judge.

[FR Doc. 2017–01358 Filed 1–19–17; 8:45 am]

BILLING CODE 1410–72–P

[4] The amounts Music Claimants have received in partial distribution for each of the 2010–13 Funds are available at *http://www.copyright.gov/licensing/distribution-fund.pdf.*

[5] The requested distributions represent partial distributions of the 2010–13 Funds, but not partial distributions to NPR or the Music Claimants, whose claims are satisfied by the requested distributions.

LIBRARY OF CONGRESS

Copyright Royalty Board

[Docket No. 17–0005–CRB–AU]

Notice of Intent To Audit

AGENCY: Copyright Royalty Board, Library of Congress.

ACTION: Public notice.

SUMMARY: The Copyright Royalty Judges announce receipt of a notice of intent to audit the 2013, 2014, and 2015 statements of account of Music Choice concerning the royalty payments its Preexisting Subscription Service and Business Establishments Service made pursuant to two statutory licenses.

FOR FURTHER INFORMATION CONTACT: Anita Brown, Program Specialist, by telephone at (202) 707–7658 or by email at *crb@loc.gov.*

SUMMARY INFORMATION: The Copyright Act, title 17 of the United States Code, grants to copyright owners of sound recordings the exclusive right to publicly perform sound recordings by means of certain digital audio transmissions, subject to limitations. Specifically, the right is limited by the statutory license in section 114 which allows nonexempt noninteractive digital subscription services, eligible nonsubscription services, and preexisting satellite digital audio radio services to perform publicly sound recordings by means of digital audio transmissions. 17 U.S.C. 114(f).

In addition, a statutory license in section 112 allows a service to make necessary ephemeral reproductions to facilitate the digital transmission of the sound recording, including for transmissions to business establishments.[1] 17 U.S.C. 112(e).

Licensees may operate under these licenses provided they pay the royalty fees and comply with the terms set by the Copyright Royalty Judges. The rates and terms for the section 112 and 114 licenses are set forth in 37 CFR parts 380 and 382–84.

As part of the terms set for these licenses, the Judges designated SoundExchange, Inc. as the Collective, *i.e.,* the organization charged with collecting the royalty payments and statements of account submitted by licensees, including those that operate preexisting subscription services and those that make ephemeral copies for transmission to business establishments. The Collective is also charged with distributing the royalties to the copyright owners and performers

[1] Subject to the limitations set forth in section 114(d)(1)(C)(iv).

entitled to receive them. *See* 37 CFR 382.2, 384.4(b).

As the designated Collective, SoundExchange may, once during a calendar year, conduct an audit of a licensee for any or all of the prior three years in order to verify royalty payments. SoundExchange must first file with the Judges a notice of intent to audit a licensee and deliver the notice to the licensee. *See* 37 CFR 382.6, 384.6.

On December 22, 2016, SoundExchange filed with the Judges a notice of intent to audit Music Choice's Preexisting Subscription Service and Business Establishment Service for the years 2013, 2014, and 2015. The Judges must publish notice in the **Federal Register** within 30 days of receipt of a notice announcing the Collective's intent to conduct an audit. *See* 37 CFR 382.6(c), 384.6(c). Today's notice fulfills this requirement with respect to SoundExchange's December 22, 2016, notice of intent to audit.

Dated: January 13, 2017.

Suzanne M. Barnett,

Chief Copyright Royalty Judge.

[FR Doc. 2017–01318 Filed 1–19–17; 8:45 am]

BILLING CODE 1410–72–P

LIBRARY OF CONGRESS

Copyright Royalty Board

[Consolidated Docket No. 14–CRB–0011–SD (2010–13)]

Distribution of 2010–13 Satellite Royalty Funds

AGENCY: Copyright Royalty Board, Library of Congress.

ACTION: Notice requesting comments.

SUMMARY: The Copyright Royalty Judges announce settlement of controversies and a request for partial distribution of satellite television retransmission royalties claimed by Music Claimants. Music Claimants include Broadcast Music, Inc. (BMI) and the American Society of Composers, Authors, and Publishers (ASCAP), as well as SESAC, Inc.

DATES: Comments are due on or before February 22, 2017.

ADDRESSES: Submit electronic comments via email to *crb@loc.gov.* Those who choose not to submit comments electronically should see ''How to Submit Comments'' in the Supplementary Information section below for physical addresses and further instructions. This notice and request is also posted on the agency's Web site (*www.loc.gov/crb*) and on *Regulations.gov* (*www.regulations.gov*).

FOR FURTHER INFORMATION CONTACT: Kimberly Whittle, Attorney-Advisor, by telephone at (202) 707–7658 or email at *crb@loc.gov.*

SUPPLEMENTARY INFORMATION: Each year satellite systems must submit royalty payments to the Register of Copyrights as required by the statutory license set forth in section 119 of the Copyright Act for the retransmission to satellite subscribers of over-the-air television and radio broadcast signals. *See* 17 U.S.C. 119(b). The Copyright Royalty Judges (Judges) oversee distribution of royalties to copyright owners whose works were included in a qualifying retransmission and who filed a timely claim for royalties. Allocation of the royalties collected occurs in one of two ways. In the first instance, the Judges may authorize distribution in accordance with a negotiated settlement among all claiming parties. 17 U.S.C. 111(d)(4)(A). If all claimants do not reach agreement with respect to the royalties, the Judges must conduct a proceeding to determine the distribution of any royalties that remain in controversy. 17 U.S.C. 111(d)(4)(B). Alternatively, the Judges may, on motion of claimants and on notice to all interested parties, authorize a partial distribution of royalties, reserving on deposit sufficient funds to resolve identified disputes. 17 U.S.C. 111(d)(4)(C), 801(b)(3)(C).

On December 15, 2016, the Judges received a motion (Joint Motion) seeking distribution by stipulation to the Music Claimants from the satellite royalty funds deposited for royalty years 2010 through 2013, inclusive (the Funds). All participants [1] in this consolidated proceeding (Moving Parties) endorsed the Joint Motion. In the Joint Motion, the Moving Parties notified the Judges that they stipulate and agree that Music Claimants shall receive a share of each of the 2010–13 Funds as follows (the Music Claimants' Share):

Year	Percentage
2010	3.50
2011	3.50
2012	3.50
2013	3.50

The Moving Parties stipulate that the value of the Music Claimants' Share is as listed above, minus the dollar value of partial distributions of the 2010–13 Funds that Music Claimants have received to date.[2]

The Moving Parties represent that there are no outstanding inter- or intra-category controversies regarding the claims in the Music Claimant category. The Parties further stipulate and agree that these sums shall not be subject to repayment once distributed, that Music Claimants need not participate further in royalty distribution proceedings related to the 2010–13 Funds, and that no additional sums shall be distributed to Music Claimants in the future with respect to the 2010–13 Funds, provided that Music Claimants shall be entitled to receive the Music Claimants' Share of any additional royalties deposited into any of the 2010–13 Funds due to any audit of any cable system operator's Statement of Account pursuant to 37 CFR 201.16 that Music Claimants joined as participating copyright owners.

The Moving Parties' further stipulate that the terms described in the Joint Motion represent a compromise and settlement and apply to the 2010, 2011, 2012, and 2013 Cable Royalty Distribution Proceedings only; no party accepts the requested allocation as precedent and no party admits to any principle underlying the Music Claimants' Share.

The Moving Parties therefore request that the Judges order a partial distribution of royalties to Music Claimants in the agreed amounts pursuant to section 801(b)(3)(C) of the Copyright Act.[3] 17 U.S.C. 801(b)(3)(C). That section requires that, before ruling on the motion, the Judges publish a notice in the **Federal Register** seeking responses to the motion for partial distribution to ascertain whether any claimant entitled to receive the subject royalties has a reasonable objection to the requested distribution. Accordingly, this Notice seeks comments from interested claimants on whether any reasonable objection exists that would preclude the distributions to Music

[1] Participants are: Motion Picture Association of America, Joint Sports Claimants, National Association of Broadcasters and the Commercial Television Claimants, Music Claimants, Canadian Claimants Group, Settling Devotional Claimants, National Public Radio, Public Broadcasting Service and the Public Television Claimants, and Multigroup Claimants.

[2] The amounts Music Claimants have received in partial distribution from each year's portion of the 2010–13 Funds were calculated pursuant to confidential settlement agreements among the parties and were received from monies distributed by the Office of the Commissioner of Baseball as Common Agent for the parties. The amount of these partial distributions constitutes Restricted information pursuant to the Protective Order in this proceeding; the amounts are redacted from the public version of the Joint Motion and are disclosed only to the parties in accordance with the terms of the settlement agreements.

[3] The requested distributions represent partial distributions of the 2010–13 Funds, but constitute final distributions to the Music Claimants, *except* that Music claimants may share in the same proportion in the event a future audit results in additional deposits into any fund at issue in this proceeding.

Claimants described in this Notice. Parties making objection to the partial distribution must advise the Judges of the existence and details of all objections by the end of the comment period. The Judges will not consider any objections with respect to the partial distribution motion that come to their attention after the close of the comment period.

The Judges have caused the joint motion (redacted public version) to be posted on the Copyright Royalty Board Web site at *http://www.loc.gov/crb.*

How To Submit Comments

Interested members of the public must submit comments to only one of the following addresses. If not commenting by email or online, commenters must submit an original of their comments, five paper copies, and an electronic version on a CD.

Email: crb@loc.gov; or

Online: www.regulations.gov; or

U.S. mail: Copyright Royalty Board, P.O. Box 70977, Washington, DC 20024–0977; or

Overnight service (only USPS Express Mail is acceptable): Copyright Royalty Board, P.O. Box 70977, Washington, DC 20024–0977; or

Commercial courier: Address package to: Copyright Royalty Board, Library of Congress, James Madison Memorial Building, LM–403, 101 Independence Avenue SE., Washington, DC 20559–6000. Deliver to: Congressional Courier Acceptance Site, 2nd Street NE and D Street NE., Washington, DC; or

Hand delivery: Library of Congress, James Madison Memorial Building, LM–401, 101 Independence Avenue SE., Washington, DC 20559–6000.

Dated: January 17, 2017.

Suzanne M. Barnett,

Chief U.S. Copyright Royalty Judge.

[FR Doc. 2017–01357 Filed 1–19–17; 8:45 am]

BILLING CODE 1410–72–P

NATIONAL SCIENCE FOUNDATION

Notice of Permits Issued Under the Antarctic Conservation Act of 1978

AGENCY: National Science Foundation.

ACTION: Notice of permits issued under the Antarctic Conservation of 1978, Public Law 95–541.

SUMMARY: The National Science Foundation (NSF) is required to publish notice of permits issued under the Antarctic Conservation Act of 1978. This is the required notice.

FOR FURTHER INFORMATION CONTACT: Nature McGinn, ACA Permit Officer, Office of Polar Programs, Rm. 755, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230. Or by email: *ACApermits@nsf.gov.*

SUPPLEMENTARY INFORMATION: On December 15, 2016, the National Science Foundation published a notice in the **Federal Register** of a permit application received. The permit was issued on January 17, 2017 to: Robert B. Dunbar, Permit No. 2017–038.

Nadene G. Kennedy,

Polar Coordination Specialist, Office of Polar Programs.

[FR Doc. 2017–01355 Filed 1–19–17; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Sunshine Act Meeting; National Science Board

The National Science Board's Executive Committee, 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 of the scheduling of a teleconference for the transaction of National Science Board business, as follows:

DATE & TIME: Wednesday, January 25, 2017 from 3:00–4:00 p.m. EST.

SUBJECT MATTER: (1) Committee Chair's opening remarks; (2) Approval of Executive Committee minutes of October 20, 2016; and (3) Discuss issues and topics for an agenda of the NSB meeting scheduled for February 21–22, 2017.

STATUS: Open.

LOCATION: This meeting will be held by teleconference at the National Science Foundation, 4201 Wilson Blvd., Arlington, VA 22230. A public listening line will be available. Members of the public must contact the Board Office (call 703–292–7000 or send an email message to *nationalsciencebrd@nsf.gov*) at least 24 hours prior to the teleconference for the public listening number.

UPDATES & POINT OF CONTACT: Please refer to the National Science Board Web site *www.nsf.gov/nsb* for additional information. Meeting information and updates (time, place, subject matter or status of meeting) may be found at *http://www.nsf.gov/nsb/notices/.* Point of contact for this meeting is: James Hamos, 4201 Wilson Blvd., Arlington, VA 22230. Telephone: (703) 292–8000.

Chris Blair,

Executive Assistant to the NSB Office.

[FR Doc. 2017–01553 Filed 1–18–17; 4:15 pm]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–412; NRC–2016–0277]

Beaver Valley Power Station, Unit 2; Consideration of Approval of Transfer of License and Conforming Amendment

AGENCY: Nuclear Regulatory Commission.

ACTION: Application for direct transfer of license; opportunity to comment, request a hearing, and petition for leave to intervene.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) received and is considering approval of an application filed by FirstEnergy Nuclear Operating Company (FENOC), acting as agent for and on behalf of FirstEnergy Nuclear Generation, LLC (FENGen), the Toledo Edison Company (TE), and the Ohio Edison Company (OE) on June 24, 2016, as supplemented on September 13, 2016, and December 15, 2016. The application seeks NRC approval of the direct transfer of License No. NPF–73 for the Beaver Valley Power Station, Unit 2, to the extent currently held by TE and OE, to FENGen. The NRC is also considering amending the renewed facility operating license for administrative purposes to reflect the proposed transfer.

DATES: Comments must be filed by February 22, 2017. A request for a hearing must be filed by February 13, 2017.

ADDRESSES: You may submit comments by any of the following methods (unless this document describes a different method for submitting comments on a specific subject):

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2016–0277. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Email comments to: Hearingdocket@nrc.gov.* If you do not receive an automatic email reply confirming receipt, then contact us at 301–415–1677.

• *Fax comments to:* Secretary, U.S. Nuclear Regulatory Commission at 301–415–1101.

• *Mail comments to:* Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Rulemakings and Adjudications Staff.

• *Hand deliver comments to:* 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. (Eastern Time) Federal workdays; telephone: 301–415–1677.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Taylor Lamb, Office of Nuclear Reactor Regulation, telephone: 301–415–7128, email: *Taylor.Lamb@nrc.gov;* U.S. Nuclear Regulatory Commission, Washington DC 20555–0001.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2016–0277 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

• *Federal rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2016–0277.

• *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*ADAMS Public Documents*'' and then select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The Beaver Valley Power Station, Unit 2, Application for Order Consenting to Transfer of Licenses and Approving Conforming License Amendments is available in ADAMS under Accession Nos. ML16182A155, ML16257A235, and ML16350A077.

• *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC–2016–0277 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *http://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Introduction

The NRC is considering the issuance of an order under § 50.80 of title 10 of the *Code of Federal Regulations* (10 CFR) approving the direct transfer of control of Beaver Valley Power Station, Unit 2, License No. NPF–73, to the extent currently held by TE and OE. The transfer would be to FENGen. The NRC is also considering amending the renewed facility operating licenses for administrative purposes to reflect the proposed transfer.

Following approval of the proposed direct transfer of control of the license, FENGen would acquire the 18.26 percent of TE's leased interest in the facility, and the 21.66 percent of OE's leased interest in the facility. FENGen currently retains 60.08 percent ownership control of the facility.

No physical changes to Beaver Valley Power Station, Unit 2, or operational changes are being proposed in the application.

The NRC's regulations at 10 CFR 50.80 state that no license, or any right thereunder, shall be transferred, directly or indirectly, through transfer of control of the license, unless the Commission gives its consent in writing. The Commission will approve an application for the direct transfer of a license, if the Commission determines that the proposed transferee is qualified to hold the license, and that the transfer is otherwise consistent with applicable provisions of law, regulations, and orders issued by the Commission.

Before issuance of the proposed conforming license amendment, the Commission will have made findings required by the Atomic Energy Act of 1954, as amended (the Act), and the Commission's regulations.

As provided in 10 CFR 2.1315, unless otherwise determined by the Commission with regard to a specific application, the Commission has determined that any amendment to the license of a utilization facility, which does no more than conform the license to reflect the transfer action involves no significant hazards consideration. No contrary determination has been made with respect to this specific license amendment application. In light of the generic determination reflected in 10 CFR 2.1315, no public comments with respect to significant hazards considerations are being solicited, notwithstanding the general comment procedures contained in 10 CFR 50.91.

III. Opportunity To Comment

Within 30 days from the date of publication of this notice, persons may submit written comments regarding the 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 as described in the **ADDRESSES** section of this document.

IV. Opportunity To Request a Hearing and Petition for Leave to Intervene

Within 20 days after the date of publication of this notice, any persons (petitioner) whose interest may be affected by this action may file a request for a hearing and petition for leave to intervene (petition) with respect to the action. Petitions shall be filed in accordance with the Commission's ''Agency Rules of Practice and Procedure'' in 10 CFR part 2. Interested persons should consult a current copy of 10 CFR 2.309. The NRC's regulations are accessible electronically from the NRC Library on the NRC's Web site at *http://www.nrc.gov/reading-rm/doc-collections/cfr/.* Alternatively, a copy of the regulations is available at the NRC's Public Document Room, located at One White Flint North, Room O1–F21, 11555 Rockville Pike (first floor), Rockville, Maryland 20852. If a petition is filed, the Commission or a presiding officer will rule on the petition and, if appropriate, a notice of a hearing will be issued.

Any person who desires access to proprietary, confidential commercial information that has been redacted from the application should contact the applicant by telephoning David W. Jenkins, Esq., FirstEnergy Corp., at 330–384–5037, for the purpose of negotiating a confidentiality agreement or a

proposed protective order with the applicant. If no agreement can be reached, persons who desire access to this information may file a motion with the Secretary and addressed to the Commission that requests the issuance of a protective order.

As required by 10 CFR 2.309(d) the petition should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements for standing: (1) The name, address, and telephone number of the petitioner; (2) the nature of the petitioner's right under the Act to be made a party to the proceeding; (3) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the petitioner's interest. In accordance with 10 CFR 2.309(f), the petition must also set forth the specific contentions which the petitioner seeks to have litigated in the proceeding. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner must provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to the specific sources and documents on which the petitioner intends to rely to support its position on the issue. The petition must include sufficient information to show that a genuine dispute exists with the applicant or licensee on a material issue of law or fact. Contentions must be limited to matters within the scope of the proceeding. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to satisfy the requirements at 10 CFR 2.309(f) with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene. Parties have the opportunity to participate fully in the conduct of the hearing with respect to resolution of that party's admitted contentions, including the opportunity to present evidence, consistent with the NRC's regulations, policies, and procedures.

Petitions must be filed no later than 20 days from the date of publication of this notice. Petitions and motions for leave to file new or amended contentions that are filed after the deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the three factors in 10 CFR 2.309(c)(1)(i) through (iii). The petition must be filed in accordance with the filing instructions in the ''Electronic Submissions (E-Filing)'' section of this document.

If a hearing is requested, and the Commission has not made a final determination on the issue of no significant hazards consideration, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to establish when the hearing is held. If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing would take place after issuance of the amendment. If the final determination is that the amendment request involves a significant hazards consideration, then any hearing held would take place before the issuance of the amendment unless the Commission finds an imminent danger to the health or safety of the public, in which case it will issue an appropriate order or rule under 10 CFR part 2.

A State, local governmental body, Federally-recognized Indian Tribe, or agency thereof, may submit a petition to the Commission to participate as a party under 10 CFR 2.309(h)(1). The petition should state the nature and extent of the petitioner's interest in the proceeding. The petition should be submitted to the Commission by February 13, 2017. The petition must be filed in accordance with the filing instructions in the ''Electronic Submissions (E-Filing)'' section of this document, and should meet the requirements for petitions set forth in this section, except that under 10 CFR 2.309(h)(2) a State, local governmental body, or Federally recognized Indian Tribe, or agency thereof does not need to address the standing requirements in 10 CFR 2.309(d) if the facility is located within its boundaries. Alternatively, a State, local governmental body, Federally-recognized Indian Tribe, or agency thereof may participate as a non-party under 10 CFR 2.315(c).

If a hearing is granted, any person who is not a party to the proceeding and is not affiliated with or represented by a party may, at the discretion of the presiding officer, be permitted to make a limited appearance pursuant to the provisions of 10 CFR 2.315(a). A person making a limited appearance may make an oral or written statement of his or her position on the issues but may not otherwise participate in the proceeding. A limited appearance may be made at any session of the hearing or at any prehearing conference, subject to the limits and conditions as may be imposed by the presiding officer. Details regarding the opportunity to make a limited appearance will be provided by the presiding officer if such sessions are scheduled.

V. Electronic Submissions (E-Filing)

All documents filed in NRC adjudicatory proceedings, including a request for hearing and petition for leave to intervene (petition), 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 that request to participate under 10 CFR 2.315(c), must be filed in accordance with the NRC's E-Filing rule (72 FR 49139; August 28, 2007, as amended at 77 FR 46562; August 3, 2012). The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media. Detailed guidance on making electronic submissions may be found in the Guidance for Electronic Submissions to the NRC and on the NRC Web site at *http://www.nrc.gov/site-help/e-submittals.html.* Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at *hearing.docket@nrc.gov,* or by telephone at 301–415–1677, to (1) request a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign submissions and access the E-Filing system for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a petition or other adjudicatory document (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public Web site at *http://*

www.nrc.gov/site-help/e-submittals/getting-started.html. Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit adjudicatory documents. Submissions must be in Portable Document Format (PDF). Additional guidance on PDF submissions is available on the NRC's public Web site at *http://www.nrc.gov/site-help/electronic-sub-ref-mat.html.* A filing is considered complete at the time the document is submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing 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 email notice confirming receipt of the document. The E-Filing system also distributes an email notice that provides access to the document to the NRC's 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 document on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before adjudicatory documents are filed so that they can obtain access to the documents via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC's Electronic Filing Help Desk through the ''Contact Us'' link located on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html,* by email to *MSHD.Resource@nrc.gov,* or by a toll-free call at 1–866–672–7640. The NRC Electronic Filing Help Desk is available between 9 a.m. and 6 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing stating why there is good cause for not filing electronically and 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, 11555 Rockville Pike, Rockville, Maryland 20852, Attention: Rulemaking and Adjudications Staff. Participants filing adjudicatory documents 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. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket which is available to the public at *https://adams.nrc.gov/ehd,* unless excluded pursuant to an order of the Commission or the presiding officer. If you do not have an NRC-issued digital ID certificate as described above, click cancel when the link requests certificates and you will be automatically directed to the NRC's electronic hearing dockets where you will be able to access any publicly available documents in a particular hearing docket. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or personal phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. For example, in some instances, individuals provide home addresses in order to demonstrate proximity to a facility or site. 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 submission.

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.

For further details with respect to this application, see the application dated June 24, 2016, as supplemented on September 13, 2016, and December 15, 2016.

Dated at Rockville, Maryland, this 17th day of January, 2017.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,

Secretary of the Commission.

[FR Doc. 2017–01317 Filed 1–19–17; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2017–77 and CP2017–104; MC2017–78 and CP2017–105]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing recent Postal Service filings for the Commission's consideration concerning negotiated service agreements. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* January 25, 2017.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the market dominant or the competitive product list, or the modification of an existing product currently appearing on the market dominant or the competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also

establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's Web site (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3007.40.

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern market dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3010, and 39 CFR part 3020, subpart B. For request(s) that the Postal Service states concern competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s).:* MC2017–77 and CP2017–104; *Filing Title:* Request of the United States Postal Service to Add Priority Mail Contract 287 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data; *Filing Acceptance Date:* January 13, 2017; *Filing Authority:* 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.*; *Public Representative*: Kenneth R. Moeller; *Comments Due:* January 25, 2017.

2. *Docket No(s).:* MC2017–78 and CP2017–105; *Filing Title:* Request of the United States Postal Service to Add Parcel Select Contract 20 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data; *Filing Acceptance Date:* January 13, 2017; *Filing Authority:* 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.*; *Public Representative:* Kenneth R. Moeller; *Comments Due:* January 25, 2017.

This notice will be published in the **Federal Register**.

Stacy L. Ruble,

Secretary.

[FR Doc. 2017–01421 Filed 1–19–17; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL SERVICE

Product Change—Priority Mail Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Effective date:* January 23, 2017.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on January 13, 2017, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add Priority Mail Contract 287 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2017–77, CP2017–104.

Stanley F. Mires,

Attorney, Federal Compliance.

[FR Doc. 2017–01311 Filed 1–19–17; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Parcel Select Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Effective date:* January 23, 2017.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on January 13, 2017, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add Parcel Select Contract 20 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2017–78, CP2017–105.

Stanley F. Mires,

Attorney, Federal Compliance.

[FR Doc. 2017–01308 Filed 1–19–17; 8:45 am]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–79802; File No. SR–NYSEArca–2016–96]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Designation of a Longer Period for Commission Action on Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change, as Modified by Amendment No. 2 Thereto, To Amend NYSE Arca Equities Rule 8.700 and To List and Trade Shares of the Managed Emerging Markets Trust Under Proposed Amended NYSE Arca Equities Rule 8.700

January 13, 2017.

On July 1, 2016, NYSE Arca, Inc. (''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend NYSE Arca Equities Rule 8.700 and to list and trade shares of the Managed Emerging Markets Trust under proposed amended NYSE Arca Equities Rule 8.700. The proposed rule change was published for comment in the **Federal Register** on July 21, 2016.[3] On August 30, 2016, pursuant to Section 19(b)(2) of the Act,[4] the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.[5] On October 18, 2016, the Commission instituted proceedings to determine whether to approve or disapprove the proposed rule change.[6] On November 4, 2016, the Exchange filed Amendment No. 1 to the proposed rule change, which replaced and superseded the original filing in its entirety.[7] On January 9, 2017, the Exchange filed Amendment No. 2 to the proposed rule change, which again replaced and superseded the original filing in its entirety.[8] The Commission

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 78345 (July 15, 2016), 81 FR 47447.

[4] 15 U.S.C. 78s(b)(2).

[5] *See* Securities Exchange Act Release No. 78727, 81 FR 61268 (September 6, 2016).

[6] *See* Securities Exchange Act Release No. 79111, 81 FR 73179 (October 24, 2016).

[7] Amendment No. 1 is available at: *https://www.sec.gov/comments/sr-nysearca-2016-96/nysearca201696-1.pdf.*

[8] Amendment No. 2 is available at: *https://www.sec.gov/comments/sr-nysearca-2016-96/nysearca201696-1473646-130472.pdf.*

received no comments on the proposed rule change.

Section 19(b)(2) of the Act[9] provides that, after initiating disapproval proceedings, the Commission shall issue an order approving or disapproving the proposed rule change not later than 180 days after the date of publication of notice of filing of the proposed rule change. The Commission may extend the period for issuing an order approving or disapproving the proposed rule change, however, by not more than 60 days if the Commission determines that a longer period is appropriate and publishes the reasons for such determination. The proposed rule change was published for notice and comment in the **Federal Register** on July 21, 2016. January 17, 2017 is 180 days from that date, and March 18, 2017 is 240 days from that date.

The Commission finds it appropriate to designate a longer period within which to issue an order approving or disapproving the proposed rule change so that it has sufficient time to consider this proposed rule change. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[10] designates March 18, 2017 as the date by which the Commission shall either approve or disapprove the proposed rule change (File No. SR–NYSEArca–2016–96), as modified by Amendment No. 2.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–01301 Filed 1–19–17; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–79793; File No. SR–NYSEArca–2016–177]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing of Proposed Rule Change Relating to the Listing and Trading of Shares of the USCF Canadian Crude Oil Index Fund Under NYSE Arca Equities Rule 8.200

January 13, 2017.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on December 30, 2016, NYSE Arca, Inc. (''Exchange'' or ''NYSE Arca'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to list and trade the shares of the following under NYSE Arca Equities Rule 8.200, Commentary .02 (''Trust Issued Receipts''): USCF Canadian Crude Oil Index Fund. The proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to list and trade shares (''Shares'') of the following under NYSE Arca Equities Rule 8.200, Commentary .02, which governs the listing and trading of Trust Issued Receipts: USCF Canadian Crude Oil Index Fund (the ''Fund'').[4]

The Fund is a new series of the United States Commodity Index Funds Trust (the ''Trust'').[5] The Fund is a commodity pool that continuously issues common shares of beneficial interest that may be purchased and sold on the Exchange. The Trust and the Fund are managed and controlled by United States Commodity Funds LLC (''USCF'' or ''Sponsor''), which is registered as a commodity pool operator (''CPO'') with the Commodity Futures Trading Commission (''CFTC'') and is a member of the National Futures Association (''NFA''). Brown Brothers Harriman & Co., Inc. will be the administrator and custodian (''Administrator'' or ''Custodian'') for the Fund. ALPS Distributors, Inc. will be the marketing agent (''Marketing Agent'') for the Fund.

The Exchange notes that the Commission has previously approved the listing and trading of other issues of Trust Issued Receipts based on oil on the Exchange,[6] trading on the Exchange of such issues pursuant to unlisted trading privileges,[7] and listing and trading of such issues on the American Stock Exchange LLC (now, NYSE MKT, LLC).[8]

Investment Objective and Principal Investments of the Fund

According to the Registration Statement, the investment objective of the Fund is for the daily changes in percentage terms of its Shares' per Share NAV to reflect the daily changes in percentage terms of the Canadian Crude Excess Return Index (the ''CCIER'' or ''Index''), plus interest income from the Fund's short-term fixed income holdings, less the Fund's expenses.

The CCIER is owned and maintained by Auspice Capital Advisors Ltd. (''Auspice'') and is designed to measure the performance of the Canadian crude oil market. It is calculated and tracked daily and reported each trading day via major market data vendors.

The Fund's investment strategy is designed to provide investors with a means of investing indirectly in Canadian crude oil and to hedge against movements in the spot price of Canadian crude oil. Specifically, the CCIER reflects the returns that an investor would expect to receive from

[9] 15 U.S.C. 78s(b)(2).

[10] *Id.*

[11] 17 CFR 200.30–3(a)(57).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] Commentary .02 to NYSE Arca Equities Rule 8.200 applies to Trust Issued Receipts that invest in ''Financial Instruments.'' The term ''Financial Instruments,'' as defined in Commentary .02(b)(4) to NYSE Arca Equities Rule 8.200, means any combination of investments, including cash; securities; options on securities and indices; futures contracts; options on futures contracts; forward contracts; equity caps, collars, and floors; and swap agreements.

[5] The Trust is registered under the Securities Act of 1933. On June 16, 2016, the Trust filed with the Commission a registration statement on Form S–1 under the Securities Act of 1933 (15 U.S.C. 77a) (''Securities Act'') relating to the Fund (File No. 333–212089) (''Registration Statement''). The description of the operation of the Trust and the Fund herein is based, in part, on the Registration Statement.

[6] *See, e.g.,* Securities Exchange Act Release No. 58457 (September 3, 2008), 73 FR 52711 (September 10, 2008) (SR–NYSEArca–2008–91).

[7] *See, e.g.,* Securities Exchange Act Release No. 58163 (July 15, 2008), 73 FR 42391 (July 21, 2008) (SR–NYSEArca–2008–73).

[8] *See, e.g.,* Securities Exchange Act Release No. 58161 (July 15, 2008), 73 FR 42380 (July 21, 2008) (SR–Amex–2008–39).

holding and rolling the futures contracts that comprise the Index.

The CCIER targets an exposure that represents an approximately 3 month rolling position in the following nearby futures contracts: (i) The ICE Crude Diff—TMX WCS 1B Index Future (ICE symbol: TDX) (the ''WCS Future''); and (ii) the ICE WTI Crude Future (ICE symbol: T) (the ''WTI Future''). The WCS Futures and WTI Futures that comprise the CCIER are referred to herein as ''Benchmark Component Futures Contracts''.

The WCS Future is a monthly cash settled future based on the TMX WCS (Western Canadian Select) Daily Weighted Average Price Index (''TMX WCS 1b Index'') traded on ICE Futures Europe. The TMX WCS 1b Index is expressed as a differential to the NYMEX WTI 1st Line Future (Calendar Month Average).

The WTI Future is the ICE West Texas Intermediate (WTI) Light Sweet Crude Oil Futures Contract traded on ICE Futures Europe.[9]

The Fund will seek to achieve its investment objective by first entering into cash-settled over-the-counter (''OTC'') total return swap and forward transactions intended to replicate the return of the CCIER (''OTC Derivatives Contracts'', as described further below) and, second, to the extent market conditions are more favorable for such futures as compared to OTC Derivatives Contracts, investing in the Benchmark Component Futures Contracts that underlie the CCIER. It will support these investments by holding the amounts of its margin, collateral and other requirements relating to these obligations in short-term obligations of the United States of two years or less (''Treasuries''), cash and cash equivalents.

Third, if constrained by regulatory requirements or in view of market conditions or if one or more of the other Benchmark Component Futures Contracts is not available, the Fund may next invest in exchange traded futures contracts that are economically identical or substantially similar to the Benchmark Component Futures Contracts, *e.g.,* futures contracts that are based on changes in the price of WTI oil traded on the Chicago Mercantile Exchange (''CME'').

When, in view of regulatory requirements and market conditions, the Fund has invested to the fullest extent possible in the OTC Derivatives Contracts and exchange-traded futures contracts, the Fund may then invest in other OTC derivative contracts and/or other contracts and instruments based on the Benchmark Component Futures Contracts or on the price of the crude oil underlying the Benchmark Component Futures Contracts, such as cash-settled options, cleared swap contracts and swap contracts other than cleared swap contracts.[10]

Market conditions that USCF currently anticipates could cause the Fund to invest in Other Crude Oil-Related Investments include those allowing the Fund to obtain greater liquidity, to execute transactions with more favorable pricing, or if the Fund or USCF exceeds position limits or accountability levels established by an exchange.

The Fund will seek to achieve its investment objective by investing so that the average daily percentage change in the Fund's NAV for any period of 30 successive valuation days will be within plus/minus 10 percent (10%) of the average daily percentage change in the CCIER over the same period. The Sponsor believes that market arbitrage opportunities will cause daily changes in the Fund's Share price on the NYSE Arca on a percentage basis to closely track the daily changes in the Fund's per Share NAV on a percentage basis. The Sponsor also believes that the net effect of this expected relationship and the expected relationship described above between the Fund's per Share NAV and the CCIER will be that the daily changes in the price of the Fund's Shares on the NYSE Arca on a percentage basis will closely track the daily changes in the CCIER on a percentage basis, plus interest income from the Fund's short-term fixed income holdings, less the Fund's expenses.[11]

The Fund will not seek to achieve its stated investment objective over a period of time greater than one day. This is because natural market forces called contango and backwardation can impact the total return on an investment in the Fund's Shares relative to a hypothetical direct investment in crude oil commodities and, in the future, it is likely that the relationship between the market price of the Fund's Shares and changes in the spot prices of the underlying commodities will continue to be so impacted by contango and backwardation.

OTC Derivatives Contracts

According to the Registration Statement, the Fund will primarily invest in OTC Derivatives Contracts that are based on Benchmark Component Futures Contracts and, in the opinion of the Sponsor, are traded in sufficient volume to permit the ready taking and liquidation of positions. Such OTC Derivatives Contracts, as well as all other Other Crude Oil-Related Investments that are OTC derivatives, will be ''swaps'' for purposes of Title VII of the Dodd-Frank Wall Street Reform and Consumer Protection Act that fall within the jurisdiction of the Commodity Futures Trading Commission.

The OTC Derivatives Contracts will be entered between two parties, outside of public exchanges, in private contracts. Unlike the exchange-traded Benchmark Component Futures Contracts, each party to an OTC Derivatives Contract bears credit risk with respect to the other party. To reduce such credit risk, the Fund will generally enter into an agreement with each counterparty based on the Master Agreement published by the International Swaps and Derivatives Association, Inc. (''ISDA'') that provides for the netting of overall exposure between counterparties.[12] In accordance with the terms and conditions of the Fund's ISDA Master Agreement, pursuant to which the Fund's OTC Derivatives Contracts will be entered into, the Fund will be entitled to increase or decrease its notional exposure to the CCIER from time to time, to among other things, manage Share purchases and reinvestment of distributions, Fund Share redemptions and market repurchases of Shares, and

[9] ICE Futures Europe, NYMEX and other futures exchanges on which the Fund may trade listed futures contracts are referred to collectively as ''Futures Exchanges''.

[10] The Benchmark Component Futures Contracts, other exchange-traded futures contracts that are economically identical or substantially similar to the Benchmark Component Futures Contracts and other contracts and instruments based on the Benchmark Component Futures Contracts, are referred to collectively as ''Other Crude Oil-Related Investments'', and together with OTC Derivatives Contracts, ''Crude Oil Interests''.

[11] While the Fund is composed of, and is therefore a measure of, the prices of the OTC Derivatives Contracts based upon futures comprising the CCIER, there is expected to be a reasonable degree of correlation between the CCIER and the cash or spot prices of the commodities underlying the Benchmark Component Futures Contracts; but the Fund's investment objective is not for its NAV or market price of Shares to equal, in dollar terms, the spot prices of the commodities underlying the Benchmark Component Futures Contracts or the prices of any particular group of futures contracts.

[12] The ISDA Master Agreement allows for parties to calculate and settle their obligations under the agreement on a ''net basis'' with a single payment. Consequently, the Sponsor's current obligations (or rights) under a swap or forward agreement are generally only equal to the net amount to be paid or received under the agreement based on the relative values of such obligations (or rights). In addition, in connection with the Master Agreements, the Sponsor will enter into ISDA Credit Support Annexes (''CSAs'') with its counterparties to mitigate counterparty credit exposure.

meet other liquidity needs. Reducing notional exposure may be achieved through different methods, including the use of offsetting forwards and partial terminations of OTC Derivatives Contracts.

The Sponsor will assess or review, as appropriate, the creditworthiness of each potential or existing counterparty to an OTC Derivatives Contract pursuant to guidelines approved by the Sponsor's board. In respect of the OTC Derivatives Contracts, the Fund will have the ability to replace a counterparty or engage additional counterparties at any time.

The daily marked-to-market value of an OTC Derivatives Contract will be based upon the performance of a notional investment in the CCIER. In turn, the performance of the CCIER will be based upon the performance of the underlying Benchmark Component Futures Contracts. Under the CSAs, the parties will be required to determine the mark-to-market value of the OTC Derivative Contract(s) on a daily basis. Subject to a minimum transfer amount, the party that is ''out of the money'' would transfer collateral in the form of cash or U.S. Treasuries to its counterparty to cover the exposure under the OTC Derivative Contract.

The Fund may also enter into multiple OTC Derivatives Contracts for the purpose of achieving its investment objective. If an OTC Derivatives Contract is terminated, the Fund may either pursue the same or other alternative investment strategies with an acceptable counterparty, or make direct investments in the Benchmark Component Futures Contracts or other investments that provide a similar return to investing in the Benchmark Component Futures Contracts.

The Fund may also enter into certain transactions where an OTC component is exchanged for a corresponding futures contract (an ''Exchange for Related Position'' or ''EFRP'' transaction).[13] The Fund may also employ spreads or straddles in its trading to mitigate the differences in its investment portfolio and its goal of tracking the price of the Benchmark Component Futures Contracts.[14]

Creation and Redemption of Shares

According to the Registration Statement, the Fund will create and redeem Shares from time to time, in one or more ''Creation Baskets'' or ''Redemption Baskets''. The creation and redemption of baskets will only be made in exchange for delivery to the Fund or the distribution by the Fund of the amount of Treasuries and/or cash represented by the baskets being created or redeemed, the amount of which will be equal to the combined NAV of the number of Shares included in the baskets being created or redeemed determined as of 4:00 p.m. Eastern Time (''E.T.'') on the day the order to create or redeem baskets is properly received.

''Authorized Participants'' are the only persons that may place orders to create and redeem baskets. Authorized Participants must be (1) registered broker dealers or other securities market participants, such as banks and other financial institutions, that are not required to register as broker-dealers to engage in securities transactions described below, and (2) Depository Trust and Clearing Participants.

On any business day, an Authorized Participant may place an order with the Marketing Agent to create one or more baskets. By placing a purchase order, an Authorized Participant agrees to deposit Treasuries, cash or a combination of Treasuries and cash with the Trust.

The total deposit required to create each basket (''Creation Basket Deposit'') is the amount of Treasuries and/or cash that is in the same proportion to the total assets of the Fund (net of estimated accrued but unpaid fees, expenses and other liabilities) on the purchase order date as the number of Shares to be created under the purchase order is in proportion to the total number of Shares outstanding on the purchase order date. The amount of cash deposit required is the difference between the aggregate market value of the Treasuries required to be included in a Creation Basket Deposit as of 4:00 p.m. E.T. on the date the order to purchase is properly received and the total required deposit.

The procedures by which an Authorized Participant can redeem one or more baskets mirror the procedures for the creation of baskets. On any business day, an Authorized Participant may place an order with the Marketing Agent to redeem one or more baskets. Redemption orders must be placed by 10:30 a.m. E.T. or the close of regular trading on the NYSE Arca, whichever is earlier.

The Sponsor may, in its discretion, suspend the right of redemption, or postpone the redemption settlement date, (1) for any period during which NYSE Arca or any of the futures exchanges upon which a Benchmark Component Futures Contract is traded is closed other than customary weekend or holiday closings, or trading on NYSE Arca or such futures exchanges is suspended or restricted, (2) for any period during which an emergency exists as a result of which delivery, disposal or evaluation of Treasuries is not reasonably practicable, or (3) for such other period as the Sponsor determines to be necessary for the protection of the shareholders.

Calculating Per Share NAV

According to the Registration Statement, the Fund's per Share NAV will be calculated by taking the current market value of its total assets; subtracting any liabilities; and dividing that total by the total number of outstanding Shares.

The Administrator will calculate the NAV of the Fund once each NYSE Arca trading day. The NAV for a normal trading day will be released after 4:00 p.m. E.T. Trading during the Core Trading Session on the NYSE Arca typically closes at 4:00 p.m. E.T. The Administrator will use the updated value of the CCIER calculated shortly after the determination by the relevant Futures Exchanges of the closing prices of the Benchmark Component Futures Contracts (determined at the earlier of the close of such exchange or 2:30 p.m. E.T.) for the contracts traded on the Futures Exchanges, but calculate or determine the value of all other investments of the Fund using market quotations, if available, or other information customarily used to determine the fair value of such investments as of the earlier of the close of the NYSE Arca or 4:00 p.m. E.T. Other information customarily used in determining fair value includes information consisting of market data in the relevant market supplied by one or more third parties including, without limitation, relevant rates, prices, yields, yield curves, volatilities, spreads, correlations or other market data in the relevant market; or information of the types described above from internal sources if that information is of the same type used by the Fund in the regular course of their business for the valuation of similar transactions. Third parties supplying quotations or market data may include, without limitation, dealers in the relevant markets, end-users of the relevant product, information vendors, brokers and other sources of market information.

Derivatives for which market quotes are readily available will be valued at market value. Local closing prices will be used for all instrument valuation purposes. Swaps traded on exchanges will use the applicable exchange closing price where available.

[13] In the most common type of EFRP transaction entered into by the Fund, the OTC component is the purchase or sale of one or more baskets of the Fund's Shares, as described below.

[14] The Fund would use a spread when it chooses to take simultaneous long and short positions in futures written on the same underlying asset, but with different delivery months.

With respect to specific derivatives, futures will generally be valued at the settlement price of the relevant exchange. A total return swap on the CCIER will be valued at the publicly available CCIER price. The CCIER, in turn, is determined by the applicable index calculation agent, which generally values the commodities underlying the Index at the last reported sale price.

Indicative Fund Value

In addition, in order to provide updated information relating to the Fund for use by investors and market professionals, the NYSE Arca will calculate and disseminate throughout the Core Trading Session on each trading day an updated Indicative Fund Value (''IFV''). The IFV will be calculated by using the prior day's closing NAV per Share of the Fund as a base and updating that value throughout the trading day to reflect changes in the most recently reported trade prices for the Benchmark Component Futures Contracts as reported by Bloomberg, L.P. or another reporting service.

The IFV will be disseminated on a per Share basis every 15 seconds during regular NYSE Arca Core Trading Session hours of 9:30 a.m. E.T. to 4:00 p.m. E.T. The normal trading hours of the ICE Exchange ends prior to the close of the Core Trading Session on NYSE Arca. As a result, there will be a gap in time at the beginning and/or the end of each day during which the Fund's Shares are traded on the NYSE Arca, but real-time futures exchange trading prices for Benchmark Component Futures Contracts traded on the ICE Exchange are not available. During such gaps in time the IFV will be calculated based on the end of day price of such Benchmark Component Futures Contracts from Futures Exchanges immediately preceding trading session. In addition, Other Crude Oil-Related Investments and Treasuries held by the Fund will be valued by the Administrator, using rates and points received from client-approved third party vendors (such as Reuters and WM Company) and advisor quotes. These investments will not be included in the IFV. The IFV will be available through on-line information services.

With respect to specific derivatives: Total return swaps may be valued intraday using the underlying asset price, or another proxy as determined to be appropriate by a third party market data provider. Exchange listed options may be valued intraday using the relevant exchange data, or another proxy as determined to be appropriate by a third party market data provider.

Availability of Information

The NAV for the Fund's Shares will be disseminated daily to all market participants at the same time. The intraday, closing prices, and settlement prices of the Benchmark Component Futures Contracts will be readily available from automated quotation systems, published or other public sources, or major market data vendors.

Complete real-time data for the Benchmark Component Futures Contracts is available by subscription from major market data vendors. ICE Futures also provides delayed futures information on current and past trading sessions and market news free of charge on its Web site. The specific contract specifications for the Benchmark Component Futures Contracts are also available on such Web site, as well as other financial informational sources. Quotation and last-sale information regarding the Shares will be disseminated through the facilities of the CTA. In addition, the Fund's Web site, *www.uscfinvestments.com,* will display the applicable end of day closing NAV. The daily holdings of the Fund will be available on the Fund's Web site. The Fund's total portfolio composition will be disclosed each business day that the NYSE Arca is open for trading, on the Fund's Web site. The Web site disclosure of portfolio holdings will be made daily and will include, as applicable, (i) the composite value of the total portfolio, (ii) the name, percentage weighting, and value of OTC Derivatives Contracts and each Benchmark Component Futures Contract, (iii) the name and value of each Treasury security and cash equivalent, and (iv) the amount of cash held in the Fund's portfolio. The Fund's Web site will be publicly accessible at no charge. This Web site disclosure of the portfolio composition of the Fund will occur at the same time as the disclosure by the Sponsor of the portfolio composition to Authorized Participants so that all market participants will be provided portfolio composition information at the same time. Therefore, the same portfolio information will be provided on the public Web site as well as in electronic files provided to Authorized Participants. Accordingly, each investor will have access to the current portfolio composition of the Fund through the Fund's Web site.

Intra-day price information for exchange-traded derivative instruments will be available from the applicable exchange and from major market data vendors. Intra-day price information for OTC options, forwards, and OTC derivative instruments will be available from major market data vendors. Intraday and closing price information for exchange-traded options and futures will be available from the applicable exchange and from major market data vendors. In addition, intra-day price information for U.S. exchange-traded options is available from the Options Price Reporting Authority.

Trading Halts

With respect to trading halts, the Exchange may consider all relevant factors in exercising its discretion to halt or suspend trading in the Shares of the Fund.[15] Trading in Shares of the Fund will be halted if the circuit breaker parameters in NYSE Arca Equities Rule 7.12 have been reached. Trading also may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable.

The Exchange may halt trading during the day in which an interruption to the dissemination of the IFV or the value of the Index occurs. If the interruption to the dissemination of the IFV, or the value of the Index persists past the trading day in which it occurred, the Exchange will halt trading no later than the beginning of the trading day following the interruption. In addition, if the Exchange becomes aware that the NAV with respect to the Shares is not disseminated to all market participants at the same time, it will halt trading in the Shares until such time as the NAV is available to all market participants.

Trading Rules

The Exchange deems the Shares to be equity securities, thus rendering trading in the Shares subject to the Exchange's existing rules governing the trading of equity securities. Shares will trade on the NYSE Arca Marketplace from 4 a.m. to 8 p.m. E.T. in accordance with NYSE Arca Equities Rule 7.34 (Opening, Core, and Late Trading Sessions). The Exchange has appropriate rules to facilitate transactions in the Shares during all trading sessions. As provided in NYSE Arca Equities Rule 7.6, the minimum price variation (''MPV'') for quoting and entry of orders in equity securities traded on the NYSE Arca Marketplace is $0.01, with the exception of securities that are priced less than $1.00 for which the MPV for order entry is $0.0001.

The Shares will conform to the initial and continued listing criteria under NYSE Arca Equities Rule 8.200. The trading of the Shares will be subject to NYSE Arca Equities Rule 8.200,

[15] *See* NYSE Arca Equities Rule 7.12.

Commentary .02(e), which sets forth certain restrictions on Equity Trading Permit (''ETP'') Holders acting as registered Market Makers in Trust Issued Receipts to facilitate surveillance. The Exchange represents that, for initial and/or continued listing, the Fund will be in compliance with Rule 10A–3 [16] under the Act, as provided by NYSE Arca Equities Rule 5.3. A minimum of 100,000 Shares will be outstanding at the commencement of trading on the Exchange.

Surveillance

The Exchange represents that trading in the Shares will be subject to the existing trading surveillances administered by the Exchange, as well as cross-market surveillances administered by the Financial Industry Regulatory Authority (''FINRA'') on behalf of the Exchange, which are designed to detect violations of Exchange rules and applicable federal securities laws.[17] The Exchange represents that these procedures are adequate to properly monitor Exchange trading of the Shares in all trading sessions and to deter and detect violations of Exchange rules and federal securities laws applicable to trading on the Exchange.

The surveillances referred to above generally focus on detecting securities trading outside their normal patterns, which could be indicative of manipulative or other violative activity. When such situations are detected, surveillance analysis follows and investigations are opened, where appropriate, to review the behavior of all relevant parties for all relevant trading violations.

The Exchange or FINRA, on behalf of the Exchange, or both, will communicate as needed regarding trading in the Shares and the Benchmark Component Futures Contracts with other markets and other entities that are members of the ISG, and the Exchange or FINRA, on behalf of the Exchange, or both, may obtain trading information regarding trading in the Shares and the Benchmark Component Futures Contracts from such markets and other entities. In addition, the Exchange may obtain information regarding trading in the Shares and the Benchmark Component Futures Contracts from markets and other entities that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement (''CSSA'').[18]

Not more than 10% of the net assets of the Fund in the aggregate invested in futures contracts shall consist of futures contracts whose principal market is not a member of the ISG or is a market with which the Exchange does not have a comprehensive surveillance sharing agreement.

In addition, the Exchange also has a general policy prohibiting the distribution of material, non-public information by its employees.

All statements and representations made in this filing regarding (a) the description of the portfolios, and (b) limitations on portfolio holdings or reference assets shall constitute continued listing requirements for listing the Shares on the Exchange.

The issuer has represented to the Exchange that it will advise the Exchange of any failure by the Fund to comply with the continued listing requirements, and, pursuant to its obligations under Section 19(g)(1) of the Act, the Exchange will monitor for compliance with the continued listing requirements. If the Fund is not in compliance with the applicable listing requirements, the Exchange will commence delisting procedures under NYSE Arca Equities Rule 5.5(m).

Information Bulletin

Prior to the commencement of trading, the Exchange will inform its ETP Holders in an Information Bulletin of the special characteristics and risks associated with trading the Shares. Specifically, the Information Bulletin will discuss the following: (1) The risks involved in trading the Shares during the Opening and Late Trading Sessions when an updated IFV will not be calculated or publicly disseminated; (2) the procedures for purchases and redemptions of Shares in Creation Baskets and Redemption Baskets (and that Shares are not individually redeemable); (3) NYSE Arca Equities Rule 9.2(a), which imposes a duty of due diligence on its ETP Holders to learn the essential facts relating to every customer prior to trading the Shares; (4) how information regarding the IFV is disseminated; (5) that a static IFV will be disseminated, between the close of trading on the CME and the close of the NYSE Arca Core Trading Session; (6) the requirement that ETP Holders deliver a prospectus to investors purchasing newly issued Shares prior to or concurrently with the confirmation of a transaction; and (7) trading information.

In addition, the Information Bulletin will advise ETP Holders, prior to the commencement of trading, of the prospectus delivery requirements applicable to the Fund. The Exchange notes that investors purchasing Shares directly from the Fund will receive a prospectus. ETP Holders purchasing Shares from the Fund for resale to investors will deliver a prospectus to such investors. The Information Bulletin will also discuss any exemptive, no-action, and interpretive relief granted by the Commission from any rules under the Act. In addition, the Information Bulletin will reference that the Fund is subject to various fees and expenses described in the Registration Statement. The Information Bulletin will also reference that the CFTC has regulatory jurisdiction over the trading of Benchmark Component Futures Contracts and the OTC Derivatives Contracts.

The Information Bulletin will also disclose the trading hours of the Shares that the NAV for the Shares will be calculated after 4:00 p.m. E.T. each trading day. The Information Bulletin will disclose that information about the Shares will be publicly available on the Fund's Web site.

2. Statutory Basis

The basis under the Act for this proposed rule change is the requirement under Section 6(b)(5) [19] that an exchange have rules that are designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to, and perfect the mechanism of a free and open market and, in general, to protect investors and the public interest.

The Exchange believes that the proposed rule change is designed to prevent fraudulent and manipulative acts and practices in that the Shares will be listed and traded on the Exchange pursuant to the initial and continued listing criteria in NYSE Arca Equities Rule 8.200. The Exchange has in place surveillance procedures that are adequate to properly monitor trading in the Shares in all trading sessions and to deter and detect violations of Exchange rules and applicable federal securities laws. The Exchange or FINRA, on behalf of the Exchange, or both, will communicate as needed regarding trading in the Shares, and Benchmark Component Futures Contracts with

[16] 17 CFR 240.10A–3.

[17] FINRA conducts cross-market surveillances on behalf of the Exchange pursuant to a regulatory services agreement. The Exchange is responsible for FINRA's performance under this regulatory services agreement.

[18] For a list of the current members of ISG, *see www.isgportal.org.* The Exchange notes that not all components of the Fund may trade on markets that are members of ISG or with which the Exchange has in place a CSSA. The Exchange has in place a CSSA with ICE Futures Europe.

[19] 15 U.S.C. 78f(b)(5).

other markets and other entities that are members of the ISG, and the Exchange or FINRA, on behalf of the Exchange, or both, may obtain trading information regarding trading in the Shares and Benchmark Component Futures Contracts from such markets and other entities. In addition, the Exchange may obtain information regarding trading in the Shares and Benchmark Component Futures Contracts from markets and other entities that are members of ISG or with which the Exchange has in place a CSSA.

Not more than 10% of the net assets of the Fund in the aggregate invested in futures contracts shall consist of futures contracts whose principal market is not a member of the ISG or is a market with which the Exchange does not have a CSSA. The Exchange has in place surveillance procedures that are adequate to properly monitor trading in the Shares in all trading sessions and to deter and detect violations of Exchange rules and applicable federal securities laws. The intraday, closing prices, and settlement prices of the Benchmark Component Futures Contracts will be readily available from the applicable Futures Exchanges' Web sites, automated quotation systems, published or other public sources, or on-line information services.

Complete real-time data for the Benchmark Component Futures Contracts is available by subscription from on-line information services. The Futures Exchanges also provide delayed futures information on current and past trading sessions and market news free of charge on their Web sites. The specific contract specifications for the Benchmark Component Futures Contracts are also available on such Web sites, as well as other financial informational sources. Information regarding exchange-traded cash-settled options and cleared swap contracts will be available from the applicable exchanges and major market data vendors. Quotation and last-sale information regarding the Shares will be disseminated through the facilities of the CTA. In addition, the Fund's Web site, will display the applicable end of day closing NAV. The Fund's total portfolio composition will be disclosed each business day that the NYSE Arca is open for trading, on the Fund's Web site. The Web site disclosure of portfolio holdings will be made daily and will include, as applicable, (i) the composite value of the total portfolio, (ii) the name, percentage weighting, and value of OTC Derivatives Contracts and each Benchmark Component Futures Contract, (iii) the name and value of each Treasury security and cash equivalent, and (iv) the amount of cash held in the Fund's portfolio. The Fund's disclosure of derivative positions will include information that market participants can use to value these positions intraday.

Prior to the commencement of trading, the Exchange will inform its Equity Trading Permit Holders in an Information Bulletin of the special characteristics and risks associated with trading the Shares. Trading in Shares of the Fund will be halted if the circuit breaker parameters in NYSE Arca Equities Rule 7.12 have been reached or because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable

The proposed rule change is designed to promote just and equitable principles of trade and to perfect the mechanism of a free and open market and, in general, to protect investors and the public interest in that it will facilitate the listing and trading of an additional type of issue of Trust Issued Receipts based on oil that will enhance competition among market participants, to the benefit of investors and the marketplace. As noted above, the Exchange has in place surveillance procedures that are adequate to properly monitor trading in the Shares in all trading sessions and to deter and detect violations of Exchange rules and applicable federal securities laws.

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. The Exchange notes that the proposed rule change will facilitate the listing and trading of an additional type of exchange-traded product that primarily hold derivatives and futures contracts and that will enhance competition among market participants, to the benefit of investors and the marketplace.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove the proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NYSEArca–2016–177 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–NYSEArca–2016–177. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make

available publicly. All submissions should refer to File Number SR–NYSEArca–2016–177 and should be submitted on or before February 13, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[20]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–01297 Filed 1–19–17; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–79792; File No. SR–NYSEARCA–2016–176]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing of Proposed Rule Change Relating to the Listing and Trading of Shares of the EtherIndex Ether Trust Under NYSE Arca Equities Rule 8.201

January 13, 2017.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the ''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on December 30, 2016, NYSE Arca, Inc. (the ''Exchange'' or ''NYSE Arca'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to list and trade shares of the following under NYSE Arca Equities Rule 8.201: EtherIndex Ether Trust (''Trust''). The proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

Under NYSE Arca Equities Rule 8.201, the Exchange may propose to list and/or trade pursuant to unlisted trading privileges (''UTP'') ''Commodity-Based Trust Shares.''[4] The Exchange proposes to list and trade shares (''Shares'') of the Trust pursuant to NYSE Arca Equities Rule 8.201.[5]

The sponsor of the Trust is EtherIndex LLC (''Sponsor''), a Delaware limited liability company. Delaware Trust Company is the trustee of the Trust (''Trustee''). The Bank of New York Mellon will be the administrator (''Administrator'') and custodian of cash of the Trust (''Cash Custodian''). Coinbase will be the custodian of the ether of the Trust (''Ether Custodian'').

According to the Registration Statement, each Share will represent a unit of fractional undivided beneficial interest in and ownership of the Trust. The activities of the Trust will be limited to (i) issuing ''Baskets'' (as described below) to ''Authorized Participants'' (as described below) in exchange for the cash or, in the Sponsor's discretion, ether (as described below), (ii) selling ether or transferring ether, at the Sponsor's discretion, as necessary to cover the Sponsor's fee and as necessary to pay Trust expenses not assumed by the Sponsor and other liabilities, (iii) selling or transferring ether in exchange for Baskets surrendered for redemption by the Authorized Participants, (iv) causing the Administrator to sell ether on the termination of the Trust and (v) engaging in all administrative and custodial procedures necessary to accomplish such activities in accordance with the provisions of relevant agreements.

According to the Registration Statement, the Trust is neither an investment company registered under the Investment Company Act of 1940, as amended,[6] nor a commodity pool for purposes of the Commodity Exchange Act (''CEA''),[7] and neither the Sponsor nor the Trustee is subject to regulation as a commodity pool operator or a commodity trading adviser in connection with the operation of the Trust.

Investment Objective

According to the Registration Statement and as further described below, the Trust's purpose will be to provide shareholders with exposure to the daily change in the U.S. dollar price of ether, before expenses and liabilities of the Trust, as measured by the price of ether in U.S. dollars as reported by the Global Digital Asset Exchange (''GDAX'') as of 4:00 p.m., Eastern Time (''E.T.''), each day (''GDAX Price'').

The Trust will not be actively managed. It will not engage in any activities designed to obtain a profit from, or to ameliorate losses caused by, changes in the market prices of ether.

Ether and the Ethereum Network

According to the Registration Statement, ether is a digital asset similar to bitcoin. It is not issued by any government, bank or central organization but rather is issued by, and transmitted through, the decentralized, open source protocol of the peer-to-peer Ethereum computer network (''Ethereum Network''). The Ethereum Network is a decentralized network of computers that run applications on a custom built ''blockchain'' (''Ethereum Blockchain'') that enables developers to create markets, store registries of debts or promises, represent the ownership of property and move funds in accordance with instructions given in the past, all without the involvement of an intermediary or counterparty. The Ethereum Blockchain is a decentralized public transaction ledger hosted on the Ethereum Network on which all ether is recorded; the blockchain records ether balances and every ether address associated with a quantity of ether (see ''Ethereum Blockchain'' below). No single entity owns or operates the Ethereum Network.

According to the Registration Statement, unlike bitcoin, ether was not designed to function purely as a store of value. Instead, ether was meant to pay for specific actions on the Ethereum Network. However, ether's market is

[20] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C.78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] Commodity-Based Trust Shares are securities issued by a trust that represent investors' discrete identifiable and undivided beneficial ownership interest in the commodities deposited into the Trust.

[5] On November 28, 2016, the Trust filed an amended registration statement (''Registration Statement'') on Form S–1 under the Securities Act of 1933 (15 U.S.C. 77a) (File No. 333–212533). The descriptions of the Trust, the Shares and ether contained herein are based, in part, on the Registration Statement.

[6] 15 U.S.C. 80a–1.

[7] 17 U.S.C. 1.

currently supported by many of the same online exchanges and the same infrastructure that has developed around the bitcoin network. Users who have historically purchased bitcoin on online exchange platforms can now buy ether on these Web sites. Ether can be converted to fiat currencies, such as the U.S. dollar, or to bitcoin, at rates determined on ether exchanges or in individual end-user-to-end-user transactions under a barter system. Each ether transaction is broadcast to the Ethereum Network and recorded in the Ethereum Blockchain.

According to the Registration Statement, unlike bitcoin, which has a fixed limit of 21,000,000 bitcoin, no limit has been established on the total supply of ether. The initial creation of ether was in connection with a crowd funding transaction in 2014 in which 60,000,000 ether were pre-sold. Another 12,000,000 ether were created for the benefit of a development fund. All additional ether have been and will be created through the ''mining'' process (see ''Ether Blockchain'' below). According to the terms of the 2014 presale, the issuance of ether from mining is capped at 18,000,000 ether per year. According to the Registration Statement, it has been reported that approximately 9,700,000 million ether have been created to date through the mining process.

Ethereum Blockchain

According to the Registration Statement, the Ethereum Blockchain is a record of every ether transaction (including the creation or ''mining'' of new ether) and every Ethereum Network public address associated with a quantity of ether. A beta version of the live blockchain was publicly launched in July 2015, and the initial production version was launched in March 2016.

The Ethereum Blockchain is comprised of a digital file, downloaded and stored, in whole or in part, on all Ethereum Network users' software programs. The Ethereum Network software can interpret the Ethereum Blockchain to determine the exact ether balance, if any, of any public ether address listed in the Ethereum Blockchain which has taken part in a transaction on the Ethereum Network.

Mining is the act of using a computer to run computations designed to help build the next block in the Ethereum Blockchain. As a computer solves a complex computational calculation related to the building of a block, its owner is rewarded with ether.[8] The Ethereum Blockchain includes all blocks that have been solved by miners and is updated to include new blocks as they are solved. As each newly solved block refers back to and connects with the immediately prior solved block, the addition of a new block adds to the Ethereum Blockchain in a manner similar to a new link being added to a chain. Each new block records outstanding ether transactions, and outstanding transactions are settled and validated through such recording. Therefore, the Ethereum Blockchain represents a complete, transparent and unbroken history of all transactions of the Ethereum Network.

According to the Registration Statement, in June 2016, the DAO, a decentralized autonomous organization using the Ethereum Network, was hacked, resulting in a loss to that organization of approximately 3.6 million ether. In response to this loss, the Ethereum community agreed to create a new ''hard fork'' on the Ethereum Blockchain which returned the lost ether to the DAO. A hard fork is a change to the underlying Ethereum protocol, which creates new rules for the Ethereum system; all Ethereum clients needed to upgrade, otherwise they would remain on the old blockchain. In creating the hard fork, the intent was to have all users of the Ethereum Network migrate to the new fork, rendering the ether on the old blockchain held by the DAO hacker useless. However, a number of users have continued to develop the old blockchain, now referred to as ''Ethereum Classic,'' resulting in a separate version of ether referred to as ''ether classic.'' Ether classic is now traded on several crypto currency exchanges. The Shares will provide shareholders with exposure to the daily change in the U.S. dollar price of ether, before expenses and liabilities of the Trust, as measured by the GDAX Price and not the price of ether classic.

Uses of Ether Blockchain

According to the Registration Statement, the Ethereum Blockchain is a general-purpose, global blockchain that can govern both financial and non-financial types of application states. Ether can be used to pay for goods and services or can be converted to fiat currencies, such as the U.S. dollar, at rates determined on ether exchanges (''Ether Exchange'')[9] or in individual end-user-to-end-user transactions under a barter system.[10] An ether private key controls the transfer or ''spending'' of ether from its associated public ether address. An ether ''wallet'' is a collection of private keys and their associated public ether addresses.

According to the Registration Statement, while the bitcoin network permits users primarily to execute value transfers, the Ethereum Network allows users to program any arbitrary code and execute it, including value transfers. Accordingly, the Ethereum Network may be viewed as a global, decentralized computer in comparison to the bitcoin network, which is more similar to a global, decentralized payment network. In addition to value transfers, the Ethereum Network enables decentralized business logic, known as ''smart contracts.'' A smart contract is a collection of code (its functions) and data (its state) that resides at a specific address on the Ethereum Blockchain. Smart contracts can interact with other contracts, make decisions, store data and send ether to others. Smart contracts are capable of automatically enforcing the terms of a given agreement among a number of parties. This code can define strict rules and consequences in the same way that a traditional legal document would, stating the obligations, benefits and penalties which may be due to either party in various different circumstances. But, unlike a traditional contract, it can also take information as an input, process that information through the rules set out in the contract and take any actions required of it as a result.

Custody of the Trust's Ether

According to the Registration Statement, the private keys that control the Trust's ether will be secured by the Ether Custodian and stored completely offline in a ''cold storage'' system. The Ether Custodian's cold storage system is founded on the principles of (i) building

[8] Attached as Exhibit 3, Item 1 is a chart illustrating the supply growth of ether during the period October 2015 through October 2016.

[9] An Ether Exchange is an online marketplace with a central limit order book, where market participants may buy, sell and trade ether. The largest Ether Exchanges are typically open on a 24-hour per day, seven-days per week basis, and publish public market data such as transaction price and volume data. Examples of Ether Exchanges are: (i) Coinbase, a digital currency wallet and platform based in San Francisco where merchants and consumers can transact with certain digital currencies; (ii) Kraken, an online exchange based in San Francisco; (iii) Bitfinex, an online exchange founded in Hong Kong; and (iv) Gemini, a New York-based online exchange that has obtained a BitLicense from the New York Department of Financial Services.

[10] Attached as Exhibit 3, Item 2 is a chart setting forth a summary of the daily number of ether transactions (*i.e.,* transfers of ether between parties on the Ethereum Network, which is different than and should not be confused with ether exchange-traded volume) from October 2015 through October 2016.

defense-in-depth against external threats, (ii) protecting against human error and (iii) guarding against misuse of insider access. The Ether Custodian's cold storage mechanism involves generating private keys on an ''air-gapped'' computer, *i.e.,* a computer that has never been connected to the internet, then splitting these keys into segments using a special algorithm to ensure no one individual knows how the key was fragmented, and finally distributing these fragments geographically so no one entity can access the cold storage without the other individuals contributing their fragment of the key. The Ether Custodian maintains insurance against theft and electronic compromise in an amount that exceeds the average value of ether and bitcoin that it holds online at any one time.

The Ether Custodian will maintain approximately three times the average of the expected creation and redemption Baskets in ether at all times in a ''hot wallet,'' which is connected to the internet, in order to provide fast access to withdrawal when needed. The average ether amount to be held in the hot wallet will initially be determined by the Sponsor and Authorized Participants. The Sponsor may direct the Ether Custodian to transfer ether from the cold storage system to the hot wallet if additional ether is required for creation and redemption Baskets. It is anticipated that less than five percent of the Trust's ether will be held in the hot wallet. The Ether Custodian will maintain the Trust's remaining ether in its cold storage system and will hold the Trust's ether in the Trust's ether custody account. The Ether Custodian will segregate the Trust's ether which will be held in unique Ethereum Network public addresses with balances that can be directly verified on the Ethereum Blockchain.

According to the Registration Statement, each Custodian will accept, on behalf of the Trust, cash or the delivery of ether from Authorized Participants into the Trust's custody accounts creation orders. In order for an Authorized Participant to redeem a Basket and receive cash or a distribution of ether from the Trust, the Custodians, upon receiving instructions from the Administrator, will sign transactions necessary to transfer ether out of the Trust's ether custody account for sale or to distribute the ether to the Ethereum Network public address specified by the Authorized Participant.

According to the Registration Statement, the Sponsor will engage an independent audit firm to periodically audit the Ether Custodian's storage of private keys and its internal controls and report to the Sponsor at least annually on such matters. Additionally, the Sponsor will engage an independent audit firm to biannually verify that the Ether Custodian can demonstrate ''proof of control'' of the private keys that control the Trust's ether. One such ''proof of control'' audit will be conducted at the end of each calendar year and the other at random.

Ether Market Price

According to the Registration Statement, the value of ether is determined by the value that various market participants place on ether through their transactions. The most common means of determining the value of ether is by surveying one or more Ether Exchanges where ether is traded publicly and transparently (*e.g.,* GDAX, Poloniex or Kraken).[11] On each online Ether Exchange, ether is traded with publicly disclosed valuations for each executed trade, measured by one or more fiat currencies such as the U.S. dollar or euro or by the widely used digital asset bitcoin.

According to the Trust, since its initial trading, ether has experienced one-day (*i.e.,* the greatest one-day change in ether price experienced on any trading day), one-month (*i.e.,* the greatest change in ether price experienced during any calendar month), one-year (*i.e.,* the greatest change in ether price experienced during any calendar year) and since-inception[12] changes of 67.5% (or $2.93), 214.8% (or $2.04), 2,748.5% (or $20.56) and 32,416% (or $21.33), respectively. All changes listed represent increases in the price of ether.[13]

[11] Attached as Exhibit 3, Item 3 is a chart comparing the ether price on Coinbase, Kraken, Gemini, Poloniex, Cexlo and Bitfinex during the period May 27, 2016 through October 21, 2016. Attached as Exhibit 3, Item 4 is a chart comparing the ether price, in 15 minute intervals, on Coinbase, Kraken and Bitfinex during the period of November 21, 2016 and into November 22, 2016.

[12] For purposes of this data, the Trust has used August 8, 2015 as the inception date.

[13] Attached as Exhibit 3, Item 5 is a chart illustrating the changes in the price of ether during the period September 2015 into October 2016. Attached as Exhibit 3, Item 6 is a chart comparing three-month volatility in the price of ether compared to three-month volatility in the prices of bitcoin, gold, silver, WTI crude oil, copper, natural gas, soybeans and coffee (''Comparison Commodities'') during the period July 2016 through September 2016. Attached as Exhibit 3, Item 7 is a chart comparing the six-month volatility in the price of ether compared to the six-month volatility in the prices of the Comparison Commodities during the period April 2016 through September 2016. Attached as Exhibit 3, Item 8 is a chart comparing the twelve-month volatility in the price of ether compared to the twelve-month volatility in the prices of the Comparison Commodities during the period October 2016 through September 2016.

The Trust

According to the Registration Statement, the Trust's assets will consist of ether. The Trust will occasionally hold cash for short periods in connection with the creation and redemption process, and to pay certain fees, expenses and liabilities. The ether held by the Ether Custodian on behalf of the Trust will only be transferred out of the Trust's ether custody account in the following circumstances: (i) Transferred to pay the Sponsor's fee; (ii) transferred to be sold for cash or distributed to Authorized Participants in connection with the redemption of Baskets; (iii) transferred to the Trust's expense account to be sold on an as-needed basis to pay Trust expenses not assumed by the Sponsor; or (iv) sold on behalf of the Trust in the event the Trust terminates and liquidates its assets or as otherwise required by law or regulation.

According to the Registration Statement, while the Sponsor will not exercise day-to-day oversight over the Trust, the Sponsor will engage the Administrator and the Custodians to assist in implementing the creation and redemption process for the Trust. The Sponsor will assume certain administrative and marketing expenses incurred by the Trust. The Trust will pay the Sponsor a fee.

Net Asset Value

On each business day, the Administrator will calculate the net asset value (''NAV'') of the Trust as measured at 4:00 p.m., E.T., using the GDAX Price. The NAV of the Trust is the asset value of the Trust less its liabilities (which include accrued but unpaid fees and expenses) divided by the number of outstanding Shares as of 4:00 p.m., E.T., each business day.

In the event that the GDAX Price is unavailable or the Sponsor determines that the GDAX Price is not an appropriate basis for evaluation of the Trust's ether, the Sponsor will instruct the Administrator to use as an alternative basis for calculating the Trust's NAV either (i) the price of ether in U.S. dollars as reported by Kraken Bitcoin Exchange as measured at 4:00 p.m., E.T., on each business day, (ii) if the Sponsor determines that the Kraken Bitcoin Exchange price is not an appropriate basis for evaluation of the Trust's ether, the price of ether in U.S. dollars as reported by the Gemini Exchange as measured at the 4:00 p.m., E.T., on each business day or (iii) if the Sponsor determines that the Kraken Bitcoin Exchange and the Gemini

Exchange prices are not appropriate bases for evaluation of the Trust's ether, the Sponsor's good faith estimate of the market price of ether. Any determination that the GDAX Price or the price on the other exchanges mentioned above is not an appropriate basis for calculating the Trust's NAV would be based upon extraordinary criteria, such as a disruption in the operation of the exchange, material reporting or calculation inaccuracies by the exchange or a material decrease in trading volume not experienced by other exchanges. In determining fair market value for ether, the Sponsor may consider the market price for ether on other Ether Exchanges or in other forums for which ether prices are published publicly.

The Sponsor will publish the Trust's NAV on the Trust's Web site as soon as practicable after calculation by the Administrator. To the extent that the NAV has been calculated using a price per ether other than the GDAX Price for such business day, the publication on the Trust's Web site will note the valuation methodology and the price per ether resulting from such calculation.

According to the Registration Statement, Authorized Participants, or their clients or customers, may have an opportunity to realize a riskless profit if they can create a Basket at a discount to the public trading price of the Shares or can redeem a Basket at a premium over the public trading price of the Shares. The Sponsor expects that the exploitation of such arbitrage opportunities by Authorized Participants and their clients and customers will tend to cause the public trading price to track the NAV closely over time.

Creation and Redemption of Shares

According to the Registration Statement, the Trust will issue and redeem Baskets, each equal to a block of 10,000 Shares, principally in exchange for the delivery to the Trust or the distribution by the Trust of the amount of cash, or at the discretion of the Sponsor, ether represented by the NAV of the Baskets being created or redeemed, the amount of which will be based on the combined ether represented by the number of Shares included in the Baskets being created or redeemed determined on the day the order to create or redeem Baskets is properly received. The Trust will issue and redeem Shares in Baskets to and from Authorized Participants. The size of a Basket is subject to change.

Orders to create and redeem Baskets may be placed only by Authorized Participants.[14] A transaction fee may be imposed to offset transfer and other transaction costs associated with creation or redemption.

Creation Procedures

On any business day, an Authorized Participant may place an order with the Transfer Agent to create one or more Baskets. Purchase orders must be placed by 1:00 p.m., E.T. The day on which the Transfer Agent receives a valid purchase order is the purchase order date. Purchase orders are irrevocable.

The total payment required to create each Basket is determined by calculating the NAV of 10,000 Shares as of the closing time of the NYSE Arca on the purchase order date. Baskets will be issued as of 9:30 a.m., E.T., on the business day immediately following the purchase order date at the applicable NAV as of the closing time of NYSE Arca on the purchase order date, but only if the required payment has been timely received.

Orders to purchase Baskets must be placed no later than 1:00 p.m., E.T., but the total payment required to create a Basket will not be determined until 4:00 p.m., E.T., on the date the purchase order is received. Authorized Participants therefore will not know the total amount of the payment required to create a Basket at the time they submit an irrevocable purchase order for the Basket.

The payment required to create a Basket typically will be made in cash, but it may also be made partially or wholly in-kind at the discretion of the Sponsor if the Authorized Participant requests to convey ether directly to the Trust. To the extent the Authorized Participant places an in-kind order to create, the Authorized Participant must deliver ether directly to the Ether Custodian and an amount of cash (or ether) referred to as the Balancing Amount [15] each no later than 1:00 p.m., E.T., on the date the purchase order is received. The amount of ether delivered by the Authorized Participant must be in an amount equal to the number of ether necessary to create a Basket as of 4:00 p.m., E.T., on the date the purchase order is received. Upon delivery of the ether to the Ether Custodian and the Balancing Amount to the Cash Custodian (or the ether component of the Balancing Amount, if applicable, to the Ether Custodian), the Administrator will cause the Trust to issue a Basket to the Authorized Participant.

According to the Registration Statement, the Sponsor acting by itself or through the Administrator may reject a creation order if: (i) It is not in proper form; (ii) it is determined by the Sponsor not to be in the best interest of the shareholders; (iii) the acceptance or receipt of the creation order would have adverse tax consequences to the Trust or shareholders; (iv) the acceptance or receipt of the creation order would, in the opinion of counsel to the Sponsor, be unlawful; (v) if circumstances outside the control of the Sponsor or its designee make it, for all practical purposes, not feasible, as determined by the Sponsor in its sole discretion, to process creations of Baskets; or (vi) for any other reason set forth in the Authorized Participant Agreement entered into with that Authorized Participant.

Redemption Procedures

According to the Registration Statement, the procedures by which an Authorized Participant can redeem one or more Baskets will mirror the procedures for the creation of Baskets. On any business day, an Authorized Participant may place an order with the Transfer Agent to redeem one or more Baskets. Redemption orders must be placed no later than 1:00 p.m., E.T. The day on which the Transfer Agent receives a valid redemption order is the redemption order date. Redemption orders are irrevocable. By placing a redemption order, an Authorized Participant agrees to deliver the Baskets to be redeemed through DTC's book-entry system to the Trust not later than 1:00 p.m., E.T., on the business day immediately following the redemption order date.

The redemption proceeds from the Trust consist of the ''cash redemption amount'' and, if making an in-kind redemption, ether. The cash redemption amount is equal to the NAV of the number of Baskets of the Trust requested in the Authorized

[14] An Authorized Participant must: (1) Be a registered broker-dealer or other securities market participant, such as a bank or other financial institution, which is not required to register as a broker-dealer to engage in securities transactions and (2) be a participant in Depository Trust Company (''DTC''). To become an Authorized Participant, a person must enter into an ''Authorized Participant Agreement'' with the Administrator and the Sponsor on behalf of the Trust. The Authorized Participant Agreement provides the procedures for the creation and redemption of Baskets as well as the amount of ether required for delivery or distribution for such creations and redemptions.

[15] The Balancing Amount is an amount equal to the difference between the NAV of the Shares (per Basket) and the ''Deposit Amount,'' which is an amount equal to the market value of ether (per Basket) which, for this purpose, is calculated in the same manner as the Trust values ether. The Balancing Amount serves to compensate for any difference between the NAV per Basket and the Deposit Amount.

Participant's redemption order as of the closing time of NYSE Arca on the redemption order date. The Cash Custodian will distribute the cash redemption amount at 4:00 p.m., E.T., on the business day immediately following the redemption order date through DTC to the account of the Authorized Participant as recorded on DTC's book-entry system. At the discretion of the Sponsor and if the Authorized Participant requests to receive ether directly, some or all of the redemption proceeds may be distributed to the Authorized Participant in-kind.

The redemption proceeds due from the Trust are delivered to the Authorized Participant at 4:00 p.m., E.T., on the business day immediately following the redemption order date if, by such time on such business day immediately following the redemption order date, the Trust's DTC account has been credited with the Baskets to be redeemed. If the Trust's DTC account has not been credited with all of the Baskets to be redeemed by such time, the redemption distribution will be delivered to the extent of whole Baskets received. Any remainder of the redemption distribution is delivered on the next business day to the extent of remaining whole Baskets received if the Sponsor receives the fee applicable to the extension of the redemption distribution date which the Sponsor may, from time to time, determine and the remaining Baskets to be redeemed are credited to the Trust's DTC account by 4:00 p.m., E.T., on such next business day. Any further outstanding amount of the redemption order shall be cancelled.

To the extent that Authorized Participant places an in-kind order to redeem a Basket, the Ether Custodian will deliver, on the business day immediately following the day the redemption order is received, ether to the Authorized Participant in an amount equal to the number of ether necessary to redeemed [sic] a Basket as of 4:00 p.m., E.T.

Availability of Information

The Trust's Web site will provide an intra-day indicative value (''IIV'') per Share updated every 15 seconds, as calculated by the Exchange or a third party financial data provider during the Exchange's Core Trading Session. The IIV will be calculated by using the prior day's closing NAV per Share as a base and updating that value during the NYSE Arca Core Trading Session to reflect changes in the value of the Trust's ether holdings during the trading day.

The IIV disseminated during the NYSE Arca Core Trading Session should not be viewed as an actual real-time update of the NAV, which will be calculated only once at the end of each trading day. The IIV will be widely disseminated on a per Share basis every 15 seconds during the NYSE Arca Core Trading Session by one or more major market data vendors. In addition, the IIV will be available through on-line information services.

The Web site for the Trust, which will be publicly accessible at no charge, will contain the following information: (a) The current NAV per Share daily and the prior business day's NAV and the reported closing price; (b) the mid-point of the bid-ask price [16] in relation to the NAV as of the time the NAV is calculated (''Bid-Ask Price'') and a calculation of the premium or discount of such price against such NAV; (c) data in chart form displaying the frequency distribution of discounts and premiums of the Bid-Ask Price against the NAV, within appropriate ranges for each of the four previous calendar quarters (or for the life of the Trust, if shorter); (d) the prospectus; and (e) other applicable quantitative information. The Trust will also disseminate the Trust's holdings on a daily basis on the Trust's Web site. The price of ether will be made available by one or more major market data vendors, updated at least every 15 seconds during the Exchange's Core Trading Session.

The NAV for the Trust will be calculated by the Administrator once a day and will be disseminated daily to all market participants at the same time. In addition, ether prices are available from automated quotation systems, published or other public sources or on-line information services. Quotation and last-sale information regarding the Shares will be disseminated through the facilities of the Consolidated Tape Association (''CTA'').

Quotation and last sale information for ether will be widely disseminated through a variety of major market data vendors. The spot price of ether is available on a 24-hour basis from major market data vendors. Information relating to trading, including price and volume information, in ether will be available from major market data vendors and from the exchanges on which ether are traded. The normal trading hours for ether exchanges are 24-hours per day, 365-days per year.

[16] The bid-ask price of the Trust is determined using the highest bid and lowest offer on the Consolidated Tape as of the time of calculation of the closing day NAV.

The Trust will provide Web site disclosure of its ether holdings daily. The Web site disclosure of the Trust's portfolio composition will occur at the same time as the disclosure by the Sponsor of the portfolio composition to Authorized Participants so that all market participants are provided portfolio composition information at the same time. Therefore, the same portfolio information will be provided on the public Web site as well as in electronic files provided to Authorized Participants. Accordingly, each investor will have access to the current portfolio composition of the Trust through the Trust's Web site.

Trading Rules

The Trust will be subject to the criteria in NYSE Arca Equities Rule 8.201, including 8.201(e), for initial and continued listing of the Shares. A minimum of 100,000 Shares will be required to be outstanding at the start of trading. With respect to application of Rule 10A–3 under the Act, the Trust will rely on the exception contained in Rule 10A–3(c)(7). The Exchange believes that the anticipated minimum number of Shares outstanding at the start of trading is sufficient to provide adequate market liquidity.

The Exchange deems the Shares to be equity securities, thus rendering trading in the Shares subject to the Exchange's existing rules governing the trading of equity securities. Trading in the Shares on the Exchange will occur in accordance with NYSE Arca Equities Rule 7.34(a). The Exchange has appropriate rules to facilitate transactions in the Shares during all trading sessions. As provided in NYSE Arca Equities Rule 7.6, the minimum price variation (''MPV'') for quoting and entry of orders in equity securities traded on the NYSE Arca Marketplace is $0.01, with the exception of securities that are priced less than $1.00 for which the MPV for order entry is $0.0001.

Further, NYSE Arca Equities Rule 8.201 sets forth certain restrictions on Equity Trading Permit Holders (''ETP Holders'') acting as registered Market Makers in the Shares to facilitate surveillance. Pursuant to NYSE Arca Equities Rule 8.201(g), an ETP Holder acting as a registered Market Maker in the Shares is required to provide the Exchange with information relating to its trading in the underlying ether. Commentary .04 of NYSE Arca Equities Rule 6.3 requires an ETP Holder acting as a registered Market Maker, and its affiliates, in the Shares to establish, maintain and enforce written policies and procedures reasonably designed to prevent the misuse of any material,

nonpublic information with respect to such products, any components of the related products, any physical asset or commodity underlying the product, applicable currencies, underlying indexes, related futures or options on futures and any related derivative instruments (including the Shares).

With respect to trading halts, the Exchange may consider all relevant factors in exercising its discretion to halt or suspend trading in the Shares. Trading on the Exchange in the Shares may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable. In addition, trading in Shares will be subject to trading halts caused by extraordinary market volatility pursuant to the Exchange's ''circuit breaker''rule.[17]

The Exchange will halt trading in the Shares if the NAV of the Trust is not calculated or disseminated daily. The Exchange may halt trading during the day in which an interruption occurs to the dissemination of the IIV. If the interruption to the dissemination of the IIV persists past the trading day in which it occurs, the Exchange will halt trading no later than the beginning of the trading day following the interruption. In addition, if the Exchange becomes aware that the NAV with respect to the Shares is not disseminated to all market participants at the same time, it will halt trading in the Shares until such time as the NAV is available to all market participants.

Surveillance

The Exchange represents that trading in the Shares will be subject to the existing trading surveillances administered by the Exchange, as well as cross-market surveillances administered by the Financial Industry Regulatory Authority (''FINRA'') on behalf of the Exchange, which are designed to detect violations of Exchange rules and applicable federal securities laws.[18] The Exchange represents that these procedures are adequate to properly monitor Exchange trading of the Shares in all trading sessions and to deter and detect violations of Exchange rules and federal securities laws applicable to trading on the Exchange.

The surveillances referred to above generally focus on detecting securities trading outside their normal patterns, which could be indicative of manipulative or other violative activity. When such situations are detected, surveillance analysis follows and investigations are opened, where appropriate, to review the behavior of all relevant parties for all relevant trading violations.

The Exchange or FINRA, on behalf of the Exchange, or both, will communicate as needed regarding trading in the Shares with other markets and other entities that are members of the Intermarket Surveillance Group (''ISG''), and the Exchange or FINRA, on behalf of the Exchange, or both, may obtain trading information regarding trading in the Shares from such markets and other entities. In addition, the Exchange may obtain information regarding trading in the Shares from markets and other entities that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement (''CSSA'').[19]

Also, pursuant to NYSE Arca Equities Rule 8.201(g), the Exchange is able to obtain information regarding trading in the Shares and the underlying ether through ETP Holders acting as registered Market Makers, in connection with such ETP Holders' proprietary or customer trades through ETP Holders which they effect on any relevant market.

The Exchange also has a general policy prohibiting the distribution of material, non-public information by its employees.

All statements and representations made in this filing regarding (i) the description of the portfolio and (ii) limitations on portfolio holdings or reference assets shall constitute continued listing requirements for listing the Shares on the Exchange. The issuer has represented to the Exchange that it will advise the Exchange of any failure by the Fund to comply with the continued listing requirements, and, pursuant to its obligations under Section 19(g)(1) of the Act, the Exchange will monitor for compliance with the continued listing requirements. If the Fund is not in compliance with the applicable listing requirements, the Exchange will commence delisting procedures under NYSE Arca Equities Rule 5.5(m).

Information Bulletin

Prior to the commencement of trading, the Exchange will inform its ETP Holders in an ''Information Bulletin'' of the special characteristics and risks associated with trading the Shares. Specifically, the Information Bulletin will discuss the following: (1) The procedures for purchases and redemptions of Shares in Baskets (including noting that the Shares are not individually redeemable); (2) NYSE Arca Equities Rule 9.2(a), which imposes a duty of due diligence on its ETP Holders to learn the essential facts relating to every customer prior to trading the Shares; (3) how [sic] information regarding how GDAX Price and the IIV are disseminated; (4) the requirement that ETP Holders deliver a prospectus to investors purchasing newly issued Shares prior to or concurrently with the confirmation of a transaction; (5) the possibility that trading spreads and the resulting premium or discount on the Shares may widen during the Opening and Late Trading Sessions, when an updated IIV will not be calculated or publicly disseminated; and (6) trading information.

In addition, the Information Bulletin will reference that the Trust is subject to various fees and expenses as described in the Registration Statement. The Information Bulletin will disclose that information about the Shares of the Trust is publicly available on the Trust's Web site.

The Information Bulletin will also discuss any relief, if granted, by the Commission or the staff from any rules under the Act.

2. Statutory Basis

The basis under the Act for this proposed rule change is the requirement under Section 6(b)(5)[20] that an exchange have rules that are designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to, and perfect the mechanism of a free and open market and, in general, to protect investors and the public interest.

The Exchange believes that the proposed rule change is designed to prevent fraudulent and manipulative acts and practices in that the Shares will be listed and traded on the Exchange pursuant to the initial and continued listing criteria in NYSE Arca Equities Rule 8.201. The Exchange has in place surveillance procedures that are adequate to properly monitor trading in the Shares in all trading sessions and to deter and detect violations of Exchange rules and applicable federal securities laws. The Exchange or FINRA, on behalf of the Exchange, or both, will communicate as needed regarding trading in the Shares with other markets

[17] *See* NYSE Arca Equities Rule 7.12.

[18] FINRA conducts cross market surveillances on behalf of the Exchange pursuant to a regulatory services agreement. The Exchange is responsible for FINRA's performance under this regulatory services agreement.

[19] For the list of current members of ISG, *see https://www.isgportal.org/home.html.*

[20] 15 U.S.C. 78f(b)(5).

that are members of the ISG, and the Exchange or FINRA, on behalf of the Exchange, or both, may obtain trading information regarding trading in the Shares from such markets. In addition, the Exchange may obtain information regarding trading in the Shares from markets that are members of ISG or with which the Exchange has in place a CSSA. Also, pursuant to NYSE Arca Equities Rule 8.201(g), the Exchange is able to obtain information regarding trading in the Shares and the underlying ether through ETP Holders acting as registered Market Makers, in connection with such ETP Holders' proprietary or customer trades through ETP Holders which they effect on any relevant market.

The proposed rule change is designed to promote just and equitable principles of trade and to protect investors and the public interest in that there is a considerable amount of ether price and ether market information available on public Web sites and through professional and subscription services. Investors may obtain on a 24-hour basis ether pricing information based on the spot price for ether from various financial information service providers. The closing price and settlement prices of ether are readily available from the Ether Exchanges and other publicly available Web sites. In addition, such prices are published in public sources or on-line information services. The Trust will provide Web site disclosure of its ether holdings daily.

Quotation and last-sale information regarding the Shares will be disseminated through the facilities of the CTA. The IIV will be widely disseminated on a per Share basis every 15 seconds during the NYSE Arca Core Trading Session by one or more major market data vendors. In addition, the IIV will be available through on-line information services. The Exchange represents that the Exchange may halt trading during the day in which an interruption to the dissemination of the IIV occurs. If the interruption to the dissemination of the IIV persists past the trading day in which it occurred, the Exchange will halt trading no later than the beginning of the trading day following the interruption. In addition, if the Exchange becomes aware that the NAV with respect to the Shares is not disseminated to all market participants at the same time, it will halt trading in the Shares until such time as the NAV is available to all market participants. The NAV per Share will be calculated daily and made available to all market participants at the same time. One or more major market data vendors will disseminate for the Trust on a daily basis information with respect to the recent NAV per Share and Shares outstanding.

The proposed rule change is designed to perfect the mechanism of a free and open market and, in general, to protect investors and the public interest in that it will facilitate the listing and trading of an additional type of exchange-traded product that will enhance competition among market participants, to the benefit of investors and the marketplace. As noted above, the Exchange has in place surveillance procedures relating to trading in the Shares and may obtain information via ISG from other exchanges that are members of ISG or with which the Exchange has entered into a CSSA. In addition, as noted above, investors will have ready access to information regarding the Trust's ether holdings, IIV and quotation and last sale information for the Shares.

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 purposes of the Act. The Exchange notes that the proposed rule change will facilitate the listing and trading of an additional type of exchange-traded product, and the first such product based on ether, which will enhance competition among market participants, to the benefit of investors and the marketplace.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will: (a) By order approve or disapprove such proposed rule change; or (b) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NYSEARCA–2016–176 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–NYSEARCA–2016–176. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing will also 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–NYSEARCA–2016–176 and should be submitted on or before February 13, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[21]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–01296 Filed 1–19–17; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–79801; File No. SR–MSRB–2016–15]

Self-Regulatory Organizations; Municipal Securities Rulemaking Board; Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 1, To Extend the MSRB's Customer Complaint and Related Recordkeeping Rules to Municipal Advisors and To Modernize Those Rules

January 13, 2017.

I. Introduction

On November 1, 2016, the Municipal Securities Rulemaking Board (the ''MSRB'' or ''Board'') filed with the Securities and Exchange Commission (the ''SEC'' or ''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change consisting of (i) proposed amendments to Rule G–10, on delivery of investor brochure, Rule G–8, on books and records to be made by brokers, dealers, and municipal securities dealers and municipal advisors, and Rule G–9, on preservation of records, and (ii) a proposed Board notice regarding electronic delivery and receipt of information by municipal advisors under Rule G–32, on disclosures in connection with primary offerings (collectively, the ''proposed rule change''). The proposed rule change was published for comment in the **Federal Register** on November 18, 2016.[3]

The Commission received five comment letters on the proposed rule change.[4] On January 10, 2017, the MSRB responded to the comments received by the Commission [5] and filed Amendment No. 1 to the proposed rule change (''Amendment No. 1'').[6] The Commission is publishing this notice to solicit comments on Amendment No. 1 to the proposed rule change from interested persons and is approving the proposed rule change, as modified by Amendment No. 1, on an accelerated basis.

II. Description of Proposed Rule Change

The proposed rule change, as modified by Amendment No. 1, consists of (i) proposed amendments to Rule G–10, on delivery of investor brochure, Rule G–8, on books and records to be made by brokers, dealers, and municipal securities dealers and municipal advisors, and Rule G–9, on preservation of records, and (ii) a proposed MSRB notice regarding electronic delivery and receipt of information by municipal advisors under Rule G–32, on disclosures in connection with primary offerings.[7]

Following the financial crisis of 2008, Congress enacted the Dodd-Frank Wall Street Reform and Consumer Protection Act (the ''Dodd-Frank Act'').[8] The Dodd-Frank Act amended Section 15B of the Exchange Act to establish a new federal regulatory regime requiring municipal advisors to register with the Commission, deeming them to owe a fiduciary duty to their municipal entity clients and granting the MSRB rulemaking authority over them. The MSRB, in the exercise of that rulemaking authority, has been developing a comprehensive regulatory framework for municipal advisors and their associated persons.[9]

Further, and concurrent with its efforts to develop a comprehensive regulatory framework for municipal advisors and their associated persons, the MSRB initiated a review of its rules and related interpretive guidance for brokers, dealers and municipal securities dealers (collectively, ''dealers'') and municipal advisors (municipal advisors, together with dealers, ''regulated entities''). The MSRB initiated that review in the context of the Board's obligation to protect investors, municipal entities, obligated persons, and the public interest. As part of that review, the MSRB solicited comments from market participants.[10] In response, market participants recommended that the Board update Rule G–10.[11] The MSRB has stated that the proposed rule change, as modified by Amendment No. 1, consisting of amendments to Rule G–10 and its related recordkeeping rules, Rules G–8 and G–9, and guidance under Rule G–32, is an important element of both MSRB regulatory initiatives.[12]

To extend its customer complaint and recordkeeping rules to municipal advisors and to modernize those rules, the Board filed the proposed rule change, as modified by Amendment No. 1, with the Commission. Specifically,

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[21] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Securities Exchange Act Release No. 79295 (November 14, 2016) (the ''Notice of Filing''), 81 FR 81837 (November 18, 2016).

[4] *See* Letters to Secretary, Commission, from Mike Nicholas, Chief Executive Officer, Bond Dealers of America (''BDA''), dated December 9, 2016 (the ''BDA Letter''); Matthew J. Gavaghan, Associate General Counsel, Janney Montgomery Scott LLC (''Janney''), dated December 9, 2016 (the ''Janney Letter''); Marnie Lambert, President, Public Investors Arbitration Bar Association (''PIABA''), dated December 9, 2016 (the ''PIABA Letter''); Susan Gaffney, Executive Director, National Association of Municipal Advisors (''NAMA''), dated December 12, 2016 (the ''NAMA Letter''); and Leo Karwejna, Chief Compliance Officer and Cheryl Maddox, General Counsel, Public Financial Management, Inc. and PFM Financial Advisors LLC (collectively, ''PFM''), dated December 13, 2016 (the ''PFM Letter'').

[5] *See* Letter to Secretary, Commission, from Pamela K. Ellis, Associate General Counsel, MSRB, dated January 10, 2017 (the ''MSRB Response Letter''), available at *https://www.sec.gov/comments/sr-msrb-2016-15/msrb201615-1473509-130471.pdf*.

[6] *See* Letter to Secretary, Commission, from Pamela K. Ellis, Associate General Counsel, MSRB, dated January 10, 2017, available at *https://www.sec.gov/comments/sr-msrb-2016-15/msrb201615-1473522-130450.pdf*. In Amendment No. 1, the MSRB partially amended the text of the proposed rule change to provide certain clarifications relating to the notifications that would be provided by municipal advisors to their municipal advisory clients and to the terms used with the recordkeeping of municipal advisory client complaints, to extend the proposed effective date, and to make other technical changes to clarify or simplify rule text.

[7] *See* Notice of Filing.

[8] Public Law No. 111–203, 124 Stat. 1376 (2010).

[9] MSRB Rule D–11 defines ''associated persons'' as follows:

> Unless the context otherwise requires or a rule of the Board otherwise specifically provides, the terms ''broker,'' ''dealer,'' ''municipal securities broker,'' ''municipal securities dealer,'' ''bank dealer,'' and ''municipal advisor'' shall refer to and include their respective associated persons. Unless otherwise specified, persons whose functions are solely clerical or ministerial shall not be considered associated persons for purposes of the Board's rules.

[10] MSRB Notice 2012–63, Request for Comment on MSRB Rules and Interpretive Guidance (Dec. 18, 2012).

[11] *See, e.g.,* Letter from David L. Cohen, Managing Director and Associate General Counsel, Securities Industry and Financial Markets Association, dated February 19, 2013, to Ronald W. Smith, Corporate Secretary, Municipal Securities Rulemaking Board (commenting that (i) the requirement to deliver an investor brochure under Rule G–10 should be eliminated, (ii) the investor brochure is of limited value, if any, to institutional investors as well as investors in municipal fund securities, and (iii) alternatively, the MSRB could accomplish the objective of Rule G–10 by posting the investor brochure on its Web site); Letter from Gerald K. Mayfield, Senior Counsel, Wells Fargo & Company Law Department, dated February 19, 2013, to Ronald W. Smith, Corporate Secretary, Municipal Securities Rulemaking Board (commenting that (i) the requirement to deliver an investor brochure under Rule G–10 should be eliminated, (ii) the investor brochure is of limited value, if any, to institutional investors as well as investors in municipal fund securities, and (iii) alternatively, the MSRB could accomplish the objective of Rule G–10 by posting the investor brochure on its Web site).

[12] *See* Notice of Filing.

the proposed rule change would (i) extend the Board's customer complaint recordkeeping requirements to all municipal advisors (*i.e.,* non-solicitor and solicitor municipal advisors) as well as align those recordkeeping requirements more closely with the customer complaint recordkeeping requirements of other financial regulators, (ii) require that all regulated entities retain their customer or municipal advisory client [13] complaint records for six years, (iii) overhaul Rule G–10 so that the rule would more closely focus on customer and municipal advisory client education and protection as well as align that rule with customer education and protection rules of other financial regulators, and (iv) extend the Board's guidance under Rule G–32, Notice Regarding Electronic Delivery and Receipt of Information by Brokers, Dealers and Municipal Securities Dealers (Nov. 20, 1998) (the ''1998 Notice''), to municipal advisors.

In summary, by regulated entity, the proposed rule change, as modified by Amendment No. 1, would do the following:

Municipal Advisors

- amend Rule G–8 to exclude municipal advisors from the definition of ''customers;''
- amend Rule G–8 to include the definition of ''municipal advisory client;''
- amend Rule G–8 to extend the requirements that are similar to the rule's customer complaint recordkeeping requirements to municipal advisory client complaint recordkeeping;
- amend Rule G–8 to provide guidance in supplementary material that would define electronic recordkeeping;
- amend Rule G–8 to provide guidance in supplementary material that would remind a municipal advisor that it may be required to promptly report certain municipal advisory client complaints to other regulatory authorities;
- amend Rule G–9 to require that the records of municipal advisory client complaints be kept for at least six years;
- amend Rule G–10 to extend requirements that are similar to the rule's dealer customer protection and education requirements to municipal advisory client protection and education; and
- extend to municipal advisors, under Rule G–32, the guidance provided by the 1998 Notice, as relevant.

Dealers

- Amend Rule G–8 to require that dealers keep a standardized complaint log electronically, using product and problem codes tailored for municipal securities, to document the written complaints of customers;
- amend Rule G–8 to define written customer complaints to include complaints received electronically by the dealer;
- amend Rule G–8 to provide guidance in supplementary material that would define electronic recordkeeping;
- amend Rule G–8 to provide guidance in supplementary material that would remind a dealer that it may be required to promptly report certain written customer complaints to other regulatory authorities; and
- amend Rule G–10 in its entirety so that the rule would more clearly focus on customer protection and education.

A detailed rule discussion of the proposed rule change's recordkeeping requirements, customer and municipal advisory client education and protection requirements, and electronic delivery guidance to municipal advisors is contained in the Notice of Filing.

The MSRB requested in the Notice of Filing that the proposed rule change be approved with an implementation date of six months after the Commission approval date for all changes.[14] Pursuant to Amendment No. 1, the MSRB now requests that the proposed rule change be approved with an implementation date of nine months after the Commission approval date for all changes.[15]

III. Summary of Comments Received and MSRB's Responses to Comments

As noted previously, the Commission received five comment letters on the proposed rule change, and the MSRB Response Letter. Commenters generally expressed support for the principles behind the proposed rule change, but also expressed various concerns or suggested revisions.

1. Effective Date

BDA urged that the MSRB provide at least 12 months, rather than the six months proposed in the Notice of Filing, to provide dealers with adequate time for implementation, especially given the resources required to implement other ongoing regulatory initiatives.[16] The MSRB acknowledged that those other regulatory initiatives require significant attention by compliance and technology staff. In response, the MSRB, pursuant to Amendment No. 1, proposes an effective date of nine months after the Commission's approval date of all changes.[17]

2. Municipal Advisor Terms

NAMA suggested that certain terms used in the proposed amendments to Rule G–8 be revised to more closely reflect terms more commonly used by municipal advisors. In particular, NAMA noted that the proposed rulemaking refers to a municipal advisory client's ''account.'' [18] NAMA stated that such a phrase does not ''translate'' to municipal advisors. In response, the MSRB, pursuant to Amendment No. 1, proposes to replace ''account'' when used with a municipal advisory client with the phrase ''number or code, if any.'' [19]

3. Customer and Municipal Advisory Client Brochures

PIABA supported giving investors information about the protections provided by the MSRB and about how to file a complaint with a regulator, noting that the proposed amendments to Rule G–10 would provide for the education of customers or municipal advisory clients before they encounter a problem.[20] PFM submitted that the ''proposed Rules . . . unnecessarily impose undue encumbrances of additional brochure delivery.'' [21] BDA also requested clarity about when a municipal advisor should send the investor brochure to a municipal advisory client, and suggested that it was not necessary to send the investor brochure to an institutional investor. BDA suggested that the Board should develop a brochure that focuses on municipal advisory clients.[22] NAMA and PFM commented that they needed

[13] The proposed rule change, as amended by Amendment No. 1, in Rule G–8(e)(ii), would define a municipal advisory client as either a municipal entity or obligated person for whom the municipal advisor engages in municipal advisory activities as defined in MSRB Rule G–42(f)(iv), or a broker, dealer, municipal securities dealer, municipal advisor, or investment adviser (as defined in section 202 of the Investment Advisers Act of 1940) on behalf of whom the municipal advisor undertakes a solicitation of a municipal entity or obligated person, as defined in Rule 15Ba1–1(n), 17 CFR 240.15Ba1–1(n), under the Act.

[14] *See* Notice of Filing.

[15] *See* Amendment No. 1.

[16] *See* BDA Letter.

[17] *See* MSRB Response Letter.

[18] *See* NAMA Letter.

[19] *See* MSRB Response Letter.

[20] *See* PIABA Letter.

[21] *See* PFM Letter.

[22] BDA states that it ''requests clarity with when a municipal advisor should send the G–10 brochure to a municipal advisory client.'' BDA also stated that ''[i]f the MSRB is committed to requiring dealers to send the investor brochure to institutional investors, BDA recommends that MSRB provide clarity on 'customer' for the purposes of G–10.'' *See* BDA Letter.

to review the brochure to provide sufficient comment.[23]

The MSRB responded by stating that, unlike the current requirements of Rule G–10, the proposed amendments to Rule G–10 would not require that a regulated entity deliver a Rule G–10 brochure to its customer or municipal advisory client, but would require that a regulated entity provide only annual notifications to its customer or municipal advisory client about the availability of the brochure on the MSRB's Web site.[24] Further, after carefully considering BDA's request for clarity regarding the use of the term ''promptly'' relating to when a municipal advisor must send the annual notifications required by the amendments to Rule G–10 to its municipal advisory client, the MSRB provided a technical change in Amendment No. 1 to clarify that ''promptly'' means ''promptly, after the establishment of a municipal advisory relationship.'' [25] Although municipal advisors may elect to provide the first notification earlier, the MSRB believes this standard is consistent with the flexibility provided by the proposed rule change to include the proposed annual notifications with other materials required to be given by municipal advisors.[26]

The MSRB further states that it believes that all customers and municipal advisory clients should be aware of the important protections provided by the MSRB's rules, the reminder that regulated entities are registered with the Commission, and the information about how to file a complaint with a regulator. Rule G–10 currently provides no exception from its requirements for institutional investors, and the MSRB believes that there is no reason why institutional investors should receive less of this information about the protections provided by MSRB rules and education than other investors.[27] As discussed in the Notice of Filing, the MSRB believes that the annual notifications required by Rule G–10 present only a slight burden to regulated entities, but could represent a significant enhancement to customer or municipal advisory client protection and education.[28]

The MSRB agrees with BDA's view that the Board should use a separate brochure focused on municipal advisory activities. The Notice of Filing contemplated a separate brochure focused on municipal advisory activities, and the MSRB has stated that it will develop such a brochure.[29] However, the MSRB notes that the content of the current investor brochure was not made part of Rule G–10. Likewise, the content of the future brochures has not been made part of the proposed amendment text.

4. Product and Problem Codes

BDA, Janney, NAMA and PFM commented on the problem and product codes that would be required by the proposed amendments to Rule G–8 for the electronic customer or municipal advisory client complaint logs.[30] BDA and Janney commented that such codes should harmonize with the problem and product codes required by FINRA Rule 4530. BDA also commented that it believed that the MSRB and the Commission have existing independent reporting systems that allow municipal entities or obligated persons to file complaints directly to a regulator, which are more appropriate systems to monitor complaints than the MSRB developing an ''expansive set of problem codes.'' BDA, NAMA, and PFM urged that the Board publish the product and problem codes for comment.[31]

The MSRB notes that it coordinates its rule interpretations and requirements with those of other financial regulators, including FINRA. This coordination has been and is occurring on an ongoing basis with respect to the product and problem codes. The MSRB is aware that having two different sets of compliance codes for dually registered regulated entities would impose significant compliance and cost burdens, and to lessen such burdens, the MSRB states that it would coordinate and harmonize the product and problem codes, and the methods for determining the appropriate codes, required by the proposed amendments to Rule G–8 with FINRA.[32]

In response to BDA's comment that the MSRB and the SEC have existing independent reporting systems that allow municipal entities or obligated persons to file complaints directly with a regulator, the MSRB states that its complaint referral system is quite different than, for example, the Commission's well-established and comprehensive independent reporting system through its Office of Investor Education and Advocacy. The MSRB notes that its role has been to provide information about how an individual or firm may make a complaint to a regulator. If an individual or a regulated entity is unsure about which regulator the individual or firm should file the complaint with, that individual or firm may submit the complaint with the MSRB, and the MSRB then will forward the complaint to the appropriate regulator. The MSRB states that, unlike the Commission, the MSRB neither enforces its own rules nor surveils regulated entities; rather, other financial regulators enforce MSRB rules and perform market surveillance functions.[33] The MSRB further notes that other financial regulators subject to the Commission's jurisdiction, such as FINRA, currently require that written customer complaints be tracked using an electronic log. In approving FINRA Rule 4530, the Commission found that the FINRA Rule 4530 was consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities association.[34]

As to the assertion that the electronic complaint log represents overregulation by the MSRB, the MSRB notes that dealers that are registered with FINRA are currently using electronic logs to track and code written customer complaints. The MSRB believes that the electronic complaint log requirement not only would assist regulators in enforcing MSRB rules and performing market surveillance, but also that the electronic complaint log would be used as a tool by regulated entities as part of their risk management programs. The MSRB believes that FINRA, the Commission, and numerous FINRA members, including members that are also registered with the MSRB, have found such electronic complaint logs to be valuable.[35]

The MSRB states that federal securities laws do not require that the Board solicit public comment on the product and problem codes to be used under the proposed amendments to Rule G–8. The MSRB notes that FINRA recently revised its product and problem codes used for reporting customer complaints under FINRA Rule 4530.[36] FINRA did not seek public comment on the revisions to those product and problem codes; the Board

[23] *See* NAMA Letter, PFM Letter.

[24] *See* MSRB Response Letter.

[25] *Id.*

[26] *Id.*

[27] *Id.*

[28] *See* Notice of Filing.

[29] *See* MSRB Response Letter.

[30] *See* BDA Letter, NAMA Letter, Janney Letter, PFM Letter.

[31] *See* BDA Letter, NAMA Letter, PFM Letter.

[32] *See* MSRB Response Letter.

[33] *Id.*

[34] Securities Exchange Act Release No. 63260 (Nov. 5, 2010), 75 FR 69508 (Nov. 12, 2010).

[35] *See* MSRB Response Letter.

[36] In 2014, FINRA updated FINRA Rule 4530's problem and product codes and provided a six-month implementation date. *See* Regulatory Notice 14–20 (May 7, 2014).

would not expect to seek public comment on the product and problem codes to be used with the proposed amendments to Rule G–8.[37]

5. Recordkeeping

BDA, NAMA, PIABA, and PFM provided comments and suggestions about the Board's proposed amendments to Rule G–8.[38] Those comments and suggestions related to the regulatory burden caused by the proposed amendments to Rule G–8, guidance as to certain of the terms used in the electronic complaint log, and guidance as to the development of the electronic complaint log itself.

PFM asserted that the proposed rule change ''unnecessarily impose[s] undue encumbrances of additional brochure delivery and recordkeeping requirements.'' [39] BDA submitted that it did not think that this type of ''complaint and recordkeeping system is valuable for municipal advisory clients,'' [40] and NAMA asserted that the recording of ''actions'' in the electronic complaint log required by the proposed amendments to Rule G–8 is not necessary because of the supervisory requirements set forth in MSRB Rule G–44.[41]

The MSRB states that it believes that the burden on regulated entities from the proposed rule change would not be significant.[42] The proposed rule change would align Rule G–8 with the customer complaint recordkeeping requirements of other financial regulators. Rule 17a–3(a)(18) under the Act [43] and FINRA Rules 4513 and 4530 require information about customer complaints that is similar to what is required by the proposed rule change. The MSRB has stated that it would harmonize its product and problem codes with those required by FINRA Rule 4530.[44]

Although the proposed rule change would represent a new recordkeeping burden on municipal advisors, the MSRB believes that it would not be a significant burden. The MSRB states that it is generally a good business practice, especially for the development of a regulated entity's risk management systems, to track written complaints using standard codes in an electronic complaint log. Any regulatory burden imposed by the proposed rulemaking is, in part, dependent upon the municipal advisor and the number of municipal advisory client complaints that the municipal advisor receives. The MSRB anticipates that smaller municipal advisors would have fewer clients and accordingly may be likely to receive fewer complaints than larger municipal advisors. Further, the MSRB states that it mitigates that regulatory burden by providing flexibility as to how those electronic records may be kept.[45]

The MSRB believes that an electronic log of complaints is necessary, and that such need is not lessened by the supervisory and compliance obligations of municipal advisors set forth in MSRB Rule G–44. The standard electronic format required by the proposed amendments would enhance the ability of financial regulators to conduct more cost-effective and efficient inspections and surveillance of regulated entities. MSRB Rule G–44 does not require that records of complaints be kept in a standard electronic format across all regulated entities. Further, the MSRB notes that many dealers that have been subject to MSRB Rule G–27, on supervision, a rule that is similar to MSRB Rule G–44, also have been subject to FINRA's electronic customer complaint recordkeeping requirements. The MSRB believes that the FINRA electronic customer complaint log requirements have proven useful in addition to general supervisory obligations.[46]

NAMA requested guidance about the meaning of certain terms to be used in the electronic complaint log.[47] The MSRB believes that the titles of the codes, as well as the brief description of those codes published by the Board, as appropriate, will provide guidance as to the terms used with the electronic complaint log. Further, as discussed above under ''Product and Problem Codes,'' the MSRB would harmonize the product and problem terms used for the electronic log of customer and municipal advisory client complaints with the codes required by FINRA Rule 4530.[48]

NAMA requested guidance as to how a municipal advisor should create an electronic complaint log. The MSRB notes that Proposed Supplementary Material .01 broadly defines electronic format to include ''any computer software program that is used for storing, organizing and/or manipulating data that can be provided promptly upon request to a regulatory authority.'' [49] The MSRB states that it has determined that the degree of flexibility the MSRB is providing with the proposed rule change about the format of the electronic complaint log is preferable at this juncture.[50]

NAMA and PFM commented about the municipal advisor record retention requirements set forth in the proposed amendments to Rule G–9. NAMA commented that municipal advisor records should be kept for five years and not six years.[51] PFM commented that the Board lacked statutory authority to extend the record retention period for municipal advisors for one year and expressed ''genuine concern regarding the misalignment regarding the proposed MSRB Rule changes and current Exchange Act requirements.'' [52]

After carefully considering the comments, the MSRB states that it has determined that the important reasons for retaining records of municipal advisory client complaints for six years remain valid. As discussed in the Notice of Filing, such retention period would assist other financial regulators with their inspections of municipal advisors (those inspections may not occur for several years after the municipal advisory client submitted the complaint) and with their surveillance of municipal advisors. Further, by requiring that municipal advisors retain records of municipal advisory client complaints for six years, the MSRB states that it would be ''leveling the playing field'' between dealers and municipal advisors and between dealer municipal advisors and non-dealer municipal advisors.[53] Dealers, including dealer municipal advisors, are required to retain records of customer complaints for six years under current Board rules.

The MSRB states that it disagrees with PFM's assertions that the Board lacks statutory authority to develop a record retention period under the Act for municipal advisor records. The MSRB notes that Section 15B(b)(2)(g) of the Act [54] specifically requires that the MSRB prescribe the records that are to be made and kept by dealers and municipal advisors and to prescribe the length of time the records are to be kept. The MSRB further notes that the Commission has approved as consistent with the Exchange Act the MSRB's several previous municipal advisor

[37] *See* MSRB Response Letter.

[38] *See* BDA Letter, NAMA Letter, PIABA Letter, PFM letter.

[39] *See* PFM Letter.

[40] *See* BDA Letter.

[41] *See* NAMA Letter.

[42] *See* MSRB Response Letter.

[43] 17 CFR 240.19b–4.

[44] *See* MSRB Response Letter.

[45] *Id.*

[46] *Id.*

[47] *See* NAMA Letter.

[48] *See* MSRB Response Letter.

[49] *See* Notice of Filing and Amendment No. 1.

[50] *See* MSRB Response Letter.

[51] *See* NAMA Letter.

[52] *See* PFM Letter.

[53] *See* MSRB Response Letter.

[54] 15 U.S.C. 78*o*–4(b)(2)(g).

recordkeeping proposals, including select six-year retention periods.[55]

6. Annual Notifications

The Commission received several comments about the annual notifications concerning the municipal advisor's registration, the MSRB's Web site address, and availability of a municipal advisory client brochure about the protections provided by the MSRB's rules and information about filing a complaint with a financial regulator required by the proposed amendments to Rule G–10 (the ''annual notifications''). Those comments concerned the location of those annual notifications and the ability to include the annual notifications with other materials. NAMA suggested that in lieu of providing the written annual notifications to their municipal advisory clients, municipal advisors should have the option to post the annual notifications on their Web sites.[56] NAMA and PFM[57] suggested that the annual notifications be included with the written disclosure of all material conflicts of interest and other information required to be made by a municipal advisor by Rule G–42(b).[58]

The MSRB states that it has carefully considered commenters' suggestions, and has determined that a municipal advisor should not have the option to post the annual notifications on its Web site in lieu of sending those notifications to its municipal advisory client. The Board believes that the purpose of the proposed amendments is best achieved by individual annual notifications to a customer or municipal advisor client. Nonetheless, if a regulated entity would like to post the annual notifications on its Web site, in addition to sending the written annual notifications to its customers or municipal advisory clients, the regulated entity may do so as long as the information on the regulated entity's Web site complies with Board and any other applicable laws, rules and regulations.[59]

As proposed, the amendments to Rule G–10 would provide a regulated entity with the flexibility to include the written annual notifications with other materials. The MSRB notes that those other materials may include the written disclosure of material conflicts of interest and other information required to be provided by a municipal advisor under MSRB Rule G–42(b). Because the proposed rule change would provide municipal advisors with the option to include the annual notifications with the written disclosure of material conflicts of interest and other information required by MSRB Rule G–42(b), the MSRB believes that the rule language, as proposed, provides sufficient flexibility to address NAMA's and PFM's suggestion that the annual notifications be included with the written disclosures required under Rule G–42(b).[60]

7. Sufficiency of Comment Period

BDA, NAMA, and PFM commented that the Board did not solicit public comment on the proposed rule change before the Board filed the proposed rule change with the Commission.[61] BDA submitted that the MSRB is proceeding with ''unnecessary haste'' and that if the MSRB issued a request for comment on the proposed rule change, it could have ''received feedback and tailored these rule amendments to the activities of municipal advisors.''[62] NAMA commented that the municipal advisor community should be afforded the same opportunity to comment prior to a proposal being sent to the Commission that the dealer community is afforded and submitted that municipal advisors would have flagged some of the vague and duplicative provisions of the proposed rulemaking as well as use of clearly inapplicable terminology.[63] PFM stated that it was ''a bit dismayed'' that the MSRB did not publish a request for comment before filing the proposed rule change with the Commission, and suggested that without such a prior comment opportunity, PFM did not have ''adequate opportunity for review and written comment.''[64]

The MSRB responds that the Commission provided market participants with the fulsome comment period generally required under the federal securities laws, which do not require the Board to seek public comment before submitting a rulemaking proposal to the Commission.[65] Market participants provided comment on the proposed rule change, and as noted earlier, in response to those comments, the Board is filing Amendment No. 1.

Further, the MSRB notes that, in this case, not only did market participants request the proposed rule change, but every commenter supported the purposes of the proposed rule change. The proposed rule change would enhance the MSRB's ability to protect and educate customers and municipal advisory clients, which protections are vital to the Board's mission. The proposed rule change also would harmonize the Board's customer complaint rule with that of other financial regulators—a goal that is important both to the Board and to market participants.[66]

8. Electronic Guidance

BDA commented that the MSRB's Notice Regarding Electronic Delivery and Receipt of Information by Brokers, Dealers and Municipal Securities Dealers—November 20, 1998 (the ''1998 Notice'') should not apply to municipal advisory relationships. BDA stated that ''[a]s with attorney-client relationships . . ., municipal entities and obligated persons know exactly how they prefer to communicate and there is no need for a Federal regulator to regulate electronic communications in those relationships.''[67]

The MSRB stated that the 1998 Notice provides dealers with the MSRB's interpretation about the use of electronic media to deliver and receive information under Board rules. The proposed rule change would extend that interpretation to municipal advisors. Without that extension, some vagueness might exist regarding municipal advisors' ability to use electronic media to deliver and receive information required under Board rules.[68]

9. Other Comments

The other suggestions that the Commission received about the proposed rule change related to (i) expansion of the proposed rule change, (ii) concerns about the complaint process, and (iii) concerns about the economic impact of the proposed rule change on small municipal advisors. PIABA supported the proposed rule change, but also suggested that the

[55] *See, e.g.,* Exchange Act Release No. 76753 (Dec. 23, 2015), 80 FR 81614 (Dec. 30, 2015) (approving Rule G–42 and amendments to Rule G–8); Exchange Act Release No. 73415 (Oct. 23, 2014), 79 FR 64423 (Oct. 29, 2014) (approving Rule G–44 and amendments to Rules G–8 and G–9).

[56] *See* NAMA Letter.

[57] *See* NAMA Letter, PFM Letter.

[58] Rule G–42(b) provides, in part: ''*Disclosure of Conflicts of Interest and Other Information.* A municipal advisor must, prior to or upon engaging in municipal advisory activities, provide to the municipal entity or obligated person client full and fair disclosure in writing of:

(i) all material conflicts of interest . . . [and]

(ii) any legal or disciplinary event that is material to the client's evaluation of the municipal advisor or the integrity of its management or advisory personnel. . . .''

[59] *See* MSRB Response Letter.

[60] *Id.*

[61] *See* BDA Letter, NAMA Letter, PFM Letter.

[62] *See* BDA Letter.

[63] *See* NAMA Letter.

[64] *See* PFM Letter.

[65] *See* MSRB Response Letter.

[66] *Id.*

[67] *See* BDA Letter.

[68] *See* MSRB Response Letter.

proposed rule change ''go a step further'' to provide investors with access to the electronic complaint logs.[69] NAMA expressed concern that the proposed rule change would require that a municipal advisory client make its complaint directly with the municipal advisor instead of with a regulator. NAMA also suggested that the Board consider the economic impact of the proposed rule change, and the cumulative effect of all Board rules on small municipal advisors.[70]

The MSRB states that it recognizes that market transparency is important for investors. However, the MSRB is concerned that requiring electronic complaint logs to be available to customers and municipal advisory clients may not only mislead them because certain complaints may not be as material as others, but also may have a chilling effect on a regulated entity's reporting of written customer or client complaints, which could undermine the goals of the rule.[71]

In addition, the proposed amendments to Rule G–10 do not set forth any requirement that a municipal advisory client make a complaint to its municipal advisor nor do those proposed amendments require that a municipal advisory client submit any complaint that it may have to a particular regulator. A municipal advisory client would continue to be able to submit its complaint to any party it considers appropriate, based on, among other things, the notifications and educational materials it receives.[72]

Further, in connection with concerns about the economic impact of the proposed rule change on small municipal advisors, the MSRB states that it anticipates that smaller municipal advisors would have fewer clients and accordingly may be likely to receive fewer complaints than larger municipal advisors.[73] Further, the MSRB states that it mitigates that regulatory burden by providing flexibility as to how those electronic records may be kept.[74]

IV. Discussion and Commission Findings

The Commission has carefully considered the proposed rule change, as modified by Amendment No. 1, the comments letters received, and the MSRB Response Letter. The Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to the MSRB.

In particular, the proposed rule change, as modified by Amendment No.1, is consistent with Sections 15B(b)(2) and 15B(b)(2)(C) of the Act.[75] Section 15B(b)(2) of the Act provides that the MSRB shall propose and adopt rules to effect the purposes of that title with respect to transactions in municipal securities effected by brokers, dealers, and municipal securities dealers and advice provided to or on behalf of municipal entities or obligated persons by brokers, dealers, municipal securities dealers, and municipal advisors with respect to municipal financial products, the issuance of municipal securities, and solicitations of municipal entities or obligated persons undertaken by brokers, dealers, municipal securities dealers and municipal advisors.[76] Section 15B(b)(2)(C) of the Act, provides that, among other things, the rules of the MSRB shall be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in municipal securities and municipal financial products, to remove impediments to and perfect the mechanism of a free and open market in municipal securities and municipal financial products, and, in general, to protect investors, municipal entities, obligated persons, and the public interest.[77] The Commission believes that the proposed rule change is reasonably designed to prevent fraudulent and manipulative practices, promote just and equitable principles of trade, foster cooperation and coordination with persons engaged in regulating transactions in municipal securities and municipal financial products, and protect investors, municipal entities, obligated persons and the public interest by developing more comprehensive and modern customer and municipal advisory client complaint and recordkeeping rules. Furthermore, the Commission believes that by focusing on customer and municipal advisory client education and protection and enhancing the related recordkeeping requirements, the proposed rule change is reasonably designed to protect investors, municipal entities, obligated persons, and the public interest. Additionally, the proposed rule change would align the MSRB's customer and municipal advisory client complaint rules and related recordkeeping requirements with those of other financial regulators which will, among other things, promote compliance with MSRB rules by providing regulated entities with the opportunity to streamline their compliance procedures. In addition, the proposed rule change, according to the MSRB, would enhance the ability of other financial regulators to conduct more cost-effective and efficient inspections and surveillance of regulated entities.

The Commission also finds that the proposed rule change, as modified by Amendment No.1, is consistent with Section 15B(b)(2)(L)(iv) of the Act in that it does not impose a regulatory burden on small municipal advisors that is not necessary or appropriate in the public interest and for the protection of investors, municipal entities, and obligated persons, provided that there is robust protection of investors against fraud.[78] Although the proposed rule change would affect all municipal advisors, including small municipal advisors, the proposed rule change is a necessary and appropriate regulatory burden in order to protect municipal entities and obligated persons. For example, under the proposed rule change, a municipal advisory client would be able to receive detailed and relevant information about its municipal advisor, the protections provided by MSRB rules, and how to make a complaint in a timely and consistent fashion.

The Commission also finds that the proposed rule change, as modified by Amendment No.1, is consistent with Section 15B(b)(2)(G) of the Act which provides that the MSRB's rules shall prescribe records to be made and kept by municipal securities brokers, municipal securities dealers, and municipal advisors and the periods for which such records shall be preserved.[79] The proposed rule change would, among other things, enhance the current customer complaint recordkeeping requirements under Rule G–8 by requiring that dealers keep more detailed information about written customer complaints in an electronic format and then would extend those recordkeeping requirements to municipal advisors. In addition, the proposed rule change would extend the

[69] *See* PIABA Letter.

[70] *See* NAMA Letter.

[71] *See* MSRB Response Letter.

[72] *Id.*

[73] *See* MSRB Response Letter.

[74] *Id.*

[75] 15 U.S.C. 78*o*–4(b)(2) and (b)(2)(C).

[76] 15 U.S.C. 78*o*–4(b)(2).

[77] 15 U.S.C. 78*o*–4(b)(2)(C).

[78] 15 U.S.C. 78*o*–4(b)(2)(L)(iv).

[79] 15 U.S.C. 78*o*–4(b)(2)(G).

six-year record retention period applicable to customer complaints to municipal advisory client complaints.

In approving the proposed rule change, as modified by Amendment No.1, the Commission has also considered the impact of the proposed rule change on efficiency, competition, and capital formation.[80] The Commission does not believe that the proposed rule change, as modified by Amendment No. 1 would impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

For the reasons noted above, the Commission believes that the proposed rule change, as modified by Amendment No. 1, is consistent with the Act.

V. Solicitation of Comments on Amendment No. 1

Interested persons are invited to submit written data, views, and arguments concerning Amendment No. 1, including whether the proposed rule change, as modified by Amendment No.1, is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–MSRB–2016–15 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549.

All submissions should refer to File Number SR–MSRB–2016–15. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the MSRB. 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–MSRB–2016–15 and should be submitted on or before February 13, 2017.

VI. Accelerated Approval of Proposed Rule Change as Modified by Amendment No. 1

The Commission finds good cause to approve the proposed rule change, as modified by Amendment No. 1, prior to the 30th day after the date of publication of Amendment No. 1 in the **Federal Register.** As discussed above, Amendment No. 1 partially amends the text of the proposed rule change to provide certain clarifications relating to the notifications that would be provided by municipal advisors to their municipal advisory clients and to the terms used with the recordkeeping of municipal advisory client complaints, to extend the proposed effective date, and to make other technical changes to clarify or simplify rule text.[81] Specifically, the changes respond to commenters' concerns, are technical in nature, and clarify or simplify the proposed rule change. The MSRB states that Amendment No. 1 in many respects eliminates unnecessary language by relying on terms that are defined in the MSRB's rule book, the Act, or Commission rules under the Act.[82] In addition, the MSRB notes that the changes are consistent with the purposes of the proposed rule change to advance the development of a comprehensive regulatory framework for municipal advisors and to update the Board's customer complaint rules. With respect to those portions of Amendment No. 1 that modify certain definitions, the MSRB notes that the proposed rule change, as described in the Notice of Filing, contemplated that the clients of both solicitor and non-solicitor municipal advisors would be covered by the proposed rule change.[83] According to the MSRB, the precision added to certain definitions by Amendment No. 1 parallels the precision with which the MSRB defines a municipal advisory client of a solicitor municipal advisor and eliminates unnecessary language.[84] The MSRB believes other technical changes made serve to clarify or simplify the proposed rule change.

For the foregoing reasons, the Commission finds good cause for approving the proposed rule change, as modified by Amendment No. 1, on an accelerated basis, pursuant to Section 19(b)(2) of the Act.

VII. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[85] that the proposed rule change, as modified by Amendment No. 1 (SR–MSRB–2016–15) be, and hereby is, approved on an accelerated basis.

For the Commission, pursuant to delegated authority.[86]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–01300 Filed 1–19–17; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–79796; File No. SR–C2–2017–003]

Self-Regulatory Organizations; C2 Options Exchange, Incorporated; Notice of Filing and Immediate Effectiveness of a Proposed Rule To Amend the Fees Schedule

January 13, 2017.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on January 3, 2017, C2 Options Exchange, Incorporated (the ''Exchange'' or ''C2'') 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 proposes to amend its Fees Schedule. The text of the proposed rule change is available on the Exchange's Web site (*http://*

[80] 15 U.S.C. 78c(f).

[81] *Supra* note 6.

[82] *See* Amendment No. 1.

[83] *See* Notice of Filing.

[84] *See* Amendment No. 1.

[85] 15 U.S.C. 78s(b)(2).

[86] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

www.c2exchange.com/Legal/), 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 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 Exchange proposes to amend its Fees Schedule. Specifically, the Exchange proposes to increase the fees charged for a CMI Login ID and FIX Login ID. The Exchange currently assesses $500 per Login ID, per month for CMI Login IDs and FIX Login IDs. The Exchange has expended significant resources setting up, providing and maintaining this connectivity and has ongoing and increasing costs associated with maintaining connectivity. The Exchange desires to recoup such costs and as such, proposes to increase the monthly fees from $500 per Login ID, per month to $550 per Login ID, per month.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[3] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[4] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with Section 6(b)(4) of the Act,[5] which requires that Exchange rules provide for the equitable allocation of reasonable dues, fees, and other charges among its Trading Permit Holders and other persons using its facilities.

The Exchange believes increasing the CMI Login ID and FIX Login ID fees is reasonable because the Exchange desires to recoup increasing costs associated with maintaining connectivity to C2. The Exchange believes it's equitable and not unfairly discriminatory because all Permit Holders will be assessed the same amount for Login ID fees.

B. Self-Regulatory Organization's Statement on Burden on Competition

C2 does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe that the proposed rule change will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because all Permit Holders will be assessed the same Login ID fees and because the increased fee will help the Exchange recoup costs associated with maintaining connectivity to the Exchange. The Exchange does not believe that the proposed change will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because it only applies to trading on the Exchange. Should the proposed change make C2 a more attractive trading venue for market participants at other exchanges, such market participants may elect to become market participants at C2.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[6] and paragraph (f) of Rule 19b–4[7] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml);* or
- Send an email to *rule-comments@sec.gov. Please include File Number SR–C2–2017–003 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–C2–2017–003. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml).* Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments

[3] 15 U.S.C. 78f(b).

[4] 15 U.S.C. 78f(b)(5).

[5] 15 U.S.C. 78f(b)(4).

[6] 15 U.S.C. 78s(b)(3)(A).

[7] 17 CFR 240.19b–4(f).

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–C2–2017–003 and should be submitted on or before February 13, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[8]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–01298 Filed 1–19–17; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–79800; File No. SR–ISEGemini–2017–01]

Self-Regulatory Organizations; ISE Gemini, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Schedule of Fees

January 13, 2017.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on January 3, 2017, ISE Gemini, LLC (''ISE Gemini'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Schedule of Fees to eliminate the Performance Routing Program.

The text of the proposed rule change is available on the Exchange's Web site at *www.ise.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Currently, the Exchange offers Performance Routing Program (''PRP) rebates to Non-ISE Gemini Market Maker,[3] Firm Proprietary,[4] Broker-Dealer,[5] and Professional Customer [6] orders based on the member's maker average daily volume (''ADV'') in Non-ISE Gemini Market Maker, Firm Proprietary, Broker-Dealer, and Professional Customer orders that improve the national best bid or offer (''NBBO'') in a series at the time of order entry (''PRP eligible contracts'').[7] Specifically, members that execute an ADV of 9,999 PRP eligible contracts or fewer are entitled to a maker rebate of $0.25 per contract in both Penny Symbols and Non-Penny Symbols for their Non-ISE Gemini Market Maker, Firm Proprietary, Broker-Dealer, and Professional Customer orders. Members that execute an ADV of 10,000 or more PRP eligible contracts are entitled to a maker rebate of $0.40 per contract in Penny Symbols and $0.65 per contract in Non-Penny Symbols for the above market participant types if the order does not improve the NBBO at the time of order entry. In addition, members that qualify for the higher tier of PRP rebates are entitled to a maker rebate of $0.47 per contract in Penny Symbols and $0.71 per contract in Non-Penny Symbols for the above market participant types if the order improves the NBBO in the series at the time it is entered.[8]

The Exchange now proposes to eliminate the PRP as this program has not been successful in attracting order flow that improves the NBBO. As proposed, members will receive a maker rebate of $0.25 per contract in Penny Symbols and Non-Penny Symbols for their Non-ISE Gemini Market Maker, Firm Proprietary, Broker-Dealer, and Professional Customer orders (*i.e.,* the current Tier 1 maker rebate). Members will no longer be able to achieve higher maker rebates based on their maker ADV in Non-ISE Gemini Market Maker, Firm Proprietary, Broker-Dealer, and Professional Customer orders that improve the NBBO in a series at the time of order entry.[9]

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[10] in general, and Section 6(b)(4) of the Act,[11] 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 it is reasonable and equitable to eliminate the PRP as this rebate program was not successful in attracting the type of order flow that it was designed to incentivize. The Exchange adopted the PRP to encourage members enter orders that improve the NBBO in order to create more trading opportunities at better prices for all market participants that trade on the Exchange. The Exchange does not believe that the PRP has met this goal, and is therefore proposing to eliminate the program. With the proposed elimination of the PRP, Non-ISE Gemini Market Maker, Firm Proprietary, Broker-Dealer, and Professional Customer orders will continue to be entitled to a maker rebate in Penny and Non-Penny Symbols that is the same as the current Tier 1 maker rebate. The current Tier 2 maker rebates for these market participant types will be removed as this tier is being eliminated with the elimination of the PRP program. The Exchange believes

[8] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] A ''Non-ISE Gemini Market Maker'' is a market maker as defined in Section 3(a)(38) of the Securities Exchange Act of 1934, as amended, registered in the same options class on another options exchange.

[4] A ''Firm Proprietary'' order is an order submitted by a member for its own proprietary account.

[5] A ''Broker-Dealer'' order is an order submitted by a member for a broker-dealer account that is not its own proprietary account.

[6] A ''Professional Customer'' is a person or entity that is not a broker/dealer and is not a Priority Customer.

[7] All eligible volume from affiliated members is aggregated in determining applicable tiers, provided there is at least 75% common ownership between the members as reflected on each member's Form BD, Schedule A.

[8] *See* Schedule of Fees, Section I., Regular Order Fees and Rebates, footnotes 14 and 15.

[9] This includes both the regular rebate for orders that do not improve the NBBO at the time of order entry, and the enhanced rebates provided in footnotes 14 and 15 of the Schedule of Fees for orders that improve the NBBO at the time of order entry. The regular rebates will now be marked ''n/a'' since there will no longer be any PRP tiers, and the associated footnotes for enhanced rebates will be eliminated.

[10] 15 U.S.C. 78f.

[11] 15 U.S.C. 78f(b)(4).

that the Tier 1 maker rebate remains competitive and will continue to incentivize members to send order flow to the Exchange. The Exchange further believes that the proposed fee change is not unfairly discriminatory as it provides equal rebates to Non-ISE Gemini Market Maker, Firm Proprietary, Broker-Dealer, and Professional Customer orders. In addition, although Priority Customer [12] and Market Maker [13] orders will be entitled to more favorable maker rebates, the Exchange does not believe that this is unfairly discriminatory. As has historically been the case, Priority Customer orders remain entitled to more favorable maker rebates in order to encourage this order flow. A Priority Customer is by definition not a broker or dealer in securities, and does not place more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s). This limitation does not apply to participants whose behavior is substantially similar to that of market professionals, including Professional Customers, who will generally submit a higher number of orders than Priority Customers. Similarly, the Exchange believes that it is not unfairly discriminatory to offer higher maker rebates to Market Makers as Market Makers are subject to additional requirements and obligations (such as quoting requirements) that other market participants are not.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[14] the Exchange does not believe that the proposed rule change will impose any burden on intermarket or intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange operates in a highly competitive market in which market participants can readily direct their order flow to competing venues. In such an environment, the Exchange must continually review, and consider adjusting, its fees and rebates to remain competitive with other exchanges. For the reasons described above, the Exchange believes that the proposed fee changes reflect this competitive environment.

[12] A ''Priority Customer'' is a person or entity that is not a broker/dealer in securities, and does not place more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s), as defined in Rule 100(a)(37A).

[13] The term Market Maker refers to ''Competitive Market Makers'' and ''Primary Market Makers'' collectively. *See* Rule 100(a)(25).

[14] 15 U.S.C. 78f(b)(8).

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

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act,[15] and Rule 19b–4(f)(2) [16] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–ISEGemini–2017–01 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–ISEGemini–2017–01. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–ISEGemini–2017–01 and should be submitted on or before February 13, 2017.

[15] 15 U.S.C. 78s(b)(3)(A)(ii).

[16] 17 CFR 240.19b–4(f)(2).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–01299 Filed 1–19–17; 8:45 am]

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[17] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–79791; File No. SR–NASDAQ–2017–002]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 7018

January 13, 2017.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on January 3, 2017, The NASDAQ Stock Market LLC (''Nasdaq'' 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.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange proposes to amend the Exchange's transaction fees at Rule 7018(a) to (1) add a new credit of $0.0030 per share for members that meet specified volume requirements on both Nasdaq and the Nasdaq Options Market (''NOM'') when adding liquidity; (2) add a new credit of $0.0030 per share for members that meet specified volume requirements on Nasdaq when adding liquidity and that qualify for Tier 4 of the Market Access and Routing Subsidy (''MARS'') program on NOM; and (3) change the current volume requirements needed to qualify for two different credits when adding liquidity in securities that are listed on exchanges other than Nasdaq or the New York Stock Exchange LLC (''NYSE'').

The text of the proposed rule change is available on the Exchange's Web site at *http://nasdaq.cchwallstreet.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend the Exchange's transaction fees at Rule 7018(a) to make three changes. Specifically, the Exchange proposes to (1) add a new credit of $0.0030 per share for members that meet specified volume requirements on both Nasdaq and NOM when adding liquidity; (2) add a new credit of $0.0030 per share for members that meet specified volume requirements on Nasdaq when adding liquidity and that qualify for Tier 4 of the MARS program on NOM; and (3) change the current volume requirements needed to qualify for two different credits when adding liquidity in securities that are listed on exchanges other than Nasdaq or the NYSE. These changes are described below.

Credit for Adding Liquidity on Nasdaq and NOM

The first change will add a new credit to members that meet a specified volume threshold on Nasdaq for displayed quotes/orders (other than Supplemental Orders or Designated Retail Orders) that add liquidity, and that also meet a specified volume threshold on NOM when adding liquidity. Specifically, a member will receive a credit of $0.0030 per share executed if the member (1) adds liquidity through one or more of its Nasdaq Market Center MPIDs during the month that, in all securities, represents at least 0.125% of Consolidated Volume during the month, and (2) adds Customer,[3] Professional,[4] Firm,[5] Non-NOM Market Maker[6] and/or Broker-Dealer[7] liquidity in Penny Pilot Options and/or Non-Penny Pilot Options of 1.15% or more of total industry ADV in the customer clearing range for Equity and ETF option contracts per day during the month on the Nasdaq Options Market. Thus, to qualify under the new proposed credit, an Exchange member must also be a NOM Participant and meet the NOM credit criteria described above, in addition to the proposed requirement that the member have more than 0.125% of Consolidated Volume during the month through one or more of its Nasdaq Market Center MPIDs.

The new credit tier will be available for transactions in securities of all three Tapes.[8] The new credit tier is therefore being added to Rules 7018(a)(1), (2), and (3), which provide the fees and credits for execution and routing of orders in Nasdaq-listed securities, New York Stock Exchange (''NYSE'')-listed securities, and securities not listed on Nasdaq or NYSE, respectively.

Credit for Adding Liquidity on Nasdaq and Qualifying for MARS Tier 4

The second change will add a new credit tier to a member for displayed quotes/orders (other than Supplemental Orders or Designated Retail Orders) that provide liquidity on Nasdaq, if the member also qualifies for Tier 4 of NOM's MARS program, as provided by NOM Rules Chapter XV Section 6. Specifically, the Exchange is proposing to provide a $0.0030 per share executed credit to a member that provides liquidity in all securities during the month through one or more of its Nasdaq Market Center MPIDs representing more than 0.50% of Consolidated Volume during the month. The member must also qualify for Tier 4 of the NOM's MARS program during the month. The MARS program provides different tiers of rebates or ''MARS Payments'' to Participants that qualify for the program. The specified MARS Payment is paid on all executed Eligible Contracts that add liquidity, which are routed to NOM through a participating NOM Participant's System and meet the requisite Eligible Contracts ADV.[9] The purpose of MARS is to pay a subsidy to NOM Participants that provide certain order routing functionalities to other NOM

[3] The term ''Customer'' applies to any transaction that is identified by a participant for clearing in the Customer range at The Options Clearing Corporation (''OCC'') which is not for the account of broker or dealer or for the account of a ''Professional,'' as defined in Chapter I, Section 1 of the NOM rules.

[4] A ''Professional'' is defined in Chapter I, Section 1 of the NOM rules as ''any person or entity that (i) is not a broker or dealer in securities, and (ii) places more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s).''

[5] The term ''Firm'' or (''F'') applies to any transaction that is identified by a Participant for clearing in the Firm range at OCC.

[6] The term ''Non-NOM Market Maker'' or (''O'') is a registered market maker on another options exchange that is not a NOM Market Maker. A Non-NOM Market Maker must append the proper Non-NOM Market Maker designation to orders routed to NOM.

[7] The term ''Broker-Dealer'' or (''B'') applies to any transaction which is not subject to any of the other transaction fees applicable within a particular category.

[8] Tape C securities are those that are listed on the Exchange, Tape A securities are those that are listed on NYSE, and Tape B securities are those that are listed on exchanges other than Nasdaq or NYSE.

[9] To qualify for the program, the Participant's routing system (''System'') is required to: (1) Enable the electronic routing of orders to all of the U.S. options exchanges, including NOM; (2) provide current consolidated market data from the U.S. options exchanges; and (3) be capable of interfacing with NOM's API to access current NOM match engine functionality. Further, the Participant's System must also cause NOM to be the one of the top three default destination exchanges for (a) individually executed marketable orders if NOM is at the national best bid or offer (''NBBO''), regardless of size or time or (b) orders that establish a new NBBO on NOM's Order Book, but allow any user to manually override NOM as a default destination on an order-by-order basis. Any NOM Participant would be permitted to avail itself of this arrangement, provided that its order routing functionality incorporates the features described above and satisfies NOM that it appears to be robust and reliable. The Participant remains solely responsible for implementing and operating its System. *See* NOM Rules, Chapter XV Section 6.

To qualify for a MARS Payment tier, a NOM Participant that has System Eligibility, as described above, must have routed the requisite number of Eligible Contracts daily in a month (''Average Daily Volume''), which were executed on NOM. For the purpose of qualifying for the MARS Payment, Eligible Contracts may include Firm, Non-NOM Market Maker, Broker-Dealer, or Joint Back Office or ''JBO'' equity option orders that add liquidity and are electronically delivered and executed. Eligible Contracts do not include Mini Option orders. *Id.*

Participants and/or use such functionalities themselves.[10] To qualify for the Tier 4 MARS Payment, a Participant must have routed at least 20,000 Eligible Contracts daily in a month that are executed and that added liquidity. Thus, to qualify under the new proposed credit under Rule 7018(a), an Exchange member must also be a NOM Participant and meet the NOM MARS credit criteria described above, in addition to the proposed requirement that the member provides more than 0.50% of Consolidated Volume during the month through one or more of its Nasdaq Market Center MPIDs.

The new credit will be available for transactions in securities of all three Tapes and accordingly the new credit tier is being added to Rules 7018(a)(1), (2), and (3), which provide the fees and credits for execution and routing of orders in Nasdaq-Listed securities, NYSE-listed securities, and securities not listed on Nasdaq or NYSE, respectively.

Change to Credit for Transactions in Tape B Securities

The Exchange is also proposing to change two of the volume-based credits that are currently offered for displayed quotes/orders (other than Supplemental Orders or Designated Retail Orders) that provide liquidity on Nasdaq in Tape B Securities. Currently, in addition to other credits that it may receive for providing liquidity, the member will receive a credit of $0.0001 per share executed if it provides liquidity in securities that are listed on exchanges other than NASDAQ or NYSE during the month representing at least 0.045% but less than 0.075% of Consolidated Volume during the month through one or more of its Nasdaq Market Center MPIDs. Nasdaq proposes to change these thresholds, so that the member will receive a credit of $0.0001 per share executed if it provides liquidity in securities that are listed on exchanges other than NASDAQ or NYSE during the month representing at least 0.06% but less than 0.12% of Consolidated Volume during the month through one or more of its Nasdaq Market Center MPIDs.

Nasdaq proposes a similar change to the next credit tier for members that provide liquidity in securities that are listed on exchanges other than Nasdaq or NYSE. Currently, in addition to other credits that it may receive for providing liquidity, the member will receive a credit of $0.0002 per share executed if it provides liquidity in securities that are listed on exchanges other than NASDAQ or NYSE during the month representing at least 0.075% of Consolidated Volume during the month through one or more of its Nasdaq Market Center MPIDs. Nasdaq proposes to change this threshold, so that the member will receive a credit of $0.0002 per share executed if it provides liquidity in securities that are listed on exchanges other than NASDAQ or NYSE during the month representing at least 0.12% of Consolidated Volume during the month through one or more of its Nasdaq Market Center MPIDs.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[11] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[12] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

Credit for Adding Liquidity on Nasdaq and NOM

The Exchange believes that the $0.0030 credit if the member meets the specified volume levels for adding liquidity on Nasdaq and NOM is reasonable. As with other credits that the Exchange provides, the credit is designed to encourage increased activity on Nasdaq and NOM. The Exchange believes that the proposed volume thresholds and the proposed credit are reasonable because they further the Exchange's goal of incentivizing greater activity by members on both Nasdaq and NOM while imposing proportionate requirements that are not unrealistic for members to achieve.

The Exchange also believes that the proposed volume thresholds and the proposed credit are reasonable because they are consistent with other volume-based credits that the Exchange offers to members for displayed quotes/orders (other than Supplemental Orders or Designated Retail Orders) that provide liquidity. Nasdaq currently offers a variety of credits for displayed quotes/orders (other than Supplemental Orders or Designated Retail Orders) that add liquidity, some of which are linked to activity on NOM and some of which relate to activity on Nasdaq only, which range from $0.0015 per share executed to $0.00305 per share executed, and which apply progressively more stringent requirements in return for higher per share executed credits. Here, the member would receive a $0.0030 per share credit for adding liquidity of at least 0.125% of Consolidated Volume on Nasdaq, and adding Customer, Professional, Firm, Non-NOM Market Maker and/or Broker-Dealer liquidity in Penny Pilot Options and/or Non-Penny Pilot Options of 1.15% or more of total industry ADV in the customer clearing range for Equity and ETF option contracts per day during the month on NOM. In comparison, the Exchange currently offers a credit of $0.00295 per share executed for members that add Customer, Professional, Firm, Non-NOM Market Maker and/or Broker-Dealer liquidity in Penny Pilot Options and/or Non-Penny Pilot Options of 1.15% or more of total industry ADV in the customer clearing range for Equity and ETF option contracts per day in a month on NOM. By way of further comparison, the Exchange provides a $0.0030 per share executed credit if a member has shares of liquidity provided in all securities through one or more of its Nasdaq Market Center MPIDs that represent more than 0.75% of Consolidated Volume during the month and the member provides a daily average of at least 5 Million shares of non-displayed liquidity. Nasdaq believes that the proposed thresholds and credit are consistent with the credits that it currently offers both for activity on Nasdaq and NOM and on Nasdaq alone, and are therefore reasonable.

The Exchange also believes that this proposed credit of $0.0030 is equitable and not unfairly discriminatory. The Exchange is proposing an additional opportunity for members to receive a credit in return for market-improving behavior. The proposed requirements for qualifying for the credit are proportionate to the amount of the proposed credit and equitably reflect the purpose of the proposed credit, which is to incentivize members to transact greater volume on Nasdaq and NOM. Nasdaq is proposing to allow members to qualify for the credit by adding liquidity on NOM in a variety of capacities—as a Customer, Professional, Firm, Non-NOM Market Maker and/or Broker-Dealer—in both Penny Pilot and Non-Penny Pilot Options in Equity and ETF options. All similarly situated members are equally capable of qualifying for the proposed credit if they choose to meet the requirements of the new credit, and the same credit will be paid to all members that qualify for it.

[10] *See* Securities Exchange Act Release No. 79251 (November 7, 2016), 81 FR 79536 (November 14, 2016) (SR–NASDAQ–2016–149).

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(4) and (5).

Nasdaq members that are not currently NOM participants are eligible to become NOM participants by amending their membership application to add NOM.[13] Finally, Nasdaq notes that it currently offers other credits that relate to activity on NOM, and other credits that do not relate to activity on NOM.[14] As such, members will continue to have opportunities to qualify for similar credits based on market participation not tied to NOM.

Credit for Adding Liquidity on Nasdaq and Qualifying for MARS Tier 4

The Exchange believes that the $0.0030 credit if the member meets the specified volume levels on Nasdaq and qualifies for Tier 4 of the NOM MARS program is reasonable. The proposed volume thresholds and the proposed credit are reasonable because they further the Exchange's goal of incentivizing greater activity on Nasdaq and NOM by members while imposing proportionate requirements that are not unrealistic for members to achieve. Nasdaq believes that requiring a member to qualify for MARS in order to qualify for the credit, as opposed to meeting a different volume-based requirement on NOM, is reasonable because MARS is designed to encourage members to provide certain order routing functionalities to other NOM Participants and/or use such functionalities themselves, and the proposed credit further incentivizes such behavior.

As with the other new credit that is being offered as part of this proposal, Nasdaq also believes that these proposed volume thresholds and credit are reasonable because they are consistent with credits that Nasdaq currently offers for activity on Nasdaq and NOM and on Nasdaq alone. Here, a member would receive a credit of $0.0030 per share executed if it provides liquidity on Nasdaq that represents more than 0.50% of Consolidated Volume, and qualifies for Tier 4 of the MARS program during the month. In comparison, a member would receive a rebate of $0.0027 per share executed if it added liquidity during the month representing more than 0.10% of Consolidated Volume through one or more of its Nasdaq Market Center MPIDs, and added Customer, Professional, Firm, Non-NOM Market Maker and/or Broker-Dealer liquidity in Non-Penny Pilot Options of 0.40% or more of total industry ADV in the customer clearing range for Equity and ETF option contracts per day in a month on NOM.

The Exchange also believes that the proposed credit is equitable and not unfairly discriminatory. The Exchange is proposing an additional opportunity for members to receive a credit in return for market-improving behavior. Requiring members to qualify for MARS Tier 4 in addition to meeting the volume requirements on Nasdaq equitably reflects the purpose of the credit, which is to incentivize members to transact greater volume on Nasdaq and NOM and to enhance the use of order routing functionalities for NOM.

As with the other new credit that is being offered as part of this proposal, all similarly situated members are equally capable of qualifying for this proposed credit if they choose to meet the requirements of the new credit, and the same credit will be paid to all members that qualify for it. Nasdaq members that are not currently NOM participants are eligible to become NOM participants by amending their membership application to add NOM. Finally, Nasdaq notes that it currently offers other credits that relate to activity on NOM, while other credits that do not relate to activity on NOM. As such, members will continue to have opportunities to qualify for similar credits based on market participation not tied to NOM.

Change to Credit for Transactions in Tape B Securities

Nasdaq believes that the change to the current credit for transactions in Tape B Securities is reasonable, equitable and not unfairly discriminatory. Nasdaq notes that the members will continue to receive the same credit—either $0.0001 or $0.0002 per share executed—as they currently receive if they meet the volume requirements. Nasdaq believes that the changes to the volume thresholds for both credits are reasonable. The purpose of the credits is to incentivize greater activity on Nasdaq in Tape B Securities. The Exchange believes that the proposed volume thresholds, coupled with the current credits, are reasonable because they are more closely aligned to the Exchange's goal of incentivizing greater activity by members in Tape B Securities than the current volume thresholds, while imposing requirements that are not unrealistic for members to achieve.

Nasdaq believes that the proposed volume changes to credits for transactions in Tape B Securities are equitable and not unfairly discriminatory. The Exchange believes that the proposed requirements are more proportionate to the amount of the current credits than the current requirements, and more equitably reflect the purpose of the current credits, which is to incentivize members to transact greater volume on Nasdaq in Tape B Securities. Moreover, all similarly situated members are equally capable of qualifying for the credits if they choose to meet the volume requirements, and the same credits will be paid to all members that qualify for them.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. In terms of inter-market competition, the Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive, or rebate opportunities available at other venues to be more favorable.

In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges and with alternative trading systems that have been exempted from compliance with the statutory standards applicable to exchanges. Because competitors are free to modify their own fees in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited.

In this instance, the proposed new credits provided to a member for execution of securities of each of the three Tapes, in addition to meeting specified thresholds on NOM, do not impose a burden on competition because the Exchange's execution services are completely voluntary and subject to extensive competition both from other exchanges and from off-exchange venues. All similarly situated members are equally capable of qualifying for the credits if they choose to meet the volume requirements, and the same credits will be paid to all

[13] Upon approval, the Nasdaq member would be charged the NOM Participant Fee of $1,000 per month, as set forth in Chapter XV, Section 10 of the NOM Rules.

[14] As noted above, Nasdaq currently offers a credit of $0.00295 per month if member adds Customer, Professional, Firm, Non-NOM Market Maker and/or Broker-Dealer liquidity in Penny Pilot Options and/or Non- Penny Pilot Options of 1.15% or more of total industry ADV in the customer clearing range for Equity and ETF option contracts per day in a month on NOM. In comparison, Nasdaq also offers a credit of $0.00305 per share executed for a member with shares of liquidity provided in all securities through one or more of its Nasdaq Market Center MPIDs that represent more than 1.25% of Consolidated Volume during the month.

members that qualify for them. Members will continue to have opportunities to qualify for similar credits based on market participation not tied to NOM. Moreover, the proposed changes are designed to reward market-improving behavior by providing new credit tiers based on various measures of such behavior, which may encourage other market venues to provide similar credits to improve their market quality. Thus, the Exchange does not believe that the proposed credits will impose any burden on competition, but may rather promote competition.

Similarly, the changes to the existing credits for transactions in Tape B Securities do not impose a burden on competition because the Exchange's execution services are completely voluntary. All similarly situated members are equally capable of qualifying for the credits if they choose to meet the volume requirements, and the same credits will be paid to all members that qualify for them. In addition, the credits for transactions in Tape B securities are designed to reward market-improving behavior, and the proposed changes are designed to better align the requirements for the credits with the actual credits.

In sum, if the changes proposed herein are unattractive to market participants, it is likely that the Exchange will lose market share as a result. Accordingly, the Exchange does not believe that the proposed changes will impair the ability of members or competing order execution venues to maintain their competitive standing in the financial markets.

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

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[15]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NASDAQ–2017–002 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–NASDAQ–2017–002. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2017–002, and should be submitted on or before February 13, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–01295 Filed 1–19–17; 8:45 am]

BILLING CODE 8011–01–P

[15] 15 U.S.C. 78s(b)(3)(A)(ii).

[16] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

Meeting of the Advisory Committee on Veterans Business Affairs

AGENCY: U.S. Small Business Administration.

ACTION: Notice of open Federal Advisory Committee Meeting.

SUMMARY: The U.S. Small Business Administration (SBA) is issuing this notice to announce the location, date, time, and agenda for the next meeting of the Advisory Committee on Veterans Business Affairs. The meeting is open to the public.

DATES: Thursday, March 9, 2017, from 9:00 a.m. to 4:00 p.m.

ADDRESSES: Eisenhower Conference Room B, located on the concourse level, U.S. Small Business Administration, 409 3rd Street SW., Washington, DC 20416.

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C., Appendix 2), SBA announces the meeting of the Advisory Committee on Veterans Business Affairs (ACVBA). The ACVBA is established pursuant to 15 U.S.C. 657(b) note, and serves as an independent source of advice and policy recommendations to the Administrator of the SBA. The purpose of this meeting is to discuss the formation and growth of small business concerns owned and controlled by veterans and service disabled veterans, to focus on strategic planning, and provide updates on past and current events.

Additional Information: This meeting is open to the public. Advance notice of attendance is requested. Anyone wishing to attend and/or make comments to the ACVBA must contact SBA's Office of Veterans Business Development no later than March 6, 2017 at *veteransbusiness@sba.gov.* Comments for the record will be limited to five minutes in the interest of time and to accommodate as many participants as possible. Written comments should also be sent to the above email no later than March 6, 2017. Special accommodation requests

should also be directed to SBA's Office of Veterans Business Development at (202) 205–6773 or *veteransbusiness@sba.gov.* For more information on veteran owned small business programs, please visit *www.sba.gov/veterans.*

Dated: January 11, 2017.

Miguel J. L Heureux,

SBA Committee Management Officer.

[FR Doc. 2017–00951 Filed 1–19–17; 8:45 am]

BILLING CODE 8025–01–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36075]

The Illinois State Toll Highway Authority—Petition for Declaratory Order

By petition filed on November 23, 2016, the Illinois State Toll Highway Authority (Tollway) seeks a declaratory order confirming that, in its effort to acquire permanent and temporary easements for the construction of five highway bridges over railroad tracks owned and operated by Soo Line Railroad Company, d/b/a Canadian Pacific Railway (CP) in Chicago, Ill., the Tollway's state law eminent domain authority is not preempted by federal law under 49 U.S.C. 10501(b). The Tollway seeks expedited consideration and has submitted a procedural schedule that provides for comment by CP as well as a period for public comment.

On December 9, 2016, CP filed a ''limited reply'' in opposition to the Tollway's request for a declaratory order and proposed procedural schedule. CP argues that the Tollway disregards the fact that the construction of the five highway bridges would lock the layout of the tollway into an alignment that goes across and through CP's Bensenville Yard. Therefore, CP asserts that the scope of this proceeding should be broadened to consider the ramifications that the Tollway's project would have on the Bensenville Yard. CP also requests that the Board allow limited discovery and proposes a procedural schedule that allows for discovery, CP's substantive reply, and public comment.[1] In the event the Board were to disallow discovery, CP proposes an alternative procedural schedule, with replies due on February 23, 2017.

As discussed below, the Board will institute a proceeding to consider whether 49 U.S.C. 10501(b) preempts the Tollway's eminent domain authority to acquire the temporary and permanent easements needed to construct highway bridges over CP's rail tracks, as well as to consider the implications of the Tollway's prospective plans to cross or go through the Bensenville Yard.

Background

The construction of the Western Access Interchange, which involves the proposed construction of five highway bridges over CP's railroad tracks, is one stage of the Tollway's Elgin O'Hare Western Access Project (EOWA Project), a multi-stage project to improve the transportation infrastructure near O'Hare International Airport (O'Hare) by creating access to the western side of O'Hare. (Tollway Pet. 2; CP Reply 4.) The EOWA Project involves the construction of an east-west tollway (the Western Access Tollway) that approaches O'Hare from the west and a north-south tollway (the Western Bypass) that would connect I–90 north of O'Hare to I–294 south of O'Hare via the airport's western perimeter. (CP Reply 4.) The Tollway's petition pertains to the Western Access Interchange, which is the planned interchange between these two new tollways.

CP has requested that the Board broaden the scope of this proceeding to consider the southern leg of the Western Bypass, because ''construction of the Western [Access] Interchange commits the Western Bypass to an alignment through Bensenville Yard,'' which is located immediately south of O'Hare and is CP's only rail yard in the Chicago Terminal. (CP Reply 9.) CP states that construction of the Western Access Interchange involves plans to build the highway bridges and a section of the southern leg of the Western Bypass to Irving Park Road, just north of the Bensenville Yard and that the Tollway has already commenced construction on a part of the tollway immediately south of the Bensenville Yard, from I–294 north to the yard's southwest property line. *Id.* Thus, CP argues that it is inevitable that the Tollway will seek to complete the Western Bypass through the Bensenville Yard.

The Tollway states that, while its ultimate goal is to connect the Western Access Tollway to I–294, the current plan is for the Western Access Tollway to stop at Irving Park Road, north of the Bensenville Yard. (Tollway Pet. 30.) The Tollway states that the phases involving the crossing of the Bensenville Yard are the last two phases of the entire EOWA Project, with construction projected to start no earlier than 2020. (Tollway Pet. 16–17, 30.) The Tollway asserts that CP's objections in this proceeding to these last phases of construction are premature, as the plans for these phases have not developed past the conceptual layout stage, and it would thus be impossible to determine whether the phases would unreasonably interfere with railroad operations. (Tollway Pet. 31.) The Tollway states that ''if and when the Tollway elects to pursue this work and [CP] refuses to cooperate, the Tollway will return to the Board with a subsequent petition related to the Bensenville Yard issues.'' (Tollway Pet. 30.) The Tollway also notes that CP's argument for considering the impact on the Bensenville Yard has been dismissed as premature by the United States District Court for the Northern District of Illinois, *see Soo Line R.R.* v. *Ill. State Toll Highway Auth.,* Case No. 15–C–10328 (N.D. Ill. Mar. 29, 2016), and CP's appeal of the dismissal is currently pending before the United States Court of Appeals for the Seventh Circuit.

Discussion and Conclusions

The Board has discretionary authority under 5 U.S.C. 554(e) and 49 U.S.C. 1321[2] to issue a declaratory order to eliminate a controversy or remove uncertainty in a case that relates to the subject matter jurisdiction of the Board. The Board has broad discretion to determine whether to issue a declaratory order. *See Intercity Transp. Co.* v. *United States,* 737 F.2d 103 (D.C. Cir. 1984); *Delegation of Auth.—Declaratory Order Proceedings,* 5 I.C.C.2d 675 (1989). The Board may also provide guidance to assist other government agencies and courts in appropriate circumstances. *See U.S. Envtl. Prot. Agency—Pet. for Declaratory Order,* FD 35803 (STB served Dec. 30, 2014); *Mid-Am. Locomotive & Car Repair, Inc.—Pet. for Declaratory Order,* FD 34599 (STB served June 6, 2005). In this case, it is appropriate to institute a proceeding so that the Board can address whether § 10501(b) preempts the Tollway's eminent domain authority to acquire the temporary and permanent easements needed to construct highway bridges over CP's tracks, as well as the potential implications of crossing or going through the Bensenville Yard. The

[1] On December 21, 2016, the Tollway filed a motion for leave to file a surreply to CP's December 9, 2016 limited reply. On January 3, 2016, CP filed a motion for leave to file a reply to the Tollway's surreply. The Board will grant both motions and will consider the filings in the interest of compiling a more complete record. *See City of Alexandria, Va.—Pet. for Declaratory Order,* FD 35157 (STB served Nov. 6, 2008) (allowing reply to reply ''[i]n the interest of compiling a full record); *Denver & Rio Grande Ry. Historical Found.—Pet. for Declaratory Order,* FD 35496, slip op. at 3 (STB served Feb. 23, 2012).

[2] The Surface Transportation Board Reauthorization Act of 2015, Public Law No. 114–110, recodified certain provisions of title 49, United States Code, redesignating 49 U.S.C. 721 as § 1321.

Tollway and CP have presented related issues that ultimately may be relevant to future construction plans and activities for the EOWA Project. Therefore, it is appropriate to institute a proceeding to provide guidance on the issues raised by both the Tollway and CP.

The Board will establish a procedural schedule for the filing of additional pleadings. The Tollway's petition will serve as its opening statement. CP's substantive reply and comments from other interested persons will be due by February 23, 2017. In its substantive reply, CP should provide an analysis that details the impact of the proposed construction projects on its rail operations. The Tollway and other interested parties may respond to CP's reply only on the issue of the potential crossing of the Bensenville Yard by March 16, 2017.

CP also requests that the Board allow for limited discovery on the Tollway's alternative alignment options, the Tollway's plans regarding the Bensenville Yard, and the basis of the Tollway's expert opinions. CP's request for discovery will be denied. The Board often does not provide for discovery in declaratory order proceedings.[3] Nor is it apparent that discovery is necessary here. Alignment options for the tollway were analyzed and discussed in the Environmental Impact Statements for the EOWA Project, which are publicly available and which CP cites in its reply. (Tollway Surreply 4; CP Reply 8.) These Environmental Impact Statements also provide information regarding the Tollway's prospective plans for the Bensenville Yard.[4] To the extent that CP wishes to challenge the Tollway's expert witness's findings on and observations of CP's rail operations, CP possesses the information on its own operations needed to call into question the bases for the expert witness's conclusions. For these reasons, the Board will not order discovery in this proceeding.

It is ordered:

1. A proceeding is instituted.

2. CP and other interested persons may file substantive replies to the Tollway's petition by February 23, 2017.

3. The Tollway and interested persons may file responses to CP's reply, limited to only the issue of the Bensenville Yard, by March 16, 2017.

4. CP's request for limited discovery is denied.

5. The Tollway's motion for leave to file a surreply is granted.

6. CP's motion for leave to file a reply to the Tollway's surreply is granted.

7. Notice of the Board's action will be published in the **Federal Register**.

8. This decision is effective on its service date.

Decided: January 17, 2017.

By the Board, Rachel D. Campbell, Director, Office of Proceedings.

Kenyatta Clay,

Clearance Clerk.

[FR Doc. 2017–01379 Filed 1–19–17; 8:45 am]

BILLING CODE 4915–01–P

[3] *See, e.g., CSX Transp. Inc.—Pet. for Declaratory Order,* FD 33388 (Sub-No. 101), slip op. at 5 (STB served Aug. 27, 2008).

[4] *See* Elgin O'Hare-West Bypass Study: Tier Two Final Environmental Impact Statement (Oct. 2012), § 3.4.2. The Final Environmental Impact Statements are available on the Illinois Department of Transportation's Web site at *http://apps.dot.illinois.gov/fileexplorer/?search=environment/Elgin-Ohare%20final%20EIS.*

TENNESSEE VALLEY AUTHORITY

Environmental Impact Statement—Transmission System Vegetation Management Program

AGENCY: Tennessee Valley Authority.

ACTION: Notice of intent.

SUMMARY: The Tennessee Valley Authority (''TVA'') intends to prepare an Environmental Impact Statement (''EIS'') to address the management of vegetation on its transmission system. In order to ensure that electric service to the public is not disrupted by outages on its transmission lines, TVA must control the vegetation on about 260,000 acres of the rights of way (''ROW'') for those lines. This EIS will programmatically consider the impacts of vegetation management activities on approximately 17,000 miles of transmission line.

DATES: Comments on the scope of the EIS must be received on or before March 20, 2017.

ADDRESSES: Written comments on the scope of the EIS should be sent to Anita E. Masters, Tennessee Valley Authority, 1101 Market Street, BR 4A, Chattanooga, Tennessee 37402. Comments also may be submitted online at *tva.com/nepa* or by email to *aemasters@tva.gov.*

FOR FURTHER INFORMATION CONTACT: For further nepa information, contact Anita Masters, 1101 Market Street BR 4A, Chattanooga, TN 37402, *aemasters@tva.gov.* For information on current row maintenance practices, see TVA's Transmission Web page (*https://www.tva.gov/Energy/Transmission-System/Right-of-Way-Maintenance*).

SUPPLEMENTARY INFORMATION: This notice is provided in accordance with the regulations promulgated by the Council on Environmental Quality (40 CFR parts 1500 to 1508) and TVA's procedures implementing the National Environmental Policy Act (NEPA) (*https://www.tva.com/Environment/Environmental-Stewardship/Environmental-Reviews/NEPA-at-TVA.*)

TVA Power System and ROW Maintenance

TVA is a federal agency and instrumentality of the United States created by and existing pursuant to the TVA Act of 1933. Its broad mission is to foster the social and economic welfare of the people of the Tennessee Valley region and to promote the proper use and conservation of the region's natural resources. One component of this mission is the generation, transmission, and sale of reliable and affordable electric energy.

TVA operates the nation's largest public power system, producing approximately four percent of all of the electricity in the nation. TVA provides electricity to most of Tennessee and parts of Virginia, North Carolina, Georgia, Alabama, Mississippi, and Kentucky. Currently, it serves more than nine million people in this seven-state region. The TVA Act requires the TVA power system to be self-supporting and operated on a nonprofit basis and directs TVA to sell electricity at rates as low as are feasible. TVA receives no taxpayer funding, deriving virtually all of its revenues from sales of electricity.

Most of the electricity is generated on the TVA system from 3 nuclear plants, 8 coal-fired plants, 9 simple-cycle combustion turbine plants, 7 combined-cycle combustion turbine plants, 29 hydroelectric dams, a pumped-storage facility, a methane-gas cofiring facility, a diesel-fired facility, non-TVA owned facilities under power purchase agreements, and various small solar photovoltaic facilities. The electricity generated by these resources is transmitted along high-voltage transmission lines to TVA business customers and local power companies. The local power companies then distribute the electricity to end users such as residents, business owners, and public entities like school systems and hospitals. Distribution lines are owned and operated by local power companies and are the power lines typically seen along streets in neighborhoods.

TVA transmission lines are high-voltage (46-kilovolts or more, with 161-kilovolt most common) and typically have three conductors (wires) suspended from large structures (towers or tall poles) in ROWs that are cleared of buildings and tall vegetation. In most cases, transmission line ROWs vary in width from about 75 feet to 200 feet, with the width increasing with the voltage of the line. Most of TVA's ROWs

are located on easements that TVA acquired from property owners who still can use easement areas in ways consistent with TVA's operation and maintenance of its transmission lines. These easements give TVA the legal right to manage vegetation within its ROWs as well as adjacent to the ROW if vegetation is tall enough to pass within ten feet of a conductor or strike a structure should it fall toward the transmission line.

TVA manages its transmission system according to industry-wide standards established by the North American Electric Reliability Corporation (NERC). Those standards state that the TVA transmission system must be able to survive single-failure events while continuing to serve customer loads with adequate voltage and no overloaded facilities while maintaining adequate transmission line clearances as required by the National Electric Safety Code (NESC).

In order to meet its goal of providing the public safe and reliable electricity, TVA must control the vegetation that would otherwise grow up on its ROWs. When trees or branches get too close to high-voltage transmission lines, electricity can arc through the air like a lightning bolt, seeking the nearest path to the ground, such as a tree. When this occurs, the electricity can cause a fault on the transmission line, severely damaging or destroying nearby property and structures (*e.g.,* houses), and injuring nearby people. The cost and disruption to people's lives when this happens can be serious even if people are not injured from the arc or flash over itself. In August 2003, a single tree contacted a transmission line in Ohio and triggered cascading transmission line failures and blackouts from Ontario, Canada to the northeastern United States. Eleven people died as a result of these blackouts and the economic impact was estimated at $6 billion. As a result of the event, mandatory reliability standards were developed and implemented. These standards are monitored and enforced by NERC.

TVA uses an integrated approach to vegetation management on its ROWs designed to encourage low-growing plant species and discourage tall-growing plant species. This includes the initial clearing of trees and other tall-growing vegetation from ROWs. Vegetation re-clearing along ROWs utilizes various management techniques including mechanical mowing (using tractor-mounted rotary mowers), tree removal by means of chain saws or other mechanized equipment, and non-restricted herbicides registered with the U.S. Environmental Protection Agency when appropriate. TVA's approach to vegetation management historically has taken into account whether the vegetation is in the ''wire zone,'' the area directly under the transmission line and between the outermost conductors, or the ''border zone,'' the areas between the wire zone and the edge of the ROW, as well as whether vegetation outside the ROW is tall enough to pass within ten feet of a conductor or strike a structure should it fall toward the transmission line.

The purpose of this EIS is to examine at a programmatic level the potential environmental impacts of vegetation management practices along the approximately 17,000 miles of TVA's transmission line within its seven-state power service area and alternative management approaches.

EIS Scope

Scoping is a process that allows the public to comment on an agency's plans for an EIS. This includes identifying issues that should be studied and those that have little significance. The public's views on alternative actions that meet the stated purpose of the EIS are also helpful in preparing an EIS.

TVA anticipates evaluating several alternative management approaches, but these could change as the NEPA EIS process progresses. As required by applicable regulations, one of those alternative approaches is the No Action Alternative, or no change to TVA's current management practices. TVA has evaluated growth rates, climate, conductor sag and sway to design a cyclical, preemptive vegetation management program that is currently practiced on TVA's transmission line system. TVA's current management practices target existing incompatible vegetation within the ROW as well as vegetation that will become incompatible in the future. Under the No Action Alternative, TVA's ROW management personnel have discretion to manage the risk associated with vegetation growth that otherwise would be cleared. This approach allows TVA's ROW management personnel to allow exceptions to having the entire width of the ROW cleared by TVA. This approach is subject to the availability of financial resources. Any ''danger'' tree adjacent to the ROW is cleared by TVA. Danger trees include any trees located beyond the cleared ROW, but that are tall enough to pass within ten feet of a conductor or strike a structure should it fall toward the transmission line. TVA would continue to maintain its ROWs consistent with this approach, or any different approach that may be mandated during development of the EIS.

A second alternative approach is utilizing integrated vegetation management (IVM) practices with a wire zone/border zone approach, where TVA sets objectives, identifies compatible and incompatible vegetation. TVA would then consider action thresholds and evaluate, select and implement the most appropriate methods to achieve the established short and long-term objectives. This vegetation control method is based on considerations of environmental impact and anticipated effectiveness, safety, reliability, economics, site topography and other factors. This approach would be subject to the availability of financial resources. Any ''danger'' trees adjacent to the ROW would be cleared by TVA.

A third alternative approach to be considered is a border-to-border (BTB) approach in which TVA would remove all vegetation except the low-growing vegetation for the width of the easement on TVA ROWs (includes both the wire and border zones as well as danger trees outside the ROWs). This approach would be subject to the availability of financial resources. TVA ROWs would take on the appearance and characteristics of natural meadows, as well as promote inflorescence by keeping woody stem counts low.

A number of natural resource impacts would be evaluated in the EIS. These include potential impacts on air quality, surface water, groundwater, aquatic ecology, vegetation, wildlife, threatened and endangered species, wetlands, forest resources, and natural areas and parks. In addition, TVA would evaluate socioeconomic impacts and impacts on archaeological and historic resources and aesthetics (visual, noise, and odors). Potential impacts from siting lines in floodplains occur when new lines are constructed and are usually addressed in the environmental reviews done for those lines. Accordingly, TVA does not plan to address floodplain impacts in this programmatic EIS unless circumstances warrant.

These analyses will be conducted at a programmatic, transmission system-wide level. For new transmission lines, TVA considers the potential effects of the initial ROW clearing and of continuing site-specific vegetation management. For ongoing vegetation management of transmission lines already on the TVA system, TVA considers potential site-specific impacts in its NEPA reviews of transmission sector analyses, including impacts on identified sensitive areas. TVA divides its entire transmission system into discrete ''sectors'' and conducts

environmental analyses within specific sectors slated for vegetation maintenance each year. TVA anticipates that these sector area analyses would continue in the future, tiering off of the programmatic EIS when it is completed.

Public Participation

The public is invited to submit comments on the scope of this EIS no later than the date identified in the ''Dates'' section of this notice. After TVA prepares a draft of the EIS, TVA will release it for public comment. TVA anticipates holding public meetings at various locations throughout TVA's seven-state service area after release of the draft EIS. Meeting details will be posted on TVA's Web site at *tva.gov/nepa.*

Dated: January 13, 2017.

M. Susan Smelley,

Director, Environmental Permitting & Compliance.

[FR Doc. 2017–01448 Filed 1–19–17; 8:45 am]

BILLING CODE 8120–08–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Generalized System of Preferences (GSP): Notice Regarding the 2016/2017 GSP Annual Product Review and Certain Country Practice Cases

AGENCY: Office of the United States Trade Representative.

ACTION: Notice of hearing and receipt of public comments.

SUMMARY: This notice announces petitions submitted in connection with the 2016/2017 GSP Annual Product Review that have been accepted for further review. This notice also sets forth the schedule for submitting comments and for a public hearing associated with the review of these petitions and products. This notice also announces the closure of the country practices review of worker rights in Fiji and Niger without change to those countries' GSP trade benefits.

FOR FURTHER INFORMATION CONTACT: Naomi Freeman, Director for GSP, Office of the United States Trade Representative, 1724 F Street NW., Washington, DC 20508. The telephone number is (202) 395–2974 and the email address is *Naomi_S_Freeman@ustr.eop.gov.*

DATES: The schedule for the 2016/2017 GSP Annual Product Review is set forth below: February 15, 2017—Due date for submission of comments, pre-hearing briefs and requests to appear at the GSP Subcommittee Public Hearing on the 2016/2017 GSP Annual Product Review. February 22, 2017—The GSP Subcommittee of the Trade Policy Staff Committee (TPSC) will convene a public hearing on all petitioned product additions, product removals, and competitive needs limitation (CNL) waiver petitions that were accepted for the 2016/2017 GSP Annual Product Review. The hearing will be held in Rooms 1 and 2, 1724 F Street NW., Washington, DC 20508, beginning at 9:30 a.m. March 15, 2017—Due date for submission of post-hearing comments or briefs in connection with the GSP Subcommittee Public Hearing.

April 2017—The U.S. International Trade Commission (USITC) is expected to publish a public version of its report providing advice on the probable economic effect of the prospective addition and removal of products and granting of CNL waiver petitions considered as part of 2016/2017 GSP Annual Product Review. Comments from interested parties on the USITC report on these products should be posted on *www.regulations.gov* in Docket Number USTR–2016–0009 following the instructions provided below and will be due ten calendar days after the date of the USITC's publication of the public version of the report. July 1, 2017—Effective date for any modifications that the President proclaims to the list of articles eligible for duty-free treatment under the GSP resulting from the 2016/2017 Annual Product Review and for determinations related to CNL waivers.

SUPPLEMENTARY INFORMATION:

Certain Country Practice Reviews

The status of country practices reviews being considered as part of the 2016/2017 GSP Annual Review is described in the list of Active and Closed Country Practices Reviews, which is available on the USTR GSP Web site at *https://ustr.gov/node/6526.* This list includes previously accepted country practices petitions. The United States Trade Representative, drawing on the advice of the TPSC, has decided to close the country practices review cases in docket number USTR–2013–0012 regarding worker rights in Fiji, and docket number USTR–2013–0005 regarding worker rights in Niger, in view of progress made by the governments of Fiji and Niger, respectively, in addressing worker rights issues in those countries.

Background

The GSP program provides for the duty-free importation of designated articles when imported from designated beneficiary developing countries. The GSP program is authorized by Title V of the Trade Act of 1974 (19 U.S.C. 2461, *et seq.*), as amended (1974 Act), and is implemented in accordance with Executive Order 11888 of November 24, 1975, as modified by subsequent Executive Orders and Presidential Proclamations.

Petitions Requesting Modifications of Product Eligibility

In a notice published in the **Federal Register** on August 25, 2016 (81 FR 58547), the Office of the U.S. Trade Representative (USTR) announced the initiation of the 2016/2017 GSP Annual Review and indicated that the interagency GSP Subcommittee of the TPSC was prepared to receive petitions to modify the list of products that are eligible for duty-free treatment under the GSP program and petitions to waive CNLs on imports of certain products from specific beneficiary countries.

The GSP Subcommittee of the TPSC has reviewed the product and CNL waiver petitions submitted in response to these announcements, and has decided to accept for review five petitions to add a product to the list of those eligible for duty-free treatment under GSP, one petition to remove a product from GSP eligibility for certain GSP beneficiary countries, and seven petitions to waive CNLs.

A list of petitions and products accepted for review is posted on the USTR Web site at *https://ustr.gov/issue-areas/preference-programs/generalized-system-preferences-gsp/current-reviews/gsp-20162017* under the title ''Petitions Accepted in the 2016/2017 GSP Annual Product Review.'' This list also can be found at *www.regulations.gov* in Docket Number USTR–2016–0009. Acceptance of a petition indicates only that the TPSC found that the subject petition warranted further consideration and that a review of the requested action will take place.

The GSP Subcommittee of the TPSC invites comments in support of or in opposition to any petition that has been accepted for the 2016/2017 GSP Annual Product Review. The GSP Subcommittee of the TPSC will also convene a public hearing on these products and petitions. See below for information on how to submit a request to testify at this hearing.

Notice of Public Hearing

The GSP Subcommittee of the TPSC will hold a hearing on Wednesday, February 22, 2017 beginning at 9:30 a.m., for products and petitions accepted for the 2016/2017 GSP Annual Product Review. The hearing will be held at 1724 F Street NW., Washington,

DC 20508 and will be open to the public. A transcript of the hearing will be made available on *www.regulations.gov* approximately two weeks after the hearing.

All interested parties wishing to make an oral presentation at the hearing must submit, following the ''Requirements for Submissions'' set out below, the name, address, telephone number, and email address (if available), of the witness(es) representing their organization by midnight, Friday, February 15, 2017. Requests to present oral testimony in connection with the public hearing must be accompanied by a written brief or summary statement, in English, and also must be received by midnight, Friday, February 15, 2017. Oral testimony before the GSP Subcommittee will be limited to five-minute presentations that summarize or supplement information contained in briefs or statements submitted for the record. Post-hearing briefs or statements will be accepted if they conform with the regulations cited below and are submitted, in English, by midnight, Friday, March 15, 2017. Parties not wishing to appear at the public hearing may submit pre-hearing and post-hearing briefs or comments by the aforementioned deadlines.

Requirements for Submissions

Submissions in response to this notice (including requests to testify, written comments, and pre-hearing and post-hearing briefs) must be submitted by the applicable deadlines set forth in this notice. All submissions must be made in English and submitted electronically via *http://www.regulations.gov,* using docket number USTR–2016–0009. Hand-delivered submissions will not be accepted. To make a submission using *http://www.regulations.gov,* enter docket number USTR–2016–0009 in the ''Search for'' field on the home page and click ''Search.'' 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'' in the ''Filter Results by'' section on the left side of the screen and click on the link entitled ''Comment Now.'' The *http://www.regulations.gov* Web site offers the option of providing comments by filling in a ''Type Comment'' field or by attaching a document using the ''Upload file(s)'' field. The Subcommittee prefers that submissions be provided in an attached document and, in such cases, that parties note ''See attached'' in the ''Type Comment'' field on the online submission form. At the beginning of the submission, or on the first page (if an attachment) should be the following text (in bold and underlined): (1) ''2016/2017 GSP Annual Product Review;'' (2) the product description and related HTS tariff number; and (3) whether the document is a ''Written Comment,'' ''Notice of Intent to Testify,'' ''Pre-hearing brief,'' or a ''Post-hearing brief.'' Submissions should not exceed thirty single-spaced, standard letter-size pages in twelve-point type, including attachments. Any data attachments to the submission should be included in the same file as the submission itself, and not as separate files.

Each submitter will receive a tracking number upon completion of the submissions procedure at *http://www.regulations.gov.* The tracking number will be the submitter's confirmation that the submission was received into *http://www.regulations.gov.* The confirmation should be kept for the submitter's records. USTR is not able to provide technical assistance for the Web site. Documents not submitted in accordance with these instructions may not be considered in this review. If unable to provide submissions as requested, please contact the GSP Program at USTR to arrange for an alternative method of transmission.

Business Confidential Submissions

An interested party requesting that information contained in a submission be treated as business confidential information must certify that such information is business confidential and would not customarily be released to the public by the submitter. Confidential business information must be clearly designated as such. The submission must be marked ''BUSINESS CONFIDENTIAL'' at the top and bottom of the cover page and each succeeding page, and the submission should indicate, via brackets, the specific information that is confidential. Additionally, ''Business Confidential'' must be included in the ''Type Comment'' field. For any submission containing business confidential information, a non-confidential version must be submitted separately (*i.e.,* not as part of the same submission with the confidential version), indicating where confidential information has been redacted. The non-confidential version will be placed in the docket and open to public inspection.

Public Viewing of Review Submissions

Submissions in response to this notice, except for information granted ''business confidential'' status under 15 CFR 2003.6, will be available for public viewing pursuant to 15 CFR 2007.6 at *http://www.regulations.gov* upon completion of processing, usually within two weeks of the relevant due date or date of the submission. Public versions of all documents relating to the 2016/2017 Annual Product Review will be made available for public viewing in docket USTR–2016–0009 at *www.regulations.gov* upon completion of processing.

Erland Herfindahl,

Deputy Assistant U.S. Trade Representative for the Generalized System of Preferences, Office of the U.S. Trade Representative.

[FR Doc. 2017–01362 Filed 1–19–17; 8:45 am]

BILLING CODE 3190–F7–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Sixty Ninth Plenary for RTCA SC–135 Environmental Testing

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

ACTION: Sixty Ninth Plenary for RTCA SC–135 Environmental Testing.

SUMMARY: The FAA is issuing this notice to advise the public of a meeting of Sixty Ninth Plenary RTCA SC–135 Environmental Testing.

DATES: The meeting will be held April 27, 2017 09:00 a.m.–05:00 p.m.

ADDRESSES: The meeting will be held at: RTCA Headquarters, 1150 18th Street NW., Suite 910, Washington, DC 20036.

FOR FURTHER INFORMATION CONTACT: Rebecca Morrison at *rmorrison@rtca.org* or 202–330–0654, or The RTCA Secretariat, 1150 18th Street NW., Suite 910, Washington, DC 20036, or by telephone at (202) 833–9339, fax at (202) 833–9434, or Web site at *http://www.rtca.org.*

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a) (2) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., App.), notice is hereby given for a meeting of the Sixty Ninth RTCA SC–135 Environmental Testing Plenary. The agenda will include the following:

Thursday, April 27, 2017—9:00 a.m. to 5:00 p.m.

1. Chairmen's Opening Remarks, Introductions.
2. Approval of Summary from the Sixty-Eighth Meeting—(RTCA Paper No. 026–17/SC135–711).
3. Review Working Group Summaries.
4. Review Schedule.
5. New/Unfinished Business.
6. Establish Date for Next SC–135 Meeting.

7. Closing.

Working Group meetings will take place on April 25–26, 2017 prior to the plenary at the same location. Attendance is open to the interested public but limited to space availability. With the approval of the chairman, 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 January 13, 2017.

Mohannad Dawoud,

Management & Program Analyst, Partnership Contracts Branch, ANG–A17, NextGen, Procurement Services Division, Federal Aviation Administration.

[FR Doc. 2017–01282 Filed 1–19–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Twenty First RTCA SC–223 Internet Protocol Suite (IPS) and AeroMACS Plenary

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

ACTION: Twenty First RTCA SC–223 Internet Protocol Suite (IPS) and AeroMACS Plenary.

SUMMARY: The FAA is issuing this notice to advise the public of a meeting of Twenty First RTCA SC–223 Internet Protocol Suite (IPS) and AeroMACS Plenary.

DATES: The meeting will be held February 28–March 01, 2017 09:00 a.m.–05:00 p.m. and March 02, 2017 09:00 a.m.–12:00 p.m.

ADDRESSES: The meeting will be held at: RTCA Headquarters, 1150 18th Street NW., Suite 910, Washington, DC 20036.

FOR FURTHER INFORMATION CONTACT: Claudia Chaudhari at *cchaudhari@rtca.org* or 202–330–0662, or The RTCA Secretariat, 1150 18th Street NW., Suite 910, Washington, DC, 20036, or by telephone at (202) 833–9339, fax at (202) 833–9434, or Web site at *http://www.rtca.org.*

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a) (2) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., App.), notice is hereby given for a meeting of the Twenty First RTCA SC–223 Aeronautical Mobile Airport Communication System Plenary. The agenda will include the following:

Tuesday, February 28th, 2017—9:00 a.m.–5:00 p.m.

1. Welcome, Introductions, Administrative Remarks
2. Review of previous meeting notes and action items
3. Review of Current State of Industry Standards
   a. ICAO WG–I
   b. AEEC IPS Sub Committee
4. Current State of Industry Activities
   a. SESAR Programs
   b. ESA IRIS Precursor
   c. Any Other Activities
5. IPS Technical Discussions
   a. Review of IPS high level profile
   b. Review of IPS RFC detail Profiles
   c. Prioritization of additional IETF RFCs for Profiling
6. Any Other Topics of Interest
7. Plans for Next Meetings
8. Review of Action Items and Meeting Summary
9. Adjourn

Wednesday March 1, 2017—9:00 a.m.–5:00 p.m.

Continue in Plenary

Thursday March 2, 2017—9:00 a.m.–12:00 p.m.

Continue in Plenary

Attendance is open to the interested public but limited to space availability. With the approval of the chairman, 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 January 17, 2017.

Mohannad Dawoud,

Management & Program Analyst, Partnership Contracts Branch, ANG–A17 NextGen, Procurement Services Division, Federal Aviation Administration.

[FR Doc. 2017–01406 Filed 1–19–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0500]

Agency Information Collection Activity: Status of Dependents Questionnaire (VA Form 21–0538).

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Veterans Benefits Administration (VBA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed revision of a currently approved collection, and allow 60 days for public comment in response to the notice.

VA Form 21–0538 is used to request certification of the status of dependents for whom additional compensation is being paid to veterans. Without this information, continued entitlement to the benefits for dependents could not be determined.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before March 24, 2017.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *www.Regulations.gov* or to Nancy J. Kessinger, Veterans Benefits Administration (20M33), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420 or email to *nancy.kessinger@va.gov.* Please refer to ''OMB Control No. 2900–0500'' in any correspondence. During the comment period, comments may be viewed online through the FDMS.

FOR FURTHER INFORMATION CONTACT: Nancy J. Kessinger at (202) 632–8924 or FAX (202) 632–8925.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Pub. L. 104–13; 44 U.S.C. 3501–21), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or

the use of other forms of information technology.

Title: Status of Dependents Questionnaire (VA Form 21–0538).

OMB Control Number: 2900–0500.

Type of Review: Revision of an approved collection.

Abstract: VA Form 21–0538 is used to request certification of the status of dependents for whom additional compensation is being paid to veterans. Without this information, continued entitlement to the benefits for dependents could not be determined.

Affected Public: Individuals or households.

Estimated Annual Burden: 14,083 hours.

Estimated Average Burden per Respondent: 10 minutes.

Frequency of Response: One time.

Estimated Number of Respondents: 84,500.

By direction of the Secretary.

Cynthia Harvey-Pryor,

Department Clearance Officer, Office of Privacy and Records Management, Department of Veterans Affairs.

[FR Doc. 2017–01398 Filed 1–19–17; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0654]

Agency Information Collection Activity: (Annual Certification of Veteran Status and Veteran relatives (VA Form 20–0344))

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Veterans Benefits Administration (VBA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed revision of a currently approved collection, and allow 60 days for public comment in response to the notice.

VA Form 20–0344 is completed by VBA employees, non-VBA employees in VBA space and Veteran Service Organization (VSO) employees who have access to benefit records. These individuals are required to provide personal identifying information for themselves and any veteran relatives, so VA is able to identify and properly protect these benefit records.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before March 24, 2017.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *www.Regulations.gov* or to Nancy J. Kessinger, Veterans Benefits Administration (20M33), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420 or email to *nancy.kessinger@va.gov.* Please refer to ''OMB Control No. 2900–0654'' in any correspondence. During the comment period, comments may be viewed online through the FDMS.

FOR FURTHER INFORMATION CONTACT: Nancy J. Kessinger at (202) 632–8924 or FAX (202) 632–8925.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Pub. L. 104–13; 44 U.S.C. 3501–21), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Title: Annual Certification of Veteran Status and Veteran Relatives (VA Form 20–0344).

OMB Control Number: 2900–0654.

Type of Review: Extension of an approved collection.

Abstract: VA Form 20–0344 is completed by VBA employees, non-VBA employees in VBA space and Veteran Service Organization (VSO) employees who have access to benefit records. These individuals are required to provide personal identifying information for themselves and any veteran relatives, so VA is able to identify and properly protect these benefit records.

Affected Public: Individuals or households.

Estimated Annual Burden: 14,000 hours.

Estimated Average Burden per Respondent: 10 minutes.

Frequency of Response: One time.

Estimated Number of Respondents: 5,834.

By direction of the Secretary.

Cynthia Harvey-Pryor,

Department Clearance Officer, Office of Privacy and Records Management, Department of Veterans Affairs.

[FR Doc. 2017–01397 Filed 1–19–17; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

Vol. 82 Monday,
No. 13 January 23, 2017

Part II

Department of Health and Human Services

Substance Abuse and Mental Health Services Administration

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 (SAMHSA), HHS.

ACTION: Revised Mandatory Guidelines by the Secretary of Health and Human Services.

SUMMARY: The Department of Health and Human Services (''HHS'' or ''Department'') has revised the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Guidelines), 73 FR 71858 (November 25, 2008) for urine testing.

DATES: *Effective Date:* October 1, 2017.

FOR FURTHER INFORMATION CONTACT: Charles LoDico, M.S., F–ABFT, Division of Workplace Programs, Center for Substance Abuse Prevention (CSAP), SAMHSA mail to: 5600 Fishers Lane, Room 16N03A, Rockville, MD 20857, telephone (240) 276–2600 or email at *charles.lodico@samhsa.hhs.gov.*

SUPPLEMENTARY INFORMATION: In particular, these revised Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine (UrMG) allow federal executive branch agencies to test for additional Schedule II drugs of the Controlled Substances Act (*i.e.,* oxycodone, oxymorphone, hydrocodone and hydromorphone) in federal drug-free workplace programs, remove methylenedioxyethylamphetamine (MDEA) from the authorized drugs in Section 3.4, add methylenedioxyamphetamine (MDA) as an initial test analyte, raise the lower pH cutoff from 3 to 4 for identifying specimens as adulterated, require MRO requalification training and re-examination at least every five years after initial MRO certification, and allow federal agencies to authorize collection of an alternate specimen (*e.g.,* oral fluid) when a donor in their program is unable to provide a sufficient amount of urine specimen at the collection site. Many of the wording changes and reorganization of the UrMG were made for clarity, to use current scientific terminology or preferred grammar, and for consistency with the OFMG.

Background

The Department of Health and Human Services (HHS), by the authority of Section 503 of Public Law 100–71, 5 U.S.C. Section 7301, and Executive Order No. 12564, has established the scientific and technical guidelines for federal workplace drug testing programs and established standards for certification of laboratories engaged in urine drug testing for federal agencies. As required, HHS originally published the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Guidelines) in the **Federal Register** [FR] on April 11, 1988 [53 FR 11979]. The Substance Abuse and Mental Health Services Administration (SAMHSA) subsequently revised the Guidelines on June 9, 1994 [59 FR 29908], September 30, 1997 [62 FR 51118], November 13, 1998 [63 FR 63483], April 13, 2004 [69 FR 19644], and November 25, 2008 [73 FR 71858] with an effective date of May 1, 2010 (correct effective date published on December 10, 2008; [73 FR 75122]). The effective date of the Guidelines was further changed to October 1, 2010 on April 30, 2010 [75 FR 22809].

The proposed Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine (UrMG) published in the **Federal Register** on May 15, 2015 (80 FR 28101) include revisions to the initial and confirmatory drug test analytes and methods for urine testing, the cutoff for reporting a urine specimen as adulterated based on low pH, and the requalification requirements for individuals serving as Medical Review Officers (MROs) and, where appropriate, include references to the use of an alternate specimen in federal workplace drug testing programs. References to an alternate specimen are not applicable until final Guidelines are implemented for the use of the alternative specimen matrix. The Department published a separate Notice in the May 15, 2015 **Federal Register** (80 FR 28054) proposing Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid (OFMG) to allow federal agencies to collect and test oral fluid specimens in their workplace drug testing programs. There was a 60-day public comment period for both **Federal Register** Notices, during which 125 commenters submitted comments on the proposed changes to the Guidelines. These commenters were comprised of individuals, organizations, and private sector companies. The comments are available for public view at *http://www.regulations.gov/.* All comments were reviewed and taken into consideration in the preparation of the revised Guidelines. The issues and concerns raised in the public comments for the UrMG are set out below. Similar comments are considered together in the discussion.

Summary of Public Comments and HHS's Response

The following comments were directed to the information and questions in the preamble.

Costs and Benefits

The Department requested comments on costs and benefits. One commenter disagreed that the cost increase for laboratories to add analytes to regulated testing will be minimal, stating that significant costs would be incurred for information technology (IT) development, as well as incremental costs for additional immunoassays (if required); for additional calibrators, controls, and internal standards; and for increased confirmatory testing costs (including data review and result certification) based on an expected increased positivity rate for opioids. One commenter disagreed with the Department's estimated 3% cost increase for Medical Review Officers (MROs) and estimated that the increase will be 10%. The commenters did not provide any substantive evidence or data to support these comments. The Department recognizes that there will be start-up costs to laboratories to implement testing for the additional analytes for regulated specimens including administrative costs, and agrees that the estimated increased costs for some MROs may exceed the 3% estimate. The Department's cost analysis was based on information provided by multiple HHS-certified laboratories and MROs, as well as the estimated number of additional positives resulting from the inclusion of the new opioid analytes. Costs are expected to vary among individual laboratories and MROs, depending on their processes and testing populations. Additional information on the estimated costs associated with these Guidelines is included under *Regulatory Impact and Notices* below.

Proposed New Analytes: Oxycodone, Oxymorphone, Hydrocodone, and Hydromorphone

Seven commenters specifically agreed with the addition of these drugs to the Guidelines. Two commenters expressed concerns over the added drugs, indicating that individuals who follow their physician's treatment plan of taking legally prescribed medication would produce positive tests, leading to greater reliance on MROs to determine whether tests are truly positive (as a result of illegal use) or are positive due to prescribed usage of the drugs, and a greater number of workers will be subject to scrutiny and their medical

records examined at length. One of the commenters maintained that such testing would exceed the legal mandate under Executive Order No. 12564 and the promulgation of scientific Guidelines by HHS pursuant to it. The Guidelines include requirements to protect individuals' privacy while maintaining public safety, including procedures for MRO review to verify legitimate drug use and maintain the confidentiality of donor drug testing records. The Department provides additional guidance in the Medical Review Officer Manual for Federal Workplace Drug Testing Programs. The inclusion of these additional drugs in the Guidelines is within the scope of the Department's regulatory authority to test for illegal drug use under Section 503(a)(1)(A)(ii)(II) of Public Law 100–71 and Executive Order No. 12564.

New Analytes—Cutoff Concentrations

Eight commenters addressed the proposed cutoffs for the added drugs: Three commenters agreed with the proposed cutoffs; four disagreed with the cutoffs for one or more of the added drugs. Of these, three commenters stated that the cutoffs are too low: Two of these commenters believe that these cutoffs will unnecessarily identify workers using prescription drugs and one commenter noted that these cutoffs will affect accurate quantitation in routine specimens. The Department recognizes that the added analytes will result in an increased number of positive opioid results requiring MRO review, and has incorporated requirements for MRO requalification and retraining at least every five years. Additional guidance and information on the added drugs will be provided in the Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs. The Department disagrees that the cutoffs will affect accurate quantitation in routine specimens. Information from HHS-certified laboratories indicates that testing at these cutoffs can be accomplished with current instrumentation. However, the Department has raised the confirmatory test cutoffs for oxycodone and oxymorphone from 50 ng/mL to 100 ng/mL. These higher cutoffs are supported by a single dose study which showed similar detection rates for oxycodone and oxymorphone using either a 50 ng/mL or 100 ng/mL cutoff.[1] Use of the 100 ng/mL confirmatory test cutoffs is expected to be less analytically challenging for laboratories.

One commenter suggested changing the oxycodone and oxymorphone initial test cutoff to 300 ng/mL and changing the hydrocodone and hydromorphone initial test cutoff to 100 ng/mL, to equate the detection times for these drugs. One commenter requested that the Department provide the justification and data used to determine the cutoff levels for the added opioids. The Department raised the oxycodone and oxymorphone confirmatory test cutoffs to 100 ng/mL as described above. The Department has evaluated the comments and has concluded that no further change is needed. The selection of cutoff concentration is not based solely on the factor of detection times and must take into consideration a variety of factors, both pharmacological and chemical. Drug potency, disposition in urine, impact and prevalence must be considered. For example, oxycodone is approximately twice as potent as hydrocodone and may be prescribed in lower doses, thus a cutoff lower than that for hydrocodone is warranted. Therefore, in selecting the cutoffs, the Department considered the detection times of equipotent doses as well as dispositional patterns of each drug in urine. Data on the disposition of hydrocodone and oxycodone in urine following administration of a single dose can be found in two recently published scientific articles.[1 2]

Medical Review Officer (MRO) Requalification—Continuing Education Units (CEUs)

The Department requested comments on requiring MRO requalification continuing education units (CEUs) and on the optimum number of credits and the appropriate CEU accreditation bodies should CEUs be required as part of MRO requalification. Three commenters agreed with requiring MRO recertification, but disagreed with the addition of CEU requirements to the Guidelines. Two commenters disagreed with specifying the number of CEUs required. Two commenters indicated that certification entities already enforce training requirements and recommended that acceptance of CEUs be handled by MRO certification boards, not the Department. Two commenters recommended a requirement of annual CEUs: One suggested 16 CEUs and the other recommended three CEUs. One commenter recommended 12 CEUs prior to initial certification, eight CEUs every five years, and also recommended two CEUs related to the new requirements/topics within two years of implementation of the revised Guidelines. The Department has evaluated the comments and has concluded that requirements for continuing education units will remain with the MRO certification entities and will not be included in the Guidelines. The Department has removed references to MRO training entities in Sections 13.2 and 13.3, because training documentation is maintained by MRO certification entities. The Department agrees with the comment that MROs should receive training on revisions to the Guidelines, and has added item Section 13.3(b) to require such training prior to the effective date of revised Guidelines.

Discussion of Sections

The Department has not included a discussion in the preamble of any sections for which public comments were not submitted or where minor typographical or grammatical changes were made.

Subpart A—Applicability

1.5 What do the terms used in these Guidelines mean?

One commenter disagreed with the definition for ''dilute specimen'' because it does not include numerical values for creatinine and specific gravity. The Department has concluded that no change is needed; the analytical (numerical) criteria for a dilute specimen are provided in Section 3.8.

One commenter requested that ''external service provider'' be defined, because this is a new term included in the proposed Guidelines. The Department agrees and has added the definition.

The Department has added the definition for ''gender identity'' to Section 1.5. This term is now used in Guidelines sections addressing observed and monitored collections as described in this preamble under Sections 4.4, 8.1, 8.10, and 8.12. Gender identity means an individual's internal sense of being male or female, which may be different from an individual's sex assigned at birth.

Two commenters disagreed with the proposed definition for ''invalid result'' which indicated that an invalid result was reported only when an HHS-certified laboratory could not complete testing or obtain a valid drug test result. The Department agrees with the commenters and has reinstituted the definition from the Guidelines effective October 1, 2010 (73 FR 71858).

To address comments described in this preamble under Section 13.1, the Department deleted the definition for ''non-medical use of a drug.''

Two commenters found the definition of ''specimen'' confusing, because the term ''sample'' used in the definition was also defined as a representative portion of a donor's specimen. The

Department agrees, and has reinstituted some wording for the definition of ''specimen'' from the Guidelines effective October 1, 2010 (73 FR 71858) for clarity.

1.6 What is an agency required to do to protect employee records?

One commenter suggested that the non-applicability of the Health Insurance Portability and Accountability Act (HIPAA) and the Health Information Technology for Economic and Clinical Health Act (HITECH) should be clearly stated in the Guidelines. The Department has evaluated the comment and has concluded that the applicability of HIPAA and other relevant privacy laws is clearly stated in Section 1.6. Accordingly, except for minor rewording for clarity, no further revisions are necessary.

1.7 What is a refusal to take a federally regulated drug test?

One commenter noted that, per Sections 8.4(c) and 8.9(b), when a collector finds an adulterant or substitution product or observes an attempt to substitute a urine specimen, this prompts a direct observed collection, not a refusal to test. The commenter suggested bringing an adulterant or a substitution product to the collection should be a refusal to test. The Department has evaluated the comment, and agrees that the collector must report a refusal to test when a donor brings materials for adulterating, substituting, or diluting the specimen to the collection site, or when the collector observes a donor's clear attempt to tamper with a specimen. The Department has revised Sections 1.7, 8.3(h), 8.4(c), and 8.9(b) accordingly.

One commenter noted that the collector does not report a refusal to test when a donor leaves the collection site before the collection process begins for a pre-employment test. The commenter recommended defining the beginning of the pre-employment test collection process as the point at which the donor is asked to present photo identification. The Department agrees with the suggestion to define the beginning of the collection process specifically for this situation. However, the Department has designated the beginning as the step described in Section 8.4(a), when the collector provides or the donor selects a specimen collection container. The Department has revised Sections 1.7(a)(2) and (3) to include a reference to this section. All subsequent items in Section 1.7(a) (*i.e.,* items 4–13) apply once the donor has arrived for the pre-employment test collection.

1.8 What are the potential consequences for refusing to take a federally regulated drug test?

The Department reworded Section 1.8(b) to clarify that the requirements in this section apply to donors who fail to appear at the collection site in a reasonable time for any test (except a pre-employment test), as described in Section 1.7(a)(1).

Subpart B—Urine Specimens

2.1 What type of specimen may be collected?

Two commenters requested clarification on the collection/testing scenario where the federal agency authorizes collection of an oral fluid specimen, but the contracted laboratory does not perform oral fluid testing. The Department has evaluated the comments and has concluded that no change is needed. This will be addressed in the federal agency plan.

2.2 Under what circumstances may a urine specimen be collected?

One commenter suggested that the cost of mandatory random drug and alcohol testing among airline pilots outweighs the benefit. The Department has evaluated the comment and has concluded that no change is needed. Airline pilots are subject to drug and alcohol testing under DOT regulations. Therefore, this public comment is not relevant to the Guidelines. In regard to drug testing of federal agency employees and applicants, each federal agency establishes its agency plan based on its mission, its employees' duties, and the potential consequences to the public health and safety or national security that could result from the failure of an employee to adequately perform their duties and responsibilities.

Subpart C—Urine Specimen Tests

3.1 Which tests are conducted on a urine specimen?

One commenter suggested changing the term ''opiates'' to ''opioids'' in the Guidelines. The Department agrees with the commenter and has changed the term ''opiates'' to ''opioids'' where appropriate to refer to oxycodone, oxymorphone, hydrocodone, and hydromorphone in addition to codeine, morphine, and 6-acetylmorphine (6-AM).

3.2 May a specimen be tested for additional drugs?

The Department reworded Section 3.2(a) to clarify the additional drug tests that may be performed on federal employee specimens.

3.3 May any of the specimens be used for other purposes?

Section 3.3 states that specimens collected pursuant to Executive Order 12564, Public Law 100–71, and these Guidelines may not be used for purposes other than drug and validity testing in accordance with Subpart C of the Guidelines. One commenter disagreed with prohibiting employees from using their drug test specimens for other purposes (*e.g.,* deoxyribonucleic acid, DNA, testing). The Department has evaluated this comment and has concluded that no change is needed. While the Guidelines do not authorize the release of urine specimens, or portions thereof, to federal employees, the Guidelines afford employees a variety of protections that ensure the identity, security and integrity of their specimens. For example, see Sections 8.5(b), 8.8, and 15.1(a).

In addition, under Public Law 100–71, Section 503(a)(1)(A)(ii)(I), HHS is mandated to establish ''strict procedures governing the chain of custody of specimens collected for drug testing . . . .'' Sections 11.7(a) and 11.20(a) also provide that an ''HHS-certified laboratory must control access to the drug testing facility, specimens, aliquots, and records,'' and must retain specimens that, among other things, have been reported ''drug positive'' for a minimum of one year. Therefore, the release of specimens to employees, or to an employee's designee, is inconsistent with the mandates of the federal drug testing process, and could significantly compromise a specimen's integrity, security, and an HHS-certified laboratory's ability to fulfill its regulatory duties under the Guidelines.

One commenter requested further clarification of the phrase ''unless authorized in accordance with [applicable] federal law'' in Section 3.3. The phrase ''unless otherwise authorized in accordance with applicable law in Section 3.3(a) does not represent a significant change from the intent of the prior Guidelines language. Section 3.3, among others, is intended to prohibit the use of specimens for purposes other than those specifically authorized by the Guidelines. However, there may be circumstances in which federal law authorizes an HHS-certified laboratory to handle a specimen in a manner that differs from the Guidelines. Therefore, the phrase ''unless authorized in accordance with applicable federal law'' in Section 3.3 of the Guidelines is intended to avoid conflict with other applicable federal law.

It should be noted that Section 3.3 specifically prohibits conducting deoxyribonucleic acid (DNA) testing on urine specimens, unless authorized in accordance with applicable federal law.

3.4 What are the drug test cutoff concentrations for urine?

The Department proposed methylenedioxyamphetamine (MDA) and methylenedioxyethylamphetamine (MDEA) as initial test analytes. Three commenters disagreed with the addition of MDA and MDEA as target analytes, stating this change would require modification of current immunoassay reagents, laboratory processes, or both. The commenters noted that this imposes an unnecessary burden for compounds with such low incidence in workplace testing. The Department has evaluated the comments and has removed MDEA from the Guidelines (*i.e.,* MDEA is no longer included as an authorized drug in Section 3.4). The number of positive MDEA specimens reported by HHS-certified laboratories (*i.e.,* information provided to the Department through the NLCP) does not support testing all specimens for MDEA in federal workplace drug testing programs. Because MDEA is a Schedule I drug, a federal agency may test specimens for MDEA in accordance with Section 3.2 (*i.e.,* on a case-by-case basis for reasonable suspicion or post accident testing, routinely with a waiver from the Secretary). The Department understands that MDA and some other analytes also have a low incidence, but believes that continued testing for these analytes is warranted in a deterrent program. In particular, inclusion of MDA as an initial and confirmatory test analyte is warranted because, in addition to being a drug of abuse, it is a metabolite of MDEA and MDMA.

An HHS-certified laboratory or Instrumented Initial Test Facility (IITF) may group analytes for initial testing. For clarity, the Department has defined the term ''grouped analytes'' where used in footnote 1 of the table in Section 3.4: ''(*i.e.,* two or more analytes that are in the same drug class and have the same initial test cutoff).''

The Department proposed criteria for immunoassays for grouped analytes such as opioids and amphetamines, specifying the minimum cross-reactivity to the other analyte(s) within the group. Two commenters disagreed with the added cross-reactivity requirements, noting this section should not attempt to provide equivalence between immunoassay and other initial testing technologies. One of these commenters suggested the Department develop separate requirements for initial test methods using an alternate technology or, alternatively, require the combined cross-reactivity of low-reacting compounds (*e.g.,* hydrocodone and hydromorphone for an opiate assay; MDA and MDEA for an amphetamines assay) to be equal to or greater than the cutoff. The other commenter recommended not allowing methods other than immunoassay for urine initial testing. One commenter stated that cross-reactivity specifications for hydromorphone are not necessary, based on their non-regulated testing results (*i.e.,* confirmatory test concentrations detected after using an immunoassay with 60% cross-reactivity for hydromorphone). The Department has evaluated the comments and has concluded that no change is needed for immunoassay cross-reactivity requirements. The requirements in Section 3.4 are necessary to ensure consistency in testing among laboratories using different immunoassay kits, as well as those using different test methods for initial drug testing. Cross-reactivity must be demonstrated and documented by the manufacturer (*e.g.,* package insert) and by the HHS-certified laboratory or IITF (*i.e.,* assay validation studies, reagent lot verification, and batch quality control for any analyte that exhibits less than 100% cross-reactivity). The Department will continue to allow the use of methods other than immunoassay for initial testing.

However, the Department has revised Section 3.4 regarding the use of alternate technology initial tests for THCA and benzoylecgonine. Depending on the technology, the confirmatory test cutoff (*i.e.,* 15 ng/mL for THCA, 100 ng/mL for benzoylecgonine) must be used as the cutoff for an initial test using an alternate technology to ensure consistent treatment of specimens. For these analytes, the immunoassay test is not specific for the target analyte for the confirmatory test. For example, immunoassays for cannabinoids react with multiple compounds that are excreted as a result of marijuana use. Therefore, it is necessary to use an immunoassay cutoff higher than that of the confirmatory test in order to detect the target analyte (THCA) at or above the confirmatory test cutoff. An initial test using an alternate technology with specificity comparable to the confirmatory test requires use of the confirmatory test cutoff.

Also in Section 3.4, the Department did not specify the target analyte to be used to calibrate an initial test for grouped analytes such as amphetamines or opioids. Three commenters noted that when an immunoassay is calibrated with a low-reacting drug, other analytes may exhibit high cross-reactivity, leading to false initial test positives. Two of these commenters also noted that this may result in possibly different cross-reactivity profiles for some structurally unrelated and concomitantly used prescription and/or over the counter drugs. One commenter noted that the option to ''include a control containing the lowest reacting analyte at its cutoff concentration in each batch'' was described in the preamble to the proposed Guidelines, but was not specified in Section 3.4 of the Guidelines. It was not the Department's intent for the laboratory or IITF to calibrate an immunoassay test using an analyte other than that specified by the manufacturer. In the preamble to the proposed UrMG, the Department described using a control containing the lowest reacting analyte at its cutoff concentration to establish the decision point (*i.e.,* when an immunoassay for grouped analytes did not demonstrate at least 80% cross-reactivity to each analyte). The Department has determined that this approach is not necessary, and will not be permitted. There are current immunoassays that meet the requirements of this section for two or more analytes in a group (*i.e.,* analytes in the same drug class that have the same initial test cutoff). As indicated in Section 3.4, the laboratory or IITF may use multiple test kits or a single kit to meet the requirements.

3.5 May an HHS-certified laboratory perform additional drug and/or specimen validity tests on a specimen at the request of the Medical Review Officer (MRO)?

One commenter recommended that HHS maintain a list of allowable additional tests and reporting criteria (*e.g.,* threshold for reporting as positive, adulterated, substituted, and/or invalid, and a limit of detection as appropriate), to ensure consistency among laboratories and within the testing program. The Department has evaluated the comment and has concluded that no change is needed. The Department does not want to limit the analytes that may be tested, and will provide guidance to laboratories as needed. It is also noted that the section requires all tests to meet appropriate validation and quality control requirements. The procedures and specimen records for such tests will be reviewed at NLCP inspections. The Department will continue to maintain a list of HHS-certified laboratories that choose to perform additional tests for regulated specimens.

One commenter asked whether an MRO could submit a blanket request to perform additional testing (*e.g.,* additional opioid metabolites) for all confirmatory specimens (*i.e.,* would laboratories be permitted to monitor the additional compounds in all confirmatory test assays?). The Department believes that testing all specimens for additional analytes may not be appropriate for some tests, especially hydrocodone, hydromorphone, oxycodone and oxymorphone. Recent studies show that testing for norhydrocodone and or noroxycodone is not necessary for the interpretation of all results.[1 2] Norhydrocodone and noroxycodone metabolites may be helpful for the MRO to interpret test results only when a donor's prescription does not support the test results. For example, a hydrocodone dose may result in urine concentrations of only hydromorphone metabolite above the cutoff. The presence of norhydrocodone metabolite would support the use of hydrocodone and validate the donor's prescription. The same could be said for interpreting test results following an oxycodone dose. The presence of noroxycodone metabolite would support the use of oxycodone when only oxymorphone was reported as positive. The Department will provide guidance on these and other additional tests that may provide useful information for the MRO in the Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs. The Department has revised Section 3.5 to clarify that HHS-certified laboratories are authorized to perform additional tests upon MRO request on a case-by-case basis, but are not authorized to routinely perform such tests without prior authorization from the Secretary or designated HHS representative, with the exception of the determination of D,L stereoisomers of amphetamine and methamphetamine. The Department will continue to allow HHS-certified laboratories to test for D,L amphetamine and methamphetamine routinely or upon MRO request. The Department will provide guidance on these and other additional tests that may provide useful information for the MRO (*e.g.,* tetrahydrocannabivarin) in the Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs.

Additional drug and specimen validity testing under Section 3.5 does not include DNA testing.

3.6 What criteria are used to report a urine specimen as adulterated?

Two commenters agreed and one disagreed with raising the lower pH cutoff from 3.0 to 4.0 for identifying specimens as adulterated. One commenter advised caution in changing specimen validity test cutoffs, and indicated that the proposed change will require updates to computer systems for reporting, calibrators, and controls. One commenter indicated that previous review of data (more than 10 years ago) indicated this change would have more than doubled the number of low pH/adulterated results reported. The commenter that disagreed with changing the pH cutoff believes HHS does not have enough scientific evidence supporting the change. The Department has evaluated the comments and has concluded that no change is needed to the proposed cutoff (*i.e.,* 4.0). As stated in the preamble to the proposed Guidelines (80 FR 28101), this decision is based on the fact that the physiologically minimum achievable urine pH that can be produced by the kidneys is about pH 4.5. Furthermore, the Department is not aware of any medical conditions or medications that would cause urine pH to be less than 4.5.

3.8 What criteria are used to report a urine specimen as dilute?

One commenter suggested removing the three-decimal place criteria for reporting a specimen as dilute. One commenter indicated that the criteria for reporting a specimen as dilute in Section 3.8 and 11.19(f) were not consistent, and that Section 3.8 does not address the situation when creatinine is between 5 and 20 mg/dL and the specific gravity is less than 1.0020. This section was intended to clarify that only HHS-certified laboratories (and not HHS-certified IITFs) may report a specimen as dilute when the creatinine concentration is greater than or equal to 2.0 mg/dL and less than or equal to 5 mg/dL, and the laboratory must use a four-decimal place refractometer for the specific gravity test. The Department will retain the three-decimal place criteria in Section 3.8(a) because both HHS-certified IITFs and laboratories may use a three-decimal place refractometer for a specific gravity screening test when the creatinine concentration is greater than 5 mg/dL and less than 20 mg/dL. However, the Department agrees that this section did not address all situations, so has revised the wording in Section 3.8(b) to be consistent with the wording in 11.19(f).

3.9 What criteria are used to report an invalid result for a urine specimen?

One commenter suggested increasing the acceptable pH range upper end from 9.0 to 9.5 due to heat during summer months. One commenter recommended that the Department define requirements to be met before a new validity marker is implemented. One commenter suggested that additional biomarkers used to support a result of invalid should be standardized across all HHS-certified laboratories and one solution to donor subversion might be random assignment of collection of alternative specimens. The Department has evaluated the comments and has concluded that no change is needed. A 2006 study on the stability of regulated drug analytes in urine slightly below and within the high pH invalid range supports the pH 9.0 decision point due to the loss of drug analytes at a pH between 9.0 and 9.5.[3]

Subpart D—Collectors

4.4 What are the requirements to be an observer for a direct observed collection?

One commenter disagreed with the requirement for an observer to be the same gender as the donor, and suggested that a physician or health care professional (regardless of gender) should be allowed to function as an observer. The commenter indicated that gender determination can be challenging (*i.e.,* transgender employees). The Department has evaluated these comments and agrees that all observed collections must be conducted in a professional manner that minimizes discomfort to the donor. The Department has revised Sections 4.4(b), 8.1(b), and 8.10 to allow the donor to be observed by a person whose gender matches the donor's gender, which is determined by the donor's gender identity (defined in Section 1.5). The donor's gender identity may be the same as or different from the donor's sex assigned at birth. The Department also revised Sections 8.1(b) and 8.12 for monitored collections, to allow the donor to be monitored by a person whose gender matches the donor's gender, unless the monitor is a medical professional (as described in Section 8.12).

The Department disagrees with the commenter's suggestion to allow an individual to serve as an observer based solely on their credentials as a physician or health care professional. Such credentials alone would not guarantee that these individuals could appropriately perform the functions of an observer (*i.e.,* as specified in Section 4.4).

The same commenter expressed concerns over the requirement for an observer to have received training, indicating that this would require

documentation and may make finding short notice observers more difficult. The Department disagrees with this comment. These are the same requirements as in the Guidelines effective October 1, 2010 (73 FR 71858). As stated in the preamble to those Guidelines, the 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 the collector maintains the confidentiality and integrity of collection information.

Subpart F—Federal Drug Testing Custody and Control Form (CCF)

6.1 What federal form is used to document custody and control?

Two commenters recommended that the Department provide instructions on recording results for the added drugs on the CCF until the Federal CCF is revised. Three commenters recommended that the CCF be revised to address the addition of the oral fluid specimen matrix. One commenter encouraged SAMHSA to modify the CCF to account for collections where multiple specimens are collected during a single collection event. The Department will publish a **Federal Register** Notice with the revised Federal CCF, including changes for the added analytes, with the same effective date as these Guidelines. Guidance on the use of the revised Federal CCF will be posted on the SAMHSA Web site *http://www.samhsa.gov/workplace.* In regard to when the collector submits multiple urine specimens (*i.e.,* different voids) collected during the same testing event, the Department has concluded that no change is needed; the collector must use a separate Federal CCF for each specimen.

6.2 What happens if the correct OMB approved Federal CCF is not available or is not used?

One commenter questioned the purpose of a Memorandum for the Record (MFR) obtained from the collector when an incorrect CCF was used for the collection. The commenter suggested that if certain information is required to be in the MFR, these requirements should be specified in the Guidelines. The commenter suggested that if the purpose of the MFR is to correct the collector's behavior (*i.e.,* using an incorrect form), then it would be more effective to reject the specimen upon receipt and indicate that it was rejected due to the use of an incorrect form. The Department has evaluated the comments and has concluded that no change is needed. Section 6.2 describes the information required in the MFR from the collector. However, the Department reworded items 6.2(b) and (c) for clarity.

Subpart H—Urine Specimen Collection Procedure

8.1 What privacy must the donor be given when providing a urine specimen?

As described in this preamble under Section 4.4, the Department has revised Section 8.1(b) to require that the gender of the observer matches the donor's gender, and that the gender of the monitor matches the donor's gender unless the monitor is a medical professional as described in Section 8.12.

8.3 What are the preliminary steps in the urine specimen collection procedure?

One commenter was concerned that the Guidelines do not mention alcohol testing, which was added to the Department of Transportation (DOT) program in 1991. Alcohol testing is outside of the scope of the Department's regulatory authority granted by Executive Order 12564 and Public Law 100–71.

In response to comments described under Sections 1.7 and 8.4 in this preamble, the Department revised Section 8.3(h) to require the collector to report a refusal to test when a donor brings materials for adulterating, substituting, or diluting a specimen to the collection site.

8.4 What steps does the collector take in the collection procedure before the donor provides a urine specimen?

The proposed section included the same requirement as the Guidelines effective October 1, 2010 (73 FR 71858) for the collector to perform an observed collection when the donor exhibits 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). One commenter stated that if the collector finds an adulterant or substitution product or observes the donor attempt to substitute a urine specimen, this should be a refusal to test. As noted under Section 1.7 in this preamble, the Department agrees that the collector must report a refusal to test when a donor brings materials for adulterating, substituting, or diluting a specimen to the collection site, or when the collector observes a donor's clear attempt to tamper with a specimen. The Department has revised Section 8.4 accordingly.

8.5 What steps does the collector take during and after the urine specimen collection procedure?

8.6 What procedure is used when the donor states that they are unable to provide a urine specimen?

Comments on these two sections are addressed here. Numerous commenters expressed concern with the Department's urine collection policy, stating that 7 to 10% of Americans have a condition (''paruresis''), described as a social anxiety disorder which prevents a person from producing urine on demand or in the presence of other people. These commenters stated that if the government wants to seek the largest group of qualified applicants, the Guidelines should specify that a diagnosis of paruresis means non-urine (*i.e.,* oral fluid) testing will automatically be provided, and that donors should not have to attempt to provide a urine specimen first. The Department has evaluated the comments and has concluded that no change is needed. The Guidelines will allow a federal agency to use any authorized specimen types (*e.g.,* urine, oral fluid, or both) in their drug testing programs. The Guidelines will continue to require that the donor be allowed reasonable attempts to provide a urine specimen as described in Sections 8.5 and 8.6, and allow collection of an authorized alternate specimen (*i.e.,* oral fluid).

Three commenters disagreed with the requirement for the collector to contact the agency representative for authorization to collect an alternate specimen each time a donor is unable to provide a sufficient volume. These commenters suggested that the Guidelines allow this to be addressed in established standard protocols for the agency. The Department agrees with the commenters. Each federal agency may decide whether to require notification in each case or whether to provide a standard protocol for collectors to follow. Sections 8.5 and 8.6 have been revised accordingly.

Also in regard to Section 8.6, one commenter indicated that some employers may wish to retain urine testing as the primary test due to a longer detection window. This commenter raised concern that some donors may claim they are unable to provide a urine specimen so that an alternative specimen (*i.e.,* OF) with a shorter detection window will be collected. The commenter suggested that the Guidelines be changed to indicate that an alternative specimen

may be collected when a donor is physiologically unable to provide a urine specimen, and not just when the donor states that they are unable to provide a urine specimen. The Department disagrees; collectors are not qualified to conduct a medical evaluation to verify or refute the donor's claim. It will be the agency's decision to collect urine or an authorized alternate specimen, and Sections 13.6 and 13.7 include procedures for medical evaluation as needed during the MRO review process.

The Department reworded Section 8.5(d) to clarify that the collector must record comments on both CCFs when two specimens from the same collection event are forwarded to a laboratory.

8.7 If the donor is unable to provide a urine specimen, may another specimen type be collected for testing?

The Department proposed within Section 8.7 that when the donor is unable to provide a urine specimen, another specimen type may be collected only if specifically authorized by the agency. One commenter disagreed with the Guidelines as written and suggested that when a donor cannot provide the primary specimen type, an alternate specimen should be collected immediately. The commenter cited the additional time and cost (evaluation of donor for ''shy bladder'') as well as the fact that the collector may not know the agency's policy on alternate specimen types. The Department has concluded that no change is needed for Section 8.7 in response to this comment. The Guidelines will continue to require that the donor be allowed reasonable attempts to provide a urine specimen as described in Sections 8.5 and 8.6. The Department has revised those sections to allow a federal agency to either require notification in each case or provide a standard protocol for collectors to follow when the donor is unable to provide a urine specimen. The Department has reworded this section to state ''Yes, if . . .'' rather than ''No, unless . . . .'' in response to a federal agency's comment and to enhance clarity. The meaning of this section remains the same.

8.8 How does the collector prepare the urine specimens?

In response to a federal agency comment, the Department deleted a sentence in item 8.8(h) that required the collector to send a copy of the Federal CCF to the HHS-certified laboratory or IITF. The Department agreed with the federal agency that this instruction is redundant because item 8.8(g) instructs the collector to distribute copies of the Federal CCF as required.

8.9 When is a direct observed collection conducted?

The proposed section included requirements for the collector to perform an observed collection when the donor exhibits conduct that clearly indicates an attempt to tamper with a specimen or the collector observed materials brought by the donor to the collection site for the purpose of adulterating, substituting, or diluting the specimen. One commenter stated that if the collector finds an adulterant or substitution product or observes the donor attempt to substitute a urine specimen, this should be a refusal to test. As noted in this preamble under Sections 1.7 and 8.4, the Department agrees that the collector must report a refusal to test when a donor brings materials for adulterating, substituting, or diluting the specimen to the collection site, or when the collector observes a donor's clear attempt to tamper with a specimen. The Department has revised Section 8.9 accordingly.

8.10 How is a direct observed collection conducted?

To address a comment described in this preamble under Section 4.4, the Department has revised Section 8.10 to allow the donor to be observed by an observer whose gender matches the donor's gender. At the beginning of the observed collection, the collector requests that the donor document the donor's gender on the Federal CCF and initial the annotation. An observer of the same gender is provided, and the collector records the name and gender of the observer on the Federal CCF.

8.12 How is a monitored collection conducted?

To address a comment described in this preamble under Section 4.4, the Department has revised Section 8.12 to allow the donor to be monitored by a monitor whose gender matches the donor's gender, 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). As described in Section 8.10, at the beginning of the monitored collection, the collector follows the same procedure as for observer selection in Section 8.10(b). That is, the collector requests that the donor document the donor's gender on the Federal CCF and initial the annotation. A monitor of the same gender is provided, and the collector records the name and gender of the monitor on the Federal CCF. A medical professional may serve as the monitor, regardless of gender.

Subpart I—HHS Certification of Laboratories and IITFs

9.5 What are the qualitative and quantitative specifications of performance testing (PT) samples?

One commenter noted that, because proposed initial test requirements allow calibration with a low-reacting analyte, PT schemes would likely need to be designed based on the specific implementation at each laboratory. The commenter provided an example: When an immunoassay is calibrated with a drug/metabolite that exhibits 50% cross-reactivity, the intended target analyte (''calibrant'') at the cutoff concentration would elicit a response well in excess of the cutoff. This could result in inaccurate initial test results (*i.e.,* a positive initial test result for a specimen containing the calibrant at a concentration below the cutoff). The commenter stated that this result could be scored as a ''false positive'' PT result. The Department has evaluated the comment and has concluded that no change is needed. As noted above regarding Section 3.4, it was not the Department's intent for the laboratory or IITF to calibrate an immunoassay test using an analyte other than that specified by the manufacturer. NLCP PT schemes are designed based on known cross-reactivity profiles of the initial tests used by HHS-certified laboratories.

Also in regard to proposed Section 9.5, one commenter suggested that the Guidelines use the same wording as in the Guidelines effective October 1, 2010 (73 FR 71858) for retest PT sample specifications (*i.e.,* ''. . . may be as low as . . .'' rather than the proposed wording ''. . . may be less than. . .''). The Department agrees and has reinstituted wording from Section 9.3 of the Guidelines effective October 1, 2010 (73 FR 71858) into Section 9.5(a)(1)(ii).

Subpart J—Blind Samples Submitted by an Agency

10.1 What are the requirements for federal agencies to submit blind samples to HHS-certified laboratories or IITFs?

Two commenters disagreed with the proposed limit to the number of blind samples required (*i.e.,* a maximum of 400 blind samples per year) in Section 10.1(b). The commenters indicated that for a large agency, there is a very large difference between 3% and 400 samples and suggested keeping only the 3% requirement. Another commenter disagreed with the 3% requirement for

blind samples and requested that the amount to be lowered to 1% to lessen the burden on employers. One commenter suggested that the wording be modified to clarify that employers are responsible for ensuring blind samples are sent to the laboratories, but that collectors are tasked with submitting the blind samples. The Department has evaluated the comments and has concluded that no change is needed. The 400 sample limit was added to reduce the burden on large agencies based on the Department's review of agencies' blind testing programs. The wording in Section 10.1(a) clearly describes the responsibilities of the federal agency and the role of the collector in blind sample submission; however, the Department reworded Section 10.3(a) for clarity as described below.

10.3 How is a blind sample submitted to an HHS-certified laboratory?

The Department has reworded Section 10.3(a) to clarify that the collector sends a blind sample to a laboratory or IITF as a split specimen (*i.e.,* Bottle A and Bottle B).

Subpart K—Laboratory

11.10 What are the requirements for an initial drug test?

One commenter noted that HHS previously required initial and confirmatory testing using different techniques, and asked whether this requirement had been removed with allowance of technologies other than immunoassay for initial testing. The commenter expressed concern that an error in the initial drug test could be repeated in the confirmatory drug test using the same method. The Department has evaluated the comments and has concluded that no change is needed. The Guidelines maintain the requirement for initial and confirmatory tests on two separate aliquots to report a result other than negative. The NLCP will review validation and quality control records, as well as specimen records, to ensure that the initial and confirmatory testing methods meet Guidelines requirements and provide scientifically and forensically supportable results.

Also in regard to the proposed Section 11.10, one commenter asked whether non-FDA cleared immunoassays were included in the category of alternate initial drug test technology. The Department has evaluated the comment and has concluded that no change is needed. This section clearly distinguishes initial tests using immunoassay from those using an alternate technology. Furthermore, Section 1.5 includes the definition for ''alternate technology initial drug test.''

11.11 What must an HHS-certified laboratory do to validate an initial drug test?

One commenter noted that an immunoassay initial test calibrated with a low-reacting analyte may not be able to meet Guidelines requirements for performance of the test around the cutoff concentration. The Department has evaluated the comments and has concluded that no change is needed. All tests must be validated by the HHS-certified laboratory to meet the requirements prior to use for regulated drug testing.

One commenter noted that the requirement in section 11.11(b) for reagent verification prior to use is an operational, not a validation, requirement. The Departments agrees with the commenter but has concluded that no change is needed. While this section addresses initial drug test validation requirements, the verification of each new reagent lot is essential to verify that lot-to-lot differences have not significantly affected assay performance as demonstrated and documented during validation. Therefore, this is the most appropriate section of the Guidelines to include the requirement.

11.12 What are the batch quality control requirements when conducting an initial drug test?

One commenter noted that this and other sections use inconsistent terminology when describing quality controls samples relative to the cutoff concentration (*i.e.,* ''25 percent above the cutoff,'' ''75 percent of the cutoff''). The commenter suggested that the Department use one version consistently. The Department has considered the comment and has concluded that no change is needed. These terms have been used in the Guidelines, in NLCP documents, and in other guidance to HHS-certified laboratories without issue.

One commenter asked whether the added analytes affect quality control content requirements. The Department has evaluated the comment and has concluded that no change is needed. The initial drug test quality control requirements in the Guidelines apply to each analyte used to calibrate the test (*i.e.,* immunoassay or alternate technology initial drug test). When a single immunoassay test is used for two or more analytes in a drug class, the HHS-certified laboratory or IITF must include a control in accordance with item 11.12(a)(2) for each analyte that has less than 100% cross-reactivity with the assay, to demonstrate that the requirement for at least 80% cross-reactivity has been met.

11.12 What are the batch quality control requirements when conducting an initial drug test?

11.15 What are the batch quality control requirements when conducting a confirmatory drug test?

Comments on these two sections are addressed here. One commenter requested clarification for the requirement for a drug-free control in initial and confirmatory drug test batches (*i.e.,* whether the control should contain no drug or whether the control should not contain the specific analyte for that test). The Department has evaluated the comment and has concluded that no change is needed. These Guidelines sections list the requirement for ''at least one control certified to contain no drug or drug metabolite,'' meaning that the control must contain no regulated drug analytes.

11.16 What are the analytical and quality control requirements for conducting specimen validity tests?

One commenter found the wording of Section 11.16(a) to be confusing, noting that a specimen would not be subjected to a second specimen validity test when the first test was in the acceptable range. The Department agrees with the comment and has revised Section 11.16(a) to correctly reflect requirements.

11.18 What are the requirements for conducting each specimen validity test?

One commenter noted that the proposed changes in the lower pH cutoff for identifying adulterated specimens and lower pH decision point for identifying invalid specimens may cause additional costs for manufacturers and laboratories. The Department has evaluated the comment and has concluded that no change is needed. The Department recognizes that the revised cutoff will necessitate changes by HHS-certified laboratories as well as by manufacturers of commercial quality control samples; however, the 4.0 pH cutoff is supported by scientific studies and workplace drug testing data, and is expected to reduce the incidence of undetected attempts to subvert the drug test.

11.19 What are the requirements for an HHS-certified laboratory to report a test result?

One commenter suggested that the Department remove the requirement for

an executed CCF as the official report for ''non-negative'' specimens and permit the use of an electronic report with the required information. The Department has evaluated the comment and has concluded that no change is needed. The Federal CCF serves as the chain of custody for the specimen from the time of collection until receipt by the laboratory and also contains the certification statement signed by the certifying scientist. The Federal CCF may be paper or electronic.

11.21 How long must an HHS-certified laboratory retain records?

In Section 11.21, the Department proposed that laboratories be allowed to convert hardcopy records to electronic records for storage and then discard the hardcopy records after six months. One commenter stated their assumption that this section did not require laboratories to convert electronic records to hardcopy records and maintain them for six months. This assumption is correct; the intent is to allow laboratories to maintain records in electronic format for the required storage period. The Department has concluded that no change is needed.

11.22 What statistical summary reports must an HHS-certified laboratory provide for urine testing?

One commenter asked why the proposed Guidelines include a requirement for a copy of the semiannual statistical summary report to be sent to the Secretary or designated HHS representative. The Department included the requirement in Section 11.22 (and in Section 12.19 for IITFs) to facilitate compilation of statistical information for the federal drug-free workplace program. This will not place an additional burden on the test facilities other than transmission of the report. The Department will continue to evaluate the effectiveness of this requirement.

Subpart M—Medical Review Officer (MRO)

13.1 Who may serve as an MRO?

Three commenters disagreed with the term ''nonmedical use of a drug'' used in Section 13.1 (and defined in Section 1.5) and indicated that the term changes the role of an MRO from review, verify and ''report a non-negative result'' to review, verify and ''interpret before reporting a result as negative or nonmedical use of a drug.'' Two commenters disagreed with use of ''interpretation of results'' to supplant ''alternative medical explanation.'' One commenter noted that this perceived change in the MRO's role represents an unjustified shifting of risk to the MRO. One commenter believes the term presents a possible legal flaw to the Guidelines, stating that this term is legally different from ''safety concern'' and places MROs in the position of being in conflict with the prescribing physician and subject to lawsuits. This commenter stated that even a lack of a finding of nonmedical use could be an issue if the donor subsequently had an accident after using the drug. The same commenter submitted five recommendations related to inclusion of prescription drugs in federal workplace drug testing programs, to address the commenter's concerns with the proposed Guidelines. These five specific recommendations pertain to matters that are outside the scope of these Guidelines, and therefore are not addressed in the Department's response below.

The responsibilities of an MRO to interpret results have largely remained the same between the Guidelines effective October 1, 2010 (73 FR 71858) and these Guidelines. As stated in Section 13.5(c) of these Guidelines, ''if the donor provides a legitimate medical explanation (*e.g.,* a valid prescription) for the positive result, the MRO reports the test result as negative to the agency.'' Accordingly, the intent of the Guidelines, in this context, is to confirm whether a positive drug test is the result of drug use under a valid prescription. Furthermore, the term ''alternate medical explanation'' has never been used in the Guidelines, but has been used in the HHS Medical Review Officer Manual for Federal Workplace Drug Testing Programs.

For the reasons above, the Department believes that the definition of ''nonmedical use of a drug'' and the requirement for a physician serving as an MRO to have knowledge of this topic do not fundamentally change the MRO's responsibilities. However, to address the commenters' concerns, the Department has removed this term from the Guidelines (*i.e.,* revised Sections 1.5 and 13.1).

The Department proposed within Section 13.1 who may serve as an MRO. One commenter requested clarification that it is the federal agency's burden to ensure that the MRO is certified. One commenter asked how the laboratory will be informed that an MRO has met requirements for re-qualification. The Department evaluated the comments and concluded that no change is needed. The MRO is an employee or a contractor of the agency. Therefore, it is the agency's responsibility to ensure that the MRO meets the Guidelines qualification requirements.

Two commenters disagreed with the requirement for MRO recertification every five years, and recommended that MROs complete training every three years. Five commenters stated support for five year requalification and examination requirements. The Department has evaluated the comments and has concluded that no change is needed. The Department will keep the five-year recertification requirement as proposed.

13.2 How are nationally recognized entities or subspecialty boards that certify MROs approved?

One commenter agreed with MRO certification/training entities submitting the delivery method and content of the MRO examination as applicable along with other required documents. One commenter agreed with extending time from one to two years for approved MRO certification/training entities' resubmission of qualifications for HHS approval. The commenter noted that they would support further extension to 3 years. One commenter recommended that approval of MRO educational courses and content be at the discretion of the MRO certification entities, not HHS. Since the certification entities and their examinations are subject to HHS oversight and approval, the commenter noted that it may be burdensome for HHS to review and approve the courses and content, and be a disincentive to development of new courses. One commenter recommended that examinations be allowed to be in-person or online with appropriate security precautions for each delivery method. The Department has evaluated the comments and agrees that the submission of training materials to HHS would possibly discourage the development of new training courses. Therefore, the review of MRO educational courses and content will not be part of the approval process for MRO certification entities. As described under *Medical Review Officer (MRO) requalification—continuing education units (CEUs)* in this preamble, the Department has removed references to MRO training entities in Section 13.2, because training documentation is maintained by MRO certification entities. The Department will only require the MRO certification entities to submit their examination and any other necessary supporting examination materials (*e.g.,* answers, examination statistics or background information on questions) that will help in the Department's evaluation of the examination. The Department will

review and evaluate the examination delivery method (*e.g.,* in-person or online) when reviewing submitted training materials to ensure that the delivery method employs appropriate security and identification procedures.

13.3 What training is required before a physician may serve as an MRO?

Five commenters disagreed and one commenter agreed with the added requirement for MRO training to include information about how to discuss substance misuse and abuse and how to access those services. The Department has evaluated the comments and has revised Section 13.3 to remove this requirement. Federal agencies may provide this information to employees and applicants to facilitate their access to effective treatment and support recovery. The Department provides information to the public on help and treatment for substance misuse and abuse, and how to access those services, on the SAMHSA Web site *http://www.samhsa.gov/.*

One commenter stated that the Department should add a requirement for MRO training on what constitutes a refusal to test. One commenter suggested that the Department should add a requirement for MRO training on when and how to report safety concerns to employers when prescription and/or over-the-counter medications may affect performance. The Department has evaluated the comments and has concluded that no change is needed. Criteria for reporting a refusal to test are covered under the topics listed in Section 13.3 such as items (a)(4) training on the Guidelines and (a)(5) procedures for interpretation, review, and reporting of results. When a donor provides a legitimate medical explanation for a positive drug test result (*e.g.,* a valid prescription), the Guidelines do not require MROs to contact federal agency employers for the purpose of reporting a safety concern. Accordingly, MRO training related to reporting ''safety concerns'' does not relate to a mandatory function under the Guidelines and, therefore, is not an essential component of required MRO training. The Department will provide additional guidance in the HHS Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs.

In addition, the Department revised Section 13.3 as described under *Medical Review Officer (MRO) requalification—continuing education units (CEUs)* in this preamble. The Department removed references to MRO training entities, because training documentation is maintained by MRO certification entities, and added item 13.3(b) to require MRO training on revised Guidelines prior to their effective date.

13.4 What are the responsibilities of an MRO?

One commenter suggested creating a subset of medical professionals trained specifically to determine fitness for duty since an MRO cannot determine fitness for duty over the telephone. The Department has evaluated the comment and has concluded that no change is needed. Fitness for duty evaluations fall outside the purview of the Guidelines.

13.5 What must an MRO do when reviewing a urine specimen's test results?

The Department has revised Section 13.5(d)(1) to include an example of documentation to support a medical explanation for a positive drug test result.

Three commenters disagreed with MRO procedures for ''a positive result for opiates'' (*i.e.,* requirement for clinical evidence of illegal use in addition to positive result) and noted that the proposed Guidelines wording was not changed to clarify that the described procedures do not apply to the added opioids. The Department agrees with the commenters and has revised Section 13.5(d) to clarify that the procedures do not apply to the added opioid analytes. Wording in Section 13.5(d)(2)(i) regarding ''clinical evidence of illegal use'' was also edited for clarity and for consistency with the wording in the OFMG.

One commenter disagreed with requirements concerning two separate specimens collected at a single test event and sent to the laboratory for testing (*e.g.,* a urine specimen outside the acceptable temperature range and the subsequently collected specimen). The proposed Guidelines require that, when one of the two specimens is negative and other is not, the MRO reports only the verified result other than negative. This commenter suggested that the MRO cancel the negative result. The Department has evaluated the comments and has concluded no change is needed. Cancellation of the test may be confusing in the situation referenced by the commenter and lead to inappropriate specimen recollection. Both the MRO and the federal agency employer will receive their Federal CCF copies with explanatory collector remarks in Step 2 including the specimen identification number of the associated specimen, and the MRO may provide additional comment in the MRO's report.

The Department also revised Section 13.5(d) to reflect the policy of the Department that passive exposure to marijuana smoke and ingestion of food products containing marijuana are not acceptable medical explanations for a positive drug test result. Individuals who are passively exposed to marijuana smoke or who consume food products containing marijuana can pose public safety and/or security risks.[4 5] Marijuana is listed as a Schedule I drug under the Controlled Substances Act.

13.6 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?

One commenter suggested the Guidelines define ''appropriate expertise'' of a physician with a list of conditions and an appropriate type of physician in an appendix. The same commenter requested medical referral information on the employer's actions when a donor could not provide a urine specimen and then could not provide an oral fluid specimen. The Department has evaluated the comments and has concluded that no change is needed. A physician who is a trained MRO will have the knowledge necessary to identify another physician with appropriate expertise for the medical evaluation. The Department will provide additional guidance in the HHS Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs as appropriate when alternate specimen types (*e.g.,* oral fluid) are allowed in federal workplace drug testing programs.

The Department clarified the definition of ''permanent or long-term medical conditions'' in Section 13.6(b)(1) based on a federal agency comment.

Subpart O—Criteria for Rejecting a Specimen for Testing

15.1 What discrepancies require an HHS-certified laboratory or an HHS-certified IITF to report a specimen as rejected for testing?

The Department revised wording in items a and b of this section, and included three additional fatal flaws as items f–h, to reflect fatal flaws for regulated donor specimens that have been identified by HHS-certified laboratories. These fatal flaws were addressed in NLCP guidance sent to all HHS-certified and applicant laboratories and IITFs on August 9, 2016. In addition, the Department revised this section to include an additional item i to allow a laboratory or IITF to reject a specimen when they identify a flaw that

prevents testing or affects the forensic defensibility of the drug test, and cannot be corrected. This general item enables laboratories and IITFs to reject specimens with fatal flaws that may be rare, but do occur. It is not possible to list all such flaws in the Guidelines.

15.3 What discrepancies are not sufficient to require an HHS-certified laboratory or an HHS-certified IITF to reject a urine specimen for testing or an MRO to cancel a test?

Two commenters indicated that inclusion of some items as insignificant discrepancies contradicts guidance provided to HHS-certified laboratories and IITFs in NLCP Notices, which required laboratories to attempt to recover missing information. One of these commenters suggested that if these items are important, they should be removed from the ''insignificant'' list. Two commenters disagreed with the Guidelines designating the listed omissions and discrepancies as ''insignificant only when they occur no more than once per month.'' The Department has evaluated the comments. The listed discrepancies would not result in rejection or cancellation. NLCP Notices requiring laboratory action are consistent with this section. However, the Department has reworded section 15.3 to not classify these errors as insignificant. While these types of errors do not warrant laboratory rejection of a specimen or MRO cancellation of a test, as noted in section 15.3(c), corrective action must be initiated when they occur more than once a month.

The commenters indicated that this section implies that the MRO must keep a log of insignificant errors by laboratory and by collection site in order to track frequency. The commenters noted that this is an unenforceable policy, that this should be a duty of inspectors of laboratories and collection sites, and that requiring MROs to keep these types of logs would create significant extra costs. One commenter suggested that item 15.3(c) be modified for the MRO to advise the collector or laboratory to retrain staff on relevant procedures to ensure that collections are completed correctly (rather than directing them to immediately take corrective action). The Department has evaluated the comments and has concluded that no change is needed. This section is the same as in the Guidelines effective October 1, 2010 (73 FR 71858).

One commenter suggested modifying 15.3(a)(5) to read ''donor identification number'' which would include a social security number or an employee identification number since many employers no longer use social security numbers for employee identification. The Department agrees and has revised Section 15.3(a)(5) to include ''employee identification number'' in addition to ''Social Security Number.''.

15.4 What discrepancies may require an MRO to cancel a test?

One commenter suggested adding the scenario where the donor did not sign the CCF because the collector forgot to ask the donor to sign, rather than the donor's refusal to sign. The Department has evaluated the comment and has concluded that no change is needed. As stated in Section 15.4, the MRO contacts the collector ''to obtain a statement to verify that the donor refused to sign the MRO copy.''

Regulatory Impact and Notices

Executive Orders 13563 and 12866

Executive Order 13563 of January 18, 2011 (Improving Regulation and Regulatory Review) states ''Our regulatory system must protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation.'' Consistent with this mandate, Executive Order 13563 requires agencies to tailor ''regulations to impose the least burden on society, consistent with obtaining regulatory objectives.'' Executive Order 13563 also requires agencies to ''identify and consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice'' while selecting ''those approaches that maximize net benefits.'' This notice presents a regulatory approach that will reduce burdens to providers and to consumers while continuing to provide adequate protections for public health and welfare.

The Secretary has examined the impact of the Guidelines under Executive Order 12866, which directs federal agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity).

According to Executive Order 12866, a regulatory action is ''significant'' if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million; adversely affecting in a material way a sector of the economy, competition, or jobs; or if it raises novel legal or policy issues. The Guidelines do establish additional regulatory requirements and allow an activity that was otherwise prohibited. The Administrative Procedure Act (APA) delineates an exception to its rulemaking procedures for ''a matter relating to agency management or personnel'' 5 U.S.C. 553(a)(2). Because the Guidelines issued by the Secretary govern federal workplace drug testing programs, HHS has taken the position that the Guidelines are a ''matter relating to agency management or personnel'' and, thus, are not subject to the APA's requirements for notice and comment rulemaking. This position is consistent with Executive Order 12564 regarding Drug-Free Workplaces, which directs the Secretary to promulgate scientific and technical guidelines for executive agency drug testing programs. However, the statute under which the mandatory guidelines were created (Pub. L. 100–71, section 503(a)(3)) required notice and comment apart from the APA. This provision provides the following:

> (3) Notwithstanding any provision of chapter 5 of title 5, United States Code, the mandatory guidelines to be published pursuant to subsection (a)(l)(A)(ii) shall be published and made effective exclusively according to the provisions of this paragraph. Notice of the mandatory guidelines proposed by the Secretary of Health and Human Services shall be published in the **Federal Register**, and interested persons shall be given not less than 60 days to submit written comments on the proposed mandatory guidelines. Following review and consideration of written comments, final mandatory guidelines shall be published in the **Federal Register** and shall become effective upon publication.

The Department included a Regulatory Impact and Notices section with cost and benefits analysis and burden estimates in the May 15, 2015 **Federal Register** Notice for the proposed UrMG (80 FR 28101), and requested public comment on all figures and assumptions. The Department's projections were developed using information from current HHS-certified urine testing laboratories, with input from DOT and the Nuclear Regulatory Commission (NRC), and cost analysis was based on information provided by multiple HHS-certified laboratories and MROs. The Department received no substantive data or evidence through public comments in favor of changing the estimated costs and benefits provided in the Department's May 2015 **Federal Register** Notice for the UrMG, and therefore, has retained the analysis and estimates provided in that notice below. Comments that related to the costs and benefits of this rule are summarized and discussed above in the Summary of Public Comments and

HHS's Response under the heading *Costs and Benefits.*

Need for Revisions to the Guidelines

The inclusion of oxycodone, oxymorphone, hydrocodone and hydromorphone in the URMG was recommended by the DTAB, reviewed by the Department's Prescription Drug Subcommittee of the Behavioral Health Coordinating Committee, and approved by the SAMHSA Administrator in January 2012. This action is supported by various data, described in this preamble.[1–4] In addition, in 2008, 12 percent of military personnel admitted to the illicit use of prescription medications. Prevalence testing by the Department of Defense (DoD) in 2009 indicated that prescription drug abuse exceeded illegal drug abuse. Because of this, hydrocodone and hydromorphone testing was added to the regular DoD drug testing panel in 2011.

Costs

Costs associated with the implementation of testing for oxycodone, oxymorphone, hydrocodone and hydromorphone will be minimal because the Department has determined that all HHS certified laboratories testing specimens from federal agencies are currently conducting tests for one or more of these analytes on non-regulated urine specimens. Likewise, there will be minimal costs associated with changing initial testing to include MDA since the current immunoassays can be adapted to test for this analyte. Laboratory personnel are currently trained and test methods have been implemented. However, there will be some administrative costs associated with adding these analytes. Prior to being allowed to test regulated specimens for these compounds, HHS certified laboratories will be required to demonstrate that their performance meets Guideline requirements by testing three (3) groups of PT samples. The Department will provide the PT samples through the National Laboratory Certification Program (NLCP) at no cost to the certified laboratories. Based on costs charged for specimen testing, laboratory costs to conduct the PT testing would range from $900 to $1,800 for each certified laboratory.

In Section 3.4, the Department included criteria for calibrating initial tests for grouped analytes such as opiates and amphetamines, and specified the cross-reactivity of the immunoassay to the other analytes(s) within the group. These Guidelines allow the use of methods other than immunoassay for initial testing. An immunoassay manufacturer may incur costs if they choose to alter their existing product and resubmit the immunoassay for FDA clearance.

For the added opiate analytes, the two immunoassays currently used for oxycodone and oxymorphone meet the requirements, and two of the three existing opiate immunoassays used in certified laboratories meet the requirements for hydrocodone and hydromorphone analysis. The opiate immunoassay that does not have sufficient cross-reactivity would be acceptable as an initial test under these Guidelines when the lowest-reacting analyte, hydromorphone, is used to establish a decision point. Therefore, the Department assumes that all certified laboratories will elect to use existing immunoassays. Thus, the costs associated with implementing the initial tests for these analytes is expected to be *de minimis.*

For amphetamines, one of the three existing methylenedioxymethamphetamine (MDMA) immunoassays used in certified laboratories meets the requirements. The remaining two exhibit insufficient cross-reactivity for MDA. These two immunoassays would be acceptable as an initial test under these Guidelines when the lowest-reacting analyte, MDA, is used to establish a decision point. An immunoassay manufacturer may incur costs if they choose to alter their existing product and resubmit the immunoassay for FDA clearance. Again, the Department assumes that certified laboratories will use the existing immunoassays and incur *de minimis* costs.

Once the testing has been implemented, the cost per specimen for initial testing for the added analytes will range from $.06 to $0.20 due to reagent costs. Current costs for each confirmatory test range from $5.00 to $10.00 for each specimen reported positive, due to sample preparation and analysis costs. Based on information from non-regulated workplace drug testing for these analytes and testing performed by the Department on de-identified federally regulated specimens in 2011, approximately 1% of the submitted specimens is expected to be confirmed as positive for the added analytes. Therefore, the added cost for confirmatory testing will be $0.05 to $0.10 per submitted specimen. This would indicate that the cost per specimen submitted for testing will increase by $0.11–$0.30. Annual recurring testing costs in the table below are based on an estimated number of 6,145,500 specimens.

The addition of the Schedule II prescription medications will require MRO review to verify legitimate drug use. Based on the positivity rates from non-regulated workplace drug testing for these analytes and the additional review of specimens confirmed positive for prescription medications, MRO costs are estimated to increase by approximately 3%. The burden of this 3% cost increase is expected to shift gradually from MROs to agencies as agencies' existing contracts expire and they renegotiate the terms of new contracts, with an increase to the total cost of a federal drug test over time to between $0.60–$1.35. This cost would indicate a total cost of $3,687,300 to $8,296,425 in the urine testing program. A federal agency may also incur additional costs (*e.g.,* additional managerial effort to arrange substitute workers) when an employee tests positive for a prescription medication and is removed from duties during the MRO verification process.

The additional costs for testing and MRO review will be incorporated into the overall cost for the federal agency submitting the specimen to the laboratory. The estimation of costs incurred is based upon overall cost to the federal agency because the review of positive specimens is usually based on all specimens submitted from an agency, rather than individual specimen testing costs or MRO review of positive specimens. Agencies may also incur some costs for training of federal employees such as drug program coordinators due to implementation of the revised Guidelines. Based on current training modules offered to drug program coordinators, and other associated costs including travel for 90% of drug program coordinators, the estimated total training cost for a one-day training session would be between $108,000 and $138,000 (*i.e.,* assuming 8 hours of time multiplied by a GS 12/13 wage including benefits and overhead adjustments). The Department will offer the choice of online or in-person training. This will eliminate travel costs for those federal agencies who choose to use online training.

RECURRING ANNUAL COSTS SUMMARY TABLE

	Lower bound	Upper bound
Reagent Costs	$368,730.00	$1,229,100.00
Additional Confirmatory tests	307,275.00	614,550.00
MRO Costs	3,687,300.00	8,296,425.00
Total annual costs	4,363,305.00	10,140,075.00

UPFRONT (ONE-TIME) COSTS SUMMARY TABLE

	Lower bound	Upper bound
Performance Testing	$27,900.00	$55,800.00
Training	108,000	138,000
Total	135,900.00	193,800.00

Benefits

The potential benefits of deterring use of oxycodone, oxymorphone, hydrocodone and hydromorphone are the prevention of their side effects (*e.g.,* anxiety, dizziness, drowsiness, fatigue, and other neurological effects), which will result in a healthier and more alert workforce as well as avoid the issues associated with addiction and rehabilitation. Since the personnel tested under this program are in positions that are safety sensitive, potential benefits include decreased risk of transportation accidents, decreased risk of low-probability high consequence events, more responsible workforce in positions of public trust, and potentially reducing individuals' dependence or addiction and the personal benefits associated with those conditions.

Considering the potential health and performance costs of narcotic abuse, the benefits to the federal workplace and the individuals within that workplace justify the inclusion of oxycodone, oxymorphone, hydrocodone and hydromorphone in Federal Workplace Drug Testing programs.

Regulatory Flexibility Analysis

For the reasons outlined above, the Secretary has determined that the Guidelines will not have a significant impact upon a substantial number of small entities within the meaning of the Regulatory Flexibility Act [5 U.S.C. 605(b)]. The flexibility added by the UrMG will not require addition expenditures. Therefore, a final regulatory flexibility analysis is not required for this notice.

The Secretary has determined that the Guidelines are not a major rule for the purpose of congressional review. For the purpose of congressional review, a major rule is one which is likely to cause an annual effect on the economy of $100 million; a major increase in costs or prices; significant effects on competition, employment, productivity, or innovation; or significant effects on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets. This is not a major rule under the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996.

Unfunded Mandates

The Secretary has examined the impact of the Guidelines under the Unfunded Mandates Reform Act (UMRA) of 1995 (Pub. L. 104–4). This notice does not trigger the requirement for a written statement under section 202(a) of the UMRA because the Guidelines do not impose a mandate that results in an expenditure of $100 million (adjusted annually for inflation) or more by either state, local, and tribal governments in the aggregate or by the private sector in any one year.

Environmental Impact

The Secretary has considered the environmental effects of the UrMG. No information or comments have been received that would affect the agency's determination there would be a significant impact on the human environment and that neither an environmental assessment nor an environmental impact statement is required.

Executive Order 13132: Federalism

The Secretary has analyzed the Guidelines in accordance with Executive Order 13132: Federalism. Executive Order 13132 requires federal agencies to carefully examine actions to determine if they contain policies that have federalism implications or that preempt state law. As defined in the Order, ''policies that have federalism implications'' refer to regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

In this notice, the Secretary revised the standards for certification of laboratories engaged in urine fluid drug testing for federal agencies and the use of urine testing in federal drug-free workplace programs. The Department of Health and Human Services, by authority of Section 503 of Public Law 100–71, 5 U.S.C. Section 7301, and Executive Order No. 12564, establishes the scientific and technical guidelines for federal workplace drug testing programs and establishes standards for certification of laboratories engaged in urine drug testing for federal agencies. Because the Mandatory Guidelines govern standards applicable to the management of federal agency personnel, there should be little, if any, 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. Accordingly, the Secretary has determined that the Guidelines do not contain policies that have federalism implications.

Paperwork Reduction Act of 1995

The Guidelines contain information collection requirements which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 [the PRA 44 U.S.C. 3507(d)]. Information collection and recordkeeping requirements which would be imposed on laboratories engaged in drug testing for federal agencies concern quality assurance and

quality control documentation, reports, performance testing, and inspections as set out in subparts H, I, K, L, M and N. Information collection and recordkeeping requirements which would be imposed on MROs engaged in drug testing services for federal agencies concern drug testing result review and reports as set out in subparts M and N. To facilitate ease of use and uniform reporting, a Federal CCF for each type of specimen collected will be developed as referenced in section 6.1. The Department will submit the information collection and recordkeeping requirements contained in the Guidelines to OMB for review and approval prior to the effective date of the final Guidelines. Information collections changed by these Guidelines are not effective until approved by OMB.

Privacy Act

The Secretary has determined that the Guidelines do not contain information collection requirements constituting a system of records under the Privacy Act. The **Federal Register** notice announcing the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine is not a system of records as noted in the information collection/recordkeeping requirements below. As required, HHS originally published the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Guidelines) in the **Federal Register** on April 11, 1988 [53 FR 11979]. SAMHSA subsequently revised the Guidelines on June 9, 1994 [59 FR 29908], September 30, 1997 [62 FR 51118], November 13, 1998 [63 FR 63483], April 13, 2004 [69 FR 19644], and November 25, 2008 [73 FR 71858] with an effective date of May 1, 2010 (correct effective date published on December 10, 2008 [73 FR 75122]). The effective date of the Guidelines was further changed to October 1, 2010 on April 30, 2010 [75 FR 22809].

Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Executive Order 13175 (65 FR 67249, November 6, 2000) requires SAMHSA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' as defined in the Executive Order, include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the federal government and the Indian tribes, or on the distribution of power and responsibilities between the federal government and Indian tribes.'' The Guidelines do not have tribal implications. The Guidelines will not have substantial direct effects on tribal governments, 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, as specified in Executive Order 13175.

Information Collection/Record Keeping Requirements

The information collection requirements (*i.e.,* reporting and recordkeeping) in the current Guidelines (73 FR 71858) are approved by the Office of Management and Budget (OMB) under control number 0930–0158. The Federal Drug Testing Custody and Control Form used to document the collection and chain of custody of urine specimens at the collection site, for laboratories to report results, and for Medical Review Officers to make a determination, the National Laboratory Certification Program (NLCP) application, the NLCP Laboratory Information Checklist, and recordkeeping requirements in the current Guidelines, as approved under control number 0930–0158, will remain in effect until these final Guidelines are effective and OMB approves the revised information collection. OMB will assign a new control number to account for changes associated with the final Guidelines.

The title, description and respondent description of the information collections are shown in the following paragraphs 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: The Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine Specimens

Description: The Mandatory Guidelines establish the scientific and technical guidelines for federal drug testing programs and establish standards for certification of laboratories engaged in drug testing for federal agencies under authority of Public Law 100–71, 5 U.S.C. 7301 note, and Executive Order No. 12564. Federal drug testing programs test applicants to sensitive positions, individuals involved in accidents, individuals for cause, and random testing of persons in sensitive positions.

Description of Respondents: Individuals or households; businesses; or other-for-profit; not-for-profit institutions.

The burden estimates in the tables below are based on the following number of respondents: 38,000 donors who apply for employment in testing designated positions, 100 collectors, 30 urine specimen testing laboratories, 1 IITF, and 100 MROs.

ESTIMATE OF ANNUAL REPORTING BURDEN

Section	Purpose	Number of respondents	Responses/ respondent	Hours/ response	Total hours
9.2(a)(1)	Laboratory or IITF [1] required to submit application for certification.	10	1	3	30
9.12(a)(3)	Materials to submit to become an HHS inspector	10	1	2	20
11.3(a)	Laboratory submits qualifications of RP to HHS	10	1	2	20
11.4(c)	Laboratory submits information to HHS on new RP or alternate RP.	10	1	2	20
11.22	Specifications for laboratory semi-annual statistical report of test results to each federal agency.	10	5	0.5	25
12.3(a)	IITF[1] submits qualifications of RT to HHS	1	1	1	1
12.4(c)	IITF[1] submits information to HHS on new RT or alternate RT.	1	1	1	1
12.19	Specifications for IITF [1] semi-annual statistical report of test results to each federal agency.	1	1	1	1

ESTIMATE OF ANNUAL REPORTING BURDEN—Continued

Section	Purpose	Number of respondents	Responses/ respondent	Hours/ response	Total hours
13.9 and 14.7	Specifies that MRO must report all verified primary and split specimen test results to the federal agency.	100	14	0.05 (3 min)	70
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 laboratory suspension/revocation is proposed.	1	1	0.5	0.5
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
Total		159			295

[1] Although IITFs are allowed under the Guidelines effective October 1, 2010 (73 FR 71858), SAMHSA has not received any IITF applications for certification to test federally regulated specimens. IITF numbers are provided in this analysis as placeholders for administrative purposes.

The following reporting requirements are also in the Guidelines, but have not been addressed in the above reporting burden table: Collector must report any unusual donor behavior or refusal to participate in the collection process on the Federal CCF [Sections 1.8, 8.9]; collector annotates the Federal CCF when a sample is a blind sample [Section 10.3(a)]; MRO notifies the federal agency and HHS when an error occurs on a blind sample [Section 10.4(c)]; Section 13.5 describes the actions an MRO takes to report a primary specimen result; Section 14.6 describes the actions an MRO takes to report a split specimen result; and Sections 13.6 and 13.7 describe the actions an MRO takes for the medical evaluation of a donor who cannot provide a urine specimen. 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
8.3(a), 8.5(f)(2) (iii), 8.6(b)(2).	Collector must contact federal agency point of contact.	100	1	0.05 (3 min)	5
11.23, 11.24	Information on drug test that laboratory must provide to federal agency upon request or to donor through MRO.	50	10	3	1,500
12.20, 12.21	Information on drug test that IITF[1] must provide to federal agency upon request or to donor through MRO.	1	1	1	1
13.8(b)	MRO must inform donor of right to request split specimen test when a positive, adulterated, or substituted result is reported.	100	14	3	4,200
Total		211			5,706

[1] Although IITFs are allowed under the Guidelines effective October 1, 2010 (73 FR 71858), SAMHSA has not certified any IITFs to test federally regulated specimens. IITF numbers are provided in this analysis as placeholders for administrative purposes.

The following disclosure requirements are also included in the 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 [Section 8.3(e) and (g)]. SAMHSA believes having the collector explain the collection procedure to the donor and 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, 8.5, 8.8	Collector completes Federal CCF for specimen collected.	100	380	0.07 (4 min)	2,534
8.8(d) & (f)	Donor initials specimen labels/seals and signs statement on the Federal CCF.	38,000	1	0.08 (5 min)	3,167

ESTIMATE OF ANNUAL RECORDKEEPING BURDEN—Continued

Section	Purpose	Number of respondents	Responses/ respondent	Hours/ response	Total hours
11.8(a) & 11.19	Laboratory completes Federal CCF upon receipt of specimen and before reporting result.	10	3,800	0.05 (3 min)	1,900
12.8(a) & 12.15	IITF[1] completes Federal CCF upon receipt of specimen and before reporting result.	1	1	1	1
13.4(d)(4),13.9(c),14.7(c)	MRO completes Federal CCF before reporting the primary or split specimen 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
Total		38,511			9,517

[1] Although IITFs are allowed under the Guidelines effective October 1, 2010 (73 FR 71858), SAMHSA has not certified any IITFs to test federally regulated specimens. IITF numbers are provided in this analysis as placeholders for administrative purposes.

The 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)(3)] and the documentation must be maintained in the collector's training file [Section 4.3(c)]. Because this is required by the current Guidelines and is consistent with general forensic requirements, 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 [Sections 8.4(c), 8.5(d)(2), 8.5(e)(1) and (2)] 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 are included in the recordkeeping burden estimated to complete the Federal CCF and is, therefore, not considered an additional recordkeeping burden. Subpart K describes a number of recordkeeping requirements for laboratories associated with their testing procedures, maintaining chain of custody, and keeping records [*i.e.,* Sections 11.1(a) and (d); 11.2(b), (c), and (d); 11.6(b); 11.7(c); 11.8; 11.11(a); 11.14(a); 11.17; 11.21(a), (b), and (c); 11.22; 11.23(a) and 11.24. These recordkeeping requirements are necessary for any laboratory 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.

Thus the total annual response burden associated with the testing of urine specimens by the laboratories and IITFs is estimated to be 15,518 hours (that is, the sum of the total hours from the above tables). This is in addition to the 1,788,809 hours currently approved by OMB under control number 0930–0158 for urine testing under the current Guidelines.

As required by section 3507(d) of the PRA, the Secretary submitted a copy of these proposed Guidelines to OMB for its review. Comments on the information collection requirements were 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.

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Dated: January 11, 2017.

Kana Enomoto,

Acting Deputy Assistant Secretary for Mental Health and Substance Use, SAMHSA.

Dated: January 11, 2017.

Sylvia M. Burwell

Secretary.

The Mandatory Guidelines using Urine Specimens 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 Using Urine Specimens

Subpart A—Applicability

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 who provide specimen collection services to the federal agencies; and

(7) Medical Review Officers (MROs) who provide drug testing review and interpretation of results services to the federal agencies.

(b) These 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.[1]

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) To ensure the full reliability and accuracy of specimen 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 signs the Federal Drug Testing Custody and Control Form at the time of specimen receipt at the HHS-certified laboratory or (for urine) the HHS-certified IITF.

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 portion of a specimen used for testing.

Alternate Responsible Person. The person who assumes professional, organizational, educational, and administrative responsibility for the day-to-day management of the HHS-certified laboratory when the responsible person is unable to fulfill 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 fulfill these obligations.

Alternate Technology Initial Drug Test. An initial drug test using technology other than immunoassay to differentiate negative specimens from those requiring further testing.

Batch. A number of specimens or aliquots handled concurrently as a group.

Biomarker. An endogenous substance used to validate a biological specimen.

Blind Sample. A sample submitted to an HHS-certified test facility for quality assurance purposes, with a fictitious identifier, so that the test facility cannot distinguish it from a donor specimen.

Calibrator. A sample of known content and analyte concentration prepared in the appropriate matrix used to define expected outcomes of a testing procedure. The test result of the calibrator is verified to be within established limits prior to use.

Cancelled Test. The result reported by the MRO to the federal agency when a specimen has been reported to the MRO as an 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 flaw exists in the forensic records (as described in Sections 15.1 and 15.2).

Carryover. The effect that occurs when a sample result (*e.g.,* drug concentration) is affected by a preceding sample during the preparation or analysis of a sample.

Certifying Scientist (CS). The individual responsible for verifying the chain of custody and scientific reliability of a 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, rejected for testing, and (for urine) negative/dilute results reported by an HHS-certified laboratory or (for urine) an HHS-certified IITF.

Chain of Custody (COC) Procedures. Procedures that document the integrity of each specimen or aliquot from the point of collection to final disposition.

Chain of Custody Documents. Forms used to document the control and security of the specimen and all aliquots. The document may account for an individual specimen, aliquot, or batch of specimens/aliquots and must include the name and signature of each individual who handled the specimen(s) or aliquot(s) and the date and purpose of the handling.

Collection Container. A receptacle used to collect a urine specimen.

Collection Site. The location where specimens are collected.

Collector. A person trained to instruct and assist a donor in providing a specimen.

Confirmatory Drug Test. A second analytical procedure performed on a separate aliquot of a specimen to identify and quantify a specific drug or drug metabolite.

Confirmatory Specimen Validity Test. A second test performed on a separate aliquot of a 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 analytical value (*e.g.,* drug or drug metabolite concentration) used as the decision point to determine a result (*e.g.,* negative, positive, adulterated, invalid, or, for urine, substituted) or the need for further testing.

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.

External Service Provider. An independent entity that performs services related to federal workplace drug testing on behalf of a federal agency, a collector/collection site, an

[1] The NRC-related information in this notice pertains to individuals subject to drug testing conducted pursuant to 10 CFR part 26, ''Fitness for Duty Programs'' (*i.e.,* employees of certain NRC-regulated entities).

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, 1988, and any amendments to those guidelines . . .'' See 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.

HHS-certified laboratory, a Medical Review Officer (MRO), or, for urine, an HHS-certified Instrumented Initial Test Facility (IITF).

Failed to Reconfirm. The result reported for a split (B) specimen when a second HHS-certified laboratory is unable to corroborate the result reported for the primary (A) 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 and chain of custody of a specimen from the time the specimen is collected until it is received by the test facility (*i.e.,* HHS-certified laboratory or, for urine, HHS-certified IITF). It may be a paper (hardcopy), electronic, or combination electronic and paper format (hybrid). The form may also be used to report the test result to the Medical Review Officer.

Gender Identity. Gender identity means an individual's internal sense of being male or female, which may be different from an individual's sex assigned at birth.

HHS. The Department of Health and Human Services.

Initial Drug Test. An analysis used to differentiate negative specimens from those requiring further testing.

Initial Specimen Validity Test. The first analysis used to determine if a specimen is invalid, adulterated, or (for urine) diluted or substituted.

Instrumented Initial Test Facility (IITF). A permanent location where (for urine) 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 3.9 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 drug testing, reporting of results, and recordkeeping are performed under the supervision of a responsible person.

Limit of Detection. The lowest concentration at which the analyte (*e.g.,* drug or drug metabolite) can be identified.

Limit of Quantification. For quantitative assays, the lowest concentration at which the identity and concentration of the analyte (*e.g.,* drug or drug metabolite) can be accurately established.

Lot. A number of units of an item (*e.g.,* reagents, quality control material) manufactured from the same starting materials within a specified period of time for which the manufacturer ensures that the items have essentially the same performance characteristics and expiration date.

Medical Review Officer (MRO). A licensed physician who reviews, verifies, and reports a specimen test result to the federal agency.

Negative Result. The result reported by an HHS-certified laboratory or (for urine) an HHS-certified IITF to an MRO when a specimen contains no drug and/or drug metabolite; or the concentration of the drug or drug metabolite is less than the cutoff for that drug or drug class.

Oral Fluid Specimen. An oral fluid specimen is collected from the donor's oral cavity and is a combination of physiological fluids produced primarily by the salivary glands.

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 a laboratory or (for urine) to an IITF 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 confirmation cutoff concentration.

Reconfirmed. The result reported for a split (B) specimen when the second HHS-certified laboratory corroborates the original result reported for the primary (A) specimen.

Rejected for Testing. The result reported by an HHS-certified laboratory or (for urine) HHS-certified IITF when no tests are performed on a specimen because of a fatal flaw or an unrecovered correctable error (see 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 an HHS-certified laboratory.

Responsible Technician (RT). The person who assumes professional, organizational, educational, and administrative responsibility for the day-to-day management of an HHS-certified IITF.

Sample. A performance testing sample, calibrator or control used during testing, or a representative portion of a donor's specimen.

Secretary. The Secretary of the U.S. Department of Health and Human Services.

Specimen. Fluid or material collected from a donor at the collection site for the purpose of a drug test.

Split Specimen Collection (for Urine). A collection in which the specimen collected is divided into a primary (A) specimen and a split (B) specimen, which are independently sealed in the presence of the donor.

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. 552a 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. 552a. 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.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule (Rule), 45 CFR parts 160 and 164, Subparts A and E, may be 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 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 the 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?

(a) As a donor for a federally regulated drug test, you have refused to take a federally regulated 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 as described in section 8.4(a);

(3) Fail to provide a specimen (*e.g.,* urine or another authorized specimen type) 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 as described in section 8.4(a);

(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 8.9 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 legitimate medical explanation for the failure as determined by the process described in Section 13.6;

(6) Fail or decline to participate in an alternate specimen collection (*e.g.,* oral fluid) 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 13.6) 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;

(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) Bring materials to the collection site for the purpose of adulterating, substituting, or diluting the specimen;

(11) Attempt to adulterate, substitute, or dilute the specimen;

(12) Possess or wear a prosthetic or other device that could be used to interfere with the collection process; or

(13) Admit to the collector or MRO that you have adulterated or substituted the specimen.

Section 1.8 What are the potential consequences for refusing to take a federally regulated drug test?

(a) As a federal agency employee or applicant, a refusal to take a test may result in the initiation of disciplinary or adverse action, up to and including removal from, or non-selection for, federal employment.

(b) When a donor has refused to participate in a part of the collection process, including failing to appear in a reasonable time for any test except a pre-employment test as described in Section 1.7(a)(1), the collector must terminate the collection process and take action as described in Section 8.13. Required action includes immediately notifying 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 and, if a Federal CCF has been initiated, documenting the refusal on the Federal CCF, signing and dating the Federal CCF, and sending all copies of the Federal CCF to the federal agency's designated representative.

(c) When documenting a refusal to test during the verification process as described in Sections 13.4, 13.5, and 13.6, the MRO must complete the MRO copy of the Federal CCF to include:

(1) Checking the refusal to test box;

(2) Providing a reason for the refusal in the remarks line; and

(3) Signing and dating the MRO copy of the Federal CCF.

Subpart B—Urine Specimens

Section 2.1 What type of specimen may be collected?

A federal agency may collect urine and/or an alternate specimen type for its workplace drug testing program. Only specimen types authorized by Mandatory Guidelines for Federal Workplace Drug Testing Programs may be collected. An agency using urine must follow these Guidelines.

Section 2.2 Under what circumstances may a urine specimen be collected?

A federal agency may collect a urine 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 urine specimen collected?

Each urine 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.

Section 2.5 How does the collector split the urine specimen?

The collector pours at least 30 mL into a specimen bottle that is designated as A (primary) and then pours at least 15 mL into a specimen bottle that is designated as B (split).

Section 2.6 When may an entity or individual release a urine specimen?

Entities and individuals subject to these Guidelines under Section 1.1 may not release specimens collected pursuant to Executive Order 12564, Public Law 100–71, and these Guidelines to donors or their designees. Specimens also may not be released to any other entity or individual unless expressly authorized by these Guidelines or by applicable federal law. This section does not prohibit a donor's request to have a split (B) specimen tested in accordance with Section 13.8.

Subpart C—Urine Drug and Specimen Validity Tests

Section 3.1 Which 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 opioids, amphetamines, and phencyclidine, as provided under Section 3.4; and

(c) Must ensure that the following specimen validity tests are conducted on each urine 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 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 internal standard, 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) On a case-by-case basis, a specimen may be tested for additional drugs, if a federal agency is conducting the collection for reasonable suspicion or post accident 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. 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 analyzing two separate aliquots of the specimen in two separate testing batches using the confirmatory analytical method. Additionally, the split (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) 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 in accordance with Subpart C of these Guidelines. Use of specimens by donors, their designees, or any other entity, for other purposes (*e.g.,* deoxyribonucleic acid, DNA, testing) is prohibited unless authorized in accordance with applicable federal law.

(b) These Guidelines are not intended to prohibit federal agencies 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 drug test cutoff concentrations for urine?

Initial test analyte	Initial test cutoff [1]	Confirmatory test analyte	Confirmatory test cutoff concentration
Marijuana metabolites (THCA) [2]	50 ng/mL [3]	THCA	15 ng/mL.
Cocaine metabolite (Benzoylecgonine).	150 ng/mL [3]	Benzoylecgonine	100 ng/mL.
Codeine/Morphine	2,000 ng/mL	Codeine	2,000 ng/mL.
		Morphine	2,000 ng/mL.
Hydrocodone/Hydromorphone	300 ng/mL	Hydrocodone	100 ng/mL.
		Hydromorphone	100 ng/mL.
Oxycodone/Oxymorphone	100 ng/mL	Oxycodone	100 ng/mL.
		Oxymorphone	100 ng/mL.
6-Acetylmorphine	10 ng/mL	6-Acetylmorphine	10 ng/mL.
Phencyclidine	25 ng/mL	Phencyclidine	25 ng/mL.
Amphetamine/Methamphetamine	500 ng/mL	Amphetamine	250 ng/mL.
		Methamphetamine	250 ng/mL.
MDMA [4]/MDA [5]	500 ng/mL	MDMA	250 ng/mL.
		MDA	250 ng/mL.

[1] For grouped analytes (*i.e.,* two or more analytes that are in the same drug class and have the same initial test cutoff):
Immunoassay: The test must be calibrated with one analyte from the group identified as the target analyte. The cross-reactivity of the immunoassay to the other analyte(s) within the group must be 80 percent or greater; if not, separate immunoassays must be used for the analytes within the group.
Alternate technology: Either one analyte or all analytes from the group must be used for calibration, depending on the technology. At least one analyte within the group must have a concentration equal to or greater than the initial test cutoff or, alternatively, the sum of the analytes present (*i.e.,* equal to or greater than the laboratory's validated limit of quantification) must be equal to or greater than the initial test cutoff.
[2] An immunoassay must be calibrated with the target analyte, Δ-9-tetrahydrocannabinol-9-carboxylic acid (THCA).
[3] *Alternate technology (THCA and benzoylecgonine):* The confirmatory test cutoff must be used for an alternate technology initial test that is specific for the target analyte (*i.e.,* 15 ng/mL for THCA, 100 ng/mL for benzoylecgonine).
[4] Methylenedioxymethamphetamine (MDMA).
[5] Methylenedioxyamphetamine (MDA).

Section 3.5 May an HHS-certified laboratory perform additional drug and/or specimen validity tests on a specimen at the request of the Medical Review Officer (MRO)?

An HHS-certified laboratory is authorized to perform additional drug and/or specimen validity tests on a case-by-case basis as necessary to provide information that the MRO would use to report a verified drug test result (*e.g.,* tetrahydrocannabivarin, specimen validity tests using biomarkers). An HHS-certified laboratory is not authorized to routinely perform additional drug and/or specimen validity tests at the request of an MRO without prior authorization from the Secretary or designated HHS representative, with the exception of the determination of D,L stereoisomers of amphetamine and methamphetamine. All tests must meet appropriate validation and quality control requirements in accordance with these Guidelines.

Section 3.6 What criteria are used to report a urine specimen as adulterated?

An HHS-certified laboratory reports a primary (A) specimen as adulterated when:

(a) The pH is less than 4 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 great than 200 mcg/mL nitrite-equivalent cutoff or an equal to or great 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 3.7 What criteria are used to report a urine specimen as substituted?

An HHS-certified laboratory reports a primary (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 3.8 What criteria are used to report a urine 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 (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 (A) specimen as 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.

Section 3.9 What criteria are used to report an invalid result for a urine specimen?

An HHS-certified laboratory reports a primary (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 4 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 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 initial drug tests on two separate aliquots (*i.e.,* valid immunoassay or alternate technology initial 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 appearances of the primary (A) and the split (B) specimens (*e.g.,* color) are clearly different; or

(m) The concentration of a biomarker is not consistent with that established for human urine for both the initial (first) test and the second test on two separate aliquots.

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 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 their own drug testing specimen.

(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 must not be related to the employee (*e.g.,* spouse, ex-spouse, relative) or a close personal friend (*e.g.,* fiancée).

Section 4.3 What are the requirements to be a collector?

(a) An individual may serve as a collector if they fulfill the following conditions:

(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 and additional information provided by the Secretary relating to these Guidelines;

(3) Is trained and qualified to collect a urine specimen. Training must include the following:

(i) All steps necessary to complete a urine collection;

(ii) Completion and distribution of the Federal CCF;

(iii) Problem collections;

(iv) Fatal flaws, correctable flaws, and how to correct problems in collections; and

(v) The collector's responsibility for maintaining the integrity of the collection process, ensuring the privacy of the donor, 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 one uneventful collection scenario, one insufficient specimen quantity scenario, one temperature out of range scenario, one scenario in which the donor refuses to sign the Federal CCF, and one scenario in which the donor refuses to 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 trainee, and the trainer must attest in writing that the mock collections are error-free.

(b) A trained collector must complete refresher training at least every five years that includes the requirements in paragraph (a) of this section.

(c) The collector must maintain the documentation of their training and provide that documentation to a federal agency when requested.

(d) An individual may not collect specimens for a federal agency until the individual's 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; 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 gender of the observer must be the same as the donor's gender, which is determined by the donor's gender identity. The observer selection process is described in Section 8.10(b).

(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) Individuals are considered qualified trainers for collectors and may train others to collect urine specimens when they have completed the following:

(1) Qualified as a trained collector and regularly conducted urine drug test collections for a period of at least one year or

(2) 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 at least every five years in accordance with the collector requirements in Section 4.3(a).

(c) A qualified trainer for collectors must maintain the documentation of the trainer's training and provide that documentation to a federal agency when requested.

Section 4.6 What must a federal agency do before a collector is permitted to collect a specimen?

A federal agency must ensure the following:

(a) The collector has satisfied the requirements described in Section 4.3;

(b) 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 training record(s); and

(c) The collector has been provided the name and telephone number of the federal agency representative.

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 urine 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 8.12.

Section 5.2 What are the requirements for a collection site?

The facility used as a collection site must have the following:

(a) Provisions to ensure donor privacy during the collection (as described in Section 8.1);

(b) A suitable and clean surface area that is not accessible to the donor for handling the specimens and completing the required paperwork;

(c) A secure temporary storage area to maintain specimens until the specimen is transferred to an HHS-certified laboratory or IITF;

(d) A restricted access area where only authorized personnel may be present during the collection;

(e) A restricted access area for the storage of 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 Where must collection site records be stored?

Collection site records must be stored at a secure site designated by the collector or the collector's employer.

Section 5.4 How long must collection site records be stored?

Collection site records (*e.g.,* collector copies of the OMB-approved Federal CCF) must be stored securely for a minimum of 2 years. The collection site may convert hardcopy records to electronic records for storage and discard the hardcopy records after 6 months.

Section 5.5 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 area during the collection procedure;

(2) Perform only one donor collection at a time;

(3) Restrict access to collection supplies before, during and after collection;

(4) Ensure that only the collector and the donor are allowed to handle the unsealed specimen;

(5) Ensure the chain of custody process is maintained and documented throughout the entire collection, storage, and transport procedures;

(6) Ensure that the Federal CCF is completed and distributed as required; and

(7) Ensure that specimens transported to an HHS-certified laboratory or IITF are sealed and placed in transport 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) Couriers, express carriers, and postal service personnel are not required to document chain of custody since specimens are sealed in packages that would indicate tampering during transit to the HHS-certified laboratory or IITF.

Section 5.6 What are the privacy requirements when collecting a urine specimen?

Collections must be performed at a site that provides reasonable privacy (as described in Section 8.1).

Subpart F—Federal Drug Testing Custody and Control Form

Section 6.1 What federal form is used to document custody and control?

The OMB-approved Federal CCF must be used to document custody and control of each specimen at the collection site.

Section 6.2 What happens if the correct OMB-approved Federal CCF is not available or is not used?

(a) The use of a non-federal CCF or an expired Federal CCF is not, by itself, a reason for the HHS-certified laboratory or IITF to automatically reject the specimen for testing or for the MRO to cancel the test.

(b) If the collector does not use the correct OMB-approved Federal CCF, the collector must document that it is a federal agency specimen collection and provide the reason that the incorrect form was used. Based on the information provided by the collector, the HHS-certified laboratory or IITF must handle and test the specimen as a federal agency specimen.

(c) If the HHS-certified laboratory, HHS-certified IITF, or MRO discovers that the collector used an incorrect form, the laboratory, IITF, or MRO must obtain a memorandum for the record from the collector describing the reason the incorrect form was used. If a memorandum for the record cannot be obtained, the laboratory or IITF reports a rejected for testing result to the MRO and the MRO cancels the test. The HHS-certified laboratory or IITF must wait at least 5 business days while attempting to obtain the memorandum before reporting a rejected for testing result to the MRO.

Subpart G—Urine Specimen Collection Containers and Bottles

Section 7.1 What is used to collect a urine specimen?

A single-use collection container with a means (*i.e.,* thermometer) to measure urine temperature and two specimen bottles must be used.

Section 7.2 What are the requirements for a urine collection container and specimen bottles?

(a) The collection container, the thermometer, and the specimen bottles must not substantially affect the composition of drugs and/or metabolites in the urine specimen.

(b) The two specimen bottles must be sealable and non-leaking, and must maintain the integrity of the specimen during storage and transport so that the specimen contained therein can be tested in an HHS-certified laboratory or IITF for the presence of drugs or their metabolites.

(c) The two specimen bottles must be sufficiently transparent to enable an objective assessment of specimen appearance and identification of abnormal physical characteristics without opening the bottle.

Section 7.3 What are the minimum performance requirements for a urine collection container and specimen bottles?

(a) The collection container must be capable of holding at least 55 mL and have a volume marking clearly noting a level of 45 mL.

(b) One of the two specimen bottles must be capable of holding at least 35 mL and the other at least 20 mL, and each must have a volume marking clearly noting the appropriate level (30 mL for the primary specimen and 15 mL for the split specimen).

(c) The thermometer may be affixed to or built into the collection container and must provide graduated temperature readings from 32–38 °C/90–100 °F. Alternatively, the collector may use another technology to measure specimen temperature (*e.g.,* thermal radiation scanning), providing the thermometer does not come into contact with the specimen.

Subpart H—Urine Specimen Collection Procedure

Section 8.1 What privacy must the donor be given when providing a urine specimen?

The following privacy requirements apply when a donor is providing a urine specimen:

(a) Only authorized personnel and the donor may be present in the restricted access area where the collection takes place.

(b) The collector is not required to be the same gender as the donor. The gender of the observer for purposes of a direct observed collection (*i.e.,* as described in Section 8.10) must be the same as the donor's gender, which is determined by the donor's gender identity. The gender of the monitor for a monitored collection (*i.e.,* as described in Section 8.12) must be the same as the donor's gender, 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 during a monitored collection.

Section 8.2 What must the collector ensure at the collection site before starting a urine specimen collection?

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 the water supply off to the toilet and flush the toilet to remove the water in the toilet when possible.

(b) Secure other sources of water (*e.g.,* shower or sink) in the enclosure where urination occurs. If the enclosure has a source of water that cannot be disabled or secured, a monitored collection must be conducted in accordance with Section 8.11.

Section 8.3 What are the preliminary steps in the urine specimen collection procedure?

The collector must take the following steps before beginning a urine specimen collection:

(a) If a donor fails to arrive at the collection site at the assigned time, the collector must follow the federal agency policy or contact the federal agency representative to obtain guidance on action to be taken.

(b) When the donor arrives at the collection site, the collector should begin the collection procedure without undue delay. For example, the collection should not be delayed because the donor states that they are unable to urinate or 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; an alternative photo 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 must not proceed with the collection.

(d) The collector must provide identification (*e.g.,* employee badge, employee list) if requested by the donor.

(e) The collector explains the basic collection procedure to the donor.

(f) The collector informs the donor that the instructions for completing the Federal Custody and Control Form are located on the back of the Federal CCF or available upon request.

(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 (*e.g.,* coat, 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 (*e.g.,* purse or briefcase) remain with the outer garments; the donor may retain the donor's wallet.

(2) The collector asks the donor to empty the donor's pockets and display the contents to ensure no items are present that could be used to adulterate or substitute the specimen.

(3) If no items are present that can be used to adulterate or substitute the specimen, the donor can place the items back into the donor's pockets and continue the collection procedure.

(4) If an item is present that appears to have been brought to the collection site with the intent to adulterate, substitute, or dilute the specimen, this is considered a refusal to test. The collector must stop the collection and report the refusal to test as described in Section 8.13. If the item appears to be inadvertently brought to the collection site, the collector must secure the item and continue the normal collection procedure.

(5) If the donor refuses to show the collector the items in the donor's pockets, this is considered a refusal to test. The collector must stop the collection and report the refusal to test as described in Section 8.13.

(i) The collector shall instruct the donor to wash and dry the donor's hands prior to urination. After washing the donor's 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.

(1) If the donor refuses to wash the donor's hands when instructed by the collector, this is considered a ''refusal to test.'' The collector must stop the collection and report the refusal to test as described in Section 8.13.

Section 8.4 What steps does the collector take in the collection procedure before the donor provides a urine specimen?

(a) The collector will provide or the donor may select a specimen collection container that is clean, unused, wrapped/sealed in original packaging and compliant with Subpart G. The specimen collection container will be opened in view of the donor.

(b) The collector instructs the donor to provide the 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 8.10) or a monitored collection (*i.e.,* as described in Section 8.12), neither the collector nor anyone else may go into the room with the donor.

(2) The collector may set a reasonable time limit for specimen collection.

(c) 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 report a refusal to test in accordance with Section 8.13.

Section 8.5 What steps does the collector take during and after the urine specimen collection procedure?

Integrity and Identity of the Specimen. The collector must take the following steps during and after the donor provides the urine specimen:

(a) The collector must inform the donor that, once the collection procedure has begun, the donor must remain at the collection site (*i.e.,* in an area designated by the collector) until the collection is complete. This includes the wait period (*i.e.,* up to 3 hours) if needed to provide a sufficient specimen as described in step (f)(2) below and in Section 8.6.

(b) 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 8.8.

(c) After the donor has given the specimen to the collector, whenever practical, the donor shall be allowed to wash the donor's hands and the donor may flush the toilet.

(d) 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 8.9. The collector must forward both specimens (*i.e.,* from the first and second collections) to an HHS-certified laboratory for testing and record a comment on the Federal CCF for each specimen.

(e) 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 8.10. The collector must forward both specimens (*i.e.,* from the first and second collections) to an HHS-certified laboratory for testing and record a comment on the Federal CCF for each specimen.

(f) 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 8.8.

(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 8.8.

(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 records the reason for not collecting a urine specimen on the Federal CCF, notifies the federal agency's designated representative for authorization of an alternate specimen to be collected, and sends the appropriate copies of the Federal CCF to the MRO and to the federal agency's designated representative. The federal agency may choose to provide the collection site with a standard protocol to follow in lieu of requiring the collector to notify the agency's designated representative for authorization in each case. If an alternate specimen is authorized, the collector may begin the collection procedure for the alternate specimen (see Section 8.7) in accordance with the Mandatory Guidelines for Federal Workplace Drug Testing Programs using the alternative specimen.

(g) If the donor fails to remain present through the completion of the collection, declines to have a direct observed collection as required in steps (d)(2) or (e)(2) above, refuses to provide a second specimen as required in step (f)(2) above, or refuses to provide an alternate specimen as authorized in step (f)(2)(iii) above, the collector stops the collection and reports the refusal to test in accordance with Section 8.13.

Section 8.6 What procedure is used when the donor states that they are unable to provide a urine specimen?

(a) If the donor states that they are unable to provide a urine specimen during the collection process, the collector requests that the donor enter the restroom (stall) and attempt to provide a urine specimen.

(b) The donor demonstrates their 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 they 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 the 3 hour wait time.

(2) If the donor states that they are 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 for authorization of an alternate specimen to be collected, and sends the appropriate copies of the Federal CCF to the MRO and to the federal agency's designated representative. The federal agency may choose to provide the collection site with a standard protocol to follow in lieu of requiring the collector to notify the agency's

designated representative for authorization in each case. If an alternate specimen is authorized, the collector may begin the collection procedure for the alternate specimen (see Section 8.7) in accordance with the Mandatory Guidelines for Federal Workplace Drug Testing Programs using the alternative specimen.

Section 8.7 If the donor is unable to provide a urine specimen, may another specimen type be collected for testing?

Yes, if the alternate specimen type is authorized by Mandatory Guidelines for Federal Workplace Drug Testing Programs and specifically authorized by the federal agency.

Section 8.8 How does the collector prepare the urine 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 ''A'' and ''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 collector instructs the donor to initial 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 must ensure that all the information required on the Federal CCF is provided.

(f) The collector asks the donor to read and sign a statement on the Federal CCF certifying that the specimens identified were collected from the donor. If the donor refuses to sign the certification statement, the collector notes the refusal on the Federal CCF and continues with the collection process.

(g) The collector signs and prints their name on the Federal CCF, completes the Federal CCF, and distributes the copies of the Federal CCF as required.

(h) The collector seals the specimens (Bottle A and Bottle B) in a package and, within 24 hours or during the next business day, sends them to the HHS-certified laboratory or IITF that will be testing the Bottle A urine specimen.

(i) If the specimen and Federal CCF are not immediately transported to an HHS-certified laboratory or IITF, they must remain under direct control of the collector or be appropriately secured under proper specimen storage conditions until transported.

(j) 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 federal agency regulation. Neither the collector nor anyone else may conduct further testing (such as specimen validity testing) on the excess urine.

Section 8.9 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 HHS-certified laboratory reports to the MRO that a specimen is invalid, and the MRO reported to the agency that there was not a legitimate 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; or

(2) The collector suspects that the donor has tampered with the specimen during a routine collection (*e.g.,* abnormal physical characteristic such as unusual color and/or odor, and/or excessive foaming when shaken).

(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 8.13).

Section 8.10 How is a direct observed collection conducted?

(a) 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's gender must be the same as the donor's gender, which is determined by the donor's gender identity, with no exception to this requirement.

(b) Before an observer is selected, the collector informs the donor that the gender of the observer will match the donor's gender, which is determined by the donor's gender identity (as defined in Section 1.5). The collector then selects the observer to conduct the observation:

(i) The collector asks the donor to identify the donor's gender on the Federal CCF and initial it.

(ii) The donor will then be provided an observer whose gender matches the donor's gender.

(iii) The collector documents the observer's name and gender on the Federal CCF.

(c) If there is no collector available of the same gender as the donor's gender, 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.

(d) 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:

(1) The observer enters the restroom with the donor;

(2) 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);

(3) The observer must not touch or handle the collection container unless the observer is also serving as the collector;

(4) After the donor has completed urinating into the collection container:

(i) If the same person serves as the observer and collector, that person may receive the collection container from the donor while they are both in the restroom;

(ii) 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.

(5) 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

(6) The collector then continues with the routine collection procedure in Section 8.3.

Section 8.11 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 8.12.

(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 8.13).

Section 8.12 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 same procedures used for selecting an observer of the appropriate gender in Section 8.10(b) must be used to select the monitor for the purposes of Section 8.12, unless the monitor is a medical professional as described above. 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 8.9.

(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, that person 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 8.3.

Section 8.13 How does the collector report a donor's refusal to test?

If there is a refusal to test as defined in Section 1.7, 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, email, 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 8.14 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 (*e.g.,* virtual, onsite, or self-evaluation).

(c) A federal agency must investigate reported collection site deficiencies (*e.g.,* specimens reported ''rejected for testing'' by an HHS-certified laboratory or IITF) and take appropriate action which may include a collection site self-assessment (*i.e.,* using the Collection Site Checklist for the Collection of Urine Specimens for Federal Agency Workplace Drug Testing Programs) or an inspection of the collection site. The inspections of these additional collection sites may 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 urine 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 HHS-certified laboratory or IITF including suspending the use of certain analytical procedures when necessary to protect the integrity of the testing process; ordering any HHS-certified laboratory or IITF to undertake corrective actions to respond to material deficiencies identified by an inspection or through performance testing; ordering any HHS-certified laboratory or IITF to send specimens or specimen aliquots to another HHS-certified 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 urine specimens for federal agencies unless it holds such certification.

Section 9.2 What is the process for a laboratory or IITF to become HHS-certified?

(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 federally regulated specimens);

(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 notification of certification from the Secretary before testing specimens for federal agencies.

Section 9.3 What is the process for a laboratory or IITF to maintain HHS certification?

(a) 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 at a minimum of every 6 months thereafter);

(2) Respond in an appropriate, timely, and complete manner to required corrective action requests if deficiencies are identified in the maintenance PT performance, during the inspections, operations, or reporting; and

(3) Satisfactorily complete corrective remedial actions, and undergo special inspection and special PT sets to maintain or restore certification when material deficiencies occur in either the PT program, inspection program, or in operations and reporting.

Section 9.4 What is the process when a laboratory or IITF does not maintain its HHS certification?

(a) A laboratory or IITF that does not maintain its HHS certification must:

(1) Stop testing federally regulated specimens;

(2) Ensure the security of federally regulated specimens and records throughout the required storage period described in Sections 11.20, 11.21, 12.18, and 14.8;

(3) Ensure access to federally regulated specimens and records in accordance with Sections 11.23, 11.24, 12.20, 12.21, and Subpart P; and

(4) Follow the HHS suspension and revocation procedures when 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 9.5 What are the qualitative and quantitative specifications of performance testing (PT) samples?

(a) PT samples used to evaluate drug tests will be prepared using the following specifications:

(1) PT samples may contain one or more of the drugs and drug metabolites in the drug classes listed in Section 3.4 and must 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 or drug metabolite;

(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 drug or metabolite may differ from 9.5(a)(1)(i) and 9.5(a)(1)(ii) 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 HHS-certified laboratory or IITF will vary but, within each calendar year, each HHS-certified 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 9.6 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 three 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 three sets of PT samples;

(3) Correctly identify at least 80 percent of the drug challenges for each initial drug test over the three sets of PT samples;

(4) For the confirmatory drug tests, correctly determine the concentrations [*i.e.,* no more than ±20 percent or ±2 standard deviations (whichever is larger) from the appropriate reference or peer group means] for at least 80 percent of the total drug challenges over the three sets of PT samples;

(5) For the confirmatory drug tests, must not obtain any drug concentration that differs by more than ±50 percent from the appropriate reference or peer group mean;

(6) For each confirmatory drug test, correctly identify and determine the concentrations [*i.e.,* no more than ±20 percent or ±2 standard deviations (whichever is larger) from the appropriate reference or peer group means] for at least 50 percent of the drug challenges for an individual drug over the three sets of PT samples;

(7) Correctly identify at least 80 percent of the total specimen validity testing challenges over the three sets of PT samples;

(8) Correctly identify at least 80 percent of the challenges for each individual specimen validity test over the three sets of PT samples;

(9) For quantitative specimen validity tests, obtain quantitative values for at least 80 percent of the total challenges over the three sets of PT samples that satisfy the following criteria:

(i) Nitrite and creatinine concentrations are no more than ±20 percent or ±2 standard deviations from the appropriate reference or peer group mean; and

(ii) pH values are no more than ±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 ±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 ±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 ±50 percent for nitrite and creatinine concentrations, ±0.8 pH units using a pH meter, ±0.0006 specific gravity units when the mean is less than 1.0100, or ±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 9.7 What are the PT requirements for an HHS-certified urine laboratory?

(a) A laboratory certified under these Guidelines must satisfy the following criteria on the maintenance PT samples:

(1) Have no false positive results;

(2) Correctly identify, confirm, and report at least 90 percent of the total drug challenges over two consecutive PT cycles;

(3) Correctly identify at least 80 percent of the drug challenges for each initial drug test over two 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 ±20 percent or ±2 standard deviations (whichever is larger) from the appropriate reference or peer group means over two 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 ±50 percent from the appropriate reference or peer group mean over two 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 ±20 percent or ±2 standard deviations (whichever is larger) from the appropriate reference or peer group means over two consecutive PT cycles;

(7) Correctly identify at least 80 percent of the total specimen validity testing challenges over two consecutive PT cycles;

(8) Correctly identify at least 80 percent of the challenges for each individual specimen validity test over two consecutive PT cycles;

(9) For quantitative specimen validity tests, obtain quantitative values for at least 80 percent of the total challenges over two consecutive PT cycles that satisfy the following criteria:

(i) Nitrite and creatinine concentrations are no more than ±20 percent or ±2 standard deviations from the appropriate reference or peer group mean;

(ii) pH values are no more than ±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 ±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 ±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 ±50 percent for nitrite and creatinine concentrations, ±0.8 pH units using a pH meter, ±0.0006 specific gravity units when the mean is less than 1.0100, or ±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 all PT cycles or to satisfy these requirements may result in suspension or revocation of an HHS-certified laboratory's certification.

Section 9.8 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 three consecutive sets of PT samples:

(1) Correctly identify at least 90 percent of the total drug challenges over the three sets of PT samples;

(2) Correctly identify at least 80 percent of the drug challenges for each individual drug test over the three sets of PT samples;

(3) Correctly identify at least 80 percent of the total specimen validity test challenges over the three sets of PT samples;

(4) Correctly identify at least 80 percent of the challenges for each individual specimen validity test over the three 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 three sets of PT samples that satisfy the following criteria:

(i) Creatinine concentrations are no more than ±20 percent or ±2 standard deviations (whichever is larger) from the appropriate reference or peer group mean; and

(ii) Specific gravity values are no more than ±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 ±50 percent for creatinine concentration, or ±0.002 specific gravity units for specific gravity.

(b) Failure to satisfy these requirements will result in disqualification.

Section 9.9 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 two consecutive PT cycles;

(2) Correctly identify at least 80 percent of the drug challenges for each individual drug test over two consecutive PT cycles;

(3) Correctly identify at least 80 percent of the total specimen validity test challenges over two consecutive PT cycles;

(4) Correctly identify at least 80 percent of the challenges for each individual specimen validity test over two 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 two consecutive PT cycles that satisfy the following criteria:

(i) Creatinine concentrations are no more than ±20 percent or ±2 standard deviations (whichever is larger) from the appropriate reference or peer group mean; and

(ii) Specific gravity values are no more than ±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 ±50 percent for creatinine concentration, or ±0.002 specific gravity units for specific gravity.

(b) Failure to participate in all PT cycles or to satisfy these requirements may result in suspension or revocation of an HHS-certified IITF's certification.

Section 9.10 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.

Section 9.11 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 at least 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 9.12 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 they satisfy the following criteria:

(1) Has experience and an educational background similar to that required for either a responsible person or a certifying scientist for an HHS-certified laboratory as described in Subpart K or as a responsible technician for an HHS-certified IITF 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.

(b) The Secretary or a federal agency may conduct an inspection at any time.

Section 9.13 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 laboratory or IITF must start the certification process from the beginning.

Section 9.14 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 deficiency) to provide any explanation for its performance and evidence that all deficiencies have been corrected.

(b) A laboratory's or IITF's HHS certification may be revoked, suspended, or no further action taken depending on the seriousness of the deficiencies and whether there is evidence that the deficiencies have been corrected and that current performance meets the requirements for certification.

(c) An HHS-certified laboratory or IITF may be required to undergo a special inspection or to test additional PT samples to address deficiencies.

(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 federally regulated specimens until the suspension is lifted or the laboratory or IITF has successfully completed the certification requirements as a new applicant laboratory or IITF.

Section 9.15 What factors are considered in determining whether revocation of a laboratory's or IITF's HHS certification is necessary?

(a) The Secretary shall revoke certification of an HHS-certified laboratory or IITF in accordance with these Guidelines if the Secretary determines that revocation is necessary to ensure fully reliable and accurate drug and specimen validity test results and reports.

(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 (*e.g.,* an HHS-certified laboratory reporting a false positive result for an employee's drug test);

(2) Unsatisfactory participation in performance testing or inspections;

(3) A material violation of a certification standard, contract term, or other condition imposed on the HHS-certified laboratory or IITF by a federal agency using the laboratory's or IITF's services;

(4) Conviction for any criminal offense committed as an incident to operation of the HHS-certified laboratory or IITF; or

(5) Any other cause that materially affects the ability of the HHS-certified laboratory or IITF to ensure fully reliable and accurate drug test results and reports.

(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 testing.

Section 9.16 What factors are considered in determining whether to suspend a laboratory's or IITF's HHS certification?

(a) The Secretary may immediately suspend (either partially or fully) a laboratory's or IITF's HHS certification to conduct drug testing for federal agencies if the Secretary has reason to believe that revocation may be required and that immediate action is necessary to protect the interests of the United States and its employees.

(b) The Secretary shall determine the period and terms of suspension based upon the facts and circumstances of the suspension and the need to ensure accurate and reliable drug testing.

Section 9.17 How does the Secretary notify an HHS-certified laboratory or IITF that action is being taken against the laboratory or IITF?

(a) When laboratory's or IITF's HHS certification is suspended or the Secretary seeks to revoke HHS certification, the Secretary shall immediately serve the HHS-certified 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 HHS-certified laboratory or IITF that has its certification revoked or suspended under Section 9.13 or Section 9.14, respectively, and the name of any HHS-certified 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 HHS 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 9.18 May a laboratory or IITF that had its HHS 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 9.17 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 HHS certification as an applicant laboratory or IITF.

Section 9.19 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**. This notice is also available on the Internet at *http://www.samhsa.gov/workplace.*

(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 collector must send the blind samples to the HHS-certified laboratory or IITF that the collector sends employee specimens.

(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 (up to a maximum of 400 blind samples). Every effort should be made to ensure that blind samples are submitted quarterly.

(c) Approximately 75 percent of the blind samples submitted each year by an agency 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 blind samples?

(a) Drug positive blind samples must be validated by the supplier as to their content using appropriate initial and confirmatory tests.

(1) Drug positive blind samples must be fortified with one or more of the drugs or metabolites listed in Section 3.4.

(2) Drug positive blind samples must contain concentrations of drugs between 1.5 and 2 times the initial drug test cutoff concentration.

(b) Drug negative blind samples (*i.e.,* certified to contain no drugs) must be validated by the supplier as negative using appropriate initial and confirmatory tests.

(c) A blind sample that is adulterated must be validated using appropriate initial and confirmatory specimen validity tests, and have the characteristics to clearly show that it is an adulterated sample at the time of validation.

(d) A blind sample that is substituted must be validated using appropriate initial and confirmatory specimen validity tests, and have the characteristics to clearly show that it is a substituted sample at the time of validation.

(e) The supplier must provide information on the blind samples' content, validation, expected results, and stability to the collection site/collector sending the blind samples to the laboratory or IITF, and must provide the information upon request to the MRO, the federal agency for which the blind sample was submitted, or the Secretary.

Section 10.3 How is a blind sample submitted to an HHS-certified laboratory or IITF?

(a) A blind sample must be submitted as a split specimen (specimens A and B) with the current Federal CCF that the HHS-certified laboratory or IITF uses for donor specimens. The collector provides the required information to ensure that the Federal CCF has been properly completed and provides 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 randomly with donor specimens rather than submitting the full complement of blind samples as a single group.

Section 10.4 What happens if an inconsistent result is reported for 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 laboratory or IITF and attempt to determine if the laboratory or IITF made an error during the testing or reporting of the sample;

(b) The MRO must contact the blind sample supplier and attempt to determine if the supplier made an error during the preparation or transfer of the sample;

(c) The MRO must contact the collector and determine if the collector made an error when preparing the blind sample for transfer to the HHS-certified laboratory or IITF;

(d) 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

(e) The Secretary shall investigate the blind sample error. A report of the Secretary's investigative findings and the corrective action taken in response to identified deficiencies must be sent to the federal agency. The Secretary shall ensure notification of the finding as appropriate to other federal agencies and coordinate any necessary actions 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 HHS-certified laboratory operations. When followed, the SOP manual ensures that all specimens are tested using the same procedures.

(b) The SOP manual must include at a minimum, 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 compliant with these Guidelines and all guidance provided by the Secretary.

(d) A copy of all procedures that have been replaced or revised and the dates on which the procedures were in effect must be maintained for at least 2 years.

Section 11.2 What are the responsibilities of the responsible person (RP)?

(a) Manage the day-to-day operations of the HHS-certified laboratory even if another individual has overall responsibility for alternate areas of a multi-specialty laboratory.

(b) Ensure that there are sufficient personnel with adequate training and experience to supervise and conduct the work of the HHS-certified laboratory. The RP must ensure the continued competency of laboratory staff by documenting their in-service training, reviewing their work performance, and verifying their skills.

(c) Maintain a complete and current SOP manual that is available to all personnel of the HHS-certified laboratory and ensure that it is followed. The SOP manual must be reviewed, signed, and dated by the RP(s) when procedures are first placed into use and when changed or when a new individual assumes responsibility for the management of the HHS-certified laboratory. The SOP must be reviewed and documented by the RP annually.

(d) Maintain a quality assurance program that ensures the proper performance and reporting of all test results; verify and monitor acceptable analytical performance for all controls and calibrators; monitor quality control testing; and document the validity, reliability, accuracy, precision, and performance characteristics of each test and test system.

(e) Initiate and implement all remedial actions necessary to maintain satisfactory operation and performance of the HHS-certified laboratory in response to the following: Quality control systems not within performance specifications; errors in result reporting or in analysis of performance testing samples; and inspection deficiencies. The RP must ensure that specimen results are not reported until all corrective actions have been taken and that the results provided are accurate and reliable.

Section 11.3 What scientific qualifications must the RP have?

The RP must have documented scientific qualifications in analytical toxicology.

Minimum qualifications are:

(a) Certification or licensure as a laboratory director by the state in forensic or clinical laboratory toxicology, a Ph.D. in one of the natural sciences, or 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) Experience in forensic toxicology with emphasis on the collection and analysis of biological specimens for drugs of abuse;

(c) Experience in forensic applications of analytical toxicology (*e.g.,* publications, court testimony, conducting research on the pharmacology and toxicology of drugs of abuse) or qualify as an expert witness in forensic toxicology;

(d) Fulfillment of the RP responsibilities and qualifications, as demonstrated by the HHS-certified laboratory's performance and verified upon interview by HHS-trained inspectors during each on-site inspection; and

(e) Qualify as a certifying scientist.

Section 11.4 What happens when the RP is absent or leaves an HHS-certified laboratory?

(a) HHS-certified laboratories must have multiple RPs or one RP and an alternate RP. If the RP(s) are concurrently absent, an alternate RP must be present and qualified to fulfill the responsibilities of the RP.

(1) If an HHS-certified laboratory is without the RP and alternate RP for 14 calendar days or less (*e.g.,* temporary absence due to vacation, illness, or business trip), the HHS-certified laboratory may continue operations and testing of federal agency specimens under the direction of a certifying scientist.

(2) The Secretary, in accordance with these Guidelines, will suspend a laboratory's HHS 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) If the RP leaves an HHS-certified laboratory:

(1) The HHS-certified laboratory may maintain certification and continue testing federally regulated 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 RP's replacement.

(2) The Secretary, in accordance with these Guidelines, will suspend a laboratory's HHS certification for all federally regulated 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 HHS-certified laboratory must submit the following documents to the Secretary: The candidate's current resume or curriculum vitae, copies of diplomas and licensures, a training plan (not to exceed 90 days) to transition the candidate into the position, an itemized comparison of the candidate's qualifications to the minimum RP qualifications described in the Guidelines, and have official academic transcript(s) submitted from the candidate's institution(s) of higher learning. The candidate must be found qualified during an on-site inspection of the HHS-certified laboratory.

(d) The HHS-certified laboratory must fulfill additional inspection and PT criteria as required prior to conducting federally regulated 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) A 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 HHS-certified laboratory relevant to the results that the individual certifies; and

(3) Training and experience in reviewing and reporting forensic test results and maintaining chain of custody, and an understanding of appropriate remedial actions in response to problems that may arise.

(b) A certifying technician must have:

(1) Training and experience in the analytical methods and forensic procedures used by the HHS-certified laboratory relevant to the results that the individual certifies; and

(2) Training and experience in reviewing and reporting forensic test results and maintaining chain of custody, and an understanding of appropriate remedial actions in response to problems that may arise.

Section 11.6 What qualifications and training must other personnel of an HHS-certified laboratory have?

(a) All HHS-certified laboratory staff (*e.g.,* technicians, administrative staff) must have the appropriate training and skills for the tasks they perform.

(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 they are permitted to work independently with federally regulated specimens. All 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 (*e.g.,* firefighters and medical rescue teams).

(c) An HHS-certified laboratory must maintain records documenting the identity of the visitor and escort, date, time of entry and exit, and purpose for access to the secured area.

Section 11.8 What are the laboratory chain of custody requirements for specimens and aliquots?

(a) HHS-certified laboratories must use chain of custody procedures (internal and external) to maintain control and accountability of specimens from the time of receipt at the laboratory through completion of testing, reporting of results, during storage, and continuing until final disposition of the specimens.

(b) HHS-certified laboratories must use chain of custody procedures to document the handling and transfer of aliquots throughout the testing process until final disposal.

(c) The chain of custody must be documented using either paper copy or electronic procedures.

(d) Each individual who handles a specimen or aliquot must sign and complete the appropriate entries on the chain of custody form when the specimen or aliquot is handled or transferred, and every individual in the chain must be identified.

(e) The date and purpose must be recorded on an appropriate chain of custody form each time a specimen or aliquot is handled or transferred.

Section 11.9 What test(s) does an HHS-certified laboratory conduct on a urine 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 may be:

(1) An immunoassay or

(2) An alternate technology (*e.g.,* spectrometry, spectroscopy).

(b) An HHS-certified laboratory must validate an initial drug test before testing specimens.

(c) Initial drug tests must be accurate and reliable for the testing of specimens when identifying drugs or their metabolites.

(d) An HHS-certified 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 the following for each initial drug test:

(1) The ability to differentiate negative specimens from those requiring further testing;

(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 (linearity);

(4) The potential for carryover;

(5) The potential for interfering substances; and

(6) The potential matrix effects if using an alternate technology.

(b) Each new lot of reagent must be verified prior to being placed into service.

(c) Each initial drug test using an alternate technology must be re-verified periodically or at least annually.

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 controls:

(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 a concentration 25 percent above the cutoff;

(3) At least one control with the drug or drug metabolite targeted at a concentration 75 percent of the cutoff; and

(4) At least one control that appears as a donor specimen to the analysts.

(b) Calibrators and controls must total at least 10 percent of the aliquots analyzed in each batch.

Section 11.13 What are the requirements for a confirmatory drug test?

(a) The analytical method must use mass spectrometric identification [*e.g.,* gas chromatography/mass spectrometry (GC/MS), liquid chromatography/mass spectrometry (LC/MS), GC/MS/MS, LC/MS/MS] or equivalent.

(b) A confirmatory drug test must be validated before it can be used to test federally regulated specimens.

(c) Confirmatory drug tests must be accurate and reliable for the testing of a urine specimen when identifying and quantifying drugs or their metabolites.

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 the following for each confirmatory drug test:

(1) The linear range of the analysis;

(2) The limit of detection;

(3) The limit of quantification;

(4) The accuracy and precision at the cutoff concentration;

(5) The accuracy (bias) and precision at 40 percent of the cutoff concentration;

(6) The potential for interfering substances;

(7) The potential for carryover; and

(8) The potential matrix effects if using liquid chromatography coupled with mass spectrometry.

(b) Each new lot of reagent must be verified prior to being placed into service.

(c) HHS-certified laboratories must re-verify each confirmatory drug test method periodically or at least annually.

Section 11.15 What are the batch quality control requirements when conducting a confirmatory drug test?

(a) At a minimum, each batch of specimens must contain the following calibrators and controls:

(1) A calibrator at the cutoff concentration;

(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 less than 40 percent of the cutoff.

(b) Calibrators and controls must total at least 10 percent of the aliquots analyzed in each batch.

Section 11.16 What are the analytical and quality control requirements for conducting specimen validity tests?

(a) Each invalid, adulterated, or substituted specimen validity test result must be based on an initial specimen validity test on one aliquot and a confirmatory specimen validity test on a second aliquot;

(b) The HHS-certified laboratory must establish acceptance criteria and analyze calibrators and controls as appropriate to verify and document the validity of the test results (required specimen validity tests are addressed 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. Each new lot of reagent must be verified prior to being placed into service.

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 the following calibrators and controls:

(i) A calibrator at 2 mg/dL;

(ii) A control in the range of 1.0 mg/dL to 1.5 mg/dL;

(iii) A control in the range of 3 mg/dL to 20 mg/dL; and

(iv) A control in the range of 21 mg/dL to 25 mg/dL.

(3) The confirmatory creatinine test (performed on those specimens with a creatinine concentration less than 2 mg/dL on the initial test) must have the following calibrators and controls:

(i) A calibrator at 2 mg/dL;

(ii) A control in the range of 1.0 mg/dL to 1.5 mg/dL; and

(iii) 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.

(2) The screening specific gravity test must have the following calibrators and 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.

(3) 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;

(4) The initial and confirmatory specific gravity tests must have the following calibrators and controls:

(i) A calibrator or control at 1.0000;

(ii) One control targeted at 1.0020;

(iii) One control in the range of 1.0040 to 1.0180; and

(iv) 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 3 to 12 to support the 4 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 4;

(ii) One calibrator at 11;

(iii) One control in the range of 3 to 3.8;

(iv) One control in the range 4.2 to 5;

(v) One control in the range of 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 3;

(ii) One calibrator at 7;

(iii) One calibrator at 10;

(iv) One control in the range of 3 to 3.8;

(v) One control in the range 4.2 to 5;

(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 pH meter test (if a pH screening test is used) or confirmatory pH meter test must have the following calibrators and controls when the result of the preceding pH test 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 3 to 3.8; and

(iv) One control in the range 4.2 to 5; and

(7) An initial pH meter test (if a pH screening test is used) or confirmatory pH meter test must have the following calibrators and controls when the result of the preceding pH test 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) Laboratories must report a test result to the agency's MRO within an average of 5 working days after receipt of the specimen. Reports must use the Federal CCF and/or an electronic report. Before any test result can be reported, it must be certified by a certifying scientist or a certifying technician (as appropriate).

(b) A primary (A) specimen is reported negative when each initial drug test is negative or if the specimen is negative upon confirmatory drug testing, and the specimen does not meet invalid criteria as described in items (h)(1) through (h)(12) below.

(c) A primary (A) specimen is reported positive for a specific drug or drug metabolite when both the initial drug test is positive and the confirmatory drug test is positive in accordance with Section 3.4.

(d) A primary (A) urine specimen is reported adulterated when:

(1) The pH is less than 4 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 (A) urine 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 (A) urine 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 HHS-certified laboratory shall contact the MRO and both will decide if testing by another HHS-certified laboratory would be useful in being able to report a positive or adulterated result. If no further testing is necessary, the HHS-certified laboratory then reports the invalid result to the MRO.

(h) A primary (A) urine 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 4 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 initial drug tests on two separate aliquots (*i.e.,* valid initial 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 HHS-certified 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 appearances of the A and B specimens are clearly different (note: A is tested).

(i) An HHS-certified laboratory shall reject a primary (A) 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 HHS-certified 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 urine specimen. For example, a specimen can be positive for a specific drug and adulterated.

(k) An HHS-certified laboratory must report the confirmatory concentration of each drug or drug metabolite reported 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 a drug or drug metabolite exceeds the validated linear range of the confirmatory test, HHS-certified laboratories may report to the MRO that the quantitative value exceeds the linear range of the test or that the quantitative value is greater than ''insert the actual value for the upper limit of the linear range,'' or laboratories may report a quantitative value above the upper limit of the linear range that was obtained by diluting an aliquot of the specimen to achieve a result within the method's linear range and multiplying the result by the appropriate dilution factor.

(n) HHS-certified laboratories may transmit test results to the MRO by various electronic means (*e.g.,* teleprinter, facsimile, or computer). Transmissions of the reports must ensure confidentiality and the results may not be reported verbally by telephone. Laboratories and external service providers must ensure the confidentiality, integrity, and availability of the data and limit access to any data transmission, storage, and retrieval system.

(o) HHS-certified laboratories must facsimile, 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 results can accurately represent the content of the custody and control form that the MRO received from the collector.

(p) For positive, adulterated, substituted, invalid, and rejected specimens, laboratories must facsimile, 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 specimens?

(a) An HHS-certified laboratory must retain specimens that were reported as positive, adulterated, substituted, or as an invalid result for a minimum of 1 year.

(b) Retained specimens must be kept in secured frozen storage (− 20 °C or less) to ensure their availability for retesting during an administrative or judicial proceeding.

(c) Federal agencies may request that the HHS-certified laboratory retain a specimen for an additional specified period of time and must make that request within the 1-year period.

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. The laboratory may convert hardcopy records to electronic records for storage and then discard the hardcopy records after 6 months.

(b) A federal agency may request the HHS-certified laboratory to maintain a 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) An HHS-certified laboratory may retain records other than those included in the documentation package beyond the normal 2-year period of time.

Section 11.22 What statistical summary reports must an HHS-certified laboratory provide for urine testing?

(a) HHS-certified laboratories must provide to each federal agency for which they perform testing a semiannual statistical summary report that must be submitted by mail, facsimile, or email within 14 working days after the end of the semiannual period. The summary report must not include any personal identifying information. A copy of the semiannual statistical summary report will also be sent to the Secretary or designated HHS representative. The semiannual statistical report contains the following information:

(1) Reporting period (inclusive dates);

(2) HHS-certified laboratory name and address;

(3) Federal agency name;

(4) 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;
(8) Number of specimens rejected for testing because of an uncorrected flaw;
(9) Number of specimens tested positive by each initial drug test;
(10) Number of specimens reported positive;
(11) Number of specimens reported positive for each drug and drug metabolite;
(12) Number of specimens reported adulterated;
(13) Number of specimens reported substituted; and
(14) Number of specimens reported as invalid result.

(b) An HHS-certified laboratory must make copies of an agency's test results available when requested to do so by the Secretary or by the federal agency for which the laboratory is performing drug-testing services.

(c) An HHS-certified laboratory must ensure that a qualified individual is available to testify in a proceeding against a federal employee when the proceeding is based on a test result reported by the laboratory.

Section 11.23 What HHS-certified laboratory information is available to a federal agency?

(a) Following a federal agency's receipt of a positive, adulterated, or substituted drug test report, the federal agency may submit a written request for copies of the records relating to the drug test results or a documentation package or any relevant certification, review, or revocation of certification records.

(b) Standard documentation packages provided by an HHS-certified laboratory must contain the following items:

(1) A cover sheet providing a brief description of the procedures and tests performed on the donor's specimen;

(2) A table of contents that lists all documents and materials in the package by page number;

(3) A copy of the Federal CCF with any attachments, internal chain of custody records for the specimen, memoranda (if any) generated by the HHS-certified laboratory, and a copy of the electronic report (if any) generated by the HHS-certified laboratory;

(4) A brief description of the HHS-certified laboratory's initial drug and specimen validity testing procedures, instrumentation, and batch quality control requirements;

(5) Copies of the initial test data for the donor's specimen with all calibrators and controls and copies of all internal chain of custody documents related to the initial tests;

(6) A brief description of the HHS-certified laboratory's confirmatory drug (and specimen validity, if applicable) testing procedures, instrumentation, and batch quality control requirements;

(7) Copies of the confirmatory test data for the donor's specimen with all calibrators and controls and copies of all internal chain of custody documents related to the confirmatory tests; and

(8) Copies of the résumé or curriculum vitae for the RP(s) and the certifying technician or certifying scientist of record.

Section 11.24 What HHS-certified laboratory information is available to a federal employee?

A federal employee who is the subject of a workplace drug test may submit a written request through the MRO and/or the federal agency requesting copies of any records relating to the employee's drug test results or a documentation package as described in Section 11.23(b) and any relevant certification, review, or revocation of certification records. Federal employees, or their designees, are not permitted access to their specimens collected pursuant to Executive Order 12564, Public Law 100–71, and these Guidelines.

Section 11.25 What types of relationships are prohibited between an HHS-certified laboratory and an MRO?

An HHS-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 HHS-certified 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 HHS-certified laboratory or have any agreement with an HHS-certified laboratory that may be construed as a potential conflict of interest.

Section 11.26 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 HHS-certified IITF operations. When followed, the SOP manual ensures that all specimens are tested consistently using the same procedures.

(b) The SOP manual must include at a minimum, 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 compliant with these Guidelines and all guidance provided by the Secretary.

(d) A copy of all procedures that have been replaced or revised and the dates on which the procedures were in effect must be maintained for two years.

Section 12.2 What are the responsibilities of the responsible technician (RT)?

(a) Manage the day-to-day operations of the HHS-certified IITF even if another individual has overall responsibility for alternate areas of a multi-specialty facility.

(b) Ensure that there are sufficient personnel with adequate training and experience to supervise and conduct the work of the HHS-certified 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 and current SOP manual that is available to all personnel of the HHS-certified IITF, and ensure that it is followed. The SOP manual must be reviewed, signed, and dated by the RT when procedures are

first placed into use or changed or when a new individual assumes responsibility for the management of the HHS-certified IITF. The SOP must be reviewed and documented by the RT annually.

(d) Maintain a quality assurance program that ensures the proper performance and reporting of all test results; verify and monitor acceptable analytical performance for all controls and calibrators; monitor quality control testing; and document the validity, reliability, accuracy, precision, and performance characteristics of each test and test system.

(e) *Initiate and implement all remedial actions necessary to maintain satisfactory operation and performance of the HHS-certified IITF in response to the following:* Quality control systems not within performance specifications, errors in result reporting or in analysis of performance testing samples, and inspection deficiencies. The RT must ensure that specimen results are not reported until all corrective actions have been taken and 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 HHS-certified IITF;

(c) Have training and experience in reviewing and reporting forensic test results and maintaining chain of custody, and an understanding of appropriate remedial actions in response to problems that may arise;

(d) Be found to fulfill RT responsibilities and qualifications, as demonstrated by the HHS-certified IITF's performance and verified upon interview by HHS-trained inspectors during each on-site inspection; and

(e) Qualify as a certifying technician.

Section 12.4 What happens when the RT is absent or leaves an HHS-certified IITF?

(a) HHS-certified IITFs must have an RT and an alternate RT. When an RT is absent, an alternate RT must be present and qualified to fulfill the responsibilities of the RT.

(1) If an HHS-certified IITF is without the RT and alternate RT for 14 calendar days or less (*e.g.,* temporary absence due to vacation, illness, business trip), the HHS-certified IITF may continue operations and testing of federal agency specimens under the direction of a certifying technician.

(2) The Secretary, in accordance with these Guidelines, will suspend an IITF's HHS 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) If the RT leaves an HHS-certified IITF:

(1) The HHS-certified IITF may maintain certification and continue testing federally regulated 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 RT's replacement.

(2) The Secretary, in accordance with these Guidelines, will suspend an IITF's HHS certification for all federally regulated specimens if the IITF does not have a permanent 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 the RT or alternate RT, the HHS-certified IITF must submit the following documents to the Secretary:* The candidate's current résumé or curriculum vitae, copies of diplomas and licensures, a training plan (not to exceed 90 days) to transition the candidate into the position, an itemized comparison of the candidate's qualifications to the minimum RT qualifications described in the Guidelines, and have official academic transcript(s) submitted from the candidate's institution(s) of higher learning. The candidate must be found qualified during an on-site inspection of the HHS-certified IITF.

(d) The HHS-certified IITF must fulfill additional inspection and PT criteria as required prior to conducting federally regulated testing under a new RT.

Section 12.5 What qualifications must an individual have to certify a result reported by an HHS-certified IITF?

A certifying technician must have:

(a) Training and experience in the analytical methods and forensic procedures used by the HHS-certified IITF relevant to the results that the individual certifies; and

(b) Training and experience in reviewing and reporting forensic test results and maintaining chain of custody, and an understanding of appropriate remedial actions in response to problems that may arise.

Section 12.6 What qualifications and training must other personnel of an HHS-certified IITF have?

(a) All HHS-certified IITF staff (*e.g.,* technicians, administrative staff) must have the appropriate training and skills for the tasks they perform.

(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 they are permitted to work independently with federally regulated specimens. All 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 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 (*e.g.,* firefighters and medical rescue teams).

(c) An HHS-certified IITF must maintain records documenting the identity of the visitor and escort, date, time of entry and exit, and purpose for the access to the secured area.

Section 12.8 What are the IITF chain of custody requirements for specimens and aliquots?

(a) HHS-certified IITFs must use chain of custody procedures (internal and external) to maintain control and accountability of specimens from the time of receipt at the IITF through completion of testing, reporting of results, during storage, and continuing until final disposition of the specimens.

(b) HHS-certified IITFs must use chain of custody procedures to document the handling and transfer of aliquots throughout the testing process until final disposal.

(c) The chain of custody must be documented using either paper copy or electronic procedures.

(d) Each individual who handles a specimen or aliquot must sign and complete the appropriate entries on the chain of custody form when the specimen or aliquot is handled or transferred, and every individual in the chain must be identified.

(e) The date and purpose must be recorded on an appropriate chain of custody form each time a specimen or aliquot is handled or transferred.

Section 12.9 What are the requirements for an initial drug test?

(a) An initial drug test may be:
(1) An immunoassay or
(2) An alternate technology (*e.g.,* spectrometry, spectroscopy).
(b) An HHS-certified IITF must validate an initial drug test before testing specimens;
(c) Initial drug tests must be accurate and reliable for the testing of urine specimens when identifying drugs or their metabolites.
(d) An HHS-certified 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 the following for each initial drug test:
(1) The ability to differentiate negative specimens from those requiring further testing;
(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 (linearity);
(4) The potential for carryover;
(5) The potential for interfering substances; and
(6) The potential matrix effects if using an alternate technology.
(b) Each new lot of reagent must be verified prior to being placed into service.
(c) Each initial drug test using an alternate technology must be re-verified periodically or at least annually.

Section 12.11 What are the batch quality control requirements when conducting an initial drug test?

(a) Each batch of specimens must contain the following calibrators and controls:
(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 a concentration 25 percent above the cutoff;
(3) At least one control with the drug or drug metabolite targeted at a concentration 75 percent of the cutoff; and
(4) At least one control that appears as a donor specimen to the analysts.
(b) Calibrators and controls must total at least 10 percent of the aliquots analyzed in each batch.

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 performing a single test on one aliquot;
(b) The HHS-certified IITF must establish acceptance criteria and analyze calibrators and controls as appropriate to verify and document the validity of the test results in accordance with 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. Each new lot of reagent must be verified prior to being placed into service.

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 the following calibrators and controls:
(i) A calibrator at 2 mg/dL;
(ii) A control in the range of 1.0 mg/dL to 1.5 mg/dL;
(iii) A control in the range of 3 mg/dL to 20 mg/dL; and
(iv) 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 greater than 5 mg/dL and less than 20 mg/dL, an IITF must perform a screening test using a refractometer to identify specific gravity values that are acceptable (equal to or greater than1.003) or dilute (equal to or greater than1.002 and less than1.003). Specimens must be forwarded to an HHS-certified laboratory when the creatinine test result is less than or equal to 5 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 calibrators and controls:
(i) A calibrator or control at 1.000;
(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 calibrators and controls:
(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 to the agency's MRO within an average of 3 working days after receipt of the specimen. Reports must use the Federal CCF and/or an electronic report. Before any test result can be reported, it must be certified by a certifying technician.
(b) A primary (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 (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 HHS-certified 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) HHS-certified IITFs may transmit test results to the MRO by various electronic means (*e.g.,* teleprinter, facsimile, or computer). Transmissions of the reports must ensure confidentiality and the results may not be reported verbally by telephone. IITFs and external service providers must ensure the confidentiality, integrity, and availability of the data and limit access to any data transmission, storage, and retrieval system.

(f) HHS-certified IITFs must facsimile, 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 results can accurately represent the content of the custody and control form that the MRO received from the collector.

(g) For rejected specimens, IITFs must facsimile, courier, mail, or electronically transmit a legible image or copy of the completed Federal CCF.

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. The IITF may convert hardcopy records to electronic records for storage and then discard the hardcopy records after six months.

(b) A federal agency may request the HHS-certified IITF to maintain a documentation package (as described in Section 12.20) 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) An HHS-certified IITF may retain records other than those included in the documentation package beyond the normal two-year period of time.

Section 12.19 What statistical summary reports must an HHS-certified IITF provide?

(a) HHS-certified IITFs must provide to each federal agency for which they perform testing a semiannual statistical summary report that must be submitted by mail, facsimile, or email within 14 working days after the end of the semiannual period. The summary report must not include any personal identifying information. A copy of the semiannual statistical summary report will also be sent to the Secretary or designated HHS representative. The semiannual statistical report contains the following information:

(1) Reporting period (inclusive dates);

(2) HHS-certified 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;

(8) Number of specimens rejected for testing because of an uncorrected flaw;

(9) Number of specimens tested positive by each initial drug test; and

(10) Number of specimens forwarded to an HHS-certified laboratory for testing.

(b) An HHS-certified IITF must make copies of an agency's test results available when requested to do so by the Secretary or by the federal agency for which the IITF is performing drug-testing services.

(c) An HHS-certified IITF must ensure that a qualified individual is available to testify in a proceeding against a federal employee when the proceeding is based on a test result reported by the IITF.

Section 12.20 What HHS-certified IITF information is available to a federal agency?

(a) Following a federal agency's receipt of a positive, adulterated, or substituted drug test report from a laboratory, the federal agency may submit a written request for copies of the IITF records relating to the drug test results or a documentation package or any relevant certification, review, or revocation of certification records.

(b) Standard documentation packages provided by an HHS-certified IITF must contain the following items:

(1) A cover sheet providing a brief description of the procedures and tests performed on the donor's specimen;

(2) A table of contents that lists all documents and materials in the package by page number;

(3) A copy of the Federal CCF with any attachments, internal chain of custody records for the specimen, memoranda (if any) generated by the HHS-certified IITF, and a copy of the electronic report (if any) generated by the HHS-certified IITF;

(4) A brief description of the HHS-certified IITF's drug and specimen validity testing procedures, instrumentation, and batch quality control requirements;

(5) Copies of all test data for the donor's specimen with all calibrators and controls and copies of all internal chain of custody documents related to the tests; and

(6) Copies of the résumé or curriculum vitae for the RT and for the certifying technician of record.

Section 12.21 What HHS-certified IITF information is available to a federal employee?

A federal employee who is the subject of a drug test may provide a written request through the MRO and/or the federal agency requesting access to any records relating to the employee's drug test results or a documentation package (as described in Section 12.20) and any relevant certification, review, or revocation of certification records.

Section 12.22 What types of relationships are 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 the 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 12.23 What type of relationship can exist between an HHS-certified IITF and an HHS-certified laboratory?

An HHS-certified IITF can 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 currently licensed physician who has:

(1) 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 13.3;

(4) Satisfactorily passed an initial examination administered by a nationally recognized entity or a subspecialty board that has been approved by the Secretary to certify MROs; and

(5) At least every five years from initial certification, completed requalification training on the topics in Section 13.3 and satisfactorily passed a requalification examination administered by a nationally recognized entity or a subspecialty board that has been approved by the Secretary to certify MROs.

Section 13.2 How are nationally recognized entities or subspecialty boards that certify MROs approved?

All nationally recognized entities or subspecialty boards which seek approval by the Secretary to certify physicians as MROs for federal workplace drug testing programs must submit their qualifications, a sample examination, and other necessary supporting examination materials (*e.g.,* answers, previous examination statistics or other background examination information, if requested). Approval will be based on an objective review of qualifications that include a copy of the MRO applicant application form, documentation that the continuing education courses are accredited by a professional organization, and the delivery method and content of the examination. Each approved MRO certification entity must resubmit their qualifications for approval every two years. The Secretary shall publish at least every two years a notice in the **Federal Register** listing those entities and subspecialty boards that have been approved. This notice is also available on the Internet at *http://www.samhsa.gov/workplace/drug-testing.*

Section 13.3 What training is required before a physician may serve as an MRO?

(a) A physician must receive training that includes a thorough review of the following:

(1) The collection procedures used to collect federal agency specimens;

(2) How to interpret test results reported by HHS-certified IITFs and laboratories (*e.g.,* negative, negative/dilute, positive, adulterated, substituted, rejected for testing, and invalid);

(3) Chain of custody, reporting, and recordkeeping requirements for federal agency specimens;

(4) The HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs for all authorized specimen types; and

(5) Procedures for interpretation, review (*e.g.,* donor interview for legitimate medical explanations, review of documentation provided by the donor to support a legitimate medical explanation), and reporting of results specified by any federal agency for which the individual may serve as an MRO;

(b) Certified MROs must complete training on any revisions to these Guidelines prior to their effective date, to continue serving as an MRO for federal agency specimens.

Section 13.4 What are the responsibilities of an MRO?

(a) The MRO must review all positive, adulterated, rejected for testing, invalid, and (for urine) substituted test results.

(b) Staff under the direct, personal supervision of the MRO may review and report negative and (for urine) 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.

(c) The MRO must discuss potential invalid results with the HHS-certified laboratory, as addressed in Section 11.19(g) to determine whether testing at another HHS-certified laboratory may be warranted.

(d) After receiving a report from an HHS-certified laboratory or (for urine) 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; and

(4) Report the verified result to the federal agency.

(e) The MRO must maintain records for a minimum of two years while maintaining the confidentiality of the information. The MRO may convert hardcopy records to electronic records for storage and discard the hardcopy records after six months.

(f) The MRO must conduct a medical examination or a review of the examining physician's findings and make a determination of refusal to test or cancelled test when a collector reports that the donor was unable to provide a specimen, as addressed in Section 8.6.

Section 13.5 What must an MRO do when reviewing a urine specimen's test results?

(a) When the HHS-certified laboratory or HHS-certified IITF reports a negative result for the primary (A) specimen, the MRO reports a negative result to the agency.

(b) When the HHS-certified laboratory or HHS-certified IITF reports a negative/dilute result for the primary (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.

(1) If the recollected specimen provides a negative or negative/dilute result, the MRO reports a negative result to the agency, with no further action required.

(2) If the recollected specimen provides a result other than negative or negative/dilute, the MRO follows the procedures in 13.5(c) through (f) for the recollected specimen.

(c) When the HHS-certified laboratory reports multiple results for the primary (A) urine specimen, as the MRO, you must follow the verification procedures described in 13.5(c) through (f) and:

(1) Report all verified positive and/or refusal to test results to the federal agency.

(2) If an invalid result was reported in conjunction with a positive, adulterated, or substituted result, do not report the verified invalid result to the federal agency at this time. The MRO reports the verified invalid result(s) for the primary (A) urine specimen only if the split specimen is tested and reported as a failure to reconfirm as described in Section 14.6(l).

(d) When the HHS-certified laboratory reports a positive result for the primary (A) specimen, the MRO must contact the donor to determine if there is any legitimate medical explanation for the positive result.

(1) If the donor provides documentation (*e.g.,* a valid

prescription) to support a legitimate medical explanation for the positive result, the MRO reports the test result as negative to the agency. If the laboratory also reports that the urine 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. The MRO follows the procedures in 13.5(b)(1) or (2) for the recollected specimen.

(i) Passive exposure to marijuana smoke is not a legitimate medical explanation for a positive THCA result.

(ii) Ingestion of food products containing marijuana is not a legitimate medical explanation for a positive THCA result.

(2) If the donor is unable to provide a legitimate medical explanation, the MRO reports a positive result to the agency for all drugs except codeine and/or morphine (see below). If the laboratory also reports that the urine specimen is dilute, the MRO may choose not to report the dilute result.

(i) For codeine and/or morphine less than 15,000 ng/mL and no legitimate medical explanation: the MRO must determine if there is clinical evidence of illegal use (in addition to the test result) to report a positive result to the agency. If there is no clinical evidence of illegal use, the MRO reports a negative result to the agency. 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).

(ii) For codeine and/or morphine equal to or greater than 15,000 ng/mL and no legitimate medical explanation: the MRO reports a positive result to the agency. 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 the HHS-certified laboratory reports an adulterated or substituted result for the primary (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 legitimate medical explanation, the MRO reports a negative result to the federal agency.

(2) If the donor is unable to provide a legitimate explanation, the MRO reports a refusal to test to the federal agency because the urine specimen was adulterated or substituted.

(f) When the HHS-certified laboratory reports an invalid result for the primary (A) urine specimen, the MRO must contact the donor to determine if there is a legitimate 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, HHS-certified IITF, and/or HHS-certified 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).

(1) If the donor provides a legitimate explanation (*e.g.,* a prescription medication) or if the MRO determines that time and temperature account for the pH in the 9.0 to 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 a legitimate explanation for the invalid result.

(2) If the donor is unable to provide a legitimate 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 urine specimen from the donor using a direct observed collection.

(i) If the specimen collected under direct observation provides a valid result, the MRO follows the procedures in 13.5(a) through (e).

(ii) If the specimen collected under direct observation provides an invalid result, the MRO reports this specimen as test cancelled and recommends that the agency collect another authorized specimen type (*e.g.,* oral fluid).

(g) When two separate specimens collected during the same testing event were sent to the HHS-certified laboratory for testing (*e.g.,* the collector sent a urine specimen out of temperature range and the subsequently collected specimen—urine or another authorized specimen type), as the MRO, you must follow the verification procedures described in Sections 13.4, 13.5, and 13.6, and:

(1) If both specimens were verified negative, report the result as negative.

(2) If one specimen was verified negative and the other was not (*i.e.,* the specimen was verified as negative/dilute or as positive, adulterated, substituted, and/or invalid), report only the verified result(s) other than negative. For example, if you verified one specimen as negative and the other as a refusal to test because the specimen was substituted, report only the refusal to the federal agency.

(3) If both specimens were verified as positive, adulterated, and/or substituted, report all results. For example, if you verified one specimen as positive and the other as a refusal to test because the specimen was adulterated, report the positive and the refusal results to the federal agency.

(4) If one specimen has been verified and the HHS-certified laboratory has not reported the result(s) of the other specimen,

(i) Report verified result(s) of positive, adulterated, or substituted immediately and do not wait to receive the result(s) of the other specimen.

(ii) Do not report a verified result of negative, negative/dilute, or invalid for the first specimen to the federal agency. Hold the report until results of both specimens have been received and verified.

(5) When the HHS-certified laboratory reports an invalid result for one or both specimens, follow the procedures in paragraph c above.

(h) When the HHS-certified laboratory or HHS-certified IITF reports a rejected for testing result for the primary (A) specimen, the MRO reports a test cancelled result to the agency and recommends that the agency collect another specimen from the donor. The recollected specimen must be the same type (*i.e.,* urine).

Section 13.6 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) When another specimen type (*e.g.,* oral fluid) was collected as authorized by the federal agency, the MRO reviews and reports the test result in accordance with the Mandatory Guidelines for Federal Workplace Drug Testing Programs using the alternative specimen.

(b) When the federal agency did not authorize the collection of an alternative specimen, 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) 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. 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 genitourinary 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.

(2) 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, after completing the evaluation, the referral physician must agree to provide a written statement to the MRO with a recommendation for one of the determinations described in paragraph (b)(3) of this section and the basis for the recommendation. The statement must not include detailed information on the employee's medical condition beyond what is necessary to explain the referral physician's conclusion.

(3) As the MRO, if another physician performed the evaluation, you must consider and assess the referral physician's recommendations in making your determination. You must make one of the following determinations and report it to the federal agency in writing:

(i) A medical condition as defined in paragraph (b)(1) of this section has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of urine, but is not a permanent or long-term disability. As the MRO, you must report a test cancelled result to the federal agency.

(ii) A permanent or long-term medical condition as defined in paragraph (b)(1) of this section has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of urine and is highly likely to prevent the employee from providing a sufficient amount of urine for a very long or indefinite period of time. As the MRO, you must follow the requirements of Section 13.7, as appropriate. If Section 13.7 is not applicable, you report a test cancelled result to the federal agency and recommend that the agency authorize collection of an alternative specimen type (*e.g.,* oral fluid) for any subsequent drug tests for the donor.

(iii) 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, you must report a refusal to test to the federal agency.

(4) When a federal agency receives a report from the MRO indicating that a test is cancelled as provided in paragraph (b)(3)(i) of this section, the agency takes no further action with respect to the donor. When a test is canceled as provided in paragraph (b)(3)(ii) of this section, the agency takes no further action with respect to the donor other than designating collection of an alternate specimen type (*i.e.,* authorized by the Mandatory Guidelines for Federal Workplace Drug Testing Programs) for any subsequent collections, in accordance with the federal agency plan. The donor remains in the random testing pool.

13.7 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 the donor 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 and the federal agency does not authorize collection of an alternative specimen. 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 13.6.

(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 13.6 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. The MRO recommends that the agency authorize collection of an alternate specimen type (*e.g.,* oral fluid) for any subsequent collections.

(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 13.6 and any further medical examination. This report must state that a permanent or long-term medical condition [as defined in Section 13.6(b)(1)] 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 13.8 Who may request a test of a split (B) specimen?

(a) For a positive, adulterated, or substituted result reported on a primary (A) specimen, a donor may request through the MRO that the split (B) specimen be tested by a second HHS-certified laboratory to verify the result reported by the first HHS-certified laboratory.

(b) The donor has 72 hours (from the time the MRO notified the donor that the donor's specimen was reported positive, adulterated, or (for urine) substituted to request a test of the split (B) specimen. The MRO must inform the donor that the donor has the opportunity to request a test of the split (B) specimen when the MRO informs the donor that a positive, adulterated, or (for urine) substituted result is being reported to the federal agency on the primary (A) specimen.

Section 13.9 How does an MRO report a primary (A) specimen test result to an agency?

(a) The MRO must report all verified results to an agency using the completed MRO copy of the Federal CCF or a separate report using a letter/memorandum format. The MRO may use various electronic means for reporting (*e.g.,* teleprinter, facsimile, or computer). Transmissions of the reports must ensure confidentiality. The MRO and external service providers must ensure the confidentiality, integrity, and availability of the data and limit access to any data transmission, storage, and retrieval system.

(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 copy of either the completed MRO copy of the Federal CCF or the separate letter/memorandum report for all positive, adulterated, and (for urine) substituted results.

(d) The MRO must not disclose numerical values of drug test results to the agency.

Section 13.10 What types of relationships are 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 (B) specimen be tested?

(a) The donor may request, verbally or in writing, through the MRO that the split (B) specimen be tested at a different (*i.e.,* second) HHS-certified laboratory when the primary (A) specimen was determined by the MRO to be positive, adulterated, or (for urine) 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 the MRO's records the verbal request from the donor to have the split (B) specimen tested.

(c) If a split (B) urine specimen cannot be tested by a second HHS-certified laboratory (*e.g.,* insufficient specimen, lost in transit, split not available, no second HHS-certified laboratory available to perform the test), the MRO reports to the federal agency 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 urine 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 (B) specimen tested by a second HHS-certified laboratory, a federal agency may have a split (B) specimen retested as part of a legal or administrative proceeding to defend an original positive, adulterated, or (for urine) substituted result.

Section 14.2 How does an HHS-certified laboratory test a split (B) specimen when the primary (A) specimen was reported positive?

(a) The testing of a split (B) specimen for a drug or metabolite is not subject to the testing cutoff concentrations established.

(b) The HHS-certified laboratory is only required to confirm the presence of the drug or metabolite that was reported positive in the primary (A) specimen.

(c) For a split (B) urine specimen, if the second HHS-certified laboratory fails to reconfirm the presence of the drug or drug metabolite that was reported by the first HHS-certified 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 (A) urine specimen and reports those results to the MRO.

Section 14.3 How does an HHS-certified laboratory test a split (B) urine specimen when the primary (A) specimen was reported adulterated?

(a) An HHS-certified laboratory must use one of the following criteria to reconfirm an adulterated result when testing a split (B) urine specimen:

(1) pH must be measured using the laboratory's confirmatory pH test with the appropriate cutoff (*i.e.,* either less than 4 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 quantification (LOQ) to reconfirm the presence of the adulterant.

(b) The second HHS-certified laboratory may only conduct the confirmatory specimen validity test(s) needed to reconfirm the adulterated result reported by the first HHS-certified laboratory.

Section 14.4 How does an HHS-certified laboratory test a split (B) urine specimen when the primary (A) specimen was reported substituted?

(a) An HHS-certified laboratory must use the following criteria to reconfirm a substituted result when testing a split (B) urine 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 HHS-certified laboratory may only conduct the confirmatory specimen validity test(s) needed to reconfirm the substituted result reported by the first HHS-certified laboratory.

Section 14.5 Who receives the split (B) specimen result?

The second HHS-certified laboratory must report the result to the MRO.

Section 14.6 What action(s) does an MRO take after receiving the split (B) urine specimen result from the second HHS-certified laboratory?

The MRO takes the following actions when the second HHS-certified laboratory reports the result for the split (B) 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 specimen. The MRO gives the donor 72 hours to request that Laboratory A retest the primary (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 (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 give 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 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 (B) specimen test result to an agency?

(a) The MRO must report all verified results to an agency using the completed MRO copy of the Federal CCF or a separate report using a letter/memorandum format. The MRO may use various electronic means for reporting (*e.g.,* teleprinter, facsimile, or computer). Transmissions of the reports must ensure confidentiality. The MRO and external service providers must ensure the confidentiality, integrity, and availability of the data and limit access to any data transmission, storage, and retrieval system.

(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 copy of either the completed MRO copy of the Federal CCF or the separate letter/memorandum report for all split specimen 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 (B) specimen?

A split (B) specimen is retained for the same period of time that a primary (A) specimen is retained and under the same storage conditions. This applies even for those cases when the split (B) specimen is tested by a second HHS-certified laboratory and the second HHS-certified laboratory does not confirm the original result reported by the first HHS-certified laboratory for the primary (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 HHS-certified 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 primary (A) or split (B) 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 either specimen label/seal;

(b) The primary (A) specimen label/seal is missing, misapplied, broken, or shows evidence of tampering and the split (B) specimen cannot be re-designated as the primary (A) specimen;

(c) The collector's printed name and signature are omitted on the Federal CCF;

(d) There is an insufficient amount of specimen for analysis in the primary (A) specimen unless the split (B) specimen can be re-designated as the primary (A) specimen;

(e) The accessioner failed to document the primary (A) specimen seal condition on the Federal CCF at the time of accessioning, and the split (B) specimen cannot be re-designated as the primary (A) specimen;

(f) The specimen was received at the HHS-certified laboratory or IITF without a CCF;

(g) The CCF was received at the HHS-certified laboratory or IITF without a specimen;

(h) The collector performed two separate collections using one CCF; or

(i) The HHS-certified laboratory or IITF identifies a flaw (other than those specified above) that prevents testing or affects the forensic defensibility of the drug test and cannot be corrected.

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 HHS-certified laboratory or IITF may report the test result for the specimen. If, after holding the specimen for at least 5 business days, the HHS-certified 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 HHS-certified 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 holding the specimen for at least 5 business days, the HHS-certified 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 urine 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 HHS-certified laboratory or IITF should not cause an HHS-certified laboratory or IITF to reject a urine specimen or cause an MRO to cancel a test:

(1) An incorrect laboratory name and address appearing 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 Social Security Number or employee identification number;

(6) A telephone 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 HHS-certified laboratory or IITF 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 at least 5 business days, the collector cannot provide a memorandum for record to attest to the fact that the collector did measure the specimen temperature, the HHS-certified 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 HHS-certified laboratory or IITF 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 their name;

(3) The certifying scientist or certifying technician fails to print their name;

(4) The certifying scientist or certifying technician accidentally initials the Federal CCF rather than signing for a specimen reported as rejected for testing;

(c) The above omissions and discrepancies should 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, HHS-certified laboratory, or HHS-certified 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 Federal CCF for a specimen being reported drug positive, adulterated, invalid, or (for urine) substituted; 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 laboratory or IITF electronic report for a specimen being reported drug positive, adulterated, invalid result, or (for urine) substituted.

(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 at least 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 they inadvertently forgot to sign the Federal CCF, but did, in fact, properly conduct the certification review. If, after at least 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 at least 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 the HHS certification of a 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 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 the official's 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 relevant 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 telephone number of the appellant's representative. In its first written submission to the reviewing official, the respondent shall specify the name, address, and telephone 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 procedures are 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 testing, which is 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 their 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 the Oral Presentation.* The presiding official will attempt to schedule the oral presentation within 30 days of the date the 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 the official's 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 their 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 an HHS-certified laboratory or IITF in writing that its certification to perform drug 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 HHS-certified 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, which is 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 their 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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Part III

Department of Transportation

Pipeline and Hazardous Materials Safety Administration

49 CFR Parts 190, 191, 192, 195, and 199
Pipeline Safety: Operator Qualification, Cost Recovery, Accident and Incident Notification, and Other Pipeline Safety Changes; Final Rule

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

49 CFR Parts 190, 191, 192, 195, and 199

[Docket No. PHMSA–2013–0163; Amdt. Nos. 190–19; 191–25; 192–123; 195–101; 199–27]

RIN 2137–AE94

Pipeline Safety: Operator Qualification, Cost Recovery, Accident and Incident Notification, and Other Pipeline Safety Changes

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: PHMSA is amending the pipeline safety regulations to address requirements of the Pipeline Safety, Regulatory Certainty, and Job Creation Act of 2011 (2011 Act), and to update and clarify certain regulatory requirements. Among other provisions, PHMSA is adding a specific time frame for telephonic or electronic notifications of accidents and incidents and adding provisions for cost recovery for design reviews of certain new projects, for the renewal of expiring special permits, and setting out the process for requesting protection of confidential commercial information. PHMSA is also amending the drug and alcohol testing requirements, and incorporating consensus standards by reference for in-line inspection (ILI) and Stress Corrosion Cracking Direct Assessment (SCCDA).

DATES: This final rule is effective March 24, 2017. The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register as of March 24, 2017.

ADDRESSES: U.S. Department of Transportation, Pipeline and Hazardous Materials Safety Administration, 1200 New Jersey Ave. SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Tewabe Asebe by telephone at 202–366–5523, by email at *Tewabe.Asebe@dot.gov,* or by mail at U.S. Department of Transportation, Pipeline and Hazardous Materials Safety Administration, 1200 New Jersey Ave. SE., Washington, DC 20590.

SUPPLEMENTARY INFORMATION:

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I. Executive Summary

A. Purpose of the Regulatory Action and Summary of the Major Provisions of the Regulatory Action in Question

The purpose of this rulemaking action is to strengthen the Federal pipeline safety regulations and to address sections 9 and 13 of the Pipeline Safety, Regulatory Certainty, and Job Creation Act of 2011 (2011 Act). Public Law 112–90. The amendment associated with section 9 of the 2011 Act limits the timeframe within which the operator must electronically or telephonically report notice of an accident or incident to within one hour of confirmed discovery of the event. PHMSA expects that quicker accident and incident reporting will lead to a safety benefit to the public, the environment, and limit property damage. The amendment associated with section 13 of the 2011 Act allows PHMSA to recover its costs for design review work PHMSA conducts on behalf of the operators, which will allow PHMSA to use its limited resources in protecting public safety. PHMSA is also providing a renewal procedure for expiring special permits, and is making other minor and administrative changes. This final rule does not include the Operator Qualification (OQ) requirements proposed under subpart N for natural gas pipelines and subpart G for hazardous liquid pipelines; however, PHMSA is proceeding with amendments to control room staff training requirements. PHMSA is delaying final action on the OQ proposals until a later date and fully expects to consider all the comments received and the recommendations of the Pipeline Advisory Committees related to those specific issues in a subsequent final rule published in the near future.

The specific amendments codified by this final rule are listed in detail below:

- Specifying an operator's accident and incident reporting time to not later than one hour after confirmed discovery and requiring revision or confirmation of initial notification within 48 hours of the confirmed discovery of the accident or incident;
- Setting up a cost recovery fee structure for design review of new gas and hazardous liquid pipelines with either overall design and construction costs totaling at least $2,500,000,000 or that contain new and novel technologies;
- Addressing the National Transportation Safety Board's (NTSB) recommendation to clarify training requirements for control room personnel;
- Providing a renewal procedure for expiring special permits;
- Excluding farm taps from the requirements of the Distribution Integrity Management Program (DIMP) requirements while proposing safety requirements for the farm taps;
- Requiring pipeline operators to report to PHMSA a change in product (*e.g.,* from liquid to gas, from crude oil to highly volatile liquids (HVL)) or a permanent reversal of flow that lasts more than 30 days;
- Providing methods for assessment tool selection by incorporating consensus standards by reference in part 195 for stress corrosion cracking direct assessment (SCCDA) that were not developed when the Integrity Management (IM) regulations were issued;
- Requiring electronic reporting of drug and alcohol testing results in part 199;
- Modifying the criteria used to make decisions about conducting post-accident drug and alcohol tests and requiring operators to keep for at least 3 years a record of the reason why post-accident drug and alcohol tests were not conducted;
- Including the procedure to request protection for confidential commercial information submitted to PHMSA;
- Adding reference to appendix B of API 1104 related to in-service welding in parts 192 and 195; and

• Amending minor editorial corrections.

B. Costs and Benefits

PHMSA has estimated annual compliance costs at $0.6 million less savings to be realized from the removal of farm taps from the Distribution Integrity Management Program requirements. PHMSA could not quantify annual benefits as readily due to data limitations. However, the improvements to and the clarification of regulations, including those for post-incident investigations along with other provisions, are designed to reduce pipeline incidents and the associated consequences, including the potential to prevent a future high-consequence event, such as those that have occurred on gas transmission and hazardous liquid pipelines in the past.

II. Background

A. Notice of Proposed Rulemaking

On July 10, 2015, PHMSA published a notice of proposed rulemaking (NPRM) to address requirements in the 2011 Act pertaining to accident and incident reporting (section 9) and cost recovery (section 13); to address certain National Transportation Safety Board (NTSB) recommendations made in response to the pipeline incidents in San Bruno CA,[1] and Marshall, MI; [2] and to update and clarify certain regulatory requirements. 80 FR 39916. Among other provisions, PHMSA proposed to add a specific time frame for telephonic or electronic notifications of accidents and incidents and to add provisions for cost recovery for design reviews of certain new projects, to add provisions for the renewal of expiring special permits, and to include the procedure for submitters of information to request PHMSA treat the information as confidential. Also, PHMSA proposed changes to the operator qualification (OQ) requirements and drug and alcohol testing requirements and proposed to incorporate consensus standards by reference for inline inspection (ILI) and Stress Corrosion Cracking Direct Assessment (SCCDA).

B. Pipeline Safety, Regulatory Certainty, and Job Creation Act of 2011 and the National Transportation Safety Board Recommendations

The Pipeline Safety, Regulatory Certainty, and Job Creation Act of 2011 was signed into law by President Barack Obama on January 3, 2012. The 2011 Act was enacted in part to enhance safety and protect the environment during the transportation of products by pipeline. H. Rept. 112–297. As discussed above, this rulemaking addresses two provisions from the 2011 Act:

• Section 9 requires PHMSA to specify a time limit for telephonic or electronic reporting of pipeline accidents and incidents

• Section 13, which is codified at 49 U.S.C. 60117(n), allows PHMSA to prescribe a fee structure and assessment methodology to recover costs associated with design and construction reviews

This rule also addresses certain National Transportation Safety Board (NTSB) recommendations arising out of the September 9, 2010, San Bruno, CA, pipeline rupture of a natural gas line that killed eight people, and the July 25, 2010, pipeline rupture in Marshall, MI, that resulted in the release of an estimated 843,444 gallons of crude oil in a wetland. The specific NTSB recommendations addressed in this rulemaking action are:

- P–11–12 on drug and alcohol testing of employees whose performance either contributed to the accident or cannot be completely discounted as a contributing factor to the accident
- P–12–3 on assessment tools incorporation by reference in part 195
- P–12–7 on team training of control center staff
- P–12–8 on extending operator qualification training requirements for all hazardous liquid and gas transmission control center staff involved in pipeline operational decisions

C. Summary of Each Topic Under Consideration

Accident and Incident Notification

Section 9 of the 2011 Act directs PHMSA to require pipeline operators to provide notification at the earliest practicable moment following confirmed discovery of an accident or incident, not to exceed 1 hour following the time of such confirmed discovery. PHMSA is amending the Federal pipeline safety regulations to require operators to provide telephonic or electronic notification of an accident or incident at the earliest practicable moment, including the amount of product loss, following confirmed discovery.

Cost Recovery for Design Reviews

On cost recovery for design reviews, section 13 of the 2011 Act allows PHMSA to prescribe a fee structure and assessment methodology to recover costs associated with any project with design review and construction costs totaling at least $2,500,000,000 and for new or novel technologies or design, as determined by the Secretary. PHMSA is amending the Federal pipeline safety regulations to prescribe a fee structure and assessment methodology for recovering costs associated with design reviews of new gas and hazardous liquid pipelines with either overall design and construction costs totaling at least $2,500,000,000 or that contain new and novel technologies.

NTSB Recommendations on Control Room Center Staff

PHMSA is addressing the NTSB recommendation to extend operator qualification requirements to control center staff involved in pipeline operational decisions (P–12–8) and to require team training for control center staff involved in pipeline operations similar to those used in other transportation modes (P–12–7).

Special Permit Renewal

On special permit renewal, PHMSA is amending § 190.341 of the Federal pipeline safety regulations to add procedures for renewing a special permit.

Farm Taps

On farm taps, PHMSA is amending the Federal pipeline safety regulations in 49 CFR part 192 to add a new section, § 192.740, to cover regulators and overpressure protection equipment for an individual service line that originates from a transmission, gathering, or production pipeline (*i.e.,* a farm tap), and to revise § 192.1003 to exclude farm taps from the requirements of the Distribution Integrity Management Program (DIMP).

Reversal of Flow or Change in Product

On reversal of flow or change in product, PHMSA is expanding the list of events in §§ 191.22 and 195.64 that require electronic notification to include the reversal of flow of product or change in product in a mainline pipeline. PHMSA is requiring operators to notify PHMSA electronically no later than 60 days before there is a reversal of the flow of product through a pipeline or when there is a change in the product flowing through a pipeline. In addition, PHMSA is amending §§ 192.14 and 195.5 to reflect the 60-day notification and to require operators to notify PHMSA when over 10 miles of pipeline is replaced.

[1] *https://www.ntsb.gov/investigations/AccidentReports/Reports/PAR1101.pdf.*

[2] *https://www.ntsb.gov/investigations/AccidentReports/Reports/PAR1201.pdf.*

Pipeline Assessment Tools

On pipeline assessment tools, PHMSA is incorporating by reference the following consensus standards into 49 CFR part 195: API STD 1163, ''In-Line Inspection Systems Qualification'' (April 2013); NACE SP0102–2010 ''Standard Practice, Inline Inspection of Pipelines'' (revised March 13, 2010); NACE SP0204–2008 ''Standard Practice, Stress Corrosion Cracking (SCC) Direct Assessment Methodology'' (reaffirmed September 18, 2008); and ANSI/ASNT ILI–PQ–2005, ''In-line Inspection Personnel Qualification and Certification'' (reapproved October 11, 2010). Also, PHMSA is allowing pipeline operators to conduct assessments using tethered or remote control tools not explicitly discussed in NACE SP0102–2010, provided the operators comply with applicable sections of NACE SP0102–2010.

Incorporation of these consensus standards will assure better consistency, accuracy and quality in pipeline assessments conducted using ILI and SCCDA.

Standards for ILI

When the part 195 IM requirements were issued, there were no consensus industry standards that addressed ILI. Since then the following standards have been published:

1. In 2002, NACE International published the first consensus industry standard that specifically addressed ILI (NACE Recommended Practice RP0102, ''Inline Inspection of Pipelines''). NACE International revised this document in 2010 and republished it as a Standard Practice, SP0102. PHMSA expects that the consistency, accuracy, and quality of pipeline ILI will be improved by incorporating the NACE International 2010 standard into the regulations. PHMSA asked the Standards Developing Organizations to develop this and the other standards and PHMSA is now adopting them to bring consistency throughout the industry. These standards provide tables to improve tool selection. PHMSA is providing hazardous liquids pipeline operators choices of tools to assess their pipelines and; therefore, PHMSA does not believe that these tool selections incur additional costs to the pipeline operators. The NACE International standard applies to ''free swimming'' inspection tools that are carried down the pipeline by the transported fluid. It does not apply to tethered or remotely controlled ILI tools. While the usage of tethered or remotely controlled ILI tools is less prevalent than the usage of free swimming tools, some pipeline IM assessments have been conducted using these tools. PHMSA believes many of the provisions in the NACE International standard can be applied to tethered or remotely controlled ILI tools and; therefore, PHMSA is allowing the use of these tools provided they generally comply with applicable sections of the NACE standard. The NACE standards were reviewed by PHMSA experts, and they agree with the provisions in the standards. Many operators are already following those guidelines. Our inspection guides will provide further instructions when this final rule is implemented.

2. In 2005, the ASNT published ANSI/ASNT ILI–PQ, ''In-line Inspection Personnel Qualification and Certification.'' The ASNT standard provides for qualification and certification requirements that are not addressed in part 195. In 2010 ASNT published ANSI/ASNT ILI–PQ with editorial changes. The incorporation of this standard into the Federal pipeline safety regulations will promote a higher level of safety by establishing consistent standards to qualify the equipment, people, processes, and software utilized by the ILI industry. This and the other standards are being used by many operators but not all. This rule will ensure that all operators use these standards. Overall cost will not change, because these consensus standards will help operators eliminate problems before they arise. SCCDA is a technique allowed for gas transmission pipelines but is not specifically addressed in § 195.452 although it is also applicable to hazardous liquid pipelines. This rulemaking action will allow HL operators to use the SCCDA technique and ASNT is one of them. The ASNT standard addresses in detail each of the following aspects, which are not currently addressed in the regulations:

- Requirements for written procedures.
- Personnel qualification levels.
- Education, training, and experience requirements.
- Training programs.
- Examinations (testing of personnel).
- Personnel certification and recertification.
- Personnel technical performance evaluations.

3. In 2005, API published API STD 1163, ''In-Line Inspection Systems Qualification Standard.'' PHMSA proposed to incorporate the 2005 API 1163 because at the time the notice of the rulemaking action was developed, the latest version of API 1163 was under development. PHMSA has evaluated the revisions made to the latest version of API 1163 and determined that the changes are not significant. Therefore, PHMSA is adopting API STD 2013 into part 195.

This Standard serves as an umbrella document that is to be used with and complements the NACE International and ASNT standards that are incorporated by reference in API STD 1163. The API standard is more comprehensive than the requirements currently in part 195. The incorporation of this standard into the Federal pipeline safety regulations will promote a higher level of safety by establishing a consistent methodology to qualify the equipment, people, processes, and software utilized by the ILI industry. The API standard addresses, in detail, each of the following aspects of ILI inspections:

- Systems qualification process.
- Personnel qualification.
- ILI system selection.
- Qualification of performance specifications.
- System operational validation.
- System results qualification.
- Reporting requirements.
- Quality management system.

Stress Corrosion Cracking (SCC) Direct Assessment

4. NACE SP0204–2008 ''Stress Corrosion Cracking Direct Assessment.'' SCC is a degradation mechanism in which steel pipe develops closely spaced tight cracks through the combined action of corrosion and tensile stress (circumferential, residual, or applied). These cracks can grow or coalesce to affect the integrity of the pipeline. SCC is one of several threats that can impact pipeline integrity. IM regulations in part 195 require that pipeline operators assess covered pipe segments periodically to detect degradation from threats that their analyses have indicated could affect the segment. Not all covered segments are subject to an SCC threat, but for those that are, SCCDA is an assessment technique that can be used to address this threat.

Part 195 presently includes no requirements applicable to the use of SCCDA. Experience has shown that pipelines can go through SCC degradation in areas where the surrounding soil has a pH near neutral (referred to as near-neutral SCC). NACE Standard Practice SP0204–2008 addresses near-neutral SCC. In addition, the NACE International recommended practice provides technical guidelines and process requirements that are both more comprehensive and rigorous for conducting SCCDA than are provided by § 192.929 or ASME/ANSI B31.8S.

The NACE standard provides additional guidance as follows:

- The factors that are important in the formation of SCC on a pipeline and what data should be collected;
- Additional factors, such as existing corrosion, which could cause SCC to form;
- Comprehensive data collection guidelines, including the relative importance of each type of data;
- Requirements to conduct close interval surveys of cathodic protection or other aboveground surveys to supplement the data collected during pre-assessment;
- Ranking factors to consider for selecting excavation locations for both near-neutral and high pH SCC;
- Requirements on conducting direct examinations, including procedures for collecting environmental data, preparing the pipe surface for examination, and conducting Magnetic Particle Inspection (MPI) examinations of the pipe; and
- Post assessment analysis of results to determine SCCDA effectiveness and assure continual improvement.

In general, NACE SP0204–2008 provides thorough and comprehensive guidelines for conducting SCCDA and is more comprehensive in scope than Appendix A3 of ASME/ANSI B31.8S. PHMSA believes that requiring the use of NACE SP0204–2008 will enhance the quality and consistency of SCCDA conducted under IM requirements.

SCC has also been the subject of research and development (R&D) programs that have been funded in whole or in part by PHMSA in recent years. PHMSA reviewed the results of several R&D programs concerning SCC as part of its consideration of whether it was appropriate to incorporate the NACE standard into the regulations. Among the reports PHMSA reviewed was ''Development of Guidelines for Identification of SCC Sites and Estimation of Re-inspection Intervals for SCC Direct Assessment,'' published by Integrity Corrosion Consulting Ltd. in May 2010.[3] This report evaluated the results of numerous studies conducted since the 1960s regarding SCC. The report used the conclusions from the studies to identify a group of 109 guidelines that pipeline operators could use to help identify sites where SCC might occur and determine appropriate re-inspection intervals when SCC is found. The guidelines address both high-pH and near-neutral-pH conditions. This report noted that the information used in developing the NACE standard consisted primarily of empirical data gathered from operators examining pipeline field conditions and failures. In contrast, the studies examined by Integrity Corrosion Consulting were mechanistic studies, and their results serve to complement the information operators have gained through field experience. PHMSA's review of the guidelines in this report identified a number of areas not addressed in detail in the NACE standard. Accordingly, PHMSA has included additional factors in § 195.588 that an operator must consider if the operator uses direct assessment to assess SCC.

PHMSA acknowledges that the NACE standard may not address all aspects of SCC management, but PHMSA considers it better to incorporate additional structured guidance that is available now rather than await future standards. There is continual improvement in technology to detect and address various SCC threats. Three different standards organizations are currently working to improve standards on SCC: ASME B31.8, NACE 204 and API 1160. PHMSA participates on these technical committees. As more knowledge is gained on other types of SCC, such as sulfide assisted SCC and when newer standards get published, PHMSA will consider adopting them.

PHMSA is revising § 195.588, which specifies requirements for the use of external corrosion direct assessment on hazardous liquid pipelines, to include reference to NACE SP0204–2008 for the conduct of SCCDA. The rule will not require that SCCDA assessments be conducted, but it will require that the NACE standard be followed if an operator elects to perform such assessments. PHMSA has included additional factors that an operator must consider to address these if the operator uses direct pipeline to assess SCC.

Post-Accident Drug and Alcohol Testing

On electronic reporting of drug and alcohol testing results, PHMSA is requiring operators electronic reporting for anti-drug testing results required in § 199.119 and alcohol testing results required in § 199.229. PHMSA is modifying these regulations to specify that it will provide notice to operators in the PHMSA Portal.[4]

On post-accident drug and alcohol testing, PHMSA is modifying §§ 199.105 and 199.225 by requiring drug testing of employees after an accident and to allow exemption from drug testing only when there is sufficient information that establishes the employee(s) had no role in the accident. Therefore, PHMSA is amending the post-accident drug testing regulation to require documentation of the decision and to keep the documentation for at least three years.

Information Made Available to the Public and Request for Protection of Confidential Commercial Information

On information made available to the public and request for confidential treatment, PHMSA is including the procedure for requesting confidential treatment of confidential commercial information submitted to PHMSA.

In-Service Welding

On in-service welding, PHMSA is revising §§ 192.225, 192.227, 195.214, and 195.222 to add reference to API 1104, Appendix B.

III. Advisory Committees Meeting

On June 2, 2016, the Gas Pipeline Advisory Committee (GPAC)[5] and the Liquid Pipeline Advisory Committee (LPAC)[6] met jointly in Arlington, Virginia. The committees are statutorily mandated advisory committees that advise PHMSA on proposed gas pipeline or hazardous liquid pipeline safety standards and risk management principles. Both committees were established in accordance with the Federal Advisory Committee Act, 5 U.S.C. App., as amended, and 49 U.S.C. 60115. Each committee consists of 15 members, with membership evenly divided among the Federal and state governments, regulated industry, and general public. The committees advise PHMSA on the technical feasibility, reasonableness, practicability, and cost-effectiveness of each proposed pipeline safety standard.

During the meeting, the committees considered the NPRM that was proposed to: Address (1) section 9 of the 2011 Act that would require operators to electronically or telephonically report notice of an accident and incident not later than one hour after the confirmed discovery; (2) address section 13 of the 2011 Act that would allow PHMSA to recover its costs for design review work PHMSA would conduct on behalf of the operators, which would allow PHMSA to use its limited resources in protecting the public safety; (3) expand the existing Operator Qualification (OQ) scope to cover new construction and certain other currently uncovered tasks; (4) provide a renewal procedure for expiring special permits; (5) exclude

[3] *https://primis.phmsa.dot.gov/matrix/PrjHome.rdm?prj=199.*

[4] *https://portal.phmsa.dot.gov/.*

[5] Officially designated as the Technical Pipeline Safety Standards Committee.

[6] Officially designated as the Technical Hazardous Liquid Pipeline Safety Standards Committee.

farm taps from the DIMP requirements and to amend part 192 to add a new section that prescribes inspection activities for pressure regulators and over-pressurization protection equipment on service lines that originate from transmission, gathering, or production pipelines; (6) incorporate by reference into 49 CFR part 195: API STD 1163, ''In-Line Inspection Systems Qualification Standard'' (August 2005); NACE Standard Practice SP0102–2010 ''Inline Inspection of Pipelines'' NACE SP0204–2008 ''Stress Corrosion Cracking Direct Assessment;'' and ANSI/ASNT ILI–PQ–2010, ''In-line Inspection Personnel Qualification and Certification'' (2010); (7) modify §§ 199.105 and 199.225 by requiring drug testing of employees after an accident and allowing exemption from drug testing only when there is sufficient information that establishes the employee(s) had no role in the accident, and requiring documentation of the decision not to perform drug testing and to keep the documentation for at least three years; (8) and include the procedure for requesting confidential treatment of information submitted to PHMSA and PHMSA's decision regarding the request.

After discussion, both Committees separately voted unanimously to recommend PHMSA implement the NPRM with certain changes. Specifically, the Committees recommended as follows:

A. Accident and Incident Notification Reporting

Some of the Gas Pipeline Advisory Committee members were concerned about the accuracy of reporting gas leak within one hour of confirmed discovery of the leak. After discussion the issue, the committee agreed to recommend removing the one-hour amount of product lost reporting requirement from where it was proposed in § 191.5(b)(5) and moving the requirement to § 191.5(c).

Also, both committees discussed the definition for ''confirmed discovery'' and separately recommended revising the definition as follows:

Confirmed Discovery: when it can be reasonably determined, based on information available to the operator at the time, that a reportable event has occurred, even if only based on a preliminary evaluation.

Responses to the Advisory Committees' Recommendations

The committees' recommendation also addresses the public comments and, therefore, PHMSA accepts the recommended changes.

B. Cost Recovery of Design Review

Both committees discussed the proposal and agreed to recommend revising the definition for ''new and novel technologies,'' as follows:

New and novel technologies means any products, designs, materials, testing, construction, inspection, or operational procedures that are not addressed in 49 CFR parts 192, 193, or 195, due to technology or design advances and innovation for new construction. Technologies that are addressed in consensus standards that are incorporated by reference into Parts 192, 193, and 195 are not ''new or novel technologies.''

Responses to the Advisory Committees' Recommendations

The committees' recommendation also addresses the public comments and, therefore, PHMSA accepts the recommended changes.

Also, both committees recommended revising the proposed § 190.405 by removing the phrases ''permitting activities, purchasing, and right of way acquisition.'' This recommendation also addresses the public comments and, therefore, PHMSA accepts the recommended changes.

C. Operator Qualification Requirements

During the meeting, the committees discussed provisions related to the operator qualification requirements proposed in the NPRM. PHMSA is delaying final action on the OQ proposals under subpart N for natural gas pipelines and subpart G for hazardous liquid pipelines until a later date and fully expects to consider all the comments received and the recommendations of the Pipeline Advisory Committees related to those specific issues in a subsequent final rule.

D. Special Permit Renewal

Both committees recommended revising § 190.341(d)(1) by replacing the word ''application'' with the phrase ''application or renewal,'' revising § 190.341(f) to limit aerial photography of pipeline segments where special permits affect public safety such as a class location special permit that allows a less stringent design factor in a populated area and allow operators to submit a summary of inline inspection survey results with permit renewals, and revising § 190.341(e) to clarify that special permit renewals must be submitted 180 days prior to the grant expiration.

Responses to the Advisory Committees' Recommendations

These committees' recommendations also address the public comments and, therefore, PHMSA accepts the recommended changes.

E. Farm Tap

The Gas Pipeline Technical Committee recommended revising § 192.740 to make the following changes: In (a) change ''originates from'' to ''directly connected to,'' and in (b) to add the phrase ''(except rupture discs) after the phrase ''relief device.''

Also, the Committee recommended revising § 192.1003(b) to make the following change: Replace the phrase ''. . . a service line that originates directly from a transmission'' with ''. . . an individual service line directly connected to a transmission.''

Responses to the Advisory Committee's Recommendations

The committee's recommendations also address the public comments and, therefore, PHMSA accepts the recommended changes.

F. Pipeline Assessment Tools

The Liquid Pipeline Advisory Committee recommended adopting the section as published in the NPRM except with the latest API STD 1163, ''In-Line Inspection Systems Qualification Standard'' (April 2013) version.

Also, a member of the advisory committee asked whether an operator has the option to run the right tools in assessing for in-line inspection and stress corrosion cracking direct assessment.

Responses to the Advisory Committee's Recommendations

The committee's recommendations also address the public comments and, therefore, PHMSA accepts the recommended changes.

With regard to the comment on right tool selection, the very reason PHMSA is incorporating these consensus industry standards into the Federal pipeline safety regulations is to guide operators to use the right tools. Operators can select the right pipeline assessment tools from the incorporated industry standards. However, if operators decide to choose assessment tools that are not incorporated by reference, the operators must justify, with data, why the selected assessment tools are better suited for their pipelines than the incorporated industry standards. In selecting assessment tools, operators should analyze the goal and objectives of the inspection and match relevant facts known about the pipeline and expected anomalies with the capabilities and performance of an assessment tool. The selected

assessment tool should have accuracy and detection capabilities, detection sensitivity, and classification capability. In addition, the sizing accuracy should be sufficient enough to enable prioritization, the location accuracy should enable locating anomalies, and the requirements for defect assessment must be adequate for the expected defect assessment algorithm.

G. On Post-Accident Drug and Alcohol Testing

Both committees recommended removing existing language at the end of § 199.105(b)(1) that states ''. . .or because of the time between that performance and the accident, it is not likely that a drug test would reveal whether the performance was affected by drug use.''

In addition, some advisory committee members requested for compliance period to address union agreement for the drug testing reporting.

Responses to the Advisory Committee's Recommendations

The committees' recommendations address the public comments. PHMSA accepts the recommended deletion for § 199.105(b). PHMSA is not requiring new recordkeeping in this rule. The only requirement is to keep records of decisions not to administer post-accident employee drug tests for at least 3 years.

H. Information Made Available to the Public and Request for Confidential Treatment

Both committees recommended to make editorial changes, including the title of the section, to reflect the agency's goal in providing a procedure for confidential commercial information submitted to PHMSA.

Responses to the Advisory Committees' Recommendations

The committees' recommendations also address the public comments and, therefore, PHMSA accepts the recommended changes.

IV. Summary and Response to Comments

PHMSA received 35 comments on the proposed rule from the National Transportation Safety Board, Pipeline Safety Trust, pipeline trade associations, the Distribution Contractors Association, the ASME B31Q Qualification of Pipeline Personnel Technical Committee, the American Medical Review Officers and the Pipeline Testing Consortium, pipeline operators, pipeline safety consultants, and citizens.

General Comments

Most of the pipeline operators' comments were in support of and similar to their trade associations; therefore, pipeline operators' comments similar to their associations are not summarized again in the specific comments. However, comments that were not addressed by the trade associations are summarized.

A. Accident and Incident Notification

1. PHMSA's Proposal

PHMSA proposed to amend the Federal pipeline safety regulations to require operators to provide telephonic or electronic notification of an accident or incident at the earliest practicable moment, including the amount of product loss, following confirmed discovery. PHMSA proposed to define ''confirmed discovery'' as: *Confirmed discovery* means there is sufficient information to determine that a reportable event may have occurred even if an evaluation has not been completed.

2. Summary of Public Comment

Definitions (§§ 191.3 and 195.2)

PHMSA received comments from trade organizations, safety groups, government entities, and others stating the proposed definition for ''confirmed discovery'' is confusing because it suggests that the operator has sufficient ''confirmed'' information that an event has occurred but also contains the phrase ''may have occurred.'' They believe ''sufficient confirmed information'' is an indication that a reportable or actual event has occurred, and the confirmed information should provide enough evidence of that event. Therefore, they urged PHMSA to revise the definition to remove ''may have'' and read ''. . . a reportable event has occurred.''

Paiute Pipeline Company and Southwest Gas Corporation proposed adding a new term ''provisional discovery'' to mean that the operator has ''sufficient information to determine that an incident has likely occurred even if an evaluation has not been completed.'' They stated that this proposed change would address confusion with the proposed.

The American Medical Review Officers and the Pipeline Testing Consortium commented that the definition for confirmed discovery is an incident/accident notification rather than a confirmation, since it is based only on ''sufficient information to determine that a reportable event may have occurred.'' They recommend that this term be replaced with ''accident notification,'' and later allowing the operator to ''confirm the notification,'' rather than ''confirm the confirmed discovery.'' They also note that the terms incident, accident, and reportable event are used throughout the proposed changes, and they recommended using the single term ''accident'' in all of PHMSA's rules. The GPAC and the LPAC both recommended that PHMSA revise the definition of confirmed discovery as ''Confirmed Discovery: When it can be reasonably determined, based on information available to the operator at the time, that a reportable event has occurred, even if only based on a preliminary evaluation.''

Immediate Notice of Certain Incidents/Accidents (§§ 191.5 and 195.52)

The NTSB and the Pipeline Safety Trust disagree with the proposed requirement to file a second NRC report within 48 hours to confirm initial incident or accident information, irrespective of whether there are changes to that information. They stated that allowing operators 48 hours to file a follow-up report with more accurate information encourages operators to provide incomplete information initially and, instead, rely on the 48-hour second notification requirement to report more accurate incident data. They were concerned that this would delay receipt of information by the NTSB or other responding agencies that is needed to decide whether to mobilize a response.

In addition, the NTSB suggested that the second notification requirement would be significantly improved if PHMSA established a follow-up reporting requirement that would be triggered only ''when the pipeline operator has confirmed that previously reported information has significantly changed,'' and that PHMSA should include guidance on what constitutes a ''significant change,'' emphasizing the number of injuries and fatalities, evacuation zone changes, release amount, environmental impact, and infrastructure and equipment damage. They also suggested PHMSA should establish a cutoff time starting with the time of the first notification, since the benefit of extending the reporting period beyond a 12-hour timeframe is negligible for NRC notifications and changes in response to decisions by notified organizations.

The American Public Gas Association (APGA), the American Gas Association (AGA), and some pipeline operators commented operators cannot provide meaningful estimates of gas loss within one hour and recommended that the estimates should be included in the proposed 48-hour update to the one-

hour notification. In addition, the AGA commented that the product loss requirement should be quantified at a loss of three million cubic feet or more. The Interstate Natural Gas Association of America (INGAA) and some pipeline operators suggested modifying the proposed language to include the ''initial estimate of amount of product loss, to the extent practicable.'' In addition, INGAA commented that PHMSA should not make the 48 hours reporting change effective until the NRC has the means to accept supplemental reports, that PHMSA should modify the definition of a ''reportable incident'' to only include significant events that include a sudden loss of pressure resulting in a large amount of gas released or a potential fatality or injury necessitating an in-patient hospitalization and only apply the one-hour timing to these significant events, and that PHMSA should extend the permissible timing for events requiring operators to report only on account of property damage estimates and minor leaks.

The American Petroleum Institute and the Association of Oil Pipe Lines (API–AOPL) and some operators commented that for the 48-hour notification, PHMSA should clarify that an operator may revise the initial estimate made to the NRC to reflect a zero sum regarding the amount of product released and the number of fatalities and/or injuries in connection with an incident in the event that a notification is made in error.

API–AOPL and some pipeline operators commented that calculating whether an incident is below the $50,000 threshold will be difficult within the one-hour time limit and that the cost threshold for notification should be eliminated. Magellan Midstream Partners commented that the $50,000 threshold should be removed, or as a reporting criterion it should be increased to $250,000 and a threshold volume of 100 barrels of released product. In addition, Magellan commented that PHMSA should consider expanding the reporting criteria to include the evacuation of residential or commercial properties and the closure of a transportation corridor such as a ship channel, railroad, state or federal highway, or city and county roads. If a threshold is retained at $50,000, Magellan recommended it should apply only to the cost of third party property damage, and not the expenses and cost of repairs to operator property.

Energy Transfer Partners suggested that the title for §§ 191.5 and 195.52 be retitled using a more accurate descriptive word such as ''prompt'' or ''timely'' in place of ''immediate.''

The GPAC proposed that PHMSA move the provision proposed in § 191.5(b)(5) addressing the amount of product lost to paragraph § 191.5(c).

3. PHMSA Response

With regards to the definitions, including the Advisory Committees' recommended definitions, the term ''confirmed discovery'' is in the 2011 Act and cannot be replaced by alternative terms. In addition, the terms ''incident'' and ''accident'' are in the 2011 Act, and replacing ''incident'' by ''accident'' throughout the Federal pipeline safety regulations would be out of the scope of this rulemaking action.

PHMSA proposed ''may have occurred'' in the definition of ''confirmed discovery'' to abide by the Congressional mandate requiring operators to alert the NRC to accidents and incidents despite not having a complete assessment. The purpose of the notification is to alert local, state, and federal agencies with notification at the earliest practicable moment so that emergency personnel or investigators can be dispatched quickly to mitigate the consequences of such an event. Without this requirement, each operator may have a different methodology in its procedures when responding to an accident or incident that could potentially take hours or days before an operator has completed its evaluation and determined that an accident or incident had in fact occurred. If an operator were allowed to wait for a definitive confirmation, based upon the procedures it has in place to identify and report accidents and incidents, even if the operator has sufficient evidence through its employees or the public, the intent of the Congressional mandate would be defeated. To address the public comments and the Advisory Committees recommendations, PHMSA has revised the definition of ''confirmed discovery.''

With regard to the immediate and secondary notifications, section 9(b)(3) of the 2011 Act directs PHMSA to require owners and operators of pipelines to revise their initial telephonic or electronic notice to the Secretary and the NRC with an estimate of the amount of the product released, an estimate of the number of fatalities and injuries, if any, and any other information determined appropriate by the Secretary within 48 hours of the accident or incident, to the extent practicable. Therefore, PHMSA proposed these requirements based on the 2011 Act.

With regard to operators updating their reporting to the NRC, PHMSA has no authority to require the NRC to update operators' initial reports without generating a new report. Section 9(c) of the 2011 Act directs the NRC to update the initial report without generating a new report. PHMSA contacted the NRC to find out how the mandate could be met, and the NRC informed PHMSA that it would require a substantial amount of funding for the Center to have this capability; however, the 2011 Act does not allocate funding for this mandate.

With regard to changing the reporting thresholds for both gas and hazardous liquid pipelines, the NPRM did not address them and they are out of scope of this rulemaking action.

B. Cost Recovery for Design Reviews

1. PHMSA's Proposal

PHMSA proposed to amend the Federal pipeline safety regulations to prescribe a fee structure and assessment methodology for recovering costs associated with design reviews of new gas and hazardous liquid pipelines with design and construction costs totaling at least $2,500,000,000 or that contain new and novel technologies.

2. Summary of Public Comment

On Proposed Definition of ''New and Novel Technologies'' (§ 190.3)

Many industry groups including API–AOPL commented that definition of ''new and novel'' is overly broad and a narrower definition should be provided in the final rule. The AGA and some pipeline operators commented that they are concerned that an operator would undergo an extensive documentation and submittal process and enter into a Master Agreement for cost recovery regardless of the scope and size of impact of the new or novel technology, and recommended specifying that the new and novel technology would be defined as requiring a special permit per 49 U.S.C. 60118(c).

INGAA and some pipeline operators also commented that the definition of ''new or novel technologies or design'' exceeds the intent of Congress' authorization because Congress only intended to authorize cost recovery for facility design reviews only and did not intend to authorize cost recovery for any potential review or inspection, including events occurring after design and construction are complete, such as the development of operational procedures or routine enforcement audits. These commenters note that conducting pipeline inspections or reviewing operational procedures

should not be included in the cost recovery methodology.

Both Advisory Committees recommended revising the definition of new and novel technologies to mean ''any products, designs, materials, testing, construction, inspection, or operational procedures that are not addressed in 49 CFR parts 192, 193, or 195, due to technology or design advances and innovation for new construction. Technologies that are addressed in consensus standards that are incorporated by reference into parts 192, 193, and 195 are not 'new or novel technologies.'''

On Applicability (§ 190.403)

API–AOPL and Kinder Morgan requested clarification from PHMSA whether the $2,500,000,000 threshold only applies to regulated assets in a master project that contains both assets regulated by the Department of Transportation and non-Department of Transportation regulated assets within the total investment. In addition, they stated that the proposed monetary threshold should only include design, material, and construction costs, and that operator overhead costs (*e.g.,* engineering, legal, right-of-way acquisition work) should be excluded from calculating the proposed threshold. Also, they requested that PHMSA modify the language proposed in § 190.403(c) to reference the appropriate section of the pipeline safety regulations for each review or inspection activity PHMSA performs as part of any safety design review.

Energy Transfer Partners asked if PHMSA intends for operators to make notification of all projects meeting the requirements, and commented that PHMSA should develop a process outside of a rulemaking whereby new and novel technologies can be expeditiously evaluated and broadly approved for use. Energy Transfer Partners also commented that it is not clear whether a single notification or multiple notifications are required. In addition, Energy Transfer Partners asked what PHMSA means by ''To the maximum extent practicable.''

The Gas Processors Association (GPA) and FlexSteel commented that the proposed rule does not clarify whether identical new technology is reviewed once or multiple times, even if different operators would be able to use the technology at different times. They asked when technology and/or design are no longer considered ''new and novel.'' The GPA and FlexSteel requested that the provisions for ''new and novel technology or design,'' including the definition and applicable cost recovery sections, be deleted from the final rulemaking.

Spectra Energy Partners commented that PHMSA should include additional language that would make it clear that technologies that are addressed in consensus standards and incorporated by reference are not ''new or novel technologies.'' They also stated that the inclusion of ''operational procedures'' in the definition goes beyond the authority granted PHMSA in the Act, and requested it be removed and provided revision to the proposed language.

On Notifications (§ 190.405)

INGAA and Kinder Morgan commented that PHMSA should revise its proposal to commence design review when the operator submits notice of its proposal because many of the proposed trigger events occur too early in the construction process for a company to commit firmly to a project. Commenters stated that many of the documents PHMSA is asking an operator to submit for a design review are not actually available 120 days prior to the proposed event, and that some of the listed documents predate receipt of a Federal Energy Regulatory Commission or other authorizing certificate. Commenters suggested that a notification date following a more certain trigger, such as the date that a Federal Energy Regulatory Commission certificate is received, would allow for timely review while ensuring that the document repository is adequately populated.

Alyeska asked PHMSA to add language that provides an alternative to the 120-day period for unique situations and circumstances.

TransCanada commented that the proposed requirements are inconsistent with the current, more general requirement (§§ 191.22(c)(1)(i) and 195.64(c)(1)(i)) to notify PHMSA at least 60 days ''before the event occurs'' including construction, and that PHMSA should compare the proposed notification requirements to the current requirements as well as revisit or rescind the September 12, 2014, Advisory Bulletin concerning construction notifications to ensure consistency and clarity regarding both the triggering event for notification and the notification period.

Spectra Energy and Texas Pipeline Association Partners commented that PHMSA's proposed definition of ''commencement of construction'' is overly broad, creating conflicts and making compliance impracticable.

Both Advisory Committees recommended deleting the phrase ''permitting activities, purchasing, and right of way acquisition'' from this section.

On Master Agreement (§ 190.407)

Energy Transfer Partners commented that there seems to be a presupposition that PHMSA will review the project, and that PHMSA and the applicant will enter into a master agreement. This section should be conditional and only require such an agreement in cases where PHMSA decides to conduct a review and the project meets a criterion for cost recovery under § 190.403. This section should also provide for the operator to have audit rights covering invoices and supporting documentation.

On the Sample Master Cost Recovery Agreement

The AGA and some pipeline operators commented that the Master Agreement process should be reciprocal in nature, and PHMSA should be required to provide timely feedback and responses through contractual deadlines applicable to the agency with clearly defined expectations for both participants in the agreement. API–AOPL commented that alternatives should be available to an operator that objects to the timeframe proposed by PHMSA to complete the safety design review; and whether the sample master agreement is meant to be authoritative or is open to comment and suggested revisions from the industry.

INGAA commented that PHMSA needs to revise its proposed cost recovery methodology by setting up a set fee schedule to put all regulated parties on notice of the projected costs and time involved in the review to help inform an operator's decision to use new technology and, therefore, seek agency design review and approval.

INGAA commented that PHMSA should consider a firm end point for design cost reimbursement when the pipeline is in-service. INGAA went on to say that PHMSA should revise its Master Cost Recovery Agreement in paragraph A(1) by stating that the review period commences when the operator submits notice of its proposal and that the agency should include examples of the type of other costs included under this section. INGAA also states that PHMSA should revise the termination date referenced in paragraph E(10) of the sample Master Cost Recovery Agreement to state ''the earlier of the termination of the review or the date the project is in-service.'' INGAA commented that the regulated community must be able to determine the range of costs and time involved prior to committing to a project. INGAA went on to say, at a minimum, operators

must be aware of the maximum potential costs charged for a design review. Without this critical information, the operator cannot determine whether the costs and time for review make it feasible to continue with the project. If PHMSA moves forward with this proposal without modification, it would dissuade operators from using advances in design and technology.

The GPA commented that the terms and conditions of the proposed Master Cost Recovery Agreement do not relate to activities related to the reach and validation of new or novel technology or design. The GPA commented that it does not believe it was PHMSA's intent, but requests that the language for the Master Cost Recovery Agreement be amended to clarify that any cost recovery will be limited to the actual cost of the project review, including only the personnel directly involved in the review. The GPA commented that the Agreement also lacks any deadlines or obligations for PHMSA to meet and therefore, any agreement that requires a payment to be made for services should include parameters to ensure the review is timely. The GPA states that this will ensure the proposal moves through the process in a prescribed time period as long as the operator delivers the materials and responses necessary for PHMSA to move forward.

TransCanada commented that the Master Agreement does not state under what circumstances the agreement would end; the list of required provisions is a ''minimum'' list, and PHMSA should clarify what other provisions would be included in the future for specific projects and whether operators would be able to negotiate the inclusion or exclusion of any provisions, and asked how a Master Agreement would be implemented for projects with long development cycles.

On Fee Structure (§ 190.409)

The AGA and some pipeline operators commented that in order for operators to properly plan and budget for the design review, there should be a defined maximum for cost recovery of each design review that is subject to modification by mutual agreement.

Energy Transfer Partners commented that the described fee structure needs to be clear, complete and agreed upon between PHMSA and the operator from the outset. As written, it is not clear that the fee structure cannot be unilaterally modified during the period of the review.

On Billing and Payment (§ 190.411)

Energy Transfer Partners commented that the operator must have the right to not only verify the calculations, but also audit the bases for the calculations—time and activity reports, expense receipts, et cetera—in much the same way the operator monitors and approves time, material and expense reimbursements to its own employees and contractors.

3. PHMSA Response

With regard to comments on definition of ''new and novel'' being overly broad, PHMSA has revised the definition by adding ''for new construction.'' The revised definition reads as: ''*New and novel technologies* means any products, designs, materials, testing, construction, inspection, or operational procedures that are not addressed in 49 CFR parts 192, 193, or 195, due to technology or design advances and innovation for new construction. Technologies that are addressed in consensus standards that are incorporated by reference into parts 192, 193, and 195 are not 'new or novel technologies.' '' This new definition also ensures that technologies are not reviewed multiple times.

Procedure reviews of the design, materials used, testing, inspections of materials and construction, and start-up operational procedures are all a part of PHMSA's Code inspections for new construction. PHMSA believes that the new definition addresses the comments received. With regard to comments on whether the Master Cost Recovery Agreement process is reciprocal, PHMSA has included facility costs that are part of the normal tariff rate recovery process.

Regarding comments that conducting pipeline inspections or reviewing operational procedures should not be included in the cost recovery methodology, PHMSA agrees for existing pipelines. However, conducting pipeline inspections or reviewing operational procedures are a main function of PHMSA inspections for new pipeline facilities. In most cases, pipelines of this cost magnitude ($2.5 billion) are in new geographical areas with new operational personnel. The time needed to conduct these inspections normally takes much more time and dedication of PHMSA inspection staff and, therefore, need to be included in the cost recovery methodology.

With regard to comments from the Advisory Committees and other stakeholders regarding trigger events occurring too early in the construction process for a company to commit firmly to a project, PHMSA agrees that some of the proposed requirements need not be included and has modified § 190.405 to exclude permitting activities, material purchasing, and the right of way acquisition from the notification requirement.

With regard to the Master Cost Recovery Agreement not relating to activities related to the reach and validation of new or novel technology or design, the Master Cost Recovery Agreement detailed in § 190.407 was provided as a sample and would be tailored to specific requests to recover PHMSA costs of personnel involved in the review of the new or novel technology.

Also, the Advisory Committees recommendations agree with PHMSA's responses to the public comments.

C. Operator Qualification Requirements and NTSB Recommendations Related to Control Room Staff Training

1. PHMSA's Proposal

PHMSA proposed to amend the Federal pipeline safety regulations in 49 CFR parts 192 and 195 relative to operator qualification requirements, to cover new construction, add clarification for covered tasks, clarify training and documentation requirements, and add program effectiveness requirements for operators to gauge the effectiveness of the OQ programs. The amendments to the OQ regulation also extend OQ requirements to operators of Type A gathering lines in Class 2 locations and Type B onshore gas gathering lines.

The amendments also address the NTSB recommendations to extend operator qualification requirements to control center staff involved in pipeline operational decisions (P–12–8) and requirements for team training of control center staff involved in pipeline operations similar to those used in other transportation modes (P–12–7).

2. Public Comments and PHMSA's Response on Scope and Definitions (§§ 192.801 and 195.501, and §§ 192.803 and 195.503), Qualification Program (§§ 192.805 and 195.505), Program Effectiveness (§§ 192.807 and 195.507), and Recordkeeping (§§ 192.809 and 195.509)

PHMSA received several comments on the new scope of operator qualifications (OQ), its definitions, operator qualification programs, program effectiveness, and OQ recordkeeping. However, during the rulemaking process, a decision was reached to not move forward with

revised OQ requirements in order to further evaluate the costs and benefits of this issue. This decision had no bearing on the proposed regulations regarding control room team training requirements; the comments received on that issue, as well as PHMSA's response, are discussed below.

Therefore, PHMSA is delaying final action on the provisions regarding (1) OQ scope and definitions as they were proposed at §§ 192.801 and 192.803 under subpart N for the natural gas pipeline regulations and at §§ 195.501 and 195.503 for subpart G for the hazardous liquid pipeline regulations, respectively; (2) qualification programs as they were proposed at §§ 192.805 and 195.505 for the natural gas pipeline regulations and the hazardous liquid pipeline regulations, respectively; (3) OQ program effectiveness as they were proposed at §§ 192.807 and 195.507 for the natural gas pipeline regulations and the hazardous liquid pipeline regulations, respectively; and (4) OQ recordkeeping as they were proposed at §§ 192.809 and 195.509 for the natural gas pipeline regulations and the hazardous liquid pipeline regulations, respectively.

PHMSA notes that revised OQ requirements will be published in a subsequent final rule in the near future, and it will consider and discuss, at length, all of the comments received for each of the topic areas listed above along with the recommendations of the Pipeline Advisory Committees, in that final rulemaking.

3. Summary of Public Comment on Control Room Management (§§ 192.631 and 195.446)

The NTSB commented that it accepts PHMSA's plan to codify the training guidance previously issued as an advisory bulletin and, therefore, agrees with the proposed changes related to operator qualifications.

The AGA requested that PHMSA allow 12 months before the final rule becoming effective, and that in § 192.631(h)(6) the operator should be allowed to determine who should be involved in the team training exercises and suggested edits to the proposed regulatory language accordingly. With regards to the proposed roles and responsibilities in § 192.631(b)(5), it requested PHMSA clearly define what is meant by 'direct' and 'supersede' in context of interacting with a controller and provided suggested edits to the proposed language.

API–AOPL requested that currently qualified workers should not be affected by this rule and, therefore, the workers should be re-qualified at the next, regular requalification scheduled interval.

Enterprise suggested that the proposed rule be modified to read as, ''the roles and responsibilities of others that could provide operational direction or guidance when a controller is performing a specific action that falls under an operator's OQ program.'' In addition, Enterprise suggested a new subparagraph (h)(7) be included in §§ 192.631 and 195.446 to include an approval process to address when a controller's decision is to be superseded.

The GPA commented that there is disconnect between the stated intent in the preamble and the actual language of the proposed rule and that the language used to describe the intent and purpose of the change differs in a meaningful way. The GPA commented that the ''roles and responsibilities'' are already defined by the current provision of subpart (b) of the respective Code; therefore, establishing a strict list of those who can override a controller could potentially paralyze a controller in an abnormal, or emergency, situation, which no operator or agency wants. The proposed new training requirement for those potentially interacting with controllers is overly broad, which potentially results in extensive unintended consequences. In addition, a bullet states PHMSA is proposing to ''modify operator qualification requirements including addressing a NTSB recommendation to clarify OQ requirements for control rooms . . .'' However, there is no reference found in the OQ section of the proposed rules; therefore, PHMSA should issue a statement in the final rule that the changes made to control room management will not have an impact on an operator's future OQ program.

Magellan commented that OQ requirements should focus on those that directly perform the duties of the control room operator because there is no discernible benefit or advantage of expanding OQ requirements to include others who do not directly perform the duties of the Control Room Operator. Also, the roles and responsible of others who have the authority to direct or supersede specific technical actions needs to be limited to direct line supervisor and management personnel—as proposed in § 195.446(b)(5), the roles, responsibilities, and qualifications of ''others'' is overly broad.

Midwest Energy Association commented that it supports the use of team training for control room training but the requirement should not be placed in the OQ section and should instead be located in the control room management § 192.631.

Northeast Gas Association commented that it does not agree with the scope for team training for control room emergency situations, and recommends that the operator should have the authority to determine which personnel types should be involved during team training. Also, PHMSA should confirm that team training is only required for personnel who interact with control center staff on an operational basis as opposed to personnel who interact with controllers on non-operational matters.

Paiute Pipeline Company and Southwest Gas Corporation commented that the proposed rulemaking under § 192.631(h)(6) is inconsistent with the NTSB safety recommendation P–12–7—the recommendation is specific and limited to control center staff during emergency conditions. Therefore, PHMSA should provide justification substantiating the need for the proposed changes in § 192.631(b)(5). Paiute Pipeline Company also asked PHMSA to clarify as to the meaning of ''specific technical actions of controllers.''

Thomas Lael Services supports the changes and commented that at the end of §§ 192.631(h)(6) and 195.446(h)(6), it would be more clear if PHMSA inserts a clarification sentence. It recommends the following, ''This training shall be included in the scope required by Subpart N in of this part'' for § 192.631(h)(6), with a corresponding change to § 195.446(h)(6) that references subpart G rather than subpart N.

TransCanada commented that for operators to conduct control room team training and exercises to include controllers ''and other individuals who would reasonably be expected to interact with controllers'' goes beyond the NTSB's July 25, 2012, recommendation to PHMSA; the phrase ''reasonably be expected to interact with controllers'' is vague and ambiguous and, therefore, that training should be limited to ''control center personnel,'' including those with the authority to direct or supersede the specific technical actions of a controller.

Vectren Energy Delivery of Indiana and Ohio commented that additional clarification is necessary for control room team training because it may involve numerous ''soft skills.''

Mr. Warren Miller commented that training as related to covered tasks should be required for initial evaluation/qualification, when a covered task has changed substantially, when someone has contributed to an accident, or no longer qualifies due to operator qualification issues. PHMSA

should clarify the required training for contractor individuals performing covered tasks on an operator's pipeline facilities. In addition, training should be required for all evaluators to ensure that evaluations are performed on each individual measures (the required KSAs) for each covered task consistently. The training and criteria for evaluators should include tracking and measuring an evaluator's performance to ensure criteria and established training is effective. In addition, specific language should be added to ensure that an evaluator will only evaluate a single individual. Criteria should be added to establish guidelines on what past experience and training each evaluator has on the specific task or field to indicate the evaluator can evaluate an individual. In addition, PHMSA should require an audit program to ensure evaluators for both operator and contract personnel are performing the evaluations as required.

4. PHMSA Response on Control Room Management (§§ 192.631 and 195.446)

As to whether the operator should be allowed to determine who should be involved in the team training exercises and suggested edits to the proposed regulatory language accordingly, it remains the responsibility of the operator to define the training and qualification requirements for personnel performing covered tasks on their pipeline facility. This includes the requirement for operators to define personnel involved in team training exercises.

As to the comment that currently qualified workers should not be required to requalify solely as a result of promulgation of the proposed rule, the control room management establishes the need for certain procedures and operating practices that would need to be incorporated into an operator's qualification program. If the prior qualification includes and meets all applicable requirements of the control room management plan and associated activities, the individual in question does not need to requalify. The rule does not specify that individuals performing covered tasks would need to be requalified solely as a result of this rulemaking action.

As to the suggestion that the terms ''direct'' and ''supersede'' in §§ 192.631(b)(5) and 192.446(b)(5) of the proposed rule be clearly defined, and to comments that these sections be ''modified,'' if field operations employee and supporting engineers who provide information or general advice to a controller are considered ''directing'' a controller on a specific action as suggested by the commenters, then these individuals are directing and superseding the controller's authority. In addition, while the control room management regulations call out certain specific individuals such as controllers, supervisors, and field personnel, understanding of the requirements of control room management and appropriate training is essential for other individuals that interact with controllers, particularly those that may affect the ability of a controller to safely monitor and control the pipeline during normal, abnormal, and emergency situations. Other individuals to which team training might pertain likely vary by operator and control room depending on specific procedures and roles in the control room, but they could include individuals such as technical advisors, engineers, leak detection analysts, and on-call support. These individuals are typically already trained in their specific job function and have some awareness of the roles and responsibilities of controllers. In many cases, they are also included in discussions or meetings that involve control room personnel. However, these individuals may not always get together to be trained on how to work together as a team. Therefore, to provide for a controller's prompt and appropriate response to operating conditions, an operator must define the roles, responsibilities and qualifications of others with the authority to direct or supersede the specific technical actions of a controller.

As to the suggestion that a new subparagraph (h)(7) be included in §§ 192.631 and 195.446 to include an approval process to address when a Controller's decision is to be superseded, because this was not proposed, it is out of the scope of the final rule.

As to the comment that PHMSA should issue a statement in the final rule that the changes made to control room management will not have an impact on an operator's future OQ program, additional requirements have been added to the control room management regulation to address the NTSB recommendation, including training. The OQ requirements prescribe the minimum requirements for operator qualification of individuals performing covered tasks on a pipeline facility, and include training.

As to the comment that OQ requirements should focus on those that directly perform the duties of the control room operator because there is no discernible benefit or advantage of expanding OQ requirements to include others who do not directly perform the duties of the control room operator, issues identified from Marshall (for hazardous liquid) and to an extent San Bruno (for gas) in the NTSB report seem to disagree. Also, the OQ requirements prescribe the minimum requirements for operator qualification of individuals performing covered tasks on a pipeline facility. It remains the responsibility of the operator to identify covered tasks.

As to the comment that the requirement should not be placed in the OQ section and should instead be located in the control room management § 192.631, team training is under § 192.631. It remains the responsibility of the operator to define the training and qualification requirements for personnel performing covered tasks on its pipeline facility. It is up to the operator as to how it documents the processes/procedures and records associated with this requirement.

As to the comment that the operator should have the authority to determine which personnel types should be involved during team training, it remains the responsibility of the operator to define the training and qualification requirements for personnel performing covered tasks on their pipeline facility. Team training might vary by operator and control room depending on specific procedures and roles in the control room.

As to the comment that team training is only required for personnel who interact with control center staff on an operational basis as opposed to personnel who interact with controllers on non-operational matters, while this may be true for some situations, some scenarios where non-operational type personnel/matters may need to be included. However, it is up to the operator to define who exactly is included and with ultimate determination of adequacy up to the inspector.

As to the comment that the proposed rulemaking under § 192.631(h)(6) is inconsistent with the NTSB safety recommendation P–12–7 because the recommendation is specific and limited to control center staff during emergency conditions and, therefore, PHMSA should provide justification substantiating the need for the proposed changes in § 192.631(b)(5) and clarify as to the meaning of ''specific technical actions of controllers,'' the NTSB recommendation is not specific to emergency conditions only. The recommendation as written is more generic to pipeline operations in general.

As to the comment that at the end of §§ 192.631(h)(6) and 195.446(h)(6) PHMSA should insert a clarification

sentence referencing Subpart N in part 192 and Subpart G in part 195, it remains the responsibility of the operator to define the training and qualification requirements for personnel performing covered tasks on their pipeline facility, to include those performing control rooms related covered tasks. All operators are required to implement the OQ regulations per subpart N in part 192 and subpart G in part 195.

Regarding comments on control room team training and exercises to include controllers, PHMSA disagrees that this section is ambiguous and goes beyond the NTSB recommendation. For example, leak detection analysts that were raised as an issue in the NTSB report on Marshall might not be considered control center personnel by a number of operators.

As to the comment that additional clarification is necessary for control room team training because it may involve numerous ''soft skills,'' PHMSA will provide guidance in a separate document.

As to the comment that training as related to covered tasks should be required for initial evaluation/qualification, when a covered task has changed substantially, when someone has contributed to an accident, or no longer qualified due to operator qualification issues, it remains the responsibility of the operator to define the training and qualification requirements for personnel performing covered tasks on their pipeline facility.

As to the comment that PHMSA should clarify the required training for contractor individuals performing covered tasks on an operator's pipeline facilities, contractors face different OQ requirements. It is correct to say that contractors working for multiple pipeline operators may face multiple, and sometimes conflicting, requirements. This is why it is essential for each pipeline operator to have and effectively implement his/her own unique OQ program. Operator qualification programs must be specific to a pipeline operator and the covered tasks performed on the operator's facilities, taking into consideration the operator's methods of construction, operation, maintenance, and emergency response along with its unique tasks, equipment, and technologies utilized.

In addition, the Advisory Committees recommended editorial changes to §§ 192.631(h)(6) and 195.446(h)(6). PHMSA accepts the editorial changes and made the recommended changes accordingly.

D. Special Permit Renewal

1. PHMSA's Proposal

PHMSA proposed to amend § 190.341 of the Federal pipeline safety regulations to add procedures for renewing a special permit.

2. Summary of Public Comment

The Pipeline Safety Trust clarified that any renewal applications will be treated the same as current initial applications in that they will be public, published on the PHMSA Web site, and subject to NEPA, and therefore suggested revising § 190.341(d)(1) by replacing the word ''application'' with ''application or renewal.''

The AGA commented that the proposed language in § 190.341(e) is ambiguous and unclear as to its purpose and asked PHMSA to revise it.

INGAA and Spectra Energy Partners commented that PHMSA should reexamine the extent of the documentation it requires as part of the renewal process and should collect summaries of reports and high-level maps rather than more extensive records.

Energy Transfer Partners objected to the addition of the phrase ''for a period of time from the date granted'' in § 190.341(d)(2). They also objected to the proposed renewal process itself, described in § 190.341(f), as overly burdensome, duplicative and unnecessarily repetitive in the amount and nature of the material required, and noted that requiring additional aerial photography rather than depicting the requested boundaries and features on the operator's GIS background is not necessary.

FlexSteel commented that to be subject to the expiration or revocation without unjust reasons or adding additional stipulations after a special permit is approved jeopardizes the feasibility of the situation, or solution being sought by the operator. They requested that PHMSA should only review the special permit to confirm satisfactory performance by permitting continued pipeline operation and questioned why the request for renewal should be incumbent on the operator and require resubmittal of the information from the original request.

The requested information should be limited to class location and high consequence area information in tabular format; the ILI requirement should be changed to the most recent information; data integration drawings should not be required as part of the special permit renewal request; and aerial photography data would not provide any meaningful information and be deleted from the requirement.

Both Advisory Committees recommended PHMSA clarify that special permit renewals must be submitted 180 days prior to the grant expiration, limit aerial photography of pipeline segments where special permits affect public safety such as a class location special permit that allows a less stringent design factor in a populated area and allow operators to submit a summary of inline inspection survey results with permit renewals, and amend the language in in § 190.341(d)(1) by replacing the word ''application'' with the phrase ''application or renewal.''

3. PHMSA Response

PHMSA agrees that renewal applications should be treated the same as current initial applications in that they will be public, published on the PHMSA Web site, subject to NEPA, and published for comments on the **Federal Register**. Therefore, PHMSA revised the amendatory language in § 190.341(d)(1) by replacing the word ''application'' with ''application or renewal.''

With regard to PHMSA reexamining the extent of the documentation it requires as part of the renewal process, § 190.341(c) already has documentation requirements for special permit requests. PHMSA is requiring identical documentation for special permit renewal requests, too. PHMSA performs extensive technical analysis on special permit applications and typically conditions a grant of a special permit on the performance of alternative measures that would provide an equal or greater level of safety. PHMSA asks for summary information for operational, maintenance, and integrity conditions in the special permit.

With regard to aerial photography data requirement, PHMSA agrees with commenters and will require aerial photography of pipeline segments where special permits affect public safety, such as a class location special permit that allows a less stringent design factor in a populated area.

With regard to the comment that PHMSA should only review the special permit to confirm satisfactory performance by permitting continued pipeline operation, PHMSA's special permit renewals are a process to ensure the special permit conditions are being implemented and that the conditions continue to be suitable for pipeline safety, environmental protection, and in the public safety interest. Therefore, a requirement for renewal of special permits is necessary.

PHMSA made the following changes to the proposed amendatory language in response to the comments: In § 190.341(e)(1) no submittal date was provided. Therefore, the section is revised to make it clear that a special permit renewal must be submitted 180 days prior to the grant expiration. Also, in § 190.341(f)(1)(v)(F), the proposed language required ILI survey results. That language is revised to allow only a summary of the most recent ILI survey results to be submitted with the permit renewal.

Regarding the expiration requirement, the renewal process in § 190.341(f)(2) allows PHMSA to request additional operational, integrity or environmental information as needed to evaluate the special permit renewal. Also, PHMSA has the right to determine the period of time from the date granted to require renewal of the special permit to assure safety, environmental protection, and public interest. The safety needs for permit renewal time intervals will vary based upon the permit type, whether material, design factor, construction or operational.

The Advisory Committees agreed with PHMSA's responses to the public comments.

E. Farm Taps

1. PHMSA's Proposal

PHMSA proposed to amends the Federal pipeline safety regulations in 49 CFR part 192 to add a new § 192.740 to cover regulators and overpressure protection equipment for an individual service line that originates from a transmission, gathering, or production pipeline (*i.e.,* a farm tap), and to revise § 192.1003 to exclude farm taps from the requirements of the Distribution Integrity Management Program (DIMP).

2. Summary of Public Comment

The AGA cautioned PHMSA that the agency's current position that ''threats to typical farm taps are limited, and most are already addressed within part 192'' could be a slippery slope allowing for various assets within distribution systems to be exempt from DIMP simply because the risks are perceived as relatively low. The AGA commented that while this new proposed requirement may be appropriate for service lines not included in DIMP, it would be a redundant and cumbersome requirement for services lines whose risks are addressed holistically through integrity management.

Similarly, INGAA commented that distribution operators will likely want to treat farm taps as part of their distribution system, and that operators that exclusively operate transmission pipelines will see no value in creating a distribution program just for the farm tap. Therefore, operators should have the option of treating a farm tap as either distribution or transmission as long as the necessary safety and reporting requirements are met.

Operators NiSource, Inc., Northern Natural Gas Company, Southwest Gas Corporation, and TransCanada all agreed that PHMSA should allow an operator the option of keeping farm taps as part of its DIMP.

CenterPoint Energy requested that PHMSA allow operators to establish their own inspection intervals or operating procedures based on the risks associated with particular types or classes of farm taps; they note that § 192.740 is basically § 192.739 and, therefore, § 192.740 should include either the exemption or at the very least language including the limitation that an operator need only verify that a rupture disc with the correct range is installed at the location.

DTE Gas Company commented that there still are threats and risks associated with farm tap service line piping between the farm tap regulator assembly and the customer, and that PHMSA should consider limiting the exception proposed in § 192.1003(b) to the components of the farm tap regulator and valve assembly between the transmission, gathering, or production line and the service line pipe.

The GPA commented that as drafted, § 192.740(a) could be interpreted to exempt additional lines from the requirements of the section. The GPA also requested PHMSA clarify whether the proposal in § 192.1003(b) applies to a service line that directly connects with an upstream production, gathering, or transmission pipeline. In addition, PHMSA should provide a five-year interval for inspection of farm taps.

Kinder Morgan suggested that a farm tap be defined as ''a pipeline that maintains the same designation as the pipeline from which it originates (transmission, storage, gathering or production) and connects to a customer owned service line.'' They also requested that transmission gathering, or production pipeline operators should not be responsible for odorization unless it is currently provided as a service to the owner of the farm tap., and that the maintenance of any odorization along with pressure regulation, overpressure protection, or other facilities should be a ''grandfathered'' function and not a new requirement as part of the proposed rule.

MidAmerican Energy Company commented that the added inspection requirements for ''farm taps'' are significantly more than what is currently required for inspection by DIMP, and that, as proposed by AGA, PHMSA should continue to allow those operators that want to address these services through DIMP or PHMSA should allow a 60-month inspection cycle due to the low risk potential. In addition, PHMSA should give consideration to removing or modifying the 60 psig requirement for pressure of services off of transmission mains for commercial/industrial customers.

Texas Pipeline Association commented that it supports a revision to § 192.1003 that states farm taps directly connected to upstream production, gathering, or transmission pipelines would be excluded from the DIMP requirements. Also, it supports the proposal in § 192.740 to require the inspection and testing of regulators and other over pressure protection equipment.

Vectren Energy Delivery of Indiana and Ohio commented that in order to comply with the proposed rule, retrofits of farm taps would be required because the current standard for a High Pressure Service does not call for a block valve upstream of the pressure relief valve. The test and inspection of the set point of the device is not possible without removing the device or modifying the fabricated assembly. They also comment that the definition of a farm tap is not clear and that current risk models in DIMP result in additional accelerated actions for farm taps when elevated risk scores are noted. Therefore, PHMSA should allow farm taps to remain within DIMP and not mandate a prescribed inspection, or adjust the language in the proposed rulemaking to allow the operator the choice to leave them in DIMP or remove them from the DIMP and follow a mandated inspection frequency.

The GPAC recommended that PHMSA amend the language defining farm taps to service lines ''directly connected to'' production, gathering, or transmission pipelines in both §§ 192.740 and 192.1003(b). The committee also requested that rupture disks be exempted from relief devices required to be inspected.

3. PHMSA Response

NAPSR originally requested the exclusion to exclude farm taps from the DIMP requirements, which PHMSA agrees with. Farm taps are single pipelines that deliver gas to a farmer or other landowner mostly in Class 1 locations, excluding them from the

DIMP requirements. However, these lines are still subject to inspection requirements for pressure regulating/limiting devices, relief devices, and automatic shutoff devices, which would provide adequate safety protection. Therefore, PHMSA is excluding farm taps from the DIMP requirements.

Regarding comments asking that farm taps be regulated at the operators' choice—under DIMP or as proposed, uniform compliance requirements for farm taps are necessary to be enforceable. In addition, some comments requested that operators have the option of treating a farm tap as either distribution or transmission; however, farm taps are distribution service lines, and operators do not have the option to treat distribution service lines as transmission lines. However, this rule decreases the compliance burden for operators by excluding farm taps from the DIMP requirements. As to the inspection requirements for the farm tap safety devices, these safety devices are not new requirements for the safe operation. Therefore, these devices need to be inspected and maintained to ensure safe operation.

With regard to comments for operators to establish their own inspection intervals, compliance cannot be effective if operators can choose their own inspection intervals because the requirements would be unenforceable. Inspection requirements are prescriptive regulations and are not intended to be risk-based or operator established inspection intervals. In addition, extending the inspection interval is not in the interest of safety, and PHMSA is keeping the interval as proposed at three years.

Regarding comments that this section could be interpreted exempt additional lines from the requirements of the section, PHMSA revised the section to read ''any service line directly connected to a production, gathering, or transmission pipeline that is not operated as part of a distribution system.'' In addition, PHMSA has revised § 192.1003(b) to reflect the comment.

Regarding comments that the definition of a farm tap is not clear, PHMSA did not propose a definition for a farm tap. A farm tap is a distribution service line. Regarding comments on grandfathering of odorization and other responsibilities, there is no grandfathering possible for something that has always been required, including requirements for odorizing distribution service lines.

Regarding comment that that rupture disks be exempted from relief devices required to be inspected, PHMSA agrees with the commenter and rupture disks are exempt from the § 192.740(b) requirement.

The Gas Advisory Committee agreed with PHMSA's responses to the public comments.

F. Reversal of Flow or Change in Product

1. PHMSA's Proposal

PHMSA proposed to expand the list of events in §§ 191.22 and 195.64 that require electronic notification to include the reversal of flow of product or change in product in a mainline pipeline. This notification is not required for pipeline systems already designed for bi-directional flow, or when the reversal is not expected to last for 30 days or less. The proposal would require operators to notify PHMSA electronically no later than 60 days before there is a reversal of the flow of product through a pipeline and also when there is a change in the product flowing through a pipeline. Examples include, but may not be limited to, changing a transported product from liquid to gas, from crude oil to HVL, and vice versa. In addition, a modification is amended to §§ 192.14 and 195.5 to reflect the 60-day notification and requiring operators to notify PHMSA when over 10 miles of pipeline is replaced because the replacement would be a major modification with safety impacts.

2. Summary of Public Comment

API–AOPL requested a 30-day notice period in the final rule or flexibility for unforeseen events that necessitate extended or immediate reversals or product conversions. API–AOPL stated that PHMSA should clarify if an operator is required to report the reversal or product conversion 60 days prior to the event or 60 days prior to when the reversal or conversion work begins. API–AOPL also requested that PHMSA clarify whether or not the agency intended that operators may commence preparations for a reversal or conversion prior to making the proposed report to the agency. In addition, they requested the notification be required only prior to physical changes being made to the system, where business confidentiality agreements restrict the knowledge of such changes.

INGAA commented that the proposed notification requirement should apply only to permanent flow reversals where an operator must change or modify its compressor facilities and related piping to accommodate a flow reversal, in which the pipeline needs the Federal Energy Regulatory Commission certificate authorization under the Natural Gas Act. For non-Federal Energy Regulatory Commission regulated pipelines, INGAA notes PHMSA would need to create another notification trigger. For non-bi-directional pipelines, the 60-day notification should be waived for an emergency or under unforeseeable circumstances.

Alyeska noted that PHMSA proposed the addition of ''replacement'' to § 195.64(c)(1)(ii), such that the regulation would require the 60-day notification for ''construction of 10 or more miles of a new or replacement pipeline.'' PHMSA's guidance and advisory bulletin ADB–2014–03 interprets the current § 195.64(c)(1)(ii) as including replacement of 10 or more contiguous miles of line pipe in an existing pipeline, and Alyeska requested PHMSA add ''contiguous'' to the new proposed § 195.64(c)(1)(ii) to reflect PHMSA's interpretation, so that multiple projects resulting in replacement of shorter pipeline segments that collectively add up to 10 or more miles are not considered subject to this rule.

DTE Gas Company commented that the word ''product'' should not apply to gas pipelines as this term is normally associated with hazardous liquid lines in § 191.22(iv). They also requested PHMSA consider excepting the notification requirement for pipelines operating in bi-directional flow modes in conjunction with storage field injection and withdrawal cycles.

Enterprise commented that PHMSA should revise the notification requirement for ''reversal of flow or change in product'' to 30 days and provide an exception from the notification requirement for lines that have previously carried other commodities or that will not require significant modification to change product service. They also requested PHMSA include additional flexibility in the regulation to provide for emergency conditions that require reversals or product conversions where advance notice is not possible.

The GPA suggested that a provision should be added to permit reporting in cases of unplanned or unanticipated reversals.

Kinder Morgan commented that there are numerous instances where the new reporting criteria cannot be reasonably met for natural gas pipeline system, since the pipeline operating conditions are based upon varying customer demand and may change quickly due to such factors as weather changes, other pipeline outages or emergencies, and even changes in daily customer demand requirements. They requested that

changes in flow direction related to seasonal or customer demands and that last more than 30 days should be excluded from this reporting requirement. These flow direction changes have been routinely performed for many gas pipeline systems for a number of years and are a normal operating practice; due to the number of new sources of natural gas, pipeline operators that have the capability of reversing their flow direction must have the flexibility to meet these varying demands as they arise and would not be reasonably able to meet a 60-day reporting requirement.

TransCanada requested that PHMSA re-examine the September 18, 2014, Advisory Bulletin and associated Guidance to Operators Regarding Flow Reversals, Product Changes and Conversion to Service to identify which requirements should be incorporated into the regulations then retire the September 18, 2014, Advisory Bulletin and Guidance.

3. PHMSA Response

With regard to PHMSA allowing a 30-day notice period, for operators to reverse the flow of most existing pipelines requires many months of planning, facility modifications, pipeline pressure testing, and other repairs. Operators also have to go through the process of getting new tariffs through a rate case process, which takes a time interval that is longer than the 60 days. Therefore, PHMSA is keeping the 60-day notice period.

With regard to PHMSA clarifying if an operator is required to report the reversal or product conversion 60 days prior to the event or 60 days prior to when the reversal or conversion work begins and business confidentiality agreements restrict the knowledge of such changes, the new paragraph requires 60 days prior to the reversal event, and § 190.23(c)(1)(i) already requires notification when costs are $10 million or over. With regard to notification requirement applying only to permanent flow reversals where the pipeline needs the FERC certificate authorization and for non-bi-directional pipelines for emergency or under unforeseeable circumstances, the flow reversal notification is for flow reversals over 30 days, unless an emergency event exists.

With regard to multiple projects resulting in replacement of shorter pipeline segments that collectively add up to 10 or more miles, a pipeline with many segments and compressor stations that are being modified for flow reversal would be considered the same reversal project.

Changes in flow direction that are related to seasonal or customer demands and last more than 30 days are not applicable to existing bi-directional pipelines. This requirement is applicable for existing one direction pipelines that are modified for bi-directional or reverse flow.

With regard to PHMSA's Advisory Bulletin and associated Guidance to Operators Regarding Flow Reversals, Product Changes and Conversion to Service dated September 18, 2014, the advisory bulletin is based upon 49 CFR parts 192 and 195 and lessons-learned/findings from inspections of operator facilities for construction, operations, maintenance, and integrity management and, therefore, is still applicable.

The Advisory Committees agreed with PHMSA's responses to the public comments.

G. Pipeline Assessment Tools

1. PHMSA's Proposal

Section 195.452 of the pipeline safety regulations specifies requirements for assuring the integrity of pipeline segments where a hazardous liquid release could affect a high consequence area (referred to in this rule as ''covered segments''). Among other requirements, the regulations require that operators of covered segments conduct assessments, which consist of direct or indirect inspection of the pipelines, to detect evidence of degradation. Section 195.452(d) requires operators to conduct a baseline assessment of all covered segments. Section 195.452(j) requires that operators conduct assessments periodically thereafter.

This rulemaking action incorporates by reference the following consensus standards into 49 CFR part 195: API STD 1163, ''In-Line Inspection Systems Qualification Standard'' (April 2013); NACE Standard Practice SP0102–2010 ''Inline Inspection of Pipelines'' NACE SP0204–2008 ''Stress Corrosion Cracking Direct Assessment;'' and ANSI/ASNT ILI–PQ–2010, ''In-line Inspection Personnel Qualification and Certification'' (2010). Also, PHMSA allows pipeline operators to conduct assessments using tethered or remote control tools not explicitly discussed in NACE SP0102–2010, provided the operators comply with applicable sections of NACE SP0102–2010.

2. Summary of Public Comment

The NTSB agreed that incorporating by reference the industry consensus standards listed in Section VII of the NPRM will improve operator pipeline assessment consistency, accuracy, and quality. Requiring a written SCCDA plan to include the pre-assessment as outlined in the NACE standard practice RP0204 would provide owner/operators with valuable information and allow them to thoroughly assess vulnerabilities to stress corrosion cracking. Furthermore, the proposed requirement that the piping assessment plan contain a ''data gathering and integration'' element addressing the four, listed factors will further improve the SCCDA process. Also, the NTSB agreed that the NACE standard practice for conducting SCCDA combined with the written plan requirements are more comprehensive and rigorous than the current regulatory requirements.

The AGA supports the incorporation of NACE SP0204–2008: Stress Corrosion Cracking (SCC) Direct Assessment Methodology by reference in pipeline safety regulations, but not with the additional proposed requirements to NACE SP0204–2008. The AGA contends that NACE SP0102–2010 does not provide detailed procedures that are applicable in all situations on all pipelines and instead provides general recommendations. And that the ANSI/ASNT ILI–PQ–2010 should not be incorporated by reference in part 195 because it is not common practice for company personnel who may review data provided by vendors to comply with the qualifications outlined by this standard. The AGA does not support the proposed regulatory language in § 195.591 because it removes the ability for operating personnel to use their engineering judgment when outlining the company's strategy for ILI.

API–AOPL requested PHMSA to clarify any instances where the requirements outlined in SP0204–2008 are intended to serve as industry guidance. PHMSA's proposed incorporation of SP0204–2008 is a significant extension of the intent underlying the SCCDA data collection process. Therefore, PHMSA should clarify the inclusion of SP0204–2008, Table 2 in the data gathering process. They also requested PHMSA provide a technical justification for the proposed minimum number of excavations, as well as justification for incorporating API STD 1163 (2005) when that standard has been updated recently. The proposal defining non-significant SCC in accordance with NACE SP0204–2008 is out of date and creates ambiguity both in terms of interpretation and enforcement; therefore, PHMSA should use the Canadian Energy Pipeline Association's (CEPA's) severity criteria, as it provides clear guidance on appropriate actions to address SCC

based on levels of SCC severity. For ILI tool standards proposed in § 195.452, PHMSA should issue additional clarifying guidance reemphasizing the need to determine the appropriate assessment technology based on an evaluation of the segment specific risks associated with each portion of the line.

Chevron Pipe Line Company commented that each proposed standard for incorporation by reference is supported by an array of associated material that is taken into consideration based on the many factors involved when assessing pipeline conditions, and therefore, PHMSA should provide adequate time beyond the comment deadline and before the final rule is issued for industry and regulatory stakeholders to adequately assess the proposal for feasibility.

Energy Transfer Partners commented that in § 195.452, regarding the capabilities of ILI tools, the operator should be able to choose tools that are appropriate for the threats identified or to obtain the data required, and it is understood that the operator needs to be able to justify such decisions. Energy Transfer Partners also commented that the mitigation requirements proposed in § 195.588(c)(4)(ii) appear to be mandated with no technical basis and are contrary to much of the expert technical opinion on such testing. The stress level achieved during the ''spike'' portion of the hydrostatic test should be an engineered pressure defined by the operator to achieve some stated goal. The operator should be able to set that goal, and the corresponding pressure, to balance the various factors involved, including post-test operating pressure, retest interval and potential activation of otherwise stable anomalies. The duration of the ''spike'' portion of the test should likewise be engineered based upon similar factors. There is technical literature and technical opinion that, particularly at the very high pressures proposed by PHMSA, holding those pressures much beyond 5 minutes, and certainly beyond 10, provides no additional benefit. They comment that PHMSA has presented no basis or justification for a 30-minute hold, and that PHMSA has not presented a technical justification for the requirement of a subpart E hydrostatic test to be conducted as a continuation of the ''spike'' portion of the test. Properly engineered pressure testing can be an effective mitigation tool for stress corrosion cracking. However, a ''one size fits all'' mandated approach to such testing is not appropriate and is not the most effective way of achieving effective mitigation and overall improvement in assurance of integrity. The pipeline operator should be responsible for determining the required testing parameters based upon the specifics of the line being tested and the established goal of the testing.

Enterprise commented that with respect to the proposed ILI tools in § 195.452(c) and (j), PHMSA should revise the proposal to clarify that a crack tool is not required for every ILI assessment or reassessment and clarify that operators need only consider the recommendations of the ILI consensus standards proposed to be incorporated by reference. They also commented that PHMSA should modify the proposed language similar to existing natural gas integrity management requirements in § 192.921(a)(1). In addition, they requested § 195.591 be clarified to state that operators need only ''consider'' the recommendations in the proposed incorporation by reference standards, and that PHMSA should incorporate the most current version of API 1163 (2010), or risk inconsistency and/or conflict with NACE RP0102 because the 2005 API 1163 standard cross-references an older (2002) version of NACE RP0102, but PHMSA's proposed incorporation risks requiring actions that are inconsistent with the 2010 NACE version of that standard which is proposed to be incorporated by the regulation.

Northeast Gas Association commented that it is concerned about additional requirements above and beyond NACE SP0204–2008 that are being proposed, such as PHMSA's proposal in § 195.588(c)(1) to require gathering and evaluating data related to stress corrosion cracking at all sites an operator excavates during the conduct of its pipeline operations both within and outside covered segments.

Thomas Lael Services provided suggested editorial comments for ILI of pipelines in proposed § 195.591 and provided additional comments and new proposals into part 192.

The LPAC recommended adopting the newer, April 2013 version of the API STD 1163, ''In-Line Inspection Systems Qualification Standard.''

3. PHMSA Response

The additional requirements were generated by PHMSA subject matter experts based on their lessons learned from the integrity management program, and expert presentations of public workshops on stress corrosion cracking, risk, and new construction. PHMSA is incorporating API STD 1163 (April 2013); NACE Standard Practice SP0102–2010, NACE SP0204–2008, and ANSI/ASNT ILI–PQ–2010 into the regulations to provide clearer guidance for conducting integrity assessments with ILI. These standards complement each other, and they will promote a higher level of safety by establishing a consistent methodology to qualify the equipment, people, processes, and software utilized by the ILI industry.

PHMSA is incorporating NACE SP0204–2008 into part 195 because it provides comprehensive, up-to-date guidelines on conducting SCCDA. It is more comprehensive in scope than Appendix A3 of ASME/ANSI B31.8S, and PHMSA has concluded the quality and consistency of SCCDA conducted under integrity management requirements would be improved by requiring the use of NACE SP0204–2008. The NACE standard provides additional guidance on: The factors that are important in the formation of stress corrosion cracking on a pipeline and what data should be collected; additional factors, such as existing corrosion, which could cause stress corrosion cracking to form; comprehensive data collection guidelines including the relative importance of each type of data; requirements to conduct close interval surveys of cathodic protection or other above-ground surveys to supplement the data collected during pre-assessment; ranking factors to consider for selecting excavation locations for both near neutral and high pH stress corrosion cracking; requirements on conducting direct examinations including procedures for collecting environmental data, preparing the pipe surface for examination, and conducting Magnetic Particle Inspection (MPI) examinations of the pipe; and post assessment analysis of results to determine SCCDA effectiveness and to assure continual improvement.

PHMSA proposed to incorporate the 2005 API 1163 because at the time the notice of the rulemaking action was developed, the latest version of API 1163 was under development. PHMSA has evaluated the revisions made to the latest version of API 1163 and determined that the changes are not significant. Therefore, PHMSA is adopting API STD 2013 into part 195. However, adopting the Canadian Energy Pipeline Association's severity criteria is out of the scope of this rulemaking action.

PHMSA provides adequate time for industry and regulatory stakeholders to adequately assess the proposal for feasibility. The agency goes through a long process of analyzing all comments, discussing summary of comments at the Advisory Committee meetings that are open to the public and getting their

recommendations and having internal review with PHMSA subject matter experts before issuing the final rule. PHMSA believes this process gives operators enough time to review the proposals.

With regard to inspection tools selections, operators always have option of using their alternative to these standards as long as the alternative tools meet equivalency or exceed the provisions in these standards.

If a pipeline includes legacy pipe or was constructed using legacy construction techniques, or the pipeline has experienced a reportable in-service accident since its most recent successful ''spike'' hydrostatic pressure test, due to an original manufacturing-related defect, a construction, installation, or fabrication-related defect, or a crack or crack-like defect, a spike pressure test would be required. Further, ongoing research and industry response to other PHMSA rulemaking actions is beginning to indicate that SCCDA is not as effective, and does not provide an equivalent understanding of pipe conditions with respect to stress corrosion cracking defects, as ILI or hydrostatic pressure testing at test pressures that exceed those test pressures (*i.e.,* ''spike'' hydrostatic pressure test). Therefore, a ''spike'' hydrostatic pressure test is well suited to address stress corrosion cracking and other cracking or crack-like defects.

With regard to a crack tool not being required for every ILI assessment or reassessment and that operators need only consider the recommendations of the ILI consensus standards proposed to be incorporated by reference, operators always have the option to use their alternative to these standards as long as the alternative tools meet equivalency or exceed the provisions in these standards. These standards are incorporated in part 195 after lessons learned from past integrity management requirement in place for years; recent high profile incidents in Marshall, MI, San Bruno, CA, and Mayflower, AR, and recommendations from the NTSB to address crack like defects, stress corrosion cracking and seam corrosion issues, have indicated that current integrity management requirements do not address all anomalies in the pipeline. Further, PHMSA is revising § 195.452(c)(1)(i)(A) to clarify the fact that operators should select the appropriate tool type to address the specific threats relative to their pipeline segments.

The LPAC agreed with PHMSA's responses to the public comments.

H. Post-Accident Drug and Alcohol Testing

1. PHMSA's Proposal

PHMSA is modifying §§ 199.105 and 199.225 by allowing exemption from post-accident drug and alcohol testing only when there is sufficient information that establishes the employee(s) had no role in the accident.

PHMSA's regulations required the documentation of decisions not to administer a post-accident alcohol test but the requirement to document decisions not to administer a post-accident drug test was only implied in the regulation, and the implied requirement is generally followed. PHMSA is amending the post-accident drug testing regulation to require documentation of the decision and to keep the documentation for at least three years.

2. Summary of Public Comment

The NTSB commented that it believes the proposed change is responsive to its recommendation.

The APGA commented that this requirement could be misinterpreted to require the operator to document actions of every utility employee after a reportable incident occurs. PHMSA uses the terms ''surviving covered employee'' and ''whose performance of a covered function'' to clarify that this proposed requirement only requires the operator to consider testing those employees who performed covered functions at the location of the incident either when the incident occurred or for some time period immediately prior to the incident; however, it does not require documentation for employees working elsewhere on the system. The APGA commented that it supports the proposed electronic submittal requirement for each annual management information system for the operator's drug and alcohol testing program.

API–AOPL commented that the proposed rule for post-accident drug and alcohol testing does not discuss whether PHMSA has a specific process in mind for those operators requesting an exemption from the proposed test-reporting requirement and that PHMSA should clarify further on the process envisioned by the agency. Additionally, they requested PHMSA articulate whether it intends to create one standardized form to be used by all industry operators to document the decision to not administer a post-accident test, or whether individual operators will be required to generate their own forms.

Enterprise commented that PHMSA should revise the post-accident drug and alcohol testing proposal to state affirmatively which employees must be tested under the regulations, and that PHMSA should generate a standard form to be used for decisions not to test, to avoid inconsistency both in application and reporting.

The American Medical Review Officers and the Pipeline Testing Consortium recommended that in §§ 199.105(b) and 199.225(a)(1) PHMSA use the same phrase ''contributed to the accident'' in the second sentence as was used in the first rather than the employee's ''role in the cause . . . of the accident.'' They also requested PHMSA remove the word ''severity'' in both sections because severity of any accident will vary, but does not affect whether a test is conducted. In addition, the discretion that an employer has in determining not to conduct a post-accident test ''because of the time between that performance and the accident, it is not likely that a drug test would reveal whether the performance was affected by drug use'' has been part of this section for years, but that makes it no less problematic. There are no scientifically acceptable criteria by which the employer could accurately make this decision; therefore, this option should be deleted from the employer's testing decision. Section 199.105(b)(2) requires documentation only on ''why the test was not promptly administered,'' but does not cover decisions made that eliminate some employees from testing all together. In contrast, § 199.117(a)(5) only covers recordkeeping for ''decisions not to administer . . . the drug test,'' but does not cover why the employer could not accomplish the testing within 32 hours; therefore, each paragraph should add its missing part. This recommendation applies also to the alcohol section of the proposed rule, where § 199.227(a)(2(i) and (b)(4) have the same issue. The proposed definition for ''covered task'' in §§ 192.803 and 195.503 runs the risk of being confused with ''covered function'' in § 199.3; therefore, the term ''covered task,'' and its definition should be used in part 199 in lieu of ''covered function.'' In addition, they provided comments to other sections of part 199 that were not proposed in this rulemaking action.

Thomas Lael Services commented that the documentation that describes why the decision not to test an individual relative to a reportable accident/incident should be kept for as long as the complete event records is kept.

The Advisory Committees recommended deleting language from § 199.105(b), ''. . . or because of the time between that performance and the accident, it is not likely that a drug test would reveal whether the performance was affected by drug use.''

3. PHMSA Response

Contrary to several commenters, this rulemaking does not establish new requirements for post-accident drug and alcohol testing. Those requirements currently exist in 49 CFR part 199. This rulemaking would modify the conditions under which an operator may decide not to test covered employees and establish a recordkeeping requirement for these decisions. Operators have been required to decide whether to post-accident test covered employees since part 199 was promulgated. Each accident is unique. PHMSA can neither state affirmatively which employees must be tested nor create a template for making the decision about post-accident testing.

An individual could ''contribute'' to an accident by causing it or by making the consequences more severe. The overall severity of the accident is irrelevant to the post-accident testing decision. The relevant question for severity is whether an employee's performance of a covered function affected the severity of the accident.

In PHMSA's proposed § 199.105(b)(2), operators would cease attempts to administer a drug test 32 hours after the accident. PHMSA concurs that ''or because of the time between that performance and the accident, it is not likely that a drug test would reveal whether the performance was affected by drug use'' should be removed from PHMSA's proposed 199.105(b)(1) and, therefore, the statement is removed.

The new post-accident recordkeeping requirements merely specify the type of records and length of retention. Details about what must be in the records are contained in other sections of the regulations. The post-accident testing sections of the regulations clarify the contents of the records on decisions not to administer post-accident tests.

Covered task is defined in parts 192 and 195. ''Covered function'' is defined in part 199 and has a meaning different from ''covered task.'' PHMSA used the term ''covered function'' appropriately in the NPRM.

Since PHMSA has not established record retention criteria for accidents, the drug and alcohol testing regulations must establish the retention period for decisions not to administer post-accident tests.

The Advisory Committees agreed with PHMSA's responses to the public comments.

I. Information Made Available to the Public and Request for Protection of Confidential Commercial Information

1. PHMSA's Proposal

When information is submitted to PHMSA during a rulemaking proceeding, as part of an application for a special permit, or for any other reason, PHMSA may make that information publicly available. PHMSA does not currently set out in the pipeline safety regulations the steps for requesting protection of confidential commercial information. PHMSA has set out such a procedure in its hazardous materials safety regulations. Therefore, to inform the public of how to request protection of confidential business information submitted to the Office of Pipeline Safety and to provide information regarding PHMSA's decision, PHMSA is including the procedure in the pipeline regulations. If PHMSA were to receive a request for information marked as confidential or identifies a need to make the information publicly available, PHMSA will conduct a review of the information under the standards set forth in the Freedom of Information Act (FOIA), 5 U.S.C. 552.

2. Summary of Public Comment

The Pipeline Safety Trust asked that PHMSA include in § 190.343(b) the criteria by which PHMSA will make the decision about whether the information requested to be confidential will be removed from public availability and make clear whether that decision is an appealable administrative order.

The American Gas Association (AGA) commented that it supported a clear path for operators to request confidentiality for submitted information, but indicated concern about PHMSA using its own judgment on when to keep that information confidential. AGA also suggested that operators should have an opportunity to classify their information related to special permits and thus their system as Sensitive Security Information.

The American Petroleum Institute (API) and the Association of Oil Pipe Lines (AOPL) commented that they did not oppose the proposal, but requested that certain clarifications be made including who would be responsible for making determinations concerning requests for confidentiality, confirmation that information will be treated as confidential if the requirements in proposed § 190.343(a) are followed and that the information would be disclosed only after a determination is made in accordance with § 190.343(3)(b). API and AOPL also requested that at minimum, operators are granted five business days from the date of receipt of a written notice before the information is publicly disclosed to object, and requested an opportunity for appeal within the agency (*e.g.,* to the Administrator or Chief Counsel).

Energy Transfer Partners commented that some materials required to be submitted to PHMSA may contain confidential information regarding the operator's markets, plans, anticipated customers, suppliers, vendors, contractors, etc. and commented that the proposed language was not particularly reassuring that confidentiality would be maintained. Energy Transfer Partners also commented that PHMSA should include the operator in the decision-making process regarding whether to disclose such information.

Enterprise Products Partners LP commented that industry has long relied on FOIA exemptions, established rules for treatment of confidential business information and judicially recognized privileges and that the rule should clarify that all such protections are retained. In addition, Enterprise Products Partners requested that PHMSA clarify that it will not post information submitted as confidential business information, FOIA exempt or privileged on its public Web site without prior notice to the submitter, allow a submitter ''at least 5 business days to substantiate a request for disclosure of information submitted as CBI, FOIA exempt or privileged, and include an expedited appeal process.''

FlexSteel commented that it strongly objects to the proposal, stating that confidential information is information that is intended to be private or secret and may be covered by patents or patents pending. FlexSteel stated that often the type of supporting documentation filed with certain project requests contain patented and confidential technological information because it is unique in nature. FlexSteel requested that proposed provision § 190.343 be removed.

Gas Processors Association (GPA) commented that it strongly objects to the proposal in § 190.343. GPA stated that pipelines are considered critical infrastructure and that virtually every aspect of their operations could be deemed sensitive. GPA requested that the proposed language in § 190.343 be removed from the final adopted rule so that it can be strengthened to provide the greatest amount of protections possible for sensitive information.

Northeast Gas Association stated that it supports the AGA's recommendation that PHMSA provide operators the option of utilizing the Protected Critical Infrastructure Information protection protocol under the Critical Infrastructure Information Act of 2002 for voluntarily submitted sensitive data.

Texas Pipeline Association (TPA) commented that more robust mechanisms for protection from disclosure than what is contained in the proposal are needed to protect Sensitive Security Information or Protected Critical Infrastructure Information. TPA recommended that the proposal in § 190.343 be removed from any final rule adoption and that procedures for protection of sensitive and confidential information be developed in a separate rulemaking.

3. PHMSA Response

With this new section, PHMSA is informing submitters of steps to follow if they wish to request protection for confidential commercial information submitted to PHMSA. This section also includes a provision regarding PHMSA's decision. After reviewing the comments received to the proposal, PHMSA has made some revisions to the title and regulatory text in § 190.343(a) and (b) for clarification.

In addition to concerns about the protection of confidential business information, several commenters raised concerns about submitting information that is sensitive for security reasons. PHMSA's intent with § 190.343 was to set out the steps for requesting protection of confidential commercial information. Therefore, in the final rule, PHMSA is revising the title of § 190.343 and regulatory text in subparagraph (a) to clarify that this section applies to the protection of confidential commercial information.

PHMSA's review and determinations regarding protection of security information involve a different process that is not the subject of this rulemaking. Prior to disclosure of information, PHMSA reviews the records to determine whether information is protected for security reasons and applies all applicable FOIA exemptions and Federal laws. The Department of Transportation and Department of Homeland Security (DHS) have procedures in place to protect information that is determined to be Sensitive Security Information (SSI). PHMSA's Office of Pipeline Safety Emergency Support and Security Division consults with Departmental and DHS/TSA security offices as necessary.

The steps set forth in § 190.343(a) serve to notify PHMSA that a submitter believes information to be confidential commercial information and ensures that PHMSA will protect the information as confidential commercial information until it conducts a release determination. Generally, such a decision will occur when PHMSA receives a FOIA request for the information and completes an analysis under FOIA, following the procedures in the Department's FOIA regulations in 49 CFR part 7. In an instance where there is not a FOIA request, but PHMSA identifies a need to make particular information available to the public to support its mission to protect people and the environment from the risks of gas, liquefied natural gas, and hazardous liquids or carbon dioxide transportation by pipeline, PHMSA will use the criteria set out in FOIA to analyze whether the information is protected by one or more of the FOIA exemptions.

Therefore, to address comments, PHMSA revised the regulatory text in § 190.343(b) to clarify that PHMSA will use the criteria set forth in FOIA if a release determination is necessary. This includes complying with the Department's FOIA regulations in 49 CFR 7.29 that require consultation with the submitter of information designated as confidential commercial information and written notification to the submitter of an intended disclosure of the information.

The procedures in § 190.343 require that at the time of submission, the submitter provide PHMSA with an explanation of why the information is confidential. Therefore, this section gives submitters an opportunity both at the time the information is submitted to PHMSA to provide an explanation of why the information is confidential commercial information and during the consultation process that PHMSA initiates if it has received a FOIA request or determined that there is a need to make the information publicly available.

In response to comments, we are also clarifying in the final rule that if after reviewing the submitter's request and explanations submitted after the consultation, PHMSA decides to disclose the information over the submitter's objections, PHMSA will provide written notification to the submitter at least five business days prior to the intended disclosure date.

As PHMSA is following a similar process to that under the Departmental FOIA regulations providing for submitter consultation and notification, PHMSA is not adding an appeal process for submitters of information. If a decision is made that the information is protected as confidential commercial information, a FOIA requester who has asked for the records has appeal rights under FOIA.

The Advisory Committees' recommendations also address the public comments received by PHMSA.

J. In-Service Welding

1. PHMSA's Proposal

PHMSA is revising 49 CFR 192.225, 192.227, 195.214, and 195.222 to add reference to API 1104, Appendix B.

2. Summary of Public Comment

The AGA supports PHMSA's proposal to incorporate API 1104 Appendix B as an acceptable section for the development of welding procedures and welder qualification. It does not believe that this change creates a new requirement to only use API 1104 Appendix B to qualify in service welding procedures or in service welders and, therefore, requests that PHMSA should provide clarification in the preamble language of the final rule by stating this incorporation does not create a new requirement.

Northeast Gas Association commented that it supports PHMSA's proposal to incorporate API 11 04 Appendix B as an acceptable section for the development of welding procedures and welder qualification, as long as this change provides another option along with the existing options in the regulations.

3. PHMSA Response

In the past, PHMSA has encouraged pipeline operators to develop and use welding procedures that address improvements in pipeline safety and many operators have developed in service welding procedures. Welding procedures developed to API 1104 Appendix B consider the risks associated with hydrogen in the weld metal, type of welding electrode, sleeve/fitting and carrier pipe materials, accelerated cooling, and stresses across the fillet welds. Parts 192 and 195 do not include the addition of API 1104 Appendix B as an acceptable section for the development of welding procedures and welder qualification. To allow in-service welding, PHMSA is adopting Appendix B of API 1104 into parts 192 and 195. Therefore, PHMSA is not creating new requirement but only including Appendix B into already adopted API 1104 to qualify in service welding procedures or in service welders to perform in-service welding operators must follow Appendix B of API 1104. In addition, currently,

PHMSA does not allow in service welding and, therefore, there are no existing options in the regulations for in service welding.

The Advisory Committees agreed with PHMSA's responses to the public comments.

K. Availability of Standards Incorporated by Reference

PHMSA currently incorporates by reference into 49 CFR parts 192, 193, and 195 all or parts of more than 60 standards and specifications developed and published by standard developing organizations (SDOs). In general, SDOs update and revise their published standards every 3 to 5 years to reflect modern technology and best technical practices.

The National Technology Transfer and Advancement Act of 1995, Public Law 104–113, directs Federal agencies to use voluntary consensus standards in lieu of government-written standards whenever possible. Voluntary consensus standards are standards developed or adopted by voluntary bodies that develop, establish, or coordinate technical standards using agreed-upon procedures. In addition, Office of Management and Budget (OMB) issued OMB Circular A–119 to implement section 12(d) of Public Law 104–113 relative to the utilization of consensus technical standards by Federal agencies. This circular provides guidance for agencies participating in voluntary consensus standards bodies and describes procedures for satisfying the reporting requirements in Public Law 104–113.

In accordance with the preceding provisions, PHMSA has the responsibility for determining, via petitions or otherwise, which currently referenced standards should be updated, revised, or removed, and which standards should be added to 49 CFR parts 192, 193, and 195. Revisions to incorporate by reference materials in 49 CFR parts 192, 193, and 195 are handled via the rulemaking process, which allows for the public and regulated entities to provide input. During the rulemaking process, PHMSA must also obtain approval from the Office of the Federal Register to incorporate by reference any new materials.

On January 3, 2012, President Obama signed the Pipeline Safety, Regulatory Certainty, and Job Creation Act of 2011, Public Law 112–90. Section 24 states, ''Beginning 1 year after the date of enactment of this subsection, the Secretary may not issue guidance or a regulation pursuant to this chapter that incorporates by reference any documents or portions thereof unless the documents or portions thereof are made available to the public, free of charge, on an Internet Web site.'' 49 U.S.C. 60102(p). On August 9, 2013, Public Law 113–30 revised 49 U.S.C. 60102(p) to replace ''1 year'' with ''3 years'' and remove the phrases ''guidance or'' and, ''on an Internet Web site.'' This resulted in the current language in 49 U.S.C. 60102(p), which now reads as follows, ''Beginning 3 years after the date of enactment of this subsection, the Secretary may not issue a regulation pursuant to this chapter that incorporates by reference any documents or portions thereof unless the documents or portions thereof are made available to the public, free of charge.''

Further, the Office of the Federal Register issued a November 7, 2014, rulemaking that revised 1 CFR 51.5 to require that agencies detail in the preamble of a rulemaking the ways the materials it incorporates by reference are reasonably available to interested parties, or how the agency worked to make those materials reasonably available to interested parties. 79 FR 66278. In relation to this rulemaking, PHMSA has contacted each SDO and has requested free public access of each standard that has been incorporation by reference. The SDOs agreed to make viewable copies of the incorporated standards available to the public at no cost. Pipeline operators interested in purchasing these standards can contact the standards organization. The contact information is provided in this rulemaking action, *see* § 195.3.

V. Regulatory Analyses and Notices

Executive Order 12866, Executive Order 13563, and DOT Regulatory Policies and Procedures

This rule is a non-significant regulatory action under Section 3(f) of Executive Order 12866, 58 FR 51735, and; therefore, it was not reviewed by the Office of Management and Budget. This rule is non-significant under the Regulatory Policies and Procedures of the Department of Transportation. 44 FR 11034.

Executive Order 12866, as supplemented by Executive Order 13563, 76 FR 3821, requires agencies regulate in the most cost-effective manner, make a reasoned determination that the benefits of the intended regulation justify its costs, and develop regulations that impose the least burden on society. In this rule, PHMSA is amending the pipeline safety regulations to:

- Add a specific time frame for telephonic or electronic notifications of accidents and incidents;
- Establish PHMSA's cost recovery procedures for new projects that cost over $2,500,000,000 or use new and novel technologies;
- Address the NTSB's recommendations to clarify training requirements for control room team members;
- Add provisions for the renewal of expiring special permits;
- Exclude farm taps from the requirements of the DIMP requirements while adding safety requirements for the farm taps;
- Require pipeline operators to report to PHMSA for permanent reversal of flow that lasts more than 30 days or to a change in product;
- Provide methods for assessment tools by incorporating consensus standards by reference in part 195 for ILI and SCCDA (also addresses part of NTSB recommendation);
- Require electronic reporting of drug and alcohol testing results in part 199;
- Modify the criteria used to make decisions about conducting post-accident drug and alcohol tests and require operators to keep for at least three years a record of the reason why post-accident drug and alcohol test was not conducted (also addresses NTSB recommendation);
- Include the procedure for requesting protection of confidential commercial information submitted to PHMSA.
- Add reference to Appendix B of API 1104 related to in-service welding in Parts 192 and 195; and
- Make minor editorial corrections.

The regulatory impact analysis found, in summary, that annual compliance costs would be approximately $0.6 million, less savings to be realized from the removal of farm taps from the Distribution Integrity Management Program (DIMP) requirements.

Annual benefits could not be quantified as readily due to data limitations and the very minor nature of many of the changes. PHMSA expects that the improvements and clarifications made to the regulations, including those for post-incident investigations along with other provisions, will reduce pipeline incidents and the associated consequences, including the potential to prevent a future high-consequence event, such as those that have occurred on gas transmission and hazardous liquid pipelines in the past.

Regulatory Flexibility Act

The Regulatory Flexibility Act requires an agency to review regulations

to assess their impact on small entities, unless the agency determines that a rule is not expected to have a significant impact on a substantial number of small entities. 5 U.S.C. 601 *et seq.* This final rule has been developed in accordance with Executive Order 13272, ''Proper Consideration of Small Entities in Agency Rulemaking,'' 67 FR 53461, and DOT's procedures and policies to promote compliance with the Regulatory Flexibility Act to ensure that potential impacts of rules on small entities are properly considered.

The Initial Regulatory Flexibility Analysis found that the rule could affect a substantial number of small entities because of the market structure of the gas and hazardous liquids pipeline industry, which includes many small entities. However, these impacts would not be significant. The post-accident drug testing provision would add $74 in documentation costs per reportable incident. The other provisions would not add appreciable costs, and at least one provision (farm taps) would yield compliance cost savings.

Description of the Reasons Why Action by PHMSA Is Being Considered

PHMSA is amending the regulations to address the 2011 Act's section 9 (accident and incident reporting requirements) to within one hour so that timely actions can be taken to pipeline accidents and incidents, and section 13 (cost recovery) so that PHMSA's limited resources for enforcement and other safety activities are not used for operators design reviews. NTSB recommendations for control room training and drug and alcohol reporting requirements are addressed under this rule. A special permit renewal procedure is added so that pipeline operators have a renewal procedure to follow to renew their expiring special permits. In addition, other non-substantive changes are amended to correct language and provide methods for assessment tools as recommended by incorporating consensus standards (this addresses parts of NTSB recommendations P–12–3 and the NACE recommendations). Specifically, these amendments address: Farm tap requirements to address the NAPSR and INGAA concerns in including farm taps under the DIMP requirements; notification for reversal of flow or change in product for more than 60 days so that PHMSA is aware of the transported product; incorporation by reference of standards to address ILI and SCCDA; and additional testing of drug and alcohol tests, electronic reporting of drug and alcohol testing results, modifying the criteria used to make decisions about conducting post-accident drug and alcohol tests and post-accident drug and alcohol testing recordkeeping to address a NTSB recommendation; the process to request confidential treatment of submitted information similar to the process currently set out in 49 CFR 105.30 of the Hazardous Materials Regulations; and, editorial amendments to correct some errors or outdated deadlines.

Succinct Statement of the Objectives of, and Legal Basis for, This Rule

Under the Federal Pipeline Safety Laws, 49 U.S.C. 60101 *et seq.,* the Secretary of Transportation must prescribe minimum safety standards for pipeline transportation and for pipeline facilities. The Secretary has delegated this authority to the PHMSA Administrator. 49 CFR 1.97(a). This rulemaking action will create changes in the regulations consistent with the protection of persons and property while changing unduly burdensome or nonsensical requirements.

Description of Small Entities to Which This Rulemaking Action Will Apply

The initial Regulatory Flexibility Analysis found that the rule could affect a substantial number of small entities because of the market structure of the gas and hazardous liquids pipeline industry, which includes many small entities. However, these impacts would not be significant. The provision to document the reason for not drug testing post-accident adds $74 in documentation costs per reportable incident. The other provisions would not add appreciable costs, and at least one provision (Farm Taps) would yield compliance cost savings, though those savings are minimal.

Description of Any Significant Alternatives to This Rule That Accomplish the Stated Objectives of Applicable Statutes and That Minimize Any Significant Economic Impact of the Rule on Small Entities, Including Alternatives Considered

PHMSA is unaware of any alternatives which would produce smaller economic impacts on small entities while at the same time meeting the objectives of the relevant statutes.

Executive Order 13175

PHMSA has analyzed this rule according to the principles and criteria in Executive Order 13175, ''Consultation and Coordination with Indian Tribal Governments,'' 65 FR 67249. The funding and consultation requirements of Executive Order 13175 do not apply because this rule does not significantly or uniquely affect the communities of Indian tribal governments or impose substantial direct compliance costs.

Paperwork Reduction Act

PHMSA has analyzed this final rule in accordance with the Paperwork Reduction Act of 1995 (PRA). Public Law 96–511. The PRA requires federal agencies to minimize paperwork burden imposed on the American public by ensuring maximum utility and quality of federal information, ensuring the use of information technology to improve government performance, and improving the federal government's accountability for managing information collection activities. Pursuant to 5 CFR 1320.8(d), PHMSA is required to provide interested members of the public and affected agencies with an opportunity to comment on information collection and recordkeeping requests. PHMSA estimates that this rulemaking action will impact the following information collections:

''Transportation of Hazardous Liquids by Pipeline: Record keeping and Accident Reporting'' identified under Office of Management and Budget (OMB) Control Number 2137–0047; ''Incident and Annual Reports for Gas Pipeline Operators'' identified under Office of Management and Budget (OMB) Control Number 2137–0522; ''Qualification of Pipeline Safety Training'' identified under Office of Management and Budget (OMB) Control Number 2137–0600; and ''National Registry of Pipeline and LNG Operators'' identified under Office of Management and Budget (OMB) Control Number 2137–0627.

PHMSA is also creating a new information collection to cover the recordkeeping requirement for post-accident drug testing: ''Post-Accident Drug Testing for Pipeline Operators.'' PHMSA will request a new Control Number from the Office of Management and Budget (OMB) for this information collection.

PHMSA will submit an information collection revision request to OMB for approval based on the requirements that need information collection in this proposed rule. The information collection is contained in the pipeline safety regulations, 49 CFR parts 190 through 199. The following information is provided for each information collection: (1) Title of the information collection; (2) OMB control number; (3) Current expiration date; (4) Type of request; (5) Abstract of the information collection activity; (6) Description of affected public; (7) Estimate of total annual reporting and recordkeeping

burden; and (8) Frequency of collection. The information collection burdens are estimated to be revised as follows:

1. *Title:* Transportation of Hazardous Liquids by Pipeline: Recordkeeping and Accident Reporting.

OMB Control Number: 2137–0047.

Current Expiration Date: December 31, 2016.

Abstract: This information collection covers recordkeeping and accident reporting by hazardous liquid pipeline operators who are subject to 49 CFR part 195. Section 195.50 specifies the definition of an ''accident'' and the reporting criteria for submitting a Hazardous Liquid Accident Report (form PHMSA F7000–1) is detailed in § 195.54. PHMSA is revising the form PHMSA F7000–1 and its instructions to include the concept of ''confirmed discovery'' as amended in this rule. Operators will be required to include the date and time of the confirmed discovery of a hazardous liquid pipeline accident. PHMSA does not expect this revision to increase the burden of reporting.

Affected Public: Hazardous liquid pipeline operators.

Annual Reporting and Recordkeeping Burden:

Total Annual Responses: 847.

Total Annual Burden Hours: 52,429.

Frequency of collection: On Occasion.

2. *Title:* Incident and Annual Reports for Gas Pipeline Operators.

OMB Control Number: 2137–0522.

Current Expiration Date: October 31, 2017.

Abstract: This rulemaking action will result in a modification to three gas incident forms to include the concept of ''confirmed discovery'' as amended in this rule. Operators will be required to include the date and time of the confirmed discovery of a natural gas pipeline incident. PHMSA does not expect this revision to increase the burden of reporting.

Affected Public: Gas pipeline operators.

Annual Reporting and Recordkeeping Burden:

Total Annual Responses: 12,164.

Total Annual Burden Hours: 92,321.

Frequency of Collection: On occasion.

3. *Title:* ''National Registry of Pipeline and LNG Operators''

OMB Control Number: 2137–0627.

Current Expiration Date: May 31, 2018.

Abstract: The National Registry of Pipeline and LNG Operators serves as the storehouse of data on regulated operators or those subject to reporting requirements under 49 CFR parts 192, 193, or 195. This registry incorporates the use of two forms: (1) The Operator Assignment Request Form (PHMSA F 1000.1) and, (2) the Operator Registry Notification Form (PHMSA F 1000.2). This rule amends § 191.22 to require operators to notify PHMSA upon the occurrence of the following: Construction of 10 or more miles of a new or replacement pipeline; construction of a new LNG plant or LNG facility; reversal of product flow direction when the reversal is expected to last more than 30 days; if a pipeline is converted for service under § 192.14, or has a change in commodity as reported on the annual report as required by § 191.17.

These notifications are estimated to be rare but would fall under the scope of Operator Notifications required by PHMSA as a result of this rule. PHMSA estimates that this new reporting requirement will add 10 new responses and 10 annual burden hours to the currently approved information collection.

Affected Public: Operators of PHMSA-Regulated Pipelines.

Annual Reporting and Recordkeeping Burden:

Total Annual Responses: 640.

Total Annual Burden Hours: 640.

Frequency of Collection: On occasion.

4. *Title:* ''Post-Accident Drug Testing for Pipeline Operators''

OMB Control Number: Will request one from OMB.

Current Expiration Date: New Collection—To be determined.

Abstract: This rule amends 49 CFR 199.227 to require operators to retain records for three years if they decide not to administer post-accident/incident drug testing on affected employees). As a result, operators who choose not to perform post-accident drug and alcohol tests on affected employees are required to keep records explaining their decision not to do so. PHMSA estimates this recordkeeping requirement will result in 609 responses and 1,218 burden hours for recordkeeping. PHMSA does not currently have an information collection which covers this requirement and will request the approval of this new collection, along with a new OMB Control Number, from the Office of Management and Budget.

Affected Public: Operators of PHMSA-Regulated Pipelines.

Annual Reporting and Recordkeeping Burden:

Total Annual Responses: 609.

Total Annual Burden Hours: 1,218.

Frequency of Collection: On occasion.

Requests for copies of these information collections should be directed to Angela Dow, Office of Pipeline Safety (PHP–30), Pipeline and Hazardous Materials Safety Administration, 2nd Floor, 1200 New Jersey Avenue SE., Washington, DC 20590–0001. Telephone: 202–366–1246.

Unfunded Mandates Reform Act of 1995

This final rule does not impose unfunded mandates under the Unfunded Mandates Reform Act of 1995. Public Law 104–4. PHMSA has determined that the rule does not impose annual expenditures on State, local, or tribal governments of the private sector in excess of $155 million, and thus, does not require an Unfunded Mandates Act analysis.[7]

National Environmental Policy Act

The National Environmental Policy Act, 42 U.S.C. 4321 through 4375, requires that Federal agencies analyze rulemaking actions to determine whether those actions will have a significant impact on the human environment. The Council on Environmental Quality regulations, 40 CFR parts 1500–1508, require Federal agencies to conduct an environmental review considering: (1) The need for the regulatory action, (2) alternatives to the regulatory action, (3) probable environmental impacts of the regulatory action and alternatives, and (4) the agencies and persons consulted during the rulemaking development process. 40 CFR 1508.9(b).

1. Purpose and Need

PHMSA's mission is to protect people and the environment from the risks of hazardous materials transportation. The purpose of this rulemaking action is to enhance pipeline integrity and safety to lessen the frequency and consequences of pipeline incidents that cause environmental degradation, personal injury, and loss of life.

The need for this action stems from the statutory mandates in sections 9 and 13 of the 2011 Act, NTSB recommendations, and the need to add new reference material and make non substantive edits. Section 9 of the 2011 Act directs PHMSA to require a specific time limit for telephonic or electronic reporting of pipeline accidents and incidents, and section 13 of the 2011 Act allows PHMSA to recover costs associated with pipeline design reviews. NTSB has made recommendations regarding the clarification of OQ requirements in control rooms, and to eliminate operator discretion with regard to post-accident drug and alcohol

[7] The Unfunded Mandates Act threshold was $100 million in 1995. Using the non-seasonally adjusted CPI–U (Index series CUUR000SA0), that number is $155 million in 2014 dollars.

testing of covered employees. In addition, PHMSA's safety regulations require periodic updates and clarifications to enhance compliance and overall safety.

2. Alternatives

In developing this rulemaking action, PHMSA considered two alternatives:

(1) No action, or

(2) Amend revisions to the pipeline safety regulations to incorporate the amendments as described in this document.

Alternative 1: PHMSA has an obligation to ensure the safe and effective transportation of hazardous liquids and gases by pipeline. The changes in this rulemaking action serve that purpose by clarifying the pipeline safety regulations and addressing Congressional mandates and NTSB safety recommendations. A failure to undertake these actions would be non-responsive to the Congressional mandates and the NTSB recommendations. Accordingly, PHMSA rejected the ''no action'' alternative.

Alternative 2: PHMSA is making certain amendments and non-substantive changes to the pipeline safety regulations to add a specific time frame for telephonic or electronic notifications of accidents and incidents and add provisions for cost recovery for design reviews of certain new projects, for the renewal of expiring special permits, and to request PHMSA keep submitted information confidential. PHMSA is also making changes to the drug and alcohol testing requirements, control room team training requirements, and is providing methods for assessment tools by incorporating consensus standards by reference for ILI and SCCDA.

3. Analysis of Environmental Impacts

The Nation's pipelines are located throughout the United States in a variety of diverse environments; from offshore locations, to highly populated urban sites, to unpopulated rural areas. The pipeline infrastructure is a network of over 2.6 million miles of pipelines that move millions of gallons of hazardous liquids and over 55 billion cubic feet of natural gas daily. The biggest source of energy is petroleum, including oil and natural gas. Together, these commodities supply 65 percent of the energy in the United States.

The physical environments potentially affected by this rule includes the airspace, water resources (*e.g.,* oceans, streams, lakes), cultural and historical resources (*e.g.,* properties listed on the National Register of Historic Places), biological and ecological resources (*e.g.,* coastal zones, wetlands, plant and animal species and their habitats, forests, grasslands, offshore marine ecosystems), and special ecological resources (*e.g.,* threatened and endangered plant and animal species and their habitats, national and State parklands, biological reserves, wild and scenic rivers) that exist directly adjacent to and within the vicinity of pipelines.

Because the pipelines subject to this rule contain hazardous materials, resources within the physically affected environments, as well as public health and safety, may be affected by pipeline incidents such as spills and leaks. Incidents on pipelines can result in fires and explosions, resulting in damage to the local environment. In addition, since pipelines often contain gas streams laden with condensates and natural gas liquids, failures also result in spills of these liquids, which can cause environmental harm. Depending on the size of a spill or gas leak and the nature of the impact zone, the impacts could vary from property damage and environmental damage to injuries or, on rare occasions, fatalities.

The amendments are improvements to the existing pipeline safety requirements and would have little or no impact on the human environment. On a national scale, the cumulative environmental damage from pipelines would most likely be reduced slightly.

For these reasons, PHMSA has concluded that neither of the alternatives discussed above would result in any significant impacts on the environment.

Preparers: This Environmental Assessment was prepared by DOT staff from PHMSA and Volpe National Transportation Systems Center (Office of the Secretary for Research and Technology (OST–R)).

4. Finding of No Significant Impact

PHMSA has determined that the selected alternative would have a positive, non-significant, impact on the human environment.

Executive Order 13132

PHMSA has analyzed this rule according to Executive Order 13132, ''Federalism,'' 64 FR 43255. The rule does not have a substantial direct effect on the States, the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government. This rule does not impose substantial direct compliance costs on State and local governments. This rule does not preempt State law for intrastate pipelines. Therefore, the consultation and funding requirements of Executive Order 13132 do not apply.

Executive Order 13211

This rule is not a ''significant energy action'' under Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use,'' 66 FR 28355. It is not likely to have a significant adverse effect on supply, distribution, or energy use. Further, the Office of Information and Regulatory Affairs has not designated this rule as a significant energy action.

Regulation Identifier Number

A regulation identifier number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in spring and fall of each year. The RIN contained in the heading of this document can be used to cross-reference this action with the United Agenda.

List of Subjects

49 CFR Part 190

Administrative practice and procedure, Penalties, Cost recovery, Special permits.

49 CFR Part 191

Incident, Pipeline safety, Reporting and recordkeeping requirements, Reversal of flow.

49 CFR Part 192

Control room, Distribution integrity management program, Gathering lines, Incorporation by reference, Operator qualification, Pipeline safety, Safety devices, Security measures.

49 CFR Part 195

Ammonia, Carbon dioxide, Control room, Corrosion control, Direct and indirect costs, Gathering lines, Incident, Incorporation by reference, Operator qualification, Petroleum, Pipeline safety, Reporting and recordkeeping requirements, Reversal of flow, and Safety devices.

49 CFR Part 199

Alcohol testing, Drug testing, Pipeline safety, Reporting and recordkeeping requirements, Safety, and Transportation.

In consideration of the foregoing, PHMSA is amending 49 CFR parts 190, 191, 192, 195, and 199 as follows:

PART 190—PIPELINE SAFETY ENFORCEMENT AND REGULATORY PROCEDURES

■ 1. The authority citation for part 190 continues to read as follows:

Authority: 33 U.S.C. 1321(b); 49 U.S.C. 60101 *et seq.;* 49 CFR 1.97.

■ 2. In § 190.3, add the definition ''New and novel technologies'' in alphabetical order to read as follows:

§ 190.3 Definitions.

* * * * *

New and novel technologies means any products, designs, materials, testing, construction, inspection, or operational procedures that are not addressed in 49 CFR parts 192, 193, or 195, due to technology or design advances and innovation for new construction. Technologies that are addressed in consensus standards that are incorporated by reference into parts 192, 193, and 195 are not ''new or novel technologies.''

* * * * *

■ 3. Amend § 190.341 by:
■ a. Revising paragraph (c)(8) and removing paragraph (c)(9) and revising paragraph (d);
■ b. Re-designating paragraphs (e) through (j) as paragraphs (g) through (l) and adding new paragraphs (e) and (f).

The additions and revisions read as follows:

§ 190.341 Special permits.

* * * * *

(c) * * *

(8) Any other information PHMSA may need to process the application including environmental analysis where necessary.

(d) *How does PHMSA handle special permit applications?*—(1) *Public notice.* Upon receipt of an application or renewal of a special permit, PHMSA will provide notice to the public of its intent to consider the application and invite comment. In addition, PHMSA may consult with other Federal agencies before granting or denying an application or renewal on matters that PHMSA believes may have significance for proceedings under their areas of responsibility.

(2) *Grants, renewals, and denials.* If the Associate Administrator determines that the application complies with the requirements of this section and that the waiver of the relevant regulation or standard is not inconsistent with pipeline safety, the Associate Administrator may grant the application, in whole or in part, for a period of time from the date granted. Conditions may be imposed on the grant if the Associate Administrator concludes they are necessary to assure safety, environmental protection, or are otherwise in the public interest. If the Associate Administrator determines that the application does not comply with the requirements of this section or that a waiver is not justified, the application will be denied. Whenever the Associate Administrator grants or denies an application, notice of the decision will be provided to the applicant. PHMSA will post all special permits on its Web site at *http://www.phmsa.dot.gov/.*

(e) *How does PHMSA handle special permit renewals?* (1) The grantee of the special permit must apply for a renewal of the permit 180 days prior to the permit expiration.

(2) If, at least 180 days before an existing special permit expires the holder files an application for renewal that is complete and conforms to the requirements of this section, the special permit will not expire until final administrative action on the application for renewal has been taken:

(i) Direct fax to PHMSA at: 202–366–4566; or

(ii) Express mail, or overnight courier to the Associate Administrator for Pipeline Safety, Pipeline and Hazardous Materials Safety Administration, 1200 New Jersey Avenue SE., Washington, DC 20590.

(f) *What information must be included in the renewal application?* (1) The renewal application must include a copy of the original special permit, the docket number on the special permit, and the following information as applicable:

(i) A summary report in accordance with the requirements of the original special permit including verification that the grantee's operations and maintenance plan (O&M Plan) is consistent with the conditions of the special permit;

(ii) Name, mailing address and telephone number of the special permit grantee;

(iii) Location of special permit—areas on the pipeline where the special permit is applicable including: Diameter, mile posts, county, and state;

(iv) Applicable usage of the special permit—original and future; and

(v) Data for the special permit segment and area identified in the special permit as needing additional inspections to include, as applicable:

(A) Pipe attributes: Pipe diameter, wall thickness, grade, seam type; and pipe coating including girth weld coating;

(B) Operating Pressure: Maximum allowable operating pressure (MAOP); class location (including boundaries on aerial photography);

(C) High Consequence Areas (HCAs): HCA boundaries on aerial photography;

(D) Material Properties: Pipeline material documentation for all pipe, fittings, flanges, and any other facilities included in the special permit. Material documentation must include: Yield strength, tensile strength, chemical composition, wall thickness, and seam type;

(E) Test Pressure: Hydrostatic test pressure and date including pressure and temperature charts and logs and any known test failures or leaks;

(F) In-line inspection (ILI): Summary of ILI survey results from all ILI tools used on the special permit segments during the previous five years or latest ILI survey result;

(G) Integrity Data and Integration: The following information, as applicable, for the past five (5) years: Hydrostatic test pressure including any known test failures or leaks; casings(any shorts); any in-service ruptures or leaks; close interval survey (CIS) surveys; depth of cover surveys; rectifier readings; test point survey readings; alternating current/direct current (AC/DC) interference surveys; pipe coating surveys; pipe coating and anomaly evaluations from pipe excavations; stress corrosion cracking (SCC), selective seam weld corrosion (SSWC) and hard spot excavations and findings; and pipe exposures from encroachments;

(H) In-service: Any in-service ruptures or leaks including repair type and failure investigation findings; and

(I) Aerial Photography: Special permit segment and special permit inspection area, if applicable.

(2) PHMSA may request additional operational, integrity or environmental assessment information prior to granting any request for special permit renewal.

(3) The existing special permit will remain in effect until PHMSA acts on the application for renewal by granting or denying the request.

* * * * *

■ 4. Section 190.343 is added to subpart D read as follows:

§ 190.343 Information made available to the public and request for protection of confidential commercial information.

When you submit information to PHMSA during a rulemaking proceeding, as part of your application for special permit or renewal, or for any other reason, we may make that information publicly available unless you ask that we keep the information confidential.

(a) *Asking for protection of confidential commercial information.* You may ask us to give confidential treatment to information you give to the agency by taking the following steps:

(1) Mark ''confidential'' on each page of the original document you would like to keep confidential.

(2) Send us, along with the original document, a second copy of the original document with the confidential commercial information deleted.

(3) Explain why the information you are submitting is confidential commercial information.

(b) *PHMSA decision.* PHMSA will treat as confidential the information that you submitted in accordance with this section, unless we notify you otherwise. If PHMSA decides to disclose the information, PHMSA will review your request to protect confidential commercial information under the criteria set forth in the Freedom of Information Act (FOIA), 5 U.S.C. 552, including following the consultation procedures set out in the Departmental FOIA regulations, 49 CFR 7.29. If PHMSA decides to disclose the information over your objections, we will notify you in writing at least five business days before the intended disclosure date.

■ 5. In part 190, subpart E is added to read as follows:

Subpart E—Cost Recovery for Design Reviews

Sec.

§ 190.401 Scope.

If PHMSA conducts a facility design and/or construction safety review or inspection in connection with a proposal to construct, expand, or operate a gas, hazardous liquid or carbon dioxide pipeline facility, or a liquefied natural gas facility that meets the applicability requirements in § 190.403, PHMSA may require the applicant proposing the project to pay the costs incurred by PHMSA relating to such review, including the cost of design and construction safety reviews or inspections.

§ 190.403 Applicability.

The following paragraph specifies which projects will be subject to the cost recovery requirements of this section.

(a) This section applies to any project that—

(1) Has design and construction costs totaling at least $2,500,000,000, as periodically adjusted by PHMSA, to take into account increases in the Consumer Price Index for all urban consumers published by the Department of Labor, based on—

(i) The cost estimate provided to the Federal Energy Regulatory Commission in an application for a certificate of public convenience and necessity for a gas pipeline facility or an application for authorization for a liquefied natural gas pipeline facility; or

(ii) A good faith estimate developed by the applicant proposing a hazardous liquid or carbon dioxide pipeline facility and submitted to the Associate Administrator. The good faith estimate for design and construction costs must include all of the applicable cost items contained in the Federal Energy Regulatory Commission application referenced in § 190.403(a)(1)(i) for a gas or LNG facility. In addition, an applicant must take into account all survey, design, material, permitting, right-of way acquisition, construction, testing, commissioning, start-up, construction financing, environmental protection, inspection, material transportation, sales tax, project contingency, and all other applicable costs, including all segments, facilities, and multi-year phases of the project;

(2) Uses new or novel technologies or design, as defined in § 190.3.

(b) The Associate Administrator may not collect design safety review fees under this section and 49 U.S.C. 60301 for the same design safety review.

(c) The Associate Administrator, after receipt of the design specifications, construction plans and procedures, and related materials, determines if cost recovery is necessary. The Associate Administrator's determination is based on the amount of PHMSA resources needed to ensure safety and environmental protection.

§ 190.405 Notification.

For any new pipeline facility construction project in which PHMSA will conduct a design review, the applicant proposing the project must notify PHMSA and provide the design specifications, construction plans and procedures, project schedule and related materials at least 120 days prior to the commencement of any of the following activities: Route surveys for construction, material manufacturing, offsite facility fabrications, construction equipment move-in activities, onsite or offsite fabrications, personnel support facility construction, and any offsite or onsite facility construction. To the maximum extent practicable, but not later than 90 days after receiving such design specifications, construction plans and procedures, and related materials, PHMSA will provide written comments, feedback, and guidance on the project.

§ 190.407 Master Agreement.

PHMSA and the applicant will enter into an agreement within 60 days after PHMSA received notification from the applicant provided in § 190.405, outlining PHMSA's recovery of the costs associated with the facility design safety review.

(a) A Master Agreement, at a minimum, includes:

(1) Itemized list of direct costs to be recovered by PHMSA;

(2) Scope of work for conducting the facility design safety review and an estimated total cost;

(3) Description of the method of periodic billing, payment, and auditing of cost recovery fees;

(4) Minimum account balance which the applicant must maintain with PHMSA at all times;

(5) Provisions for reconciling differences between total amount billed and the final cost of the design review, including provisions for returning any excess payments to the applicant at the conclusion of the project;

(6) A principal point of contact for both PHMSA and the applicant; and

(7) Provisions for terminating the agreement.

(8) A project reimbursement cost schedule based upon the project timing and scope.

(b) [Reserved]

§ 190.409 Fee structure.

The fee charged is based on the direct costs that PHMSA incurs in conducting the facility design safety review (including construction review and inspections), and will be based only on costs necessary for conducting the facility design safety review. ''Necessary for'' means that but for the facility design safety review, the costs would not have been incurred and that the costs cover only those activities and items without which the facility design safety review cannot be completed.

(a) Costs qualifying for cost recovery include, but are not limited to—

(1) Personnel costs based upon total cost to PHMSA;

(2) Travel, lodging and subsistence;

(3) Vehicle mileage;

(4) Other direct services, materials and supplies;

(5) Other direct costs as may be specified in the Master Agreement.

(b) [Reserved]

§ 190.411 Procedures for billing and payment of fee.

All PHMSA cost calculations for billing purposes are determined from the best available PHMSA records.

(a) PHMSA bills an applicant for cost recovery fees as specified in the Master Agreement, but the applicant will not be billed more frequently than quarterly.

(1) PHMSA will itemize cost recovery bills in sufficient detail to allow independent verification of calculations.

(2) [Reserved]

(b) PHMSA will monitor the applicant's account balance. Should the account balance fall below the required minimum balance specified in the Master Agreement, PHMSA may request at any time the applicant submit payment within 30 days to maintain the minimum balance.

(c) PHMSA will provide an updated estimate of costs to the applicant on or near October 1st of each calendar year.

(d) Payment of cost recovery fees is due within 30 days of issuance of a bill for the fees. If payment is not made within 30 days, PHMSA may charge an annual rate of interest (as set by the Department of Treasury's Statutory Debt Collection Authorities) on any outstanding debt, as specified in the Master Agreement.

(e) Payment of the cost recovery fee by the applicant does not obligate or prevent PHMSA from taking any particular action during safety inspections on the project.

PART 191—TRANSPORTATION OF NATURAL AND OTHER GAS BY PIPELINE; ANNUAL REPORTS, INCIDENT REPORTS, AND SAFETY-RELATED CONDITION REPORTS

■ 6. The authority citation for part 191 is revised to read as follows:

Authority: 49 U.S.C. 5121, 60102, 60103, 60104, 60108, 60117, 60118, 60124, 60132, and 60141; and 49 CFR 1.97.

■ 7. In § 191.3, add the definition ''Confirmed Discovery'' in alphabetical order to read as follows:

§ 191.3 Definitions.

* * * * *

Confirmed Discovery means when it can be reasonably determined, based on information available to the operator at the time a reportable event has occurred, even if only based on a preliminary evaluation.

* * * * *

■ 8. In § 191.5, paragraph (a) is revised and paragraph (c) is added to read as follows:

§ 191.5 Immediate notice of certain incidents.

(a) At the earliest practicable moment following discovery, but no later than one hour after confirmed discovery, each operator must give notice in accordance with paragraph (b) of this section of each incident as defined in § 191.3.

* * * * *

(c) Within 48 hours after the confirmed discovery of an incident, to the extent practicable, an operator must revise or confirm its initial telephonic notice required in paragraph (b) of this section with an estimate of the amount of product released, an estimate of the number of fatalities and injuries, and all other significant facts that are known by the operator that are relevant to the cause of the incident or extent of the damages. If there are no changes or revisions to the initial report, the operator must confirm the estimates in its initial report.

■ 9. In § 191.22, paragraph (c)(1)(ii) is revised and paragraphs (c)(1)(v) and (c)(1)(vi) are added to read as follows:

§ 191.22 National Registry of Pipeline and LNG operators

* * * * *

(c) * * *

(1) * * *

(ii) Construction of 10 or more miles of a new or replacement pipeline;

* * * * *

(v) Reversal of product flow direction when the reversal is expected to last more than 30 days. This notification is not required for pipeline systems already designed for bi-directional flow; or

(vi) A pipeline converted for service under § 192.14 of this chapter, or a change in commodity as reported on the annual report as required by § 191.17.

* * * * *

PART 192—TRANSPORTATION OF NATURAL AND OTHER GAS BY PIPELINE: MINIMUM FEDERAL SAFETY STANDARDS

■ 10. The authority citation for part 192 is revised to read as follows:

Authority: 49 U.S.C. 5103, 60102, 60104, 60108, 60109, 60110, 60113, 60116, 60118, 60137, 60141; and 49 CFR 1.97.

■ 11. In § 192.14, paragraph (c) is added to read as follows

§ 192.14 Conversion to service subject to this part.

* * * * *

(c) An operator converting a pipeline from service not previously covered by this part must notify PHMSA 60 days before the conversion occurs as required by § 191.22 of this chapter.

■ 12. In Section 192.175, paragraph (b) is revised to read as follows:

§ 192.175 Pipe-type and bottle-type holders.

* * * * *

(b) Each pipe-type or bottle-type holder must have minimum clearance from other holders in accordance with the following formula:

C = (3D*P*F)/1000) in inches; (C = (3D*P*F*)/6,895) in millimeters

in which:

C = Minimum clearance between pipe containers or bottles in inches (millimeters).
D = Outside diameter of pipe containers or bottles in inches (millimeters).
P = Maximum allowable operating pressure, psi (kPa) gauge.
F = Design factor as set forth in § 192.111 of this part.

■ 13. In § 192.225, paragraph (a) is revised to read as follows:

§ 192.225 Welding procedures.

(a) Welding must be performed by a qualified welder or welding operator in accordance with welding procedures qualified under section 5, section 12, Appendix A or Appendix B of API Std 1104 (incorporated by reference, *see* § 192.7), or section IX of the ASME Boiler and Pressure Vessel Code (ASME BPVC) (incorporated by reference, *see* § 192.7) to produce welds meeting the requirements of this subpart. The quality of the test welds used to qualify welding procedures must be determined by destructive testing in accordance with the applicable welding standard(s).

* * * * *

■ 14. In § 192.227, paragraph (a) is revised to read as follows:

§ 192.227 Qualification of welders.

(a) Except as provided in paragraph (b) of this section, each welder or welding operator must be qualified in accordance with section 6, section 12, Appendix A or Appendix B of API Std 1104 (incorporated by reference, *see* § 192.7), or section IX of the ASME Boiler and Pressure Vessel Code (ASME BPVC) (incorporated by reference, *see* § 192.7). However, a welder or welding operator qualified under an earlier edition than the listed in § 192.7 of this part may weld but may not requalify under that earlier edition.

* * * * *

■ 15. In § 192.631, paragraphs (b)(3) and (4) are revised, paragraph (b)(5) is added, paragraphs (h)(4) and (5) are revised, and paragraph (h)(6) is added to read as follows:

§ 192.631 Control room management.

* * * * *

(b) * * *

(3) A controller's role during an emergency, even if the controller is not the first to detect the emergency, including the controller's responsibility to take specific actions and to communicate with others;

(4) A method of recording controller shift-changes and any hand-over of responsibility between controllers; and

(5) The roles, responsibilities and qualifications of others with the authority to direct or supersede the specific technical actions of a controller.

* * * * *

(h) * * *

(4) Training that will provide a controller a working knowledge of the pipeline system, especially during the development of abnormal operating conditions;

(5) For pipeline operating setups that are periodically, but infrequently used, providing an opportunity for controllers to review relevant procedures in advance of their application; and

(6) Control room team training and exercises that include both controllers and other individuals, defined by the operator, who would reasonably be expected to operationally collaborate with controllers (control room personnel) during normal, abnormal or emergency situations. Operators must comply with the team training requirements under this paragraph by no later than January 23, 2018.

* * * * *

■ 16. Section 192.740 is added to read as follows:

§ 192.740 Pressure regulating, limiting, and overpressure protection—Individual service lines directly connected to production, gathering, or transmission pipelines.

(a) This section applies, except as provided in paragraph (c) of this section, to any service line directly connected to a production, gathering, or transmission pipeline that is not operated as part of a distribution system.

(b) Each pressure regulating or limiting device, relief device (except rupture discs), automatic shutoff device, and associated equipment must be inspected and tested at least once every 3 calendar years, not exceeding 39 months, to determine that it is:

(1) In good mechanical condition;

(2) Adequate from the standpoint of capacity and reliability of operation for the service in which it is employed;

(3) Set to control or relieve at the correct pressure consistent with the pressure limits of § 192.197; and to limit the pressure on the inlet of the service regulator to 60 psi (414 kPa) gauge or less in case the upstream regulator fails to function properly; and

(4) Properly installed and protected from dirt, liquids, or other conditions that might prevent proper operation.

(c) This section does not apply to equipment installed on service lines that only serve engines that power irrigation pumps.

■ 17. Section 192.1003 is revised to read as follows:

§ 192.1003 What do the regulations in this subpart cover?

(a) *General.* Unless exempted in paragraph (b) of this section this subpart prescribes minimum requirements for an IM program for any gas distribution pipeline covered under this part, including liquefied petroleum gas systems. A gas distribution operator, other than a master meter operator or a small LPG operator, must follow the requirements in §§ 192.1005 through 192.1013 of this subpart. A master meter operator or small LPG operator of a gas distribution pipeline must follow the requirements in § 192.1015 of this subpart.

(b) *Exceptions.* This subpart does not apply to an individual service line directly connected to a transmission, gathering, or production pipeline.

PART 195—TRANSPORTATION OF HAZARDOUS LIQUIDS BY PIPELINE

■ 18. The authority citation for part 195 continues to read as follows:

Authority: 49 U.S.C. 5103, 60102, 60104, 60108, 60109, 60116, 60118, 60132, 60137, and 49 CFR 1.97.

■ 19. In § 195.2, add the definitions ''Confirmed discovery,'' ''In-Line Inspection (ILI),'' ''In-Line Inspection Tool or Instrumented Internal Inspection Device,'' and ''Significant stress corrosion cracking'' in alphabetical order to read as follows:

§ 195.2 Definitions.

* * * * *

Confirmed Discovery means when it can be reasonably determined, based on information available to the operator at the time a reportable event has occurred, even if only based on a preliminary evaluation.

* * * * *

In-Line Inspection (ILI) means the inspection of a pipeline from the interior of the pipe using an in-line inspection tool. Also called *intelligent* or *smart pigging.*

In-Line Inspection Tool or *Instrumented Internal Inspection Device* means a device or vehicle that uses a non-destructive testing technique to inspect the pipeline from the inside. Also known as *intelligent* or *smart pig.*

* * * * *

Significant Stress Corrosion Cracking means a stress corrosion cracking (SCC) cluster in which the deepest crack, in a series of interacting cracks, is greater than 10% of the wall thickness and the total interacting length of the cracks is equal to or greater than 75% of the critical length of a 50% through-wall flaw that would fail at a stress level of 110% of SMYS.

* * * * *

■ 20. In § 195.3:

■ a. Add paragraph (b)(23);

■ b. Revise paragraph (c)(2);

■ c. Redesignate paragraphs (d) through (h) as (e) through (i) respectively and add a new paragraph (d); and

■ d. Amend newly redesignated paragraph (g) by adding paragraphs (g)(3) and (4); and

■ e. Revise newly redesignated paragraph (i)(1).

The additions and revisions read as follows:

§ 195.3 Incorporation by reference.

* * * * *

(b) * * *

(23) API Standard 1163, ''In-Line Inspection Systems Qualification'' Second edition, April 2013, (API Std 1163), IBR approved for § 195.591.

* * * * *

(c) * * *

(2) ASME/ANSI B31G–1991 (Reaffirmed 2004), ''Manual for Determining the Remaining Strength of Corroded Pipelines,'' 2004, (ASME/ANSI B31G), IBR approved for §§ 195.452(h); 195.587; and 195.588(c).

* * * * *

(d) American Society for Nondestructive Testing, P.O. Box 28518, 1711 Arlingate Lane, Columbus, OH 43228. *https://asnt.org.*

(1) ANSI/ASNT ILI–PQ–2005(2010), ''In-line Inspection Personnel Qualification and Certification'' reapproved October 11, 2010, (ANSI/ASNT ILI–PQ), IBR approved for § 195.591.

(2) [Reserved]

* * * * *

(g) * * *

(3) NACE SP0102–2010, ''Standard Practice, Inline Inspection of Pipelines'' revised March 13, 2010, (NACE SP0102), IBR approved for § 195.591.

(4) NACE SP0204–2008, ''Standard Practice, Stress Corrosion Cracking (SSC) Direct Assessment Methodology'' reaffirmed September 18, 2008, (NACE SP0204), IBR approved for § 195.588(c).

* * * * *

(i) * * *

(1) AGA Pipeline Research Committee, Project PR–3–805 ''A Modified Criterion for Evaluating the Remaining Strength of Corroded Pipe,'' December 22, 1989, (PR–3–805 (RSTRING)). IBR approved for §§ 195.452(h); 195.587; and 195.588(c).

* * * * *

■ 21. In § 195.5, paragraph (d) is added to read as follows:

§ 195.5 Conversion to service subject to this part.

* * * * *

(d) An operator converting a pipeline from service not previously covered by this part must notify PHMSA 60 days before the conversion occurs as required by § 195.64.

■ 22. In § 195.52, paragraph (a) introductory text and paragraph (d) are revised to read as follows:

§ 195.52 Immediate notice of certain accidents.

(a) *Notice requirements.* At the earliest practicable moment following discovery, of a release of the hazardous liquid or carbon dioxide transported resulting in an event described in § 195.50, but no later than one hour after confirmed discovery, the operator of the system must give notice, in accordance with paragraph (b) of this section of any failure that:

* * * * *

(d) *New information.* Within 48 hours after the confirmed discovery of an accident, to the extent practicable, an operator must revise or confirm its initial telephonic notice required in paragraph (b) of this section with a revised estimate of the amount of product released, location of the failure, time of the failure, a revised estimate of the number of fatalities and injuries, and all other significant facts that are known by the operator that are relevant to the cause of the accident or extent of the damages. If there are no changes or revisions to the initial report, the operator must confirm the estimates in its initial report.

§ 195.64 [Amended]

■ 23. In § 195.64, in paragraph (a), the term ''hazardous liquid'' is removed and replaced with the term ''hazardous liquid or carbon dioxide'' in the first sentence.

■ 24. In § 195.64, paragraph (c)(1)(ii) is revised and paragraphs (c)(1)(iii) and (iv) are added to read as follows:

§ 195.64 National Registry of Pipeline and LNG operators

* * * * *

(c) * * *

(1) * * *

(ii) Construction of 10 or more miles of a new or replacement hazardous liquid or carbon dioxide pipeline;

(iii) Reversal of product flow direction when the reversal is expected to last more than 30 days. This notification is not required for pipeline systems already designed for bi-directional flow; or

(iv) A pipeline converted for service under § 195.5, or a change in commodity as reported on the annual report as required by § 195.49.

* * * * *

■ 25. In § 195.120, the section heading and paragraph (a) are revised to read as follows:

§ 195.120 Passage of In-Line Inspection tools.

(a) Except as provided in paragraphs (b) and (c) of this section, each new pipeline and each replacement of line pipe, valve, fitting, or other line component in a pipeline must be designed and constructed to accommodate the passage of an In-Line Inspection tool, in accordance with NACE SP0102–2010, Section 7 (incorporated by reference, *see* § 195.3).

* * * * *

■ 26. In § 195.214, paragraph (a) is revised to read as follows:

§ 195.214 Welding procedures.

(a) Welding must be performed by a qualified welder or welding operator in accordance with welding procedures qualified under section 5, section 12, Appendix A or Appendix B of API Std 1104 (incorporated by reference, see § 195.3), or Section IX of the ASME Boiler and Pressure Vessel Code (ASME BPVC) (incorporated by reference, *see* § 195.3). The quality of the test welds used to qualify the welding procedures must be determined by destructive testing.

* * * * *

■ 27. In § 195.222, paragraph (a) is revised to read as follows:

§ 195.222 Welders and welding operators: Qualification of welders and welding operators.

(a) Each welder or welding operator must be qualified in accordance with section 6, section 12, Appendix A or Appendix B of API Std 1104 (incorporated by reference, *see* § 195.3), or section IX of the ASME Boiler and Pressure Vessel Code (ASME BPVC), (incorporated by reference, *see* § 195.3) except that a welder or welding operator qualified under an earlier edition than listed in § 195.3, may weld but may not requalify under that earlier edition.

* * * * *

§ 195.248 [Amended]

■ 28. In § 195.248, the phrase ''100 feet (30 millimeters)'' is removed and ''100 feet (30.5 meters)'' is added in its place in the table to paragraph (a).

■ 29. In § 195.446, revise paragraphs (b)(3) and (4), add paragraph (b)(5), revise paragraphs (h)(4) and (5), and add paragraph (h)(6) to read as follows:

§ 195.446 Control room management.

* * * * *

(b) * * *

(3) A controller's role during an emergency, even if the controller is not the first to detect the emergency, including the controller's responsibility to take specific actions and to communicate with others;

(4) A method of recording controller shift-changes and any hand-over of responsibility between controllers; and

(5) The roles, responsibilities and qualifications of others who have the authority to direct or supersede the specific technical actions of controllers.

* * * * *

(h) * * *

(4) Training that will provide a controller a working knowledge of the pipeline system, especially during the development of abnormal operating conditions;

(5) For pipeline operating setups that are periodically, but infrequently used, providing an opportunity for controllers to review relevant procedures in advance of their application; and

(6) Control room team training and exercises that include both controllers and other individuals, defined by the operator, who would reasonably be expected to operationally collaborate with controllers (control room personnel) during normal, abnormal or emergency situations. Operators must comply with the team training requirements under this paragraph no later than January 23, 2018.

* * * * *

■ 30. In § 195.452, paragraph (a)(4) is added and paragraphs (c)(1)(i)(A) and (j)(5)(i) are revised to read as follows:

§ 195.452 Pipeline integrity management in high consequence areas.

(a) * * *

(4) Low stress pipelines as specified in § 195.12.

* * * * *

(c) * * *

(1) * * *

(i) * * *

(A) In-Line Inspection tool or tools capable of detecting corrosion and deformation anomalies, including dents, gouges, and grooves. For pipeline segments that are susceptible to cracks

(pipe body and weld seams), an operator must use an in-line inspection tool or tools capable of detecting crack anomalies. When performing an assessment using an In-Line Inspection Tool, an operator must comply with § 195.591;

* * * * *

(j) * * *

(5) * * *

(i) In-Line Inspection tool or tools capable of detecting corrosion and deformation anomalies, including dents, gouges, and grooves. For pipeline segments that are susceptible to cracks (pipe body and weld seams), an operator must use an in-line inspection tool or tools capable of detecting crack anomalies. When performing an assessment using an In-Line Inspection tool, an operator must comply with § 195.591;

* * * * *

■ 31. In § 195.588, paragraph (a) is revised and paragraph (c) is added to read as follows:

§ 195.588 What standards apply to direct assessment?

(a) If you use direct assessment on an onshore pipeline to evaluate the effects of external corrosion or stress corrosion cracking, you must follow the requirements of this section. This section does not apply to methods associated with direct assessment, such as close interval surveys, voltage gradient surveys, or examination of exposed pipelines, when used separately from the direct assessment process.

* * * * *

(c) If you use direct assessment on an onshore pipeline to evaluate the effects of stress corrosion cracking, you must develop and follow a Stress Corrosion Cracking Direct Assessment plan that meets all requirements and recommendations of NACE SP0204–2008 (incorporated by reference, *see* § 195.3) and that implements all four steps of the Stress Corrosion Cracking Direct Assessment process including pre-assessment, indirect inspection, detailed examination and post-assessment. As specified in NACE SP0204–2008, Section 1.1.7, Stress Corrosion Cracking Direct Assessment is complementary with other inspection methods such as in-line inspection or hydrostatic testing and is not necessarily an alternative or replacement for these methods in all instances. In addition, the plan must provide for—

(1) *Data gathering and integration.* An operator's plan must provide for a systematic process to collect and evaluate data to identify whether the conditions for stress corrosion cracking are present and to prioritize the segments for assessment in accordance with NACE SP0204–2008, Sections 3 and 4, and Table 1. This process must also include gathering and evaluating data related to SCC at all sites an operator excavates during the conduct of its pipeline operations (both within and outside covered segments) where the criteria in NACE SP0204–2008 indicate the potential for Stress Corrosion Cracking Direct Assessment. This data gathering process must be conducted in accordance with NACE SP0204–2008, Section 5.3, and must include, at a minimum, all data listed in NACE SP0204–2008, Table 2. Further, an operator must analyze the following factors as part of this evaluation:

(i) The effects of a carbonate-bicarbonate environment, including the implications of any factors that promote the production of a carbonate-bicarbonate environment such as soil temperature, moisture, factors that affect the rate of carbon dioxide generation, and/or cathodic protection.

(ii) The effects of cyclic loading conditions on the susceptibility and propagation of SCC in both high-pH and near-neutral-pH environments.

(iii) The effects of variations in applied cathodic protection such as overprotection, cathodic protection loss for extended periods, and high negative potentials.

(iv) The effects of coatings that shield cathodic protection when disbonded from the pipe.

(v) Other factors that affect the mechanistic properties associated with SCC including but not limited to operating pressures, high tensile residual stresses, and the presence of sulfides.

(2) *Indirect inspection.* In addition to the requirements and recommendations of NACE SP0204–2008, Section 4, the plan's procedures for indirect inspection must include provisions for conducting at least two different, but complementary, indirect assessment electrical surveys, and the basis on the selections as the most appropriate for the pipeline segment based on the data gathering and integration step.

(3) *Direct examination.* In addition to the requirements and recommendations of NACE SP0204–2008, Section 5, the plan's procedures for direct examination must provide for conducting a minimum of four direct examinations within the SCC segment at locations determined to be the most likely for SCC to occur.

(4) *Remediation and mitigation.* If any indication of SCC is discovered in a segment, an operator must mitigate the threat in accordance with one of the following applicable methods:

(i) Non-significant SCC, as defined by NACE SP0204–2008, may be mitigated by either hydrostatic testing in accordance with paragraph (b)(4)(ii) of this section, or by grinding out with verification by Non-Destructive Examination (NDE) methods that the SCC defect is removed and repairing the pipe. If grinding is used for repair, the remaining strength of the pipe at the repair location must be determined using ASME/ANSI B31G or RSTRENG (incorporated by reference, *see* § 195.3) and must be sufficient to meet the design requirements of subpart C of this part.

(ii) Significant SCC must be mitigated using a hydrostatic testing program with a minimum test pressure between 100% up to 110% of the specified minimum yield strength for a 30-minute spike test immediately followed by a pressure test in accordance with subpart E of this part. The test pressure for the entire sequence must be continuously maintained for at least 8 hours, in accordance with subpart E of this part. Any test failures due to SCC must be repaired by replacement of the pipe segment, and the segment retested until the pipe passes the complete test without leakage. Pipe segments that have SCC present, but that pass the pressure test, may be repaired by grinding in accordance with paragraph (c)(4)(i) of this section.

(5) *Post assessment.* In addition to the requirements and recommendations of NACE SP0204–2008, sections 6.3, periodic reassessment, and 6.4, effectiveness of Stress Corrosion Cracking Direct Assessment, the plan's procedures for post assessment must include development of a reassessment plan based on the susceptibility of the operator's pipe to Stress Corrosion Cracking as well as on the behavior mechanism of identified cracking. Factors to be considered include, but are not limited to:

(i) Evaluation of discovered crack clusters during the direct examination step in accordance with NACE SP0204–2008, sections 5.3.5.7, 5.4, and 5.5;

(ii) Conditions conducive to creation of the carbonate-bicarbonate environment;

(iii) Conditions in the application (or loss) of cathodic protection that can create or exacerbate SCC;

(iv) Operating temperature and pressure conditions;

(v) Cyclic loading conditions;

(vi) Conditions that influence crack initiation and growth rates;

(vii) The effects of interacting crack clusters;

(viii) The presence of sulfides; and

(ix) Disbonded coatings that shield CP from the pipe.

■ 32. Section 195.591 is added to read as follows:

§ 195.591 In-Line inspection of pipelines.

When conducting in-line inspection of pipelines required by this part, each operator must comply with the requirements and recommendations of API Std 1163, *Inline Inspection Systems Qualification Standard;* ANSI/ASNT ILI–PQ, *Inline Inspection Personnel Qualification and Certification;* and NACE SP0102–2010, *Inline Inspection of Pipelines* (incorporated by reference, see § 195.3). An in-line inspection may also be conducted using tethered or remote control tools provided they generally comply with those sections of NACE SP0102–2010 that are applicable.

PART 199—DRUG AND ALCOHOL TESTING

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

Authority: 49 U.S.C. 5103, 60102, 60104, 60108, 60117, and 60118; 49 CFR 1.97.

■ 34. In § 199.105, paragraph (b) is revised to read as follows:

§ 199.105 Drug tests required.

* * * * *

(b) *Post-accident testing.* (1) As soon as possible but no later than 32 hours after an accident, an operator must drug test each surviving covered employee whose performance of a covered function either contributed to the accident or cannot be completely discounted as a contributing factor to the accident. An operator may decide not to test under this paragraph but such a decision must be based on specific information that the covered employee's performance had no role in the cause(s) or severity of the accident.

(2) If a test required by this section is not administered within the 32 hours following the accident, the operator must prepare and maintain its decision stating the reasons why the test was not promptly administered. If a test required by paragraph (b)(1) of this section is not administered within 32 hours following the accident, the operator must cease attempts to administer a drug test and must state in the record the reasons for not administering the test.

* * * * *

■ 35. In § 199.117, paragraph (a)(5) is added to read as follows:

§ 199.117 Recordkeeping.

(a) * * *

(5) Records of decisions not to administer post-accident employee drug tests must be kept for at least 3 years.

* * * * *

■ 36. In § 199.119, paragraphs (a) and (b) are revised to read as follows:

§ 199.119 Reporting of anti-drug testing results.

(a) Each large operator (having more than 50 covered employees) must submit an annual Management Information System (MIS) report to PHMSA of its anti-drug testing using the MIS form and instructions as required by 49 CFR part 40 (at § 40.26 and appendix H to part 40), not later than March 15 of each year for the prior calendar year (January 1 through December 31). The Administrator may require by notice in the PHMSA Portal (*https://portal.phmsa.dot.gov/phmsaportallanding*) that small operators (50 or fewer covered employees), not otherwise required to submit annual MIS reports, to prepare and submit such reports to PHMSA.

(b) Each report required under this section must be submitted electronically at *http://damis.dot.gov.* An operator may obtain the user name and password needed for electronic reporting from the PHMSA Portal (*https://portal.phmsa.dot.gov/phmsaportallanding*). If electronic reporting imposes an undue burden and hardship, the operator may submit a written request for an alternative reporting method to the Information Resources Manager, Office of Pipeline Safety, Pipeline and Hazardous Materials Safety Administration, 1200 New Jersey Avenue SE., Washington, DC 20590. The request must describe the undue burden and hardship. PHMSA will review the request and may authorize, in writing, an alternative reporting method. An authorization will state the period for which it is valid, which may be indefinite. An operator must contact PHMSA at 202–366–8075, or electronically to *informationresourcesmanager@dot.gov* to make arrangements for submitting a report that is due after a request for alternative reporting is submitted but before an authorization or denial is received.

* * * * *

■ 37. In § 199.225, the introductory text and paragraph (a)(1) are revised to read as follows:

§ 199.225 Alcohol tests required.

Each operator must conduct the following types of alcohol tests for the presence of alcohol:

(a) * * *

(1) As soon as practicable following an accident, each operator must test each surviving covered employee for alcohol if that employee's performance of a covered function either contributed to the accident or cannot be completely discounted as a contributing factor to the accident. The decision not to administer a test under this section must be based on specific information that the covered employee's performance had no role in the cause(s) or severity of the accident.

* * * * *

■ 38. In § 199.227, paragraph (b)(4) is added to read as follows:

§ 199.227 Retention of records.

* * * * *

(b) * * *

(4) *Three years.* Records of decisions not to administer post-accident employee alcohol tests must be kept for a minimum of three years.

* * * * *

■ 39. In § 199.229, paragraphs (a) and (c) are revised as follows:

§ 199.229 Reporting of alcohol testing results.

(a) Each large operator (having more than 50 covered employees) must submit an annual MIS report to PHMSA of its alcohol testing results using the MIS form and instructions as required by 49 CFR part 40 (at § 40.26 and appendix H to part 40), not later than March 15 of each year for the prior calendar year (January 1 through December 31). The Administrator may require by notice in the PHMSA Portal (*https://portal.phmsa.dot.gov/phmsaportallanding*) that small operators (50 or fewer covered employees), not otherwise required to submit annual MIS reports, to prepare and submit such reports to PHMSA.

* * * * *

(c) Each report required under this section must be submitted electronically at *http://damis.dot.gov.* An operator may obtain the user name and password needed for electronic reporting from the PHMSA Portal (*https://portal.phmsa.dot.gov/phmsaportallanding*). If electronic reporting imposes an undue burden and hardship, the operator may submit a written request for an alternative reporting method to the Information Resources Manager, Office of Pipeline Safety, Pipeline and Hazardous Materials Safety Administration, 1200 New Jersey Avenue SE., Washington, DC 20590. The request must describe the undue burden and hardship. PHMSA will review the request and may authorize, in writing, an alternative

reporting method. An authorization will state the period for which it is valid, which may be indefinite. An operator must contact PHMSA at 202–366–8075, or electronically to *informationresourcesmanager@dot.gov* to make arrangements for submitting a report that is due after a request for alternative reporting is submitted but before an authorization or denial is received.

* * * * *

Issued in Washington, DC, on December 22, 2016, under authority delegated in 49 CFR Part 1.97.

Marie Therese Dominguez,

Administrator.

[FR Doc. 2016–31461 Filed 1–19–17; 8:45 am]

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Part IV

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 1132

Tobacco Product Standard for N-Nitrosonornicotine Level in Finished Smokeless Tobacco Products; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1132

[Docket No. FDA–2016–N–2527]

Tobacco Product Standard for N-Nitrosonornicotine Level in Finished Smokeless Tobacco Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing a tobacco product standard that would establish a limit of N-nitrosonornicotine (NNN) in finished smokeless tobacco products. FDA is taking this action because NNN is a potent carcinogenic agent found in smokeless tobacco products and is a major contributor to the elevated cancer risks associated with smokeless tobacco use. Because products with higher NNN levels pose higher risks of cancer, FDA finds that establishing a NNN limit in finished smokeless tobacco products is appropriate for the protection of the public health.

DATES: Submit either electronic or written comments on the proposed rule by April 10, 2017. In accordance with 21 CFR 10.40(c), in finalizing this rulemaking FDA will review and consider all comments submitted before the time for comment on this proposed regulation has expired. If your comment is submitted after the expiration of the comment period, it will not be reviewed and considered by FDA unless you apply for, and receive, an extension of the comment period pursuant to 21 CFR 10.40(b)(3). Submit comments on information collection issues under the Paperwork Reduction Act of 1995 (the PRA) by February 22, 2017, (see the ''Paperwork Reduction Act of 1995'' section). See section VII of this document for the proposed effective date of a final ruled based on this document.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–N–2527 for ''Tobacco Product Standard for N-nitrosonornicotine Level in Finished Smokeless Tobacco Products.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit comments on information collection issues to the Office of Management and Budget in the following ways:

• Fax to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or email to *oira_submission@omb.eop.gov.* All comments should be identified with the title, Tobacco Product Standard: NNN Level in Finished Smokeless Tobacco Products.

FOR FURTHER INFORMATION CONTACT: Beth Buckler or Colleen Lee, Office of Regulations, Center for Tobacco Products (CTP), Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 877–287–1373, *CTPRegulations@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

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I. Executive Summary

A. Purpose of the Proposed Rule

FDA is proposing a tobacco product standard that would establish a limit of NNN in finished smokeless tobacco products sold in the United States. NNN is a potent carcinogenic agent found in smokeless tobacco products and is a major contributor to the elevated cancer risks associated with smokeless tobacco use. By FDA's estimates, in the 20 years following implementation of the proposed product standard, approximately 12,700 new cases of oral cancer and approximately 2,200 oral cancer deaths would be prevented in the United States because of this rule. Moreover, during that 20-year period, FDA estimates that approximately 15,200 life years would be gained as a result of the proposed standard. Because oral cancer is associated with significant health and economic impacts, we expect positive public health benefits due to prevention of new and fatal cancer cases. For the reasons discussed in the preamble of this rule, FDA finds that the proposed standard would be appropriate for the protection of the public health.

B. Summary of the Major Provisions of the Proposed Rule

This proposed rule would establish a limit of NNN in finished smokeless tobacco products. Under the proposed rule, no person may manufacture, distribute, sell, or offer for distribution or sale within the United States a finished smokeless tobacco product that is not in compliance with the product standard. However, the proposed rule would provide an exception for tobacco retailers and distributors; we would not consider tobacco retailers and distributors to be in violation of part 1132 as it relates to the sale or distribution of finished smokeless tobacco products that exceed the allowed NNN level if they meet certain criteria set forth in the rule.

The proposed rule would require that the mean level of NNN in any batch of finished smokeless tobacco products not exceed 1.0 microgram per gram (µg/g) of tobacco (on a dry weight basis) at any time through the product's labeled expiration date as determined by specified product testing. The rule would require that all finished smokeless tobacco products have an expiration date and provide that the expiration date be no later than the final date the manufacturer can demonstrate that the NNN level in the finished smokeless tobacco product conforms to the limit when the product is stored under its intended conditions (*e.g.,* room temperature or refrigeration).

To ensure that products conform to the product standard, the proposed rule would establish requirements for testing the products. Two types of testing would be required for smokeless tobacco products—stability testing and batch testing. Stability testing would be required to assess the stability of the NNN level in the finished smokeless tobacco products and to establish and verify the product's expiration date and storage conditions. In addition, each batch of finished smokeless tobacco product would be required to be tested to determine whether the products conform to the proposed NNN level. The proposed rule would also establish the standard test method (to be incorporated by reference) and requirements for using an alternative test method as well as the sampling requirements for all testing.

The proposed rule would require that the labels of finished smokeless tobacco products contain a manufacturing code, expiration date, and, if applicable, storage conditions for the finished smokeless tobacco product (such as refrigeration). In addition, the proposed rule would require manufacturers of finished smokeless tobacco products to establish and maintain certain records.

C. Legal Authority

This proposed rule is being issued upon FDA's authority to establish a tobacco product standard under section 907 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 387g) including authority related to the reduction of constituents or harmful components in tobacco products under section 907(a)(4)(A)(ii) and to the testing of tobacco products under section 907(a)(4)(B)(ii) through (iv); FDA's authorities related to the sale and distribution of tobacco products under sections 907(a)(4)(B)(v) and 906(d); FDA's authority to require tobacco product manufacturers to establish and maintain records under section 909 of the FD&C Act (21 U.S.C. 387i); FDA's authorities related to adulterated and misbranded tobacco products under sections 902 and 903 (21 U.S.C. 387b and 387c); FDA's authorities related to prohibited acts under section 301 of the FD&C Act (21 U.S.C. 331); and FDA's rulemaking and inspection authorities under sections 701 and 704 of the FD&C Act (21 U.S.C. 371 and 374).

D. Costs and Benefits

The costs of the proposed rule, when finalized, will be due to affected entities ensuring that the smokeless tobacco products comply with the proposed product standard. We have estimated the annualized costs associated with the proposed rule over 20 years to be between $17.91 million and $42.72 million using a 3 percent discount rate, with a primary value of $30.31 million, and between $20.11 million and $50.57 million, with a primary value of $35.34 million using a 7 percent discount rate. The primary estimate for the present value of total quantified costs over 20 years is approximately $450.97 million at a 3 percent discount rate and $374.36 million at a 7 percent discount rate.

NNN is a carcinogenic agent found in smokeless tobacco products. As described in the preamble of the proposed rule, on the basis of the available scientific evidence, FDA has determined that NNN is the predominant driver of excess oral cancer risk among smokeless tobacco users. We quantify benefits associated with the proposed rule in the form of reduced oral cancer morbidity and mortality attributable to smokeless tobacco. As described in section V.A.3 of the preamble of the proposed rule, we also expect the standard to reduce the risk of esophageal cancer, and it may reduce the risks of other cancers such as pancreatic, laryngeal, prostate, and lung cancer. However, there is more limited information to directly quantify these health benefits. As such, we only consider estimated reductions in oral cancer as the quantified benefit of the proposed product standard.

Most of the estimated benefits arise from quality life-years gains gained from reduced oral cancer mortality. The

annualized value over 20 years of quality adjusted life-years gained from reduced oral cancer mortality ranges from $228.66 million to $2.46 billion at a 3 percent discount rate, with a primary value of $858.46 million. Using a 7 percent discount rate, the annualized value of quality life-years gained from averted deaths ranges from $182.01 million to $1.96 billion, with a primary value of $683.34 million. The primary estimate of the present value of mortality reductions quantified over 20 years is $12.77 billion at a 3 percent discount rate and $7.24 billion at a 7 percent discount rate. The annualized value over 20 years of quality adjusted life-years gained from reduced oral cancer mortality and morbidity ranges from approximately $283.95 million to $3.05 billion at a 3 percent discount rate, with a primary value of $1.06 billion, and approximately $246.40 million to $2.65 billion, with a primary value of $0.92 billion at a 7 percent discount rate. The primary estimate of the present value of total quantified benefits over 20 years is approximately $15.86 billion at a 3 percent discount rate and $9.80 billion at a 7 percent discount rate for reductions in oral cancer alone. These values are likely an underestimate of the benefits associated with the proposed rule, as we do not quantify reductions in mortality and morbidity from cancers other than oral cancer. Costs and benefits are summarized in table 8 of the preamble of the proposed rule.

II. Background Information

A. Purpose

FDA is issuing this proposed rule to address the harm caused by the toxicant NNN in smokeless tobacco products. When Congress enacted the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) in 2009, it included the finding that ''the Food and Drug Administration is a regulatory agency with the scientific expertise to identify harmful substances in products to which consumers are exposed, [and] to design standards to limit exposure to those substances'' (section 2(44) of the Tobacco Control Act).

Smokeless tobacco products, including those currently marketed in the United States, have been demonstrated to cause certain types of cancer. Several authoritative reviews have been conducted on the relationship between smokeless tobacco use and cancer risk and have reached similar conclusions (Refs. 1, 2, 3, 4). The International Agency for Research on Cancer (IARC) concluded in its 2007 monograph ''Smokeless Tobacco and Some Tobacco-Specific Nitrosamines'' that there is sufficient evidence in humans to indicate that smokeless tobacco is carcinogenic and that it causes oral and pancreatic cancer (Ref. 1). IARC confirmed these findings of the carcinogenicity of smokeless tobacco in a 2012 review, concluding that there is sufficient evidence in both humans and experimental animal studies that smokeless tobacco causes oral, esophageal, and pancreatic cancer (Ref. 2). In addition, a 2014 report on smokeless tobacco by the National Cancer Institute (NCI) and Centers for Disease Control and Prevention (CDC) estimated that smokeless tobacco use is responsible for approximately 1,600 new cases of oral cancer, 200 cases of esophageal cancer, and 500 cases of pancreatic cancer in the United States each year (Ref. 4).

NNN [1] is a potent carcinogenic agent found in smokeless tobacco products and is a major contributor to the elevated cancer risks associated with smokeless tobacco use (see section IV, Rationale for Developing a Standard for NNN, of this document). NNN levels vary substantially across subcategories of smokeless tobacco products (*e.g.,* moist snuff, chewing tobacco, dry snuff) and within product subcategories (*e.g.,* moist snuff) (Ref. 5, 10). International comparisons of oral cancer rates and smokeless tobacco products suggest that products with higher NNN levels may pose higher risks of cancer (Refs. 6, 100). FDA is using its authority to propose a standard that would reduce tobacco-related harms by establishing a limit of NNN in smokeless tobacco products sold in the United States (see section V of this document).

FDA is proposing that the standard would apply to finished smokeless tobacco products. Although NNN is also found in other tobacco products, this rule focuses solely on NNN levels in smokeless tobacco products, and not on additional products. Different measures are required to evaluate the contribution to cancer of NNN among users of other tobacco products, such as combustible products like cigarettes and dissolvable tobacco products that do not meet the statutory definition of ''smokeless tobacco product.'' For example, additional factors, such as polycyclic aromatic hydrocarbons (PAH), aldehydes and other chemicals (Refs. 147, 106), contribute to the cancer burden associated with combustible products, which make the relationship between NNN and cancer in these products different from that in smokeless tobacco products. With regard to dissolvable tobacco products that do not meet the statutory definition of smokeless tobacco, different product testing methods than the ones developed and available for smokeless tobacco, as described in this proposal, may be necessary to evaluate NNN in these products because they do not consist of cut, ground, powdered or leaf tobacco. Therefore, at this stage, FDA has chosen to focus on smokeless tobacco and has evaluated data relevant to establishing an NNN limit in smokeless tobacco products.

This proposed product standard would require that the mean level of NNN in any batch of finished smokeless tobacco products not exceed 1.0 µg/g of tobacco (on a dry weight basis) at any time through the product's labeled expiration date as determined by testing in compliance with § 1132.12 (proposed § 1132.10). FDA expects that, in the 20 years following implementation of the proposed product standard, approximately 12,700 new cases of oral cancer and approximately 2,200 oral cancer deaths would be prevented in the United States because of this rule. Moreover, during that 20-year period, approximately 15,200 life years would be gained in the United States as a result of the proposed standard. We believe that the main source of variability in the estimated impacts would be different assumptions about oral cancer relative risks due to smokeless tobacco use. Using alternate relative risk estimates that are somewhat lower and higher than our main estimate results in approximately 7,300 to 24,000 new cases of oral cancer prevented and 1,300 to 4,200 oral cancer deaths prevented over the 20-year period. Because oral cancer is associated with significant health and economic impacts, we expect positive public health benefits due to prevention of new and fatal cancer cases. These benefits are discussed in detail in section V of this proposed rule. Accordingly, based on the information discussed in the following sections of the preamble to this proposed rule, FDA finds that the proposed standard would be appropriate for the protection of the public health.

B. Legal Authority

1. Product Standard

The Tobacco Control Act was enacted on June 22, 2009, amending the FD&C Act and providing FDA with the authority to regulate tobacco products (Pub. L. 111–31; 123 Stat. 1776). Among

[1] Since 2012, manufacturers have been required to test and report to FDA the levels of harmful and potentially harmful constituents (HPHCs), including NNN, in each tobacco product (section 904(A)(3) of the FD&C Act).

the authorities provided to FDA is the authority to establish tobacco product standards. To establish a tobacco product standard, section 907(a)(3)(A) and (B) of the FD&C Act (21 U.S.C. 387g(a)(3)(A) and (B)) requires that we find that the standard is appropriate for the protection of the public health, taking into consideration scientific evidence concerning:

- The risks and benefits of the proposed standard to the population as a whole, including users and nonusers of tobacco products;
- The increased or decreased likelihood that existing users of tobacco products will stop using such products; and
- The increased or decreased likelihood that those who do not use tobacco products will start using such products.

2. NNN Limit

Section 907 of the FD&C Act authorizes FDA to promulgate tobacco product standards that are appropriate for the protection of the public health, including provisions, where appropriate, for the reduction or elimination of constituents or harmful components of tobacco products (section 907(a)(4)(A)(ii) of the FD&C Act). This proposed rule would limit the level of NNN in finished smokeless tobacco products. To ensure that finished smokeless tobacco products comply with the proposed NNN level, FDA also is including provisions to require that tobacco product manufacturers test their products on a sample basis (*i.e.,* batch testing) using a specified testing procedure for conformance with the limit pursuant to section 907(a)(4)(B)(ii) and (iv) of the FD&C Act.

3. Sale and Distribution Restrictions

Section 907(a)(4)(B)(v) states that product standards must, where appropriate for the protection of public health, include provisions requiring that the sale and distribution of the tobacco products be restricted but only to the extent that the sale and distribution of a tobacco product may be restricted under section 906(d). Similar to section 907, section 906(d) of the FD&C Act gives FDA authority to require restrictions on the sale and distribution of tobacco products by regulation if the Agency determines that such regulation would be appropriate for the protection of the public health. The finding as to whether a sales and distribution regulation is appropriate for the protection of the public health must be determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco products, and must take into account:

- The increased or decreased likelihood that existing users of tobacco products will stop using such products; and
- The increased or decreased likelihood that those who do not use tobacco products will start using such products (see section 906(d)(1) of the FD&C Act).

Under these authorities along with section 701, which provides FDA with the authority to ''promulgate regulations for the efficient enforcement of this Act,'' FDA is including provisions to restrict the manufacture, sale, and distribution of finished smokeless tobacco products that are not in compliance with this standard. Specifically, FDA is proposing to require that no person may manufacture, distribute, sell, or offer for distribution or sale within the United States a finished smokeless tobacco product that is not in compliance with part 1132 (proposed § 1132.1(b)). However, tobacco retailers and distributors would not be considered in violation of part 1132 as it relates to the sale or distribution or offer for sale or distribution of finished smokeless tobacco products that exceed the NNN level required in proposed § 1132.10 if they: (1) Store and transport the finished smokeless tobacco products according to the package label, (2) do not sell or distribute or offer for sale or distribution finished smokeless tobacco products past their expiration date, except to return expired products to the manufacturer, (3) do not conceal, alter or remove the expiration date or storage conditions on the package label, and (4) do not sell or distribute or offer for sale or distribution finished smokeless tobacco products that are open or have broken seals (proposed § 1132.1(c)). FDA is proposing this exception for tobacco retailers and distributors because they are not in a position to know or to confirm by testing whether the smokeless tobacco products they are selling or distributing or offering for sale or distribution comply with the proposed NNN level.

FDA is also proposing, under these authorities, to require that the labels of finished smokeless tobacco products contain a manufacturing code, expiration date, and, if applicable, storage conditions for the finished smokeless tobacco product (proposed § 1132.30). The labeling requirement for storage conditions is also consistent with FDA's authority under section 907(a)(4)(C), which provides that a product standard shall, where appropriate, require the use and prescribe the format and content of labeling for the proper use of the tobacco product. These label requirements would enable FDA to determine whether a product on store shelves purports to comply with the standard, link the product to its manufacturing history so that compliance with the standard can be verified, provide traceability of the product in the event of a nonconforming product investigation and corrective action, and ensure that the product is handled and stored under appropriate conditions, in accordance with the standard. In addition, the proposed manufacturing code would serve as a common identifier that will provide a history of the manufacturing, processing, packaging, labeling, holding, and initial distribution of the tobacco product from records maintained by the smokeless tobacco product manufacturer. The expiration date would also inform retailers that the manufacturer has not demonstrated compliance with the standard beyond the date after which the product should not be sold to consumers.

Manufacturers would be responsible for ensuring that finished smokeless tobacco products contain labels with a manufacturing code, expiration date, and, if applicable, storage conditions prior to sale and commercial distribution. In addition, retailers and distributors would be responsible for not selling or distributing or offering for sale or distribution finished smokeless tobacco products that lack the required labels, not concealing, altering, or removing the expiration date or storage conditions on the package label, not selling or distributing or offering for sale or distribution finished smokeless tobacco products after their expiration date (except to return expired product to the manufacturer), not selling or distributing or offering for sale or distribution finished tobacco products that are open or have broken seals, and, if applicable, storing finished smokeless tobacco product in accordance with the package label.

Because these requirements would assist FDA in enforcing the standard and would ensure that manufacturers and retailers are selling product that complies with the standard, the Agency has found all of these requirements to be appropriate for the protection of the public health consistent with sections 907(a)(4)(B)(v) and 906(d).

4. Testing Requirements

FDA's proposed rule contains provisions regarding testing requirements under sections

907(a)(4)(B) and 907(a)(4)(A)(iii) of the FD&C Act to ensure that finished smokeless tobacco products conform to the requirements of the product standard before they are distributed to consumers and remain in conformance until their expiration date. Section 907(a)(4)(B)(ii) provides that a product standard must, where appropriate for the protection of public health, include ''provisions for the testing (on a sample basis or, if necessary, on an individual basis) of the tobacco product.'' In addition, section 907(a)(4)(B)(iv) provides that, where appropriate for the protection of public health, a product standard must include provisions requiring that the results of the tests of the tobacco product required under section 907(a)(4)(B)(ii) show that the product is in conformity with the portions of the standard for which the tests were required.

Consistent with these statutory provisions, proposed §§ 1132.12, 1132.14, 1132.16, and 1132.18 would establish product testing and sampling plan requirements. Proposed § 1132.12 would require two types of testing for smokeless tobacco products—stability testing and batch testing. Proposed § 1132.12(a) would require testing to assess the stability of the NNN level in finished smokeless tobacco products and to establish and verify the product's expiration date and storage conditions (either room temperature or refrigeration). Proposed § 1132.12(b) would require manufacturers to conduct testing on each batch of finished smokeless tobacco product to determine whether the products conform to the proposed NNN level. Proposed § 1132.12(c) would require the tobacco product manufacturer to document all testing. Proposed §§ 1132.14 and 1132.16 would establish the standard and alternative test methods, while § 1132.18 would establish the sampling requirements for all testing.

Section 907(a)(4)(A)(iii) states that product standards must include provisions that are appropriate for the protection of the public health, including provisions, where appropriate, relating to any requirement under subparagraph 907(a)(4)(B). As discussed, FDA is proposing specific testing requirements in §§ 1132.12, 1132.14, 1132.16, and 1132.18. To support these proposed requirements, proposed § 1132.22(b) would require that if the mean of the representative samples from any batch of a finished smokeless tobacco product is determined to be out of conformance with the requirements of § 1132.10, or a finished smokeless tobacco product's expiration date must be shortened due to the results of annual real-time stability testing, or if FDA notifies a tobacco product manufacturer that a distributed finished smokeless tobacco product does not conform to the requirements of part 1132, the manufacturer would have to conduct an investigation to determine the scope of the nonconformity and locations to which nonconforming products have been distributed. This proposed requirement would ensure that any reports of nonconforming products, whether as a result of manufacturer testing or otherwise, are examined and investigated and that appropriate measures are taken to ensure that additional nonconforming product batches are not distributed to consumers and to prevent future nonconformity.

FDA finds that such provisions are appropriate for the protection of the public health and relate to requirements under section 907(a)(4)(B) because they will help to ensure that the finished smokeless tobacco products are properly tested and conform to the requirements of the proposed product standard.

5. Recordkeeping

Section 909 of the FD&C Act authorizes FDA to require tobacco product manufacturers to establish and maintain records, make reports, and provide such information as the Agency may by regulation reasonably require to assure that a tobacco product is not adulterated or misbranded and to otherwise protect public health. In addition, section 701(a) of the FD&C Act authorizes FDA to promulgate regulations for the efficient enforcement of the FD&C Act. The recordkeeping requirements would help FDA with the efficient enforcement of the product standard issued under the FD&C Act.

FDA is proposing to require that manufacturers of smokeless tobacco products maintain records regarding the product testing (*i.e.,* stability and batch testing), including a full report of the source data and results; all notifications of an alternative test method and source data for alternative test method validation; all sampling plans and reports; documentation that the persons performing sampling have sufficient education, training, and experience to accomplish the assigned functions; all identification, investigation, segregation, and disposition procedures; and all nonconforming product investigations and rework (*i.e.,* the processing of nonconforming finished smokeless tobacco products to meet the requirements of part 1132).

FDA is also proposing to require copies of all records be retained for a period of not less than 4 years from the date of distribution of the finished smokeless tobacco product that is the subject of the record, except that certain records relating to alternative test methods would be required to be retained for a period of not less than 4 years after the last date the method is used. Retention of these records would help ensure that finished smokeless tobacco products are in conformance with the proposed standard and are not adulterated or misbranded.

C. Additional Considerations and Requests for Comment

1. Section 907 of the FD&C Act

FDA is required by section 907 of the FD&C Act to consider the following information submitted in connection with a proposed product standard:

- For a proposed product standard to require the reduction or elimination of an additive, constituent, or other component of a tobacco product because FDA has found that the additive, constituent, or other component is or may be harmful, scientific evidence submitted that demonstrates that the proposed standard will not reduce or eliminate the risk of illness or injury (section 907(a)(3)(B)(ii) of the FD&C Act).
- Information submitted regarding the technical achievability of compliance with the standard (section 907(b)(1) of the FD&C Act).
- All other information submitted, including information concerning the countervailing effects of the tobacco product standard on the health of adolescent tobacco users, adult tobacco users, or nontobacco users, such as the creation of a significant demand for contraband or other tobacco products that do not meet the requirements of Chapter IX of the FD&C Act and the significance of such demand (section 907(b)(2) of the FD&C Act).

As required by section 907(c)(2) of the FD&C Act, FDA invites interested persons to submit a draft or proposed tobacco product standard for the Agency's consideration (section 907(c)(2)(B)) and information regarding structuring the standard so as not to advantage foreign-grown tobacco over domestically grown tobacco (section 907(c)(2)(C)). In addition, FDA invites the Secretary of Agriculture to provide any information or analysis which the Secretary of Agriculture believes is relevant to the proposed tobacco product standard (section 907(c)(2)(D) of the FD&C Act).

FDA is requesting the documents and information described in this section with this proposed rule. Such documents and information may be

submitted in accordance with the ''Instructions'' included in the preliminary information section of this document.

Section 907(d)(5) of the FD&C Act allows the Agency to refer a proposed regulation for the establishment of a tobacco product standard to the Tobacco Products Scientific Advisory Committee (TPSAC) at the Agency's own initiative or in response to a request for good cause made before the expiration of the comment period. If FDA opts to refer this proposed regulation to TPSAC, the Agency will publish a notice in the **Federal Register** announcing the TPSAC meeting to discuss this proposal.

2. Pathways to Market

To legally market a new tobacco product in the United States, a tobacco product manufacturer must receive authorization from FDA permitting the marketing of the new tobacco product under one of three pathways for legally marketing a new tobacco product: (1) The manufacturer obtains an order under section 910(c)(1)(A)(i) of the FD&C Act (order after review of a premarket tobacco application under section 910(b)); (2) the manufacturer obtains an order finding the new product substantially equivalent to a predicate tobacco product and in compliance with the requirements of the FD&C Act under section 910(a)(2)(A)(i) (order after review of a substantial equivalence (SE) report submitted under section 905(j) of the FD&C Act); or (3) the manufacturer makes a request under 21 CFR 1107.1, obtains an exemption from the requirements related to substantial equivalence (section 905(j)(3)(A)), and at least 90 days before commercially marketing the product, submits a report under section 905(j) including the information required in section 905(j)(1)(A)(ii) and (j)(1)(B).

A smokeless tobacco product that has been modified to comply with the product standard would be a ''new tobacco product'' and subject to premarket review. FDA believes that changes made solely to bring a smokeless tobacco product in compliance with the proposed rule would be appropriate for an SE submission. We believe it is possible for manufacturers to modify their product so that it is both in compliance with the proposed product standard and substantially equivalent to an appropriate predicate product (*i.e.,* products that are grandfathered or SE).

FDA believes that manufacturers would likely choose to comply with the proposed standard in a manner that makes the modified products eligible for the SE pathway. For products that are eligible for an SE report, FDA is considering whether a change to the level of NNN in smokeless tobacco products could be reviewed with the submission of an SE report containing a reduced, specific set of information that focuses on the changes to the smokeless tobacco where the SE report demonstrates that the only modifications made to the new product were made to comply with the NNN product standard and do not present different questions of public health (*e.g.,* significant increase in another harmful or potentially harmful constituent (HPHC)). As there may be multiple modifications needed to comply with the product standard, FDA requests comments as to the type of modifications that may allow a reduced amount of information to proceed through the SE pathway, and what types of brief, specific supporting information submitted as part of a substantial equivalence application could demonstrate that modifications made to comply with this product standard do not cause the new product to raise different questions of public health.

III. Scope of Proposed Standard

Scientific evidence documents that smokeless tobacco products cause certain types of cancer (Refs. 1, 2, 3, 4). As discussed in section IV of this document, NNN is a potent carcinogenic agent found in smokeless tobacco products and is a major contributor to the elevated cancer risks associated with smokeless tobacco use (Refs. 7, 8, 1, 2).

FDA is issuing this proposed standard to address the harm to smokeless tobacco users caused by NNN by establishing a limit for NNN in finished smokeless tobacco products (see proposed § 1132.10), thereby reducing exposure to this harmful toxicant. NNN levels vary substantially across subcategories of smokeless tobacco products (*e.g.,* moist snuff, chewing tobacco, dry snuff) and within product subcategories (*e.g.,* moist snuff) (Ref. 5). Geographical comparisons show that oral cancer rates among smokeless tobacco users are higher in areas where smokeless tobacco products have higher NNN levels (Refs. 6, 100). Given this geographic variation and the toxicological evidence described in the preamble of this rule, we expect that lowering the level of NNN in smokeless tobacco products in the United States will lower the rate of oral cancers among smokeless tobacco users. FDA concludes that establishing a limit for NNN in finished smokeless tobacco products is appropriate for the protection of the public health (see section V of this document).

A. Smokeless Tobacco Products

The term ''smokeless tobacco'' covers a wide range of tobacco products that are used orally or nasally without combustion (Ref. 1). Smokeless tobacco is defined in section 900(18) of the FD&C Act as ''any tobacco product that consists of cut, ground, powdered, or leaf tobacco and that is intended to be placed in the oral or nasal cavity.'' This includes moist snuff, snus, dry snuff, chewing tobacco, and some dissolvables. Some dissolvable tobacco products do not meet the statutory definition of ''smokeless tobacco product'' because they do not contain cut, ground, powdered, or leaf tobacco; instead, these products contain nicotine extracted from tobacco. Dissolvable products that do not meet the statutory definition of ''smokeless tobacco product'' are not covered by this proposed rule.

Moist snuff is the most popular type of smokeless tobacco in the United States (Refs. 4, 131). It is typically made of fire-cured or air-cured tobacco that has been finely ground or shredded and fermented (Ref. 4). Moist snuff may contain up to 60 percent moisture and it is often flavored (*e.g.,* wintergreen) (Refs. 4, 10). It is sold as loose tobacco or in sachets or small pouches (Ref. 1). When loose moist snuff is used, a small amount (*e.g.,* a pinch or dip) is placed and held between the lip or cheek and gum and typically is held in the mouth for at least 30 minutes (Refs. 1, 5). Excess saliva may be spit out or swallowed (Ref. 1). When pouched moist snuff is used, a sachet or small pouch containing the tobacco is placed and held between the lip or cheek and gum but it does not require spitting (Ref. 9).

Snus is a type of moist snuff and it can have different characteristics depending on where it is manufactured. Swedish snus products generally have much lower levels of tobacco-specific nitrosamines (TSNAs) than smokeless tobacco products found in the United States (Refs. 5, 6, 10), and, therefore, they were of particular interest in the development of this proposed rule.

Swedish snus is commonly used in Sweden but it is relatively new to the U.S. market (Refs. 4, 11). It typically consists of low-nitrosamine tobacco that has been air-cured, moistened, ground, and heat treated (Refs. 4, 12, 11). Swedish snus may contain up to 50 percent moisture and some flavoring but no added sugars (Refs. 13, 14, 11). Swedish snus is sold as loose tobacco or in sachets (Refs. 4, 12, 11). It is placed between the cheek and gum and does not require spitting (Refs. 1, 15).

In Sweden, all snus manufacturers must adhere to the requirements of the Swedish Food Act. In addition, a smokeless tobacco manufacturer developed the GothiaTek voluntary standard, which establishes limits for the tobacco (*e.g.,* low-nitrosamine raw tobacco that has been air-cured or sun-cured) and other ingredients as well as the manufacturing process (Refs. 11, 4). The current GothiaTek standard for NNN and 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK) (combined) in snus is 0.95 µg/g wet weight [2] tobacco, which would be about 2 µg/g (combined NNN and NNK) dry weight tobacco (Refs. 13, 16). Swedish snus that is made using the GothiaTek standard tends to have lower levels of toxicants, including NNN, than other smokeless tobacco products in other countries (Ref. 4).

Swedish snus is usually refrigerated by retailers to maintain its quality and taste but refrigeration is not generally required to maintain stability because modern Swedish snus production techniques achieve very low levels of microbial activity and yield no new nitrosamine formation even when held at room temperature (Ref. 11). One of the methods used to limit microbial activity is pasteurization. In this process, the leaf tobacco is ground and subjected to heat treatment. The heating is achieved by combining the tobacco with water and salt, placed in closed process blenders, and using steam to achieve temperatures up to 80 to 100 °C for several hours (Ref. 11).

In recent years, some U.S. tobacco manufacturers began introducing snus products (*e.g.,* Marlboro Snus and Camel Snus) in the United States (Ref. 17). Some of the early marketing of these tobacco products emphasized the Swedish origins of snus but there is limited data available on whether the chemical composition or manufacturing processes of these products are equivalent to Swedish snus (Refs. 4, 18, 19). Studies indicate that early versions of these snus products would not comply with the current GothiaTek standard for NNN and NNK (*i.e.,* 0.95 µg/g per wet weight combined) (Ref. 13). From the limited information available, snus manufactured in the United States appears to consist of tobacco that has been air-cured or sun-cured and is pasteurized or heat treated (Refs. 20, 21). It may contain up to 34 percent moisture and may contain some flavoring, flavoring strip, and/or sweeteners (Ref. 4, 56). It is generally sold portioned in sachets or small pouches (Ref. 4).

Unlike the relatively higher moisture content of moist snuff, dry snuff usually has a moisture content of less than 10 percent (Ref. 1). Dry snuff is a powdered tobacco product that may be used orally or nasally, although nasal use is rare in the United States (Ref. 4). Typically dry snuff is made with tobacco that has been fire-cured, fermented, and finely ground or pulverized into a powder (Refs. 1, 4). A pinch or dip of dry snuff is typically held between the cheek and gum (Ref. 1).

Chewing tobacco is sold as loose leaf, plug, or twist. It is typically fire-cured or air-cured tobacco that has been fermented or aged (Refs. 4, 1). It may be flavored and sweetened and then processed into a plug, twist, or loose leaf (Refs. 4, 1). Chewing tobacco may be chewed or held in the mouth (*i.e.,* dipped) (Ref. 5).

Dissolvable tobacco products that are smokeless tobacco products are generally made of finely ground tobacco and sold as small lozenges, sticks (toothpick), or strips (Refs. 4, 5). Such dissolvable tobacco products may be flavored and may have a moisture content ranging from 1 to 20 percent, depending on the product (Refs. 9, 22, 56). As the name suggests, a dissolvable tobacco product is placed in the mouth until it dissolves.

B. Current Prevalence and Initiation Rates

In the United States, smokeless tobacco products are predominately used by men and high school age boys. According to the 2014 National Survey on Drug Use and Health, an estimated 8.7 million (3.3 percent) Americans aged 12 and over were current (any use in the past month) smokeless tobacco users (chewing tobacco or snuff) in 2014, which is generally similar to the percentage of smokeless tobacco users estimated by this study for most years from 2002 to 2013 (Ref. 23). An estimated 6.4 percent of males over the age of 12 were current smokeless tobacco users, while only 0.3 percent of females were current users (Ref. 24 at tables 2.9B, 2.10B). Among adults, the highest prevalence of current use of smokeless tobacco was observed among young adults aged 18 to 25 at 5.6 percent (Ref. 24 at 18). According to the National Youth Tobacco Survey, in 2015, there were an estimated 1.1 million middle and high school students that reported current (past 30 day) use of chewing tobacco, snuff or dip, snus, or dissolvable tobacco products (Ref. 25). The overall level of current smokeless tobacco product usage was 6 percent among high school students, and 1.8 percent among middle school students (Ref. 25). Among youth, the prevalence of smokeless tobacco use varies by sex and race. In 2015, 10 percent of male high school students reported current use of smokeless tobacco, including snus and dissolvables, compared with 1.8 percent of female high school students (Ref. 25). Among high school students, the prevalence of current use of smokeless tobacco, including snus and dissolvables, was highest among non-Hispanic White students (7.8 percent), followed by Hispanic students (4.8 percent), and non-Hispanic Black students (1.9 percent) (Ref. 25).

An estimated 1.0 million Americans aged 12 or older used smokeless tobacco for the first time in 2014 (Ref. 24 at table 4.5B). Nearly 75 percent of these new initiates were male and about 42 percent were under age 18 when they first used a smokeless tobacco product (Ref. 24 at tables 4.6B, 4.9A). The average age at first use of smokeless tobacco among recent initiates in 2014 was 19.0 years, which was similar to the 2013 estimate (Refs. 26, 24 at table 4.13B).

IV. Rationale for Developing a Standard for NNN

A. Smokeless Tobacco is Carcinogenic

The scientific evidence demonstrates that smokeless tobacco products cause certain types of cancer, and that cancer rates are higher in regions of the world where smokeless tobacco products have higher levels of NNN. In 1986, the Surgeon General of the United States released a report finding that ''users of smokeless tobacco products face a strongly increased risk of oral cancer'' (Ref. 27). In 2007, IARC classified smokeless tobacco as carcinogenic to humans (Group 1), concluding that sufficient evidence in humans demonstrate that smokeless tobacco causes cancers of the oral cavity and pancreas (Ref. 1). IARC confirmed these findings of the carcinogenicity of smokeless tobacco in a 2012 review, concluding that there is sufficient evidence in both humans and experimental animal studies that smokeless tobacco causes oral, esophageal, and pancreatic cancer (Ref. 2). The Scientific Committee on Emerging and Newly Identified Health Risks (Ref. 3) was tasked by the European Commission to evaluate the cancer risks of smokeless tobacco products, with particular attention to moist snuff, which, in the European Union is available only in Sweden, in the form of snus. It concluded in its

[2] The term ''wet weight'' refers to the weight of tobacco as used by the consumer, while the term ''dry weight'' refers to the weight of tobacco after the removal of water.

2008 review that smokeless tobacco products cause esophageal and pancreatic cancer in humans and that studies in the United States demonstrate an increased risk of oral cancer among smokeless tobacco users, however, the evidence for ''users of Swedish moist snuff (snus) is less clear'' (Ref. 3). More recently, the National Cancer Institute (NCI), National Institutes of Health, in coordination with the Centers for Disease Control and Prevention (CDC) published a report on smokeless tobacco use and health effects in 2014, concluding that smokeless tobacco use causes oral, esophageal, and pancreatic cancer (Ref. 4).

TABLE 1—CONCLUSIONS OF AUTHORITATIVE REVIEWS ON SMOKELESS TOBACCO AND CANCER RISK

Authoritative body	Year	Conclusions
Surgeon General of the United States.	1986	''In summary, users of smokeless tobacco products face a strongly increased risk of oral cancer, particularly for the tissues that come in contact with the tobacco.''
International Agency for Research on Cancer (IARC).	2007	''There is sufficient evidence in humans for the carcinogenicity of smokeless tobacco. Smokeless tobacco causes cancers of the oral cavity and pancreas.''
Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR).	2008	''STP [smokeless tobacco products] are carcinogenic to humans and the pancreas has been identified as a main target organ. All STP cause localised oral lesions and a high risk for development of oral cancer has been shown for various STP but the evidence for oral cancer in users of Swedish moist snuff (snus) is less clear.''
International Agency for Research on Cancer (IARC).	2012	''There is sufficient evidence in humans for the carcinogenicity of smokeless tobacco. Smokeless tobacco causes cancers of the oral cavity, oesophagus and pancreas.''
National Cancer Institute (NCI)	2014	''There is sufficient evidence that ST [smokeless tobacco] products cause addiction, precancerous oral lesions, and cancer of the oral cavity, esophagus, and pancreas, and adverse reproductive and developmental effects including stillbirth, preterm birth, and low birth weight.''

B. NNN in Smokeless Tobacco Products is Carcinogenic

Smokeless tobacco products contain thousands of chemical constituents, including carcinogens such as TSNAs (Refs. 2, 1, 4). TSNAs are formed from nitrosation, a chemical reaction between tobacco alkaloids (nicotine, nornicotine, anatabine, and anabasine) and nitrosating agents such as nitrite (Refs. 28, 2). Because TSNAs are formed from tobacco alkaloids, they are only found in tobacco products (Ref. 28).

In smokeless tobacco, TSNAs are present at a level capable of causing cancer (Ref. 4). Of the five TSNAs identified in tobacco products, NNN and 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK) have been classified by IARC as carcinogenic to humans (Group 1) (Refs. 2, 4).[3]

The relatively high level of these carcinogens has led the World Health Organization (WHO) to call for limits on these constituents in tobacco products (Ref. 78). Tobacco science researchers have also called for the reduction of TSNAs in smokeless tobacco products due to their potential impact on the increased cancer risk associated with smokeless tobacco use (Refs. 175, 176).

1. Evidence for NNN Carcinogenicity in Animals

There is sufficient evidence to indicate NNN may act as both a local and systemic carcinogen in experimental animals. Studies have shown that NNN given by various routes of administration consistently causes oral and esophageal tumors in rats, as well as nasal cavity and tracheal tumors across multiple species, with noted route- and species-specific differences (Refs. 7, 178, 148, 59, 94, 149 through 160). Rats are more likely to develop tumors in the esophagus, oral and nasal cavity following oral or subcutaneous exposure to NNN (Refs. 7, 59, 94, 95, 148, 149) whereas mice develop tumors in lung, forestomach, and to a limited extent liver (Refs. 155, 156, 160). In hamsters, tracheal tumors and nasal cavity tumors are observed following oral or intraperitoneal exposure to NNN (Refs. 59, 151), with tracheal tumors also observed following subcutaneous exposure (Ref. 152). Studies in experimental animals also demonstrate that NNN can induce tumor formation in a dose-dependent manner. For example, in rats, a dose-dependent formation of nasal cavity tumors has been observed following subcutaneous or oral exposure (via gastric instillation) to NNN (Refs. 149, 161). In hamsters, NNN stimulates tumors of the nasal cavity, trachea and liver in a dose-dependent manner following subcutaneous exposure (Ref. 151).

Although a dose-dependent relationship between oral and esophageal tumor formation following exposure to NNN has not been extensively studied, chronic oral exposure to NNN via drinking water clearly identifies oral cavity and esophageal tissues as the major targets of tumorigenesis in animals (Refs. 7, 95). As indicated previously, sites of tumor formation following exposure to NNN are not limited to oral and esophageal tissues. Studies in experimental animals demonstrate oral exposure to NNN stimulates tumor formation in other tissues, such as nasal cavity, stomach, lung and liver (Refs. 151, 155, 156, 161, 178, 179). However, the number of tumors observed in oral and esophageal tissues are often greater than the number of tumors observed in other, non-target tissues. For example, a greater number of rats were reported to develop tumors in the esophagus compared with the lung following exposure to NNN in liquid diet (Ref. 94). Another study reported a similar trend, with esophageal and oral tumors observed in 35 and 18 percent of rats exposed to NNN via oral gavage, respectively, whereas only 5 percent of exposed animals developed lung tumors (Ref. 178). A more recent study by Balbo et al. (Ref. 7) found that 100 percent of rats treated orally with NNN in their drinking water developed malignant oral tumors. A high incidence of esophageal tumors has been consistently observed in rats following oral exposure to NNN across studies, with 83 percent of animals developing esophageal tumors following exposure via liquid diet (Ref. 94) and 60 to 100 percent of animals developing esophageal tumors following exposure via drinking water (Refs. 148, 95, 59, 7).

The high incidence of tumor formation in esophageal and oral tissue observed in experimental animal studies is consistent with what is known regarding the metabolism of NNN and subsequent DNA adduct formation in target tissues. NNN is a genotoxic carcinogen, it reacts with DNA and is assumed to exhibit proportional

[3] Section IV.D.3 explains why FDA is not proposing a product standard for NNK levels in smokeless tobacco at this time.

responses at low doses (Refs. 168, 169). The general understanding of the mechanism of action (MOA) of NNN-induced carcinogenicity centers around its metabolic activation. The metabolic activation of NNN leads to the formation of DNA and hemoglobin adducts and subsequent mutagenicity, ultimately resulting in cancer. NNN can be metabolized by 2′-hydroxylation and 5′-hydroxylation, with the 2′-hydroxylation the more predominant metabolic pathway (Ref. 8). The noted DNA adducts formed from NNN are POB–DNA via the 2′-hydroxylation pathway (Refs. 172, 173, 177) and py-py-dI via the 5′-hydroxylation pathway (Ref. 169). NNN has a chiral center at the 2′-position and exists in 2 enantiomeric forms, (*R*)–NNN and (*S*)–NNN, with (*S*)–NNN being the predominant enantiomer in smokeless tobacco products (Refs. 180, 181).

The MOA for NNN-induced carcinogenicity is supported by the pattern of mutagenesis and DNA adduct formation in target tissues following oral exposure to NNN in experimental animals. For example, NNN was found to be mutagenic in tongue, oral and esophageal tissue in mice following oral exposure via drinking water (Ref. 174). Both POB–DNA and py-py-dI adducts have been detected in the oral cavity, esophageal mucosa, nasal cavity, liver and lung of rats following exposure to NNN via drinking water (Refs. 169 through 173). Additionally, dose-dependent formation of POB–DNA adducts has been observed in oral, esophageal and nasal mucosa following oral exposure to NNN (Ref. 170), as has py-py-dI (Ref. 169). A greater number of DNA adduct formation has been also been observed in oral and esophageal tissues compared with other sites, consistent with previous findings of increased tumor formation in oral and esophageal tissues compared with other sites (Refs. 94, 178). For example, POB-adduct formation was greater in oral cavity and esophageal mucosa compared with lung or liver in rats following oral exposure to (*S*)-NNN via drinking water (Refs. 171, 172). These findings are consistent with previous reports of increased oral and esophageal tumor formation as compared with other tissues (Refs. 94, 178) and the reported high incidence of oral and esophageal tumors following oral exposure to NNN in rats (Refs. 7, 95).

Recent evidence has demonstrated target organ specificity for the carcinogenic effects of NNN and NNK in animals and in humans. As previously discussed, NNN's carcinogenic effects have been documented in the esophagus, nasal, and oral cavities when administered orally to animals (Refs. 7, 59, 95, 148), which provides some degree of concordance with effects observed at these sites in epidemiological studies (Refs. 77, 96). In contrast, NNK is known for being a powerful systemic lung carcinogen. NNK causes lung tumors in animals, including mice, rats, and hamsters, independent of the route of administration (Refs. 8, 149, 162 through 167). Even when animals are given NNK orally, a dose-dependent formation of lung tumors is observed (Refs. 164, 165, 166). Indeed, a recent study found 100 percent of animals receiving NNK via oral exposure developed lung tumors (Ref. 167). However, no oral cavity or esophageal tumors have been reported in animals exposed only to NNK (Ref. 8).

2. Evidence for NNN Carcinogenicity in Humans

Although the data on NNN exposure in humans is more limited, two recent epidemiological studies have found strong associations between NNN and cancer risk among cigarette smokers, providing evidence that increased exposure to NNN through use of certain tobacco products is associated with greater risk of head, neck, and esophageal cancer in tobacco users. In one nested case-control study among Chinese men, urinary levels of NNN in smokers were significantly associated with increased risk of developing esophageal cancer, but not lung cancer, after controlling urinary total NNAL (used to measure NNK exposure), smoking intensity and duration, alcohol consumption, and urinary cotinine (nicotine metabolite used to measure nicotine exposure) (Ref. 77). In the same cohort, total urinary NNAL was independently and significantly associated with increased risk of developing lung cancer (Ref. 183), whereas no association was observed between urinary total NNAL and esophageal cancer risk (Ref 77). In a second case-control study, mean levels of NNN were significantly higher in cases diagnosed with head and neck squamous cell carcinoma compared to matched controls, although no adjustment was made for potential confounding factors (Ref. 96). Although these studies were conducted among smokers, they support the significant role of NNN in cancer development in humans and are highly relevant to smokeless tobacco users, who have comparable levels of exposure to NNN and NNK as those of cigarette users (Refs. 97, 72, 98, 99). Moreover, these epidemiological findings support the target organ specificity and cancer risk associated with exposure to NNN (oral and esophageal) versus NNK (lung) that are observed in experimental animals (see section IV.B.1).

3. Geographic Differences in Cancer Risks From Smokeless Tobacco Use

Although there is some heterogeneity among particular study estimates, research on the association between smokeless tobacco use and oral cancer risk generally has found significant differences in risk by geographic region. For the United States, Boffetta et al. analyzed nine oral cancer risk estimates from seven independent studies that either adjusted for smoking or were restricted to never smokers and found a summary relative risk for smokeless tobacco use of 2.6 (Ref. 100). Lee and Hamling published a separate analysis that generated an overall relative risk estimate of 2.16 from all available U.S. studies (Ref. 114). The authors also generated estimates of never smoker oral cancer relative risks (a relative risk of 3.33) for 5 studies and smoking-adjusted oral cancer relative risks (a relative risk of 1.65) for 12 studies for U.S. smokeless tobacco users. Toombak, a smokeless tobacco product commonly used in Sudan, has been found to have a relative risk for oral cancer of 3.9 (Refs. 104, 4), while in India and Pakistan use of smokeless tobacco products, including pattiwala, naswar, khaini, and zarda, was associated with relative risks for oral cancer as high as 14 (Ref. 1 at table 71). In Scandinavia, increased oral cancer risks were observed in some but not all studies (Refs. 92, 188, 189, 191, 192).

The geographic variations in oral cancer risks are believed to be due to differences in product toxicant content (Ref. 100). TSNA concentrations in smokeless tobacco products vary by product and region; NNN levels are generally lowest in snus manufactured in Sweden, while NNN levels in smokeless tobacco products sold in the United States are typically higher (Refs. 11, 13, 5, 10). Many smokeless tobacco products sold elsewhere in the world, including in India and Sudan, contain even higher levels of NNN and other carcinogens than those in the United States (Refs. 206, 105). These analyses, in addition to the toxicological evidence demonstrating that NNN is a potent oral cavity and esophageal carcinogen, provide strong support for a relationship between smokeless tobacco use, NNN levels in these products, and oral cancer risk by geographic region. Thus, FDA believes that reducing NNN levels in smokeless tobacco products would reduce cancer risk.

C. NNN in Smokeless Tobacco Products

1. Formation of NNN in Smokeless Tobacco Products

NNN is formed either by the nitrosation of nicotine with the loss of a methyl group or by nitrosation of nornicotine, primarily during the curing of tobacco (Ref. 29). Nicotine is a tertiary amine while nornicotine is a secondary amine; the rate of nitrosation of tertiary amines is slow compared to the rate of nitrosation of secondary amines (Ref. 30). As the concentration of nicotine in smokeless tobacco products is typically three orders of magnitude larger than the TSNA concentration, NNN formation does not have a significant impact on product nicotine levels (Refs. 5, 10).

The primary nitrosating agent is nitrite (Ref. 31). Reduction of nitrate by bacteria such as halotolerant micrococci, Coryneforms, and halophilic rods during the fermentation process is the primary source of nitrite in smokeless tobacco products (Ref. 34). Nitrogen-rich fertilizer is also a source of nitrate and, upon reduction, nitrite (Ref. 41). Higher NNN levels are found in tobacco crops fertilized with nitrogen-rich fertilizers compared to fertilizers with lower nitrogen content (Refs. 42, 34). Tobacco and smokeless tobacco products with low nitrite concentrations have low levels of NNN, while products high in nitrite contain higher concentrations of NNN (Refs. 32, 31).

There is limited evidence to support that an appreciable amount of NNN is formed from nicotine or its metabolites in humans (Refs. 193, 194). The reaction of dietary precursors with nitrosating agents supplied by the diet can result in the endogenous formation of N-nitrosamines in humans (Refs. 195, 196, 197). The acidic environment in the stomach creates favorable conditions for nitrosation to occur (Ref. 198) and nitrosation of nornicotine has been observed in vitro under simulated gastric conditions, whereas nitrosation of nicotine has not been observed (Ref. 199). To date, there is not sufficient data in humans to indicate any significant in vivo NNN synthesis.

NNK is primarily formed through nitrosation of nicotine during the later stages of tobacco processing (*i.e.,* curing and fermentation) (Ref. 33). Similar to NNN, the primary nitrosating agent is nitrite and products with low nitrite concentrations have low levels of NNK while products with high nitrite concentrations have high levels of NNK (Refs. 32, 31).

2. Factors That Influence NNN Levels

NNN levels in tobacco can vary significantly from year to year, intra-year, and farm-to-farm (Ref. 34). Although tobacco plants inherently produce a small amount of NNN (Refs. 35, 1), a wide variety of factors can affect the final levels of NNN found in the finished tobacco product (Ref. 1). These factors, which can either increase or decrease NNN levels in smokeless tobacco products, include the tobacco type (*e.g.,* dark air-cured tobacco, Bright leaf tobacco, Burley tobacco), growing conditions (*e.g.,* geographic region, climate, rainfall), curing techniques (*e.g.,* fire, flue, air, sun), production process (*e.g.,* additives), and storage conditions (*e.g.,* temperature, humidity, duration) (Ref. 1). As discussed in section IV.E, because there are many factors that can influence the NNN level in smokeless tobacco products, there also are a number of options available to manufacturers to reduce and control NNN levels in order to meet the requirements of this proposed standard.

a. Tobacco Type

Studies have shown differences in NNN levels prior to curing and processing among different varieties of tobacco. Higher NNN concentrations have been found in Burley and dark tobacco compared to flue-cured Bright leaf tobacco (Ref. 36). Burley tobacco also contains more NNN compared to Virginia and Oriental types, whether grown in the same or different geographical locations (Ref. 37).

The use of selectively bred ''low converter'' tobacco seed has been shown to result in lower nornicotine (precursor to NNN) levels in tobacco (Refs. 38, 39, 40). The amount of NNN in a tobacco variety before curing or processing is dependent on the amount of its precursor nornicotine, which in turn is dependent on the amount of its precursor nicotine (Ref. 38). Nornicotine is normally present at very low levels compared to nicotine, but tobacco plants, through a process called ''conversion,'' can convert some of their nicotine to nornicotine (Ref. 39). Low converter seeds come from plants which, through selective breeding and genetic engineering, have a lower potential to convert nicotine to nornicotine (Ref. 40).

b. Growing Conditions

- *Climate.* Weather is a significant factor in NNN formation. Increased rainfall, including more frequent intense weather systems such as hurricanes, correlate with higher levels of TSNAs (Ref. 34). Specifically, wetter conditions that increase relative humidity during the growing season are more conducive to increases in total TSNA formation.
- *Fertilizer.* Nitrogen rich fertilizer can also have a profound effect on nitrate and NNN levels found in tobacco (Ref. 41). Higher NNN levels are found in crops fertilized with nitrogen-rich fertilizers compared to fertilizers with lower nitrogen content (Refs. 42, 43, 34). This is because, when nitrogen-rich fertilizer is used during tobacco growing, more nitrogen is incorporated into the leaves of the tobacco in the form of nitrate. As the tobacco leaves are cured, the nitrate acts as a substrate for microorganisms reducing the nitrate to nitrite. The nitrite reacts with alkaloids such as nicotine or nornicotine in the tobacco during curing to form higher levels of TSNAs such as NNN.

c. Curing Techniques

There are four main methods for curing tobacco: Sun, air, flue, and fire curing. Sun-cured tobacco is cured on outdoor racks exposed to the sun while air-cured tobacco is cured on racks in a well-ventilated barn under ambient temperatures (Ref. 4). Flue and fire curing occur in artificially heated and ventilated barns. Flue-cured tobacco is cured on racks in a barn or other enclosed structure with an external heat source (*e.g.,* heat exchanger, propane or diesel heaters) so the tobacco isn't exposed to smoke (Refs. 34, 200). In contrast, fire-cured tobacco is cured on racks in a barn and exposed directly to smoke from a wood fire (Ref. 201). Curing can take from a few days to several weeks depending on the curing method (Ref. 44). The curing process not only dries out and preserves the tobacco but also imparts characteristic flavor.

During the curing process, the curing method, humidity, air flow, temperature, and the fuel used for heating the tobacco influence the extent to which the NNN level changes (Refs. 45, 46). Studies have shown that flue and fire-curing tobacco results in higher NNN levels than when the same tobacco is air-cured (Refs. 47, 42, 1). In addition, air-curing during periods of high relative humidity produces tobacco with higher amounts of TSNAs and nitrite (Ref. 46). However, TSNAs in tobacco were shown to be lower when cured by reducing humidity by improving the air circulation or by using an indirect heating source to limit exposure to smoke (Refs. 46, 48). Furthermore, direct flue curing with liquid propane gas leads to higher NNN levels than fire curing or indirect flue curing (Ref. 49).

d. Production Process

During production, microorganisms (bacteria, fungi, and yeast) on tobacco play a significant role in the generation of nitrite and the subsequent formation of TSNAs (Ref. 202). The microorganisms can come from a variety of sources including the soil and surrounding environment, or unsanitary manufacturing conditions (Ref. 12).

Fermentation is commonly used in the production of U.S. smokeless tobacco products. Fermentation imparts flavor and contributes to higher nitrite and NNN levels (Ref. 50). Reduction of nitrate by bacteria during the fermentation process is the primary source of nitrite in smokeless tobacco products (Ref. 34). The increased nitrite concentration subsequently contributes to the nitrosation of amino alkaloids and the formation of NNN.

In contrast, certain processing methods have been reported to help limit the levels of NNN formed during production. For example, using non-nitrate reducing bacteria during the fermentation process (*i.e.,* through seeding or starter culture) can lower NNN yields (Refs. 34, 51). Cleaning and sanitizing all equipment used in the processing and manufacturing of smokeless tobacco products, including the fermentation equipment, can lower microorganisms on tobacco and lower NNN yields (Ref. 34). In addition, using closed process blenders at a high temperature, adding bicarbonate and carbonate salt solutions to control pH, adding humectants, and pasteurization or heat treatment can lower microbial activity during production, leading to lower NNN levels in smokeless tobacco products (Ref. 11).

e. Storage Conditions

Storage conditions (*i.e.,* temperature and humidity) and the duration of storage have been shown to influence NNN levels. Cured tobacco leaves and finished smokeless tobacco products are stored until they are processed or consumed. Tobacco leaves are often stored on farms for up to 3 months prior to sale to tobacco product manufacturers. Once sold, the tobacco may be stored for another 18 months before it is manufactured into a finished product (Ref. 41).

Researchers have reported a 2-fold increase in NNN levels in sun-cured tobacco and a 3-fold increase in NNN levels in Burley tobacco when stored at ambient temperatures over a 1-year period (Ref. 41). Further, studies have shown that storage temperatures as low as 27 °C can lead to increased NNN formation in air-cured Burley tobacco, and that the rate of increase becomes greater as the temperature is increased (Ref. 41). In addition, air-cured Burley tobacco stored at higher temperature (24 °C v. 32 °C) and higher relative humidity levels (70 v. 83 percent) showed increases in both nitrite and NNN levels (Ref. 52).

Similar to cured tobacco, high temperature, high humidity, and extended storage can cause levels of NNN to increase in smokeless tobacco products. As smokeless tobacco products ''age,'' the water content can change, leading to bacterial growth, and the pH and nicotine content can decrease, causing nitrosamine levels such as NNN to rise (Ref. 11).

Studies have shown that NNN increases in moist snuff and dry snuff when stored at 24 °C for 24 days (Refs. 53, 54). Exposing moist and dry snuff to ambient air, such as when a product is opened and closed between dips, also increases NNN concentrations (Ref. 53). Similar to cured tobacco leaves, the storage of moist snuff at low temperatures (4 °C) reduces the increase in NNN that was seen when the same product is stored at ambient conditions (Ref. 55).

Humidity levels during storage can have an even greater influence than temperature on NNN formation in finished smokeless tobacco products. Specifically, the NNN levels in moist and dry snuff can be increased just by raising the relative humidity during storage from 22 to 50 percent (Ref. 54). Moreover, the combined effects of humidity and temperature are enhanced in products with higher moisture content (Ref. 54). Yet, storage conditions do not have the same effect on all types of smokeless tobacco. Studies on storage of chewing tobacco did not show the same increase in NNN as seen with moist and dry snuff, which suggests that some tobacco blends may be less prone to producing nitrosamines during storage (Refs. 53, 54). Furthermore, although retailers are encouraged to refrigerate Swedish snus to maintain ''perceived product freshness,'' the product's low bacterial activity may stabilize the NNN level even when stored at room temperature (Ref. 11).

3. Levels of NNN in U.S. Smokeless Tobacco Products

The levels of NNN in smokeless tobacco products on the U.S. market can vary by several orders of magnitude, not only among different subcategories of products, but also among products in the same subcategory (table 2, Refs. 5, 10, 56). After measuring NNN levels in 46 different smokeless tobacco products available in the United States from 2006 and 2007, Borgerding et al. found NNN levels ranged from below the limit of quantification (0.02 µg/g) to 14.4 µg/g per dry weight (Ref. 5). As shown in table 2, the NNN levels within the class of moist snuff and dry snuff ranged from 0.6 to 12.8 µg/g per dry weight and 5.91 to 12.0 µg/g per dry weight, respectively (Ref. 5).

A more recent study by Ammann et al. examined 34 products purchased in the United States in 2015 (Ref. 10). In line with the Borgerding study, Ammann et al. found NNN levels ranged from 0.64 to 12.0 µg/g per dry weight (Ref. 10). The NNN levels for moist snuff ranged from 1.0 to 9.5 µg/g per dry weight while the NNN levels for dry snuff ranged from 5.91 to 12.0 µg/g per dry weight (Ref. 10).

The range of NNN levels described in these studies have been confirmed by numerous other studies. Stepanov et al. reported a similar range for moist snuff (3.8 to 6.9 µg/g per dry weight) with dry snuff ranging from 0.95 to 5.3 µg/g per dry weight (Ref. 13). In a separate study, Stepanov et al. reported a wide range of NNN levels in 11 dissolvables that are smokeless tobacco products (0.27 to 2.7 µg/g per dry weight) (Ref. 56). Finally, Lawler et al. reported a wide range of NNN levels in chewing tobacco (0.94 to 2.8 per wet weight which equates to 1.2 to 3.6 µg/g per dry weight) and in dry snuff (6.1 to 31 µg/g per wet weight which equates to 6.5 to 33 µg/g per dry weight) (Ref. 20).

TABLE 2—NNN CONCENTRATION AND MARKET SHARE OF SMOKELESS TOBACCO PRODUCTS SOLD IN THE UNITED STATES

Smokeless tobacco product	Mean[1] and range of NNN measured in µg/g dry weight (number of products)			Market share[2] (%)
	Stepanov et al., 2014	Borgerding et al., 2012	Amman et al., 2016	
Dissolvable	1.78; 0.27–2.66; (11)			<0.1
Chewing Tobacco (Loose leaf, plug, chew).		2.21; 0.66–5.05; (8)	2.24; 0.92–4.60; (8)	5.2
Dry Snuff		5.53; 0.81–14.42; (10)	7.50; 5.91–12.00; (4)	0.7

TABLE 2—NNN CONCENTRATION AND MARKET SHARE OF SMOKELESS TOBACCO PRODUCTS SOLD IN THE UNITED STATES—Continued

Smokeless tobacco product	Mean[1] and range of NNN measured in μg/g dry weight (number of products)			Market share[2] (%)
	Stepanov et al., 2014	Borgerding et al., 2012	Amman et al., 2016	
Moist Snuff		3.76; 0.66–12.77; (28)	3.01; 0.64–9.50; (22)	94.1
Mean NNN across product categories		3.87	3.36	
Market share adjusted mean across product subcategories[3].		3.69	3.01	

[1] Mean values were determined by averaging the NNN concentrations across a smokeless tobacco product subcategory in each of the three representative studies.

[2] Market share data was based on 2015 retail scan data from Nielsen.

[3] In order to calculate a market share adjusted mean the mean of each subcategory was multiplied by its representative market share (*e.g.,* Chewing Tobacco [NNN] × .052). These values for each subcategory were then summed to estimate a market share weighted mean across all smokeless tobacco product subcategories examined.

The range of the NNN levels in the studies discussed in this subsection suggest that there exists the potential to reduce the levels of NNN in all smokeless tobacco through manipulation of starting materials and curing processes, as well as careful control of manufacturing and storage practices.

D. Basis for the NNN Limit in the Proposed Standard

As discussed in section IV.B of this document, the scientific evidence supports that NNN is a potent carcinogenic agent found in smokeless tobacco products and that NNN in smokeless tobacco products is a major factor underlying oral and esophageal cancers. The epidemiological evidence indicates populations who use smokeless tobacco products with lower levels of NNN have lower cancer risks (Refs. 4, 100, 101). Thus, it is anticipated that reducing levels of NNN in tobacco products in the United States will reduce the incidence of oral and esophageal cancers among smokeless tobacco users.

Based on our assessment of the evidence, we are proposing that the mean level of NNN in any batch of finished smokeless tobacco products not exceed 1.0 μg/g of tobacco (on a dry weight basis) at any time through the product's labeled expiration date as determined by testing in compliance with § 1132.12 (proposed § 1132.10). In selecting the NNN limit in this proposed standard, FDA took into consideration the epidemiological evidence demonstrating differences in observed cancer risks between users of smokeless tobacco products manufactured in the United States and in Sweden, and the technical achievability of the proposed limit. To estimate the anticipated health benefits of the proposed standard, FDA modeled the estimated cancer risk reduction determined by reducing NNN levels in smokeless tobacco products from current levels.

As NNN appears to have a genotoxic mode of action, FDA followed the U.S. Environmental Protection Agency's (EPA's) guidance for carcinogen risk assessment and assumed a linear relationship in the low-dose region of the dose-response model (Ref. 203). Using this model, the risk of cancer is linearly reduced as exposure to NNN approaches zero. While a limit of 0.0 μg/g for NNN would maximize cancer risk reduction to smokeless tobacco users, there is limited information on NNN levels lower than the proposed standard and their technical achievability. We note, however, that an NNN level of 1.0 μg/g of tobacco has been achieved in some smokeless tobacco products sold in the United States and is thus achievable using current technology. As discussed in section II.C of this document, FDA may consider a lower NNN level in the future. In addition, FDA welcomes comments on the technical achievability of complying with the proposed standard in this rule.

FDA modelled NNN attributable cancer risk to estimate the potential benefits to public health. Specifically, FDA modelled the effect an NNN smokeless tobacco product standard would have on reducing the cancer risk to a population exposed to NNN through use of smokeless products. This analysis is described in detail in this section.

FDA also considered the epidemiological evidence demonstrating differences in observed cancer risks between users of smokeless tobacco products manufactured in the United States and in Sweden. We focused on epidemiological evidence from Sweden because Swedish smokeless tobacco products tend to have lower levels of NNN than other smokeless tobacco products (Refs. 100, 114), which helps inform our public health analysis of a product standard limiting NNN. As discussed in section IV.B of this document, epidemiological studies demonstrate a lower risk of oral cancer from the use of Swedish snus in Sweden compared to other smokeless tobacco products in other countries. It is anticipated that the proposed product standard of 1.0 μg/g dry weight would bring the NNN level in U.S. smokeless tobacco products in line with those of Swedish snus.

With respect to risk reduction, FDA assumed that changes in the growing conditions and changes in product curing and processing may be necessary to achieve lower NNN levels in smokeless tobacco products. As discussed in section IV.E, it appears that there are several options for achieving the proposed NNN limit.

We note that FDA's approach to establishing the proposed limit differs from that of other regulatory agencies, such as the EPA and the U.S. Occupational Safety and Health Administration (OSHA), which set regulatory exposure limits based upon a risk level deemed to be ''acceptable'' or ''negligible'' (Refs. 204, 205 at appendix B). FDA expects that although the cancer risks posed by smokeless tobacco products that meet the proposed standard would be lowered, use of these products would still pose increased cancer risks, including increased oral cancer risks, compared with not using smokeless tobacco products. Thus, the proposed product standard establishing a limit for NNN in smokeless tobacco products is not intended to communicate that such levels are ''acceptable'' or ''negligible'' from a public health perspective.

1. Excess Lifetime Cancer Risk of NNN in U.S. Smokeless Tobacco Products

FDA estimated the excess lifetime cancer risk (ELCR) for oral cancer associated with the current NNN levels in U.S. smokeless tobacco products and compared it to an estimate of the ELCR

under the proposed standard. We calculated the ELCR with and without the proposed product standard to estimate the extent to which the proposed standard can reduce the risk of cancer among smokeless tobacco users in the United States. Then FDA used the resulting reduction in lifetime cancer risk to estimate the potential decrease in oral cancer cases as a result of this rule.

Given the variability associated with smokeless tobacco use (frequency, quantity) and lack of data regarding the dose-response relationship for NNN in humans, FDA is using the ELCR calculation to provide an understanding of the relative, rather than absolute, risk associated with different product classes and the impact of the proposed product standard on users of smokeless tobacco.

As demonstrated by Equation 1, which FDA used to calculate the excess lifetime cancer risk, the ELCR is a unitless probability (*e.g.,* 1 in 10,000 chance). The equation is based on the U.S. Environmental Protection Agency Risk Assessment Guidance (Ref. 57). The key variables in the equation are: (1) The level of NNN in the product (*i.e.,* concentration in product as used); (2) the amount of product (mass) used each day; (3) the amount of NNN that leaves the product during use (*i.e.,* percent extracted) and the amount of the extracted NNN that is absorbed by the body (*i.e.,* absorption rate); (4) the length of time the product is used over a lifetime, which is determined by the years of use (*i.e.,* exposure duration) over the lifetime (*i.e.,* averaging time); (5) body weight of the user; and (6) the cancer slope factor (CSF), which is used to represent the dose-response relationship between NNN and cancer incidence. As each of these variables is associated with wide variability, we attempted to derive average values to estimate a population average ELCR. Below we describe the assumptions that are used in this analysis and the justification for those assumptions. Because of limitations in data, particularly with regard to data underlying the CSF, the ELCR calculation is not used to assess absolute cancer risk. Instead, the ELCR is used to estimate the percent reduction in cancer risk associated with implementing an NNN limit for smokeless tobacco products. FDA welcomes public comments on alternative assumptions that may affect the ELCR estimate. Commenters should provide explanations as to why the alternative assumptions may lead to more robust estimates of the ELCR associated with this product standard.

Equation 1—ELCR Calculation

$$ELCR = CxIR\ x\ \frac{AB\ x\ EF\ x\ ED}{BW\ x\ AT}\ x\ CSF$$

C = Concentration of NNN in product as used (µg/g wet weight)
IR = Intake rate (mg of wet (as used)) product used per day (12 g/day; 2.5 g/day for dissolvables)
AB = Absorption rate, how much of product NNN is transferred to the user (60 percent)
EF = Exposure frequency (365 days/year)
ED = Exposure duration (60 years)
BW = Body weight in kg (70 kg)
AT = Averaging time (365 days/year; 78 years)
CSF = Cancer slope factor (1.4 mg/kg/day)

As defined by the EPA guidelines, the cancer slope factor (CSF) is ''an upper bound (approximating a 95percent confidence limit) on the increased cancer risk from a lifetime exposure to an agent. This estimate, usually expressed in units of proportion (of a population) affected per mg/kg/day, is generally reserved for use in the low-dose region of the dose-response relationship; that is, for exposures corresponding to risks less than 1 in 100. This term is usually used to refer to oral slope factors (*i.e.,* slope factors used for assessing ingestion exposure).'' (Ref. 190).

For this ELCR assessment, FDA uses the CSF for NNN generated by the California Environmental Protection Agency (CalEPA) in 1992 (Ref. 93). Although this CSF has been used as the basis for several published analyses (Refs. 207, 208, 209, 74, 210, 211, 102), it has significant limitations. The CalEPA CSF of 1.4 (milligram per kilogram per day (mg/kg/day))$^{-1}$ for NNN is based upon tumor data from hamsters orally exposed to NNN in drinking water in a study conducted by Hecht et al. (Ref. 59), which compared a single dose scenario with a control group. The CalEPA thus generated a slope by drawing a line between the two points (tumor rate at a single dose and tumor rate in the control group). EPA's 2005 Cancer Guidelines and subsequent Benchmark Dose Guidance elaborate extensively on the determination of the point of departure (POD) for generating a CSF (Refs. 203, 187). More specifically, EPA recommends that the starting point for subsequent extrapolations and analyses be the lowest dose adequately supported by the data. However, in a single dose study, without an understanding of the shape of the exposure-response curve at lower doses, there is potentially significant bias in the derivation of the CSF—leading to subsequent uncertainty in the modeling of cancer risk. Thus, as noted above, FDA's ELCR calculation is only used to estimate relative risk of alternative exposure scenarios, not absolute risk. FDA welcomes public comment on whether there is a more robust CSF available for NNN.

For the concentration of NNN in the product, FDA used the Borgerding et al. and Ammann et al. data (Refs. 5, 10) to represent the range of levels of NNN in current smokeless products, which ranged from below the limit of quantification (0.02 µg/g) to 14.4 µg/g per dry weight. We chose these studies because they are the most comprehensive studies of NNN levels in U.S. smokeless tobacco products and the levels are similar to levels which have been reported by other investigators (see section IV.C.3). These studies also reported the moisture content of the smokeless tobacco products, which FDA used to determine the products wet weight NNN levels (*i.e.,* what a user would be exposed to). This calculation involves taking the dry weight NNN measurement and accounting for the moisture found in the product when used by consumers [NNN µg/g dry weight] × [1-moisture content] = [µg/g wet weight (as used)].

For the intake rate (mass of product used each day), FDA chose an average use assumption of 12 g of wet product per day, every day based on an experimental study in the United States that indicated that the range of the most common form of smokeless tobacco use, moist snuff, is between 5.1 and 42.5 g/day (Ref. 60), with an average use of 12 g/day (Ref. 60). This study is widely cited for estimating average smokeless tobacco use (Refs. 132, 212, 213). The 12 g/day assumed estimate is consistent with studies that look at use in terms of the number of tins (container holding the smokeless tobacco product) of tobacco consumed (Refs. 61 through 71). These studies' estimates ranged from 1.2 tins to 4.6 tins/week, with an average of 3.68 tins/week (0.53 tin/day. Based on an average size of a tin of 1 ounce (or slightly more than 28 g), we estimate

that the average amount of smokeless tobacco product used is approximately 15 g/day [0.53 tin/day × 28 g/tin = 14.84 g/day], which suggests an assumption of 12 g/day is not unreasonable.

Conventional moist snuff constitutes the overwhelming majority of the smokeless tobacco market in the United States (Ref. 131). The figure of 12 g/day among moist snuff users does provide a reasonable average estimate of what most U.S. smokeless tobacco users of most product subcategories consume on a daily basis. However, FDA recognizes that the amount of smokeless tobacco used in a day varies by product. In particular, some dissolvable smokeless tobacco products weigh as little as one-fifth or one-quarter as much (Ref. 56). Therefore, 2.5 g/day was used for our ELCR calculations for daily use of dissolvable products based upon a usage study by Krautter et al. (Ref. 15).

The extraction percentage, or fraction of TSNAs removed from a smokeless tobacco product while in use, has been reported to range from 10 to 85 percent (Refs. 58, 73, 74). Hecht et al. analyzed extraction and direct absorption of TSNAs in humans. A measured amount of smokeless tobacco was inserted into the oral cavity for 30 minutes. All saliva was collected during use of the product and three consecutive 24-hour urine samples were analyzed. The amount of TSNAs before and after use of the smokeless tobacco product was determined along with analysis of the expectorated saliva and urine samples. The individual subject data provided by Hecht et al. yields a median extraction of 60 percent (59 ± 23 percent) (Ref. 58). Other studies also cite 60 percent as an estimate of the amount of TSNAs extracted from smokeless tobacco (Refs. 73, 74).

FDA assumed the absorption rate for the average user to be 100 percent of the extracted 60 percent of the concentration of TSNAs found within a given smokeless product. This assumption is precautionary because it assumes that the user is exposed to the total amount of NNN extracted from the product, even though some of the NNN in saliva may be excreted without being absorbed. Therefore, the absorption rate used for the ELCR calculations is 60 percent (*i.e.,* 100 percent absorption of the 60 percent extracted NNN).

FDA used 60 years of product use as the exposure duration for the ELCR calculations assuming initiation at or near 19 years of age (Ref. 23) and an average life span of 78 years for the general population (Ref. 75). We used 78 years because it is the recommended value from the EPA (Ref. 75) to use when calculating excess lifetime cancer risk due to toxicant exposure in the absence of specific data on the population of interest (*i.e.,* smokeless tobacco users). Upon initiation, FDA assumed daily use (365 days/year) of an average mass of 12 g of wet product per day. In addition, FDA used an average adult body weight of 70 kg in the ELCR calculations, which is consistent with EPA practices (Ref. 57).

Table 3 shows the estimated ELCR calculated by using the mean NNN concentration of several different categories of smokeless tobacco products sold in the United States from table 2, using Equation 1 and the assumptions described in this section. Given the assumed linear nature of the CSF, use of products with lower NNN levels has a lower ELCR while use of products with higher NNN levels has the highest ELCR. For example, use of dissolvables with a mean level of NNN of 1.6 μg/g (as used) has a very low ELCR of 0.4 in 10,000, while use of dry snuff with a level of NNN of 5.1–7.0 μg/g (as used) has an ELCR of 5.6–7.6 in 10,000. The current market share adjusted mean NNN level of all U.S. smokeless tobacco products reported by the Borgerding and Ammann studies is 1.7–1.8 μg/g wet weight (as used), the use of which corresponds to an estimated ELCR of 1.9–2.0 in 10,000.

TABLE 3—ESTIMATED ELCR FOR SUBCATEGORIES OF U.S. SMOKELESS TOBACCO PRODUCTS

Smokeless tobacco product	ELCR (expressed as "n" in 10,000)		
	Stepanov et al., 2014	Borgerding et al., 2012	Ammann et al., 2016
Dissolvables	0.4	.....	.....
Dry Snuff	.....	5.6	7.6
Chewing Tobacco	.....	1.8	2.0
Moist Snuff	.....	2.0	1.8
Mean ELCR across product categories	.....	2.7	2.6
Market share adjusted ELCR across product subcategories	.....	2.0	1.9

[1] In order to calculate a market share adjusted mean ELCR, the mean of each subcategory was multiplied by its representative market share (table 2). These values for each subcategory were then summed to estimate a market share weighted mean across all smokeless tobacco product subcategories examined.

Using the same assumptions as above (Intake rate, NNN CSF), FDA estimated the ELCR for use of smokeless tobacco products with differing levels of NNN (dry weight, *e.g.,* 0.5, 1.0, 2.0 μg/g) and how these levels would compare to the current market estimates (table 4). FDA first carried out a moisture correction on the dry weight concentrations (0.5, 1.0, and 2.0 μg/g dry weight) to determine an ''as used'' (wet weight) NNN concentration. This estimation was based upon the moisture concentrations from the Ammann et al. study (Ref. 10), and weighted by recent subcategory market share data. As shown in table 4, we estimate that, compared to the current market, hypothetical market-wide NNN levels of 0.5, 1.0 and 2.0 μg/g dry weight would reduce the ELCR by 83.2, 66.3 and 31.6 percent, respectively.

TABLE 4—ELCR FOR HYPOTHETICAL MARKET-WIDE MEAN NNN LEVELS AND COMPARISON TO CURRENT MARKET ELCR

NNN (μg/g dry weight)	NNN (μg/g, wet weight, as used)	ELCR (n in 10,000)	% Reduction in ELCR as compared to current market [1]
0.5	0.3	0.32	83.2
1.0	0.6	0.64	66.3

TABLE 4—ELCR FOR HYPOTHETICAL MARKET-WIDE MEAN NNN LEVELS AND COMPARISON TO CURRENT MARKET ELCR—Continued

NNN (μg/g dry weight)	NNN (μg/g, wet weight, as used)	ELCR (n in 10,000)	% Reduction in ELCR as compared to current market [1]
2.0	1.2	1.3	31.6

[1] Percent reduction in ELCR compared to the market weighted mean ELCR value from Amman et al., 1.9 (table 3).

2. ELCR of NNN in Swedish Snus

As noted earlier, Swedish snus generally has a lower NNN level than other smokeless tobacco products sold in the United States, and as discussed in section IV.B.3, some epidemiological studies demonstrate a lower risk of oral cancer from the use of Swedish snus in Scandinavia when compared to the use of other smokeless tobacco products in the United States (Refs. 100, 114). Substituting the mean NNN level of 0.55 μg/g (wet weight) that is in Swedish snus (Ref. 5), into Equation 1 yields an ELCR of 0.59 in 10,000. As the proposed product standard of 1 μg/g dry weight for NNN would result in bringing U.S. smokeless tobacco products in line with NNN levels in Swedish snus, it is not surprising that the ELCR for such a hypothetical market-wide mean NNN level (table 4) would be almost the same as that estimated for Swedish snus.

Our analysis indicates that users of smokeless tobacco products would have their ELCR reduced by approximately 65 percent if the market adjusted mean of NNN in smokeless tobacco products was reduced from that of the current market to 1.0 μg/g dry weight (table 4). This value would approximate the ELCR of the Swedish snus exposure scenario which epidemiological data suggests has a lower cancer risk.

3. Conclusion

Setting the proposed limit for NNN in finished smokeless tobacco products means that, on average, in a population of daily users of smokeless tobacco products, over their life time, there would be an approximately 65 percent reduction in ELCR, compared with lifetime daily use of a population that used smokeless tobacco products with NNN levels at the current level. In section V, we calculate the impact of an estimated 65 percent reduction in cancer risk on expected incidence of oral cancer in the United States.

We note that FDA considered setting a product standard for both NNN and NNK. However, FDA is proposing a product standard for only NNN at this time because of the more limited data available on the relationship between NNK and smokeless tobacco-related cancer risk. In particular, NNK is noted for its consistent systemic lung carcinogenicity (Ref. 8). However, the relationship between smokeless tobacco use and lung cancer is a matter of ongoing investigation and a definitive association has not been established (Refs. 3, 4).

NNN and NNK constitute potent carcinogens in smokeless tobacco (Refs. 4, 78) and levels of these two TSNAs are often correlated in smokeless tobacco products (Refs. 5, 20). Because many methods available to reduce NNN also reduce NNK, there is some evidence that a product standard that requires lower NNN levels will potentially result in lower NNK levels as well (Ref. 84).

A market survey of 16 snus brands sold in Sweden in 1983, prior to the adoption of the GothiaTek voluntary quality control standard, showed average NNN levels of 3.8 μg/g of tobacco and average NNK levels of 0.8 μg/g of tobacco per wet weight (Ref. 84). In 2002, after GothiaTek was adopted, a market survey of 23 snus brands sold in Sweden showed NNN levels decreased to 0.49 μg/g of tobacco and NNK levels decreased to 0.19 μg/g of tobacco per wet weight (Ref. 84). More recent analyses of constituents in smokeless tobacco products manufactured in the United States indicate that smokeless tobacco brands that are lower in NNN content are also lower in NNK (Refs. 5, 20). Additionally a study by Song et al. (Ref. 6), examined the NNN and NNK levels of conventional and low-TSNA smokeless tobacco products on the U.S. market. NNN:NNK ratios were 3.1 and 3.7 for the conventional and low-TSNA varieties, respectively, which is in line with results from previous studies (Refs. 5, 20). Accordingly, we anticipate a potential reduction of NNK in smokeless tobacco in response to the proposed rule for NNN. We note that, in 2009, the WHO Study Group on Tobacco Product Regulation recommended a regulatory limit for NNN and NNK (combined) of 2 μg/g dry weight of tobacco (Ref. 78). Given the ratio of NNN to NNK in smokeless tobacco products, where the level of NNN is generally greater than the level of NNK, any smokeless tobacco product that meets the proposed NNN standard is likely to also meet the levels recommended by the WHO for NNN and NNK.

E. Information on Technical Achievability

Section 907(b)(1) of the Tobacco Control Act requires FDA to consider information submitted in connection with a proposed product standard regarding technical achievability of compliance with the product standard. FDA, therefore, invites public comment addressing the technical achievability of this proposed product standard, and specifically requests submission of evidence and data to support such comments. FDA has also chosen to consider available information regarding technical achievability in developing this proposed rule and it appears that there are several options for achieving the proposed NNN limit.

As described in more detail in section IV.C.2, there are many factors that can influence the level of NNN in smokeless tobacco products. Accordingly, there are a number of options available to manufacturers to reduce and control NNN levels in finished smokeless tobacco products including, but not limited to, the following:

- Using a type of tobacco with lower concentrations of NNN (*e.g.,* Bright tobacco or low-converter types of Burley tobacco);
- Using tobacco grown with limited use of nitrogen-rich fertilizer on tobacco crops;
- Using tobacco processed with a different curing method (*e.g.,* air curing instead of flue curing the same tobacco) or a modification of a currently used curing method to minimize its effect on NNN levels (*e.g.,* reducing humidity during curing by improving air circulation);
- Using tobacco that had a bacteriostatic, bactericidal, or heated solution (25 to 55 °C) applied to tobacco leaves during the growing, harvesting, or curing processes to reduce the number of bacteria in the tobacco leaves and thereby reduce the NNN level;
- Using a non-nitrate reducing bacteria ''starter culture'' for the fermentation process;
- Using cleaned and sanitized equipment for processing and

manufacturing smokeless tobacco products;

- Adding humectants, sodium chloride, or other additives to lower water activity and reduce microbial growth;
- Adding bicarbonate and carbonate salt solutions to control pH;
- Pasteurization or heat treatment;
- Storing tobacco leaves and finished smokeless tobacco products at lower temperatures and relative humidity levels; and
- Limiting the duration of storage.

For products that are already near the proposed limit, one of these options may be sufficient to bring the product into compliance with the proposed standard, while products which currently have levels of NNN well above the proposed limit may need to use a combination of options. To the extent that any change in the processing of smokeless tobacco products (*e.g.,* curing, fermentation) affects the products flavor, FDA expects that manufacturers would be able to adjust the flavor profile of finished smokeless tobacco products through minor changes in flavor ingredients. This proposed rule also could spur innovation and development of additional methods and technologies to reduce NNN levels in smokeless tobacco products.

The proposed rule does not prescribe specific methods or processes for meeting the proposed NNN level, so that smokeless tobacco product manufacturers would have flexibility in identifying appropriate methods or processes for reducing the NNN level in their products. Because certain snus, moist snuff, and chewing tobacco already contain low NNN levels, FDA expects that manufacturers of many of those products may not need to make any manufacturing changes to meet the proposed NNN level (Refs. 5, 10, 56). (Such manufacturers would remain subject to the proposed standard, including its testing, sampling, labeling, and recordkeeping requirements.) Thus, FDA expects some smokeless tobacco products may require minimal changes to the manufacturing process to meet the proposed NNN level, while other products may require extensive changes to the manufacturing process to comply with the proposed level (Ref. 56). A smokeless tobacco product that has been modified to comply with the product standard would be a ''new tobacco product'' and subject to premarket review.

F. Analytical Method

To test for the NNN limit in this product standard, FDA proposes that smokeless tobacco product manufacturers use the validated method that has been developed at FDA's Southeast Regional Laboratory (SRL) in Atlanta, GA (Determination of N-nitrosonornicotine (NNN) in Smokeless Tobacco and Tobacco Filler by HPLC–MS/MS, LIB No. 4620, January 2017) (Ref. 79). The results from the test method demonstrate a high level of specificity, accuracy, and precision in measuring a range of NNN levels across a variety of smokeless tobacco products. Requiring that a single test method be used would ensure that all of these factors are met and would permit comparison of test results among finished smokeless tobacco products and testing facilities. However, FDA is proposing that other methods may be used if they meet the requirements in § 1132.16 (Alternative test method).

Numerous methods have been published that use either high-performance liquid chromatography/mass spectrometry (LC–MS) or gas chromatography (GC), combined with thermal energy analyzer (TEA) detectors to determine the content of NNN in tobacco. The validated test method that FDA is proposing to incorporate by reference in § 1132.5(a) utilizes LC–MS and has an analysis time of 8 minutes. The method has a limit of quantification of 0.4 μg/g of NNN, a linear range of 0.4 to 1.6 μg/g, and a method detection limit of 0.1 μg/g. The method performance parameters for the standard method for NNN quantification in smokeless tobacco products do not differ significantly from the method performance parameters of other methods that are currently in use. This method uses an extraction solvent of 100 milliMolar (mM) ammonium acetate in high performance liquid chromatography (HPLC) grade water and a gradient of 5 to 50 percent of 5 mM ammonium acetate in 95 percent acetonitrile at a 0.5 milliliter per minute flow rate. Analysis is conducted after a known amount of carbon-13-labeled NNN is added to the tobacco, extracted for 5 minutes with 100 mM ammonium acetate at elevated temperature and pressure, dried, and reconstituted in methanol and ammonium acetate buffer.

The method includes the determination of NNN levels as well as moisture content, so the NNN level on a dry weight basis can be calculated. In this method, water levels are determined according to International Organization for Standardization (ISO) standards ISO 6488:2004 and ISO 6488:2004/Cor 1:2008 or ISO 16632:2013. Validation of this method was done using the smokeless tobacco reference products for snus (CRP–1) and for moist snuff (CRP–2), as well as the University of Kentucky cigarette reference product (3R4F cigarette tobacco filler). Tobacco samples with NNN levels expected to be higher than 4 μg/g tobacco were analyzed after dilution because they were too concentrated for analysis. This method was proven to be applicable for tobacco products with various moisture levels, including cigarette tobacco filler, snus, dry snuff, chewing tobacco, and moist snuff.

HPLC is favored over gas chromatography (GC) because it allows for faster analysis and sample preparation, although validated methods exist for analysis of NNN well below the level specified in § 1132.10 by either LC or GC. Mass spectrometer (MS) detection is favored over thermal energy analyzer (TEA) detection because of the possibility of using isotopically-labeled NNN as an internal standard, which controls for variation in sample preparation. In addition, instrumentation to perform LC–MS analysis is more readily available than for GC–TEA and, therefore, manufacturers or analytical laboratories wishing to establish this method themselves will have better access to equipment. The internal standard is NNN that has been specially labeled with isotopes of hydrogen and carbon, deuterium or carbon-13, respectively. The isotopic-labeling of the internal NNN standard increases the mass of the internal standard relative to naturally occurring NNN, and the internal standard appears as a distinct signal in the mass spectrometer detector. Because the analyst knows the quantity of internal standard added to the tobacco at the beginning of sample preparation, the detector signal of the internal standard can be used to quantify the amount of natural NNN present in the sample. The isotopically-labeled internal standard is chemically identical to NNN, so the internal standard used for MS controls for all variations in NNN levels that arise during sample preparation and extraction. The available scientific evidence suggests that deuterated and carbon-13-labeled internal standards are equally acceptable for NNN analysis. Internal standards used for TEA differ from internal standards used for MS because they are chemically different from NNN. Therefore, slight differences may exist between the yield of NNN and the yield of the internal standard during the extraction and sample preparation steps. The limits of detection for NNN by MS may be lower than limits of detection by TEA. However, validated methods exist

for analysis of NNN well below the level specified in § 1132.10 by either MS or TEA.

Over the years a variety of analytical methods have been developed for the detection of NNN in smokeless tobacco products. For example, the Cooperation Centre for Scientific Research Relative to Tobacco (CORESTA) published CORESTA 72, an LC–MS method for determining NNN levels in smokeless tobacco using a low calibration standard of 0.015 µg/g of tobacco, extraction in 100 mM ammonium acetate, and a deuterium-labeled NNN internal standard (Ref. 80). CDC published an LC–MS method for smokeless tobacco with an extraction in ethyl acetate and use of a carbon-13-labeled NNN internal standard with an effective limit of detection of 0.072 µg/g NNN and an 8 minute analysis time (Refs. 81, 82). The Swedish National Food Administration published an LC–MS method for smokeless tobacco with extraction in ethyl acetate, a limit of detection of 0.010 µg/g NNN, a 15 minute analysis time, and quantification using an external NNN standard (Refs. 83, 84). British American Tobacco published an LC–MS method for smokeless tobacco with extraction in methanol, a deuterium-labeled NNN internal standard, and no published limit of detection (Ref. 85).

The American Health Foundation published several similar GC–TEA methods for NNN in chewing tobacco using extraction in a buffer containing ascorbic acid, a 24 minute analysis time, and confirmation by MS of the TEA signal corresponding to NNN (Refs. 86, 87, 88). Health Canada published Official Method T–309, which is a GC–TEA method for NNN in tobacco using extractions in a buffer of ascorbic acid in dichloromethane, an internal standard of N-nitrosopentyl-(3-picolyl)-amine, a lowest calibration standard corresponding to about 0.2 µg/g tobacco, and a 35-minute analysis run time (Ref. 89).

Other approaches besides LC–MS and GC–TEA have been explored to measure NNN in tobacco filler. These methods have included two ISO methods using gas chromatography with chemiluminescence detection (ISO 22303:2008 and ISO 22304:2008), an American Health Foundation method using HPLC with ultraviolet absorption detection followed by confirmation of the peak by MS (Ref. 90), and a Swedish Match method using an NNN-specific antibody in immunoassays (Ref. 91).

Although there are various methods to test for NNN, only the CORESTA 72 method has been externally validated via round-robin method validation studies in accordance with ISO 5725–2 (ISO 5725–2:1994) and only the SRL method tests on a dry weight basis. Thus, FDA concluded that levels of 1.0 µg/g or lower on a dry weight basis of NNN in tobacco could be reliably measured either by SRL's method or by optimizing existing common methods to meet the requirements of § 1132.16 (Alternative test method).

V. Standard Is Appropriate for the Protection of the Public Health

The Tobacco Control Act authorizes FDA to adopt tobacco product standards by regulation if it finds ''that a tobacco product standard is appropriate for the protection of the public health'' (section 907(a)(3)(A) of the FD&C Act). The Notice of Proposed Rulemaking (NPRM) for such a product standard must set forth this finding with supporting justification, which FDA is doing here (section 907(c)(2)(A) of the FD&C Act).

In order to make this finding, FDA must consider scientific evidence concerning—

- The risks and benefits to the population as a whole, including users and nonusers of tobacco products, of the proposed standard;
- The increased or decreased likelihood that existing users of tobacco products will stop using such products; and
- The increased or decreased likelihood that those who do not use tobacco products will start using such products. Section 907(a)(3)(B)(i) of the FD&C Act.

As discussed in this section of the document, FDA has considered scientific evidence related to all three factors. Based on these considerations, we find that the proposed standard is appropriate for the protection of public health, because it will reduce the harm associated with the use of smokeless tobacco products and FDA does not expect that the product standard will increase the likelihood that non-users will initiate tobacco or decrease the likelihood that users will quit tobacco use in a manner that would offset the benefits of the reduced cancer risk.

A. Benefits to the Population as a Whole

As discussed in section IV, on the basis of the best available scientific evidence, FDA has determined that NNN is the predominant driver of excess oral cancer risk among smokeless tobacco users. This determination is based on multiple, consistent lines of evidence. First, several authoritative reviews have concluded smokeless tobacco products, including those currently marketed in the United States, cause cancer (Refs. 1, 2, 3, 4). Second, NNN is a potent carcinogenic agent found in smokeless tobacco and, along with NNK, another TSNA, is labeled as Group 1 (known human carcinogen) by IARC (Refs. 1, 2). Third, substantial recent evidence supports site-specific concordance of the carcinogenic effects of NNN in animal and human epidemiologic studies. In particular, oral and esophageal tissues have been identified as targets for NNN-induced carcinogenicity (Refs. 7, 95, 171, 172), with observation of tumors in the oral cavity and esophagus following oral exposure to NNN in experimental animals (Refs. 7, 59, 94, 95, 148, 178). These animal studies suggest a degree of concordance with effects observed at these sites in epidemiologic studies (Refs. 77, 96). Finally, several authoritative reviews have observed differences in the magnitude of cancer risks due to smokeless tobacco use across regions of the world, which have been found to correlate highly with variation in the levels of tobacco specific nitrosamines in smokeless products (Refs. 1, 4).

The proposed product standard is intended to reduce tobacco-related harms by requiring lower levels of NNN (and likely also leading to concomitantly lower NNK levels) in smokeless tobacco products sold in the United States. In this section, we describe the expected benefits of the proposed standard to the population as a whole, including specifically the benefits of reducing the number of new cases of and deaths from oral cancer attributable to smokeless tobacco.

In this section, FDA generates estimates of the number of new cases and fatal cases of oral cancer that would be avoided over the 20 years following implementation of the proposed product standard. We estimate that approximately 12,700 new cases of oral cancer and approximately 2,200 oral cancer deaths would be prevented in the United States. Moreover, during that 20-year period, approximately 15,200 life years would be gained as a result of the proposed standard. Because oral cancer is associated with significant health and economic impacts, we expect positive public health benefits due to prevention of new and fatal oral cancer cases. We also expect that the proposed standard would reduce the number of new and fatal cases of esophageal cancer among continuing smokeless tobacco users and may reduce the risk of pancreatic cancer as well.

1. Estimated Impact of Proposed NNN Standard on New and Fatal Oral Cancers

The analysis in section IV.C suggests that the estimated lifetime cancer risk (ELCR) would drop by approximately 65 percent under the scenario where the proposed product standard for smokeless tobacco products was fully implemented, and while assuming that all other variables remained constant (*e.g.,* user habits). Thus, over time, FDA expects implementation of the proposed product standard to reduce the number of incident cases (*i.e.,* those new cases of oral cancer that occur over time in the smokeless tobacco user population) and fatal cases of oral cancer by reducing the concentrations of a potent oral carcinogen in smokeless tobacco products (Ref. 107). To estimate the potential impact of the standard on morbidity and mortality, we first model the annual number of new cases and deaths from oral cancer that are attributable to smokeless tobacco use in the United States. We then estimate the number of these cases, both those new cases that occur (incident cases) and those that are fatal, that would be prevented as a result of the proposed standard by reducing the population attributable risk by 65 percent. Relative risk estimates used to model the population attributable risk come from a published systematic review and meta-analysis of studies of oral cancer among U.S. smokeless tobacco users (Ref. 100).

More specifically, as described in section IV.C of this document, FDA estimates, by comparing its calculation of the ELCR using the NNN levels of currently marketed U.S. smokeless tobacco products to its calculation of the hypothetical ELCR using the proposed standard, that meeting the standard would result in, on average, a 65 percent reduction in the excess lifetime cancer risk due to NNN among U.S. smokeless tobacco users. Given the apparently predominant role of nitrosamines in smokeless tobacco cancer risk, we assume that the 65 percent reduction can be applied directly to the excess oral cancer risks attributable to smokeless tobacco in general. Public comment is sought on the strength of the assumptions underlying this approach to estimate the anticipated public health effects of the rule, and whether alternative approaches may exist. Commenters should provide evidence supporting alternative assumptions or approaches to estimating likely reduction in incidence of oral cancers associated with an implementation of the proposed product standard.

The analysis quantifies the estimated public health impact of the proposed product standard in terms of new and fatal cases of oral cancer. Oral cancer is used as the endpoint of interest because of the established strong relationship between smokeless tobacco use and oral cancer risk, as well as the identification of NNN as a known, potent oral carcinogen. There are also a relatively large number of published estimates of oral cancer risk among U.S. smokeless tobacco users.

As described in this section, we also expect the standard to reduce the risk of esophageal cancer and it may reduce the risks of cancer at additional sites. However, limited data are available to permit direct quantification of this health benefit (Ref. 100). As such, we focus here on estimating the potential benefits of the proposed product standard in reducing the number of new and fatal cases of oral cancer in the United States.

We use the population attributable risk formula introduced by Levin (Ref. 108) and subsequently used extensively by the CDC in its Smoking-Attributable Mortality, Morbidity, and Economic Costs (SAMMEC) methodology for modeling smoking-attributable mortality (Ref. 109). Population attributable risk (PAR) is calculated as the proportion of cases of disease that are attributable to the risk factor as:

$$PAR = \frac{P_e(RR - 1)}{1 + P_e(RR - 1)}$$

where P_e is the prevalence of the exposure and *RR* is the relative risk of disease among the exposed compared with the unexposed. The resulting proportion is then multiplied by the total number of cases of disease in the population to estimate the number of cases that are attributable to the risk factor.

We first estimate smokeless tobacco-attributable oral cancer cases and deaths for the United States in 2010. We use this year because of the availability of all relevant data inputs, including smokeless tobacco use prevalence estimates from the same data source used in CDC's SAMMEC method for estimating cigarette smoking-attributable mortality. Because the National Survey on Drug Use and Health reports that smokeless tobacco use prevalence has been relatively consistent among youth and adults in recent years (Ref. 23), these estimates also serve as a general measure of the effects of smokeless tobacco use on oral cancer in the United States in subsequent years. We estimate the U.S. prevalence of smokeless tobacco use using 2010 National Health Interview Survey data (Ref. 111). Current smokeless tobacco use is defined as reporting having used either chewing tobacco or snuff at least 20 times in one's life and currently using that product every day or some days. Age- and sex-specific prevalence of current smokeless tobacco use is reported in table 5, along with the number of new and fatal oral cancer cases in the United States in 2010. The latter were obtained from United States Cancer Statistics data available on CDC's WONDER Web site (Refs. 112, 182, 184, 185, 186). Newly diagnosed (incident) oral cancer cases and oral cancer deaths attributable to use of smokeless tobacco products, stratified by age group and sex, are also reported in table 5. Oral cancer cases attributable to smokeless tobacco accounts for 3.4 percent of all newly diagnosed oral cancer cases.

TABLE 5—PREVALENCE OF CURRENT SMOKELESS TOBACCO USE AND NUMBER OF NEWLY DIAGNOSED AND FATAL CASES OF ORAL CANCER IN THE UNITED STATES, BY AGE GROUP AND SEX, U.S. 2010

	Smokeless tobacco use prevalence [1] (%)	Newly diagnosed oral cancer cases [2]	Oral cancer deaths [2]	Attributable oral cancer cases	Attributable oral cancer deaths	Attributable fraction (%)
Males:						

TABLE 5—PREVALENCE OF CURRENT SMOKELESS TOBACCO USE AND NUMBER OF NEWLY DIAGNOSED AND FATAL CASES OF ORAL CANCER IN THE UNITED STATES, BY AGE GROUP AND SEX, U.S. 2010—Continued

	Smokeless tobacco use prevalence [1] (%)	Newly diagnosed oral cancer cases [2]	Oral cancer deaths [2]	Attributable oral cancer cases	Attributable oral cancer deaths	Attributable fraction (%)
35–64 years	4.6	15,960	2,770	808	140	5.1
65+ years	3.9	10,351	2,997	444	128	4.3
Females:						
35–64 years	0.2	5,322	832	15	<10	0.3
65+ years	0.3	5,664	1,699	19	<10	0.3

[1] Source is the 2010 National Health Interview Survey conducted by the National Center for Health Statistics (Ref. 111).
[2] Source is CDC WONDER, 2010 for cancers of the lip, oral cavity and pharynx (Ref. 112).

In calculating the population attributable risk, FDA used summary relative risks for the relationship between smokeless tobacco use and oral cancer risk derived from a meta-analysis of epidemiology studies published by Boffetta et al. in 2008 (Ref. 100). Boffetta's analysis, based on nine relative risk estimates from seven independent studies, generated a summary relative risk of 2.6 (95 percent confidence interval of 1.3–5.2) for oral cancer associated with the use of chewing tobacco or snuff in the United States. The authors state that this meta-analysis included studies of smokeless tobacco use among non-smokers or among non-smokers and smokers with adjustment for smoking. These risks were used in estimates of the population burden of smokeless tobacco use in the United States, presented in a recent NCI and CDC report on smokeless tobacco use and global public health (Ref. 4).

One study notes that two of the estimates included in Boffetta et al.'s meta-analysis, from a study by Stockwell and Lyman examining the associations between smokeless tobacco use and mouth/gum cancers and tongue cancer, likely did not adjust for cigarette smoking and consequently yielded considerably larger risk estimates than would have likely been observed with adjustment (Refs. 103, 110). To understand the sensitivity of the overall results to this study, we replicated Boffetta et al.'s summary relative risk estimate (where relative risk was 2.6), then re-analyzed the data omitting the two estimates from Stockwell and Lyman. The latter analysis yielded a summary relative risk of 2.16 (with a 95 percent confidence interval of 1.08–4.33). This value matched the overall relative risk estimate from an independent meta-analysis of the relationship between smokeless tobacco use and oral cancer risk in the United States that was published in 2009 by Lee and Hamling (*i.e.,* a relative risk of 2.16; and a 95 percent confidence interval of 1.55–3.02), although based on different methods and a different set of studies. In this analysis, we use the relative risk of 2.16 as the summary relative risk for oral cancer among smokeless tobacco users as the relative risk in 2010 (*i.e.,* in the absence of the proposed standard). Although we believe this relative risk represents the best available estimates based on the research literature, it should be noted that the accuracy and precision of particular study estimates may be somewhat limited due to sample size and changes in study participants' smokeless tobacco use and risk over time.

Table 6 shows that an estimated 1,300 new cases of oral cancer in the United States in 2010 were attributable to smokeless tobacco use using this summary relative risk. These estimates are generally comparable to those reported in the recent NCI and CDC smokeless tobacco report (Ref. 4). The majority of these cases occur among men, which is consistent with low rates of smokeless tobacco use among women.

We use similar methods to estimate the number of oral cancer deaths in the United States in 2010 that were attributable to smokeless tobacco use, with the only difference being that we use the number of oral cancer deaths during this year, rather than new diagnoses during the year, in the population-attributable risk calculations. We also estimate the life years that were lost due to these oral cancer deaths attributable to smokeless tobacco use. We obtain the median ages at death for those dying of oral cancer by sex and age group (35–64 years and 65+ years) for the United States in 2010 (Ref. 112) and life expectancy estimates by sex at these ages from life tables for the United States in 2010 produced by the National Center for Health Statistics (Ref. 113). These life expectancy values are then multiplied by the number of attributable oral cancer deaths for each group to estimate the number of life years that were lost due to oral cancer. In this case, all future life years lost due to oral cancer deaths were assigned to the year in which the death occurred.

Table 6 shows that an estimated 300 oral cancer deaths in the United States in 2010 were attributable to smokeless tobacco use. These deaths represent an eventual loss of 4,900 life years. Consistent with the data on new cases and deaths from oral cancer shown in table 5 and with the lower rates of smokeless use among women, the majority of attributable deaths and life years lost occur among men.

TABLE 6—ESTIMATED ORAL CANCER CASES, DEATHS, AND CORRESPONDING LIFE YEARS LOST ATTRIBUTABLE TO SMOKELESS TOBACCO USE, U.S. 2010

Attributable new oral cancer cases	Attributable oral cancer deaths	Life years lost due to attributable oral cancer deaths
1,300	300	4,900

Note: Smokeless tobacco attributable oral cancer cases and deaths are rounded to the nearest hundred and estimated from information presented in table 5 including the U.S. summary relative risk value reported by Boffetta et al. (Ref. 100), as revised by FDA.

We also conducted a sensitivity analysis using other oral cancer relative risk estimates from the meta-analysis conducted by Lee and Hamling (Ref. 114). Lee and Hamling's analysis generated estimates of never smoker oral cancer relative risks (a relative risk of 3.33 and a 95 percent confidence interval of 1.76–6.32) for 5 studies and smoking-adjusted oral cancer relative risks (a relative risk of 1.65 and a 95 percent confidence interval of 1.22–2.25) for 12 studies for U.S. smokeless tobacco users. Lee and Hamling prioritized estimates for the population of smokers and nonsmokers that adjusted for smoking status over estimates for never smokers in studies that reported both types of estimates in contrast to Boffetta et al., who did the reverse. We did not use Lee and Hamling's never smoker relative risk in the main analysis because the number of studies that reported these risks is limited and only two of these estimates adjust for alcohol consumption. We also did not use Lee and Hamling's smoking-adjusted relative risk in the main analysis because smokeless tobacco risks that control for smoking may over-adjust if individuals who both smoke and use smokeless tobacco are more likely to smoke less or quit smoking compared with exclusive smokers (Refs. 192, 92). These relative risks were used to generate population-attributable risk estimates with the other inputs used above. Using these alternative relative risks yields estimates of approximately 700 to 2,500 new oral cancer cases in the United States that are attributable to smokeless tobacco use per year. Similarly, using these relative risks yields estimates of attributable oral cancer deaths ranging from approximately 200 to 500 per year.

We then use similar methods to project the effect of the proposed product standard on oral cancer attributable to smokeless tobacco use in the United States over time. The proposed standard would reduce the levels of NNN in U.S. smokeless tobacco products and is also expected to reduce NNK levels. As described in this section, the proposed standard is predicted to eventually reduce excess lifetime oral cancer risks among U.S. smokeless tobacco users by 65 percent, on average. This reduction in population cancer risk would likely occur over a period of time, given that some smokeless tobacco users may still develop oral cancer at the higher risk level after implementation of the proposed product standard due to previous exposure to higher NNN levels in smokeless tobacco products. For the purposes of generating projections, we assume that any final rule on the tobacco product standard for NNN would become effective 3 years after the date of publication of the final rule (see section VII, Proposed Effective Date) and that public health benefits would begin to accrue once the standard is in effect.

In estimating the health impact of the proposed standard on smokeless tobacco users, we begin with an oral cancer relative risk for smokeless tobacco users in the United States of 2.16 from FDA's revised meta-analysis of Boffetta et al. (Ref. 100). This relative risk indicates an increase in oral cancer risk of 116 percent among smokeless tobacco users compared with never users. We then reduce this value by 65 percent based on toxicological evidence relating the estimated average reduction in the dose of NNN to lifetime cancer risk under the proposed standard. The result is a reduction in the estimated relative risk of oral cancer to 1.41 under the proposed product standard. FDA used the following calculation: $(1 + (2.16 - 1) \times (1 - 0.65) = 1.41)$ for this determination.

We use studies of relevant cancer risks for former tobacco users by time since cessation to provide information about risk reductions over time after reductions in toxicant exposure. Due to limited data on the timing of cancer risk reduction after smokeless tobacco cessation, we applied estimates of relative risks by time since cessation for former cigarette smokers to approximate the time it takes for excess cancer risk to be eliminated after quitting smokeless tobacco. Estimates from cigarette smokers help inform our estimation of the trajectory of oral cancer risk reduction that could be expected as a result of reducing regular exposure to tobacco-related carcinogens. These studies generally find higher risks for oral cancer for former smokers during the first 10 years after smoking cessation compared to never smokers, but not necessarily thereafter (Refs. 115, 2). We therefore project that reductions in new oral cancer cases attributable to smokeless tobacco use would be fully realized over a 10-year period after manufacturers are in compliance with the product standard, with the reduction occurring in 10 percent increments until the full benefit is reached. We also assume that, in the absence of the proposed standard, new cancer cases attributable to smokeless tobacco use in the United States would remain constant over time, given that the National Survey on Drug Use and Health data show that smokeless tobacco use has remained relatively consistent among youth and adults since 2000 (Ref. 23). Using this approach and the revised Boffetta relative risk, we estimate that approximately 12,700 new cases of oral cancer would be prevented in the United States in the 20 years following implementation of the proposed product standard (table 7), which represents a 50 percent reduction in estimated smokeless-attributable oral cancer cases over that time period. We use the same approach to project the effect of the proposed standard on oral cancer deaths, once again assuming that reductions in deaths would be realized over a 10-year period but also assuming that this reduction will begin 3 years after implementation of the standard due to previously existing or developing cases of oral cancer. In this case, we assign the life years gained due to reductions in oral cancer deaths to the years in which the additional life years are actually lived. We estimate that approximately 2,200 oral cancer deaths would be prevented, and approximately 15,200 life years gained in the United States in the 20 years following implementation of the product standard (table 7). This represents a 40 percent reduction in estimated smokeless-attributable oral cancer deaths as a result of the product standard over a 20 year period.

We also conducted sensitivity analyses of these projections with the alternative summary relative risks from Lee and Hamling. Using the smoking-adjusted relative risk for oral cancer of 1.65 for U.S. smokeless tobacco users, we obtain a cumulative reduction of approximately 7,300 oral cancer cases and 1,300 oral cancer deaths over a 20-year period with the product standard. With the never smoker relative risk of 3.33, we obtain a reduction of approximately 24,000 oral cancer cases and 4,200 oral cancer deaths during the period.

We also examined possible impacts from changes to input values in these calculations. Specifically, we estimated changes in the public health benefits due to differences in smokeless tobacco prevalence and the length of time in which the full oral cancer risk reduction will be observed among U.S. smokeless tobacco users. These analyses are in the Uncertainty and Sensitivity Analysis, section II.G, of the Regulatory Impact Analysis associated with this proposed rule.

TABLE 7—PROJECTED CUMULATIVE DIFFERENCE IN NEW ORAL CANCER CASES AND ORAL CANCER DEATHS ATTRIBUTABLE TO SMOKELESS TOBACCO USE IN THE U.S. AND CORRESPONDING LIFE YEARS GAINED DUE TO IMPLEMENTATION OF THE PROPOSED STANDARD

Years after full implementation of the standard	Cumulative difference in attributable cases	Cumulative difference in attributable deaths	Cumulative life years gained
10 years	4,500	500	1,500
20 years	12,700	2,200	15,200

Note: Estimates in the table are rounded to the nearest hundred.

2. Additional Public Health Benefits From Reducing Oral Cancer

As a result of this proposed rule, we estimate considerable public health benefit to the United States resulting from reduced risk of oral cancer among smokeless tobacco users due to reductions in NNN (and concomitant reductions in NNK) levels in smokeless tobacco. The public health impact of oral cancer is estimated to be considerable in size. In the United States, about 65 percent of oral cancer patients survive at least 5 years with disease and those individuals who survive oral cancer can face profound challenges and reductions in quality of life.

Oral cancer patients and survivors can face major functional problems when performing basic tasks of daily living such as eating and talking. Treatment procedures can result in disfigurement or other serious cosmetic problems that also adversely impact quality of life (Ref. 116). Surgical treatments for head and neck cancers have been found to be associated with subsequent self-image issues and social isolation that increased with the level of disfigurement (Ref. 117). Patients with head and neck cancers also report high levels of anxiety and depressive symptoms (Ref. 116), and even long-term survivors report high levels of psychological distress (Ref. 118).

In the United States in 2010, approximately $3.63 billion annually was spent on medical treatment and followup care for all head and neck cancers (Ref. 119), which includes cancers of the oral cavity, pharynx, larynx, nasal cavity, and salivary glands (Ref. 120). The proposed standard will benefit public health by preventing thousands of new oral cancer cases and deaths caused by smokeless tobacco use over the next two decades.

3. Unquantified Potential Reductions in Other Cancers

In addition to reducing the risk of oral cancer, lower levels of NNN in smokeless tobacco under the proposed standard are expected to lower the risk of esophageal cancer. Smokeless tobacco use has been identified as a cause of esophageal cancer (Refs. 1, 2) and NNN has been directly linked to esophageal cancer in numerous animal studies (Ref. 8) and in an epidemiological study of smokers (Ref. 77). However, limited data are available, so the health benefit cannot be directly quantified.

Pancreatic cancer has also been identified as causally related to smokeless tobacco use (Refs. 1, 2). Lower levels of NNN (and potential reductions in NNK) in U.S. smokeless tobacco under the proposed standard have the potential to reduce the incidence of pancreatic cancer. Boffetta et al. reported the relative risk of pancreatic cancer from four studies of U.S. smokeless tobacco users to be elevated (*i.e.,* a relative risk of 1.4), although not statistically significant. Yet, estimates of pancreatic cancer relative risks have not consistently been reported to be higher in U.S. smokeless tobacco studies compared with Scandinavian snus product studies (Refs. 100, 114).

Lower levels of NNN in smokeless tobacco may also reduce the incidence of laryngeal and prostate cancers. Lee and Hamling's (Ref. 114) review found U.S. smokeless tobacco use was significantly associated with laryngeal cancer in four studies including one study that adjusted for cigarette smoking. More recently, Zhou et al. (Ref. 122) found that use of smokeless tobacco for 10 or more years was associated with elevated risk of laryngeal cancer. Lee and Hamling (Ref. 114) also found a statistically significant association between U.S. smokeless tobacco use and prostate cancer. Although NNN has not specifically been linked with an increased risk of these cancers, it is a potent carcinogen and smokeless tobacco product use can result in exposure throughout the human body.

Given that U.S. smokeless products contain high amounts of NNK, and NNK is a recognized systemic lung carcinogen (Ref. 8) in experimental animals, potential reductions in NNK levels in smokeless tobacco as a result of the proposed NNN standard may lead to some reduction in lung cancer risk. There is some evidence linking smokeless tobacco use to lung cancer (Ref. 121), although a definitive association has not been established in authoritative reviews (Refs. 3, 4).

B. The Likelihood That Existing Users of Tobacco Products Will Stop Using Such Products

Although data are lacking on perceptions of smokeless tobacco toxicants, including NNN, and cessation, there is some evidence on users' motivations for quitting smokeless tobacco. Some studies suggest that concerns about developing health problems are among the common motives that smokeless tobacco users provide for quitting (Refs. 123, 124). These studies suggest that if the proposed standard affects consumer perceptions about the harms of smokeless tobacco use, it may influence their cessation motivations. Specifically, if current smokeless tobacco users interpret an NNN product standard to mean the health risks from smokeless tobacco use will be lower after the standard is in effect, this might reduce some users' motivations to quit. It is worth noting, however, that while the magnitude of risk would be changed by implementation of the proposed standard, appreciable cancer risk would remain. Accordingly, users would still have a strong incentive to quit. FDA, therefore, does not expect the proposed product standard to appreciably discourage cessation of smokeless tobacco products in such a way as to offset the beneficial public health impact from reduced cancer risk.

Although data are lacking on perceptions of smokeless tobacco product toxicants, including NNN and the effect of awareness on cessation behaviors, prevalence of smokeless tobacco use would need to increase substantially in order to offset the reduction in cancer risk expected as a result of this rule. The magnitude of the change needed can be estimated using the population attributable risk calculation presented in section V.A.1 of this document. The calculation

includes the product of the excess relative risk (RR–1) and the prevalence of smokeless tobacco use. Therefore, smokeless tobacco use prevalence would need to nearly triple in order to completely offset the expected reduction in excess lifetime cancer risk to the equivalent of approximately one-third of the baseline cancer risk.

While there is evidence that exposure to media can lead to health behavior changes (Refs. 126, 127), it is unclear whether media coverage of this proposed product standard would promote sustained behavior change in the form of increased or decreased likelihood of smokeless tobacco cessation.

Methods used to reduce NNN levels as a result of this proposed rule may or may not produce changes that affect the sensory experiences of smokeless tobacco use. Consumers' sensory experiences can in turn influence their perceptions of product harms (Refs. 128, 129, 130), which can impact product use. However, for moist snuff, which constitutes the overwhelming majority of the smokeless tobacco market in the United States (Ref. 131), manufacturers have already identified ways to reduce nitrosamine content without negatively impacting the taste or user experience (see sections IV.C and IV.E of this document). Smokeless tobacco products are heavily flavored and the presence of flavors is a significant driver of consumer acceptance of these products (Ref. 70). The proposed standard does not prevent the addition of flavors to offset any changes in the taste of the product due to the methods used to reduce NNN to meet the proposed standard.

C. The Likelihood That Non-Users Will Start Using Tobacco Products

The proposed product standard is not expected to substantially increase, if at all, the likelihood that those who do not use smokeless tobacco will take up the product. Public perception is that smokeless tobacco use has some potential harms (Refs. 76, 133, 134, 135, 136). At this time we are not aware of direct scientific evidence demonstrating that the proposed smokeless tobacco product standard would influence consumers' perceptions of product appeal, relative risk, and absolute risk, or behaviors. Even if the proposed standard were to result in some changes to perceptions and behaviors, FDA believes that they would not offset the beneficial public health impact from reduced cancer risk. As described in this section, FDA estimates that the prevalence of smokeless tobacco use would have to nearly triple in order to offset the expected excess cancer risk reduction due to the proposed rule.

Data are not available on consumers' awareness and perceptions of NNN in smokeless products, although a single published study in a U.S. adult sample of smokers and non-smokers found awareness of and knowledge about NNN in cigarette smoke was low, particularly in comparison to other constituents (Ref. 125). Although there is very low awareness of NNN as a constituent, it is possible that some non-users of smokeless tobacco will be aware of the proposed standard and interpret it to mean that smokeless tobacco is less harmful than other tobacco products and this could, in turn, affect smokeless tobacco initiation. Research suggests that risk perceptions of tobacco use—that is, judgments about its harmfulness—can influence tobacco initiation (Refs. 137, 138). However, if the proposed standard were to result in additional uptake of smokeless tobacco use in the population, this could either decrease or increase the expected health benefits of the proposed standard. If cigarette smokers who would not otherwise quit smoking completely switched to smokeless tobacco products as a result of this standard, we would expect additional reduction in risk to these individual users. If cigarette smokers became dual users of cigarettes and smokeless tobacco products, this could have varying impacts depending on the extent to which such dual use led to substantial reductions in cigarette consumption or led to delayed cessation of tobacco products altogether. Conversely, the anticipated net population health benefits of the standard would be reduced if it led substantial numbers of never or former tobacco users to begin or resume using smokeless tobacco products.

In the case that some adolescents and young adults become aware that FDA is taking steps to reduce the harmfulness of smokeless tobacco products, FDA expects that any impact on smokeless tobacco initiation would be limited. First, smokeless tobacco initiation among youth has been shown to be associated with social influences such as actual or perceived peer use (Refs. 139, 140) to a greater extent than perceptions of the long-term health effects. Further, youth curiosity about smokeless tobacco is lower than curiosity about cigars or cigarettes (Ref. 141), suggesting that fewer adolescents are at risk for future use, compared to many other tobacco products. Thus, at the population level, very few adolescents are likely to be aware that FDA is taking an action related to NNN in smokeless tobacco products, and, even if there were some awareness, given that the standard is related to reducing long-term health effects, it is unlikely to have an impact on youth initiation.

It is possible that some former users could potentially relapse back to smokeless tobacco use due to perceptions of lower risk. Although specific data on relapse among smokeless users is not available, there is some data on relapse among smokers. For example, predictors of relapse for smokers who reported they had quit between study waves were assessed in one of the few studies assessing relapse in the general population and not part of a clinical trial. Neither the perceived costs of smoking (such as thoughts about the harms of smoking) nor benefits of quitting (including health benefits) were related to relapse (Ref. 142). However, nicotine dependence is related to relapse among smokers (Refs. 143, 144); and because smokeless tobacco products also deliver nicotine, FDA expects that the same reason for relapse would apply to former smokeless tobacco users and that changes to perceptions of costs and benefits would have little effect on relapse rates. Overall, the extent to which the proposed standard may influence behaviors of non-users and former users is likely to be minimal since health-related reasons are not among the main drivers of smokeless tobacco use initiation or relapse. Finally, HHS plans to continue developing and implementing public education campaigns to help prevent initiation of all tobacco products, including smokeless tobacco.

D. Conclusion

NNN is a potent carcinogenic agent found in smokeless tobacco and, along with NNK, another TSNA, is a major contributor to the elevated cancer risks associated with smokeless tobacco use. Oral and esophageal tissues have been identified as targets for NNN-induced carcinogenicity, when NNN was administered orally in animal studies, which indicates some concordance with effects observed at these sites in epidemiologic studies. NNN levels in most smokeless tobacco manufactured in the United States are higher than NNN levels in smokeless tobacco manufactured in Sweden. Oral cancer risks in U.S. smokeless tobacco users are elevated compared to the oral cancer risks in Scandinavian users. The proposed product standard is expected to reduce tobacco-related harms by reducing the levels of NNN in smokeless tobacco products sold in the United States, thereby reducing the risk of oral

cancer in smokeless users. By our estimates, in the 20 years following implementation of the proposed product standard, approximately 12,700 new cases of oral cancer and approximately 2,200 oral cancer deaths would be prevented in the United States. Moreover, during that 20-year period, approximately 15,200 life years would be gained as a result of the proposed standard. This represents a substantial benefit to the public health. Because oral cancer is associated with significant impacts on health and quality of life, we expect positive public health benefits due to prevention of new and fatal cancer cases. We also expect the proposed product standard to reduce the risk of esophageal cancer among smokeless tobacco users, and it may reduce the incidence of other cancer types; however, there is limited data available to directly quantify this health benefit.

Based on currently available evidence discussed previously, we do not anticipate the proposed standard would have behavioral impacts on smokeless tobacco initiation, cessation, switching to other products, or dual use in a way that would offset the public health benefits of the reduced cancer risk that would result from the proposed standard. Even if the proposed standard were to result in some instances of decreased smokeless tobacco cessation or increased initiation among non-users of tobacco, we would not expect the magnitude of these effects to be comparable to the public health benefits of the proposed rule. As described in this section, FDA estimates that the prevalence of smokeless tobacco use would have to nearly triple in order to offset the excess cancer risk reduction expected due to the proposed rule. In addition, to the extent that cigarette smokers who cannot or will not quit smoking are motivated to switch completely to smokeless tobacco due to perceptions of lower risk, this complete switching could result in additional benefits to public health through reduced risks to these individual users.

Accordingly, for the reasons discussed in this section, we find that the proposed standard is appropriate for the protection of public health. It would reduce the cancer risk posed by smokeless tobacco products and FDA does not expect that the product standard would increase the likelihood that non-users would initiate tobacco or decrease the likelihood that users will quit tobacco use. Even if the proposed standard were to result in some instances of decreased smokeless tobacco cessation or increased initiation among non-users of tobacco, we would not expect the magnitude of these effects to offset the benefits of the reduced cancer risk.

VI. Description of Proposed Regulation

A. General Provisions (Proposed Subpart A)

1. Scope (Proposed § 1132.1)

Proposed § 1132.1 identifies the scope of products that would be subject to this NNN product standard. FDA intends for this proposed standard to cover finished smokeless tobacco products, which are defined in proposed § 1132.3 (proposed § 1132.1(a)). This includes moist snuff, snus, dry snuff, chewing tobacco, and some dissolvables. Some dissolvable tobacco products do not meet the statutory definition of ''smokeless tobacco product'' because they do not contain cut, ground, powdered, or leaf tobacco; instead, these products contain nicotine extracted from tobacco. Dissolvable products that do not meet the statutory definition of ''smokeless tobacco product'' are not covered by this proposed rule. As previously noted, this rule focuses on smokeless tobacco products because different measures are required to address NNN in other tobacco products.

Proposed § 1132.1(b) states that no person may manufacture, distribute, sell, or offer for sale or distribution within the United States a finished smokeless tobacco product that is not in compliance with this part. For example, FDA would not consider finished smokeless tobacco products to be in compliance with this part if they exceed the NNN level set forth in proposed § 1132.10, the package label does not have a manufacturing code or expiration date, or the package label has a manufacturing code or expiration date that has been altered, mutilated, destroyed, obliterated, obstructed, concealed, or removed in whole or in part.

This provision is not intended to restrict the manufacture of smokeless tobacco products intended for export. Consistent with section 801(e)(1) of the FD&C Act, a tobacco product intended for export shall not be deemed to be in violation of section 907 or this product standard, if it meets the criteria enumerated in section 801(e)(1) of the FD&C Act, including not being sold or offered for sale in domestic commerce.

Proposed § 1132.1(c) explains that tobacco retailers and distributors will not be considered in violation of this part as it relates to the sale or distribution or offer for sale or distribution of finished smokeless tobacco products that exceed the NNN level set forth in § 1132.10 if they: (1) Store and transport the finished smokeless tobacco products according to the package label, (2) do not sell or distribute or offer for sale or distribution finished smokeless tobacco products past their expiration date, except to return expired products to the manufacturer, (3) do not conceal, alter, or remove the expiration date or storage conditions on the package label, and (4) do not sell or distribute or offer for sale or distribution finished smokeless tobacco products that are open or have broken seals.

FDA is proposing this exception for tobacco retailers and distributors because they cannot reasonably know or confirm by testing whether the smokeless tobacco products they are selling or distributing or offering for sale or distribution comply with the proposed NNN level. Provided that the tobacco retailers and distributors meet the requirements set forth in proposed § 1132.1(c)(1) through (4), FDA will not consider them to be in violation of part 1132 as it relates to the sale or distribution or offer for sale or distribution of products that exceed the NNN level set forth in proposed § 1132.10.

We note that tobacco retailers and distributors would need to meet all of the requirements in proposed § 1132.1(c) in order to be considered in compliance with this part as it relates to the sale or distribution or offer for sale or distribution of smokeless tobacco products that exceed the NNN level set forth in proposed § 1132.10. A retailer or distributor who, for example, covers the expiration date or storage conditions with a sticker, changes the expiration date, or scratches off the expiration date or storage conditions on the package label would not meet the requirements in proposed § 1132.1(c)(3). Furthermore, a retailer who sells finished smokeless tobacco products that are open or have broken seals would not meet the requirements in proposed § 1132.1(c)(4), because doing so could lead to changes in the NNN level, especially if it is exposed to heat or humidity.

2. Definitions (Proposed § 1132.3)

Proposed § 1132.3 provides the definitions for the terms used in the proposed rule. Several of these definitions are included in the FD&C Act or have been used in other regulatory documents.

- *Batch:* FDA proposes to define ''batch'' as a specific identified amount of a finished smokeless tobacco product produced in a unit of time or quantity and that is intended to have the same characteristics. As stated in section 910(a)(3)(B) of the FD&C Act,

characteristics means the ''materials, ingredients, design, composition, heating source, or other features of a tobacco product.''

• *Commercial distribution:* FDA proposes to define ''commercial distribution'' as any distribution of a finished smokeless tobacco product to consumers or to another person through sale or otherwise, but does not include interplant transfers of a tobacco product between registered establishments within the same parent, subsidiary, and/or affiliate company, nor does it include providing a tobacco product for product testing where such product is not made available for consumption or resale.

• *Finished smokeless tobacco product:* We propose to define ''finished smokeless tobacco product'' as a smokeless tobacco product including all parts and components, packaged for consumer use, but it would not include a component, part, or accessory sold without tobacco. A product that is ''packaged for consumer use'' would have the package label on the product. For example, a tin or can of loose snuff or a pouch containing chewing tobacco, with package labels, would meet this definition.

• *Manufacturing code:* FDA proposes to define ''manufacturing code'' as any distinctive sequence or combination of letters, numbers, or symbols that begins with the manufacturing date in 2-digit numerical values in the month, day, year format (mmddyy) followed by the batch number from which the production batch can be identified. The purpose of the manufacturing code is to allow manufacturers and FDA to identify the production batch of a particular product that has been released for commercial distribution. This information would help determine the product's history (*e.g.,* batch testing records) and assist manufacturers and FDA in the event of a nonconforming product investigation and any corrective actions that stem from the nonconforming product investigation.

• *Manufacturing date:* We propose to define ''manufacturing date'' as the month, day, and year that a smokeless tobacco product is packaged for consumer use (*i.e.,* when the package label has been added to the product). The manufacturing date is included in the manufacturing code, which can be used by the manufacturer and FDA to help determine the product's history (*e.g.,* batch testing history) in the event of a nonconforming product investigation.

• *N-nitrosonornicotine (NNN):* FDA proposes to define ''N-nitrosonornicotine'' as a tobacco-specific nitrosamine (TSNA) with the chemical formula C[9]H[11]N[3]O.

• *New tobacco product:* As defined in section 910(a) of the FD&C Act, the term ''new tobacco product'' means: (1) Any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007; or (2) any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007.

• *Package:* As defined in section 900(13) of the FD&C Act, the term ''package'' means a pack, box, carton, or container of any kind or, if no other container, any wrapping (including cellophane) in which a tobacco product is offered for sale, sold, or otherwise distributed to consumers.

• *Performance criteria:* FDA proposes to define ''performance criteria'' as the validation requirements for the acceptability of an analytical test method, including accuracy, precision, recovery, linearity, specificity, limit of quantitation, limit of detection, robustness, and range.

• *Person:* As defined in section 201(e) of the FD&C Act, the term ''person'' includes an individual, partnership, corporation, or association.

• *Rework:* We propose to define ''rework'' as the processing of nonconforming finished smokeless tobacco products to meet the requirements of this part.

• *Smokeless tobacco:* As defined in section 900(18) of the FD&C Act, the term ''smokeless tobacco'' means any tobacco product that consists of cut, ground, powdered, or leaf tobacco and that is intended to be placed in the oral or nasal cavity. This includes moist snuff, snus, dry snuff, chewing tobacco, and some dissolvables. Some dissolvable tobacco products do not meet the statutory definition of ''smokeless tobacco product'' because they do not contain cut, ground, powdered, or leaf tobacco; instead, these products contain nicotine extracted from tobacco. Dissolvable products that do not meet the statutory definition of ''smokeless tobacco product'' are not covered by this proposed rule.

• *Source data:* FDA proposes to define ''source data'' as all information contained in original laboratory records or exact copies of original records of experimental findings, observations, or other activities used for the creation, reconstruction, and evaluation of a study or other laboratory work. Source data includes any laboratory worksheets, notebooks, correspondence, notes, and other documentation (regardless of capture medium) that are the result of original observations and activities of a laboratory study or other laboratory work.

Source data could include protocols and standard operating procedures, information regarding calibration of equipment used to measure or test samples, test standards, and the standard curves used to determine the measure of the samples being tested or of the accuracy and reliability of the test. This type of information may be needed to fully evaluate, for example, whether the product meets the product standard. In addition, if there are any problems with the data, the manufacturer and FDA would be able to use the source data to reconstruct the study or lab work, which could help identify and correct any deviations. In accordance with proposed § 1132.32, source data records would have to be maintained by the manufacturer.

• *Tobacco product:* As defined in section 201(rr) of the FD&C Act, the term ''tobacco product'' means any product that is made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product). The term ''tobacco product'' does not mean an article that is a drug under section 201(g)(1), a device under section 201(h), or a combination product described in section 503(g) of the FD&C Act (21 U.S.C. 321(g)(1), 321(h), and 353(g)).

• *Tobacco product manufacturer:* As defined in section 900(20) of the FD&C Act, ''tobacco product manufacturer'' means any person, including a repacker or relabeler, who manufactures, fabricates, assembles, processes, or labels a tobacco product or imports a finished tobacco product for sale or distribution in the United States.

• *Tobacco-specific nitrosamine (TSNA):* We propose to define ''tobacco-specific nitrosamine'' to mean a chemical compound formed through the chemical reaction involving the nitrosation of nicotine, nornicotine, anabasine, or anatabine during the growing, curing, processing, or storage of tobacco.

• *United States:* As defined in section 900(22) of the FD&C Act, the term ''United States'' means the 50 states of the United States of America and the District of Columbia, the Commonwealth of Puerto Rico, Guam,

the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, Johnston Atoll, the Northern Mariana Islands, and any other trust territory or possession of the United States.

3. Incorporation by Reference (Proposed § 1132.5)

Proposed § 1132.5 identifies the materials that FDA proposes to incorporate by reference in this part. Information that is incorporated by reference would have the same force and effect as language explicitly stated in the codified. Under the proposed rule, a tobacco product manufacturer would be required to follow procedures and methods for testing as described in any standards incorporated by reference, unless the manufacturer meets the requirements in § 1132.16 for an alternative test method.

FDA is proposing to incorporate by reference a validated method developed by FDA's SRL to be the standard test method for NNN in smokeless tobacco products (proposed §§ 1132.5(a) and 1132.14). As discussed in section IV.F of this document, the results from the test method demonstrate a high level of specificity, accuracy, and precision in measuring a range of NNN levels across a variety of smokeless tobacco products.

If the proposed incorporation by reference is approved by the Office of the Federal Register and incorporated in the final rule, interested parties would be able to examine the incorporated material at the National Archives and Records Administration (NARA) and at FDA's Division of Dockets Management (proposed § 1132.5(b)), and obtain copies of the standard test method by contacting FDA's Center for Tobacco Products at the addresses and/or Web sites listed in proposed § 1132.5(b)(2).

If FDA subsequently determines that a test method, which has been incorporated by reference in a final rule, should be replaced with another method or updated, FDA will update the regulation in accordance with the Administrative Procedure Act (5 U.S.C. 553) and obtain approval of the change to the incorporation by reference in accordance with 1 CFR part 51.

Proposed § 1132.5(c) explains that if tobacco manufacturers or testing laboratories using these standards find an inconsistency between a material incorporated by reference in this part and definitions or methods described by FDA in proposed part 1132, the definitions or methods in proposed part 1132 take precedence.

B. Product Requirements (Proposed Subpart B)

1. NNN Level (Proposed § 1132.10)

For the reasons discussed in section IV of this document, FDA is proposing that the mean level of NNN in any batch of finished smokeless tobacco products must not exceed 1.0 µg/g of tobacco (on a dry weight basis) at any time through the product's labeled expiration date as determined by testing in compliance with § 1132.12. Under the proposed rule, manufacturers would be required to test their finished smokeless tobacco products using the standard test method in § 1132.14 or the alternative test method in § 1132.16.

In proposing to set the limit in terms of a batch mean, FDA has tentatively determined that the mean value is more appropriate than a limit applied to each unit produced from the entire batch of a product, given that the cancer risk is due to long term and repeated exposure, and given the variability of NNN in this agricultural product. Although we expect some degree of variability in NNN to exist in smokeless tobacco products, we recognize there may be circumstances where there could be wide ranges in the variability of NNN for some smokeless tobacco products, resulting in reduced consistency among the units produced and reduced predictability of compliance with a standard requiring that each unit meet a specific limit. FDA is requesting scientific data that could be used to determine the expected distribution of individual results for samples for a per-batch mean limit of an NNN level of 1.0 µg/g of tobacco on a dry weight basis (see proposed § 1132.10). FDA also requests comment on the compliance implications of the currently proposed approach.

NNN-related cancer risk is due to long term and repeated exposure to NNN. Under the currently proposed approach, as long as the mean of each batch consistently conforms to the NNN level of 1.0 µg/g of tobacco (on a dry weight basis) in accordance with § 1132.10, FDA expects that the long term impact from an occasional exposure to a product with slightly higher NNN level will be offset by the exposure to slightly lower levels. Therefore, any random variation that may exist is not expected to negatively impact the public health benefit of the proposed standard, which is based on reduction of excess lifetime cancer risk.

FDA also is considering an alternative approach that includes setting a standard where the specified NNN level of 1.0 µg/g of tobacco (on a dry weight basis) would apply to all units produced from the entire batch, rather than to a per-batch mean. This alternative approach would thereby require the manufacturer to ensure compliance of each unit made from a batch despite some expected random variation of the NNN level between units. This could further increase the public health benefits of this product standard. However, in instances where manufacturers determined that some units within a batch had levels of NNN above the limit and others had levels below the limit, this alternative approach could add costs for manufacturers (*e.g.,* costs of rejecting or reworking the batch) or require them to manufacture product with NNN levels lower than the NNN level of 1.0 µg/g of tobacco (on a dry weight basis) in order to minimize the risk of having to reject a batch based on random variation. FDA currently believes that this is not necessary to achieve the public health goals of the proposed standard, but invites input on this point.

We invite comments on FDA's proposed approach and on the alternative approach and their implications for compliance with the limit, and public health impact. We also invite comments or information on batch sampling methods or other approaches manufacturers might use to determine compliance with an absolute limit on all units produced from a batch given the expected variability of NNN in relevant products.

2. Product Testing (Proposed § 1132.12)

Proposed § 1132.12 contains provisions for the testing of smokeless tobacco products. FDA is proposing to require two types of testing—stability testing and batch testing.

a. *Stability testing.* Proposed § 1132.12(a) would require each tobacco product manufacturer to conduct testing to assess the stability of the NNN level in its finished smokeless tobacco products. Given the variability of NNN levels in current smokeless tobacco products (see section IV.B.1 of this document), stability testing would help ensure that the NNN level in finished smokeless tobacco products is being properly monitored and controlled and that it remains in conformance with the proposed limit through the product's labeled expiration date. The initial stability testing would establish the rate of change of the NNN level for a product and the annual stability testing would identify any changes to the rate of change of the NNN level in that product.

Manufacturers would be required to use the results of stability testing to establish and verify the product's expiration date and storage conditions

(either room temperature or refrigeration). Proposed § 1132.20 would require all finished smokeless tobacco products to have an expiration date established by stability testing. This date would have to be no later than the final date the manufacturer can demonstrate that the NNN level in the finished smokeless tobacco product conforms to § 1132.10 when the product is stored under its intended conditions (*e.g.,* room temperature or refrigeration).

When conducting stability testing, manufacturers would be required to use either the standard test method in § 1132.14 or an alternative test method that meets the requirements in § 1132.16 and samples would have to be selected in accordance with the requirements set forth in § 1132.18(a) and (c) (proposed § 1132.12(a)(1)).

Proposed § 1132.12(a)(2) would require each manufacturer to establish and maintain a written protocol for all stability testing, that fully describes the methodology used to determine the stability of the NNN level, including the test method used (the standard test method in proposed § 1132.14 or an alternative test method in accordance with proposed § 1132.16), the sampling plan and procedures required by proposed § 1132.18(a) and (c), and the storage conditions.

Proposed § 1132.12(a)(3) requires initial real-time stability testing that covers each finished smokeless tobacco product. In certain circumstances, it may not be necessary to conduct initial real-time stability testing on a particular product because the results from initial real-time stability testing conducted on another similar product apply. For example, a manufacturer who manufactures moist snuff in a tin and moist snuff in a pouch would be required to conduct initial real-time stability testing on both products, because the tin and the pouch could have different impacts on the NNN level and, thus, on the stability of the finished products. In contrast, a manufacturer who manufactures two finished products, where the only difference between them is a slight change in flavor ingredients that does not affect NNN levels, would only be required to conduct initial real-time stability testing on only one of the two products. The results from that testing would apply to both products and the testing would be considered to cover both products. Other examples of differences between products that would not require additional initial real-time stability testing, if initial real time stability testing has already been conducted on one of the products, include slight changes in acids, bases, or other pH modifiers with no resulting change in final pH. This provision is intended to reduce the burden on the manufacturer, while ensuring that there is initial real-time stability data that applies to all finished tobacco products, thus preserving the goal of the requirement.

Manufacturers would be required to use the results from initial stability testing to establish an expiration date and appropriate storage conditions (either room temperature or refrigeration) for the finished product. We believe that room temperature or refrigeration are the most likely storage conditions for smokeless tobacco products because most current smokeless tobacco products are stored at room temperature while some snus products are refrigerated. FDA does not expect that manufacturers would choose to freeze their finished smokeless tobacco products. The expiration date and storage conditions would be required to be displayed on the package label in accordance with proposed § 1132.30.

For initial real-time stability testing, FDA is proposing that, at a minimum, samples be tested within 7 days of manufacture to determine the starting NNN level and at the expected expiration date (proposed § 1132.12(a)(3)(i)). Testing the NNN level at various time points is intended to ensure that the NNN level in finished smokeless tobacco will conform to § 1132.10 through the determined expiration date under the intended storage conditions. If the proposed storage condition is room temperature, samples for initial real-time stability testing would have to be stored at 25 ± 2 degrees Celsius and 60 ± 5% relative humidity (proposed § 1132.12(a)(3)(i)(A)) and, if the proposed storage condition is refrigeration, samples would have to be stored at 5 ± 2 degrees Celsius (proposed § 1132.12(a)(3)(i)(B)).

FDA believes manufacturers will likely choose to test at several additional time points to determine the rate of NNN change, if any. Testing of additional time points could allow the manufacturer to establish an acceptable expiration date even if testing shows the finished smokeless tobacco product would exceed the level set forth in § 1132.10 at the expected expiration date. For example, a manufacturer may initially expect its product to have a conforming NNN level for a period of 8 months, based on history of experience with similar products. If instead of only testing the product at 7 days and at 8 months, the manufacturer chooses to test at 7 days, 6 months, and 8 months, that manufacturer would still be able to establish an expiration date for its product (at 6 months) if the testing results showed that the product conforms at 6 months but not at 8 months. Because NNN levels in the product would only increase over time, manufacturers would also be able to choose a shorter expiration date if they wish (Ref. 11). For instance, if stability testing demonstrated the NNN level remains in conformance with proposed § 1132.10 through at least 6 months, the manufacturer could choose to use a 4-month expiration date if the manufacturer did not want the product sold after that time period due to freshness or taste changes.

FDA is proposing to allow manufacturers to conduct accelerated stability testing concurrently with initial real-time stability testing to establish the product's expiration date and storage conditions (proposed § 1132.12(a)(3)(ii)). The manufacturer would be allowed to use an expiration date of no longer than 1 year based on initial accelerated stability testing. Accelerated stability studies provide preliminary information on NNN levels over time and are of shorter duration than long-term stability studies. By allowing manufacturers to conduct accelerated stability testing, FDA intends to reduce the time required to bring new products to market without adversely impacting public health.

Proposed § 1132.12(a)(3)(iii) would require that, at a minimum, samples for initial accelerated stability testing be tested at three time points within a 6-month period. This testing paradigm is similar to one used for stability testing for drugs. We would require the first time point be within 7 days of manufacture and the last time point at 6 months after manufacture. Because it may not always be possible to test exactly 6 months after manufacture, FDA notes that testing conducted within the week prior to or the week after the 6 month date of manufacture would be considered to meet this requirement. If the proposed storage condition is room temperature, samples for accelerated stability testing would have to be stored at 40 ± 2 degrees Celsius and 75 ± 5% relative humidity (proposed § 1132.12(a)(3)(iii)(A)) and, if the proposed storage condition is refrigeration, samples would have to be stored at 25 ± 2 degrees Celsius and 60 ± 5% relative humidity (proposed § 1132.12(a)(3)(iii)(B)). Because higher temperatures and humidity can increase the biological activity, these conditions will accelerate any increases in the NNN level, thereby providing a prediction of the stability of the NNN for a 12-month period under normal conditions.

Proposed § 1132.12(a)(3)(iv) would require the manufacturer to use the results of initial real-time stability testing to establish an expiration date and storage conditions if initial accelerated stability testing shows the NNN level in finished smokeless tobacco products will not conform to proposed § 1132.10. If the NNN levels do not conform after 6 months of accelerated testing conditions, then there will be insufficient evidence to project that NNN levels will conform after 12 months of normal conditions. Accordingly, this accelerated data may not be used to forecast an expiration date.

FDA is also proposing to require manufacturers to conduct annual real-time stability testing on each finished smokeless tobacco product to verify the results of the initial stability testing and, given the variability of NNN in tobacco, to ensure that the established expiration date and storage conditions remain appropriate and don't need to be changed (proposed § 1132.12(a)(4)). Accelerated stability testing would not be permitted for annual stability testing. We propose that accelerated stability testing be permitted for initial stability testing to reduce the time required to bring new products to market without adversely impacting public health. However, accelerated testing is unnecessary for annual stability testing because these products would already be on the market.

Proposed § 1132.12(a)(4)(i) would generally require annual real-time stability testing to begin within 12 months of the completion of initial stability testing and then annually thereafter, with no longer than 12 months between testing. When a manufacturer has not conducted initial real-time stability testing on a particular smokeless tobacco product because it has determined that the results from initial real-time stability testing conducted on another product apply, annual stability testing would have to begin when the product is first released for commercial distribution and then annually thereafter, with no longer than 12 months between testing (proposed § 1132.12(a)(4)(ii)). Samples for annual real-time stability testing, at a minimum, would have to be tested within 7 days of manufacture to determine the starting NNN level and at the established expiration date (proposed § 1132.12(a)(4)(iii)) to determine the final NNN level and provide assurance that the NNN level conforms to the standard through the expiration date. Also, similar to initial real-time stability testing, the samples would have to be stored at room temperature or refrigeration in accordance with proposed § 1132.12(a)(4)(iii)(A) and (B).

FDA proposes that, if the results of the most recent annual real-time stability testing do not support the finished smokeless tobacco product's previously established expiration date, the manufacturer must use the results of the most recent annual real-time stability testing to establish a new expiration date (proposed § 1132.12(a)(4)(iv)). After a new expiration date has been established, the package labels of all affected finished smokeless tobacco products that have not been released for commercial distribution would be required to display the new expiration date and storage conditions in accordance with proposed § 1132.30. Furthermore, if the expiration date must be shortened, the manufacturer would be required to conduct, fully document, and maintain records of an investigation to determine why the results of the most recent annual real-time stability testing do not support the product's previously established expiration date (proposed § 1132.12(a)(4)(v) and (a)(2)).

b. *Batch testing.* FDA is proposing that tobacco product manufacturers conduct testing on each batch of finished smokeless tobacco product to ensure that the products conform with proposed § 1132.10 prior to commercial distribution (proposed § 1132.12(b)). Testing each batch prior to its release into commercial distribution provides assurance to the manufacturer and FDA that each batch conforms to the proposed standard. Any problems with the NNN level that may arise during production (*e.g.,* problems due to the pasteurization equipment not heating correctly) would be detected by batch testing. In addition, finished product that does not conform to the standard would not be released for commercial distribution.

The manufacturer would be required to use either the standard test method in proposed § 1132.14 or an alternative test method that meets the requirements in proposed § 1132.16 and samples would have to be selected in accordance with the requirements set forth in § 1132.18(b) and (c) (proposed § 1132.12(b)).

FDA expects tobacco product manufacturers would use the results of batch testing and annual stability testing (proposed § 1132.12(a)) to inform their determination that a batch of finished smokeless tobacco product conforms to the proposed NNN level (proposed § 1132.10) at the time of release for commercial distribution and through the expiration date. For example, since finished smokeless tobacco products would have to conform with the proposed NNN level at batch testing and through their expiration date, the NNN level at batch testing would have to be low enough to ensure that the NNN level remains compliant until the expiration date. FDA believes that most manufacturers will develop products which have no, or minimal, changes in NNN over time. However, that is not required by this product standard. For instance, if stability testing demonstrates that the mean NNN level in a batch increases by 0.2 µg/g of tobacco on a dry weight basis over a 6 month expiration period, batch testing that demonstrates the mean NNN level is below 0.75 µg/g of tobacco on a dry weight basis would be in conformance because the mean NNN level of the batch would be expected to remain below 1.0 µg/g of tobacco on a dry weight basis at least through the expiration date of 6 months. We expect that any changes in a rate of increase would be observed and investigated during annual stability testing.

c. *Documentation of test results.* Proposed § 1132.12(c) would require the tobacco product manufacturer to maintain a full report of the source data and results of all stability and batch testing. This report would need to include the full identification of the smokeless tobacco product that is the subject of the report, including the product subcategory, brand, subbrand, package size and quantity of product (mass and, if portioned, count) and, for portioned tobacco products, the size (mass) of each portion. Subcategories of smokeless tobacco products include, for example, loose moist snuff, portioned moist snuff, loose snus, portioned snus, loose dry snuff, certain dissolvables, loose chewing tobacco, and portioned chewing tobacco.

In addition, the report would have to include the following:

- NNN level of each sample tested;
- Mean NNN level and standard deviation;
- The location, including facility name and address, from which each sample was pulled;
- The manufacturing code of each sample tested or, for samples for initial stability testing with no manufacturing code, an identifying code created by the manufacturer;
- The testing date and location, including the testing facility name and address;
- The test method and sampling procedure used;
- All tobacco product reference standard test results;

• The names and qualifications of the person(s) conducting the testing;

• The equipment used (including documentation to show that the equipment is appropriate for its intended use and has been calibrated); and

• For batch testing only, the criteria used to make a decision to accept or reject each batch and the decision made with respect to each batch (*e.g.,* accept, reject) based on the results of the product testing, including the NNN level of the individual batch and the results of the product's stability testing. For example, the criteria for accepting a batch of product whose stability testing demonstrates no change in the mean NNN level would be a batch mean NNN level less than or at 1.0 µg/g of tobacco, while the acceptance criteria for a batch of product whose stability testing demonstrates an increase of 0.2 µg in mean NNN level per gram of tobacco over the expiration period would be a batch mean NNN level at or below 0.8 µg/g of tobacco. The manufacturer would also be required to keep records, where applicable, of the decision made and justification with respect to the results of a nonconforming product investigation required under proposed § 1132.22. For example, if a batch initially tests out of compliance and a nonconforming product investigation finds the NNN levels were erroneously high because of a malfunction of the testing equipment, the manufacturer could determine that the batch is acceptable for release if the NNN levels are in conformance after the equipment has been fixed. The manufacturer would be required to keep the records of the decision made and the justification.

3. Standard Test Method (Proposed § 1132.14)

Proposed § 1132.14 states that the standard test method is the method entitled ''Determination of N-nitrosonornicotine (NNN) in Smokeless Tobacco and Tobacco Filler by HPLC–MS/MS,'' that is incorporated by reference in § 1132.5(a). The standard test method is explained in further detail in section IV.F, Analytical Method. If FDA subsequently determines that a test method, which has been incorporated by reference in a final rule, should be replaced with another method or updated, FDA will update the regulation in accordance with the Administrative Procedure Act (5 U.S.C. 553) and obtain approval of the change to the incorporation by reference in accordance with 1 CFR part 51.

4. Alternative Test Method (Proposed § 1132.16)

If a tobacco product manufacturer were to choose not to use the standard test method in § 1132.14 to test each batch, the manufacturer would be required to use a validated alternative test method that conforms to the requirements of proposed § 1132.16. The performance criteria of the alternative test method would have to meet or exceed the performance criteria of the standard test method (proposed § 1132.16). FDA would consider the following parameters to assess the performance criteria of an alternative test method: Accuracy, precision, linearity, specificity, limit of quantitation, limit of detection, robustness, and range.

Proposed § 1132.16(a) would require that, before using a validated alternative test method, the manufacturer notify the Director of the Office of Science for FDA's Center for Tobacco Products. By requiring prior notification, we hope to help manufacturers to avoid using a test method that does not meet the requirements in § 1132.16 and being unable to release for commercial distribution any product tested using that method. Notification also allows FDA to track what methods are being used, by whom, and for what products. This information can be used to inform FDA inspectors regarding the use of an alternative test method. In addition, if any issues arise with regard to a specific alternative test method, FDA would be aware of other manufacturers who may also be affected.

A manufacturer seeking to use a validated alternative test method could not begin to use this method until 60 calendar days after the date FDA receives the notification regarding the alternative test method. This would allow time for FDA to review and act on the notification. Smokeless tobacco manufacturers would be informed of FDA's receipt of the notification through the automated Document Control Center process. A manufacturer may not begin or continue using the alternative test method if FDA notifies the manufacturer that it has not been demonstrated to meet the requirements of § 1132.16.

The notification would have to contain the information required by proposed § 1132.16(b) and be in the format discussed in proposed § 1132.16(d). Proposed § 1132.16(b) provides the required contents for the notification of use of an alternative test method. The notification would be required to include the following information:

• General information;

• A comprehensive index and table of contents;

• Summary of the notification; and

• Complete description of the method.

In addition, FDA may request clarification and other relevant information, if needed (proposed § 1132.16(c)).

The set of general information would be submitted on the FDA-provided form, a draft of which FDA is making available as a reference for review and comment (Ref. 145). The form would include the following information:

• Date the manufacturer submitted the notification to FDA;

• Identification of the submission as a notification of an alternative test method;

• Manufacturer's name, address, and contact information;

• Identification of and contact information (including name, mailing address, email address, and telephone number) for an authorized representative of the manufacturer (which could be a U.S. agent for the manufacturer);

• Identification of the subcategories of finished smokeless tobacco products (*e.g.,* loose moist snuff, portioned moist snuff, loose snus, portioned snus, loose dry snuff, certain dissolvables, loose chewing tobacco, portioned chewing tobacco, or other) that can be analyzed using the alternative test method; and

• The testing facility's name and address.

The summary section of the notification would have to contain the following information:

• Identification of the standard test method for which the alternative test method is being proposed;

• A concise description of the performance criteria of the alternative test method;

• A concise explanation regarding the manufacturer's rationale for proposing to use the alternative test method; and

• A concise comparison of the similarities and differences between the alternative and standard test methods.

As stated in proposed § 1132.16(b)(4), the manufacturer would be required to provide a complete description of the method with sufficient detail to enable FDA to evaluate whether the information demonstrates that the alternative test method meets or exceeds the performance criteria of the standard test method set forth in § 1132.14. This description would have to include a complete explanation of the manner in which the alternative test method is proposed to deviate from the standard test method in § 1132.14. The

description would have to include an explanation with scientific rationale and supporting data, as well as a complete copy of the testing protocol, to demonstrate that the alternative method meets or exceeds the performance criteria established for the standard test method. In proposed § 1132.16(b)(4)(ii) and (c), the manufacturer also would have to include any data and information from other studies comparing the alternative test method to the standard test method and, if requested by FDA, any other relevant information needed to evaluate the alternative test method (*e.g.,* statistical analysis comparing the alternative test method to the standard test method, proficiency test results, or evidence of technical competence).

Proposed § 1132.16(d) provides the format for a manufacturer's notification of use of an alternative test method. First, the notification would have to be submitted using the FDA-provided form and all information would have to be organized, legible, and written in the English language. The comprehensive index and table of contents (required by proposed § 1132.16(b)) would provide sufficient organization for the document. FDA expects that the manufacturer will submit this form using the Agency's electronic system. The manufacturer's notification and all supporting information would be required to be in an electronic format that the Agency can process, review, and archive. Current information about electronic submission preparation (*e.g.,* acceptable file formats, technical specifications, data standards) and transmission requirements may be found on the FDA Web site.

FDA is proposing to require that tobacco manufacturers use the electronic format for the submission of this information to facilitate our review of the data submitted. Electronic submission of information is consistent with the Government Paperwork Elimination Act (Pub. L. 105–277), which requires that Federal Agencies allow individuals or entities to submit information or transact business with the Agency electronically.

A smokeless tobacco manufacturer that is not able to submit a notification of use of an alternative test method in an electronic format could submit a written request to the Center for Tobacco Products explaining in detail why the company cannot submit the notification in an electronic format and requesting an alternative format (as provided in proposed § 1132.16(d)(3)).

Proposed § 1132.16(d)(3) would provide that, if a manufacturer cannot submit a form electronically, the manufacturer may submit a request for a waiver. A waiver would be granted only if the use of electronic means is not reasonable. If FDA grants the manufacturer's waiver request, the Agency will provide information as to how and where to submit the notification and supporting documentation in paper format.

If a manufacturer seeks a waiver, the manufacturer must send a legible written request in the English language to the Document Control Center, with a notation ''ATTN: Office of Science,'' to the address included in our Web site at *www.fda.gov/TobaccoProducts.* The address can also be obtained by calling 1–877–CTP–2373 (1–877–287–1373). The waiver request would have to contain the following information: The name and address of the tobacco product manufacturer that wishes to submit the notification; the name and contact information of the manufacturer's authorized representative (which could be a U.S. agent for the manufacturer); and a statement and rationale as to why the creation and/or submission of information in electronic format is not reasonable (such statement must be signed by the authorized representative of the tobacco product manufacturer).

Proposed § 1132.16(e) clarifies the applicability of an alternative test method. An alternative test method could be implemented only by the tobacco product manufacturer who submitted the notification and only with respect to the subcategories of finished smokeless tobacco products that were the subject of the notification. We are proposing this approach because an alternative test method that is appropriate for one subcategory of smokeless tobacco product (*e.g.,* moist snuff) may not be generalizable to other subcategories of smokeless products (*e.g.,* chewing tobacco). Also, because some test methods may be proprietary or may have been developed by the manufacturer for a specific product, FDA believes it is important for the manufacturer to notify FDA and fully describe the method they plan to use and the products on which they intend to use it.

Other manufacturers interested in similar or identical alternative test methods would have to submit their own notification following the procedures of proposed § 1132.16. Therefore, if a manufacturer previously submitted a notification of an alternative test method and later sells the company to another manufacturer, the new manufacturer would have to submit a notification if it wished to continue using the alternative method. This would ensure that FDA is aware of which manufacturers are using an alternative test method. Similarly, if the original notification pertains to one subcategory of smokeless tobacco (*e.g.,* moist snuff), and the manufacturer also decides to use the method to test another subcategory of product (*e.g.,* dry snuff), the manufacturer would have to submit a new notification in accordance with proposed § 1132.16. A new notification would be needed because an alternative test method may not be suitable for testing of other product subcategories and the test method would need to be evaluated for them before it can be used by the manufacturer.

Proposed § 1132.16(f) indicates that FDA will acknowledge the receipt of a notification of an alternative test method. If the applicant submits the notification electronically, FDA will acknowledge receipt electronically. This provision also reiterates that there is a waiting period before a smokeless tobacco manufacturer may begin using the alternative test method. A manufacturer could start using an alternative test method beginning 60 calendar days after FDA's receipt of a complete notification unless the Agency notifies the manufacturer otherwise.

Proposed § 1132.16(f)(1) provides that, if the notification is complete when FDA receives it, the 60 calendar day waiting period would begin on the date the Agency receives the notification. If the notification did not contain all of the information required by proposed § 1132.16(b) and was, therefore, incomplete, FDA would not accept the notification and would inform the submitter (proposed § 1132.16(f)(2)). Upon notice from FDA that the notification is incomplete, the manufacturer may not supplement the submission, but rather would be required to submit a new notification that includes all the information required in proposed § 1132.16(b). Providing all of the information in one complete notification will facilitate FDA's review so that it can act expeditiously on the notification. The manufacturer would not be able to use the alternative test method until the end of the 60-day waiting period following submission of the new, complete notification, provided it has not received an FDA notification informing the submitter otherwise. If FDA informs the manufacturer during the 60 calendar day waiting period that the manufacturer has not demonstrated that the alternative test method meets or exceeds the performance criteria of the standard test method, the manufacturer would be prohibited from implementing

the alternative test method. If FDA makes this determination after the 60 calendar day period has ended and the manufacturer has already begun using the procedure, the smokeless tobacco manufacturer would have to immediately cease using the alternative test method upon receipt of FDA's notification.

Proposed § 1132.16(f)(4) explains that acceptance of a notification does not constitute a finding by the Agency that an alternative test method meets or exceeds the performance criteria of the standard test method set forth in § 1132.14.

5. Sampling Plans and Procedures (Proposed § 1132.18)

Proposed § 1132.18 would require each smokeless tobacco manufacturer to design and implement sampling plans for stability testing and batch testing. These sampling plans would be used in conjunction with the product testing required in proposed § 1132.12 (stability testing and batch testing) and would provide procedures for the manufacturer to select samples to demonstrate conformance with the proposed NNN level.

Proposed § 1132.18(a) would require each tobacco product manufacturer to design and implement a sampling plan or plans for all stability testing required in proposed § 1132.12(a) based on a valid statistical rationale to demonstrate that the finished smokeless tobacco product's expiration date is appropriate under the intended storage conditions. One sampling plan could cover multiple products (*e.g.,* different flavors of the same basic core tobacco blend and cut), but multiple plans would be needed if the products are sufficiently different from one another in processing or materials (*e.g.,* one product is expected to have a very stable NNN level, whereas in another the NNN level increases steadily over time).

The sampling plan would have to ensure that samples taken are representative and randomly selected. Furthermore, to account for the variability of NNN in the smokeless tobacco products, the following factors would have to be based on adequate statistical criteria: The confidence intervals, the level of necessary precision, and the number of finished products sampled. Finally, proposed § 1132.18(a) would require each sampling plan to fully describe the sampling methodology with scientific rationale, incorporate all sources of variability (including variability of the analytic method and the NNN levels), and describe the sample size needed (including a full description of how the sample size is calculated) consistent with the sampling design to achieve the sampling objective.

Similarly, proposed § 1132.18(b) would require each tobacco product manufacturer to design and implement a sampling plan or plans for all batch testing required in § 1132.12(b) based on a valid statistical rationale to ensure that the finished smokeless tobacco product consistently conforms to the NNN level set forth in proposed § 1132.10. One sampling plan could cover multiple products (*e.g.,* different flavors of the same basic core tobacco blend and cut), but multiple plans would be needed if the products are sufficiently different from one another in processing or materials (*e.g.,* one product is expected to have a very stable NNN level, whereas in another the NNN level increases steadily over time).

The sampling plan would have to ensure that the samples taken are representative of an entire batch and are randomly selected and collected from each batch for testing. To account for the variability of the NNN levels in the finished smokeless tobacco products, the following factors would have to be based on adequate statistical criteria: The confidence intervals, the level of necessary precision, and the number of finished products sampled. The sampling plan would also have to take into account the manufacturing quality history of the manufacturer (*e.g.,* batch testing records and nonconforming product investigations). For example, a manufacturer who has a high number of nonconforming product investigations or high number of batch rejection records may need to create a more robust sampling plan because of their history of producing nonconforming products.

In addition, the sampling plan would have to contain a full description of the sampling methodology, with scientific rationale, incorporate all sources of variability (including variability of the analytic method and the NNN levels across batches), and describe the sample size needed (including a full description of how the sample size is calculated) consistent with the sampling design to achieve the sampling objective. Finally, the sampling plan would also need to fully describe the criteria the manufacturer will use to make a decision to accept or reject each batch. For example, the criteria for accepting a batch of a product would depend on the results of the stability testing. If stability testing demonstrates no change in mean NNN level, the acceptance criteria could be a batch mean NNN level less than or at 1.0 µg/g of tobacco on a dry weight basis. If the stability demonstrates an increase of 0.2 µg of mean NNN level per gram of tobacco on a dry weight basis over the expiration period, the acceptance criteria would need to be a batch mean NNN level below 0.8 µg/g of tobacco on a dry weight basis. In those cases, the batch of product is acceptable because the manufacturer would expect the batch mean NNN level to remain at or below 1.0 µg/g of tobacco on a dry weight basis through the expiration date.

Proposed § 1132.18(c) would require that samples be collected and examined in accordance with certain procedures.

Under proposed § 1132.18(c)(1), test samples for initial real-time and accelerated stability testing would have to consist of:

- Smokeless tobacco product that has been manufactured using the same production processes as products manufactured for consumer use and packaged in the identical package that will be used for the finished smokeless tobacco product, but it need not have the product package label; or
- Finished smokeless tobacco product as it is intended to be sold or distributed to consumers.

This provision would allow flexibility for the manufacturer to determine the sample to be tested. It also recognizes that, at this early stage, a manufacturer may not want to or may not be able to create package labels for new smokeless tobacco products. For example, in accordance with § 1132.30 a package label would need to have the expiration date for the product. Prior to completing initial stability testing, the manufacturer might not know what the appropriate expiration date would be. Similarly, we expect a manufacturer of a new smokeless tobacco product would be most likely to sample smokeless tobacco that meets the requirements of § 1132.18(c)(1)(i) to minimize costs. In contrast, we would expect a manufacturer whose smokeless tobacco products may already conform to the proposed standard to test its finished smokeless tobacco product (§ 1132.18(c)(1)(ii)) rather than product that has been manufactured specifically for testing purposes.

Proposed § 1132.18(c)(2) would require that test samples for annual real-time stability testing and batch testing consist of the finished smokeless tobacco product as it is intended to be sold or distributed to consumers and not of a separate production sample. This is intended to ensure the samples tested are representative of the product to be sold or distributed to consumers.

Under proposed § 1132.18(c)(3), all test samples would need to be stored according to the intended storage

conditions for the finished smokeless tobacco product (either room temperature or refrigeration), except that test samples for initial accelerated stability testing must be stored in accordance with proposed § 1132.12(a)(3)(iii). The manufacturer would have to include all of its factories, stock rooms, warehouses, and other locations containing finished smokeless tobacco products in the population to be sampled. Because a batch may include product that is in the warehouse and product that is in the factory, or in a place between the warehouse and factory, this would ensure the sample is representative of the entire population (batch) of finished smokeless tobacco products packaged for consumer use.

Proposed § 1132.18(c)(4) sets forth when samples must be taken for testing. Samples for stability testing would have to be taken within 7 days of the manufacturing date and tested in accordance with proposed § 1132.12(a). This would ensure the samples for stability testing are tested as soon as possible after manufacturing to establish the starting NNN level. It also provides sufficient time for the sample to be shipped to a laboratory for testing. Samples for batch testing would have to be taken from each batch and tested within 30 calendar days of the manufacturing date.

The amount of material acquired during sampling would have to be sufficient for the test methods in proposed §§ 1132.14 or 1132.16, including any repeats that may be necessary. For example, repeat tests would be necessary if the test material was damaged prior to or during the analysis. Samples would have to be randomly selected in accordance with the applicable sampling plan and taken within the same day. This would ensure that there has not been any degradation or change in part of the samples.

Proposed § 1132.18(c)(5) would require that sampling be performed by persons who have sufficient education, training, and experience to accomplish the assigned functions. This would allow the manufacturer the flexibility to determine the education, training, and experience needed to perform this function. For example, the manufacturer may determine that a person has the necessary education, training, and experience for the position if they have completed course work or training in statistics, been trained by the manufacturer on sampling procedures, or have prior work experience.

Under proposed § 1132.18(c)(6), each sample would have to be identified by the following information:

- Full identification of the smokeless tobacco product sampled, including product subcategory, brand, and subbrand, package size and quantity of the product (mass and, if portioned, count) and, for portioned tobacco products, the size (mass) of each portion;
- Manufacturing code or, for samples for initial stability testing with no manufacturing code, an identifying code created by the manufacturer;
- The date on which the sample was taken;
- The sampling location (including the address of the facility and specific location within the facility where the sample was taken);
- The name of the person(s) who collected the sample; and
- The location where the sample will be stored and tested (including the facility name and address).

This information would be generated at the time the samples are pulled for testing.

The purpose of this information is to fully identify each sample, including what the product is, and when and where it was taken. These records would serve dual purposes. First, they can be used to verify that a company is following its sampling plan and the procedures required under this part, including the number of samples pulled, when they are pulled, and the locations from where they are pulled. Second, these records can be used to generate some of the information for the report required under proposed § 1132.18(c)(9). The records also document the start of sampling process.

Proposed § 1132.18(c)(7) provides packing requirements for samples that are sent for testing. Samples would have to be packed securely to protect against damage that might occur during shipment to the testing facility, including mechanical damage or severe changes in humidity or temperature that may affect the NNN level. The samples would have to be sent to the testing facility by the most expeditious means in order to arrive no later than 3 calendar days after shipment. This is intended to minimize the potential for damage to or contamination of the samples and would help to ensure that the testing is completed within the specified time periods. The smokeless tobacco manufacturer would also have to send, under separate cover, a list of the samples (identified by the relevant information required by proposed § 1132.18(c)(6)) included in each shipment to the testing facility. This would ensure the laboratory receives a complete list of the samples to be tested.

Proposed § 1132.18(c)(8) would require that all the samples for a specific stability or batch test be tested at the same testing facility to ensure consistency among the procedures used and to protect against sample degradation.

Proposed § 1132.18(c)(9) provides sampling requirements for the testing facility responsible for testing the manufacturer's samples. Once the samples arrive at the testing facility, a representative of the facility would have to ensure that the samples are inspected, accounted for, and stored under the finished smokeless tobacco product's intended storage conditions (*e.g.,* room temperature or refrigeration) except that test samples for initial accelerated stability testing must be stored in accordance with § 1132.12(a)(3)(iii). The facility would then be responsible for generating a report for the stability or batch test that includes the following information:

- Full identification of the smokeless tobacco product sampled, including product subcategory, brand, and subbrand, package size and quantity of the product (mass and, if portioned, count) and, for portioned tobacco products, the size(mass) of each portion;
- Manufacturing code or, for samples for initial stability testing with no manufacturing code, an identifying code created by the manufacturer;
- The date when the samples were taken from the batch, if available;
- Locations where samples were drawn (including the address and specific locations within any facilities where the samples were taken), if available;
- The number of test samples drawn; and
- Complete records of the samples received and tested, including the date of receipt, the identifier of all persons who tested the samples, and the test results.

This information would be generated once the samples arrive at the testing facility. Unlike the information required under proposed § 1132.18(c)(6), this report would be an aggregate report for all the samples taken from a batch. The primary purpose of this information, along with the information required by proposed § 1132.18(c)(6), would be to establish the chain of custody for the samples from the time they were taken up through their transfer to the testing facility where they will be tested. The smokeless tobacco manufacturer would be required to maintain the sampling information in accordance with proposed § 1132.32. Thus, the manufacturer would be responsible for obtaining this information from the

testing facility. FDA also expects that this information would be integrated into the records required by proposed § 1132.12(c) to provide information across the batch.

Proposed § 1132.18(c)(10) explains that the manufacturer would be required to withhold from commercial distribution each batch until it has been sampled and tested, and the tobacco product manufacturer has made a decision to accept and release the batch. The manufacturer would be required to reject any nonconforming products as discussed in proposed § 1132.22.

6. Expiration Date (Proposed § 1132.20)

Proposed § 1132.20 would require all finished smokeless tobacco products to have an expiration date established by stability testing. The expiration date would be required to be set no later than the final date the manufacturer can demonstrate the finished smokeless tobacco product will not exceed the NNN limit in proposed § 1132.10 when stored under its intended conditions (*i.e.,* either room temperature or refrigeration). FDA considered requiring manufacturers to determine the time point at which the NNN level exceeds the limit. However, FDA rejected this approach because manufacturers may develop products with stable NNN levels that do not exceed the NNN limit for a prolonged period (*e.g.,* 5 years) and requiring manufacturers to conduct stability testing for that entire period would be unnecessary. FDA also considered mandating a specific expiration period (*e.g.,* 6 months or 1 year) but determined this may be too restrictive and stifle innovation. Accordingly, FDA believes the proposed approach would provide manufacturers more flexibility in establishing an expiration date that conforms to the NNN level.

Requiring an expiration date that is established by stability testing provides assurance that the NNN level will remain in conformance with the product standard for the specified time period. The expiration date also informs retailers that the manufacturer has not demonstrated compliance with the product standard beyond that date and the product cannot be sold to consumers. The expiration date also allows FDA inspectors to quickly determine if products for sale in a retail establishment purport to be in conformance with the product standard.

7. Nonconforming Product (Proposed § 1132.22)

Proposed § 1132.22 would require manufacturers to establish procedures for handling nonconforming smokeless tobacco products. Proposed § 1132.22(a) would require tobacco product manufacturers to establish and maintain procedures to identify, investigate, segregate, and make disposition decisions (*i.e.,* acceptance, rejection, or rework) about nonconforming finished smokeless tobacco products to prevent their release for commercial distribution. FDA interprets ''establish and maintain'' for purposes of proposed § 1132.22(a) to mean define, document (in writing or electronically), implement, follow, and, when necessary, update. This section allows manufacturers the flexibility to determine how they will perform these activities.

Proposed § 1132.22(b) would require tobacco product manufacturers to conduct an investigation if:

- The mean of the representative samples from any batch of finished smokeless tobacco product is determined to be out of conformance with the requirements of § 1132.10,
- A finished smokeless tobacco product's expiration date must be shortened due to the results of annual real-time stability testing, or
- FDA notifies the smokeless tobacco manufacturer that a distributed finished smokeless tobacco product does not conform to the requirements of part 1132.

The purpose of a nonconforming product investigation would be to determine the extent and the cause, if possible, of the nonconformity so that, if identified early, the product is not processed further or released for commercial distribution. In addition, it would help to prevent recurrence of the nonconformity.

The manufacturer would be required to conduct an investigation to determine the extent of the nonconformity upon identification of a nonconforming product and, as applicable, the locations where the nonconforming products have been distributed. We expect the manufacturer would be able to determine the locations of the initial consignees (*e.g.,* wholesalers, distributors, retailers) where the affected products were shipped in the event a corrective action needs to be taken. The investigation would have to include an examination of all relevant processes, operations, records, complaints, any corrective actions taken, and any other relevant sources of information concerning the nonconforming product. For example, a manufacturer could determine the extent of the nonconformity by examining records and in-process control records for any batches, or portions of batches that have been rejected during either in-process or finished inspection for failing to meet any or all of the product's specifications. Furthermore, in the event that a similar nonconforming product is identified in a different batch, a manufacturer's investigation could include any applicable information and records from the previous nonconforming product investigation that are relevant to determining the extent of nonconformity of the affected batch.

The manufacturer would have to fully document any investigation, including any materials reviewed, name of the person(s) making the disposition decisions, justification for the disposition decisions, results of retesting, decisions with respect to reworking, and followup results from the investigation (*e.g.,* corrective actions). FDA may inspect these records to verify the manufacturer has adequately performed an investigation.

Proposed § 1132.22(c) would require tobacco product manufacturers to reject any batch of a finished smokeless tobacco product if the mean of the representative samples from the batch does not meet the requirements of § 1132.10 unless a disposition decision and justification to release the batch is made after an investigation shows the batch meets the requirements of part 1132. Manufacturers would not be able to simply resample a batch until the mean conforms with the proposed NNN limit in § 1132.10 if a previous mean did not meet the requirements of part 1132. If the initial mean was not in conformance, the manufacturer must conduct a nonconforming product investigation. If the manufacturer, for instance, determines the NNN levels were erroneously high because of a malfunction of the testing equipment, and the batch tests in conformance after repair of the equipment, the manufacturer could determine that the batch is acceptable for release into commercial distribution.

Proposed § 1132.22(d) would allow smokeless tobacco manufacturers to rework a batch of a nonconforming finished smokeless tobacco product, which does not conform to the requirements of part 1132, to bring it into conformance with all the requirements of the part before it may be released for commercial distribution. However, FDA thinks it is unlikely that a manufacturer would rework nonconforming finished smokeless tobacco product because this would likely require removing the product from its container and then mixing it with smokeless tobacco product with very low NNN levels to ensure that the final product did not exceed the

proposed NNN limit.[4] We welcome information and comments on this provision.

C. Labeling and Recordkeeping Requirements (Proposed Subpart C)

1. Package Label Requirements (Proposed § 1132.30)

Proposed § 1132.30 would require that the package label of all finished smokeless tobacco products include a manufacturing code, expiration date, and, if applicable, storage conditions. FDA is proposing to require that the labels of finished smokeless tobacco products contain a manufacturing code, expiration date, and, if applicable, storage conditions for the finished smokeless tobacco product (proposed § 1132.30) so that FDA can determine whether a product on store shelves purports to be in conformance with the product standard and link the product to records that substantiate its conformance. These requirements would also help ensure that the product is handled and stored under appropriate conditions so that the product remains in compliance with the standard and would help FDA verify that retailers are storing products appropriately. The information would be required to be printed on or permanently affixed to the package in a manner that assures it will remain on the packaging or label through the expected duration of use of the product by the consumer. In addition, it would have to appear clearly, legibly, and indelibly in the English language.

The purpose of the manufacturing code is to allow manufacturers and FDA to be able to link the product to a specific batch that has been released for commercial distribution, which would be helpful in the event of a nonconforming product investigation or in the event that corrective or preventive actions should be taken. The manufacturing code could also help determine the history of the manufacturing, processing, packaging, labeling, holding, and initial distribution of the tobacco product from records maintained by the smokeless tobacco product manufacturer. The expiration date on the package label would have to appear in two-digit numerical values in the following format: ''Expires on month/day/year.'' The expiration date informs retailers that the manufacturer has not demonstrated compliance with the product standard beyond that date and the product cannot be sold to consumers. The expiration date also allows FDA inspectors to quickly determine if products for sale in a retail establishment purport to be in conformance with the product standard and if retailers are selling expired products.

Storage conditions would be required to be on the label if the finished smokeless tobacco product must be kept in refrigerated storage to conform with the product standard until the expiration date (as determined by stability testing) and the package label would be required to bear the wording: ''Keep Refrigerated.'' However, no wording would be required to be on the package label if the product's intended storage condition is room temperature. We note that proposed § 1132.1 states that retailers and distributers would not be in violation of part 1132 as it relates to the sale or distribution or offer for sale or distribution of smokeless tobacco products that exceed the NNN limit if they, among other things, store and transport the finished tobacco product according to the package label and do not sell or distribute or offer for sale or distribution finished smokeless tobacco products past their expiration date. Requiring package labels with an expiration date and storage conditions would allow retailers and distributers to handle the product in accordance with the manufacturer's intent so the product remains in conformance with the product standard.

2. Recordkeeping Requirements (Proposed § 1132.32)

Proposed § 1132.32 includes two recordkeeping requirements. This information is necessary for FDA to ascertain and confirm that smokeless tobacco products are in compliance with the proposed standard.

First, proposed § 1132.32(a) would require that each facility that manufactures finished smokeless tobacco products establish and maintain records containing the following information:

1. Full documentation of stability testing protocols and the results of initial and annual stability testing under § 1132.12(a), including all information specified in § 1132.12(c).

2. All investigations under § 1132.12(a)(4)(v).

3. The source data and results of batch testing conducted to determine conformance with § 1132.10, including all information specified in § 1132.12(c).

4. All notifications of an alternative test method and all related correspondence under § 1132.16;

5. All source data for the alternative test method validation;

6. All sampling plans and reports under § 1132.18;

7. Documentation that the persons performing sampling under § 1132.18 have sufficient education, training, and experience to accomplish the assigned functions;

8. All identification, investigation, segregation, and disposition decision procedures under § 1132.22(a); and

9. All nonconforming product investigations and rework under § 1132.22(b) and (d).

Second, proposed § 1132.32(b) provides certain specifications for these records. The records would have to be legible and written in English. Documents that have been translated from a foreign language into English would have to be accompanied by the foreign language version of the document and a certification by the manufacturer's authorized representative (which could be a U.S. agent for the manufacturer) that the English language translation is complete and accurate. All records would be required to be readily available for inspection and copying or other means of reproduction by FDA upon request during an inspection.[5] Requested records that are maintained offsite would have to be made available within 24 hours or, if that is not feasible, as soon as possible before the close of the inspection. While we expect that most records can be made available to FDA within 24 hours, we recognize that, in some cases, additional time may be needed to retrieve records from a third party or archival storage. Records that can be immediately retrieved from another location, including by computer or other electronic means, would meet the requirement that the records be readily available.

In addition, proposed § 1132.32(c) would require that the records kept under this part be retained for at least 4 years from the date of commercial

[4] Based on comments provided by the Alcohol and Tobacco Tax and Trade Bureau (TTB), we understand that this process would likely constitute the manufacture of tobacco products for purposes of the Internal Revenue Code. Under the Internal Revenue Code, the manufacture of tobacco products requires a permit as a manufacturer of tobacco products from TTB. As we understand TTB's permitting requirements, entities lacking a manufacturing permit, including importers, may not engage in manufacturing activities. We also understand that certain provisions of the Internal Revenue Code prohibit importers of tobacco products from repackaging tobacco products after such products are released from customs custody.

[5] Several laws govern the confidentiality of information submitted under sections 907 and 909 of the FD&C Act, including sections 301(j) and 906(c) of the FD&C Act (21 U.S.C. 331(j) and 387f(c)), the Trade Secrets Act (18 U.S.C. 1905), and the Freedom of Information Act (FOIA) (5 U.S.C. 552), as well as FDA's regulations in 21 CFR part 20.

distribution of the finished smokeless tobacco product that is the subject of the record. However, for records relating to alternative test methods under § 1132.16, the required 4-year retention period would be for a period not less than 4 years after the last date the method that is the subject of the record is used (*e.g.,* 4 years from the last date the manufacturer used an alternative test method). FDA has selected 4 years as a means to help ensure that the records would be available for at least one biennial FDA inspection under sections 704 and 905(g) of the FD&C Act.

FDA considered not requiring specific recordkeeping requirements and, instead, allowing the manufacturer to determine recordkeeping needs but, FDA believes that detailed recordkeeping requirements are necessary to confirm that the finished smokeless tobacco products are in compliance with the proposed standard. For example, requiring manufacturers to fully document their stability testing protocols and test results will enable FDA to confirm that the manufacturer's test method and protocols are adequate to meet the requirements of part 1132. In addition, requiring nonconforming product records will help the manufacturer and FDA determine the extent of the nonconformity and, as applicable, the locations where the nonconforming products have been distributed, in the event of a recall or enforcement action (*e.g.,* seizure).

VII. Proposed Effective Date

FDA proposes that any final rule on the tobacco product standard for NNN that may issue based on this proposal become effective 3 years after the date of publication of the final rule. FDA believes this approach would allow adequate time for developing any necessary changes in technology to achieve the NNN level, for any changes made to manufacturers' tobacco purchasing choices and curing methods, and for any preparation or changes needed in facilities. In addition, FDA believes that it will provide adequate time for manufacturers to seek and obtain marketing authorization from FDA for their new tobacco products. New tobacco products are subject to enforcement if they are on the market without FDA authorization.

Therefore, after the effective date of a final rule for this proposed tobacco product standard, no person would be allowed to manufacture, distribute, sell, or offer for sale or distribution within the United States any finished smokeless tobacco product that does not comply with the rule. After the effective date of the final rule, manufacturers would not be allowed to introduce into domestic commerce any finished smokeless tobacco product that does not comply with the requirements of the final rule, irrespective of the date of manufacture. However, retailers would be permitted to sell-off existing inventory of noncompliant finished smokeless tobacco products manufactured before the effective date for 60 days after the effective date of the final rule. FDA notes that keeping products with higher NNN levels on the market for an extended period of time after the effective date of the rule is not in the interest of public health.

VIII. Incorporation by Reference

FDA is proposing to incorporate by reference the test method entitled, ''Determination of N-nitrosonornicotine (NNN) in Smokeless Tobacco and Tobacco Filler by HPLC–MS/MS,'' LIB No. 4620, January 2017 (Ref. 79). You may obtain a free copy of the material proposed to be incorporated from the Docket at *www.regulations.gov* or from the Food and Drug Administration, Center for Tobacco Products, 10903 New Hampshire Ave., Silver Spring, MD 20993, 1–888–463–6332.

This is a technical document developed by FDA specifically for use in tobacco testing facilities. FDA developed this test method for NNN in order to streamline the testing process and reduce testing costs. Other available methods test for all TSNAs while this test method is limited to NNN. As such it is a highly specific method that reduces testing costs while ensuring that the results from the test method demonstrate a high level of specificity, accuracy, and precision in measuring a range of NNN levels across a variety of smokeless tobacco products.

This test method relies on several ISO standards for determining moisture content in tobacco and tobacco products—ISO 6488:2004, ISO 6488:2004/Cor 1:2008, and ISO 16632:2013. FDA is not proposing to incorporate these standards by reference. You may purchase a copy of the ISO standards from the International Organization for Standardization, 1, ch. de la Voie-Creuse, Case Postale 56, CH–1211, Geneva 20, Switzerland, or from the American National Standards Institute, 1899 L Street NW., 11th Floor, Washington, DC 20036, or on the Internet at *http://www.iso.org* or *www.ansi.org.* We note that these ISO standards are relatively inexpensive (about $50 each) and may already be used by tobacco testing facilities.

For the reasons set forth in this section, FDA considers the test method proposed to be incorporated by reference to be reasonably available and usable by testing facilities (see 1 CFR 51.5(a) and 51.7).

IX. Economic Analysis of Impacts

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the proposed rule. We believe that this proposed rule is an economically significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because many smokeless tobacco products may need to be reformulated, and reformulation represents the main driver of the costs of the rule, we tentatively find that the proposed rule would have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $146 million, using the most current (2015) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would result in an expenditure in any year that meets or exceeds this amount.

The proposed rule would establish a product standard for all finished smokeless tobacco products. Specifically, the proposed rule would require that all finished smokeless tobacco products comply with a limit for NNN in such products in order to be marketed and distributed for sale in the United States. This proposed product standard would require that the mean level of NNN in any batch of finished

smokeless tobacco products not exceed 1.0 µg/g of tobacco (on a dry weight basis) at any time through the product's labeled expiration date as determined by product testing. The proposed standard also includes requirements on the sale and distribution of smokeless tobacco products, product testing, labeling, and recordkeeping.[6]

The costs of the proposed rule, when finalized, will be due to affected entities ensuring that the smokeless tobacco products comply with the proposed product standard. We have estimated that the annualized costs associated with the proposed rule over 20 years to be between $17.91 million and $42.72 million using a 3 percent discount rate, with a primary value of $30.31 million, and between $20.11 million and $50.57 million, with a primary value of $35.34 million using a 7 percent discount rate. The primary estimate for the present value of total quantified costs over 20 years is approximately $450.97 million at a 3 percent discount rate and $374.36 million at a 7 percent discount rate.

NNN is a carcinogenic agent found in smokeless tobacco products. As described in the preamble, on the basis of the available scientific evidence, FDA has determined that NNN is the predominant driver of excess oral cancer risk among smokeless tobacco users.

We quantify benefits associated with the proposed rule in the form of reduced oral cancer morbidity and mortality attributable to smokeless tobacco. As described in section V.A.3 of the preamble of the proposed rule, we also expect the standard to reduce the risk of esophageal cancer and it may reduce the risks of other cancers such as pancreatic, laryngeal, prostate, and lung cancer. However, there is more limited information to directly quantify these health benefits. As such, we only consider reductions in oral cancer as the quantified benefit of the proposed product standard.

Most of the estimated benefits arise from quality life-years gains gained from reduced oral cancer mortality. The annualized value over 20 years of quality adjusted life-years gained from reduced oral cancer mortality ranges from $228.66 million to $2.46 billion at a 3 percent discount rate, with a primary value of $858.46 million. Using a 7 percent discount rate, the annualized value of quality life-years gained from averted deaths ranges from $182.01 million to $1.96 billion, with a primary value of $683.34 million. The primary estimate of the present value of mortality reductions quantified over 20 years is $12.77 billion at a 3 percent discount rate and $7.24 billion at a 7 percent discount rate. The annualized value over 20 years of quality adjusted life-years gained from reduced oral cancer mortality and morbidity ranges from approximately $283.95 million to $3.05 billion at a 3 percent discount rate, with a primary value of $1.06 billion, and approximately $246.40 million to $2.65 billion, with a primary value of $0.92 billion at a 7 percent discount rate. The primary estimate of the present value of total quantified benefits over 20 years is approximately $15.86 billion at a 3 percent discount rate and $9.80 billion at a 7 percent discount rate for reductions in oral cancer alone. These values are likely an underestimate of the benefits associated with the proposed rule, as we do not quantify reductions in mortality and morbidity from cancers other than oral cancer. Costs and benefits are summarized in table 8.

The full analysis of economic impacts is available in the docket for this proposed rule (Ref. 146) and at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

TABLE 8—SUMMARY OF BENEFITS, COSTS AND DISTRIBUTIONAL EFFECTS OF PROPOSED RULE

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered (years)	
Benefits:							
Annualized Monetized millions/year.	$924.91	$246.40	$2,647.21	2015	7	20	Most of the health benefits included in the totals would be realized more than 20 years after publication of the final rule, but the risk reductions associated with these benefits occur during the 20-year period beginning at publication of the final rule.
	$1,065.92	$ 283.95	$3,051.09	2015	3	20	
Annualized					7	20	
Quantified					3	20 years	
Qualitative							Potential cost savings from net life-time reduction in medical care utilization; additional health benefits from reduction in other toxicants correlated with NNN; reduction in cancers, other than oral cancers
Costs:							
Annualized	$35.34	$20.11	$50.57	2015	7	20	
Monetized millions/year	$30.31	$17.91	$42.72	2015	3	20	
Annualized					7	20	
Quantified					3	20	
Qualitative							
Transfers:							
Federal Annualized				7	20		
Monetized $millions/year					3	20	
	From:			To:			
Other Annualized					7	20	

[6] The proposed product standard includes a number of requirements in addition to the actual NNN limit, including requirements related to product testing, recordkeeping, and sale and distribution restrictions. However, generally, this analysis uses the term product standard as shorthand for the NNN limit requirement. Similarly when we discuss anticipated compliance status and compliant versus noncompliant products, we generally refer to compliance with the NNN limit requirement.

TABLE 8—SUMMARY OF BENEFITS, COSTS AND DISTRIBUTIONAL EFFECTS OF PROPOSED RULE—Continued

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered (years)	
Monetized $millions/year	.....	.....	.....	.....	3	20	.....
	From:			To:			
Effects	*State, Local or Tribal Government:* None estimated. *Small Business:* The average cost per small entity is largest in Year 1 and range between $2.67 million and $7.97 million. Reformulation costs and stability testing represent the largest proportion of costs—up to 60 percent of average sales for entities with fewer than 50 employees and up to 13 percent of average sales for entities with 50–100 employees. *Wages:* None estimated. *Growth:* None estimated.						

X. Analysis of Environmental Impact

The Agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The Agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday. Under FDA's regulations implementing the National Environmental Policy Act (21 CFR part 25), an action of this type would require an environmental assessment under 21 CFR 25.20.

XI. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). A description of these provisions is given in the *Description* section of this document with an estimate of the annual reporting, recordkeeping, and third-party disclosure 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 each collection of information.

FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Tobacco Product Standard: NNN Level in Finished Smokeless Tobacco Products.

Description: FDA is proposing a product standard to establish a limit of NNN in finished smokeless tobacco products sold in the United States. Products with higher NNN levels pose higher risks of cancer and FDA finds that establishing a NNN limit in finished smokeless tobacco products is appropriate for the protection of the public health. Proposed § 1132.10 would require that the mean level of NNN in any batch of finished smokeless tobacco products not exceed 1.0 µg/g of tobacco (on a dry weight basis) at any time through the product's labeled expiration date as determined by testing in compliance with § 1132.12. Proposed §§ 1132.12, 1132.14, 1132.16, and 1132.18 would establish product testing and sampling plan requirements. Proposed § 1132.12 would require two types of testing for smokeless tobacco products—stability testing and batch testing. Proposed § 1132.12(a) would require initial and annual stability testing to assess the stability of the NNN level in finished smokeless tobacco products and to establish and verify the product's expiration date and storage conditions (either room temperature or refrigeration). Proposed § 1132.12(b) would require manufacturers to conduct batch testing on each batch of finished smokeless tobacco product to determine whether the products conform to the proposed NNN limit. Proposed § 1132.12(c) would require the tobacco product manufacturer to document all testing.

Proposed §§ 1132.14 and 1132.16 would establish the standard and alternative test methods. If a tobacco product manufacturer were to choose not to use the standard test method in § 1132.14 to test its smokeless tobacco products, the manufacturer would be required to use a validated alternative test method that conforms to the requirements of proposed § 1132.16. Proposed § 1132.16(a) would require that, before using a validated alternative test method, the manufacturer notify the Center for Tobacco Products.

Proposed§ 1132.18 would establish the sampling requirements for all testing. These sampling requirements would be used in conjunction with the product testing required in proposed § 1132.12 (stability testing and batch testing) and would provide procedures for the manufacturer to select samples to demonstrate conformance with the proposed NNN limit.

Proposed § 1132.22 would require tobacco product manufacturers to establish and maintain procedures to identify, investigate, segregate, and make disposition decisions about nonconforming finished smokeless tobacco products in order to prevent their release for commercial distribution and to conduct investigations related to nonconforming products.

Under proposed § 1132.30, the labels of finished smokeless tobacco products would be required to contain a manufacturing code, expiration date, and, if applicable, storage conditions for the finished smokeless tobacco product. The information would have to be printed on or permanently affixed to the package assuring that the label remains intact through the expected duration of use. It must appear clearly, legibly, and indelibly in the English language. The expiration date must appear on the packaging in two-digit numerical values. If the manufacturer determines by stability testing that meets the requirements in § 1132.12 that the finished smokeless tobacco product must be stored in a refrigerator, the package label must state ''Keep Refrigerated.'' The manufacturing code would provide a history of the manufacturing, processing, packaging, labeling, holding, and initial

distribution of the product from records maintained by the tobacco product manufacturer.

Proposed § 1132.32 would require that tobacco product manufacturers maintain records regarding the product testing (*i.e.,* stability and batch testing), including protocols and a full report of the source data and results; records regarding investigations related to shortening of expiration dates based on results of annual stability testing; all notifications of an alternative test method and source data for alternative test method validation; all sampling plans and reports; documentation that the persons performing sampling have sufficient education, training, and experience to accomplish the assigned functions; all identification, investigation, segregation, and disposition procedures related to nonconforming products; and all nonconforming product investigations and rework (*i.e.,* the processing of nonconforming finished smokeless tobacco products to meet the requirements of part 1132). FDA is also proposing to require copies of all records be retained for a period of not less than 4 years from the date of commercial distribution of the finished smokeless tobacco product that is the subject of the record, except that certain records relating to alternative test methods would be required to be retained for a period of not less than 4 years after the last date the method is used. FDA has selected 4 years as a means to help ensure that the records would be available for at least one biennial FDA inspection under sections 704 and 905(g) of the FD&C Act.

Description of Respondents: The provisions of this standard would apply to finished smokeless tobacco products. Finished smokeless tobacco product means a smokeless tobacco product, including all parts and components, packaged for consumer use, except for components, parts, or accessories sold without tobacco. The respondents are therefore manufacturers of smokeless tobacco products.

FDA estimates the burden of this collection of information as follows:

TABLE 9—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR part	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
§ 1132.16 Alternative Test Method (FDA Form 3979)	23	1	23	20	460
§ 1132.16 Waiver from Electronic Submission	2	1	2	.75	2
Total					462

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] The burden in the reporting chart corresponds to table 23 ''Estimated Costs to Industry Associated with Notifications to FDA Regarding Use of Alternative Testing Methods'' in the RIA.

TABLE 10—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity (units)	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Change in process (Formulations)	68	1	68	8	544
Ingredient change (Formulations)	28	1	28	8	224
No change (Formulations)	60	1	60	4	240
Labeling records, annual after year 1 (UPCs)	1255	1	1255	2	2,510
Initial Stability Testing records (Manufacturers)	23	8	184	4	736
Annual Stability Testing records (Manufacturers)	23	3	69	4	276
Batch Testing (products)	784	28	21,952	4	87,808
Batch Testing records (Manufacturers)	23	1	23	4	92
Procedures for nonconforming products and related investigations (Manufacturers)	23	1	23	4	92
Notifications, alternate testing methods (Manufacturers)	23	2	46	0.75	35
Total [1]					92,557

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] The burden in the recordkeeping chart corresponds to table 24 ''Estimated Recordkeeping Costs to Industry'' and table 13 ''Estimated Number of Batch Tests'' in the RIA.

TABLE 11—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity (units)	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Package Labeling Change Minor (UPCs)	459	1	459	10	4,590
Package Labeling Change Major (UPCs)	8	1	8	23	184
Initial Stability Testing (one time) (Products)	784	168	131,712	2	263,424
Initial Stability Testing (recurring) (Products)	784	6.72	5,268	2	10,536
Annual Stability Testing (Products)	784	60.48	47,416	2	94,832
Sampling Plans (Products)	784	1	784	2	1,568
Total [1]					370,360

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] The burden in the third-party disclosure chart corresponds to table 12 ''Estimated Costs Associated with Proposed Stability Testing Requirements'' and table 15 ''Products with Expiration and Storage Information'' in the RIA.

FDA's burden estimates are based on the regulatory impact analysis, Agency expertise, registration and listing data, company revenue information from Dunn & Bradstreet, and comparing to other online sources in order to categorize the entities and number of products.

Table 9 describes the annual reporting burden as a result of the requirements proposed in § 1132.16 submitting a notification of an alternative test method and requesting a waiver from electronic submission of such a notification. FDA estimates that it will receive 23 notifications for alternative test methods using FDA Form 3979 (Ref. 145) for a total of 460 hours. Because some of the manufacturers may currently be conducting these reports, the RIA anticipates that there would be between 1 and 23 manufacturers affected. For PRA purposes we have used the high estimate of 23. FDA also estimates that 2 respondents will submit a waiver request from electronic submission. Therefore, the total estimated reporting burden for this proposed rule is 462 hours.

Table 10 outlines the recordkeeping requirements that are proposed in § 1132.32. We note that recordkeeping time burden activities are derived from the respective models (RTI International, 2015a; RTI International, 2015a; RTI International, 2015(b). FDA estimates recordkeeping time burden related to product reformulation (change in process, ingredient change, and no change) to involve 156 formulations for total of 1,008 hours. For recordkeeping burden related to certain labeling records, FDA estimates that after year one 1,255 affected Universal Product Code (UPC) records will be kept annually for a total of 2,510 hours. The number of UPCs subject to these recordkeeping requirements is determined by multiplying the number of UPCs in each product category by the percent of products with expiration date information.

We estimate that batch testing will be conducted for 784 products (21,952 tests per year) for a total of 87,808 hours. Proposed § 1132.32 requires records to be maintained for stability and batch tests. FDA estimates that 23 manufacturers will maintain records related to initial stability testing, annual stability testing, and batch testing for a total of 1104 hours. Records are also required to be maintained of procedures for nonconforming products and related investigations. We estimate that 23 manufacturers will maintain these records for a total of 92 hours. Proposed § 1132.32 requires manufacturers to maintain all notifications of an alternative test method. We estimate that 23 manufacturers will maintain these records for a total of 35 burden hours. Therefore, the total estimated recordkeeping hours are 92,557.

Table 11 represents third party disclosures (package labeling) that a respondent must display. This table also covers the proposed stability testing that must occur for the label. Labeling burden is estimated by using data on the number of active UPCs from Nielsen Inc., and the estimated percentage of products with expiration and storage information come from FDA Registration and Listing database (as of March 1, 2016). To derive the number of UPCs subject to a labeling change that includes storage information, we assume that only those products that are currently refrigerated but for which we did not find evidence that the labeling exists would incur such labeling change. Thus, we estimate that these different products that would likely be affected by labeling changes would include up to 467 UPCs (derived by assuming that each product would be associated with one unique UPC).

Since all products already have either an expiration date or a manufactured on date, adding an expiration date or storage conditions to labeling would be considered a minor change if product label redesign is not needed and major if product label redesign is needed. FDA believes that labeling changes associated with adding storage information is assumed to be ''major'' to incorporate uncertainty regarding product label redesign. We estimate that 459 affected UPCs will undergo minor labeling changes for a total of 4,590 hours. Additionally, FDA estimates that 8 affected UPCs will undergo major labeling changes regarding storage information for a total of 184 hours.

Since establishing and verifying a product's expiration date and storage conditions on a label requires actual stability testing we categorize this burden under third party disclosures. For PRA purposes we have categorized stability testing under third party disclosures. For example, in accordance with § 1132.30 a package label would need to have the expiration date for the product. Prior to completing initial stability testing, the manufacturer might not know what the appropriate expiration date would be. Since the testing will inform the label we believe it is appropriate for the burden to fall under this category. We estimate that 784 products would undergo initial stability testing, and annual stability testing each year thereafter. FDA estimates that in year 1 there would be 131,712 initial tests for a total of 263,424 hours. After the first year we estimate that there would be 5,268 initial tests for a total of 10,536 hours. After the initial testing we expect 47,416 annual tests per year for total of 94,832 hours.

FDA included sampling plans in the third party disclosure chart because each tobacco product manufacturer would be required to demonstrate that the finished smokeless tobacco product's expiration date (on the label) is appropriate under the intended storage conditions, and to do so the manufacturer would conduct testing pursuant to sampling plans. In developing a sampling plan for NNN in smokeless tobacco products a manufacturer must take into account the size of a batch, the variation of NNN in their product, the margin of error around their analytical techniques, and any other variables they can justify as pertinent to their calculation. While the development of a sampling plan would require some data analysis and determination of assumptions, we believe that the development of a sampling plan could cover multiple products. In addition once a sampling plan had been developed we believe that there would be significant redundancy in the development of subsequent plans which would reduce the time needed to complete them. Ultimately we have estimated that the time for the development of a sampling plan would average 2 hours per product for a total of 1,568 hours. Therefore, the total third party disclosure burden is estimated to be 370,360 hours.

FDA estimates that the total burden imposed by these proposed requirements will be 463,379 hours (462 reporting, 92,557 recordkeeping, and 370,360 third party disclosures).

This proposed rule also refers to previously approved collections of information found in FDA regulations. The collections of information in section 905(j) of the FD&C Act (substantial equivalence reports) have been approved under OMB control number 0910–0673.

To ensure that comments on information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB (see **ADDRESSES**). All comments should be identified with the title of the information collection.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3407(d)), the Agency has submitted the information collection provisions of this proposed rule to OMB for review. These requirements will not be effective until FDA obtains OMB approval. FDA will

publish a notice concerning OMB approval of these requirements in the **Federal Register**.

XII. Executive Order 13132

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule, if finalized, would not contain policies that would have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Agency tentatively concludes that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

XIII. Executive Order 13175

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13175. We have tentatively concluded that the rule does not contain policies that would 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. The Agency solicits comments from tribal officials on any potential impact on Indian tribes from this proposed action.

XIV. References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *http://www.regulations.gov.* FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

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List of Subjects in 21 CFR Part 1132

Administrative practice and procedure, Incorporation by reference, Labeling, Smokeless tobacco, Tobacco products.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that chapter I of title 21 of the Code of Federal Regulations be amended by adding part 1132 to subchapter K to read as follows:

PART 1132—PRODUCT STANDARD: DETERMINATION OF N-NITROSONORNICOTINE (NNN) LEVEL IN FINISHED SMOKELESS TOBACCO PRODUCTS

Subpart A—General Provisions

Subpart B—Product Requirements

Subpart C—Labeling and Recordkeeping Requirements

Authority: 21 U.S.C. 331, 371, 374, 387b, 387c, 387f(d), 387g, 387i.

Subpart A—General Provisions

§ 1132.1 Scope.

(a) This part sets forth the requirements for the maximum level of N-nitrosonornicotine (NNN) in finished smokeless tobacco products. The provisions of this standard apply to finished smokeless tobacco products as defined in § 1132.3.

(b) No person may manufacture, distribute, sell, or offer for sale or distribution within the United States a

finished smokeless tobacco product that is not in compliance with this part.

(c) Tobacco retailers and distributors will not be considered in violation of this part as it relates to the sale or distribution or offer for sale or distribution of finished smokeless tobacco products that exceed the NNN level set forth in § 1132.10 if they:

(1) Store and transport the finished smokeless tobacco products according to the package label;

(2) Do not sell or distribute or offer for sale or distribution finished smokeless tobacco products past their expiration date, except to return expired products to the manufacturer;

(3) Do not conceal, alter, or remove the expiration date or storage conditions on the package label; and

(4) Do not sell or distribute or offer for sale or distribution finished smokeless tobacco products that are open or have broken seals.

§ 1132.3 Definitions.

For purposes of this part:

Batch means a specific identified amount of a finished smokeless tobacco product produced in a unit of time or quantity and that is intended to have the same characteristics.

Commercial distribution means any distribution of a finished smokeless tobacco product to consumers or to another person through sale or otherwise, but does not include interplant transfers of a tobacco product between registered establishments within the same parent, subsidiary, and/or affiliate company, nor does it include providing a tobacco product for product testing where such product is not made available for consumption or resale.

Finished smokeless tobacco product means a smokeless tobacco product, including all parts and components, packaged for consumer use, except for components, parts, or accessories sold without tobacco. An example of a finished smokeless tobacco product is a tin or can of loose snuff or a pouch containing chewing tobacco.

Manufacturing code means any distinctive sequence or combination of letters, numbers, or symbols that begins with the manufacturing date in 2-digit numerical values in the month, day, year format (mmddyy) followed by the batch number from which the production batch can be identified.

Manufacturing date means the month, day, and year that a smokeless tobacco product is packaged for consumer use (*i.e.,* when the package label has been added to the product).

N-nitrosonornicotine (NNN) means a tobacco-specific nitrosamine (TSNA) with the chemical formula C[9]H[11]N[3]O.

New tobacco product means:

(1) Any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007; or

(2) Any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007.

Package means a pack, box, carton, or container of any kind or, if no other container, any wrapping (including cellophane), in which a tobacco product is offered for sale, sold, or otherwise distributed to consumers.

Performance criteria means the validation requirements for the acceptability of an analytical test method, including accuracy, precision, recovery, linearity, specificity, limit of quantitation, limit of detection, robustness, and range.

Person includes an individual, partnership, corporation, or association.

Rework means the processing of nonconforming finished smokeless tobacco products to meet the requirements of this part.

Smokeless tobacco means any tobacco product that consists of cut, ground, powdered, or leaf tobacco and that is intended to be placed in the oral or nasal cavity.

Source data means all information contained in original laboratory records or exact copies of original records of experimental findings, observations, or other activities used for the creation, reconstruction, and evaluation of a study or other laboratory work. Source data includes any laboratory worksheets, notebooks, correspondence, notes, and other documentation (regardless of capture medium) that are the result of original observations and activities of a laboratory study or other laboratory work.

Tobacco product, as stated in section 201(rr) of the Federal Food, Drug, and Cosmetic Act in relevant part:

(1) Means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product); and

(2) Does not mean an article that is a drug defined in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act, a device defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act, or a combination product described in section 503(g) of the Federal Food, Drug, and Cosmetic Act.

Tobacco product manufacturer means any person, including a repacker or relabeler, who:

(1) Manufactures, fabricates, assembles, processes, or labels a tobacco product; or

(2) Imports a finished tobacco product for sale or distribution in the United States.

Tobacco-specific nitrosamine (TSNA) means a chemical compound formed through the chemical reaction involving the nitrosation of nicotine, nornicotine, anabasine, or anatabine during the growing, curing, processing, or storage of tobacco.

United States means the 50 States of the United States of America and the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, Johnston Atoll, the Northern Mariana Islands, and any other trust territory or possession of the United States.

§ 1132.5 Incorporation by reference.

(a) The Director of the Federal Register approves this material for incorporation by reference into this part in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy of the material from the sources listed below. You may inspect a copy at the U.S. Food and Drug Administration, Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852 or the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(b) Center for Tobacco Products, U.S. Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993; 1–888–463–6332.

(1) ''Determination of N-nitrosonornicotine (NNN) in Smokeless Tobacco and Tobacco Filler by HPLC–MS/MS,'' LIB No. 4620, January 2017; into § 1132.14. (Also available at *http://www.fda.gov/ScienceResearch/FieldScience/ucm231463.htm.*)

(2) [Reserved]

Subpart B—Product Requirements

§ 1132.10 NNN level.

The mean level of NNN in any batch of finished smokeless tobacco product

must not exceed 1.0 microgram per gram (μg/g) of tobacco (on a dry weight basis) at any time through the product's labeled expiration date as determined by testing in compliance with § 1132.12.

§ 1132.12 Product testing.

(a) *Stability testing.* Each tobacco product manufacturer must conduct testing to assess the stability of the NNN level in its finished smokeless tobacco products. The results of stability testing must be used to establish and verify the product's expiration date and storage conditions (either room temperature or refrigeration).

(1) *Test method.* The manufacturer must use either the standard test method in § 1132.14 or an alternative test method that meets the requirements set forth in § 1132.16. Samples for testing must be selected in accordance with the requirements set forth in § 1132.18(a) and (c).

(2) *Written protocol.* Each manufacturer must establish and maintain a written protocol that addresses all stability testing. The protocol must fully describe the methodology used to determine the stability of the NNN level, including the test method used (the standard test method in § 1132.14 or an alternative test method in accordance with § 1132.16), the sampling plan and procedures required by § 1132.18(a) and (c), and the storage conditions.

(3) *Initial stability testing.* A manufacturer must conduct initial real-time stability testing that covers each finished smokeless tobacco product and use the results to establish an expiration date and appropriate storage conditions (either room temperature or refrigeration) for the product. The expiration date and storage conditions must be displayed on the package label in accordance with § 1132.30.

(i) For initial real-time stability testing, at a minimum, samples must be tested within 7 days of manufacture and at the expected expiration date.

(A) If the proposed storage condition is room temperature, samples for initial real-time stability testing must be stored at 25 ± 2 degrees Celsius and 60 ± 5% relative humidity.

(B) If the proposed storage condition is refrigeration, samples for initial real-time stability testing must be stored at 5 ± 2 degrees Celsius.

(ii) If initial real-time stability testing is in progress but not yet complete, the manufacturer may concurrently conduct accelerated stability testing to establish the product's expiration date and storage conditions. The manufacturer may use an expiration date of no longer than 1 year based on initial accelerated stability testing.

(iii) For initial accelerated stability testing, at a minimum, samples must be tested at three time points within a 6 month period. The first time point must be within 7 days of manufacture and the last time point at 6 months after manufacture.

(A) If the proposed storage condition is room temperature, samples for initial accelerated stability testing must be stored at 40 ± 2 degrees Celsius and 75 ± 5% relative humidity.

(B) If the proposed storage condition is refrigeration, samples for initial accelerated stability testing must be stored at 25 ± 2 degrees Celsius and 60 ± 5% relative humidity.

(iv) If initial accelerated stability testing shows the NNN level in the finished smokeless tobacco products will not conform to § 1132.10, the manufacturer must establish an expiration date and storage conditions, as determined by the results of initial real-time stability testing.

(4) *Annual stability testing.* A manufacturer must conduct annual real-time stability testing on each finished smokeless tobacco product to verify the results of the initial stability testing and to ensure that the expiration date and storage conditions remain appropriate. Accelerated stability testing may not be used for annual stability testing.

(i) Except as provided in paragraph (a)(4)(ii) of this section, annual real-time stability testing must begin within 12 months of the completion of initial stability testing and then annually thereafter, with no longer than 12 months between testing.

(ii) When a manufacturer has not conducted initial real-time stability testing on a particular smokeless tobacco product because it has determined that the results from initial real-time stability testing conducted on another product apply, annual real-time stability testing must begin when the product is first released for commercial distribution and then annually thereafter, with no longer than 12 months between testing.

(iii) For annual real-time stability testing, at a minimum, samples must be tested within 7 days of manufacture and at the established expiration date.

(A) If the intended storage condition is room temperature, samples for annual real-time stability testing must be stored at 25 ± 2 degrees Celsius and 60% ± 5% relative humidity.

(B) If the intended storage condition is refrigeration, samples for annual real-time stability testing must be stored at 5 ± 2 degrees Celsius.

(iv) If the results of the most recent annual real-time stability testing do not support the finished smokeless tobacco product's expiration date, the manufacturer must use those results to establish a new expiration date. After a new expiration date has been established, the package labels of all affected finished smokeless tobacco products that have not been released for commercial distribution must display the new expiration date and storage conditions, in accordance with § 1132.30.

(v) If the finished smokeless tobacco product's expiration date must be shortened due to the results of the annual real-time stability testing, the manufacturer must conduct an investigation to determine why the results of the most recent stability testing do not support the product's previously established expiration date. The investigation must be fully documented and the records maintained in accordance with § 1132.32.

(b) *Batch testing.* Tobacco product manufacturers must conduct testing on each batch of finished smokeless tobacco product to ensure that the products conform with § 1132.10. The manufacturer must use either the standard test method in § 1132.14 or an alternative test method that meets the requirements set forth in § 1132.16. Samples for testing each batch to determine if a product conforms with § 1132.10 must be selected in accordance with the requirements set forth in § 1132.18(b) and (c).

(c) *Documentation of test results.* A full report of the source data and results of all stability and batch testing must be maintained by the tobacco product manufacturer in accordance with § 1132.32, including the following:

(1) Full identification of the smokeless tobacco product that is the subject of the report, including product subcategory, brand, subbrand, package size and quantity of product (mass and, if portioned, count) and, for portioned tobacco products, the size (mass) of each portion;

(2) NNN level of each sample tested;

(3) Mean NNN level and standard deviation;

(4) The batch manufacturing date and location, including facility name and address;

(5) The location, including facility name and address, from which each sample was pulled;

(6) The manufacturing code of each sample tested or, for samples for initial stability testing with no manufacturing code, an identifying code created by the manufacturer;

(7) The testing date and location, including the testing facility name and address;

(8) The test method and sampling procedure used;

(9) All tobacco product reference standard test results;

(10) The names and qualifications of the person(s) conducting the testing;

(11) The equipment used (including documentation to show that the equipment is appropriate for its intended use and has been calibrated); and

(12) For batch testing only, the criteria used to make a decision to accept or reject each batch and the decision made with respect to each batch (*e.g.,* accept, reject) based on the results of the product testing, including, where applicable, the NNN level of the individual batch, the results of the product's stability testing, and the decision made and justification with respect to the results of a nonconforming product investigation under § 1132.22.

§ 1132.14 Standard test method.

(a) The standard test method for this part is the method entitled ''Determination of N-nitrosonornicotine (NNN) in Smokeless Tobacco and Tobacco Filler by HPLC–MS/MS,'', incorporated by reference in § 1132.5.

(b) In the event of an inconsistency between a material incorporated by reference and the definitions and methods described in this part, definitions and methods in this part will apply.

§ 1132.16 Alternative test method.

Tobacco product manufacturers may use a validated alternative test method in accordance with this section, only if the alternative method meets or exceeds the performance criteria of the standard test method set forth in § 1132.14.

(a) *Notice requirement.* Tobacco product manufacturers who intend to use a validated alternative test method to that listed in § 1132.14 for determining conformance with § 1132.10 must notify the Director, Office of Science, Center for Tobacco Products, before beginning use of the alternative test method. Manufacturers may begin using the alternative test method 60 calendar days after FDA receives the notification as set forth in paragraph (f) of this section unless FDA notifies the manufacturer that the alternative test method has not been demonstrated to meet or exceed the performance criteria of the standard test method set forth in § 1132.14.

(b) *Contents of notification of an alternative test method.* The manufacturer must include in the notification of an alternative test method the following information:

(1) *General information.* The following information must be submitted using the form that FDA provides:

(i) The date the manufacturer submitted the notification to FDA;

(ii) Identification of the submission as a notification of an alternative test method;

(iii) The manufacturer's name, address, and contact information;

(iv) Identification of and contact information for an authorized representative of the manufacturer (which could be a U.S. agent for the manufacturer), including name, address (mailing and email), and telephone number;

(v) Identification of the subcategories of finished smokeless tobacco products that can be analyzed using the alternative test method; and

(vi) The testing facility's name and address.

(2) *Index and table of contents.* A comprehensive index and table of contents.

(3) *Summary.* The notification must include a summary section that contains the following information:

(i) Identification of the standard test method for which the alternative test method is being proposed;

(ii) A concise description of the performance criteria of the alternative test method;

(iii) A concise explanation of why the manufacturer is proposing to use the alternative test method; and

(iv) A concise comparison of the similarities and differences between the alternative test method and the standard test method.

(4) *Complete description.* The notification must describe the alternative test method in sufficient detail to enable FDA to evaluate whether the information provided demonstrates that the alternative test method meets or exceeds the performance criteria of the standard test method set forth in § 1132.14. This description must include:

(i) A complete description of the manner in which the alternative test method is proposed to deviate from the standard test method and a complete explanation, with scientific rationale and supported by appropriate data, including a complete copy of the testing protocol, to demonstrate that the alternative test method meets or exceeds the performance criteria of the standard test method set forth in § 1132.14; and

(ii) Any data and information from other studies comparing the alternative test method to the standard test method.

(c) *Relevant information.* If requested by FDA, the manufacturer must submit any other relevant information needed to evaluate the alternative test method.

(d) *Format for notifications of an alternative test method.*

(1) *General requirements.* All notifications must be submitted using the form that FDA provides and must be well-organized and legible, and written in English.

(2) *Electronic format requirement.* Except as provided in paragraph (d)(3) of this section, notifications of an alternative test method must be submitted using the Agency's electronic system. The notification and all supporting information must be in an electronic format that the Agency can process, review, and archive.

(3) *Waivers from electronic format requirement.* If a notification cannot be submitted electronically, a waiver may be requested. Waivers will be granted only if use of electronic means is not reasonable for the tobacco product manufacturer requesting the waiver. If FDA grants the waiver request, FDA will provide information on where to send the notification in paper form. To request a waiver, manufacturers must send a written request that is legible and in English to the Document Control Center (ATTN: Office of Science) at the address included on our Web site. The written request must contain the following information:

(i) The name and address of the tobacco product manufacturer that wishes to submit the notification, the name of an authorized representative of the manufacturer (which could be a U.S. agent for the manufacturer), and their contact information.

(ii) A statement that creation and/or submission of information in electronic format is not reasonable for the manufacturer requesting the waiver, and an explanation of why creation and/or submission in electronic format is not reasonable. This statement must be signed by a person who is authorized to make the declaration on behalf of the tobacco product manufacturer.

(e) *Applicability of an alternative test method.* An alternative test method may be implemented only by the tobacco product manufacturer that submitted the notification and only with respect to the subcategories of finished smokeless tobacco products that were the subject of the notification. Other manufacturers interested in similar or identical alternative test methods must submit their own notifications following the procedures of this section.

(f) *Action on notifications.* FDA will acknowledge the receipt of a notification of an alternative test

method. Manufacturers may implement an alternative test method beginning 60 calendar days after FDA receives the notification of alternative test method unless FDA notifies them otherwise.

(1) If a notification is complete when received, the 60 calendar day period begins on the date FDA receives the notification.

(2) If any element required under paragraph (b) of this section is missing from a notification, FDA will not accept the notification submission and will inform the manufacturer.

(3) If FDA determines that an alternative test method has not been demonstrated to meet or exceed the performance criteria of the standard test method set forth in § 1132.14, FDA will inform the submitter. If FDA informs the submitter during the 60 calendar day period, the submitter must not implement the alternative test method. If FDA determines that an alternative test method does not comply with this section after the 60 calendar day period, FDA will provide a written determination to the submitter and the submitter must immediately cease using the alternative test method.

(4) Acceptance of a notification submission does not constitute a finding by the Agency that the alternative test method meets or exceeds the performance criteria of the standard test method set forth in § 1132.14.

§ 1132.18 Sampling plans and procedures.

(a) *Sampling plan for stability testing.* Each tobacco product manufacturer must design and implement a sampling plan or plans for all stability testing required in § 1132.12(a) based on a valid statistical rationale to demonstrate that the finished smokeless tobacco product's expiration date is appropriate under the intended storage conditions. The sampling plan must ensure that samples taken are representative and randomly selected. To account for the variability of the NNN in smokeless tobacco products, the following factors must be based on adequate statistical criteria: The confidence intervals, the level of necessary precision, and the number of finished products sampled. Each sampling plan must fully describe the sampling methodology, with scientific rationale, incorporate all sources of variability (including variability of the analytic method and NNN levels), and describe the sample size needed (including a full description of how the sample size is calculated) consistent with the sampling design to achieve the sampling objective.

(b) *Sampling plan for batch testing.* Each tobacco product manufacturer must design and implement a sampling plan or plans for all batch testing required in § 1132.12(b) based on a valid statistical rationale to ensure that the finished smokeless tobacco product consistently conforms to the NNN level set forth in § 1132.10. The sampling plan must ensure that samples taken are representative of an entire batch and are randomly selected and collected from each batch for testing. To account for the variability of NNN in the finished smokeless tobacco products, the following factors must be based on adequate statistical criteria: The confidence intervals, the level of necessary precision, and the number of finished products sampled. The sampling plan must take into account the manufacturing quality history of the manufacturer. Each sampling plan must fully describe the sampling methodology, with scientific rationale, incorporate all sources of variability (including variability of the analytic method and the NNN levels), and describe the sample size needed (including a full description of how the sample size is calculated) consistent with the sampling design to achieve the sampling objective. The sampling plan must also fully describe the criteria the manufacturer will use to make a decision to accept or reject each batch.

(c) *Sampling procedures.* Test samples must be collected and examined in accordance with the following procedures:

(1) Test samples for initial real-time and accelerated stability testing are to consist of:

(i) Smokeless tobacco product that has been manufactured using the same production processes as products manufactured for consumer use and packaged in the identical package that will be used for the finished smokeless tobacco product, but it need not have the product package label; or

(ii) Finished smokeless tobacco product as it is intended to be sold or distributed to consumers.

(2) Test samples for annual real-time stability testing and batch testing are to consist of the finished smokeless tobacco product as it is intended to be sold or distributed to consumers and not of a separate production sample.

(3) All test samples must be stored according to the intended storage conditions for the finished smokeless tobacco product, except that test samples for initial accelerated stability testing must be stored in accordance with § 1132.12(a)(3)(iii). A tobacco product manufacturer must include all of its factories, stock rooms, warehouses, and other locations containing finished smokeless tobacco products in the population to be sampled.

(4) Test samples for stability testing must be taken within 7 days of the manufacturing date and tested in accordance with § 1132.12(a). Test samples for batch testing must be taken from each batch and tested within 30 calendar days of the manufacturing date. The amount of material acquired during sampling must be sufficient for the test methods in §§ 1132.14 or 1132.16, including any repeats that may be necessary (*e.g.,* because test material was damaged prior to or during analysis). Samples must be randomly selected in accordance with the applicable sampling plan and the samples must be taken within the same day.

(5) Sampling must be performed by persons who have sufficient education, training, and experience to accomplish the assigned functions.

(6) Each test sample must be identified so that the following information can be determined:

(i) Full identification of the smokeless tobacco product sampled, including product subcategory, brand, subbrand, package size and quantity of product (mass and, if portioned, count) and, for portioned tobacco products, the size (mass) of each portion;

(ii) The manufacturing code or, for samples for initial stability testing with no manufacturing code, an identifying code created by the manufacturer;

(iii) The date on which the sample was taken;

(iv) The sampling location (including the address of the facility and specific location within the facility where the sample was taken);

(v) The name of the person(s) who collected the sample; and

(vi) The location where the sample will be stored and tested (including the facility name and address).

(7) Samples sent for testing must be packed securely with adequate protection against damage (*e.g.,* mechanical damage, severe changes in humidity or temperature) and sent to the testing facility by the most expeditious means, arriving no later than 3 calendar days after shipment. A list of the samples in each shipment must be sent to the testing facility under separate cover.

(8) All samples for a specific stability or batch test must be tested at the same facility.

(9) Once test samples arrive at the testing facility they must be inspected, accounted for, and stored under the finished smokeless tobacco product's intended storage conditions (*e.g.,* room temperature or refrigeration) except that

test samples for initial accelerated stability testing must be stored in accordance with § 1132.12(a)(3)(iii), and a report that includes the following information must be generated for the stability or batch test and be maintained by the tobacco product manufacturer in accordance with § 1132.32:

(i) Full identification of the smokeless tobacco product, including product subcategory, brand, subbrand, package size and quantity of product (mass and, if portioned, count) and, for portioned tobacco products, the size (mass) of each portion;

(ii) The manufacturing code or, for samples for initial stability testing with no manufacturing code, an identifying code created by the manufacturer;

(iii) The date on which samples were taken, if available;

(iv) The locations where samples were drawn (including the address and specific locations within any facilities where samples were taken), if available;

(v) The number of test samples drawn;

(vi) Complete records of the samples received and tested, including the date of receipt, the identifier of all persons who tested the samples, and the test results.

(10) For batch testing only, each batch must be withheld from commercial distribution until it has been sampled and tested, and a decision has been made by the tobacco product manufacturer that it may be released for commercial distribution.

§ 1132.20 Expiration date.

All finished smokeless tobacco products must have an expiration date established by stability testing. The expiration date must be set no later than the final date the manufacturer can demonstrate the finished smokeless tobacco product conforms to § 1132.10 when stored under its intended conditions (*e.g.,* room temperature or refrigeration).

§ 1132.22 Nonconforming product.

(a) *General requirements.* Tobacco product manufacturers must establish and maintain procedures to identify, investigate, segregate, and make disposition decisions about nonconforming finished smokeless tobacco products in order to prevent their release for commercial distribution.

(b) *Investigation.* The tobacco product manufacturer must conduct an investigation to determine the extent of the nonconformity and, as applicable, the locations where the nonconforming products have been distributed if the mean of the representative samples from any batch of finished smokeless tobacco product is determined to be out of conformance with the requirements of § 1132.10, or a finished smokeless tobacco product's expiration date must be shortened due to the results of annual real-time stability testing, or if FDA notifies a tobacco product manufacturer that a distributed finished smokeless tobacco product does not conform to the requirements of this part. The investigation must include, but is not limited to, examination of all relevant processes, operations, records, complaints, any corrective actions taken, and any other relevant sources of information concerning the nonconforming product. The investigation must be fully documented, including any materials reviewed, name of the person(s) making the disposition decisions, justification for the disposition decisions, results of retesting, decisions with respect to reworking, and followup resulting from the investigation.

(c) *Rejection of nonconforming product.* Tobacco product manufacturers must reject a batch of a finished smokeless tobacco product if the mean of the representative samples from the batch does not conform to the requirements of this part unless a disposition decision and justification to release the batch is made after an investigation shows that the batch meets the requirements of this part.

(d) *Rework of nonconforming product.* If appropriate, a manufacturer may rework a batch of a finished smokeless tobacco product that does not conform to the requirements of this part. The reworked batch of finished smokeless tobacco product must be determined to conform to all the requirements of this part with a disposition decision and justification before it may be released for commercial distribution.

Subpart C—Labeling and Recordkeeping Requirements

§ 1132.30 Package label requirements.

The package of a finished smokeless tobacco product must have a label that includes the manufacturing code, expiration date, and, if applicable, storage conditions for the smokeless tobacco product as follows:

(a) The information must be printed on or permanently affixed to the package in a manner that assures it will remain on the packaging or label through the expected duration of use of the product by the consumer. It must appear clearly, legibly, and indelibly in the English language.

(b) The expiration date must appear on the packaging in two-digit numerical values in the following format: ''Expires on month/day/year.''

(c) If the manufacturer determines by stability testing that meets the requirements in § 1132.12 that the finished smokeless tobacco product must be stored in a refrigerator, the package label must state ''Keep Refrigerated.''

(d) It must be possible to determine from the manufacturing code the history of the manufacturing, processing, packaging, labeling, holding, and initial distribution of the product from records maintained by the tobacco product manufacturer.

§ 1132.32 Recordkeeping requirements.

(a) Each facility that manufactures tobacco products subject to this part must establish and maintain records of the following information:

(1) Full documentation of stability testing protocols and the results of initial and annual stability testing under § 1132.12(a), including all information specified in § 1132.12(c);

(2) All investigations under § 1132.12(a)(4)(v);

(3) The source data and results of batch testing conducted to determine conformance with § 1132.10, including all information specified in § 1132.12(c);

(4) All notifications of an alternative test method and all related correspondence under § 1132.16;

(5) All source data for alternative test method validation;

(6) All sampling plans and reports under § 1132.18;

(7) Documentation that the persons performing sampling under § 1132.18 have sufficient education, training, and experience to accomplish the assigned functions;

(8) All identification, investigation, segregation, and disposition decision procedures under § 1132.22(a); and

(9) All nonconforming product investigations and rework under § 1132.22(b) and (d).

(b) The records must be legible and written in English. Documents that have been translated from a foreign language into English must be accompanied by the foreign language version of the document and a certification by the manufacturer's authorized representative (which could be a U.S. agent for the manufacturer) that the English language translation is complete and accurate. All records must be readily available for inspection and copying or other means of reproduction by FDA upon request during an inspection. Requested records that are maintained offsite must be made available within 24 hours or, if that is not feasible, as soon as possible before

the close of the inspection. Records that can be immediately retrieved from another location, including by computer or other electronic means, meet the requirements of this paragraph.

(c) Copies of all records required under this part must be retained for a period of not less than 4 years from the date of commercial distribution of the finished smokeless tobacco product that is the subject of the record, or, for records relating to alternative test methods under § 1132.16, for a period of not less than 4 years after the last date the method that is the subject of the record is used.

Dated: January 12, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–01030 Filed 1–19–17; 8:45 am]

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Part V

Department of Housing and Urban Development

Operations Notice for the Expansion of the Moving To Work Demonstration Program Solicitation of Comment; Notice

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5994–N–01]

Operations Notice for the Expansion of the Moving To Work Demonstration Program Solicitation of Comment

AGENCY: Office of Public and Indian Housing, HUD.

ACTION: Notice; solicitation of comment.

SUMMARY: The Public Housing/Section 8 Moving to Work (MTW) demonstration program was first established under Section 204 of the Omnibus Consolidated Rescissions and Appropriations Act of 1996 to provide statutory and regulatory flexibility to participating public housing agencies (PHAs) under three statutory objectives. Those three statutory objectives are: To reduce cost and achieve greater cost effectiveness in federal expenditures; to give incentives to families with children where the head of household is working, is seeking work, or is preparing for work by participating in job training, educational programs, or programs that assist people to obtain employment and become economically self-sufficient; and to increase housing choices for eligible low-income families.

Section 239 of the Fiscal Year 2016 Appropriations Act, Public Law 114–113 (2016 MTW Expansion Statute), signed by the President in December of 2015, authorizes HUD to expand the MTW demonstration program from the current level of 39 PHAs to an additional 100 PHAs over a period of seven years. In this notice, HUD seeks public comment on the draft Operations Notice for the Expansion of the MTW demonstration program (Operations Notice). The Operations Notice establishes requirements for the implementation and continued operations of the MTW demonstration program pursuant to the 2016 MTW Expansion Statute. HUD seeks public comment on all aspects of the Operations Notice and on specific areas for comment identified throughout this notice. HUD also seeks comment on the topic of regionalization in the MTW demonstration, which is discussed in Section 9 of the Operations Notice. Appendix C of this notice contains a listing of all of the questions in which HUD seeks public comment.

DATES: *Comment Due Date:* March 24, 2017.

ADDRESSES: Interested persons are invited to submit comments regarding this notice to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW., Room 10276, Washington, DC 20410–0500. Communications must refer to the above docket number and title.

Electronic Submission of Comments. Interested persons may submit comments electronically through the Federal eRulemaking Portal at *www.regulations.gov.* HUD strongly encourages commenters to submit comments electronically. Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, ensures timely receipt by HUD, and enables HUD to make them immediately available to the public. Comments submitted electronically through the *www.regulations.gov* Web site can be viewed by other commenters and interested members of the public. Commenters should follow the instructions provided on that site to submit comments electronically.

Note: To receive consideration as public comments, comments must be submitted through one of the two methods specified above. Again, all submissions must refer to the docket number and title of the notice.

No Facsimile Comments. Facsimile (fax) comments are not acceptable.

Public Inspection of Public Comments. All properly submitted comments and communications submitted to HUD will be available for public inspection and copying between 8 a.m. and 5 p.m. weekdays at the above address. Due to security measures at the HUD Headquarters building, an appointment to review the public comments must be scheduled in advance by calling the Regulations Division at 202–708–3055 (this is not a toll-free number). Individuals with speech or hearing impairments may access this number via TTY by calling the Federal Relay Service at 1–800–877–8339 (this is a toll-free number). Copies of all comments submitted are available for inspection and downloading at *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Marianne Nazzaro, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 7th Street SW., Room 4130, Washington, DC 20410; email address *mtw-info@hud.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

MTW Demonstration Program

The MTW demonstration program was first established under Section 204 of Title II of section 101(e) of the Omnibus Consolidated Rescissions and Appropriations Act of 1996, Public Law 104–134, 110 Stat. 1321–281; 42 U.S.C. 1437f note (1996 MTW Statute) [1] to provide statutory and regulatory flexibility [2] to participating PHAs under three statutory objectives. Those three statutory objectives are to:

- Reduce cost and achieve greater cost effectiveness in federal expenditures;
- give incentives to families with children where the head of household is working; is seeking work; or is preparing for work by participating in job training, educational programs, or programs that assist people to obtain employment and become economically self-sufficient; and
- increase housing choices for eligible low-income families.

To achieve these objectives, PHAs selected for participation in the MTW demonstration are given exemptions from many existing public housing and voucher rules and offered more flexibility with how they use their Federal funds. MTW agencies use the opportunities presented by MTW to better address local housing needs. Learning from the experience of MTW agencies, HUD develops new housing policy recommendations that can positively impact assisted housing delivery for all PHAs nationwide.

In addition to statutory and regulatory relief,[3] MTW agencies have the flexibility to apply fungibility between public housing operating, public housing capital, and Housing Choice Voucher (HCV) assistance into an agency-wide funding source referred to as the ''MTW Block Grant.'' [4] Use of the MTW Block Grant as a source of providing funding for eligible MTW activities across the three programs does not negate the need to track the funding to its original source.

Throughout participation in the MTW demonstration program, all MTW agencies must continue to meet five statutory requirements established under the 1996 MTW Statute. These five statutory requirements are:

[1] PHAs currently operating an MTW demonstration program include PHAs with an active MTW agreement as of December 15, 2015. PHAs currently operating an MTW program do not include PHAs that previously participated in the MTW demonstration and later left the demonstration.

[2] The MTW demonstration program may only provide certain flexibilities under the 1937 Act. For more information on the history of the MTW demonstration program, please go to: *www.hud.gov/mtw.*

[3] For more information about the MTW demonstration program and the specific programs of current MTW agencies, please refer to the MTW Web site at: *http://www.hud.gov/mtw.*

[4] Funds awarded under Sections 8(o), 9(d), and 9(e) of the 1937 Act are eligible for inclusion in the MTW Block Grant, with the exception of funds provided for specific non-MTW HCV sub-programs.

(1) To ensure at least 75 percent of families assisted are very low-income as defined in Section 3(b)(2) of the U.S. Housing Act of 1937 (the 1937 Act);

(2) to establish a reasonable rent policy that is designed to encourage employment and self-sufficiency;

(3) to continue to assist substantially the same total number of eligible low-income families as would have been served had funds not been combined; [5]

(4) to maintain a comparable mix of families (by family size) as would have been provided had the funds not been used under the MTW demonstration program; and

(5) to ensure housing assisted under the MTW demonstration program meets housing quality standards established or approved by the Secretary.

There are currently 39 PHAs [6] participating in the MTW demonstration program. The administrative structure for these 39 PHAs is outlined in the Standard MTW Agreement, a contract between each current MTW PHA and HUD. The 2016 MTW Expansion Statute extended the term of the Standard MTW Agreement through each of the current MTW PHA's 2028 fiscal year.

2016 Expansion to the MTW Demonstration Program

As directed by the 2016 MTW Expansion Statute, HUD is authorized to expand the MTW demonstration program from the current level of 39 PHAs to an additional 100 PHAs over a period of seven years. In expanding the MTW demonstration, HUD intends to build on the successes and lessons from the demonstration thus far. The vision for the MTW expansion is to learn from MTW interventions in order to improve the delivery of federally assisted housing and promote self-sufficiency for low-income families across the nation. Through the expansion, HUD will extend flexibility to a broader range of PHAs both in terms of size and geographic diversity and will balance the flexibility inherent in MTW with the need for measurement and evaluation at the outset.

HUD will select the additional 100 PHAs in cohorts, with applications for each cohort to be sought via PIH Notice.[7] For each cohort of agencies selected, the 2016 MTW Expansion Statute requires HUD to direct all the agencies in the cohort to implement one specific policy change, which HUD will rigorously evaluate. PHAs may implement additional policy changes. The MTW Research Advisory Committee, described further below, advised HUD on the policy changes to be tested through the new cohorts of MTW agencies and the methods of research and evaluation.

Eligibility and Selection for the Expansion of the MTW Demonstration

The 2016 MTW Expansion Statute provides that the 100 MTW agencies selected must be high performers, at the time of application to the demonstration, and represent geographic diversity across the country. Further, the statute provides that of these 100 PHAs:

- No less than 50 PHAs shall administer 1,000 or fewer aggregate housing voucher and public housing units;
- no less than 47 PHAs shall administer 1,001–6,000 aggregate housing voucher and public housing units;
- no more than 3 PHAs shall administer 6,001–27,000 aggregate housing voucher and public housing units;
- no PHA shall be granted MTW designation if it administers more than 27,000 aggregate housing voucher and public housing units; and
- five of the PHAs selected shall be agencies with a Rental Assistance Demonstration (RAD) portfolio award.

HUD will issue separate notices, by cohort, soliciting applications from eligible PHAs for participation in the MTW demonstration. These notices, when issued, will outline the specific application submission requirements, evaluation criteria, and process HUD will use when selecting PHAs for MTW participation.

MTW Research Advisory Committee

The 2016 MTW Expansion Statute established the MTW Research Advisory Committee (the Committee). The Committee is governed by the Federal Advisory Committee Act (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees. The purpose of the Committee is to provide independent advice with respect to the policies to be studied through the MTW expansion and the methods of research and evaluation related. The Advisory Committee is charged with advising HUD on the following:

- Policy proposals and evaluation methods for the MTW demonstration to inform the one specific policy change required for each cohort of agencies;
- rigorous research methodologies to measure the impact of policy changes studied;
- policy changes adopted by MTW agencies that have proven successful and can be applied more broadly to all PHAs; and
- statutory and/or regulatory changes (specific waivers and program and policy flexibility) necessary to implement policy changes for all PHAs.

The Committee has no role in reviewing or selecting the 100 PHAs to participate in the expansion of the MTW demonstration.

The Committee members were appointed in June 2016 by the HUD Secretary and chosen to ensure balance, diversity, and a broad representation of ideas.[8] The Committee includes program and research experts from HUD; a representation of MTW agencies, including current and former residents; and independent subject matter experts in housing policy research.

PHAs are reminded that the MTW demonstration program does not permit waivers related to fair housing, nondiscrimination, labor standards, or environmental requirements. Other subject matter prohibited from waivers or restricted with respect to waivers is discussed elsewhere in this notice.

Operations Notice for the Expansion of the MTW Demonstration

HUD's guiding principles for the expansion of the MTW demonstration are: (1) Simplify; (2) learn; and (3) apply. HUD seeks to design and test new approaches to providing and administering housing assistance and then to apply the lessons learned

[5] HUD's verification method detailed in Section 6(c)(i) of this notice.

[6] The 39 PHAs are: Alaska Housing Finance Corporation; Atlanta Housing Authority; Housing Authority of the City of Baltimore; Boulder Housing Partners; Cambridge Housing Authority; Housing Authority of Champaign County; Charlotte Housing Authority; Chicago Housing Authority; Housing Authority of Columbus, Georgia; District of Columbia Housing Authority; Delaware State Housing Authority; Fairfax County Redevelopment and Housing Authority; Holyoke Housing Authority; Keene Housing; King County Housing Authority; Lawrence-Douglas County Housing Authority; Massachusetts Department of Housing and Community Development; Minneapolis Public Housing Authority; Housing Authority of the City of New Haven; Oakland Housing Authority; Orlando Housing Authority; Philadelphia Housing Authority; Housing Authority of the City of Pittsburgh; Portage Metropolitan Housing Authority; Home Forward (Portland, OR); Housing Authority of the City of Reno; San Antonio Housing Authority; Housing Authority of the County of San Bernardino; San Diego Housing Commission; Housing Authority of the County of San Mateo; Housing Authority of the County of Santa Clara/City of San Jose; Seattle Housing Authority; Tacoma Housing Authority; Tulare County Housing Authority; and Vancouver Housing Authority.

[7] PIH Notice 2017–01 provides the Request for Applications for the first cohort of PHAs to be selected pursuant to the 2016 MTW Expansion Statute.

[8] For more information on the establishment, purpose, members and meeting content of the MTW Research Advisory Committee, please go to: *http://go.usa.gov/xZnj9*.

nationwide, all within a framework of simplifying program administration. The Operations Notice is a first step toward implementing this vision. The Operations Notice describes a new framework for the MTW demonstration that streamlines and simplifies HUD's oversight of participating PHAs while providing for rigorous evaluation of specific policy changes. The new framework would apply to all PHAs designated as an MTW PHA pursuant to the 2016 MTW Expansion Statute and to any previously-designated MTW agencies that agree to operate under the new framework. These PHAs are referred to in the Operations Notice as ''MTW agencies.'' Participation in the new framework will be formalized by an amendment to the PHA's Annual Contributions Contract (ACC), or other agreement as determined by HUD.

A key feature of the new framework is that PHAs will not be required to seek HUD's approval for some of the waivers identified in the Operations Notice, as determined by HUD. Instead, via the Operations Notice, HUD will grant a set of general waivers to all MTW agencies when they are so designated. In addition, HUD seeks to reduce the data collection and reporting requirements for PHAs under the new framework, focusing on financial data, basic program monitoring and performance assessment, and evaluation of the specific policy changes to be tested through each cohort. HUD will rely on existing data and reporting that PHAs will continue to submit through HUD administrative systems.

HUD is seeking comment on the draft Operations Notice because robust public comment is critical to ensuring that the Operations Notice effectively positions MTW agencies to be able to meet the demonstration's goals of increasing cost effectiveness, self-sufficiency, and housing choice.

The Operations Notice is organized into 12 sections as follows:

1. Purpose and Applicability
2. Waivers
  a. General Waivers
  b. Conditional Waivers
  c. Cohort-specific Waivers
3. Term of Participation
4. Funding, MTW Block Grant, and Financial Reporting
  a. Level of Funding
  b. Calculation of Funding
  c. MTW Block Grant and Flexibility in Use of Funds
  d. Financial Reporting and Auditing
5. Evaluation
  a. Program-wide Evaluation
  b. Cohort-specific Evaluation
6. Program Administration and Oversight
  a. Planning and Reporting
  b. Performance Assessment
  c. Monitoring and Oversight
7. Rental Assistance Demonstration Program
8. Applying MTW Flexibilities to Special Purpose Vouchers
  a. Veterans Affairs Supportive Housing (HUD–VASH)
  b. Family Unification Program (FUP)
  c. Non-Elderly Persons with Disabilities (NED) Vouchers
  d. Enhanced Vouchers and Tenant Protection Vouchers
9. Regionalization
10. Applicability of Other Federal, State, and Local Requirements
11. MTW Agencies Admitted Prior to 2016 MTW Expansion Statute
12. Sanctions, Terminations, and Default

HUD seeks comment on all 12 sections of the Operations Notice, as well as Appendix A General Waivers, and Appendix B Conditional Waivers, which outline available waivers and MTW activities that may be implemented by MTW agencies. In addition, for some sections of the Operations Notice, HUD identifies specific topics for comment and poses questions on those topics.

The majority of the Operations Notice applies only to MTW agencies, defined above as PHAs designated MTW pursuant to the 2016 MTW Expansion Statute and any previously-designated MTW agencies that agree to operate under the new framework. However, Section 9 of the Notice (Regionalization) also applies to existing MTW agencies, that is, those with an active MTW agreement as of December 15, 2015.

II. Draft Operations Notice

1. Purpose and Applicability

The Operations Notice establishes requirements for the implementation and continued operation of the expansion of the MTW demonstration program pursuant to the 2016 MTW Expansion Statute. The Operations Notice applies to all PHAs designated as MTW pursuant to the 2016 MTW Expansion Statute and to any previously-designated MTW PHA that elects to operate under the terms of this Notice.

Through an amended ACC, or other agreement as determined by HUD, an MTW agency agrees to abide by the program structure, flexibilities, and terms and conditions detailed in the Operations Notice for the term of the agency's participation in MTW demonstration. HUD may supplement the Operations Notice with PIH Notices providing more detailed guidance and reserves the right to revise the Operations Notice to address unforeseen circumstances and programmatic clarifications. Any significant updates to the Operations Notice by HUD will be preceded by a public comment period. Additionally, HUD will develop informational materials to address various program elements that HUD will post on the MTW Web site.

Unless otherwise provided in the Operations Notice, a PHA's MTW program applies to all of the agency's public housing assisted units (including agency-owned properties and units comprising a part of mixed-income, mixed finance communities), tenant-based Section 8 HCV assistance, project-based Section 8 voucher assistance under Section 8(o), and Homeownership units developed using Section 8(y) HCV assistance. This Operating Notice *does not* apply to Section 8 HCV assistance that is required: (i) For payments to other public housing agencies under Section 8 HCV portability billing procedures; (ii) to meet particular purposes for which HUD has expressly committed the assistance to the agency; [9] or (iii) to meet existing contractual obligations of the agency to a third party (such as HAP contracts with owners under the agency's Section 8 HCV program), unless a third party agrees to PBV activities implemented under the MTW program with the agency.

2. Waivers

Pursuant to this section of the Operations Notice, HUD delegates to the MTW agency the authority to pursue locally-driven policies, procedures, and programs with the aim of developing more efficient ways to provide and administer housing assistance that increases housing choice, gives incentives to low, very-low, and extremely low-income families to achieve economic self-sufficiency, and reduce costs and achieve greater cost-effectiveness in federal expenditures. Many of these policies, procedures and programs require waivers of existing statutory and regulatory requirements. HUD therefore waives certain provisions of the 1937 Act as well as HUD's implementing requirements and regulations to implement the PHA's MTW demonstration activities as described in this Notice. Certain provisions of the 1937 Act will continue to apply to the PHA and the assistance received pursuant to the Act. These ongoing provisions, as well as other applicable federal, state, and local requirements, are described in Section 10 of this Operations Notice.

[9] Five Year Mainstream Vouchers, Moderate Rehabilitation Renewals, HUD-Veterans Affairs Supportive Housing (HUD–VASH) Vouchers, Non-Elderly Disabled (NED) Vouchers, and Family Unification Program (FUP) Vouchers are not part of the MTW demonstration program.

This Notice discusses three categories of waivers, and the associated activities, that MTW agencies may pursue—general waivers; conditional waivers; and cohort-specific waivers. This Notice specifies the process for implementing MTW activities using the waivers under each category. Appendix A—General Waivers and Appendix B—Conditional Waivers provide the complete list of waivers and associated activities available for all MTW agencies. General Waivers are available to MTW agencies without HUD review—beyond the MTW application review. Conditional Waivers are available following additional HUD review and approval, as described generally in Appendix B. Cohort-Specific Waivers will be defined in a series of notices soliciting applications for participation in MTW.

Appendices A and B provide an overview of the General and Conditional Waivers. The actual statutory and regulatory provisions that will be waived will be more clearly identified in the final Operations Notice, in response to this notice and further refinement. The specific statutory and regulatory provisions that will be covered by the waivers will be included in the final MTW Operations Notice, which is anticipated to be published later this summer. Please note that in adopting an MTW program, HUD and PHA may not waive or otherwise deviate from compliance with Fair Housing and Civil Rights laws and regulations.

While MTW activities are listed by specific waiver, MTW agencies may group activities together to create more comprehensive initiatives at the local level.

MTW agencies are subject to all remaining regulatory and statutory requirements, unless an activity is specifically and explicitly authorized in the Notice via the attached waivers, in which case the agency is exempt from the applicable regulatory and statutory requirements under the 1937 Act. The five statutory requirements established under the 1996 MTW Statute cannot be waived. Additionally, in implementing activities, MTW agencies remain subject to all other terms, conditions, and obligations under this Notice, and all other federal requirements applicable to public housing, HCV, PBV, and PHAs. To the extent any MTW activity conflicts with any of the five statutory requirements or other applicable requirements, HUD reserves the right to require the MTW agency to discontinue the activity or to revise it so that the requirements are complied with. HUD also reserves the right to require an MTW agency to discontinue any activity derived from a waiver should it have unforeseen, significant negative impacts on families, as determined by HUD.

HUD understands that MTW agencies may wish to undertake activities that are not listed in Appendix A and Appendix B. If an MTW agency wishes to implement activities or request waivers that are not included in Appendix A or Appendix B, the MTW agency may seek approval from HUD for doing so via the MTW Supplement to the Annual Plan. (The MTW Supplement is discussed in Section 6 of this Notice.) The MTW agency must obtain explicit prior written approval from HUD for each additional activity and waiver.

If HUD determines that an activity(s) derived from either a general waiver or a conditional waiver would impact or conflict with the specific policy(s) to be studied in the MTW agency's cohort group, the MTW agency will not be able to conduct that activity(s) until the evaluation of the specific policy change has concluded. (Once the evaluation of the policy change is completed, the MTW agency may implement the conflicting activities for the remainder of the agency's term of MTW participation.) Any MTW activities that would impact or conflict with the cohort-specific policy change will be identified in the respective Selection Notice so that the MTW agency is aware of this potential restriction on its use of waivers before it enters the MTW demonstration program.

a. General Waivers

The MTW activities derived from the general waivers, within the specified program parameters listed in Appendix A, are available to all MTW agencies when the MTW ACC amendment, or other agreement to be determined by HUD, is executed. The MTW PHA must indicate via the MTW Supplement to its Annual Plan the MTW activities that it will undertake from the general waivers category. Prior HUD approval is not required to implement activities from the general waivers category.

Appendix A contains the full list of general waivers currently available, the MTW activities associated with these general waivers, and the specific parameters around the implementation of those activities.

b. Conditional Waivers

Conditional waivers listed in Appendix B are available to all MTW agencies within certain program parameters, but implementation of these MTW activities may not begin until additional information is received, vetted, and approved by HUD. The additional information required for each activity associated with a conditional waiver will be specified in the MTW Supplement to the Annual Plan (see Section 6 of this Notice). Conditional waivers are expected to have a greater and more direct impact on assisted households. Consequently, HUD seeks to ensure that adequate protections are in place for participants and MTW agencies prior to implementation. The additional information required must be submitted by the MTW agency via the MTW Supplement and reviewed and approved by HUD before the MTW PHA may implement the activity. Additional information may also be required throughout the time the MTW agency is conducting an activity associated with a conditional waiver. Upon request from the Department for the continued oversight of the conditional waivers, MTW agencies must provide hardship policies, impact analyses and/or other information required by HUD.

Appendix B provides the full list of conditional waivers, the activities associated with these conditional waivers, and any specific parameters around the implementation of those activities.

Waivers and MTW activities that are not provided as a general waiver or conditional waiver may be proposed by MTW agencies to HUD. Such waivers may be needed to implement an initiative being pursued by an MTW agency or may be the result of a local condition. Additional waivers will be reviewed on a case-by-case basis as part of the MTW Supplement review process. MTW agencies may not seek or obtain waivers from nondiscrimination or equal opportunity requirements.

c. Cohort-Specific Waivers

A cohort-specific waiver is one that is not included in the general waivers or conditional waivers categories and that is available exclusively to an MTW agency that is implementing a cohort-specific policy change that requires the waivers. At the time of selection to MTW, each agency will be selected into an evaluative cohort that seeks to test a specific policy change, as specified in that cohort's Selection Notice. To the extent that one or more additional waivers, beyond the general waivers or conditional waivers, are needed to implement a specific policy change, HUD will grant that waiver(s) to the MTW agencies in the cohort as cohort-specific waivers.

The cohort-specific waiver and the associated activity(s) will be described in detail in the applicable Selection Notice so that the MTW agency is aware of this in advance of entry to the MTW demonstration program. One or more

cohort-specific waivers may be associated with a particular cohort of MTW agencies. It is possible that the specific policy changes to be tested through a given cohort would not need any cohort-specific waivers. Cohort-specific waivers and the associated MTW activities may only be used to the extent allowed under the applicable evaluative framework provided by HUD in the applicable Selection Notice.

More detail on the specific statutory and regulatory citations will be included in the final Operations Notice, which will be published later this summer. Please note that certain regulations will be interpreted to protect Fair Housing and Civil Rights laws and regulations.

Specific Areas for Comment on Waivers

HUD is seeking comment on the general waivers and conditional waivers presented in Appendix A and Appendix B. HUD is specifically seeking comment on the following questions regarding waivers:

- Does the list of general waivers, MTW activities, and parameters in Appendix A and Appendix B contain the needed flexibility to achieve the three MTW statutory objectives? If not, what waivers, activities, and/or parameters are missing?
- Are there any MTW activities and/or waivers that should not be included as general waivers, available to all MTW agencies without prior HUD approval?
- Are there any MTW activities and/or waivers that should not be included as conditional waivers but rather should be included as general waivers, or not included at all?
- Does the list of conditional waivers, MTW activities, and parameters in Appendix B contain the needed flexibility to implement any alternative income-based rent model? If not, what waivers, activities, and/or parameters are missing?

3. Term of Participation

The term of each agency's MTW designation expires at the end of the MTW agency's Fiscal Year 2028. All general and conditional waivers provided through the Operations Notice expire at the end of the agency's term of participation. However, cohort-specific waivers provided to enable a cohort-specific policy change will be extended beyond the agency's term of participation with HUD's specific approval if HUD determines that additional time is needed to evaluate the policy change.

The MTW agency must end all activities requiring MTW-specific waivers upon expiration of MTW participation, as HUD cannot guarantee that it will be able to extend any waivers beyond that point. For this reason, when entering into contracts with third-parties that draw upon MTW flexibility, the agency should disclose that such flexibility is only available during the term of the agency's participation in the MTW demonstration as permitted in this notice. An exception is third-party contracts that relate to the cohort-specific policy change and associated waiver(s), if HUD determines that additional time beyond the end of the PHA's MTW term is needed to evaluate the policy change and specifically approves an extension of the cohort-specific waiver(s).

It is the MTW agency's responsibility to plan for the expiration of its MTW agreement and associated waivers. HUD recommends that MTW agencies begin transition planning[10] at least one year in advance of the expiration of its MTW designation. Not later than nine months prior to the agency's expiration date, the agency must submit a transition plan to HUD that describes the agency's plans for phasing out the MTW-specific waivers that it is using, and describes the agency's plans for re-establishing regular reporting to HUD on a standard schedule. After submitting the transition plan to HUD, MTW agencies will begin drafting changes to their policies and procedures documents, notifying participants of any changes to the terms of their residency or rent calculation, planning for the submission of standard data to HUD, and re-training PHA staff as needed.

Specific Areas for Comment on MTW Term of Participation

With respect to the term of MTW participation, HUD is specifically seeking comment on the following questions:

- Assuming all cohorts are selected between 2017 and 2020, is the end of each MTW agency's Fiscal Year 2028 an appropriate timeframe for MTW participation, and understanding that HUD may extend cohort-specific waivers to accommodate evaluation of MTW activities that require additional time?
- Is there a preferable length or structure for the term of MTW participation?

HUD will develop additional guidance on the required elements of the transition plan and a recommended transition process via PIH Notice. HUD is specifically seeking comment on:

- What elements of the MTW agency's transition plan should be mandatory?
- What elements of the transition process should HUD require in order to protect participants from potential harm and minimize disruptions to agency operations?

4. Funding, MTW Block Grant, and Financial Reporting

During the term of the demonstration, HUD will provide the MTW agencies designated pursuant to the 2016 MTW Expansion Statute with public housing Operating Fund subsidies, public housing Capital Fund program (CFP) grants, and Section 8 HCV assistance, as provided in this notice. CFP grants may include Formula grants, Demolition or Disposition Transitional Funding (DDTF, included in regular Formula grants) as well as Replacement Housing Factor (RHF) grants (superseded by DDTF). The funding amount for MTW agencies may be increased by additional allocations of vouchers or by replacement public housing units to which the agency is awarded over the term of its participation in the MTW demonstration.

MTW agencies will have the flexibility to apply fungibility between public housing operating, public housing capital, and HCV assistance into an agency-wide funding source referred to as the ''MTW Block Grant.'' The agency must complete an annual audit pursuant to the Single Audit Act requirements set forth in 2 CFR 200 Subpart F, including any applicable Compliance Supplement(s), as determined by the auditor, to be relevant to MTW and other programs. The Single Audit Act-compliant audit must be submitted to HUD in accordance with HUD regulations.

a. Level of Funding

The 1996 MTW Statute and the 2016 MTW Expansion Statute prohibit MTW agencies from receiving any more or any less funding than they would receive if they were not participating in the MTW demonstration.

The 1996 MTW Statute states, in part, that, ''The amount of assistance received under section 8, section 9, or pursuant to section 14 by a public housing agency participating in the demonstration under this part shall not be diminished by its participation.'' In addition, the 2016 MTW Expansion Statute states, in part, that, ''No PHA granted this designation through this section shall receive more funding under sections 8 or 9 of the 1937 Act than they otherwise would have received absent this designation.''

[10] *https://portal.hud.gov/hudportal/documents/huddoc?id=DOC_10542.pdf.*

b. Calculation of Funding

i. Public Housing Operating Fund Subsidy

(a) The calculation of an MTW PHA's Operating Fund subsidy eligibility will continue in accordance with operating subsidy formula law, regulations, and appropriations act requirements.

(b) The agency may use these funds for any eligible activity permissible under Section 9(e)(1) of the 1937 Act or, if the agency proposes to use the funding as part of the MTW Block Grant, it may use these funds for any eligible activity permissible under Section 8(o), 9(d)(1) and 9(e)(1) and as specified in this Notice.

(c) For operating subsidy funding provided in years prior to the designation of the agency as an MTW agency, the agency may use any accumulated operating reserves for eligible MTW purposes, subject to applicable provisions of this Notice, subsequent legislation, including appropriations acts, and HUD and other federal requirements.

ii. Public Housing Capital Fund Formula and Grants

(a) The agency's Public Housing Capital Fund formula characteristics and grant amounts, including DDTF and RHF, will continue to be calculated in accordance with public housing law, regulations, and appropriations act requirements. Capital Funds will be disbursed in accordance with standard HUD procedures for disbursement of public housing Capital Fund grants, provided however that the agency may not accelerate drawdown of funds in order to fund reserves.

(b) In requisitioning Capital Fund grant funds, the MTW agency will not be required to provide line item detail in HUD's Line of Credit Control System (LOCCS), but will request the funds using a single MTW line item with the exception of grant funds required for payment of debt service pursuant to the Capital Fund Financing Program (CFFP). The agency will provide to HUD information on all capital activities funded by the MTW Block Grant as necessary to ensure compliance with requirements outside the scope of MTW, including environmental review requirements and Energy and Performance Information Center (EPIC) reporting requirements.

(c) The agency may use these funds for any eligible activity permissible under Section 9(d)(1) of the 1937 Act or, if the agency proposes to use the funding as part of the MTW Block Grant, it may use these funds for any eligible activity permissible under Section 8(o), 9(d)(1) and 9(e)(1) and as specified in this Notice. CFP funds not included in the MTW Block Grant are subject to all requirements relevant to non-MTW agency CFP funding, including eligible activities and cost limits.

(d) For Capital Funds provided in years prior to the designation of the agency as an MTW agency, the agency may use such funds for eligible MTW purposes, subject to applicable provisions of this Notice, subsequent legislation, including appropriations acts, and HUD and other federal requirements.

(e) The agency remains subject to the requirements of Section 9(j) of the 1937 Act with respect to Capital Fund grants. Section 9(d) funds remain subject to the obligation and expenditure deadlines and requirements provided in Section 9(j) despite the fact that they are combined in a single block grant fund. Capital Funds awarded to MTW agencies must be obligated within two years and expended within four years of award. Funds not obligated or expended within those timeframes will be subject to recapture. As with all PHAs, an MTW PHA may requisition CFP funds from HUD only when such funds are due and payable, unless HUD approves another payment schedule.

iii. Housing Choice Voucher (HCV) Funding

(a) For the calendar year after the MTW agency joins the MTW demonstration (the ''Initial Year''), an agency's HCV HAP renewal funding will be calculated based on the previous CY's HAP expenses reported in VMS that originated from HAP funds adjusted by any applicable inflation factor and national proration, in accordance with the funding formula in the appropriations act used for all HCV agencies. This adjusted amount will be the agency's Annual Voucher Budget Authority (AVBA) for the initial year of MTW participation.

(b) For subsequent years, the HCV HAP renewal funding will be calculated as follows:

(i) HCV HAP Renewal funding will be calculated based on (i) the previous CY's HAP expenses reported in VMS that originated from HAP funds plus (ii) the previous CY's eligible non-HAP MTW expenses (subject to the conditions and percentage limitations described below) and (iii) the eligible non-HAP MTW commitments and obligations (subject to the conditions, percentage limitations and utilization requirements described below), the sum of which will be adjusted by any applicable inflation factor appropriate for the HAP and non-HAP expenses and national proration for the current CY. The resulting adjusted amount is the agency's AVBA for the current CY. The amount of non-HAP expenses and the amount of commitments and obligations that may be included in the above calculation are subject to percentage limitations and utilization requirements described below.

(ii) An MTW agency is required to spend at least 90% of its CY AVBA on eligible HAP expenses each year. If the MTW agency meets this requirement but the actual HAP expenses did not exceed 100% of its CY AVBA, then the agency's eligible non-HAP MTW expenses and the agency's commitments and obligations will be included in its renewal funding eligibility for the next CY as described herein. The amount of eligible non-HAP MTW expenses, commitments, and obligations that will be included in the renewal calculation is limited to the lower of: (a) The amount of AVBA expended, committed, or obligated for eligible non-HAP MTW expenses as reported and validated in VMS, or (b) the amount of AVBA that was not used for HAP expenses, or (c) 10% of AVBA.

(iii) Only HAP expenses that originated from HAP Funds (including HAP reserves) are included in the HAP renewal funding formula. Public Housing Operating funds and Capital funds, and Section 8 Administrative Fee funds that may have been used for HAP expenses as part of MTW flexibility will not be included in the following calendar year's renewal funding formula.

(iv) If an MTW agency expends 100% or more of its AVBA in HAP expenses in a given year, the total HAP expenses will be used for the next CY's Renewal funding formula to the extent that the HAP expenses originated from HAP or HAP reserves. However, none of the funds provided in the renewal formula may be used to fund a total number or unit months under lease which exceeds the MTW agency's authorized level of unit months available under the MTW agency's ACC, in accordance with the funding formula used for non-MTW agencies.

(c) Additional details about the HCV Renewal funding formula are provided below:

(i) Budget Utilization Requirement. Starting in the Initial Year of MTW funding, and for the duration of its participation in the MTW demonstration, the MTW agency must spend at least 90 percent of each CY's MTW AVBA on HCVP eligible HAP expenses in the funded year. Eligible HAP expenses are defined in HUD's

Voucher Management System (VMS) guidebook (or the guidebook of any successor system). HUD's VMS (or its successor system) will be the data source to verify compliance with the HCVP budget utilization requirement throughout the duration of participation in the MTW demonstration. If performance below the 90% utilization requirement persists, HUD may take appropriate corrective actions including, but not limited to, the restriction of uses of funds, other administrative actions, including the termination of the MTW agency's participation in the MTW demonstration.

(ii) HAP-Originated Reserves. Any reserves the MTW agency has accumulated prior to the start of the Initial Year may be used for any eligible MTW activity. If pre-existing reserves before the start of the Initial Year are used for HAP expenses, those expenses will be included in the subsequent year's funding formula to the extent those funds originated from HAP. Any sum generated by the MTW agency in the Restricted Net Position (RNP) account or HUD-held reserves after the effective date that the MTW agency receives MTW designation shall remain available and may be used for all eligible MTW activities, subject to applicable provisions of this Notice, subsequent legislation, including appropriations acts, and other HUD requirements. HAP-Originated reserves accumulated after the effective date that the MTW agency receives MTW designation will be included in the subsequent year's funding formula if spent on HAP expenses.

(iii) Limitation of Amount of HUD-Held Reserves. The maximum HAP-Originated funds in HUD-held reserves cannot exceed 100% of AVBA. If the total amount of HAP-Originated reserves at CY end exceeds 100% of AVBA, any reserves originated from HAP in excess of this amount will be reduced from the subsequent year's funding formula.

(iv) Cash Management Requirements Apply. All undisbursed HAP funds including HAP-Originated reserve funds will be held as HUD-held reserves per OMB cash management requirements and can be requested by the MTW agency when HAP (or non-HAP) immediate need exceeds the scheduled HAP and Fee monthly disbursements, but only after consideration of available MTW agency-held RNP or unrestricted net position (UNA), respectively. Any sum held by the MTW agency as excess administrative fee funds (Unrestricted Net Position) shall remain available to the MTW agency. All excess administrative fee funds may be used for any eligible MTW activities.

(v) Commitments/Obligations of Funds. Commitments and obligations of funds that will be used for eligible MTW activities in the future will receive consideration in the HCV Renewal funding formula as described above. Committed and obligated funds remain part of HUD-held reserves until drawn down and all cash management requirements and other rules applicable to reserve amounts apply. In addition, committed and obligated funds may be subject to HUD reserve offsets as part of future Congressional Appropriations Bills.

- Commitments. A commitment is the setting aside or earmarking of undisbursed and unobligated funds to be used for eligible MTW activities in the future. An MTW agency may commit funds to planned future MTW eligible uses, as evidenced in the MTW Supplement to the Annual Plan which must be adopted by the board. For commitments to qualify for consideration in the Renewal funding formula, an MTW agency must describe its future plans to use the funds for a certain type of MTW eligible use with sufficient supporting detail in the MTW Supplement to the Annual PHA Plan. Such detail may include the program type (*i.e.,* public housing, housing voucher, both, or local, non-traditional), development number/name, description of work or activity, quantity, estimated cost, anticipated timeline, and other information as applicable. Committed unspent MTW funds must be reported in VMS in the Unspent MTW Funds section (see VMS User's Manual for more details). An MTW agency may update and revise commitments as necessary, in response to changing local conditions.
- Obligations. An obligation is a legally binding agreement that will require an outlay or expenditure of funds, immediately or in the future. An example of an obligation is an executed construction contract between the MTW agency and a construction company. Obligated unspent MTW funds must be reported in VMS in the Unspent MTW Funds section (see VMS User's Manual for more details). HUD intends to exclude obligated funds in HUD-held reserves from Congressional offset to the extent that future statutory language would allow such exclusion.

(vi) Administrative Fees. The administrative fee rates used to calculate fee eligibility for MTW agencies shall be established according to the same methodology used to establish administrative fee rates for all other public housing agencies. Administrative fees will be paid on the basis of units leased as of the first day of each month; this data will be extracted from VMS at the close of each reporting cycle. Administrative fees for MTW agencies are also subject to the national proration factor and any other appropriations act requirements to the total eligibility amount.

(vii) Incremental Vouchers. If the MTW agency receives incremental HCVP vouchers and funding (including tenant protection vouchers), other than special purpose vouchers (described in (x) below), renewal funding for those vouchers will be included in the MTW HCV renewal funding eligibility calculation for the following year. (See Section 8 of this Operations Notice for further discussion of tenant protection and other special purpose vouchers.) The MTW agency's renewal funding eligibility (which includes renewal funding associated with these vouchers) remains subject to the budget utilization requirement detailed above. The renewal amount is based on the MTW per unit cost (PUC), any months not covered by initial increment, and adjusted by the inflation factor. Incremental vouchers included in the MTW agency's renewal funding eligibility will be funded pursuant to the current year's per unit funding amount.

(viii) Adjustments for the first-time renewal of certain vouchers. HUD will also make adjustments to the renewal funding for the first-time renewal of certain vouchers that are included in the MTW HAP renewal calculation when the funding increment will expire during the CY.

(ix) Applicable inflation factor and proration. The same applicable inflation factor that applies for non-MTW agencies will be applied each CY to determine the MTW agency's HAP funding renewal eligibility. Likewise, the MTW agency's HAP funding renewal eligibility is subject to the same national proration as non-MTW agencies' renewal eligibility, based on the total eligibility of all MTW agencies compared to the actual amount appropriated for HAP renewal funding for the CY.

(x) Rental Assistance Demonstration (RAD). Any vouchers received as part of a RAD component I conversion shall be added to the ACC for the remainder of the CY in which they are awarded. HUD will issue a new increment of voucher funding in support of those vouchers for the first full CY following a RAD component I conversion. In subsequent years, voucher funding for RAD converted units will be renewed under the MTW HCV renewal funding

calculation, based on a weighted MTW per unit cost (PUC), plus inflation factor and the applicable proration factor. RAD component II conversions are funded in accordance with the incremental voucher section above. Administrative fees for RAD vouchers will be established based on the same methodology used to establish administrative fees in (vi) of this section. Fees for RAD vouchers will be prorated at the same level that applies to all non-MTW agencies.

(xi) Voucher Programs Not Included in MTW Program. Vouchers and funding provided for the following special purpose vouchers, whether for new allocations or renewal of existing increments, shall not be included in the HCV MTW Program renewal calculation: Five Year Mainstream, Moderate Rehabilitation renewals, Veterans Affairs Supportive Housing (VASH), Non-Elderly Disabled (NED), and Family Unification Program (FUP). These vouchers will be renewed under the regular voucher renewal requirements as provided under the appropriations acts. Special purpose vouchers are discussed in more detail in Section 8 of this Operations Notice.

c. MTW Block Grant and Flexibility

An agency participating in the MTW demonstration program may combine public housing Operating and Capital Funds provided under Sections 9(d) and 9(e) of the 1937 Act and voucher program funds provided under Section 8 of the 1937 Act as the MTW Block Grant. Certain provisions of Sections 8 and 9 of the 1937 Act and 24 CFR 982 are waived as necessary, to implement the MTW Block Grant. MTW Block Grant flexibility is optional and does not require prior HUD approval.

The agency may use MTW Block Grant funds for any eligible activity under Sections 9(d)(1), 9(e)(1) and Section 8(o) of the 1937 Act and for the local, non-traditional activities specified in this Notice, including Appendix A and B. Within the scope of the permissible eligible activities, the agency can carry out the purposes of the MTW demonstration program to provide flexibility in the design and administration of housing assistance to eligible families; (1) To reduce cost and achieve greater cost effectiveness in federal expenditures, (2) to give incentives to families with children where the head of household is working, seeking work, or is preparing for work by participating in job training, educational programs, or programs that assist people to obtain employment and become economically self-sufficient, and (3) to increase housing choices for low-income families.

The agency may use MTW Block Grant funds to support the evaluation of MTW activities subject to reasonable cost requirements set forth in 2 CFR part 200.

d. Financial Reporting and Auditing

MTW agencies must submit year-end unaudited and audited financial information to the Department using the Financial Data Schedule (FDS) contained in the Real Estate Assessment Center's (REAC) Financial Assessment Subsystem (FASS–PH), or its successor system. Financial reporting requirements for MTW agencies are currently posted on the REAC Web site at *http://www.hud.gov/offices/reac/products/fass/fass_pdf/mtw-reporting.pdf.*

An MTW agency must submit unaudited financial information into REAC's FASS–PH, or its successor system, within 60 days of the end of its fiscal year, and audited financial information with nine months of the end of its fiscal year. REAC reviews financial submissions for basic financial soundness (*e.g.,* cash balances, accounts receivable and accounts payable, quick ratio, current ratio, etc.). The MTW agency will keep project level budgeting and accounting and report financial information in the FDS. The MTW agency will abide by project level management reviews in accordance with Asset Management guidance contained in PIH Notice 2007–9, or any successor guidance. The MTW agency will conform to the cost requirements of 2 CFR 200 and any HUD implementation thereof.

The MTW agency must procure an Independent Public Accountant (IPA) to perform an annual audit pursuant to federal requirements at 2 CFR part 200 and 24 CFR 990.190, or successor, as well as any audit compliance supplements developed specifically for use with the MTW demonstration. An MTW agency that may be otherwise exempt from a single audit will be required to perform an annual financial statement audit as a condition of becoming an MTW agency under the MTW Expansion.

Completed IPA audits must be submitted to HUD in accordance with current HUD regulations. HUD will review the IPA audits of MTW agencies to determine appropriate action relative to any findings, prepare recommendations for audit finding resolution, and follow up with MTW agencies to assure finding closure. If there are audit findings related to the MTW program itself, HUD will monitor the resolution of all audit findings.

Specific Areas for Comment on Funding, MTW Block Grant, and Financial Reporting

With respect to funding, MTW Block Grant, and financial reporting, HUD is specifically seeking comment on the following questions:

- Is a 90 percent HAP budget utilization requirement the appropriate amount?
- What sanctions or restrictions should HUD consider using should an MTW agency continue to fail to meet the budget utilization requirement?
- Are there other methods for calculating HCV funding that HUD should consider?
- Are there other factors HUD should consider in the calculation of funding?
- Are there any comments or clarifications needed in relation to funding, the MTW Block Grant, or financial reporting?

5. Evaluation

As a condition of participating in the MTW demonstration, MTW agencies agree to cooperate fully with HUD and its contractors in the monitoring and evaluation of the MTW demonstration, to keep records, and to submit reports and other information as required by HUD. This includes any data collection required for the use of waivers (*e.g.,* conditional waivers) and any evaluation efforts that HUD undertakes for the cohort-specific policy changes.

MTW is a demonstration that provides PHAs flexibilities to innovate and try different approaches to housing assistance in order to achieve at least one of the three statutory objectives laid out in the 1996 MTW Statute. At its core, the demonstration is an opportunity for PHAs, participants, HUD, stakeholders and the general public to learn from different approaches to providing federal housing assistance to low-income families. This includes learning from approaches that are effective and produce desired outcomes, and from approaches that are less effective than anticipated and where results may have unintended consequences.

Because PHAs have the ability to use different flexibilities calling on multiple MTW waivers that serve local populations in various parts of the country, interpreting PHA-reported performance metrics data on the effects of an individual MTW activity is not always clear-cut. Consequently, and while adhering to the guiding principles for the expansion (simplify, learn, and apply), HUD will create and develop an

evaluation system that will tell the story of the MTW demonstration through the lens of the three statutory objectives relating to cost effectiveness, self-sufficiency, and housing choice.

HUD envisions two types of evaluation—program-wide evaluation and cohort-specific evaluation. Through this notice, HUD is seeking feedback on each of these evaluation types.

a. Program-Wide Evaluation

Program-wide evaluation would seek to assess whether or not, and to what extent, MTW agencies use Federal dollars more efficiently, help residents find employment and become self-sufficient, and increase housing choices for low-income families. HUD intends to develop performance metrics for program-wide evaluation that are based, to the extent possible, on information already being collected from MTW agencies through existing HUD administrative data systems. HUD may determine and require that some additional reporting is necessary to effectively evaluate MTW.

The following are examples of potential performance metrics that could be used for each statutory objective; the list is not exhaustive and will be revised further with feedback from this notice and additional internal evaluation:

MTW statutory objective:	Potential performance metrics
1. Reduce cost and achieve greater cost effectiveness in federal expenditures.	• Administrative cost savings per unit in direct program administration (HCVP and public housing) and indirect costs. • Changes in rental revenue. • Changes in number of families served.
2. Give incentives to families with children where the head of household is working; is seeking work; or is preparing for work by participating in job training, educational programs, or programs that assist people to obtain employment and become economically self-sufficient.	• Changes in employment rates or hours worked. • Changes in earned income levels since entering the program. • Changes in rent burden. • Changes in number of households receiving supportive services aimed to increase self-sufficiency.
3. Increase housing choices for eligible low-income families	• Changes in the quality and type of housing stock accessible to extremely low-income, very low-income, and low-income households. • Changes in the percentage of households moving to or living in areas with lower rates of poverty. • Changes in occupancy rates in public housing and utilization rates of housing vouchers. • Changes in average applicant time on waiting list.

b. Cohort-Specific Evaluation

The 2016 MTW Expansion Statute requires HUD to direct all the agencies in a cohort to implement one specific policy change and to conduct a rigorous evaluation of the one specific policy change. The MTW Research Advisory Committee has considered input from the public and advised HUD on the policy changes to be tested through the new cohorts of MTW agencies and on the methods of research and evaluation.

The cohort-specific policy change and evaluation methods will be described in the applicable Selection Notice so that the MTW agency is aware, in advance of application to the MTW demonstration program, of the policy it will be required to implement and the evaluation requirements. The specific evaluation methods (and requirements for participating MTW agencies) will vary based on the policy changes to be tested. Some cohorts of MTW agencies may be required to participate in Randomized Control Trials (RCTs), while others may be required to participate in detailed process studies or ethnographic research. HUD's Office of Policy Development and Research is seeking funding for evaluating cohort-specific policy changes. In all cases, the purpose of the evaluation will be to measure the outcomes associated with the specific policy change(s) in order to offer policy recommendations for implementing the policy change(s) across all PHAs.

HUD will determine the length and timeframe for the evaluation based on the recommendations of the MTW Research Advisory Committee. In some cases, the evaluation timeframe may extend beyond the agency's term of MTW participation. The MTW agency is required to participate in the evaluation for the full timeframe designated by HUD. HUD intends to extend waivers beyond the agency's term of participation to the extent that those waivers are needed to support the evaluation of the specific policy change and HUD determines that additional time is needed to evaluate the policy change.

Specific Areas for Comment on Evaluation

With respect to the program-wide evaluation, HUD is specifically seeking comment on the following questions:

- Is there any information not captured in HUD administrative data systems that would provide informative data points or performance metrics for evaluating the MTW demonstration?
- What are measures of MTW activities that ''reduce cost and achieve greater cost effectiveness in Federal expenditures'' that can apply to and are either being reported in existing HUD systems or can be reported by every MTW agency?
- What are measures of MTW activities that ''give incentives to families with children where the head of household is working, seeking work, or is preparing for work by participating in job training, educational programs, or programs that assist people to obtain employment and become economically self-sufficient'' that can apply to and are either being reported in existing HUD systems or can be reported by every MTW agency?
- Should HUD standardize a definition of ''self-sufficient''? If so what elements of self-sufficiency should be included in HUD's definition?
- What are measures of MTW activities that ''increase housing choices for low-income families'' that can apply to and are either being reported in existing HUD systems or can be reported by every MTW agency?
- What is the best way to capture and report exit data on families exiting the Public Housing, HCV, and local non-traditional housing programs? What are the appropriate exit reasons to capture?
- Is there any information not captured in HUD administrative data systems that would be informative data points or performance metrics in terms of evaluating the MTW demonstration?
- In the list of performance metrics provided above, should any be clarified or removed?
- Are there any alternative or additional metrics that would enhance

performance evaluation on the MTW demonstration?

With respect to the cohort-specific evaluation, HUD will consider the advice provided by the MTW Research Advisory Committee.

6. Program Administration and Oversight

In general, MTW agencies will be subject to the same planning and reporting protocols as non-MTW agencies, including the PHA Plan (5-Year Plan and Annual Plan) and Capital Fund planning. MTW agencies must also report data in HUD data systems, as required.

New protocols and instruments will be developed for assessing MTW PHA performance, and incorporated into HUD's Public Housing Assessment System (PHAS) and Section Eight Management Program (SEMAP), or successor assessment systems. In addition, HUD will employ standard program compliance and monitoring approaches including assessment of relative risk and on-site monitoring conducted by HUD or by entities contracted by HUD

a. Planning and Reporting

i. The PHA Plan

MTW agencies must adhere to Public Housing Agency Plan regulations at 24 CFR part 903, any implementing HUD Notices and guidance, as well as any succeeding regulations. The PHA Plan consists of the 5-Year Plan that a PHA must submit to HUD once every five PHA fiscal years and the Annual Plan that the PHA must submit to HUD for each PHA's fiscal year. Any HUD assistance that the PHA is authorized to use under the MTW demonstration must be used in accordance with the PHA's Annual Plan, as applicable.

Annual and 5-Year Plans must be submitted in a format prescribed by HUD. Currently, submission format requirements are outlined in Notice PIH 2015–18 (HA), issued October 23, 2015, which is effective until amended, superseded or rescinded. The MTW agency must submit:

- HUD–50075–5Y, the 5-Year Plan
- HUD–50075–HP, the Annual Plan for high performing agencies, along with supporting documents
  - HUD 50077–ST–HCV–HP
  - HUD–50077–SL
  - Resident Advisory Board (RAB) comments received
  - Any challenged elements of the Plan
- MTW Supplement to the Annual Plan (under development)

As an MTW agency, all PHA Plan information must be provided in the context of the PHA's participation in the MTW demonstration. This includes taking into account the waivers and flexibilities afforded to the MTW agency. To this end, the MTW agency will provide and HUD will make available to the public, an MTW Supplement to the Annual Plan, in a format to be developed by HUD. HUD anticipates that MTW agencies would use the MTW Supplement to the Annual Plan to:

(a) Indicate the MTW activities and associated waivers that the agency will undertake in the Annual Plan year that require general waivers (Appendix A) using a check-box or other simple format.

(b) Indicate the MTW activities and associated waivers that the agency will undertake in the Annual Plan year that require conditional waivers (Appendix B) using a check-box or other simple format.

(c) Indicate the MTW activities that the agency will undertake in the Annual Plan year that require cohort-specific waivers (as applicable and identified in each cohort's Selection Notice), and the cohort-specific waivers to be used, using a check-box or other simple, non-narrative format.

(d) Submit specific information or data required by HUD for any conditional waiver(s) the agency intends to use for the first time in the Annual Plan year.

(e) Submit data or reporting required for the ongoing use of any MTW waivers from the preceding year.

(f) Submit data required for HUD's verification of the MTW agency's compliance with the five statutory requirements established under the 1996 MTW Statute.

(g) Request HUD approval for any MTW activities and waivers that the MTW agency seeks to implement in the Annual Plan year that are outside of the lists of general, conditional, and cohort-specific waivers.

Non-MTW PHAs with a combined unit total of 550 or less public housing units and vouchers and that are not designated as troubled under PHAS and that do not have a failing score under SEMAP are exempt from the requirement to submit the Annual Plan. Per this Operations Notice, MTW agencies with a combined unit total of 550 or less public housing units and vouchers would be required, at a minimum, to submit the MTW Supplement to the Annual Plan on an annual basis.

MTW agencies must submit to HUD the Annual PHA Plan, including any required attachments and the MTW supplement, no later than seventy-five (75) days prior to the start of the agency's fiscal year.[11] Before submission to HUD, the PHA must have a 45-day public review period and a public hearing. PHAs must consider, in consultation with the RABs, all the comments received at the public hearing. The recommendations received must be submitted by the PHAs as a required attachment to the Plan. PHAs must also include a narrative describing their analysis of the recommendations and the decisions made on these recommendations. PHAs must also obtain the proper signed certifications and board certification.

HUD will notify the MTW agency in writing if HUD objects to any provisions or information in the Annual Plan or the MTW supplement. When the MTW agency submits its Plan seventy-five (75) days in advance of its fiscal year, HUD will respond to the MTW agency within 75 days. If HUD does not respond to the MTW agency within 75 days after an on-time receipt of the Annual Plan, the agency's Annual Plan (and MTW Supplement) is approved. If HUD does not receive the agency's Annual Plan on time, the Plan is not approved until HUD responds.

ii. Admissions and Continued Occupancy Policy (ACOP) and Administrative Plan

The MTW agency must update its ACOP and Administrative Plan to be consistent with the MTW activities and related waivers that it implements. The agency may not implement an MTW activity or waiver until the relevant sections of the ACOP and/or Administrative Plan are updated. MTW agencies must provide HUD with electronic versions of the ACOP and Administrative Plan upon request. If the MTW agency implements an activity using the local, non-traditional uses of funds waiver, the MTW agency must create and update an implementing document specifically for such activity.

In addition, the PHA must review its Administrative Plan, ACOP, and other selection and admissions related policies to ensure that they comply with Departmental regulations and other directives concerning the use of criminal records and other criminal activity in admissions and continued occupancy decisions. The PHA's policies and procedures may not permit the automatic exclusion of an applicant

[11] It is understood that the requirements in the remainder of this section refer to the Annual Plan and the MTW Supplement if the MTW agency is required to submit the Annual Plan and only to the MTW Supplement if the MTW agency is not required to submit an Annual Plan as discussed in the previous paragraph.

or participant on the basis of the record of a criminal arrest alone. The same applies to policies and procedures concerning prospective tenant screening by landlords and other third parties. HUD may review the PHA's admissions and continued occupancy policies to ensure compliance with HUD requirements concerning criminal records and criminal activity. For more information, see the related letter from HUD's Office of General Counsel at: *https://portal.hud.gov/hudportal/documents/huddoc?id=HUD_OGCGuidAppFHAStandCR.pdf* and PIH's related notice at *https://portal.hud.gov/hudportal/documents/huddoc?id=PIH2015-19.pdf.*

iii. Capital Planning and Reporting

MTW agencies must adhere to CFP regulations at 24 CFR part 905, any implementing HUD Notices and guidance, as well as any succeeding regulations.

As noted previously, MTW agencies are funded in accordance with CFP regulations and formula funds are calculated and distributed in the same manner as non-MTW agencies.

MTW agencies have the authority and flexibility to combine CFP funds with other funds as part of the MTW Block Grant. HUD will award a Capital Fund grant to the MTW agencies, in keeping with the standard process for all PHAs. The Field Office will spread the funds in LOCCs to the MTW agencies in the same manner as for the non-MTW agencies. As with other PHAs, an MTW PHA may requisition Capital Funds from HUD only when such funds are due and payable, unless HUD approves another payment schedule. To the extent that the MTW agency places CFP funding in the MTW Block Grant, the CFP funding would be recorded on Budget Line Item (BLI) 1492 (Moving to Work) on form HUD–50075.1. CFP funds entered on BLI 1492 would not need to be broken out and itemized in the part II supporting pages of the HUD–50075.1. However, an MTW PHA may not accelerate drawdowns of funds in order to fund reserves.

An MTW agency is not required to include all or a portion of its CFP grant in the MTW Block Grant. To the extent that the MTW agency wishes to dedicate all or a portion of its CFP grant to specific capital improvements, the agency may record CFP funding on any BLI on form HUD–50075.1 other than BLI 1492.

iv. Inventory Management System (IMS)/PIH Information Center (PIC) Reporting

Data from HUD's Inventory Management System (IMS) and PIH Information Center (PIC), or successor systems, is critical to all aspects of program administration, including HUD monitoring and tracking of MTW agency progress in meeting the MTW statutory objectives. IMS/PIC data is used to establish funding eligibility levels for both Operating Subsidy and Capital Fund grants. Further, HUD relies on IMS/PIC data to provide a thorough and comprehensive view of PHA program performance and compliance.

MTW agencies are required to submit the following information to HUD via IMS/PIC (or its successor system):

- Family data to IMS/PIC using Form HUD–50058 or Form HUD–50058 MTW (or successor forms) and in compliance with HUD's 50058 or 50058 MTW submission requirements for MTW agencies. HUD will identify which form the MTW agencies will submit for families in the publication of the final Operations Notice. MTW agencies must report information on all families receiving some form of tenant-based or project-based housing assistance, either directly or indirectly, as well as all public housing families, to at least a 95 percent level.
- Current building and unit information in the development module of IMS/PIC (or successor system).
- Basic data about the PHA (address, phone number, email address, etc.).

HUD will monitor MTW agency reporting to IMS/PIC (or successor system) to ensure compliance and provide technical assistance to MTW agencies as needed.

v. Voucher Management System (VMS) Reporting

MTW agencies are required to report voucher utilization in the Voucher Management System (VMS), or its successor system. There are several areas in which VMS reporting is different for MTW agencies. These areas are highlighted in the VMS User's Manual (*http://portal.hud.gov/hudportal/documents/huddoc?id=instructions.pdf*) which details the VMS reporting requirements.

HUD will monitor each MTW agency's VMS reporting to ensure compliance and provide technical assistance to MTW agencies as needed.

vi. General Reporting Requirement

In addition to the reporting requirements outlined in this Operations Notice, MTW agencies are required to comply with any and all HUD reporting requirements not specifically waived by HUD for participation in the MTW demonstration program, including the requirement (discussed in Section 5) to comply with HUD's evaluation of the specific-policy changes being implemented by cohort.

b. Performance Assessment

Assessing the performance of PHAs (both MTW and non-MTW) helps the delivery of services in the public housing and voucher programs and enhances trust among PHAs, public housing participants, HUD, and the general public. To facilitate this effort, HUD will provide management tools for effectively and fairly measuring the performance of a PHA in essential housing operations.

Currently, HUD uses PHAS and SEMAP to assess risk and identify underperforming PHAs in the traditional public housing and voucher programs. However, since some of the MTW flexibilities make it difficult to accurately depict the performance of MTW agencies under the existing systems, HUD will develop alternative, MTW-specific performance indicators in consultation with MTW agencies and incorporate them into PHAS and SEMAP (or successor assessment system(s)). MTW agencies may not opt out of the MTW-specific successor system(s).

i. Public Housing Assessment System (PHAS)

MTW agencies are scored in PHAS but they can elect not to receive the overall score (MTW agencies continue to receive PHAS sub-scores even if they elect not to receive the overall score). If an MTW agency elects to receive its overall PHAS score, the agency must continue to be scored for the duration of the demonstration, or until the agency is assessed under performance indicators designed specifically for MTW agencies in a successor system(s) to PHAS, whichever comes first. Once developed, MTW agencies that elect not to receive an overall PHAS score must be assessed under the MTW-specific successor system(s).

Per the 1996 MTW statute, when providing public housing, the MTW agency must ensure that the housing is safe, decent, sanitary, and in good repair, according to the physical inspection protocols established and approved by HUD. Thus, MTW agencies continue to be subject to HUD physical inspections. To the extent that HUD physical inspections reveal deficiencies, the MTW agency must continue to

address these deficiencies in accordance with existing physical inspection requirements. If an MTW agency does not maintain public housing adequately, as evidenced by the physical inspection performed by HUD and is determined to be troubled in this area, HUD will determine appropriate remedial actions. The actions to be taken by HUD and the PHA will include actions statutorily required and such other actions as may be determined appropriate by HUD. These actions may include developing and executing a Memorandum of Agreement (MOA) with the MTW agency, suspension or termination of the MTW ACC amendment, or other agreement to be determined by HUD, in accordance with the provisions therein, or such other actions legally available to the Department.

MTW agencies must continue to submit year-end financial information into the Financial Data Schedule (FDS) or successor system, as discussed earlier.

ii. Section 8 Management Assessment System (SEMAP)

MTW agencies are scored in SEMAP but they can elect not to receive the overall score. If an MTW agency elects to receive its overall SEMAP score, the agency must continue to be scored for the duration of the demonstration, or until the agency is assessed under an assessment system designed specifically for MTW agencies, whichever comes first. Once developed, MTW agencies that opt out of SEMAP must be assessed under the MTW-specific successor system(s).

iii. MTW-specific Assessment

HUD will develop new performance indicators for evaluating MTW agencies and for measuring the relative progress of assisted families toward self-sufficiency. Such MTW-specific performance indicators will be incorporated into PHAS and SEMAP (or successor system(s)) for purposes of MTW agencies and will address PHA performance (general public housing and Section 8 HCV management, as well as MTW-specific activities) and PHA risk associated with MTW.

c. Monitoring and Oversight

MTW agencies remain subject to the full range of HUD monitoring and oversight efforts including, but not limited to, annual risk assessments, on-site monitoring reviews, monitoring reviews relating to VMS reporting and rent reasonableness, review of the accuracy of data reported into HUD data systems, use of HUD data systems to assess PHA program performance, among other activities.

i. MTW Statutory Requirements

Throughout participation in the MTW demonstration program, all MTW agencies must continue to meet five statutory requirements established under the 1996 MTW Statute. HUD will monitor and determine MTW agencies' compliance with these five requirements as follows:

MTW statutory requirement:	HUD verification approach:
1. MTW agencies must ensure that at least 75 percent of the families assisted are very low income families, as defined in section 3(b)(2) of the 1937 Act..	HUD will verify this requirement by pulling Public Housing and HCV data from PIC, or its successor system, and the MTW agency will provide income data for its families served through local, non-traditional housing programs, if any, in the MTW Supplement to the Annual Plan.
2. MTW agencies must establish a reasonable rent policy.	HUD will verify this requirement through its review of the MTW Supplement to the Annual Plan.
3. MTW agencies must continue to assist substantially the same total number of eligible low-income families as would have been served had the amounts not been combined..	HUD will verify this requirement in accordance with the calculation in Notice PIH–2013–02, Baseline Methodology for MTW agencies, or successor notice.
4. MTW agencies must maintain a comparable mix of families (by family size) as would have been provided had the amounts not been used under the demonstration..	HUD will verify this requirement by pulling Public Housing and HCV data from PIC, or successor system.
5. MTW agencies must ensure that housing assisted under the demonstration meets housing quality standards established or approved by the Secretary..	HUD will verify this requirement through its review of PHAS Physical scores, or successor assessment system.

ii. Income Integrity and Enterprise Income Verification System (EIV) Reviews

MTW agencies are required to comply with the final rule regarding EIV issued December 29, 2009, and utilize EIV for all income verifications. EIV has been modified for MTW agencies so that family information submitted in PIC will not expire for 40 months, in order to accommodate agencies choosing to extend recertification periods for up to three years.

MTW agencies are subject to HUD review to ensure compliance with EIV requirements as well as monitor the accuracy and integrity of the MTW agencies' income and rent determination policies, procedures, and outcomes.

iii. MTW Site Visit

HUD will periodically conduct a site visit to provide guidance, discuss the MTW agency's MTW activities, and offer needed technical assistance regarding its program. The purpose of the site visit will be to confirm reported agency MTW activities, to review the status and effectiveness of the agency's MTW strategies, and to identify and resolve outstanding MTW related issues.

The MTW agency shall give HUD access, at reasonable times and places, to all requested sources of information including access to files, access to units and an opportunity to interview agency staff and assisted participants.

Where travel funding or staff resources are not available to facilitate in-person site visits, HUD may exercise the option to conduct remote site visits via telephone, videoconference, or webinar.

To the extent possible, HUD will coordinate the MTW site visit with other site visits to be conducted by HUD.

iv. Housing Choice Voucher Utilization

HUD will monitor HCV utilization at MTW agencies and it will ensure that HCV funds are fully utilized, subject to Section 6(a)(iii)(c) of this notice. Where leasing levels are inconsistent, HUD may take appropriate actions to work with the MTW agency to increase leasing and utilization.

v. Public Housing Occupancy

HUD will monitor public housing occupancy rates for MTW agencies. In instances where the MTW agency's public housing occupancy rate falls

below 96 percent, HUD may require, at its discretion, that the MTW agency enter into an Occupancy Action Plan to address the occupancy issues. The Occupancy Action Plan will include the cause of the occupancy issue, the intended solution, and reasonable timeframes to address the cause of the occupancy issue.

vi. Additional Monitoring and Oversight

HUD may, based on the MTW agency's risks and at HUD's discretion, conduct management, financial, or other reviews of the MTW agency. The MTW agency shall respond to any findings with appropriate corrective action(s).

In addition, HUD will make use of all HUD data systems and available information to conduct ongoing remote monitoring and oversight actions for MTW agencies, consistent with the results of the PIH risk assessment.

Specific areas for comment on Program Administration and Oversight

With respect to planning and reporting requirements for MTW agencies, HUD is specifically seeking comment on the following questions:

- Is the MTW Supplement to the Annual Plan, as described, an appropriate mechanism for HUD to track MTW agencies' activities and use of waivers? Are there specific elements that should be included in the MTW Supplement to the Annual Plan?
- Should MTW agencies with a combined unit total of 550 or less public housing units and Section 8 vouchers be exempt from the requirement to submit the Annual Plan? If so, how should HUD collect information on the activities and waivers implemented over the course of the demonstration?
- Do you have suggestions for how HUD can strengthen the public engagement process to ensure that participants have an opportunity to offer meaningful input in the selection and implementation of MTW activities?

With respect to public housing and voucher program performance assessment for MTW agencies, HUD is specifically seeking comment on the following questions:

- How could HUD measure public housing and voucher program performance for MTW agencies and incorporate those measures into PHAS and SEMAP?
- Are there MTW-specific indicators that should be included in a revised PHAS and SEMAP assessment?
- Should an MTW agency retain its high-performer status in PHAS or SEMAP until MTW specific indicators are developed?

With respect to monitoring and oversight for MTW agencies, HUD is specifically seeking comment on the following questions:

- Are HUD's monitoring and oversight efforts sufficient for MTW agencies?
- What are the specific areas of risk that should be considered for MTW agencies?
- Are there additional areas that should be monitored for MTW agencies?

7. Rental Assistance Demonstration (RAD) Program

MTW agencies converting public housing program units to Section 8 assistance under the Rental Assistance Demonstration (RAD) program are able to retain MTW regulatory and statutory flexibilities in the management of those units, subject to RAD requirements, if the conversion is to Section 8 Project-Based Voucher (PBV) assistance. MTW agencies converting projects under RAD to PBV may continue to undertake flexibilities except to the extent limited by RAD, as described in the RAD Notice, PIH–2012–32, REV–2 or its successor notice.[12]

8. Applying MTW Flexibilities to Special Purpose Vouchers

Special Purpose Vouchers (SPVs) are specifically provided for by Congress in line item appropriations which distinguish them from regular vouchers. Generally, SPVs are not part of the MTW demonstration. Following is guidance on how MTW flexibilities may be applied to specific types of SPVs, which can be found on the MTW Web site[13].

a. Veteran Affairs Supportive Housing (HUD–VASH)

HUD–VASH vouchers have separate operating requirements and must be administered in accordance with the requirements listed at *www.hud.gov/offices/pih/programs/hcv/vash.* The operating requirements waive and alter many of the standard HCV statutes and regulations at 24 CFR 982. Unless stated in the HUD–VASH operating requirements, however, the regulatory requirements at 24 CFR 982 and all other HUD directives for the HCV program are applicable to HUD–VASH vouchers. PHAs may submit a request to HUD to operate HUD–VASH vouchers in accordance with MTW administrative flexibilities.

b. Family Unification Program (FUP)

The FUP NOFA language allows vouchers to be administered in accordance with MTW operations unless MTW provisions are inconsistent with the appropriations act or requirements of the FUP NOFA. In the event of a conflict between the Final Operations Notice and the appropriations act or FUP NOFA language, the act and NOFA govern.

c. Non-elderly Persons with Disabilities (NED) Vouchers

The NED NOFA language allows vouchers to be administered in accordance with operations unless MTW provisions are inconsistent with the appropriations act or requirements of the NED NOFA. In the event of a conflict between the Final Operations Notice and the appropriations act or FUP NOFA language, the act and NOFA govern.

d. Enhanced Vouchers and Tenant Protection Vouchers

Enhanced and tenant protection vouchers funds will be fungible one year after a family receives the voucher. The family must still be provided assistance until the end of the initial protection period which lasts until the family moves out of the residence where the voucher was originally received or is terminated from the program. Once the initial protection period ends, the enhanced or tenant protection voucher becomes a regular voucher. MTW agencies must follow the procedures described in PIH Notice 2013–27, or its successor notice, when the recipient of an enhanced voucher voluntarily agrees to relinquish such assistance in exchange for the provision of PBV assistance.

9. Regionalization

The 2016 MTW Expansion Statute states that:

- The Secretary may, at the request of an MTW agency and one or more adjacent PHAs in the same area, designate that MTW agency as a regional agency.
- An MTW agency may be selected as a regional agency if the Secretary determines that unified administration of assistance under sections 8 and 9 by that agency across multiple jurisdictions will lead to a) efficiencies and to b) greater housing choice for low-income persons in the region.
- A regional MTW agency may administer the assistance under sections 8 and 9 of the 1937 Act for the participating agencies within its region pursuant to the terms of its MTW ACC

[12] Notices and laws related to RAD can be found at *http://portal.hud.gov/hudportal/HUD?src=/RAD/library/notices.*

[13] *https://portal.hud.gov/hudportal/documents/huddoc?id=DOC_10495.pdf.*

amendment, or other agreement to be determined by HUD, with HUD.

• The Secretary may agree to extend the term of the ACC amendment, or other agreement to be determined by HUD, and to make any necessary changes to accommodate regionalization.

HUD will operationalize this regionalization provision through the same terms and conditions as the MTW Operations Notice. HUD will issue a separate PIH Notice addressing the criteria for designation as a regional MTW agency, the mechanisms for administration by the regional MTW agency on behalf of participating agencies, and the procedures for extending or modifying MTW activities to accommodate regionalization.

Specific Areas for Comment on Regionalization

In anticipation of the guidance that HUD plans to issue on regionalization, HUD seeks comment on the following issues:

• How should ''adjacent'' be defined for the purposes of identifying which PHAs should be allowed to be part of an MTW agency's regional agency designation? Should regional MTW agencies extend across state borders?

• What flexibilities should the regional MTW agency be able to administer on behalf of its regional partners? Should the partner PHAs have full flexibility in the use of funds?

• How should regional partners be included in the MTW evaluation process? What data should they need to submit in conjunction with the MTW agency?

• What form of governance structure, if any, should be formed between the regional MTW agency and its partner PHAs?

• What form should the agreement (*i.e.,* contract, memorandum of understanding, partnership agreement, etc.) take between the regional MTW agency and its PHA partners?

• Should the criteria for regionalization be the same for current MTW agencies and PHAs that join under the expansion?

• Should HUD issue a revised Public Housing and Voucher Consortia Rule to further the regionalization concept?

10. Applicability of Other Federal, State, and Local Requirements

Notwithstanding the MTW waivers described in this Operations Notice, the following provisions of the 1937 Act continue to apply to MTW agencies and the assistance received pursuant to the 1937 Act:

i. The terms ''low-income families'' and ''very low-income families'' shall continue to be defined by reference to Section 3(b)(2) of the 1937 Act (42 U.S.C. 1437a(b)(2));

ii. Section 12 of the 1937 Act (42 U.S.C. 1437j), as amended, shall apply to housing assisted under the demonstration, other than housing assisted solely due to occupancy by families receiving tenant-based assistance; and

iii. Section 18 of the 1937 Act (42 U.S.C. 1437p, as amended by Section 1002(d) of Public Law 104–19, Section 201(b)(1) of Public Law 104–134, and Section 201(b) of Public Law 104–202), governing demolition and disposition, shall continue to apply to public housing notwithstanding any use of the housing under MTW.

iv. Section 8(r)(1) of the 1937 Act on HCV portability shall continue to apply unless provided as a cohort-specific waiver and associated activity(s) in an evaluative cohort as necessary to implement comprehensive rent reform and occupancy policies. Such a cohort-specific waiver and associated activity(s) would contain, at a minimum, exceptions for requests to port due to employment, education, health and safety and reasonable accommodation.

Notwithstanding any requirement contained in this Notice or any MTW waiver granted herein, other federal, state and local requirements applicable to public housing or HCV assistance will continue to apply. The ACC Amendment, or agreement to be determined by HUD, will place in HUD the authority to determine if any future law or future regulation conflicts with any MTW-related agreement or Notice. If a future law conflicts, the law shall be implemented, and no breach of contract claim, or any claim for monetary damages, may result from the conflict or implementation of the conflicting law or regulation.

If any requirement applicable to public housing, outside of the 1937 Act, contains a provision that conflicts or is inconsistent with any MTW waiver granted by HUD, the PHA remains subject to the terms of that non-1937 Act requirement. Such requirements include, but are not limited to:

• *Requirements for Federal Funds:* Notwithstanding the flexibilities described in this Notice, the public housing and voucher funding provided to MTW agencies remain federal funds and are subject to any and all other federal requirements outside of the 1937 Act (*e.g.,* including but not limited to competitive HUD NOFAs under which the MTW agency has received an award, state and local laws, federal statutes other than the 1937 Act (including appropriations acts), and OMB Circulars and requirements), as modified from time to time. The MTW agency's expenditures must comply with 2 CFR part 200 and other applicable federal requirements, which provide basic guidelines for the use of federal funds, including the requirements of this Notice.

• *National Environmental Policy Act (NEPA):* MTW agencies must comply with NEPA, 24 CFR part 50 or Part 58, as applicable, and other related federal laws and authorities identified in 24 CFR part 50 or Part 58, as applicable.

• *Fair Housing and Equal Opportunity:* As with the administration of all HUD programs and all HUD-assisted activities, fair housing and civil rights issues apply to the administration of MTW demonstration programs. This includes actions and policies that may have a discriminatory effect on the basis of race, color, sex, national origin, religion, disability, or familial status (see 24 CFR part 1 and part 100 subpart G) or that may impede, obstruct, prevent, or undermine efforts to affirmatively further fair housing. PHA Plans must include a civil rights certification required by Section 5A of the 1937 Act and implemented by regulation at 24 CFR 903.7(o) and 903.15, as well as a statement of the PHA's strategies and actions to achieve fair housing goals outlined in an approved Assessment of Fair Housing consistent with 24 CFR 5.154. If the PHA does not have a HUD accepted AFH, it must still provide a civil rights certification and statement of the PHA's fair housing strategies, which would be informed by the corresponding jurisdiction's AFH or Analysis of Impediments to Fair Housing Choice and the PHA's assessment of its own operations.

All PHAs, including MTW agencies, are obligated to comply with non-discrimination and equal opportunity laws and implementing regulation, including those in 24 CFR 5.105. Specific laws and regulations must be viewed in their entirety for full compliance, as this Operations Notice does not incorporate a complete discussion of all legal authorities. For example, PHAs, including MTW agencies, are required to comply with the Fair Housing Act, Title VI of the Civil Rights Act of 1964, Section 504 of the Rehabilitation Act of 1973, Title II of the Americans with Disabilities Act of 1990, Architectural Barriers Act of 1968, Executive Order 11063: Equal Opportunity in Housing, Executive Order 13166: Improving Access to

Services for Persons with Limited English Proficiency, HUD's Equal Access Rule (24 CFR 5.105(a)(2), Age Discrimination Act of 1975, and Title IX of the Education Amendments Act of 1972, as well as HUD and government-wide regulations implementing these authorities.. PHAs should review PIH Notice 2011–31 for more details.

• *Court Orders and Voluntary Compliance Agreements:* MTW agencies must comply with the terms of any applicable court orders or Voluntary Compliance Agreements that are in existence or may come into existence during the term of the ACC Amendment, or other agreement as determined by HUD, The PHA must cooperate fully with any investigation by the HUD Office of Inspector General or any other investigative and law enforcement agencies of the U.S. Government.

11. MTW Agencies Admitted Prior to 2016 MTW Expansion Statute

The 39 MTW agencies that entered the MTW demonstration prior to the 2016 MTW Expansion Statute adhere to an administrative structure outlined in the Standard MTW Agreement, a contract between each current PHA and HUD. The 2016 MTW Expansion Statute extended the term of the Standard MTW Agreement for these existing MTW agencies through each PHA's 2028 fiscal year.

Some PHAs that entered the MTW demonstration prior to the 2016 MTW Expansion Statute may wish to opt out of their Standard MTW Agreement and join the MTW Expansion. HUD will support an existing MTW PHA's request to join the MTW Expansion provided that:

• The PHA makes the change at the end of its fiscal year, so that it does not have part of a fiscal year under the Standard Agreement and part under the new framework;

• The PHA follows the same public comment and Board resolution process as would be required for amending the Standard MTW Agreement; and

• The PHA agrees to all the terms and conditions that apply to MTW agencies admitted pursuant to the 2016 MTW Expansion Statute, including all of the provisions of this Operations Notice and the accompanying ACC amendment, or other agreement as determined by HUD.

The only difference between an MTW agency admitted pursuant to the 2016 MTW Expansion Statute and an existing MTW PHA that elects to join the new framework will be that the existing MTW PHA joining the framework described in this Operations Notice will not be required to implement the specific policy change associated with each cohort of post-2016 MTW agencies and will not be required to participate in the evaluation of that specific policy change.

Specific areas for comment on MTW Agencies Admitted Prior to 2016 MTW Expansion Statute

With respect to MTW agencies admitted prior to the 2016 MTW Expansion Statute, HUD is specifically seeking comment on the following questions:

• Is it appropriate to permit existing MTW agencies to come under the framework of this Operations Notice and associated ACC amendment, or other agreement as determined by HUD?

• Should these existing PHAs be subject to any different or supplemental requirements?

12. Sanctions, Terminations and Default

If the MTW agency violates any of the requirements outlined in this Notice, HUD is authorized to take any corrective or remedial action. Sanctions, terminations, and default are covered in the PHA's MTW ACC amendment, or other agreement as determined by HUD.

III. Environmental Impact

1. Purpose and Applicability

A Finding of No Significant Impact (FONSI) with respect to the environment has been made in accordance with HUD regulations in 24 CFR part 50 that implement section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332(2)(C)). The FONSI will be available for public inspection on *www.regulations.gov.*

Dated: January 13, 2017.

Jemine A. Bryon,

General Deputy Assistant, Secretary for Public and Indian Housing.

APPENDIX A—GENERAL WAIVERS

Waiver name	Waiver description	Regulations waived	Available activities	Parameters
Activities Related to Public Housing and Housing Choice Vouchers				
Limited Lease Terms.	The Agency may develop and adopt a program to limit the term of assistance in Section 8 and 9 programs in order to create a new limited lease term housing program. Successful participants in these programs will be eligible for transfer to the Agency's public housing or HCV programs. The Agency will ensure that these programs do not have a disparate impact on protected classes, and will be operated in a manner that is consistent with the requirements of nondiscrimination and equal opportunity authorities, including but not limited to Section 504 of the Rehabilitation Act. More specifically, under no circumstances will residents of such programs be required to participate in supportive services that are targeted at persons with disabilities in general, or persons with any specific disability. In addition, admission to any of the programs or priority for supportive services developed under this section will not be conditioned on a diagnosis or specific disability of a member of an applicant or participant family. This section is not intended to govern the designation of housing that is subject to Section 7 of the 1937 Act.	Certain provisions of Sections 3, 4, 5, 6, 8, and 9 of the 1937 Act and 24 CFR 966 Subpart A, 960 Subpart B, and 982.303.	*Limited Lease Term Housing Program (PH):* The Agency may create a limited lease term housing program with reasonable conditions in its public housing program. *Limited Lease Term Housing Program (HCV):* The Agency may create a limited lease term housing program with reasonable conditions in its HCV program.	Successful participants must be eligible to transfer into regular public housing/HCV programs; must not have disparate impact on a protected class or other protected characteristic; policies, procedures, and programs must be consistent with applicable nondiscrimination and equal opportunity authorities, including but not limited to Section 504 of the Rehabilitation Act; participants are not required to participate in services targeted to persons with disabilities; admission is not conditioned on a diagnosis or specific disability of an applicant or participant family. The term of assistance may not be shorter than 6 months. Agencies seeking to create a limited lease term program that goes beyond the activities listed in this waiver may propose an activity under the Local Non-Traditional Activities Rental Subsidy Program Waiver located in the Conditional Waivers.
Homeownership Program.	The Agency is authorized to use the Section 8 Homeownership Program as the basis for providing homeownership opportunities to families who are low-income, including public housing residents, HCV or PBV tenants, or other low-income families. Participants in this Homeownership Program will be subject to the Section 8 occupancy and admission requirements. Subject to subsidy layering review, the Agency is authorized to apply the Section 8 Homeownership requirements to families who are low-income, including public housing and other low-income families. The Section 8 Homeownership requirements can be modified to provide soft second mortgages or down payment assistance to participating low-income families or to provide monthly HAP payments to HCV recipients.	Certain provisions of Sections 5, 9, 24, 32, 35, 8(o)(15) and 8(y) of the 1937 Act, 24 CFR 905, 906, 24 CFR 982.625 through 982.643.	*Homeownership (Both):* The Agency may create a homeownership program that includes soft second mortgages or down payment assistance to low income families including PH residents, PBV and HCV families in lieu of monthly HAP.	Inventory removal of current public housing units must be approved in advance by HUD. The Agency is required to submit a Section 32 homeownership application to HUD via the Inventory Removal Submodule of IMS/PIC. If the Agency is seeking to waive portions of 24 CFR 906, then the Agency must include those regulations as part of the Section 32 Homeownership application. Note that the disposition requirements of Section 18 and 24 CFR Part 970 do not apply to the sale of public housing units in accordance with the Section 32 homeownership plan. Assistance under this waiver is still subject to subsidy layering review. Recruitment, eligibility, and selection policies and procedures must be consistent with the Department's nondiscrimination and equal opportunity requirements.

APPENDIX A—GENERAL WAIVERS—Continued

Waiver name	Waiver description	Regulations waived	Available activities	Parameters
Authorizations Related to Family Self Sufficiency.	The Agency is authorized to operate any of its existing self-sufficiency and training programs, including its Family Self-Sufficiency (FSS) Program and any successor programs exempt from certain HUD program requirements. If the Agency receives dedicated funding for an FSS coordinator, such funds must be used to employ a self-sufficiency coordinator. In developing and operating such programs, the Agency is authorized to establish strategic relationships and partnerships with local private and public agencies and service providers to leverage expertise and funding. In implementing this waiver, the Agency must execute a contract of participation, or other locally developed agreement, that is at least 5 years but no more than 10 years. However, notwithstanding the above, any funds granted pursuant to a competition must be used in accordance with the NOFA and the approved application and work plan.	Certain provisions of Section 23 of the 1937 Act and 24 CFR 984.	*Waive Operating a Required FSS Program (Both):* The Agency is authorized to waive its requirement to operate the traditional FSS program. *Alternative to Program Coordinating Committee (Both):* The Agency is authorized to create an alternative structure for securing local resources to support an FSS program.	
	.....	.....	*Alternative Family Selection Procedures (Both):* The Agency is authorized to develop its own recruitment and selection procedures for its FSS program(s).	Recruitment, eligibility, and selection policies and procedures must be consistent with the Department's nondiscrimination and equal opportunity requirements. Agency may not require families to participate in the program as a condition of receiving housing assistance. Agency may not include current work status, work history and/or source of income as part of the selection criteria. ''Family'' is not limited to families with a member who is able to work full time, but is defined broadly so as not to exclude families with a member who is disabled but able to work, disabled but unable to work, or working as a caregiver for a family member with a disability.
	.....	.....	*Modify or Eliminate the Contract of Participation (Both):* The Agency is authorized to modify the terms of, or eliminate the contract of participation, in lieu of a local form.	The Agency may modify the terms of the contract of participation to align with adjustments made to its FSS program(s) using MTW flexibility. Further, the Agency may discontinue use of the contract of participation and instead employ a locally-developed agreement that codifies the terms of participation.

APPENDIX A—GENERAL WAIVERS—Continued

Waiver name	Waiver description	Regulations waived	Available activities	Parameters
	.....	.....	*Policies for Addressing Increases in Family Income (Both):* The Agency is authorized to set its own policies for addressing increases in family income during participation in the FSS program.	Consistent with the goals and structure of its MTW FSS program, the Agency can set policies for whether income increases are recognized for purposes of increasing rent or changing the amount of funds moved to escrow/savings through the program. The Agency may not use income increases during participation in the FSS program to change a family's eligibility status for purposes of participation in the FSS program or for the receipt public housing or HCV assistance.
	.....	.....	*Calculating FSS Credits (Both):* The Agency is authorized to create alternative methods for computing the family's FSS credit.	The Agency may set policies to defer income increases to savings OR to allow participants to earn savings deposits based on meeting certain program milestones. Such policies must be made clear to participants in writing prior to starting their participation in the program.
	.....	.....	*Disbursement of Savings (Both):* The Agency may set its own policies for when savings funds can be disbursed to participants.	Consistent with the goals and structure of its MTW FSS program, the Agency can set policies for when savings are disbursed to participants. This could mean all funds are disbursed at once, or at certain key points of participation. Such policies must be made clear to participants in writing prior to starting their participation in the program.
Activities Related to Public Housing				
PH—Initial, Annual and Interim Income Review Process.	The Agency is authorized to restructure the initial, annual and interim review process in the public housing program in order to affect the frequency of the reviews and the methods and process used to establish the integrity of the income information provided. In addition, the Agency is expressly authorized to adopt a local system of income verification in lieu of the current HUD system. For example, the Agency may implement alternate time frames for validity of verification or adopt policies for verification of income and assets through sources other than those currently allowed under the 1937 Act. The terms ''low-income families'' and ''very low-income families'' shall continue to be defined by reference to Section 3(b)(2) of the 1937 Act (42 U.S.C. 1437a(b)(2)). HUD has defined ''Annual Income'' at 24 CFR 5.609 and MTW Agencies must determine the eligibility of the family in accordance with provisions of 24 CFR 5.609.	Certain provisions of sections 3(a)(1) and 3(a)(2) of the 1937 Act and 24 CFR 966.4 and 960.257.	*Alternate Reexamination Schedule for Workable Households (PH):* The Agency may establish an alternate reexamination schedule for workable households. *Alternate Reexamination Schedule for Elderly/Disabled Households (PH):* The Agency may establish an alternate reexamination schedule for elderly and/or disabled households. *Alternate Verification Policy (PH):* The Agency may verify information provided by the participant in alternate ways.	Reexaminations must occur at least every three years. Must allow at least one interim adjustment at the request of the household per year. Reexaminations must occur at least every four years. Must continue to allow interim adjustments at the request of the household. The Agency must determine the eligibility of a families in accordance with 24 CFR 5.609. Prior to the implementation of the activity a hardship policy and impact analysis must be developed and adopted in accordance with MTW guidance.

APPENDIX A—GENERAL WAIVERS—Continued

Waiver name	Waiver description	Regulations waived	Available activities	Parameters
Activities Related to Housing Choice Vouchers				
HCV—Operational Policies and Procedures.	The Agency is authorized to define, adopt and implement a reexamination program that differs from the reexamination program currently mandated in the 1937 Act and its implementing regulations. The terms ''low-income families'' and ''very low-income families'' shall continue to be defined by reference to Section 3(b)(2) of the 1937 Act (42 U.S.C. 1437a(b)(2)).	Certain provisions of Section 8(o)(5), 8(o)(7) and 8(o)(13)(F) of the 1937 Act and 24 CFR 982.516 and 982.162(b).	*Alternate Reexamination Schedule for Workable Households (HCV):* The Agency may establish an alternate reexamination schedule for workable households.	Reexaminations must occur at least every three years. Must allow at least one interim adjustment at the request of the household per year. The Department will develop a rider to the HAP contract that reflects MTW authorizations that adjust the current elements of the HAP contract.
	.....	.....	*Alternate Reexamination Schedule for Elderly/Disabled Households (HCV):* The Agency may establish an alternate reexamination schedule for elderly and/or disabled households.	Reexaminations must occur at least every four years. Must continue to allow interim adjustments at the request of the household. The Department will develop a rider to the HAP contract that reflects MTW authorizations that adjust the current elements of the HAP contract.
	.....	.....	*Alternate Verification Policy (HCV):* The Agency may verify information provided by the participant in alternate ways.	The Agency must determine the eligibility of a families in accordance with 24 CFR 5.609. Prior to the implementation of the activity a hardship policy and impact analysis must be developed and adopted in accordance with MTW guidance. The Department will develop a rider to the HAP contract that reflects MTW authorizations that adjust the current elements of the HAP contract.
HCV—Leasing Incentives.	The Agency is authorized to determine a damage claim and/or vacancy loss policy and payment policy for occupied units that differs from the policy requirements currently mandated in the 1937 Act and its implementing regulations. Damage and vacancy authority are subject to state and local laws.	Certain provisions of Section 8(o)(9), of the 1937 Act and 24 CFR 982.311.	*Vacancy Loss (HCV):* The Agency may provide landlords with vacancy loss payments up to 3 months.	The Agency must update its Administrative Plan to reflect vacancy loss claim policy. In order to incentivize landlords to lease to HCV families an Agency may provide vacancy loss payments to landlords whether or not a family is terminated.
	.....	.....	*Damage Claims (HCV):* The Agency may provide landlords with compensation in the event that a tenant leaves the unit with significant damage.	The Agency must update its Administrative Plan to reflect damage claim policy. In implementing this activity, the tenant's security deposit should first be used to cover damages before the Agency provides compensation to a landlord.

APPENDIX A—GENERAL WAIVERS—Continued

Waiver name	Waiver description	Regulations waived	Available activities	Parameters
PBV—Unit Cap Percentage Waiver.	The Agency is authorized to use for project-based assistance up to 50% of its total authorized units as long as units are located in census tracts with no more than 20% poverty rate and/or house at-risk populations defined as an individual or family that does not have sufficient resources or support networks immediately available to prevent them from moving to an emergency shelter or lacks a fixed, regular, and adequate nighttime residence.	Section 8(o)(13)(B) of the 1937 Act and 24 CFR 983.6.	*Raise PBV Unit Cap (PBV):* The Agency may project-base up to 50% of its authorized units.	The Agency is subject to the PBV Section of PIH Notice 2015–05 or any successor notice and/or guidance. If more than 20% of the total authorized units are project based, the additional units must meet one of the following criteria: house people who meet the HUD definition of homeless; house vulnerable populations; house veterans; provide supportive housing for elderly or disabled; or be located in areas of high-opportunity. Agency must comply with Fair Housing and Civil Rights requirements. The Agency is subject to Notice 2013–27.
PBV—Development Percentage Waiver.	The Agency is authorized to determine the percentage of units within a development that can be project-based that differs from the percentage currently mandated in the 1937 Act and its implementing regulations. In using this authorization, the Agency must place units in locally defined areas of opportunity.	Section 8(o)(13)(B) of the 1937 Act and 24 CFR 983.56.	*Raise PBV Cap Within a Development to 50% PBV (PBV):* The Agency may raise the PBV cap within a development to 50%. Raise PBV Cap Within a Development to 75% PBV (PBV): The Agency may raise the PBV cap within a development to 75%. *Raise PBV Cap Within a Development to 100% (PBV):* The Agency may raise the PBV cap within a development to 100%.	The Agency is subject to the PBV Section of PIH Notice 2015–05 or any successor notice and/or guidance. If more than 20% of the units in a development are project-based, the additional units must meet one of the following criteria: house people who meet the HUD definition of homeless; house vulnerable populations; house veterans; provide supportive housing for elderly or disabled; is located in an area of high opportunity; or is a market-rate rental property owned by the Agency. The Agency must comply with Fair Housing and Civil Rights requirements. Agency is subject to Notice PIH 2013–27.
PBV—Elimination of Competitive Process.	Subject to subsidy layering review, the Agency is authorized to project-base Section 8 assistance at properties owned by a single asset entity of the Agency that are not public housing properties, subject to HUD's requirements regarding subsidy layering. Project-based assistance for such owned units does not need to be competitively bid, nor are the owned units subject to any required assessments for voluntary conversion. Agency still needs to complete site selection requirements. This waiver does not waive 24 CFR 983.57 despite reference to Part 983, Subpart B. This waiver also does not waive the requirement of 24 CFR 983.59(b) that HQS inspections be performed by an independent entity.	Certain provisions of Sections 8(o)(13)(B and D) of the 1937 Act and 24 CFR 982.1, 982.352 and 24 CFR Part 983 Subpart B.	*Eliminate PBV Competitive Process (PBV):* The Agency may eliminate the competitive process in the award of PBVs to properties owned by a single asset entity of the Agency that are not public housing.	The Agency is still subject to the PBV Section of Notice PIH 2015–05 or any successor notice and/or guidance. Agency is subject to Notice PIH 2013–27. This waiver does not waive Part 983, Subpart B in its entirety and Agency must still comply with 24 CFR 983.57 and 983.59(b) which requires that HQS inspections be completed by independent entities.

APPENDIX A—GENERAL WAIVERS—Continued

Waiver name	Waiver description	Regulations waived	Available activities	Parameters
PBV—Alternate Competitive Process.	The Agency is authorized to establish a reasonable competitive process or utilize an existing local competitive process for project-basing leased housing assistance at units that meet existing Housing Quality Standards and that are owned by non-profit, for-profit housing entities, or a single asset entity of the Agency.	Certain provisions of 24 CFR 983.51.	*Establish Alternate PBV Competitive Process (PBV):* The Agency may establish an alternate competitive process in the award PBVs.	Agency is subject to PBV Section of Notice PIH 2015–05 or any successor notice and/or guidance. Agency is subject to Notice PIH 2013–27.
PBV—Operational Policies and Procedures.	The Agency is authorized to determine the time period for amending the PBV HAP contract to add units thereto, the length of the lease period, when vouchers expire, and when vouchers will be issued or reissued.	Certain provisions of Sections 8(o)(7)(a), 8(o)(13)(F) and 8(o)(13)(G) of the 1937 Act and 24 CFR 983 Subpart F.	*Add Units to PBV HAP Contract (PBV):* The Agency may add units to a PBV HAP contract at any time.	The anniversary and expiration date for any additional units added to a PBV HAP contract must be the same as that for the original units under the PBV HAP contract.

APPENDIX B—CONDITIONAL WAIVERS

No.	Waiver name	Waiver description	Regulations waived	Available activities	Parameters
			Activities Related to Public Housing		
1	PH—Leases	The Agency is authorized to develop and adopt a new form of local lease and establish community rules and reasonable tenant fees based on proven private management models (subject to State and local laws), provided that no-cause evictions are not permitted and the Agency allows for grievance procedures.	Certain provisions of Section 6(l) of the 1937 Act and 24 CFR 966.4.	*Establish Community Rules through Local Lease (PH):* The Agency may establish community rules through a local lease. *Establish Reasonable Fees through Local Lease (PH):* The Agency may charge fees that are reasonable and cost effective through a local lease.	Agency may only implement changes to the lease under this activity that do not require either a regulatory or statutory waiver. Fair Housing and other civil rights requirements continue to apply. An appeals process and hardship policy must be put in place. The hardship policy must be developed and adopted in accordance with MTW guidance.
2	PH—Rent Policies.	The Agency is authorized to determine family payment, including the total tenant payment, the minimum rent, utility reimbursements and tenant rent. The Agency is authorized to adopt and implement any reasonable policies for setting rents in public housing, including but not limited to: Establishing definitions of income and adjusted income or earned income disallowance that differ from those in current statues and regulations. Agency must comply with Section 3(b)(2) of the Act to determine eligibility.	Certain provisions of Section 3(a)(2), 3(a)(3)(A) and Section 6(l) of the 1937 Act and 24 CFR 5.603, 5.611, 5.628, 5.630, 5.632, 5.634 and 960.255 and 966 Subpart A.	*Rent Policies (PH): Income bands*—The Agency may implement changes to the rent calculation in order to create a system based upon rent bands. Such rent policies are structured using two variables: (1) Income bands, or ranges, that assign dollar increments that have been determined locally by the Agency, and (2) bedroom size. In a table, the y-axis lists the income bands and the x-axis lists the various bedroom sizes. In creating this system, the Agency may also adopt a flat rent policy within each income band instead of calculating rent based on adjusted income. The income bands may result in total tenant payment being more than 30%.	The rent bands must be set in accordance with bedroom size. A hardship policy must be put in place. The hardship policy must be developed and adopted in accordance with MTW guidance.
				Rent Policies (PH): Flat Rents—The Agency may establish flat rents based on bedroom size.	
				Rent Policies (PH): Minimum Rent—The Agency may implement a minimum rent policy that is targeted towards work able families.	Minimum rent may not exceed $250. Tenant rents may be calculated between 25% to 50% of adjusted income. Hardship policy, impact analysis, and any other information required by HUD for the oversight of this policy must be provided to HUD upon request.
				Rent Policies (PH): Other Income-Based Rent Model—The Agency may calculate rent at an alternative adjusted income.	
				Rent Policies (PH): Gross Income Rents—The Agency may calculate rent as a percentage of gross income that does not include income deductions and/or exemptions.	The gross income calculation may not exceed 40% of rent burden for working families and 27% for elderly and/or disabled households.
				Rent Policies (PH): Alternative Utility Allowance—The Agency may create a utility schedule(s) for all units based upon bedroom size, the property location and/or the types of utilities paid by resident.	The Agency should review its schedule of utility allowances each year, and must revise its allowance for a utility category if there has been a change of 10 percent or more from the prior year. The Agency must maintain information supporting its annual review of utility allowances and any revisions made in its utility allowance schedule.

APPENDIX B—CONDITIONAL WAIVERS—Continued

No.	Waiver name	Waiver description	Regulations waived	Available activities	Parameters
3	PH—Work Requirements.	The Agency is authorized to implement a requirement that a specified segment of its public housing residents work as a condition of tenancy subject to subject to all applicable Fair Housing Requirements and the mandatory admission and prohibition requirements imposed by sections 576–578 of the Quality Housing and Work Responsibility Act of 1998 and Section 428 of Public Law 105–276. Those individuals exempt from the Community Service Requirement in accordance with Section 12(c)(2)(A), (B), (D) and (E) of the 1937 Act are also exempt from the Agency's work requirement.	Certain provisions of Section 3 of the 1937 Act and 24 CFR 960.206.	*Work Requirement (PH):* The Agency may implement a work requirement for public housing residents between the ages of 18 and 54. The requirement shall be no less than 15 hours of work per week and no more than 30 hours of work per week. Work requirements shall not be applied to exclude, or have the effect of excluding, the admission of or participation by persons with disabilities or families that include persons with disabilities. Work requirements shall not apply to person with disabilities or families that include persons with disabilities. However, persons with disabilities and families that include persons with disabilities must have equal access to the full range of program services and other incentives.	Residents must have the opportunity to utilize the provisions of the Agency's Grievance Procedure to resolve a dispute regarding a determination that a resident has failed to comply with the work requirement. The Agency must update its ACOP to include a description of the circumstances in which residents shall be exempt for the requirement and hardship policies. The ACOP should include a description of what is considered work as well as other activities that shall be considered acceptable substitutes for work. Services, or referrals to services, must be provided by the Agency to support preparing families to comply with this requirement. The hardship policy in the ACOP should apply to residents who are actively trying to comply with the Agency's work requirement, but are having difficulties obtaining work or an acceptable substitute. The ACOP should also describe the consequences of failure to comply with the work requirement. Agencies may not implement the PH-Work Requirements Waiver on individuals exempted from the Community Service Requirement under Section 12(c)(2)(A), (B), (D) and (E). While the work requirements do not apply to persons with disabilities or families that include a person with disabilities, such persons and families are not precluded from working or engaging in substitute activities (such as caring for a family member who is disabled). Regardless of the level of engagement with work or substitute activities, persons and families that include persons with disabilities must have equal access to services or referral to services to support their efforts to obtain work or an acceptable substitute, and any other services or other incentives associated with the program.
4	PH—Term Limits.	The Agency is authorized to adopt and implement term limits for its Public Housing program.	Certain provisions of Section 3(a)(3)(A) and Section 6(l) of the 1937 Act and 24 CFR 5.603 and 966 Subpart A.	*Term Limits (PH):* The Agency may limit the duration for which a family receives housing assistance.	The term of assistance may not be shorter than 5 years except in the case of short-term transitional housing programs. Services, or referrals to services, must be provided by the Agency to support preparing families for the termination of assistance. A hardship policy must also be created to address extenuating circumstances. Hardship information and any other information required by HUD for the oversight of this policy must be provided to HUD upon request. Agency must also conduct an impact analysis prior to the implementation of this activity. An Agency may not retroactively apply the 5-year term limit to families currently residing in public housing.
5	PH—Income Deductions and Exclusions.	The Agency is authorized to restructure the initial, annual and interim review process in the public housing program in order to affect the income deductions and exclusions. The terms ''low-income families'' and ''very low-income families'' shall continue to be defined by Section 3(b)(2) of the 1937 Act (42 U.S.C. 1437a(b)(2)). HUD has defined ''Annual Income'' at 24 CFR 5.609 and MTW Agencies must determine the eligibility of the family in accordance with provisions of 24 CFR 5.609.	Certain provisions of sections 3(a)(1) and 3(a)(2) of the 1937 Act and 24 CFR 5.611, 966.4 and 960.257.	*Elimination of Deduction(s) (PH):* The Agency may eliminate one, some or all deductions. *Standard Deductions (PH):* The Agency may replace existing deduction(s) with a standard deduction(s). *Alternate Income Inclusions/Exclusions (PH):* The Agency may establish alternate policies to include or exclude certain forms of participant income during the income review and rent calculation process. These alternate policies must be consistent with the inclusions and exclusions at 24 CFR 5.609.	The Agency must determine the initial eligibility of a families in accordance with 24 CFR 5.609. Prior to the implementation of the activity a hardship policy and impact analysis must be developed and adopted in accordance with MTW guidance. Agencies are required to follow 24 CFR 5.609(c) and other federal statutes that specifically exclude certain income sources from being counted as income.
			Activities Related to Housing Choice Vouchers		
1	HCV—Earned Income Disregard.	The Agency must comply with Section 3(b)(2) of the Act to determine eligibility. The Agency may calculate the tenant's share of rent in a manner other than that required by statute and regulation in order to eliminate or create an alternative Earned Income Disregard which may not be used to determine eligibility or recertification. Rent calculations must comply with Fair Housing and Civil Rights requirements.	Certain provisions of Sections 16(b) of the 1937 Act and 24 CFR 5.603, 5.609, 5.611, 5.628, 982.516, 982.201 and 982 Subpart E.	*EID (HCV):* The Agency may eliminate the Earned Income Disregard from the calculation of the tenant's share of the rent. *EID (HCV):* The Agency may create an alternative to the Earned Income Disregard in order to calculate the tenant's share of the rent.	

APPENDIX B—CONDITIONAL WAIVERS—Continued

No.	Waiver name	Waiver description	Regulations waived	Available activities	Parameters
2	HCV & PBV—Reexamination Policies and Lease Terms.	The Agency is authorized to define, adopt and implement a reexamination program that differs from the reexamination program currently mandated in the 1937 Act and its implementing regulations. The terms ''low-income families'' and ''very low-income families'' shall continue to be defined by reference to Section 3(b)(2) of the 1937 Act (42 U.S.C. 1437a(b)(2)).	Certain provisions of Section 8(o)(5), 8(o)(7) and 8(o)(13)(F) and (G) of the 1937 Act and 24 CFR 982.516 and 982.162(b).	*Elimination of Deduction(s) (HCV):* The Agency may eliminate one, some or all deductions. *Standard Deductions (HCV):* The Agency may replace existing deduction(s) with a standard deduction(s). *Alternate Income Inclusions/Exclusions (HCV):* The Agency may establish alternate ways to include or exclude participant income.	The Agency must determine the eligibility of a families in accordance with 24 CFR 5.609. Prior to the implementation of the activity a hardship policy and impact analysis must be developed and adopted in accordance with MTW guidance. The Department will develop a rider to the HAP contract that reflects MTW authorizations that adjust the current elements of the HAP contract.
		The Agency is authorized to determine the length of the HAP contract, the length of the lease period, when vouchers expire, and when vouchers will be issued or reissued.	Certain provisions of Sections 8(o)(7)(a), 8(o)(13)(F) and 8(o)(13)(G) of the 1937 Act and 24 CFR 983 Subpart F.	*Length of HAP Contract (HCV & PBV):* The Agency may change the term of a HAP contract. *Alteration of HAP Contract (HCV & PBV):* The Agency may alter the length of the lease period, when vouchers expire and when vouchers will be issued or reissued.	Agencies implementing revised lease terms, including length of lease period for HCV and PBV families, must demonstrate how the altered lease terms, including length, benefit the tenant. The anniversary and expiration date for any additional units added to a PBV HAP contract must be the same as that for the original units under the PBV HAP contract. The Department develop a rider to the HAP contract that reflects MTW authorizations that adjust the current elements of the HAP contract.
3	HCV & PBV—Tenant Term Limits.	The Agency is authorized to implement term limits for HCV and PBV units designated as part of the MTW Demonstration.	Certain provisions of Section 8(o)(7) and 8(o)(13)(F)–(G) of the 1937 Act and 24 CFR 982 Subpart L and 983 Subpart E.	*Term Limits (HCV & PBV):* The Agency may limit the duration for which a family receives housing assistance.	The term of assistance may not be shorter than 5 years except in the case of short-term transitional housing programs. Services, or referrals to services, must be provided by the Agency to support preparing families for the termination of assistance. A hardship policy must also be created to address extenuating circumstances. Hardship information and any other information required by HUD for the oversight of this policy must be provided to HUD upon request. Agency must also conduct an impact analysis prior to the implementation of this activity.
4	HCV & PBV—Rent Policies.	The Agency is authorized to adopt and implement any reasonable policy to establish payment standards, rents or subsidy levels for tenant-based assistance that differ from the currently mandated program requirements in the 1937 Act and its implementing regulations. The Agency is authorized to adopt and implement any reasonable policies to calculate the tenant portion of the rent that differ from the currently mandated program requirements in the 1937 Act and its implementing regulations.	Certain provisions of Sections 8(o)(2)(A), 8(o)(2)(B), 8(o)(3), 3(a)(1), 8(o)(2)(C), and 8(o)(13)(H)–(I) of the 1937 Act and 24 CFR 982.508, 982.503 and 982.518.	*Rent Policies (HCV & PBV): Payment Standards*—The Agency is authorized to adopt and implement any reasonable policy to establish payment standards that do not exceed 200% of the FMR. This may include the setting of payment standards outside of the basic range, and creating multiple payment standards based on variations in the local rental market.	A hardship policy must also be created to address extenuating circumstances. Hardship information and any other information required by HUD for the oversight of this policy must be provided to HUD upon request.
				Rent Policies (HCV & PBV): Income Bands—The Agency may implement changes to the rent calculation in order to create a system based upon rent bands. Such rent policies are structured using two variables: (1) Income bands, or ranges, that assign dollar increments that have been determined locally by the Agency, and (2) bedroom size. In a table, the y-axis lists the income bands and the x-axis lists the various bedroom sizes. In creating this system, the Agency may also adopt a flat rent policy within each income band instead of calculating rent based on adjusted income.	A hardship policy must also be created to address extenuating circumstances. Hardship information and any other information required by HUD for the oversight of this policy must be provided to HUD upon request.
			Certain provisions of Sections 8(o)(1), 8(o)(2), 8(o)(3), 8(o)(10) and 8(o)(13)(H)–(I) of the 1937 Act and 24 CFR 982.508.	*Rent Policies (HCV & PBV): Initial Rent Burden*—The Agency may waive the maximum family share at initial occupancy of 40% of the family's adjusted monthly income.	A hardship policy must also be created to address extenuating circumstances. Hardship information and any other information required by HUD for the oversight of this policy must be provided to HUD upon request. Agency must also conduct an impact analysis.
			Certain provisions of Sections 8(o)(1), 8(o)(2), 8(o)(3), 8(o)(10) and 8(o)(13)(H)–(I) of the 1937 Act, 24 CFR 982.518, 982.308, 982.451, 983 Subpart E, 982.508, and 982.503.	*Rent Policies (HCV & PBV): Stepped Rent*—The Agency may create a stepped rent model that alters the family's rent payment on a fixed schedule in both frequency and amount. Implementation of this activity may only occur if the Stepped Rent activity is combined with another Rent Policy waiver identified in HCV-Rent Policies Available Activities.	Rent increases may not occur more than once per year. This activity may only apply to non-elderly and/or non-elderly and disabled residents. Agency must implement a grace period policy for HCV families that reach zero HAP through this activity. The grace period would allow families to receive zero HAP for at least six months before being transitioned off the HCV program.
			Certain provisions of Sections 8(o)(1), 8(o)(2), 8(o)(3), 8(o)(10) and 8(o)(13)(H)–(I) of the 1937 Act and 24 CFR 982.518.	*Rent Policies (HCV & PBV): Minimum Rent*—The Agency is authorized to adopt and implement any reasonable policies to calculate the tenant portion of the rent that differ from the currently mandated program requirements in the 1937 Act and its implementing regulations.	Minimum rent may not exceed $250. Tenant rents may be calculated between 25% to 50% of adjusted income. Hardship policy, impact analysis, and any other information required by HUD for the oversight of this policy must be provided to HUD upon request.

APPENDIX B—CONDITIONAL WAIVERS—Continued

No.	Waiver name	Waiver description	Regulations waived	Available activities	Parameters
		The Agency is authorized to determine contract rents and increases and to determine the content of the HAP contract that differ from the currently mandated program requirements in the 1937 Act and its implementing regulations.	Certain provisions of Sections 8(o)(1)(B) and 8(o)(13)(H) of the 1937 Act and 24 CFR 982.308, 982.451 and 983 Subpart E.	*Rent Policies (HCV & PBV): Contract Rents*—The Agency is authorized to determine contract rents and increases and to determine the content of the HAP contracts that differ from the currently mandated program requirements in the 1937 Act and its implementing regulations.	A family's rents may be calculated between 25% to 50% of adjusted income. Any lease alteration(s) must comply with State and local law. A hardship policy must be put in place. The hardship policy must be developed and adopted in accordance with MTW guidance.
5	HCV & PBV–Rent Reasonableness.	The Agency is authorized to develop a local process to determine rent reasonableness that differs from the currently mandated program requirements in the 1937 Act and its implementing regulations. Agency must determine that rents charged by owners are reasonable before entering into a HAP contract.	Certain provisions of Section 8(o)(10) of the 1937 Act and 24 CFR 982.507.	*Rent Reasonableness (HCV & PBV):* The Agency is authorized to develop a local process to determine rent reasonableness that differs from the currently mandated program requirements in the 1937 Act and its implementing regulations.	Agencies must provide, for HUD's approval, an alternative measure to determine that rents charged by owners to voucher participants are reasonable.
6	HCV & PBV—Work Requirements.	The Agency is authorized to implement a requirement that a specified segment of its HCV and PBV residents work as a condition of tenancy subject to all applicable Fair Housing Requirements.	Certain provisions of Sections 8(o)(7)(a), 8(o)(13)(F), and 8(o)(13)(G) of the 1937 Act and 24 CFR 982.303, 982.309 and 983 Support F.	*Work Requirement (HCV & PBV):* The Agency may implement a work requirement for HCV and PBV residents between the ages of 18 and 54. The requirement shall be no less than 15 hours of work per week and no more than 30 hours of work per week. The Agency shall provide supportive services to assist families obtain employment or an acceptable substitute. Work requirements shall not be applied to exclude, or have the effect of excluding, the admission of or participation by persons with disabilities or families that include persons with disabilities. Work requirements shall not apply to persons with disabilities or families that include persons with disabilities. However, persons with disabilities and families that include persons with disabilities must have equal access to the full range of program services and other incentives.	The Agency must update its Administrative Plan to include a description of the circumstances in which families shall be exempt from the requirement. The Administrative Plan must also include a hardship policy. The Administrative Plan should include a description of what is considered work as well as other activities that shall be considered acceptable substitutes for work. Services, or referrals to services, must be provided by the Agency to support preparing families for the termination of assistance. The hardship policy in the Administrative Plan should apply to families who are actively trying to comply with the Agency's work requirement, but are having difficulties obtaining work or an acceptable substitute. The Administrative Plan should also describe the consequences of failure to comply with the work requirement.
7	PBV Unit Types	Subject to subsidy layering review, the Agency is authorized to determine property eligibility criteria, including types of units currently prohibited by Section 8 regulations so long as these units are rental housing and meet HQS.	Certain provisions of Section 8(p) of the 1937 Act and 24 CFR 983.53(a)–(b) and 982 Subparts H and M.	*PBV Unit Types:* As long as units are rental housing and meet HQS, the Agency may attach and pay PBV assistance for units in various types of housing including housing described at 24 CFR 983.53(a)(3), (5) and (6).	The Agency must provide a transition plan to both the affected residents and HUD prior to the end of the demonstration. If the Agency places a PBV unit in a public housing project, then the Agency will not receive operating funds for that PH unit. PBV units must comply with HQS and be consistent with fair housing deconcentration requirements. This waiver is subject to subsidy layering review.
			Activities Related to Local, Non-Traditional		
1	Local Non-Traditional Activities—Rental Subsidy Programs.	The Agency is authorized to use MTW funds to provide rental subsidy to a third-party entity.	N/A	*Rental Subsidy Programs:* The Agency may provide funds for supportive housing programs and services. *Rental Subsidy Programs:* The Agency may provide funds for homeless/transitional housing programs and services. *Rental Subsidy Programs:* The Agency may provide funds for the creation of a local rental subsidy program that addresses special needs populations.	Agency is subject to Notice PIH 2011–45 or any successor notice and/or guidance. Any MTW funds awarded to a third party provider must be competitively bid.
2	Local Non-Traditional Activities—Service Provision.	The Agency is authorized to use MTW funds to provide supportive services to eligible participants.	N/A	*Service Provision:* The Agency may provide services for residents of other Agency owned or managed low-income housing that is not public housing or Housing Choice Voucher assistance. *Service Provision:* The Agency may provide services for low-income non-residents. *Service Provision:* The Agency may provide supportive services subsidies or budgets for low-income families. *Service Provision:* The Agency may contract with a third party provider for the provision of services to eligible participants.	Agency is subject to Notice PIH 2011–45 or any successor notice and/or guidance. Any MTW funds awarded to a third party provider must be competitively bid.
3	Local Non-Traditional Activities—Housing Development Programs.	The Agency is authorized to contribute MTW funds to the development of affordable housing outside of Sections 8 and 9.	N/A	*LIHTC Development:* The Agency may contribute MTW funds towards a Low Income Housing Tax Credit project. *Affordable Housing Development:* The Agency may contribute MTW funds towards the development of housing for low-income families.	Agency is subject to Notice PIH 2011–45 or any successor notice and/or guidance. The use of federal funds must be consistent with the requirements of 2 CFR 200 and other basic federal principles.

Appendix C—Public Comments To Be Solicited Through MTW Operations Notice

Waivers

Does the list of general waivers, MTW activities, and parameters in Appendix A and Appendix B contain the needed flexibility to achieve the three MTW statutory objectives? If not, what waivers, activities, and/or parameters are missing?

Are there any MTW activities and/or waivers that should not be included as general waivers, available to all MTW agencies without prior HUD approval?

Are there any MTW activities and/or waivers that should not be included as conditional waivers but rather should be included as general waivers, or not included at all?

Does the list of conditional waivers, MTW activities, and parameters in Appendix B contain the needed flexibility to implement any alternative income-based rent model? If not, what waivers, activities, and/or parameters are missing?

Term of Participation

Assuming all cohorts are selected between 2017 and 2020, is the end of each MTW agency's Fiscal Year 2028 an appropriate timeframe for MTW participation, and understanding that HUD may extend cohort-specific waivers to accommodate evaluation of MTW activities that require additional time?

Is there a preferable length or structure for the term of MTW participation?

What elements of the MTW agency's transition plan should be mandatory?

What elements of the transition process should HUD require in order to protect residents from potential harm and minimize disruptions to agency operations?

Funding, Single Fund Budget, and Financial Reporting

Is a 90 percent HAP budget utilization requirement the appropriate amount?

What sanctions or restrictions should HUD consider using should an MTW agency continue to fail to meet the budget utilization requirement?

Are there other methods for calculating HCV funding that HUD should consider?

Are there other factors HUD should consider in the calculation of funding?

Are there any comments or clarifications needed in relation to funding, the MTW Block Grant, or financial reporting?

Evaluation

Is there any information not captured in HUD administrative data systems that would provide informative data points or performance metrics for evaluating the MTW demonstration?

What are measures of activities that ''reduce cost and achieve greater cost effectiveness in Federal expenditures'' that can apply to and are either being reported in existing HUD systems or can be reported by every MTW agency?

What are measures of activities that ''give incentives to families with children where the head of household is working, seeking work, or is preparing for work by participating in job training, educational programs, or programs that assist people to obtain employment and become economically self-sufficient'' that can apply to and are either being reported in existing HUD systems or can be reported by every MTW agency?

Should HUD standardize a definition of ''self-sufficient''? If so what elements of self-sufficiency should be included in HUD's definition?

What are measures of MTW activities that ''increase housing choices for low-income families'' that can apply to and are either being reported in existing HUD systems or can be reported by every MTW agency?

What is the best way to capture and report exit data on families exiting the Public Housing, HCV, and local non-traditional housing programs? What are the appropriate exit reasons to capture?

Is there any information not captured in HUD administrative data systems that would be informative data points or performance metrics in terms of evaluating the MTW demonstration?

In the list of performance metrics provided above, should any be clarified or removed?

Are there any alternative or additional metrics that would enhance performance evaluation on the MTW demonstration?

Program Administration and Oversight

Is the MTW Supplement to the Annual Plan, as described, an appropriate mechanism for HUD to track MTW agencies' activities and use of waivers? Are there specific elements that should be included in the MTW Supplement to the Annual Plan?

Should MTW agencies with a combined unit total of 550 or less public housing units and Section 8 vouchers be exempt from the requirement to submit the Annual Plan? If so, how should HUD collect information on the activities and waivers implemented over the course of the demonstration?

Do you have suggestions for how HUD can strengthen the public engagement process to ensure that residents have an opportunity to offer meaningful input in the selection and implementation of MTW activities?

How could HUD measure public housing and voucher program performance for MTW agencies and incorporate those measures into PHAS and SEMAP?

Are there MTW-specific indicators that should be included in a revised PHAS and SEMAP assessment?

Should an MTW agency retain its high-performer status in PHAS or SEMAP until MTW specific indicators are developed?

Are HUD's monitoring and oversight efforts sufficient for MTW agencies?

What are the specific areas of risk that should be considered for MTW agencies?

Are there additional areas that should be monitored for MTW agencies?

Regionalization

How should ''adjacent'' be defined for the purposes of identifying which PHAs should be allowed to be part of an MTW agency's regional agency designation? Should regional MTW agencies extend across state borders?

What flexibilities should the regional MWT agency be able to administer on behalf of its regional partners? Should the partner PHAs have full flexibility in the use of funds?

What form of governance structure, if any, should be formed between the regional MTW agency and its partner PHAs?

What form should the agreement (i.e., contract, memorandum of understanding, partnership agreement, etc.) take between the regional MTW agency and its PHA partners?

Should the criteria for regionalization be the same for current MTW agencies and PHAs that join under the expansion?

Should HUD issue a revised Public Housing and Voucher Consortia Rule to further the regionalization concept?

MTW Agencies Admitted Prior to 2016 MTW Expansion Statute

Is it appropriate to permit existing MTW agencies to come under the framework of this Operations Notice and associated MTW agreement?

Should these existing PHAs be subject to any different or supplemental requirements?

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Part VI

Department of the Treasury

Office of the Comptroller of the Currency

12 CFR Parts 5, 7, 8, et al.
Economic Growth and Regulatory Paperwork Reduction Act of 1996 Amendments; Final Rule

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

12 CFR Parts 5, 7, 8, 9, 10, 11, 12, 16, 18, 31, 150, 151, 155, 162, 163, 193, 194, 197

[Docket ID OCC–2016–0002]

RIN 1557–AD95F

Economic Growth and Regulatory Paperwork Reduction Act of 1996 Amendments

AGENCY: Office of the Comptroller of the Currency, Treasury.

ACTION: Final rule.

SUMMARY: As part of its review under the Economic Growth and Regulatory Paperwork Reduction Act of 1996, the Office of the Comptroller of the Currency (OCC) is revising certain of its rules to remove outdated or otherwise unnecessary provisions. Specifically, the OCC is: revising certain licensing rules related to chartering applications, business combinations involving Federal mutual savings associations, and notices for changes in permanent capital; clarifying national bank director oath requirements; revising certain fiduciary activity requirements for national banks and Federal savings associations; removing certain financial disclosure regulations for national banks; removing certain unnecessary regulatory reporting, accounting, and management policy regulations for Federal savings associations; updating the electronic activities regulation for Federal savings associations; integrating and updating OCC regulations for national banks and Federal savings associations relating to municipal securities dealers, Securities Exchange Act disclosure rules, and securities offering disclosure rules; updating and revising recordkeeping and confirmation requirements for national banks' and Federal savings associations' securities transactions; integrating and updating regulations relating to insider and affiliate transactions; and making other technical and clarifying changes.

DATES: This final rule is effective on April 1, 2017.

FOR FURTHER INFORMATION CONTACT: For additional information, contact Heidi Thomas, Special Counsel; or Rima Kundnani, Attorney, Legislative and Regulatory Activities Division, 202–649–5490, for persons who are deaf or hard of hearing, TTY, 202–649–5597, Office of the Comptroller of the Currency, 400 7th Street SW., Washington, DC 20219.

SUPPLEMENTARY INFORMATION:

I. Background

Section 2222 of the Economic Growth and Regulatory Paperwork Reduction Act of 1996 (EGRPRA) [1] requires that, at least once every 10 years, the Federal Financial Institutions Examination Council (FFIEC) and each appropriate Federal banking agency (Agency or, collectively, Agencies) represented on the FFIEC (the OCC, Federal Deposit Insurance Corporation (FDIC), and the Board of Governors of the Federal Reserve System (Federal Reserve Board)) conduct a review of the regulations prescribed by the FFIEC or Agency. The purpose of this review is to identify outdated or otherwise unnecessary regulatory requirements imposed on insured depository institutions.

EGRPRA requires the Agencies to provide public notice and seek comment on one or more categories of regulations at regular intervals so that all Agency regulations are published for comment within a 10-year cycle. EGRPRA also directs the Agencies to categorize their regulations by type, publish the categories, and invite the public to identify areas of regulations that are ''outdated, unnecessary, or unduly burdensome.'' [2] Once the Agencies have published the categories of regulations for comment, EGRPRA requires the Agencies to publish a comment summary and discuss the significant issues raised by the commenters. The statute also directs the Agencies to ''eliminate unnecessary regulations to the extent that such action is appropriate.'' [3] Finally, EGRPRA requires the FFIEC to submit a report to Congress summarizing significant issues and their relative merits. The report also must analyze whether the Agencies can address these issues through regulatory change or whether legislative action is required.

The Agencies completed the first EGRPRA review in 2006. The Agencies expect to complete the current EGRPRA review process by the end of 2016.

As with the first EGRPRA review, the Agencies have elected to conduct this current review jointly. The Agencies have divided their regulations into 12 categories and published four **Federal Register** notices,[4] each requesting public comment on three of these categories. Additionally, the Agencies held a series of six outreach meetings to provide an opportunity for bankers, consumer and community groups, and other interested parties to present their views on the Agencies' regulations directly to Agency principals, senior Agency management, and Agency staff.[5]

The OCC believes it is unnecessary to wait until the end of the EGRPRA process before acting to reduce regulatory burden where possible.[6] To this end, the OCC published a Notice of Proposed Rulemaking (proposed rule or proposal) on March 14, 2016 [7] that included amendments in response to some of the comments the OCC received on its rules to date.[8] The proposed rule also included amendments to OCC rules derived from the OCC's most recent internal review of its rules to identify outdated or unnecessary provisions beyond those suggested by EGRPRA commenters. Furthermore, the proposed rule included amendments that would integrate a number of national bank and Federal savings association rules. These proposed amendments remove unnecessary or outdated provisions and streamline and simplify OCC rules, thereby reducing regulatory burden on

[1] Pub. L 104–208 (1996), codified at 12 U.S.C. 3311(b).

[2] *Id.* at 3311(a).

[3] *Id.* at 3311(d)(2).

[4] *See* 79 FR 32172 (June 4, 2014); 80 FR 7980 (Feb. 13, 2015); 80 FR 32046 (June 5, 2015), and 80 FR 79724 (Dec. 23, 2015). More information on the current EGRPRA process, including the **Federal Register** notices, outreach meetings, and public comments received, is available at *http://egrpra.ffiec.gov/index.html.*

[5] These public outreach meetings took place in Los Angeles, California on December 2, 2014; Dallas, Texas on February 4, 2015; Boston, Massachusetts on May 4, 2015; Kansas City, Missouri on August 4, 2015 (which focused on rural banking issues), Chicago, Illinois on October 19, 2015; and Washington, DC on December 2, 2015.

[6] We note that the OCC already has finalized or proposed a number of changes to our rules, in addition to this EGRPRA rulemaking. Last year, we incorporated a number of changes suggested by EGRPRA commenters into a final rule that integrates the OCC's national bank and Federal savings association licensing rules. (80 FR 28346 (May 18, 2015)). In addition, pursuant to the Fixing America's Surface Transportation (FAST) Act, the Agencies issued an interim final rule that provides for an 18-month examination cycle for qualifying 1- and 2-rated institutions with assets of between $500 million and $1 billion. This rule provides an 18-month examination cycle for 1-rated banks up to 1 billion in assets, and gives the Agencies the authority to provide an 18-month examination cycle for 2-rated banks with up to $1 billion in assets. (81 FR 10063 (Feb. 29, 2016)). Furthermore, the Agencies, acting through the FFIEC, have sought comment on proposals to eliminate or revise several items on the Consolidated Reports of Condition (Call Report). (*See* 80 FR 56539 (Sept. 18, 2015)). The Agencies also published a proposal for a streamlined call report for small institutions under $1 billion (*See* 81 FR 54190 (Aug. 15, 2016)). These Call Report initiatives are consistent with the feedback the OCC, FDIC, and Federal Reserve Board have received in this EGRPRA review.

[7] 81 FR 13607.

[8] The OCC is continuing to review EGRPRA comments on OCC rules to determine whether additional amendments are appropriate.

national banks and Federal savings associations.[9]

II. Summary of Public Comments

The OCC received four comment letters in response to this proposed rule. One trade association stated that it had no objection to the proposed rule.[10] A financial institution also stated that it had no objection to the various items in the proposal, but noted that the proposal does not reduce regulatory burden on the day-to-day servicing and offering of products to bank customers and consumers, noting as an example the paperwork burden associated with mortgage loans. It specifically requested that the OCC consider proposing additional reforms to simplify the process for consumers.

Another trade association, while noting that the proposed rule is an early effort by the OCC to remove regulatory burden through the EGRPRA review, applauded the OCC's effort through this rulemaking to remove certain outdated and otherwise unnecessarily burdensome provisions. This commenter also provided specific substantive comments on the proposed amendments relating to fiduciary activities (12 CFR parts 9 and 150), recordkeeping and confirmation requirements for securities transactions (12 CFR parts 12 and 151), and the sale of securities at a Federal savings association office (12 CFR 163.76). These comments are discussed in detail, below.[11]

As a general response to these commenters, the OCC notes that it will continue to review our rules under the EGRPRA process to determine whether further reductions in burden are warranted. We will propose additional amendments to our rules where appropriate.

II. Description of the Final Rule

The OCC is adopting the amendments as proposed with the removal of the technical amendments to 12 CFR part 4 and one clarifying change to 12 CFR 9.13 (custody of fiduciary assets). A section-by-section discussion of the proposed rule, the public comments received, and the resulting final rule are set forth below.

Organization and Functions, Availability and Release of Information (12 CFR Part 4)

Twelve CFR part 4 describes the organization and functions of the OCC and sets forth the standards, policies, and procedures that the OCC applies in administering the Freedom of Information Act (FOIA) and requests for non-public OCC information, among other things. The proposed rule included technical amendments to update and correct the OCC address in several sections and replace ''Licensing Department'' with ''Licensing Division'' and ''Disclosure Officer'' with ''Freedom of Information Act Officer.'' Additionally, the proposed rule would have updated the OCC's FOIA rules to remove references to the Office of Thrift Supervision (OTS) that are no longer necessary.

Since the publication of the proposed rule, Congress enacted the FOIA Improvement Act of 2016,[12] which makes a number of changes to FOIA that necessitate further amendments to the OCC's FOIA rules in 12 CFR part 4. To avoid confusion and to include all OCC FOIA rule changes in one rulemaking, we have removed the part 4 amendments in this EGRPRA final rule and will include them in a separate FOIA rulemaking.

Rules, Policies, and Procedures for Corporate Activities (12 CFR Part 5)

Twelve CFR part 5 sets forth the OCC's rules for corporate activities and filings. These rules were included in the first EGRPRA **Federal Register** request for comments and, as indicated above, the OCC's final rule integrating the OCC's national bank and Federal savings association licensing rules incorporated changes that reflect some of the comments received in response to that notice. As discussed below, the proposed rule included a number of additional amendments to part 5 that reflected further review of these licensing rules by the OCC since the adoption of this final rule.

Change in charter purpose or type (12 CFR 5.20, 5.53). The OCC proposed to amend §§ 5.20 and 5.53 to clarify what type of application is to be used when an existing national bank or Federal savings association proposes to change the purpose and type of charter under which it operates. The OCC charters national banks and Federal savings associations that are authorized to conduct any activity permitted for a national bank or a Federal savings association, respectively (sometimes called ''full-service charters''). The OCC also charters national banks and Federal savings associations whose activities are limited to a special purpose. The most common types of special purpose institutions are (1) those whose operations are limited to those of a trust company and activities related thereto, and (2) those that conduct only a credit card business. Other special purpose charter types include: Bankers' banks, community development banks, and cash management banks.

When the OCC grants approval for a special purpose institution, the approval decision generally includes a condition requiring the institution to conduct only the limited activity. If the institution later desires to expand the scope of its business, it must seek OCC approval. A later expansion to include additional business warrants a new review to determine if the institution has the financial and managerial resources to conduct the expanded business. Similarly, when an institution that has a full-service charter later desires to limit itself to a special purpose and conduct only one business line, the OCC reviews the change to ascertain whether the institution could continue to operate safely and soundly after it narrows its focus and to evaluate the institution's proposed capital, staffing, business plan, and risk management systems.

Currently, filings to change the purpose of a charter have no established framework and the OCC addresses them on a case-by-case basis when an institution inquires. Recently revised § 5.53 [13] now covers transactions that are similar to a change in purpose and type of charter (*i.e.,* transactions that involve substantial changes in an institution's assets, liabilities, or business lines). Because the changes to an institution's assets, liabilities, and business lines that would be involved in a change in the purpose of a charter would necessitate a filing under § 5.53, we proposed to clarify § 5.53 to expressly add change in charter type to the transactions that are covered by § 5.53. We also proposed additional provisions to § 5.20(l), where special purpose charters are discussed, that describe changes in charter purpose, set out the requirement for an application, and direct institutions to § 5.53 for the relevant application.

We received no specific comments on these proposed amendments to §§ 5.20 and 5.53 and adopt them as proposed.

[9] The amendments included in this rulemaking amend rules issued only by the OCC and do not reflect comments submitted on rules the OCC has issued jointly with other agencies. We will address any modifications to interagency rules through a separate interagency rulemaking.

[10] This commenter also addressed the Volcker rule, 12 CFR part 44, Bank Secrecy Act rules, 12 CFR part 21, and the appraisal rule, 12 CFR part 34, which are outside the scope of this rulemaking.

[11] The fourth comment letter, from an individual, addressed the Volcker rule and Community Reinvestment Act. These topics are outside the scope of this rulemaking.

[12] Public Law 114–185 (2016).

[13] The OCC amended § 5.53 in July 2015. *See* 80 FR 28346 (May 18, 2015).

Business combinations involving Federal mutual savings associations (12 CFR 5.33). Twelve CFR 5.33 sets forth the provisions governing business combinations involving depository institutions within the OCC's jurisdiction, including Federal mutual savings associations. Paragraph (n)(2)(iii) of this section currently provides that if any combining Federal savings association is a mutual savings association, the resulting institution must be a mutually held savings association, unless the transaction is approved under 12 CFR part 192, which governs mutual to stock conversions, or involves a mutual holding company reorganization under 12 U.S.C. 1467a(o).[14] Consequently, unless one of these two exceptions applies, the resulting institution may not be a mutually held state-chartered savings bank.[15]

However, the merger authority set forth in 12 CFR 5.33(n)(2)(iii) is narrower than the merger authority granted to all Federal savings associations under the Home Owners' Loan Act (HOLA). Specifically, section 10(s) of the HOLA [16] provides that ''[s]ubject to sections 5(d)(3) and 18(c) of the Federal Deposit Insurance Act (FDI Act) and all other applicable laws, any Federal savings association may acquire or be acquired by any insured depository institution.'' The statute, therefore, does not limit the resulting institution in such transactions to a savings association.[17]

Under § 5.33(n)(2)(iii), Federal mutual savings associations and mutual state-chartered savings banks that seek to combine must undertake a multi-step transaction. For example, a Federal mutual savings association generally may convert to a mutual state-chartered savings association or a mutual state-chartered savings bank pursuant to section 5(i)(3) of the HOLA, and thereafter combine with a mutual state-chartered savings bank. Such a process, while accomplishing the same purpose as a direct merger, is more expensive and time consuming than a direct merger and results in unnecessary regulatory burden for the institutions involved.

Accordingly, the OCC proposed to amend § 5.33(n)(2)(iii) to permit a mutual depository institution insured by the FDIC, *i.e.,* either a mutual savings association or a mutual savings bank, to be the resulting institution in a combination involving a Federal mutual savings association. This amendment would simplify combinations involving mutual savings banks, thereby reducing regulatory burden and costs associated with such transactions imposed under the current rule. We note that this amendment would continue to require the resulting institution to have a mutual charter so as not to implicate the mutual-to-stock conversion regulations, 12 CFR part 192.

The OCC also proposed to amend 12 CFR 5.33(n)(2)(iii)(B) to allow a mutual Federal savings association to merge into an FDIC-insured depository institution subsidiary of a state-chartered mutual holding company. Currently, under the exception, a mutual Federal savings association may merge into a subsidiary savings association of a section 10(o) mutual holding company, provided the depositors of the resulting association have membership rights in the mutual holding company.[18] The exception does not allow the merger of a mutual Federal savings association into a state savings bank subsidiary of a mutual holding company that is established under state law. As a result, in order for the mutual Federal savings association to merge into a state savings bank subsidiary of a mutual holding company organized under state law, it must first convert to a state-chartered savings association or state-chartered savings bank, and then combine with the state-chartered savings bank.

In addition, we proposed to amend § 5.33(n)(2)(iii)(B) so that mergers of mutual Federal savings associations into subsidiaries of section 10(o) and non-section 10(o) mutual holding companies are treated similarly. As with the amendment to § 5.33(n)(2)(iii) described above, this amendment would reduce regulatory burden and costs associated with such transactions imposed under the current rule.

We received no specific comments on these proposed amendments to § 5.33 and adopt them as proposed.

Changes in permanent capital (12 CFR 5.46). Under 12 CFR 5.46, a national bank must submit an application to the OCC and receive prior approval for certain increases or decreases to the bank's permanent capital accounts. In addition, a national bank must submit an after-the-fact notice of all increases or decreases to the bank's permanent capital accounts. Furthermore, pursuant to 12 U.S.C. 57, the OCC must certify all increases to a national bank's permanent capital accounts resulting from cash or other assets for the increase to be considered valid. The purpose of these requirements is to inform the OCC whenever the bank's board of directors decides to change the capital structure of the institution, including when accepting additional funds from a parent holding company, issuing new shares or stock, or redeeming an existing issue of preferred stock.

The OCC receives a number of applications and notices for changes to permanent capital that arise solely from applying U.S. generally accepted accounting principles (GAAP). For example, U.S. GAAP may allow a national bank to revalue certain balance sheet accounts, including permanent capital accounts, for a period after the conclusion of a merger or acquisition. As 12 U.S.C. 1831n generally requires all insured depository institutions, including national banks, to apply U.S. GAAP when preparing their financial statements, there is limited value in requiring licensing filings or certifications solely because the bank is complying with that statute by applying U.S. GAAP. These accounting adjustments often are not material and typically are reviewed by the bank's internal accounting staff and external auditors. In addition, many of the accounting adjustments relate back to transactions reviewed or approved by the OCC under other rules, such as mergers, acquisitions, or divestitures. Furthermore, these accounting adjustments do not result in increases from cash paid or other assets and therefore do not require certification by the OCC pursuant to 12 U.S.C. 57.

We proposed to amend § 5.46 to create an exemption for national banks from the prior approval, notification, and certification requirements for all changes to permanent capital that result solely from application of U.S. GAAP, and do not otherwise involve the receipt of cash or other assets. However, proposed § 5.46 would continue to require a notice for material accounting adjustments, which the amendment defines as an increase or decrease greater than 5 percent of the bank's total

[14] Section 10(o) of the HOLA.

[15] This paragraph is generally consistent with the rule as issued by the former OTS and originally republished by the OCC as 12 CFR 146.2(a)(4). The OCC moved this provision to § 5.33 in its licensing integration rule. *See* 80 FR 28346 (May 18, 2015).

[16] 12 U.S.C. 1467a(s).

[17] Section 5(i) of the HOLA (12 U.S.C. 1464(i)) provides that transactions involving the conversion of a Federal mutual savings association to a stock Federal savings association, and vice versa, must comply with OCC regulations. As indicated above, OCC regulations relating to mutual to stock conversions are set forth at 12 CFR part 192. By limiting the resulting institution to a mutual institution, both the current rule and the amendment ensure that combinations involving Federal mutual savings associations are consistent with the mutual to stock conversion regulations at 12 CFR part 192.

[18] The OCC deems this type of transaction to be one type of mutual holding company reorganization.

permanent capital prior to the adjustments in the most recent quarter, or if the national bank is subject to a letter, order, directive, written agreement, or otherwise that is related to changes in permanent capital. The national bank would be required to provide the notice within 30 days after the end of the quarter in which the material accounting adjustment occurred, and include the amount of the adjustment, a description, and a citation to the applicable U.S. GAAP provision.

The OCC did not propose a similar change to § 5.45, Increases in permanent capital of a Federal stock savings association. Section 5.45 requires a Federal savings association to submit an application to the OCC and receive prior approval for increases to its permanent capital accounts under the same circumstances that national banks are required to submit an application under § 5.46(g)(1)(ii). However, unlike the national bank rule, § 5.45 requires an after-the-fact notice of the increase only if the savings association was required to obtain prior approval of the increase. In addition, there is no statutory requirement that the OCC certify the increase in capital. For these reasons, an amendment similar to the one adopted for § 5.46 is not needed for § 5.45.

The OCC, however, did propose a clarifying change to § 5.45(g)(4)(i). The current wording of that section is unclear to whether a Federal savings association that increases its permanent capital account must file a notice for all increases, rather than only in the circumstances in which the savings association is required to obtain prior approval. In adopting this provision, the OCC intended the notice to be filed only in cases in which prior approval was required. We proposed to amend § 5.45(g)(4)(i) to specifically provide that an after-the-fact notice is required only if the capital increase was subject to prior approval by the OCC.

We received no specific comments on the proposed amendments to §§ 5.46 and 5.45 and adopt them as proposed.

Additional technical changes to 12 CFR part 5. The proposed rule also included additional technical changes to 12 CFR part 5. First, we proposed to amend § 5.8, Public notice, to provide that the public notice of a licensing-related filing must include the closing date of the 30-day public comment period only if this information is available at the time of publication. We proposed this change because the OCC treats the comment period differently in business combinations than in other transactions. For other transactions, the comment period starts when the public notice is published. For business combinations, the comment period starts on the latest of the publication date, the date when the OCC makes the application available in the OCC's FOIA Reading Room, or the date when the OCC publishes the application in the OCC Weekly Bulletin. When the national bank or Federal savings association files the application with the OCC and publishes the notice, it typically would not know when the other two events will occur, and so would not know the comment period closing-date for these transactions at the time the public notice is published. However, in order to assist the public in determining this date, the proposed rule required that the notice include a statement indicating that information about the transaction, including the comment period closing-date, may be found in the OCC's Weekly Bulletin.

Second, for a similar reason, we proposed a technical correction to paragraph (i) of 12 CFR 5.33, Business combinations involving a national bank or Federal savings association. In general, paragraph (i) provides that a business reorganization filing or a filing that qualifies for a streamlined application is deemed approved by the OCC on the latter of the 45th day after the OCC receives the application or the 15th day after the close of the public comment period. However, because the 30-day public comment period for business combinations starts on the later of the date that the filing is published in the OCC Weekly Bulletin or the date it is available in the OCC's FOIA Reading Room, and because this date will always be after the OCC receives the application, 15 days after the close of the public comment period always will be later than the 45th day after the OCC receives the application. Therefore, the reference to the 45-day period in § 5.33(i) is unnecessary and confusing, and we proposed to remove it.

Third, we proposed to correct inaccurate cross-references in paragraphs (j)(3) and (4) of § 5.21, Federal mutual savings association charter and bylaws. Specifically, the references to paragraphs (j)(2) would be changed to paragraph (j)(3).

Fourth, we proposed to correct an inaccurate cross-reference in § 5.33(o)(3)(i) by replacing the reference to paragraph (n)(3) with paragraph (o)(3).

Fifth, we proposed to correct an inaccurate cross-reference to the definition of the term ''tax-qualified employee stock benefit plan'' in § 5.50(f)(2)(ii)(E) by replacing ''§ 192.2(a)(39)'' with ''§ 192.25.''

Lastly, we proposed to amend § 5.66, Dividends payable in property other than cash, to provide that a national bank must submit a request for prior approval of a non-cash dividend to the appropriate OCC licensing office. Currently, this section provides that the OCC must approve a non-cash dividend but does not indicate where a bank must submit the request for approval. The only direction provided in OCC dividend rules as to where a dividend application should be filed is contained in § 5.64(c)(3), which provides that a national bank must submit its request for prior approval for cash dividends to the appropriate OCC supervisory office. Because the OCC reviews non-cash dividends in the appropriate licensing office, and not the appropriate supervisory office, the amendment to § 5.66 would remove any confusion as to where a bank must submit non-cash dividend applications.

We received no specific comments on these proposed technical amendments and adopt them as proposed.

The OCC also is adopting additional technical and procedural amendments not included in the proposed rule. First, we are replacing the term ''main office'' with ''home office'' both in paragraph (j)(3)(iii) of § 5.21, Federal mutual savings association charter and bylaws, and in paragraph (j)(2)(iii) of § 5.22, Federal stock savings association charter and bylaws. ''Main office'' is the appropriate term for national banks, while ''home office'' is the appropriate term for Federal savings associations. Second, we are making a change in OCC procedure in paragraph (e)(2)(ii) of § 5.48, Voluntary liquidation of a national bank or Federal savings association. Currently, this provision requires a bank or savings association to receive the OCC's supervisory non-objection to a liquidation plan before beginning the liquidation. We are amending this provision to allow a non-supervisory office of the OCC, such as the OCC Licensing Division, to provide this non-objection.

National Bank Director Oaths (12 CFR 7.2008).

Twelve U.S.C. 73 sets forth the requirements for national bank director oaths. Specifically, this statute requires that, when appointed or elected, each national bank director must take an oath that he or she (1) will diligently and honestly administer the affairs of the bank, (2) not knowingly violate or willingly permit to be violated any applicable laws, and (3) is the owner in good faith of the requisite shares of stock and that the stock is not pledged as security for any loan or debt. The statute requires the oath to be notarized and immediately transmitted to the

Comptroller and filed in the Comptroller's office for 10 years.

Twelve CFR 7.2008 implements this statutory requirement. Specifically, § 7.2008 provides that: (1) A notary public, including one who is a director but not an officer of the national bank, may administer the oath of directors; (2) each director attending the organization meeting must execute either a joint or individual oath, and a director not attending the organization meeting (the first meeting after the election of the directors) must execute the individual oath; (3) a director must take another oath upon re-election, notwithstanding uninterrupted service; and (4) the national bank must file the original executed oaths of directors with the OCC and retain a copy in the bank's records in accordance with the Comptroller's Corporate Manual filing and recordkeeping instructions for executed oaths of directors. This provision also notes that appropriate sample oaths are located in the Comptroller's Corporate Manual.

Twelve CFR 7.2008 was included in the third **Federal Register** EGRPRA notice and the OCC did not receive any comments on this provision in response to this request for comment. However, after conducting its own internal review, the OCC proposed to amend § 7.2008 to clarify when the director oath must be taken. As proposed, § 7.2008 would follow the statute more closely by requiring a director to execute either a joint or individual oath at the first meeting of the board of directors that the director attends after the director is appointed or elected. This proposed amendment also would remove the reference to ''organizational meeting,'' which we believe does not adequately convey when a director must execute the oath in all cases, including when a director is appointed.

The OCC also proposed to replace obsolete references to the Comptroller's Corporate Manual with references to *www.occ.gov* [19] and to correct a spelling error in § 7.2008.

We received no specific comments on these proposed amendments to § 7.2008 and adopt them as proposed.

Fidelity Bonds (12 CFR part 7, §§ 163.180, 163.190, and 163.191).

Twelve CFR 7.2013 requires all national bank officers and employees to have adequate fidelity bond coverage. It also states that the bank's directors may be liable for losses incurred in the absence of such bonds and that directors should not serve as bond sureties. Furthermore, the rule provides that the bank's directors should determine the appropriate amount of bond coverage, premised on consideration of the bank's internal auditing safeguards, number of employees, deposit liabilities, and amount of cash and securities normally held by the bank.

Twelve CFR 163.180(c), 163.190, and 163.191 contain the fidelity bond rules applicable to Federal savings associations. While §§ 163.190 and 7.2013 are similar, the Federal savings association rules are more prescriptive and apply not only to officers and employees, but also to directors and agents. In addition, under § 163.190(b), the Federal savings association's management must determine the amount of coverage, based on the potential risk exposure. Section 163.190(c) also directs the Federal savings association to provide supplemental coverage beyond that provided by the insurance underwriter industry's standard forms if the board determines that additional coverage is warranted. Furthermore, § 163.190(d) requires the Federal savings association's board of directors to approve the association's bond coverage, with this approval documented in the board's minutes, and to review annually the adequacy of coverage. Section 163.191 provides an alternative means of calculating the bond coverage that is appropriate for a Federal savings association agent, in lieu of the calculation provided in § 163.190. Finally, § 163.180(c) states that a Federal savings association maintaining a bond required by § 163.190 must promptly notify the bond company and file proof of loss for any covered loss that is greater than twice the bond's deductible amount.

Twelve CFR 163.180(c), 163.190, and 163.191 were included in the fourth **Federal Register** EGRPRA notice, and the OCC did not receive any comments on these rules in response to this request for comment. However, after conducting its own internal review, the OCC finds that some of the requirements are unnecessary or overly detailed, and more appropriately addressed in guidance or left to the institution's judgment, as is currently the case for national banks. The OCC also finds that other provisions in the savings association rules should be continued and applied, as modified, to national banks. Therefore, the OCC proposed to remove §§ 163.180(c), 163.190 and 163.191 and apply § 7.2013, as amended and as described below, to Federal savings associations.

As a result of removing § 163.190, Federal savings associations would no longer be required to maintain fidelity bonds for directors who do not also serve as officers or employees. We proposed to remove this requirement because fidelity bond coverage generally is not available for directors unless they also are acting as officers or employees. In addition, the activities in which outside directors engage generally do not expose financial institutions to the types of losses covered by fidelity bonds. Furthermore, as a result of this proposed amendment, the board of directors of a Federal savings association no longer would be required to assess annually the adequacy of bond coverage for the association officers and employees.

We also proposed to remove the requirement in § 163.180(c) because we find that a regulatory requirement that a Federal savings association notify its bond insurance company and file proof of loss for certain claims is unnecessary. The terms of a fidelity bond contract itself require such notification, and it is a prudent business practice for a financial institution. Furthermore, the Corporate and Risk Governance booklet of the *Comptroller's Handbook* states that ''[a]ll fidelity bonds require that a loss be reported to the bonding company within a specified time after a reportable item comes to the attention of management. Management should diligently report all potential claims . . . because failure to file a timely report may jeopardize coverage for that loss.'' [20]

In addition, we proposed to modify the treatment of fidelity bond coverage for certain agents of Federal savings associations. Currently, § 163.191 requires fidelity bond coverage for any agent who has control over or access to cash, securities, or other property of a Federal savings association. There is no comparable requirement for agents of national banks. Instead of a mandatory requirement for agent bonding, we proposed to amend § 7.2013 to provide that the boards of directors of both banks and savings associations should consider whether agents who have access to assets of a bank or savings association also should have fidelity bond coverage. The OCC recognizes that agents providing financial services, such as cash handling or payment processing, to a financial institution potentially expose that institution to significant risks. The OCC believes that these risks and associated risk mitigation strategies, including the scope and size of fidelity

[19] The OCC's Web site contains general instructions for filing the oath of directors and a sample individual oath and joint oath at *http://www.occ.gov/publications/publications-by-type/licensing-manuals/index-licensing-manuals.html.*

[20] Corporate and Risk Governance booklet of the *Comptroller's Handbook,* p. 63 (July 2016).

bond coverage for agents, are best addressed by the board of directors.

Finally, § 7.2013(b) currently provides that a national bank's board of directors should determine the appropriate amount of fidelity bond coverage. This language is in contrast to that in § 163.190, which makes clear that this determination is mandatory. For safety and soundness reasons, the OCC believes that both national bank and Federal savings association boards of directors should be required to determine the appropriate bond coverage and proposed to amend § 7.2013(b) to make clear that this determination is a mandatory requirement. We also proposed to amend this section to allow a board committee, as an alternative to the entire board, to assess fidelity bond coverage.

We did not received any specific comments on these proposed amendments to part 7 and §§ 163.180, 163.190, and 163.191 and adopt them as proposed.

Assessments (12 CFR Part 8)

The OCC collects semiannual assessments from national banks, Federal savings associations, Federal branches, and Federal agencies in accordance with 12 CFR part 8. The OCC is adopting a technical amendment to the definition of ''[f]ull-service trust Federal savings association'' in 12 CFR 8.6(c)(iv) not included in the proposed rule. The amendment removes the extraneous word ''trust'' from the title, which corrects a drafting error from an earlier rulemaking in which the OCC combined certain rules of the OCC and the former OTS.[21] This amendment will not affect the method for collecting assessments or the amount of assessments collected by the OCC.

Fiduciary Activities (12 CFR Parts 9 and 150)

Twelve CFR parts 9 and 150 set forth the standards that apply to the fiduciary activities of national banks and Federal savings associations, respectively. Parts 9 and 150 were included in the first EGRPRA **Federal Register** notice, and the OCC proposed revisions to these rules to reflect some of the public comments received in response to this notice. One commenter to the proposed rule provided a number of comments on these revisions. These comments and the revisions as adopted in this final rule are discussed below.

Custody of fiduciary assets. Sections 9.13 and 150.230 require a national bank or Federal savings association, respectively, to place all fiduciary account assets in the joint custody or control of no fewer than two of the fiduciary officers or employees designated by the bank's or savings association's board of directors or to maintain fiduciary investments off premises, if consistent with applicable law and if the bank maintains adequate safeguards and controls. The OCC proposed to amend § 9.13 to add a new § 150.245 to provide relief for arrangements under which a national bank or Federal savings association is deemed a fiduciary solely because it provides investment advice for a fee. If, under such an arrangement the bank or savings association is a fiduciary merely because it provides such advice and does not have investment discretion, the OCC does not believe that it should be required to have custody of the fiduciary assets. Specifically, the OCC proposed to amend § 9.13(a) to provide that a national bank that is deemed a fiduciary based solely on its provision of investment advice for a fee, as that capacity is defined in 12 CFR 9.101(a), is not required to serve as custodian when offering those fiduciary services. Similarly, proposed § 150.245 provides that a Federal savings association that is deemed a fiduciary based solely on its provision of investment advice for a fee, as that capacity is defined in 12 CFR 9.101(a), would not be required to maintain custody or control of fiduciary assets as set forth in § 150.220 or 150.240.

We received one comment on this proposed change, which suggested that the proposal does not go far enough in that it leaves many other arrangements unaddressed and may raise uncertainty about common scenarios that arise even in traditional fiduciary relationships, such as when a client does not wish to grant the bank custody of fiduciary assets. It suggested that the final rule also provide that a national bank that has not been granted custody of fiduciary assets may still act as a fiduciary with respect to those assets, if consistent with applicable law.

The OCC does not agree with the comment. Such arrangements may pose additional risks to account beneficiaries as well as additional liabilities to bank fiduciaries. The proposed amendment was deliberately and narrowly focused on situations where a bank or Federal savings association is deemed a fiduciary based solely on the provision of investment advice for a fee, as that capacity is defined in § 9.101(a). Banks that act in any other fiduciary capacity, such as directed trustees or banks that have sole or shared investment discretion, still are required to maintain custody of fiduciary assets in accordance with § 9.13(a).

However, to avoid any confusion about the intent of the amendment the final rule specifically cross-references the definition of ''investment advisor'' instead of referencing the provision of investment advice for a fee and states that, in order not to be required to serve as custodian, the bank may not have any other specified fiduciary capacity. Specifically, as adopted in the final rule, this amendment now provides that a bank that is deemed a fiduciary based solely on its capacity as investment advisor, as that capacity is defined in § 9.101(a), and has no other fiduciary capacity as enumerated in § 9.2(e) is not required to serve as custodian when offering those fiduciary services. This language is substantively identical to the language in proposed § 9.13 but provides banks with more clarity regarding their obligations. We have made corresponding changes to § 150.245.

Deposits of securities with state authorities. Pursuant to 12 U.S.C. 92a(f), § 9.14(a) provides that if a state requires corporations acting in a fiduciary capacity to deposit securities with state authorities for the protection of private or court trusts, a national bank must make a similar deposit with state authorities before acting as a private or court-appointed trustee in that state. If the state authorities refuse to accept the deposit, the bank must instead deposit the securities with the Federal Reserve Bank of the district in which the national bank is located. Section 150.490 contains a nearly identical requirement for Federal savings associations, except that savings associations must deposit the securities with state authorities or the applicable Federal Home Loan Bank. The OCC proposed to amend § 9.14(a) to permit national banks to deposit these securities either with the Federal Home Loan Bank of which the bank is a member or with the appropriate Federal Reserve Bank. Because Federal savings associations may not be members of a Federal Reserve Bank, the OCC cannot make a reciprocal amendment to § 150.490.

One commenter requested that the OCC amend § 9.14 further to provide that if a bank makes a best effort to comply with this provision but is unable to meet the deposit requirement because of a state's refusal or inaction, the bank will be deemed to have complied. The OCC does not agree with this suggested change. Twelve U.S.C. 92a(f) specifically requires national banks to make these deposits. Thus, amending 12 CFR 9.14 to deem a bank

[21] 76 FR 43566 (July 21, 2011).

to have complied when it has not actually made the deposit would be inconsistent with the plain language of the statute. Furthermore, the OCC believes that the option of depositing such funds with either a Federal Reserve Bank or a Federal Home Loan Bank, in the case of national banks, or with a Federal Home Loan Bank, in the case of Federal savings associations, provides these entities with a feasible method of complying with the regulation and statute when a state refuses to accept the deposit. The OCC therefore adopts the amendment as proposed.

Collective investment funds. Section 9.18 permits a national bank, where consistent with applicable law, to invest assets that it holds as fiduciary in specified collective investment funds. Section 150.260 permits Federal savings associations also to invest funds in a fiduciary account in collective investment funds, and provides that in establishing and administering such funds, Federal savings associations must comply with the requirements of § 9.18. Therefore, the amendments to § 9.18 made by this rulemaking also apply to Federal savings associations.

Section 9.18(b)(1) requires a national bank to establish and maintain each collective investment fund in accordance with a written plan approved by a resolution of the bank's board of directors or by a committee authorized by the board. This provision also requires the bank to make a copy of the plan available for public inspection at its main office during all banking hours and to provide a copy of the plan to any person who requests it.

In response to a comment letter received as part of the EGRPRA review process, the OCC proposed to amend § 9.18(b)(1) to require instead that the bank make a copy of the investment fund plan available to the public either at its main office or on its Web site. Although it is appropriate to provide the public access to this plan, we agree that requiring a bank to make the plan available for public inspection at its main office is unnecessarily burdensome and is not the most efficient method for public inspection in today's electronic environment. The proposal maintained the option for access to the plan at a main office for those small banks that may not have a Web site, and also clarified that a bank may satisfy the requirement to provide a copy of the plan to any person who requests it by providing it in either written or electronic form.

The one commenter that discussed this amendment supported it, noting that it would allow banks to lower distribution costs, while satisfying participants' requests for the information through electronic mail or an internet Web site. The OCC adopts this amendment as proposed.

Section 9.18(c)(2) provides that a national bank may collectively invest assets that it holds as fiduciary in a mini-fund. A mini-fund is a fund that a bank maintains for the collective investment of cash balances received or held by the bank in its capacity as trustee, executor, administrator, guardian, or custodian under the Uniform Gifts to Minors Act that the bank considers too small to be invested separately in an economically efficient manner. This section further provides that the total assets in a mini-fund must not exceed $1,000,000 and the number of participating accounts must not exceed 100.

A comment on this rule received as part of the EGRPRA review process requested that the OCC periodically adjust the asset limit for mini-funds in § 9.18(c)(2) to account for inflation and economic growth. This commenter also noted that the current limit of $1 million was last updated in 1996 [22] and suggested that the OCC raise the threshold to at least $1.5 million, which is the inflation-adjusted value of $1 million in 1996. The OCC agreed with this commenter and proposed to amend § 9.18(c)(2) to increase the threshold to $1,500,000, with an annual adjustment for inflation. The OCC believes this change will continue to make mini-funds a feasible investment option for national banks.

The same commenter supported the increased threshold in the proposed rule. However, this commenter also noted that this proposed threshold may be too low to provide a feasible investment option for many banks and asked that the OCC consider adjustments as needed. The OCC does not believe that a threshold higher than the one proposed is necessary at this time, as it reflects the inflation adjusted value of the original threshold. Furthermore, this amendment provides that the OCC will adjust this amount to reflect inflation on a yearly basis.

This commenter also recommended a number of additional amendments to § 9.18. Section 9.18(b)(5)(iii) provides that a bank managing certain collective investment funds invested primarily in real estate or other assets that are not readily marketable may require a prior notice period not to exceed one year for withdrawals. The commenter requested that the OCC amend this provision to replace references to ''real estate'' with references to ''assets that are illiquid or otherwise not readily marketable'' so that other illiquid assets such as guaranteed investment contracts, synthetic investment contracts, or separate account contracts with limits on transferability, may be recognized. The commenter also requested that the OCC amend the rule to permit national banks to require advance withdrawal notices longer than one year so that banks would not need to request such an extension from the OCC on a case-by-case basis. The OCC does not agree with either of these suggestions. The introduction of the term ''assets that are illiquid'' could be interpreted too broadly and, for example, could result in national banks denying participants access to funds when a collective investment fund holds assets that become illiquid due to adverse market conditions. The OCC also believes that banks should continue to be required to support, on a case-by-case basis, any request to extend the advance notice requirement.

Lastly, this commenter requested that the OCC allow flexibility in the timing of a final audit required by 12 CFR 9.18(b)(6), which requires a national bank administering a collective investment fund to prepare a financial audit of the fund once every 12 months. The commenter specifically recommended allowing a bank that is terminating a fund within 15 months after the last audit to wait until the fund has terminated to complete the final audit. The OCC does not agree with this recommendation. In many cases, banks should be able to plan fund terminations at or just prior to the end of a plan year. To the extent that circumstances beyond their control prevent the fund from closing as planned, those same circumstances may delay the closing beyond 15 months, delaying the audit without reducing expenses.

For the reasons stated above, the OCC adopts the proposed amendments to § 9.18 as proposed.

Additional suggested amendments. This commenter provided other suggested amendments to the OCC's fiduciary rules, most of which the commenter previously included in its response to the first **Federal Register** EGRPRA notice. The OCC did not include these amendments in the proposed rule, and has not included them in the final rule, for the reasons discussed below.

First, the commenter requested that we amend § 9.8(a), which requires national banks to maintain fiduciary account records for a period of three years from the later of the termination

[22] *See* 61 FR 68554 (Dec. 30, 1996).

of the account or the termination of any litigation relating to an account, to provide instead that these account records be retained for a ''necessary period'' or to refer to applicable law on the retention of documents. The term ''necessary period'' is too vague and the OCC declined to propose this change.

Second, this commenter also requested that the OCC amend 12 CFR 9.10(b)(1), which imposes requirements and restrictions on national banks that hold fiduciary funds that are awaiting investment or distribution by the bank. Section 9.10(b) specifically requires a bank to collateralize funds held in a fiduciary account if the funds are not insured by the FDIC. The commenter recommended that the OCC not require a bank to collateralize funds if the funds are directed by a third party or in the governing instrument. The commenter noted that in these situations, a third party and not the bank decides how to hold the funds at the bank, thus eliminating conflict of interest or self-dealing on the part of the bank. However, national banks are required to collateralize deposits by statute regardless of whether the bank has discretion to deposit fiduciary funds at the bank.[23] This collateralization is for protection of the trust funds. Customers providing direction to a bank to self-deposit may not fully understand the protection that they would forego by doing so. Also, in many cases, the party that could direct a bank to self-deposit may not be the party protected by the pledge. The directing party may benefit from foregoing the pledge, but not share in the risk. For these reasons, the OCC declined to include this amendment in the proposed rule.

Third, 12 CFR 9.10(b)(2) stipulates the types of collateral with which a bank may satisfy the requirements of 12 CFR 9.10(b)(1). This commenter requested that the OCC expand the list of acceptable collateral listed in § 9.10(b)(2) to include other instruments that provide protection from loss similar to that provided by surety bonds, and the commenter proposed language that would allow a bank to determine whether a collateral instrument provides such ''similar protection.'' The OCC finds that this proposed change is overly broad and subject to misinterpretation, and, therefore, did not include it in the proposed rule.

Lastly, this commenter urged the OCC to address electronic recordkeeping for fiduciary accounts in 12 CFR 9.8, noting that such guidance would provide clarity when state law is silent as to the medium of recordkeeping. The commenter noted that many bank fiduciaries are confused as to which fiduciary documents are covered by the Electronic Signatures in Global and National Commerce Act (E-Sign Act).[24] The commenter requested that the OCC expressly permit the electronic retention of documents to satisfy regulatory requirements.

The OCC notes that section 101 of the E-Sign Act provides that certain records may not be invalidated merely by virtue of being in an electronic format. However, section 103 of the E-Sign Act exempts from section 101 contracts or other records to the extent that they are governed by statutes, regulations, or other rules of law governing the creation and execution of wills, codicils, or testamentary trusts.[25] Generally, wills, codicils, and testamentary trusts are governed by state law. Section 9.8 does not prohibit the electronic recordkeeping of fiduciary documents. However, in light of the provisions in the E-Sign Act, the authority to declare that fiduciary records may be kept electronically if such records are subject to state law is unclear. Therefore, electronic recordkeeping is permissible for purposes of part 9 if such recordkeeping is permitted by state law, and we decline to amend our rule specifically to permit electronic retention of such fiduciary documents.

Municipal Securities Dealers (12 CFR Part 10)

Part 10 requires that a national bank (or a separately identifiable department or division of a national bank) that acts as a municipal securities dealer, and an associated person that acts as a municipal securities principal or representative, file certain forms with the OCC. Specifically, § 10.2 requires national banks to submit to the OCC Form MSD–4 (Uniform Application for Municipal Securities Principal or Municipal Securities Representative Associated with a Bank Municipal Securities Dealer) before associating with a municipal securities principal or municipal securities representative. Within 30 days of terminating such person's association with the bank, the bank must file with the OCC Form MSD–5 (Uniform Termination Notice for Municipal Securities Principal or Municipal Securities Representative Associated with a Bank Municipal Securities Dealer). Although there is no equivalent regulation applicable to Federal savings associations, these institutions and associated persons currently file these same forms with the OCC pursuant to Municipal Securities Rulemaking Board (MSRB) rules, as incorporated in an OTS Chief Counsel Opinion.[26]

Part 10 was included in the fourth **Federal Register** EGRPRA notice and the OCC did not receive any comments on this rule in response to this request for comment. However, in order to coordinate and harmonize the requirements applicable to these practices, the OCC proposed to codify this OTS opinion in OCC regulations by amending part 10 to include Federal savings associations. In addition, the OCC proposed minor technical changes to update part 10. First, we proposed to update the citation to MSRB Rule G–7(b) in § 10.2(a) to reflect MSRB revisions to this rule. Second, we proposed to amend § 10.2(c) to allow national banks to obtain Forms MSD–4 and MSD–5 [27] on *http://www.banknet.gov/* instead of by contacting the OCC in writing.[28] Third, we proposed to replace the street address of the MSRB, provided to assist institutions in obtaining MSRB rules, with the MSRB's internet address.

We did not receive any specific comments on the proposed codification and technical amendments and adopt them as proposed. This codification will not change the requirements applicable to Federal savings associations. Furthermore, by codifying this filing in OCC rules instead of referring to it in an opinion letter, this change will identify more clearly this requirement for Federal savings associations.

Securities Exchange Act Rules (12 CFR Parts 11 and 194)

Twelve CFR parts 11 and 194 set forth the periodic reporting requirements for

[23] 12 U.S.C. 92a(d).

[24] 15 U.S.C. 7001 *et seq.*

[25] 15 U.S.C. 7003.

[26] OTS Chief Counsel Opinion (OTS Op. Oct. 29, 2001) (noting that a Federal savings association engaged in municipal securities underwriting and dealing must comply with applicable laws and regulations, financial reporting requirements, and Municipal Securities Rulemaking Board (MSRB) rules). MSRB rules include requirements to file forms with the ''appropriate regulatory agency.'' *See, e.g.,* MSRB Rule G–7. The Exchange Act provides that the OCC is the appropriate regulatory agency with respect to a municipal securities dealer that is a Federal savings association. 15 U.S.C. 78c(a)(34)(A)(i).

[27] We note that Forms MSD–4 and MSD–5 are uniform forms developed by the Federal Reserve Board, FDIC and OCC and that these forms expressly state that they be *mailed* to the appropriate regulatory agency. Therefore, the OCC cannot amend part 10 to provide for the electronic filing of these forms until the Federal Reserve Board, FDIC, and OCC jointly decide to permit electronic filing.

[28] BankNet is the OCC's secure Web site for communicating with and receiving information from national banks and Federal savings associations. BankNet is only available to OCC-regulated institutions and is not available to the public.

national banks and Federal savings associations, respectively, with securities registered under the Securities Exchange Act of 1934 (Exchange Act). These rules were included in the fourth **Federal Register** EGRPRA notice, and the OCC did not receive any specific comments on these rules in response to this request for comment, although we previously had received more general comments requesting that the OCC permit electronic filings. In light of the similar statutory provisions that apply to national banks and Federal savings associations as implemented by these parts, the OCC proposed to remove part 194 and amend part 11 to include Federal savings associations. In addition, we proposed to amend § 11.2 pursuant to the Jumpstart Our Business Startups Act (JOBS Act),[29] to permit the electronic filing of periodic reporting requirements, and to make technical, non-substantive edits and clarifications to part 11. These changes would reduce duplication and create efficiencies by establishing a single set of rules for all entities supervised by the OCC with respect to the Exchange Act disclosure rules, while not changing the requirements applicable to national banks or Federal savings associations. These specific amendments are discussed below.

Authority and OMB control number (§ 11.1). Section 11.1 sets forth the OCC's authority to issue rules for national banks with respect to the Exchange Act as well as the Office of Management and Budget (OMB) control number assigned to part 11 for purposes of the Paperwork Reduction Act (PRA). The OCC proposed to amend this section to include its authority with respect to Federal savings associations. We also proposed to remove the reference to the OMB control number, as it is not required to be included in regulatory text and the OCC has generally not included such numbers in recently published regulations.

We did not receive any specific comments on these proposed amendments to § 11.1 and adopt them as proposed. This removal is technical and will not affect the OCC's responsibilities under the PRA.

Reporting requirements for registered national banks (§ 11.2). The OCC proposed to add a new paragraph (c) to § 11.2 to state explicitly that references to registration requirements under the Securities Act of 1933 (Securities Act) pertain to the registration requirements under 12 CFR part 16. We did not receive any specific comments on this proposed amendment and therefore adopt it as proposed. This change will clarify the applicable requirements for national banks and Federal savings associations.

Emerging growth company eligibility (§ 11.2). The JOBS Act amended the Exchange Act to create a new class of issuer known as an emerging growth company.[30] An emerging growth company is defined generally as an issuer that had total annual gross revenues of less than $1 billion during its most recently completed fiscal year.[31] The JOBS Act provides scaled disclosure provisions for emerging growth companies, including, among other things: (1) An exemption from proxy statement requirements concerning shareholder approval of executive compensation under section 14A of the Exchange Act; [32] (2) an exemption from proxy statement requirements concerning disclosure of executive compensation versus performance under section 14(i) of the Exchange Act; [33] (3) a limitation of applicable time periods for disclosures required under Regulation S–K [34] for selected financial data; [35] (4) treatment as a smaller reporting company for purposes of executive compensation disclosures required under Regulation S–K, Item 402; [36] and (5) an exemption from auditor attestation provisions concerning internal financial reporting controls required by the Sarbanes-Oxley Act of 2002.[37]

The JOBS Act and the Exchange Act contain exclusions from emerging growth company eligibility that are based on public offerings that an issuer makes under the Securities Act. First, the JOBS Act provides that an issuer is not eligible for emerging growth company status if it engaged in a public securities offering pursuant to an effective Securities Act registration statement on or before December 8, 2011.[38] Second, the Exchange Act, as amended by the JOBS Act, provides that an issuer may not remain an emerging growth company beyond the close of the fiscal year following the fifth anniversary of the issuer's first securities offering under a Securities Act registration statement.[39] Because national banks and Federal savings associations file registration statements under OCC regulations rather than the Securities Act, these exclusions do not technically apply to banks and savings associations.

Section 12(i) of the Exchange Act requires the OCC to issue substantially similar regulations as the Securities and Exchange Commission (SEC) for those provisions of the Exchange Act for which it is vested authority with respect to banks and savings associations.[40] Parts 11 and 194 generally require national banks and Federal savings associations, respectively, with securities registered under sections 12(b) or 12(g) of the Exchange Act [41] to comply with certain Exchange Act rules. Therefore, pursuant to the JOBS Act, the OCC proposed to add a new paragraph (d) to § 11.2 to clarify national bank and Federal savings association eligibility for emerging growth company treatment for those provisions of the Exchange Act that the OCC administers. The intent of this amendment is to ensure equivalent treatment of banks and savings associations with non-bank issuers. This amendment also would provide that a bank or savings association eligible for emerging growth company status may choose to forgo such exemption and instead comply with the requirements that apply to a bank or savings association that is not an emerging growth company. Furthermore, the amendment would provide that: (1) A bank or savings association is not an emerging growth company if it sold common equity securities on or before December 8, 2011, pursuant to a registration statement or offering circular filed under 12 CFR part 16 or 197, or under the former OTS rule at 12 CFR 563g; and (2) emerging growth company status for banks and savings associations terminates no later than the end of the fiscal year following the fifth anniversary of the first sale of its common equity securities pursuant to a registration statement or offering circular under 12 CFR parts 16, 197 or 563g.[42]

We did not receive any specific comments on this proposed amendment to § 11.2 and adopt it as proposed.

Filing requirements and inspection of documents (§ 11.3). Several comments

[29] Public Law 112–106, 126 Stat. 306 (2012).

[30] JOBS Act, section 101(b), amending section 3(a) of the Exchange Act (15 U.S.C. 78c(a)).

[31] Exchange Act, section 3(a)(80) (15 U.S.C. 78c(a)(80)).

[32] Exchange Act, section 14A(e) (15 U.S.C. 78n–1(e)).

[33] Exchange Act, section 14(i) (15 U.S.C. 78n(i)).

[34] 17 CFR 210.1–01 *et seq.*

[35] Exchange Act, section 13(a) (15 U.S.C. 78m(a)).

[36] 12 CFR 229.402.

[37] Public Law 107–204, section 404, 116 Stat. 789 (2002) (15 U.S.C. 7262(b)).

[38] JOBS Act, section 101(d) (15 U.S.C. 77b(note)).

[39] Exchange Act, section 3(a)(80) (15 U.S.C. 78c(a)(80)).

[40] 15 U.S.C. 78l(i).

[41] 15 U.S.C. 78l(b), (g).

[42] The JOBS Act and the Exchange Act, as amended by the JOBS Act, contain equivalent restrictions for non-banks. However, these restrictions are based on when an issuer files a registration statement under the Securities Act.

received during the EGRPRA review process requested that the OCC permit national banks and Federal savings associations to submit forms and reports to the OCC electronically. The OCC agrees that electronic filings are more efficient and less costly for national banks and Federal savings associations, are more efficient for the OCC to review, and provide a quicker response time for banks and savings associations. Therefore, we proposed to amend part 11 to provide for the electronic submission of required filings.[43]

Section 11.3(a) currently requires national banks to submit by mail, fax, or otherwise four copies of all papers required to be filed with the OCC (pursuant to the Exchange Act or regulations thereunder) to the Securities and Corporate Practices (SCP) Division of the OCC. Through incorporation of SEC Rule 12b–11,[44] part 194 requires Federal savings associations to file three copies of Exchange Act filings with the SCP Division. We proposed to amend § 11.3(a)(1) to require instead that national banks and Federal savings associations submit one copy of their filings through electronic mail to the OCC at *http://www.banknet.gov/*.[45]

The proposed rule also included an amendment to § 11.3 to provide that documents may be signed electronically using the signature provision in SEC Rule 12b–11. SEC Rule 12b–11 provides that required signatures for Exchange Act filings may be signed using typed signatures or duplicated or facsimile versions of manual signatures. Where typed, duplicated, or facsimile signatures are used, each signatory to the filing is required to ''manually sign a signature page or other document authenticating, acknowledging, or otherwise adopting his or her signature that appears in the filing.'' [46] As provided by Rule 12b–11, the national bank or Federal savings association must retain this document for five years and, upon request, provide a copy to the OCC.

The OCC also proposed an exception to the general electronic filing requirement to permit the use of paper filings where unanticipated technical difficulties prevent the use of electronic filings. This exception is modeled on the SEC's General Rules and Regulations for Electronic Filings, Regulation S–T, Rule 201,[47] which provides a temporary hardship exemption to the SEC's Electronic Data Gathering, Analysis, and Retrieval system (EDGAR) filing requirements in cases of unanticipated technical difficulties. Similar to Rule 201, the OCC notes that use of this exception should be extremely limited and should be relied upon only when unusual and unexpected circumstances create technical impediments to the use of electronic filings. However, this exception would not be available for statements of beneficial ownership that must be made through the *FDICconnect* platform, which requires electronic filings.[48]

Current § 11.3(a)(3)(i) provides that the date on which papers are actually received by the OCC shall be the date of filing, if the person or bank filing the papers has complied with all applicable requirements. The OCC proposed to update this provision to conform to the electronic filing requirement. Specifically, an electronic filing whose submission is commenced on a nonholiday weekday on or before 5:30 p.m. Eastern Standard or Daylight Savings Time, whichever is currently in effect, would be deemed received by the OCC on the same business day. An electronic filing whose submission is commenced after 5:30 p.m. Eastern Standard or Daylight Savings Time, whichever is currently in effect, or on a Saturday, Sunday, or Federal holiday would be deemed received by the OCC on the next business day. The proposal also included a new paragraph (a)(3)(iii) to § 11.3 to provide that if an electronic filer in good faith attempts to file a document pursuant to this part in a timely manner but the filing is delayed due to technical difficulties beyond the electronic filer's control, the electronic filer may request that the OCC adjust the filing date. The OCC may grant the request if it appears that such adjustment is appropriate and consistent with the public interest and the protection of investors. These rules for dating an electronic filing, and for providing a waiver for technical difficulties with the filing, also are derived from SEC Regulation S–T.[49]

Finally, the OCC proposed the following technical amendments to part 11. First, the OCC proposed to rename the paragraph heading of § 11.3(a)(3)(ii), which establishes filing dates for statements of beneficial ownership that must be made through the *FDICconnect* platform,[50] from *Electronic filings* to *Beneficial ownership filings.* This new heading would more accurately reflect the final rule's application of electronic filing requirements to all part 11 filings, not just those made under § 11.3(a)(3)(ii).

Second, the OCC proposed to delete paragraph (a)(4) of § 11.3. This paragraph provides a mandatory compliance date of January 1, 2004 for 12 CFR part 11. However, as this date has now passed, this mandatory compliance date no longer is needed in the rule text.

Third, the OCC proposed to amend § 11.4(b), which currently provides that filing fees must be paid by check, to reflect the electronic filing of documents and the additional payment options now available. Specifically, the amendment would permit filing fees to be paid by means acceptable to the OCC, in addition to by check. We note that the OCC currently is not imposing any filing fees for part 11 filings and is not adopting any fees as part of this rulemaking.

As a consequence of proposing to amend part 11 to include Federal savings associations, the OCC proposed to remove part 194 in its entirety. The OCC notes that removing § 194.3, which addresses liability for certain forward-looking statements made by Federal savings associations, would not change the applicability of the requirements of this section for Federal savings associations. Specifically, the text of § 194.3 is substantially similar to the SEC Rule 3b–6,[51] which currently applies to national banks by reference in § 11.2. Therefore, because part 11 (and its cross-reference to the SEC Rule 3b-6) would apply to Federal savings associations, the requirements imposed by current § 194.3 would continue to apply to Federal savings associations.

Furthermore, we note that the removal of §§ 194.801 and 194.802, Interpretations for Federal savings associations filing statements pursuant to the Exchange Act, is not intended to be a substantive change in how these filings are conducted. The interpretations included in these sections are now widely accepted and no longer need to be included in a rule. Therefore, the removal of these sections would not change how Federal savings associations prepare their reports.

The OCC did not receive any specific comments on the proposed amendments to § 11.3 and the removal of part 194

[43] The OCC currently permits the electronic submission of a number of other filings, for example, Call Reports, and public welfare investment notifications and proposals.

[44] 17 CFR 240.12b–11.

[45] As described elsewhere in this final rule, the OCC also is amending part 16, Securities offering disclosure rules, to provide for electronic submissions.

[46] *Id.*

[47] 17 CFR 232.201.

[48] *See* 70 FR 46403 (Aug. 10, 2005). FDICconnect is the secure internet channel for FDIC-insured institutions to conduct business and exchange information with the FDIC.

[49] 17 CFR part 232.

[50] *See* 70 FR 46403 (Aug. 10, 2005).

[51] 17 CFR 240.3b–6.

and adopts the amendments and removal as proposed.

Recordkeeping and Confirmation Requirements for Securities Transactions (12 CFR Parts 12 and 151)

Twelve CFR parts 12 and 151 establish recordkeeping and confirmation requirements for national banks and Federal savings associations, respectively, that engage in securities transactions for their customers. These rules were included in the fourth **Federal Register** EGRPRA notice and the OCC did not receive any comments on them in response to this request for comment. However, based on our internal review of these rules, the OCC proposed a number of amendments to both parts 12 and 151. We received one comment on these amendments, with respect to 12 CFR 12.102, National bank use of electronic communications as customer notifications, as discussed below.

Definitions. The OCC proposed to revise the definition of ''municipal security'' at §§ 12.2(i)(3) and 151.40 to remove an outdated citation to the Internal Revenue Code. We are adopting this change as proposed.

Recordkeeping. Section 12.3 and subpart A of part 151 establish recordkeeping requirements for securities transactions conducted by national banks and Federal savings associations, respectively. Section 151.60(b) prescribes more detailed procedures for record maintenance and storage for Federal savings associations than prescribed for national banks in § 12.3(b). Specifically, § 12.3(b) provides that the required records must clearly and accurately reflect the information required and provide an adequate basis for the audit of the information, and that record maintenance may include the use of automated or electronic records provided the records are easily retrievable, readily available for inspection, and capable of being reproduced in a hard copy. In addition to what is required for national banks, § 151.60(b) imposes requirements related to indexing, paper storage, electronic storage, and the provision of records to examiners. The OCC proposed to remove § 151.60(b) and revise § 151.60(a) to include the less detailed maintenance and storage procedures found in the national bank rule. The OCC believes that this approach would provide a Federal savings association with more flexibility in making internal business decisions about record storage and maintenance.

Current § 151.60(c), redesignated in the proposed rule as § 151.60(b), provides that a Federal savings association may use a third-party service provider to provide record storage or maintenance. The current national bank rule does not include a similar third-party provision. The OCC proposed to amend § 12.3 to clarify that a national bank may use a third-party service provider for record storage and maintenance provided that the bank maintains effective oversight to ensure that the records are easily retrievable, are readily available for inspection, can be reproduced in a hard copy, and follow applicable OCC guidance.[52]

The OCC did not receive any specific comments on these proposed amendments to §§ 12.3 and 151.60 and adopts them as proposed.

Content and time of notification. Sections 12.4 and 151.70, respectively, require national banks and Federal savings associations that effect securities transactions for their customers to provide notifications of the transactions. Under the current rule, a national bank or Federal savings association may choose among several types of notification. Pursuant to §§ 12.4(a) and 151.90, a national bank or Federal savings association, respectively, may provide the customer a written notice that includes the information set forth in those sections. Sections 12.5 and 151.100 permit a national bank or Federal savings association, respectively, to fulfill the notification requirement through alternative means that vary by the type of account. For transactions that use a registered broker-dealer, § 151.80(a) allows the Federal savings association to satisfy the requirement of § 151.70 by having the registered broker-dealer send the confirmation statement directly to the customer or by having the Federal savings association send a copy of the broker-dealer's confirmation to the customer. If the broker-dealer has the necessary account level information to send the confirmation directly to the customer, the Federal savings association need not send out an additional written notification of the transaction. In contrast, under § 12.4(b), a national bank may send a copy of the broker-dealer's confirmation but is not expressly permitted to satisfy the requirement by having the broker-dealer send the confirmation directly to the customer.

The OCC believes that most national banks and Federal savings associations, particularly community institutions, effect securities transactions for customers through registered broker-dealers. To avoid duplicative reporting to customers and to reduce burden on institutions, the OCC proposed to amend § 12.4(b) to follow the approach of § 151.80. With this amendment, both national banks and Federal savings associations could direct a broker-dealer to mail confirmations to customers without requiring that a duplicate be sent by the bank or savings association, thereby reducing regulatory burden for national banks. This approach also would reduce confusion that may result when a customer receives duplicate confirmations for the same transaction from two different parties.

In addition, the OCC proposed to amend § 151.80 to reduce regulatory burden on Federal savings associations. Currently, § 151.80(b) requires a Federal savings association that receives or will receive remuneration from any source, including the customer, in connection with the transaction to provide the customer a statement of the source and amount of the remuneration in addition to the registered broker-dealer confirmation. The OCC proposed to amend this provision to provide that, when such remuneration is determined by a written agreement between the Federal savings association and the customer, the savings association does not need to provide this remuneration statement for each securities transaction. This change is consistent with § 12.4(b), which does not require a national bank to provide a statement of the source and amount of remuneration in these circumstances.

The OCC did not receive any specific comments on these proposed amendments to §§ 12.4 and 151.70 and adopts them as proposed.

National bank disclosure of remuneration for mutual fund transactions. The OCC proposed to remove the interpretation in § 12.101, national bank disclosure of remuneration for mutual fund transactions. The OCC does not intend to change any existing practices with this amendment. Instead, the OCC believes that this issue is obsolete because of recent SEC actions.[53] The OCC did not receive any specific comments on this proposed removal and adopts it as proposed.

National bank use of electronic communications as customer notifications. Section 12.102 allows national banks, in appropriate situations, to comply with the written customer notification requirements in

[52] *See* OCC Bulletin 2013–29, Third-Party Relationships: Risk Management Guidance (Oct. 30, 2013).

[53] For example, the SEC now requires all mutual funds to disclose their fee structures in registration statements. *http://www.sec.gov/about/forms/formn-1a.pdf.*

§§ 12.4 and 12.5 by using electronic communications or, if a customer has a facsimile machine, through facsimile transmission. To satisfy the notification delivery requirement by other electronic communication, the parties must agree to use electronic instead of hard-copy notifications, the parties must have the ability to print or download the electronic notification, the recipient must be able to affirm or reject trades through electronic notification, the system cannot automatically delete the electronic notification, and both parties must have the capacity to receive electronic messages. Federal savings associations are subject to a similar provision at § 151.110. The OCC finds that the use of electronic communications has become widespread and is provided for in state and Federal law, such as the E-Sign Act, which allows for electronic communications with customers. Therefore, §§ 12.102 and 151.110 are outdated and duplicative of existing law, and we proposed to remove them.

We received one comment on this proposed amendment, which was critical of removing this guidance for banks on the use of electronic communications. However, the OCC continues to believe that these provisions are outdated and not necessary in the current electronic environment. We therefore adopt the amendment as proposed.

Securities Offering Disclosures (12 CFR Parts 16 and 197)

Twelve CFR parts 16 and 197 set forth securities offering disclosure rules for national banks and Federal savings associations, respectively. These rules are based on the Securities Act [54] and certain Securities Act rules, to the extent appropriate for banks.[55] These rules were included in the fourth **Federal Register** EGRPRA notice, and the OCC did not receive any specific comments in response to this request for comment, although, as indicated above, we previously had received comments requesting that the OCC permit electronic filings.

In light of the similar provisions that apply to national banks and Federal savings associations, the OCC proposed to amend part 16 to include Federal savings associations and to remove part 197. In addition, the OCC proposed to incorporate some provisions of part 197 into part 16, to provide for the electronic submission of filings required under part 16, and to update the part 16 filing fees provision. The OCC also proposed technical changes throughout part 16 to update citations to SEC rules and to replace all references to ''Commission'' with ''SEC.'' The OCC believes that these amendments would reduce duplication and create efficiencies by establishing a single set of rules for all entities supervised by the OCC with respect to securities offerings. In addition, integrating savings associations into part 16 would clarify disclosure requirements for these institutions and provide them with additional exemptions, as described below. Furthermore, providing for the electronic submission of securities filings would reduce burden for both national banks and Federal savings associations.

These specific amendments are discussed below.

The JOBS Act, addressed above in the discussion of part 11, amended the Securities Act and directed the SEC both to amend existing Securities Act rules and to write new rules to implement certain JOBS Act provisions. Generally, the JOBS Act seeks to ease securities offering disclosure requirements and periodic reporting obligations for certain issuers, including emerging growth companies.[56] It also creates new Securities Act private placement exemptions for crowdfunding [57] and small company capital formation.[58] In addition, the JOBS Act includes provisions that reduce restrictions on certain research and communications concerning emerging growth company securities offerings.[59] The OCC generally intends for part 16 to remain consistent with the Securities Act, including those provisions amended under the JOBS Act, and SEC rules. Part 16 incorporates through cross-references various SEC rules that the JOBS Act directs the SEC to amend. Therefore, amendments to these SEC rules are incorporated into part 16 by virtue of these cross-references.[60]

Registration statement: form and content. The OCC proposed to replace the offering circular currently required under § 197.2 and the corresponding form and content requirements of § 197.7 with a registration statement and prospectus required by §§ 16.3 and 16.15 for national banks. We received no comments on this proposed change and adopt it as proposed. Requiring the use of the same form by both national banks and Federal savings associations will provide a consistent set of disclosure standards and format for investors. The OCC believes that this change will not impose any undue regulatory burden on Federal savings associations because these forms provide similar information to potential investors.

Communications not deemed an offer. Both §§ 16.4 and 197.2(b) provide that certain communications by national banks or Federal savings associations about their securities are not deemed to be offers. However, § 16.4 more closely follows SEC regulations by additionally exempting summary prospectuses covered by SEC Rule 431,[61] notices of certain proposed unregistered offerings covered by SEC Rule 135c,[62] publications or distributions of research reports by brokers or dealers covered by SEC Rules 138 and 139,[63] and certain communications made after providing a prospectus. Amending part 16 to include Federal savings associations would afford them the additional communication exemptions under the

[54] National bank and Federal savings association securities are generally exempt from the Securities Act. Securities Act, sections 3(a)(2) and (5) (15 U.S.C. 77c(a)(2) and (5)).

[55] 59 FR 54789 (Nov. 2, 1994) (''[Part 16] generally requires national bank securities offering documents to conform to the form for registration that the bank would use if it had to register the securities under the Securities Act. Accordingly, the final rule cross-references a number of provisions of the Securities Act and a number of SEC rules.'')

[56] As indicated in the discussion of part 11, above, an emerging growth company is a new category of issuer created under the JOBS Act. Generally, an emerging growth company is an issuer that had total annual gross revenues of less than $1 billion during its most recently completed fiscal year. Securities Act section 2(a)(19) (15 U.S.C. 77b(a)(19)). An emerging growth company is eligible to rely on certain scaled disclosure requirements for registration statements filed under the Securities Act. For example, an emerging growth company need not present more than two years of audited financial statements in a registration statement for an initial public offering. Securities Act section 7(a) (15 U.S.C. 77g(a)). *C.f.* SEC Regulation S–X, Rule 3–02 (17 CFR 210.3–02) (requiring three years of audited financial statements). We note that under 12 CFR 16.15(e), the OCC does not generally require audited financial statements in securities offering documents for national banks in organization. An emerging growth company also is eligible for scaled disclosure requirements in the context of Exchange Act periodic reporting. A detailed discussion of this relief is set forth above in the discussion of part 11.

[57] Securities Act, section 4(a)(6) (15 U.S.C. 77d(a)(6)) (crowdfunding creates a registration exemption for offerings of up to $1 million, provided that individual investments do not exceed certain thresholds and the issuer satisfies other conditions in the JOBS Act).

[58] Securities Act, section 3(b) (15 U.S.C. 77c(b)) (directing the SEC to create a registration exemption for securities offerings of up to $50 million).

[59] Securities Act, sections 2(a)(3) and 5(d) (15 U.S.C. 77b(a)(3) and 77e(d)).

[60] The SEC has adopted amendments to Regulation A under the Securities Act to implement section 401 of the JOBS Act. 80 FR 21806 (Apr. 20, 2015). The SEC also has adopted amendments to Rule 506 of Regulation D and Rule 144A under the Securities Act to implement section 201(a) of the JOBS Act. 78 FR 44771 (July 24, 2013).

[61] 17 CFR 230.431.

[62] 17 CFR 230.135c.

[63] 17 CFR 230.138 and 230.139.

SEC rules currently available to national banks. The OCC received no comments on this change and adopts it as proposed.

Exemptions. Section 16.5 provides exemptions to the general registration requirements for national bank securities under § 16.3. These exemptions significantly overlap with the § 197.3 exemptions to the registration requirements for Federal savings associations. However, § 16.5 applies SEC Rules 152[64] (private placement exemption), 152a[65] (exemption for sales of certain fractional interests) to transactions exempt under section 4 of the Securities Act[66]), and 236[67] (offerings to shareholders in connection with a stock dividend, stock split, conversion, or merger) while § 197.3(b) does not. By amending § 16.5 to include Federal savings associations, the additional exemptions provided by these two SEC rules would apply to transactions by Federal savings associations.

Section 16.5(f) specifically exempts transactions that satisfy the requirements of SEC Rule 701[68] regarding offers and sales of securities pursuant to certain compensatory benefit plans and contracts relating to compensation. Section 197.3 does not cross-reference SEC Rule 701 but rather provides in § 197.3(g) a narrower exemption for sales only to officers, directors, or employees through an employee benefit plan or a dividend or interest reinvestment plan that has been approved by shareholders. In particular, § 197.3(g) does not exempt sales made through compensatory benefit plans for consultants, advisors, and family members, as does SEC Rule 701.

By amending § 16.5 to include Federal savings associations, the exemption available for savings associations would be expanded to cover all such sales exempted by SEC Rule 701. Although the OCC did not propose to incorporate the § 197.3(g) requirement regarding shareholder approval of compensation plans, Federal savings associations still must follow all applicable corporate governance requirements under their charter provisions. Additionally, national banks and Federal savings associations that are subject to the Federal proxy rules must comply with SEC rules issued under Exchange Act Section 14A[69] concerning shareholder approval of executive compensation and golden parachute payments.

The OCC notes that under paragraph (e) of § 197.3 certain collateralized securities issued by Federal savings associations currently are exempt from registration. Federal savings associations also rely upon SEC Regulation D[70] in addition to § 197.3(e) for this exemption.[71] Therefore, the OCC did not propose to maintain the exemption in § 197.3(e) because of the availability of the Regulation D private placement exemption in part 16.

We received no comments on these proposed changes to exemptions and adopt them as proposed. We believe that these changes will provide savings associations with additional flexibility when issuing securities, resulting in reduced costs and less regulatory burden for such issuances.[72]

Sales of nonconvertible debt. The OCC proposed to apply § 16.6, sales of nonconvertible debt, to Federal savings associations. While Federal savings associations have previously sold nonconvertible debt under similar restrictions through various interpretive letters, the OCC believes that adopting a single set of requirements is simpler and more efficient for Federal savings associations. We received no comments on this proposed change and adopt it as proposed.

Small issues. Section 16.8 provides an exemption for small issues of national bank securities under the SEC's Regulation A.[73] Currently, Federal savings associations do not have a Regulation A exemption for small issuances. The OCC proposed to amend § 16.8 to include savings associations. We received no comments on this proposed change and adopt it as proposed. As a result of this amendment, Federal savings associations will be able to issue small amounts of securities and remain exempt from filing registration statements and prospectuses, thereby reducing regulatory burden.

Securities offered and sold in holding company dissolution. Section 16.9 provides an exemption for securities offered and sold in a holding company dissolution. Part 197 does not contain a similar provision; however, Federal savings associations have relied on SEC rules for these transactions pursuant to informal OTS staff guidance. The OCC proposed to apply § 16.9 to securities issued by Federal savings associations to provide more certainty as to the applicability of the § 16.9 exemption to these transactions. We received no comments on this proposed change and adopt it as proposed.

Effectiveness. Section 16.16 provides that a registration statement and amendments will become effective in accordance with § 8(a) and (c) of the Securities Act and SEC Regulation C, 17 CFR part 230, which is the 20th day after filing or sooner if so determined by the OCC. Section 197.6 contains the same effective date but does not reference Regulation C. The Federal savings association rule also contains other provisions regarding a delay in effectiveness and provides that the OCC may pursue any remedy under section 5(d) of the HOLA if it appears that the offering circular contains any material misstatement or omission. The OCC proposed to apply § 16.16 to Federal savings associations. We received no comments on this proposed change and adopt it as proposed. As a result, SEC regulation C now applies to Federal savings associations instead of these additional provisions in § 197.6.

Sales of securities at an office of a savings association. Section 197.17 provides that the sale of securities of a Federal savings association or its affiliates at an office of the savings association may only be made in accordance with the provisions of § 163.76.[74] Section 163.76 generally prohibits the offer or sale of debt or equity securities issued by a Federal savings association or an affiliate at an office of the association, unless the equity securities are issued by the association or the affiliate in connection with the association's conversion from the mutual to stock form of organization and certain conditions are met. The OCC proposed to amend part 16 by adding a new § 16.10 to maintain this restriction on the sale of a Federal

[64] 17 CFR 230.152.

[65] 17 CFR 230.152a.

[66] 15 U.S.C. 77d.

[67] 17 CFR 230.236.

[68] 17 CFR 230.701.

[69] 15 U.S.C. 78n–1. Section 951 of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act) added section 14A to the Exchange Act.

[70] 17 CFR 230.501 *et seq.*

[71] 12 CFR 197.4(a).

[72] The OCC notes that the JOBS Act amended section 4 of the Securities Act to create a private placement exemption for crowdfunding (Securities Act, section 4(a)(6), 15 U.S.C. 77d(a)(6)), and the SEC has adopted rules to implement this exemption (80 FR 71387 (Nov. 16, 2015)). National banks and Federal savings associations may not rely on the private placement exemption for crowdfunding in Securities Act section 4(a)(6) unless and until the OCC adopts rules implementing this provision for national banks and Federal savings associations or affirmatively adopts SEC rules that implement this provision. At this time, the OCC is not proposing to amend its rules to permit the private placement exemption for crowdfunding.

[73] 17 CFR 230.251 *et seq.*

[74] Section 197.17 includes an inaccurate cross-reference to § 197.76. We have provided the correct cross-reference in the discussion above and in the proposed rule. *See* proposed § 16.10.

savings association's or affiliate's securities.

The OCC specifically requested in the proposed rule that commenters opine on whether the OCC should remove the limitations on the offer or sale of debt or equity securities at an office of a Federal savings association in light of amendments to the Exchange Act made by the Gramm-Leach-Bliley Act,[75] rules promulgated by the Financial Industry Regulatory Authority,[76] and the Interagency Statement on Retail Sales of Nondeposit Investment Products, all of which govern securities activities conducted on the premises of OCC-regulated financial institutions [77] In the alternative, the OCC asked whether we should amend part 16 to prohibit a national bank from offering or selling debt or equity securities issued by the bank or an affiliate at an office of the bank.

We received one comment on new § 16.10. This commenter did not agree with the suggestion to apply this restriction to national banks as it would be an increase in regulatory burden. In addition, this commenter suggested that the OCC remove this restriction for Federal savings associations. After further review of this provision, the OCC has decided to adopt the provision as proposed and maintain the restriction on Federal savings associations but not apply it to national banks. This provision was enacted in response to the savings and loan crisis of the 1980s, which had a devastating effect on the thrift industry as well as on its customers. This provision has prevented the recurrence of similar events and we believe that the benefit of this restriction outweighs any burden the restriction imposes on Federal savings associations. As there is no historical rationale for this restriction to be placed on national banks, and because we do not see a current need for this restriction to apply to national banks, we have not expanded it to cover these institutions.

Filing requirements and inspection of documents. Current §§ 16.17 and 197.5 require national banks and Federal savings associations, respectively, to submit by mail or otherwise four copies of all registration statements, offering documents, amendments, notices, or other documents to the SCP Division or, if related to a bank in organization or a de novo Federal savings association, to the appropriate district office. Similar to the amendment to § 11.3, the OCC proposed to amend § 16.17 to require instead that banks and savings associations submit one copy of their filings electronically to the SCP Division or the appropriate district office, as applicable, through *http://www.banknet.gov/.* Pursuant to proposed § 16.17(g), any filing of amendments or revisions to previously filed documents must include two copies, one of which must be marked to indicate clearly and precisely, by underlining or in some other appropriate manner, the changes made. Current § 16.17(e) requires a total of four copies of amendments or revisions.

The amendments to § 16.17 also provide that documents may be signed electronically using the signature provision in SEC Rule 402.[78] As indicated in the discussion of part 11, above, this SEC rule provides that required signatures may be typed or may be duplicated or facsimile versions of manual signatures. Where typed, duplicated, or facsimile signatures are used, each signatory to the filing is required to ''manually sign a signature page or other document authenticating, acknowledging, or otherwise adopting his or her signature that appears in the filing.'' [79] As provided by Rule 402, this document must be retained for five years and, upon request, a copy must be provided to the OCC.

Current §§ 16.17(d) and 197.1 provide the date on which papers are actually received by the OCC shall be the date of filing, if the person or bank filing the papers has complied with all applicable requirements. As with the amendment to § 11.3(a)(3)(i), the OCC proposed to update § 16.17(d) to conform to the electronic filing requirement. Specifically, we proposed that an electronic filing that is commenced on a nonholiday weekday on or before 5:30 p.m. Eastern Standard or Daylight Savings Time, whichever is currently in effect, would be deemed received by the OCC on the same business day. An electronic filing whose submission is commenced after 5:30 p.m. Eastern Standard or Daylight Savings Time, whichever is currently in effect, or on a Saturday, Sunday, or Federal holiday would be deemed received by the OCC on the next business day. We note, however, that paragraph (e) provides that with respect to any registration statement or any post-effective amendment filed pursuant to SEC Rule 462(b),[80] the cut-off time is 10 p.m. to be consistent with corresponding SEC rules.

As with section § 11.3(a)(3)(iii), proposed § 16.17(d) provided that if an electronic filer in good faith attempts to file a document pursuant to this part in a timely manner but the filing is delayed due to technical difficulties beyond the electronic filer's control, the electronic filer may request that the OCC adjust the filing date. The OCC may grant the request if it appears that such adjustment is appropriate and consistent with the public interest and the protection of investors. As indicated above, these rules for dating an electronic filing, and for providing a waiver for technical difficulties with the filing, are derived from SEC Regulation S–T.[81]

The OCC also proposed a new § 16.17(f) to establish an exception to the general electronic filing requirements that permits the use of paper filings where unanticipated technical difficulties prevent the use of electronic filings. This exception is modeled on SEC Regulation S–T, Rule 201,[82] which provides a temporary hardship exemption to the SEC's EDGAR filing requirements in cases of unanticipated technical difficulties. Similar to Rule 201, the OCC notes that the use of this exception should be extremely limited and should be relied upon only when unusual and unexpected circumstances create technical impediments to the use of electronic filings.

Finally, the OCC proposed technical changes to § 16.17(h), currently § 16.17(f), to update a cross-reference to 12 CFR part 4.

The OCC did not receive any comments on these proposed changes to the filing requirements in § 16.17 and we adopt them as proposed.

Use of prospectus. Section 16.18 provides that no person may use a prospectus or amendment declared effective by the OCC more than nine months after the effective date unless the information contained in the prospectus or amendment is as of a date not more than 16 months prior to the date of use. Furthermore, this section provides that no person may use a prospectus if an event arises or fact changes after the effective date that causes the prospectus to contain an untrue statement of material fact or to omit a material fact that causes the prospectus to be misleading until an amendment reflecting the event or change has been filed with and declared effective by the OCC. The OCC proposed

[75] *See* 15 U.S.C. 78c(a)(4). *See also* Regulation R, 17 CFR 247.100 *et seq.*

[76] *See* FINRA Rule 3160.

[77] *See* OCC Bulletin 94–13, Non deposit Investment Sales Examination Procedures (Feb. 24, 1994) and OCC Bulletin 95–52, Retail Sales of Nondeposit Investment Products (Sept. 22, 1995).

[78] 17 CFR 230.402.

[79] *Id.*

[80] 17 CFR 230.462(b).

[81] 17 CFR 232.

[82] 17 CFR 232.201.

to apply § 16.18 to Federal savings associations. We received no comments on this proposed change and adopt it as proposed. Because § 197.8 contains similar provisions, this amendment will not result in any changes for Federal savings associations.

Withdrawal or abandonment. In general, § 16.19 provides that a registration statement, amendment, or exhibit may be withdrawn prior to its effective date. Furthermore, this section provides that the OCC may deem abandoned a registration statement or amendment that has been on file with the OCC for nine months and has not become effective. The OCC proposed to apply § 16.19 to Federal savings associations. We received no comments on this proposed change and adopt it as proposed. Because § 197.11 contains the same provisions as § 16.19, applying § 16.19 to Federal savings associations will not result in any changes for Federal savings associations.

Request for interpretive advice or no-objection letter. As proposed, the OCC is adopting the amendment to § 16.30 that updates the cross-reference to where the address for filing a request for interpretive advice or a no-objection letter may be found.

Escrow requirement. For national banks, § 16.31 provides the OCC with discretion to require the establishment of an escrow account, while § 197.9 automatically requires an escrow account for Federal savings associations. By amending part 16 to include Federal savings associations and deleting § 197.9, the OCC proposed to remove the mandatory escrow requirement for Federal savings associations. We received no comments on this proposed change and adopt it as proposed.

Fraudulent transactions/unsafe or unsound practices. Section 16.32 prohibits fraudulent transactions in the offer or sale of bank securities and deems such transactions to be an unsafe or unsound practice under 12 U.S.C. 1818. Section 197.10 contains a similar prohibition. However, § 16.32 specifically cross-references the investor protections under section 17 of the Securities Act [83] and references SEC Rule 175 [84] on forward-looking statements. Although section 17 by its terms applies to Federal savings associations regardless of the OCC rule, neither it nor SEC Rule 175 is referenced in § 197.10. The OCC proposed to amend § 16.32 to include Federal savings associations. As a result, part 16 would put Federal savings associations on notice that the Securities Act section 17 investor protections apply. Furthermore, Federal savings associations would have the additional clarifying guidance on the liability of forward-looking statements provided by SEC Rule 175. We received no comments on this proposed change and adopt it as proposed.

Filing fees. Section 16.33 provides that the required filing fees, as provided for in the Notice of Comptroller of the Currency Fees published pursuant to 12 CFR 8.8, must accompany filings made pursuant to part 16. The OCC proposed to amend § 16.33(a) to clarify that the OCC may require filing fees before it may accept a filing. In addition, as with § 11.4, we proposed to amend § 16.33(b) to provide that such fees may be paid by means acceptable to the OCC, in addition to by check, to reflect the additional payment options now available. We received no comments on these proposed filing fee changes and adopt them as proposed. We note that the OCC is not currently imposing any filing fees for part 16 filings and is not imposing any new fees as part of this rulemaking.

Waiver and interpretive advice requests. The proposed rule did not include the blanket waiver provisions contained in §§ 197.14 and 197.15. Commenters did not discuss these provisions and the final rule as adopted does not contain these blanket waivers. However, we note that the OCC will continue to provide interpretive advice or no-objection letters under the terms provided in § 16.30. We also note that 12 CFR 100.2 provides that the Comptroller may, for good cause and to the extent permitted by statute, waive the applicability of any provision of 12 CFR parts 1 through 197, with respect to Federal savings associations.

Current and periodic reports. Section 197.18 requires a Federal savings association to file certain periodic reports with the OCC after its offering circular becomes effective, even if the savings association is not otherwise required to register its securities with the OCC under the Exchange Act. This filing requirement applies to Federal savings associations until the securities to which the savings association's offering circular relates are held of record by fewer than 300 persons in any fiscal year other than the fiscal year in which the offering circular becomes effective. The FDIC and the Federal Reserve Board have not imposed a comparable obligation on state banks, and the OCC removed this obligation on national banks in 2008.[85] Instead, a state or national bank is subject to Exchange Act periodic and current reporting requirements if the bank's total assets exceed $10,000,000 and it has a class of equity security (other than an exempted security) held of record by 2,000 or more persons.[86]

The proposed rule did not include filing requirement contained in § 197.18. As a result, a Federal savings association instead would be subject to Exchange Act periodic and current reporting requirements if it has total assets exceeding $10,000,000 and a class of equity security (other than an exempted security) held of record by 2,000 or more persons.[87] Commenters did not discuss the removal of this filing requirement and we adopt this change as proposed. As a result of this final rule, current and periodic reporting requirements for national banks and Federal savings associations will be identical. In addition, regulatory burden will be reduced by eliminating such filing requirements for Federal savings associations with fewer than 1,200 holders of record.[88] Financial information about a savings association will continue to be publicly available to investors through quarterly financial information, including balance sheets and statements of income, which is part of a savings association's Call Reports and is available at *https://cdr.ffiec.gov/public/*.

Periodic sales reports. Under § 197.12 Federal savings associations must file periodic reports on the sales of securities that are registered under § 197.2 or that are otherwise exempt from registration under § 197.4 (non-public offerings, including Regulation D and sales to 35 or more persons). National banks do not have to file similar reports. Institutions generally sell securities for the purpose of increasing their capital. The OCC can review any increases to a Federal savings association's capital through the institution's quarterly Call Report, and therefore the periodic sales report provides limited additional value for supervision. Furthermore, § 5.45 requires Federal savings associations subject to capital plans or other regulatory actions to file reports for increases in permanent capital, so the Securities Sales Report is redundant in cases that present the most supervisory

[83] 15 U.S.C. 77q.

[84] 17 CFR 230.175.

[85] 73 FR 22216 (Apr. 24, 2008).

[86] Exchange Act, section 12(g) (15 U.S.C. 78l(g)), as amended by section 601(a) of the JOBS Act.

[87] *Id.*

[88] *Id.* National banks and Federal savings associations that are currently registered under section 12(g) of the Exchange Act and have 1,200 or more holders of record for a class of securities must continue to comply with current and periodic reporting requirements.

risk.[89] Therefore, the OCC proposed to not include in part 16 the § 197.12 requirement that Federal savings associations file reports on sales of securities. We did not receive any comments on the removal of the periodic sales report requirement and adopt this change as proposed.

Disclosure of Financial and Other Information by National Banks (12 CFR Part 18)

Twelve CFR part 18 sets forth annual financial disclosure requirements for national banks. Specifically, part 18 requires national banks to prepare annual disclosure statements as of December 31 to be made available to bank security holders by March 31 of the following year. The rule specifies the types of information that must be included in the disclosure statements, which includes, at a minimum, certain information from the bank's Call Report. The Comptroller may require the inclusion of other information and the bank may include an optional narrative. Section 18.5 provides alternative ways a bank may meet the disclosure statement requirement. These alternatives include allowing Exchange Act registered banks to use the bank's annual report and allowing banks with audited financial statements to use those statements provided the statements include certain required information.

Although we did not receive any specific comments on part 18 during the EGRPRA review process, the OCC proposed to remove this rule to reduce unnecessary burden. The information part 18 requires a national bank to disclose is contained in other publicly available documents, such as the Call Report and the Uniform Bank Performance Report. Part 18 is therefore duplicative and unnecessary. We note that the Federal Reserve Board and the former OTS rescinded similar regulations for state member banks and savings associations, respectively. The OTS repealed 12 CFR 562.3 in December 1995 and the Federal Reserve Board eliminated 12 CFR 208.17 in 1998.[90]

We did not receive any specific comments on the removal of part 18 and, therefore, adopt the removal as proposed.

Extensions of Credit to Insiders and Affiliate Transactions (12 CFR Part 31, §§ 163.41 and 163.43

National banks and Federal savings associations must comply with rules of the Federal Reserve Board regarding extensions of credit to insiders, 12 CFR part 215 (Regulation O), which implements sections 22(g) and 22(h) of the Federal Reserve Act, and transactions with affiliates, 12 CFR part 223 (Regulation W), which implements sections 23A and 23B of the Federal Reserve Act.[91] Twelve CFR part 31 and 12 CFR 163.41 and 163.43 address these transactions for national banks and Federal savings associations, respectively. Specifically, § 31.2 requires national banks to comply with Regulation O. Appendix A to part 31 provides interpretive guidance on the application of Regulation W to deposits between affiliated banks. Sections 163.41 and 163.43 contain general statements that refer Federal savings associations to applicable regulations of the Federal Reserve Board, *i.e.,* Regulation O and Regulation W.

The OCC proposed to consolidate its rules that address insider lending and affiliate transactions by amending part 31 to state clearly that both national banks and Federal savings associations must comply with Regulation O and Regulation W and by removing §§ 163.41 and 163.43. Moreover, the OCC proposed to amend part 31 to add the statutory standards for authorizing an exemption from section 23A in accordance with section 608 of the Dodd-Frank Act.

Specifically, we proposed to add ''Federal savings associations'' to the text of § 31.2, Insider lending restrictions and reporting requirements, and to add a new § 31.3 to require both national banks and Federal savings associations to comply with the affiliate transaction requirements contained in Regulation W. Proposed § 31.3(b) clarified that the OCC administers and enforces affiliate transaction requirements as they apply to national banks and Federal savings associations.

Furthermore, proposed § 31.3(c) implemented the standards for authorizing an exemption from section 23A, as provided by section 608 of the Dodd-Frank Act. Section 608 amends section 23A and section 11 of the HOLA to authorize the OCC to exempt, by order, a transaction of a national bank or Federal savings association, respectively, from the affiliate transaction requirements of section 23A and section 11 of the HOLA if: (1) The OCC and the Federal Reserve Board jointly find the exemption to be in the public interest and consistent with the purposes of section 23A and section 11, as applicable, and (2) within 60 days of receiving notice of such finding, the FDIC does not object in writing to the finding based on a determination that the exemption presents an unacceptable risk to the Deposit Insurance Fund.[92] Proposed § 31.3(d) described the procedures that a national bank and Federal savings association must follow for requesting such an exemption. These procedures are modeled after the Federal Reserve Board's existing procedures in Regulation W.

Under the proposal, appendix A to part 31, which is specific to national banks, remains unchanged. However, the proposal amended appendix B, which contains a comparison between selected provisions of Regulation O and the OCC's lending limits rule, 12 CFR part 32, to include Federal savings associations and to make technical changes.

Lastly, the proposal updated the authority provision in § 31.1 to reference the appropriate statutory cite for Federal savings association, 12 U.S.C. 1463 and 1468, and to correct a duplicative reference to 12 U.S.C. 1817(k).

The OCC did not receive any specific comments on these proposed amendments to Part 31 and the removal of §§ 163.41 and 163.43, and we therefore adopt these changes as proposed.

It should be noted that the OCC may impose additional restrictions on any transaction between a Federal savings association or national bank and its affiliates that the OCC determines to be necessary to protect the safety and soundness of the institution.[93] This authority is unaffected by and not addressed in this final rule.

Electronic Operations and Activities of Federal Savings Associations (12 CFR Part 155)

Twelve CFR part 155 addresses the use of technology by Federal savings associations to deliver products and services. Specifically, § 155.200 provides that a Federal savings association may use electronic means or facilities to perform any function, or provide any product or service, as part of an otherwise authorized activity. In addition, § 155.200 permits Federal savings associations to use, or participate with others to use, electronic

[89] Section 5.46 requires national banks to file reports for increases in permanent capital.

[90] 60 FR 66866 (Dec. 27, 1995); 63 FR 37630 (July 13, 1998).

[91] 12 U.S.C. 371c, 371c–1, 375a, and 375b. In general, section 11 of the HOLA, 12 U.S.C. 1468, applies sections 22(g), 22(h), 23A and 23B of the Federal Reserve Act to savings associations in the same manner and to the same extent as if the savings association were a member bank.

[92] *See* section 608(a)(4)(A)(iv) of the Dodd-Frank Act (exemption authority for national banks) and section 608(c) of the Dodd-Frank Act (exemption authority for Federal savings associations).

[93] *See, e.g.,* 12 U.S.C. 93a, 371c(f)(2)(B)(i), 481, 1468(a)(4), 1468(b)(2), and 1831p–1.

means or facilities to perform any function, or provide any product or service, as part of an authorized activity; and to market and sell, or participate with others to market and sell, electronic capacities and by-products to third parties in order to optimize the use of resources, if the savings association acquired or developed these capacities and by-products in good faith as part of providing financial services. These authorizations are similar to what is provided for national banks in 12 CFR part 7, subpart E.

Section 155.210 requires management of the savings association to take steps to identify, assess and mitigate potential risks, establish prudent internal controls, and implement security measures designed to prevent unauthorized access, prevent fraud, and comply with applicable security device requirements of part 168.

Paragraph (a) of § 155.300 provides that Federal savings associations are not required to inform the OCC before using electronic means or facilities, except as provided in paragraphs (b) and (c) and encourages Federal savings associations to discuss any planned new products or services that will use electronic means or facilities with their assigned OCC supervisory office. Paragraph (b) of § 155.300 requires a Federal savings association to file a written notice with the OCC prior to establishing a transactional Web site. Paragraph (c) of § 155.300 requires a Federal savings association to follow any written procedures the OCC imposes with respect to any supervisory or compliance concerns regarding its use of electronic means or facilities. Finally, § 155.310 provides the procedures for filing the transactional Web site notice.

Part 155 was included in the first EGRPRA **Federal Register** request for comment. In response to this request, we received comments recommending that the OCC remove the transactional Web site prior notice requirement in § 155.300(b). The OCC agrees that this notice is no longer necessary and proposed to remove it, along with the related procedural requirements in § 155.310.

Furthermore, the OCC proposed to remove the remaining paragraphs of § 155.300. Paragraph (a) is no longer relevant without the requirement for a transactional Web site notice. Paragraph (c) is unnecessary as, pursuant to the OCC's safety and soundness authority, Federal savings associations are required to comply with any written procedures the OCC imposes for supervisory or compliance reasons.

Finally, the OCC proposed other non-substantive changes to update the rule and to present the regulatory provisions in a format more consistent with the OCC's other rules.

We received no specific comments on the removal of these provisions and the OCC adopts the amendments as proposed. Nonetheless, the OCC encourages Federal savings associations to discuss any planned new products or services that will use electronic means or facilities with their assigned OCC supervisory office.

Regulatory Reporting Requirements for Federal Savings Associations (12 CFR Part 162 and § 163.180)

Twelve CFR part 162 and § 163.180(a) set forth regulatory reporting and auditing standards and requirements for Federal savings associations. These rules were included in the first EGRPRA **Federal Register** notice and the OCC did not receive any comments on these rules in response to this request for comment. However, after conducting its own review of these rules, the OCC proposed to revise 12 CFR part 162 and remove § 163.180(a) in order to eliminate duplicative requirements.

Various Federal statutes impose reporting and audit requirements on Federal savings associations and national banks. Specifically, 12 U.S.C. 161(a) provides that national banks must submit reports of condition to the Comptroller in accordance with the requirements of the FDI Act. Twelve U.S.C. 1464(v)(1) is the comparable statute for Federal savings associations. In addition, 12 U.S.C. 1831m and FDIC implementing regulations at 12 CFR part 363 require insured depository institutions above a specified asset threshold to have annual independent audits and to submit annual reports and audited financial statements to the FDIC and the appropriate Federal banking agency.[94] These financial statements must be prepared in accordance with GAAP and such other disclosure requirements as the FDIC and the appropriate Federal banking agency may prescribe.[95] The *Interagency Policy Statement on External Audit Programs of Banks and Savings Associations* (1999 Interagency Policy Statement)[96] provides unified interagency guidance regarding independent external auditing programs of community banks and savings associations that are exempt from 12 CFR part 363 (*i.e.,* institutions with less than $500 million in total assets) or that are not otherwise subject to audit requirements by order, agreement, statute, or agency regulations. Furthermore, 12 U.S.C. 1463(b)(1) requires the Comptroller, by regulation, to prescribe uniform accounting and disclosure standards for Federal savings associations' compliance with all applicable regulations.

As indicated above, 12 CFR part 162 and § 163.180(a) also contain regulatory reporting and auditing requirements for Federal savings associations. Specifically, § 162.1 requires Federal savings associations to use forms prescribed by the OCC and to follow such regulatory reporting requirements as the OCC may require. This section also requires Federal savings associations and their affiliates to maintain accurate and complete records of all business transactions that support the regulatory reports submitted to the OCC and any financial reports prepared in accordance with GAAP. These records must be maintained in the United States and must be readily accessible by the OCC for examination and other supervisory purposes within five business days upon request by the OCC, at a location acceptable to the OCC.

Section 162.2 sets forth the minimum requirements to be included in all reports to the OCC, including Call Reports. In general, these reports must incorporate GAAP, as well as additional safety and soundness requirements more stringent than GAAP that the Comptroller prescribes. Section 163.180(a) provides that Federal savings associations and their service corporations must submit periodic and other reports as required by the appropriate Federal banking agency. Both §§ 162.1 and 162.2 implement the 12 U.S.C. 1463(b)(1) requirement, described above, that the OCC issue regulations prescribing uniform accounting and disclosure standards for Federal savings associations' compliance with all applicable regulations.

Section 162.4 sets forth requirements and standards for audits of Federal

[94] Among other requirements, 12 CFR part 363 requires insured depository institutions with total assets above certain thresholds to assess the effectiveness of internal controls over financial reporting, to establish independent audit committees, and to comply with related reporting requirements.

[95] Other statutes further clarify the use of GAAP by insured depository institutions. *See, e.g.,* 12 U.S.C. 1831n(a)(2)(A) (the accounting principles applicable to reports or statements required to be filed with Federal banking agencies by insured depository institutions shall be uniform and consistent with GAAP) and 12 U.S.C. 1831n(a)(2)(B) (in certain circumstances, the appropriate Federal banking agency or the FDIC may, with respect to such reports or statements, prescribe an accounting principle applicable to such institutions that is no less stringent than GAAP).

[96] *See* OCC Bulletin 99–37, Interagency Policy Statement on External Auditing Programs (Oct. 7, 1999) and 64 FR 52319 (Sept. 28, 1999).

savings associations. It generally provides that the OCC may require, at any time, an independent audit of a Federal savings association's financial statements when necessary for safety and soundness reasons. It further requires an independent audit if a Federal savings association receives a CAMELS rating of 3, 4, or 5, specifies qualifications for independent public accountants, and states that audit engagement letters provide the OCC with access to and copies of any work papers, policies, and procedures relating to the services performed.

There are no comparable OCC regulations for national banks. However, the OCC applies and enforces the above-referenced statutory requirements, as well as the applicable FDIC reporting and auditing requirements, with respect to both national banks and Federal savings associations.

The OCC proposed to remove the requirements contained in §§ 162.1 and 162.2. The OCC has adequate authority pursuant to its general examination authority to obtain records and reports from Federal savings associations, as well as national banks.[97] Furthermore, the frequently changing nature of accounting standards and disclosures makes it impractical to codify detailed standards in a regulation.

The OCC also proposed to remove the audit requirements of § 162.4 and the reporting requirements of § 163.180(a) because they are unnecessarily repetitive of other requirements. The OCC has adequate statutory authority to require reports and 12 CFR 363 already specifies requirements for independent audits and auditors for both Federal savings associations and national banks. In addition, as with national banks, the OCC does not believe that it is necessary to articulate this authority for Federal savings associations in a regulation.[98]

Because 12 U.S.C. 1463(b)(1) requires the Comptroller to prescribe by regulation uniform accounting and disclosure standards for Federal savings associations, the proposal included a provision requiring that a Federal savings association incorporate U.S. GAAP and the disclosure standards included therein when complying with all applicable regulations, unless otherwise specified by statute or regulation or by the OCC. We believe that this guidance satisfies the statutory requirement while being flexible enough to accommodate the evolving nature of the standards and disclosures. With respect to national banks, a similar regulation is not required by statute and would be redundant with other provisions that require compliance with GAAP, such as 12 U.S.C. 1831m and 1831n(a)(2), discussed above. We note that we proposed to reference GAAP as ''U.S. GAAP'' in this provision to clarify that the reference is to GAAP as used in the United States, in light of evolving global accounting standards.

We did not receive any specific comments on these proposed amendments to part 162 and § 163.180 and adopt them as proposed. We note that rescission of §§ 162.4 and 163.180(a) will not affect the OCC's ability, pursuant to our safety and soundness authority, to require at any time an independent audit of a Federal savings association, or to access work papers and related documents prepared in connection with any audit of a Federal savings association.[99]

Furthermore, the OCC reminds Federal savings associations that rescinding § 162.4 does not eliminate or affect the requirement that a savings association with $500 million or more in assets obtain an annual audit pursuant to 12 U.S.C. 1831m and 12 CFR part 363, nor does it minimize the importance of administering an external audit program. The OCC encourages all national banks and Federal savings associations, regardless of size, to have independent external reviews of their operations and financial statements and to establish audit committees made up entirely of outside directors. The form of that review can range from financial statement audits by independent public accountants to agreed-upon procedures (*i.e.,* directors' examinations) performed by other independent and qualified persons. In particular, Federal savings associations should be familiar with 12 CFR part 363 and the 1999 Interagency Policy Statement, which apply to all insured depository institutions.

Management and Financial Policies (12 CFR 163.161)

Twelve CFR 163.161(a)(1) generally requires each Federal savings association and each service corporation to be well-managed, to operate in a safe and sound manner, and to pursue financial policies that are safe and consistent with economical home financing and the purposes of savings associations. Section 163.161(a)(2) requires each Federal savings association and service corporation to maintain sufficient liquidity to ensure its safe and sound operations. Section 163.161(b) addresses the compensation of Federal savings association and service corporation officers, directors, and employees.

Federal savings associations and national banks are subject to many other regulations and guidance that require sound management and financial policies. Part 30 of the OCC's regulations contain guidelines establishing operational and managerial standards for safety and soundness applicable to national banks and Federal savings associations. Among other things, these safety and soundness guidelines, which implement the statutory safety and soundness provisions at section 39 of the FDI Act,[100] address executive compensation.[101] Furthermore, the OCC, along with the other Federal banking agencies, issued a joint policy statement in 2010 that provides guidance for the sound management of liquidity risk.[102] This policy statement is both more detailed and more current than the provisions of the regulation and is applicable to both national banks and Federal savings associations.

Section 163.161 was included in the third EGRPRA **Federal Register** notice. Although we did not receive any comments on this section in response to this request for comment, we determined that § 163.161 duplicates the provisions discussed above. Therefore, the OCC proposed to delete § 163.161 in its entirety. We did not receive any specific comments on this deletion, and adopt the amendment as proposed.

Financial Derivatives Transactions by Federal Savings Associations (12 CFR 163.172)

Twelve CFR 163.172 states that a Federal savings association may engage in a transaction involving a financial derivative provided that the association is authorized to invest in the assets underlying the derivative, the transaction is safe and sound, and the savings association's board of directors and management satisfy certain prudential requirements. It also states that, in general, if a Federal savings association should engage in a financial derivative transaction, it should do so to reduce its risk exposure.

[97] *See* 12 U.S.C. 1464(d)(1)(B) (Federal savings associations) and 12 U.S.C. 481 (national banks). *See also* 12 U.S.C. 1817.

[98] *See, e.g.,* 12 U.S.C. 1817(a)(3) and 12 CFR part 304 with respect to reports and 12 CFR part 363 and the *Interagency Policy Statement on External Audit Programs of Banks and Savings Associations* (64 FR 52319, Sept. 28, 1999) with respect to audits.

[99] *See* 12 U.S.C. 1831p–1.

[100] 12 U.S.C. 1831p–1.

[101] 12 CFR part 30, appendix A. The OCC, FDIC, and Federal Reserve Board also issued joint agency guidance on incentive compensation in 2010. *See* 75 FR 36395 (June 25, 2010).

[102] *Interagency Policy Statement on Funding and Liquidity Risk Management,* 75 FR 13656 (Mar. 13, 2010).

Section 163.172(a) defines ''financial derivative'' as a financial contract whose value depends on the value of one or more underlying assets, indices, or reference rates. It states that the most common types of financial derivatives are futures, forward commitments, options, and swaps.

We note that the OCC does not have a comparable regulation governing national bank derivative transactions, but has addressed these activities through interpretive letters.

Section 163.172 was included in the fourth EGRPRA **Federal Register** notice and we did not receive any comments on this section in response to this request for comment. However, to clarify any confusion caused by the wording of the current rule, the OCC proposed to replace the term ''forward commitment'' with ''forward contract.'' A ''forward commitment'' generally refers to an agreement to loan funds in the future and is not a financial derivative. In contrast, a ''forward contract'' is a well-known type of financial derivative to which this rule should apply. We do not expect this change to have a material effect on Federal savings associations or the securities marketplace. The OCC also proposed other non-substantive changes to clarify the rule further and to present the regulatory provisions in a format more consistent with the OCC's other rules.

We did not receive any specific comments on these amendments and adopt them as proposed.

Accounting Requirements (12 CFR Part 193)

Twelve U.S.C. 1463(b)(2)(A) requires savings associations to use U.S. GAAP in preparing reports to regulators. Part 193 requires Federal savings associations to make disclosures in financial statements filed in conversion applications or under the Exchange Act. These disclosures are in addition to those required under U.S. GAAP.

Part 193 was included in the fourth EGRPRA **Federal Register** notice and we did not receive any comments on this rule in response to this request for comment. The OCC determined, however, that the additional financial disclosures required by part 193 are, in most cases, substantially similar to and largely repetitive of otherwise applicable public disclosure requirements that a Federal savings association or its holding company must satisfy under the Securities Act, the Exchange Act, or OCC regulations. Therefore, the OCC proposed to delete part 193. We did not receive any specific comments on the removal of part 193, and we adopt this removal as proposed. We note that Federal savings associations still are required to follow U.S. GAAP reporting and disclosure requirements.

III. Regulatory Analysis

Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act (RFA), an agency must prepare a regulatory flexibility analysis for all proposed and final rules that describes the impact of the rule on small entities.[103] Under section 605(b) of the RFA, this analysis is not required if the head of the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities and publishes its certification and a short explanatory statement in the **Federal Register** along with its rule.

The OCC currently supervises approximately 1,032 small entities.[104] Because some of the rule's provisions could affect any national bank and other provisions could affect any Federal savings association, the rule could have an impact on a substantial number of OCC-supervised small entities.

We believe that substantially all of national banks' and Federal savings associations' direct costs will be associated with reviewing the amendments and, when necessary, modifying policies and procedures to correct any inconsistencies between banks' internal policies and the modified rules. Once the bank has implemented the amendments, these costs will dissipate. We estimate that the monetized direct cost per bank or savings association will range from a low of approximately $1 thousand to a high of approximately $8 thousand. Using the upper bound average direct cost per entity, we believe the rule might have a significant economic impact on approximately three OCC-supervised small entities, which is not a substantial number. In other words, although the rule could have an impact on a substantial number of small entities, this impact might be significant for only a few small entities. Therefore the OCC certifies that this final rule does not have a significant economic impact on a substantial number of small entities supervised by the OCC. Accordingly, a regulatory flexibility analysis is not required.

We note that in determining this compliance cost, we do not offset the direct cost imposed by the rulemaking with savings that certain banks and savings associations will realize as a result of the rulemaking. Therefore, the cost described here does not include offsetting reductions in regulatory cost and burden.

Unfunded Mandates Reform Act of 1995

The OCC has analyzed the final rule under the factors in the Unfunded Mandates Reform Act of 1995 (UMRA).[105] Under this analysis, the OCC considered whether the proposed rule includes a Federal mandate that may result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year (adjusted annually for inflation). The UMRA does not apply to regulations that incorporate requirements specifically set forth in law.

The OCC finds that the rule does not trigger the UMRA cost threshold because we estimate that the UMRA cost is *nil.* The OCC believes that substantially all of banks' and savings associations' direct costs will be implementation costs associated with reviewing the amendments and, when necessary, modifying policies and procedures to correct any inconsistencies between banks' internal policies and the modified rules. Because these costs are not associated with mandates, they are not UMRA costs. Accordingly, the OCC has not prepared the written statement described in section 202 of the UMRA.

IV. Administrative Law Matters

Notice and Comment

Pursuant to the Administrative Procedure Act (APA), at 5 U.S.C. 553(b)(B), notice and comment are required prior to the issuance of a final rule unless an agency, for good cause, finds that ''notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.'' This final rule includes four amendments not originally included in the proposed rule published on March 14, 2016. Three of these amendments replace inaccurate terms in 12 CFR 5.21, 5.22, and 8.6(c)(3)(iv) and are purely technical in

[103] *See* 5 U.S.C. 601 *et seq.*

[104] We base our estimate of the number of small entities on the Small Business Administration's size thresholds for commercial banks and savings institutions, and trust companies, which are $550 million and $38.5 million, respectively. Consistent with the General Principles of Affiliation 13 CFR 121.103(a), we count the assets of affiliated financial institutions when determining if we should classify a bank or savings association as a small entity. We use December 31, 2015, to determine size because a ''financial institution's assets are determined by averaging the assets reported on its four quarterly financial statements for the preceding year.'' *See* footnote 8 of the U.S. Small Business Administration's *Table of Size Standards.*

[105] 2 U.S.C. 1531 *et seq.*

nature. The fourth amendment modifies a reference in 12 CFR 5.48 to an internal agency procedure that does not affect a national bank, a Federal savings association, or other non-OCC party. Because these amendments are either technical changes or only affect the OCC, the OCC has good cause to conclude that advance notice and comment under the APA are not necessary prior to their issuance.

Effective Date

The APA requires that a substantive rule must be published not less than 30 days before its effective date, unless, among other things, the rule grants or recognizes an exemption or relieves a restriction.[106] Section 302 of the Riegle Community Development and Regulatory Improvement Act of 1994 (RCDRIA) requires that regulations imposing additional reporting, disclosure, or other requirements on insured depository institutions take effect on the first day of the calendar quarter after publication of the final rule, unless, among other things, the agency determines for good cause that the regulations should become effective before such time.[107] The April 1, 2017 effective date of this final rule meets both the APA and RCDRIA effective date requirements, as it will take effect at least 30 days after its publication date of January 23, 2017 and on the first day of the calendar quarter following publication, April 1, 2017.

Section 302 of the RCDRIA also requires the OCC to consider, consistent with the principles of safety and soundness and the public interest, any administrative burdens the final rule would place on insured depository institutions, including small depository institutions, and their customers as well as the benefits of such regulations when determining the effective date and administrative compliance requirements of new regulations that impose new reporting, disclosure, or other requirements on insured depository institutions.[108] The OCC has considered the changes made by this final rule and believes that the effective date of April 1, 2017 should provide national banks and Federal savings associations with adequate time to comply with these changes as they do not involve major revisions to bank or savings association operations. Furthermore, many of the changes will reduce burden on banks and savings associations or clarify requirements, which will lessen the administrative compliance burden of our regulations on these institutions. Some of these changes also will also benefit bank and savings association customers in that they eliminate unnecessary mailings or provide additional methods to access bank services or information.

Paperwork Reduction Act

Under the PRA of 1995,[109] the OCC may not conduct or sponsor, and a person is not required to respond to, an information collection unless the information collection displays a valid OMB control number. The OCC has submitted the information collection requirements imposed by this final rule to OMB for review.

The OCC also submitted the information collection requirements imposed by the proposed rule to OMB at the time the proposed rule was published. OMB filed comments on the information collections, instructing the OCC to examine public comment in response to the proposed rule and include in the supporting statement of the next submission, to be submitted to OMB at the final rule stage, a description of how the OCC has responded to any public comments on the collection, including comments on maximizing the practical utility of the collection and minimizing the burden. The OCC received no comments regarding the information collections and has resubmitted them to OMB for review in connection with the final rule.

The final rule amends § 5.20, where special purpose charters are discussed, to describe changes in charter purpose, set out the requirement for an application, and direct institutions to § 5.53 for the relevant application. A nonmaterial change has been filed with OMB for these revisions.

Section 9.18(b)(1) has been revised to replace the requirement that a national bank make a copy of any collective investment fund plan available for public inspection at its main office with the requirement that the plan could instead be available to the public on its Web site. A nonmaterial change has been filed with OMB for this revision.

Part 194 is removed and Federal savings associations would follow part 11. Section 11.3 has been revised to require that fewer copies be filed and to allow electronic signatures. A nonmaterial change has been filed with OMB for these revisions.

Section 12.4(b) has been amended to allow institutions to direct a broker-dealer to mail confirmations to customers without requiring a duplicate or other form of notification specified in § 12.4 or § 12.5 to be sent by the institution. Sections 12.101 and 12.102, which require the disclosure of remuneration for mutual fund transactions and electronic communications, have been removed. Section 151.60(a) and (b) have been amended to include the less detailed maintenance and storage procedures for customer securities transaction records found in part 12. Section 151.60(b) also has been amended to allow use of a third-party service provider for records storage and maintenance. Section 151.80 has been amended to provide that a Federal savings association that has previously determined compensation in a written agreement with the customer would not need to provide a remuneration statement for each securities transaction. The Recordkeeping Requirements for Securities Transactions information collection covering parts 12 and 151 has been submitted to OMB for review:

Title: Recordkeeping Requirements for Securities Transactions.

OMB Control No.: 1557–0142.

Frequency of Response: On occasion.

Affected Public: Businesses or other for-profit organizations.

Estimated Number of Respondents:

Current: 399.

Revised: 399.

Estimated Total Annual Burden:

Current: 2,315 hours.

Revised: 1,916 hours.

Part 197 has been removed and Federal savings associations will follow part 16. In addition, § 16.5 has been amended to provide additional exemptions for private placements and sales of certain fractional interests for Federal savings associations. The filing requirement in § 197.18 for periodic reports on sales of securities has been removed and Federal savings associations with total assets exceeding $10,000,000 and a class of equity security (other than exempted security) held of record by 2,000 or more persons are subject to Exchange Act periodic and current reporting requirements. Section 16.17 has been revised to (i) reduce from four paper copies to one electronic copy the number of copies of documents required to be filed for banks and Federal savings associations and banks and Federal savings associations in organization, with certain paper submission exceptions; and (ii) reduces from four to two the number of paper copies of amendments that must be filed. In addition, documents may be signed electronically using the signature provision in SEC Rule 402. The Securities Offering Disclosure information collection covering parts 16

[106] 5 U.S.C. 553(d)(1).

[107] 12 U.S.C. 4802.

[108] 12 U.S.C. 4802.

[109] 44 U.S.C. 3501 *et seq.*

and 197 has been submitted to OMB for review:

Title: Securities Offering Disclosure Rules.

OMB Control No.: 1557–0120.

Frequency of Response: On occasion.

Affected Public: Businesses or other for-profit organizations.

Estimated Number of Respondents:

Current: 61.

Revised: 37.

Estimated Total Burden:

Current: 1,310 hours.

Revised: 814 hours.

Part 18 is removed and the related information collection, OMB Control No. 1557–0182, has been discontinued.

Section 31.3(d) is added to provide procedures to be followed when seeking exemption from 23A of the Federal Reserve Act. A request for a new control number for this collection has been submitted to OMB:

Title: Extensions of Credit to Insiders and Transactions with Affiliates.

OMB Control No.: 1557–NEW.

Frequency of Response: On occasion.

Affected Public: Businesses or other for-profit organizations.

Estimated Number of Respondents: 1 respondent.

Estimated Total Annual Burden: 10 hours.

The notice requirement in § 155.310, requiring a Federal savings association to file a written notice with the OCC at least 30 days prior to establishing a transactional Web site, has been removed. Therefore, OMB Control No. 1557–0301, covering § 155.310, has been discontinued.

The duplicative reporting requirements found in §§ 162.1 and 162.4 have been removed. The General Reporting and Recordkeeping information collection covering part 162 has been submitted to OMB for review:

Title: General Reporting and Recordkeeping.

OMB Control No.: 1557–0266.

Frequency of Response: On occasion.

Affected Public: Businesses or other for-profit organizations.

Estimated Number of Respondents:

Current: 500.

Revised: 500.

Estimated Total Annual Burden:

Current: 68,345 hours.

Revised: 67,845 hours.

Comments continue to be invited on:

(a) Whether the collections of information are necessary for the proper performance of the functions of the OCC, including whether the information has practical utility;

(b) The accuracy of the OCC's estimates of the burden of the collections of information;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of the collections on respondents, including through the use of automated collection techniques or other forms of information technology; and

(e) Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

IV. Redesignation Tables

Subject	Current rule	Final rule
Electronic Notice for Securities Transactions	12 CFR 151.110	Removed.
Transactions with Affiliates	163.41	§ 31.3.
Loans by savings associations to their executive officers, directors and principal shareholders	163.43	§ 31.2.
Management and Financial Policies	163.161	Removed.
Periodic Reports	12 CFR 163.180(a)	Removed.
Notification of Loss and Reports of Increase in Deductible Amount of Bond	12 CFR 163.180(c)	§ 7.2013.
Bonds for Directors, Officers, Employees, and Agents; Form of and Amount of Bonds	12 CFR 163.190	§ 7.2013.
Bonds for Agents	12 CFR 163.191	§ 7.2013.
Accounting Requirements	12 CFR part 193	Removed.
Securities of Federal Savings Associations	12 CFR part 194	12 CFR part 11.
Requirements under certain sections of the Securities Exchange Act of 1934	§ 194.1	§ 11.2, § 11.3, § 11.4.
Liability for certain statements by Federal savings associations	§ 194.3.	
Form and content of financial statements	§ 194.210	§ 11.2.
Application of this subpart	§ 194.801.	
Description of business	§ 194.802.	
Securities Offerings	12 CFR part 197	12 CFR part 16.
Definitions	§ 197.1	§ 16.2.
Offering circular requirement	§ 197.2(a)	§ 16.3(a).ROW≤
—In General.		
—Communications not deemed an offer	§ 197.2(b)	§ 16.4.
—Preliminary offering circular	§ 197.2(c)	§ 16.3(b).
Exemptions	§ 197.3	§ 16.5.
Non-public offering	§ 197.4	§ 16.7.
Filing and signature requirements	§ 197.5	§ 16.17.
Effective date	§ 197.6	§ 16.16.
Form, content, and accounting	§ 197.7	§ 16.15.
Use of the offering circular	§ 197.8	§ 16.18.
Escrow requirement	§ 197.9	§ 16.31.
Unsafe or unsound practices	§ 197.10	§ 16.32.
Withdrawal or abandonment	§ 197.11	§ 16.19.
Securities sale report	§ 197.12	
Public disclosure and confidential treatment	§ 197.13	§ 16.17(f).
Waiver	§ 197.14.	
Requests for interpretive advice or waiver	§ 197.15	§ 16.30.
Delayed or continuous offering and sale of securities	§ 197.16.	
Sales of securities at an office of a savings association	§ 197.17	§ 16.10.
Current and periodic reports	§ 197.18.	
Approval of the security	§ 197.19.	
Filing of copies of offering circulars in certain exempt offerings	§ 197.21.	
Form for Securities Sale Report (Appendix A)	§ 197, Appendix A.	

List of Subjects

12 CFR Part 5

Administrative practice and procedure, Federal savings associations, National banks, Reporting and recordkeeping requirements, Securities.

12 CFR Part 7

Computer technology, Credit, Insurance, Investments, Federal savings associations, National banks, Reporting and recordkeeping requirements, Securities, Surety bonds.

12 CFR Part 8

Assessments, National banks, Reporting and recordkeeping requirements, Savings associations.

12 CFR Part 9

Estates, Investments, National banks, Reporting and recordkeeping requirements, Trusts and trustees.

12 CFR Part 10

Federal savings associations, National banks, Reporting and recordkeeping requirements, Securities.

12 CFR Part 11

Confidential business information, Federal savings associations, National banks, Reporting and recordkeeping requirements, Securities.

12 CFR Part 12

National banks, Reporting and recordkeeping requirements, Securities.

12 CFR Part 16

Federal savings associations, National banks, Reporting and recordkeeping requirements, Securities.

12 CFR Part 18

National banks, Reporting and recordkeeping requirements.

12 CFR Part 31

Credit, Federal savings associations, National banks, Reporting and recordkeeping requirements.

12 CFR Part 150

Administrative practice and procedure, Reporting and recordkeeping requirements, Federal savings associations, Trusts and trustees.

12 CFR Part 151

Reporting and recordkeeping requirements, Federal savings associations, Securities, Trusts and trustees.

12 CFR Part 155

Accounting, Consumer protection, Electronic funds transfers, Reporting and recordkeeping requirements, Federal savings associations.

12 CFR Part 162

Accounting, Reporting and recordkeeping requirements, Federal savings associations.

12 CFR Part 163

Accounting, Administrative practice and procedure, Advertising, Conflict of interests, Crime, Currency, Investments, Mortgages, Reporting and recordkeeping requirements, Savings associations, Securities.

12 CFR Part 193

Accounting, Federal savings associations, Securities.

12 CFR Part 194

Authority delegations (Government agencies), Reporting and recordkeeping requirements.

12 CFR Part 197

Reporting and recordkeeping requirements, Federal savings associations, Securities.

For the reasons set forth in the preamble, and under the authority of 12 U.S.C. 93a and 5412(b)(2)(B), chapter I of title 12 of the Code of Federal Regulations is amended as follows:

PART 5—RULES, POLICIES, AND PROCEDURES FOR CORPORATE ACTIVITIES

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

Authority: 12 U.S.C. 1 *et seq.,* 24a, 93a, 215a–2, 215a–3, 481, 1462a, 1463, 1464, 2901 *et seq.,* 3907, and 5412(b)(2)(B).

§ 5.8 [Amended]

■ 2. Section 5.8 is amended in paragraph (b) by:
■ a. Adding the phrase ''(if known at the time of publication of the notice)'' after the phrase ''the closing date of the public comment period''; and
■ b. Adding the phrase ''that the public may find information about the filing (including the closing date of the comment period) in the OCC's Weekly Bulletin available at *www.occ.gov,*'' before the phrase ''and any other information that the OCC requires''.

■ 3. Section 5.20 is amended by:
■ a. Adding a sentence at the end of paragraph (b);
■ b. Adding a sentence at the end of paragraph (c);
■ c. Redesignating the text in paragraph (l) as paragraph (l)(1) and adding a heading to newly redesignated paragraph (l)(1); and
■ d. Adding paragraph (l)(2).

The revisions and additions read as follows:

§ 5.20 Organizing a national bank or Federal savings association.

* * * * *

(b) * * * An existing national bank or Federal savings association desiring to change the purpose of its charter shall submit an application and obtain prior OCC approval.

(c) * * * This section also describes the requirements for an existing national bank or Federal savings association to change the purpose of its charter and refers such institutions to § 5.53 for the procedures to follow.

* * * * *

(l) *Special purpose institutions*—(1) *In general.* * * *

(2) *Changes in charter purpose.* An existing national bank or Federal savings association whose activities are limited to a special purpose that desires to change to another special purpose, to add another special purpose, or to no longer be limited to a special purpose charter shall submit an application and obtain prior OCC approval under § 5.53. An existing national bank or Federal savings association whose activities are not limited that desires to limit its activities and become a special purpose institution shall submit an application and obtain prior OCC approval under § 5.53.

§ 5.21 [Amended]

■ 4. Section 5.21 is amended by:
■ a. In paragraph (j)(3)(i)(B), removing the phrase ''paragraph (j)(2)'' and adding in its place the phrase ''paragraph (j)(3)'';
■ b. In paragraph (j)(3)(ii), removing the phrase ''paragraph (j)(2)(i)(A)'' and adding in its place the phrase ''paragraph (j)(3)(i)(A)'';
■ c. In paragraph (j)(3)(iii):
■ i. Removing the phrase ''main office'' and adding in its place the phrase ''home office''; and
■ ii. Removing the phrase ''paragraph (j)(2)(i)(A)'' wherever it appears and adding in its place the phrase ''paragraph (j)(3)(i)(A)''; and
■ d. In paragraph (j)(4):
■ i. Removing the phrase ''paragraph (j)(2)(ii)'' and adding in its place the phrase ''paragraph (j)(3)(ii)''; and
■ ii. Removing the phrase ''paragraph (j)(2)(i)'' and adding in its place the phrase ''paragraph (j)(3)(i)''.

§ 5.22 [Amended]

■ 5. Section 5.22 is amended in paragraph (j)(2)(iii) by removing the phrase ''main office'' and adding in its place the phrase ''home office''.

§ 5.33 [Amended]

■ 6. Section 5.33 is amended by:

■ a. In paragraph (i), removing the phrase ''the 45th day after the application is received by the OCC, or the 15th day after the close of the comment period, whichever is later,'' and adding in its place the phrase ''the 15th day after the close of the comment period,'';
■ b. In paragraph (n)(2)(iii) introductory text, removing the phrase ''mutually held savings association,'' and adding in its place the phrase ''mutually held depository institution that is insured by the FDIC,'';
■ c. In paragraph (n)(2)(iii)(B), adding the phrase ''or a similar transaction under state law'' at the end of the sentence; and
■ d. In paragraph (o)(3)(i), removing the phrase ''paragraph (n)(3)'' and adding in its place the phrase ''paragraph (o)(3)''.

§ 5.45 [Amended]

■ 7. Section 5.45 is amended in paragraph (g)(4)(i) introductory text by removing the word ''After'' and adding in its place the phrase ''If prior approval is required pursuant to this paragraph (g), after''.

■ 8. Section 5.46 is amended by adding paragraph (i)(6) to read as follows:

§ 5.46 Changes in permanent capital of a national bank.

* * * * *

(i) * * *

(6) *Exception for accounting adjustments.* (i) Changes to the permanent capital accounts that result solely from application of U.S. generally accepted accounting principles are not subject to the prior approval or notice requirements in paragraph (i)(1), (3), or (4) of this section, as applicable.

(ii) Within 30 days after the end of the quarter in which the adjustment occurred, a bank must notify the OCC if the accounting adjustment resulted in an increase or decrease to permanent capital in an amount greater than 5% of the bank's total permanent capital prior to the adjustments; or, if the bank is subject to a letter, order, directive, written agreement, or otherwise related to changes in permanent capital. The notification must include the amount and description of the adjustment, including the applicable provision of U.S. GAAP.

* * * * *

§ 5.48 [Amended]

■ 9. Section 5.48 is amended in paragraph (e)(2)(ii) by removing the word ''supervisory''.

§ 5.50 [Amended]

■ 10. Section 5.50 is amended in paragraph (f)(2)(ii)(E) by removing ''§ 192.2(a)(39)'' and adding in its place ''§ 192.25''.

■ 11. Section 5.53 is amended by:
■ a. Removing the word ''or'' at the end of paragraph (c)(1)(iii);
■ b. Removing the period at the end of paragraph (c)(1)(iv) and adding in its place ''; or''; and
■ c. Adding a paragraph (c)(1)(v); and
■ d. Revising paragraph (d)(3)(ii).

The addition and revision read as follows:

§ 5.53 Substantial asset change by a national bank or Federal savings association.

* * * * *

(c) * * *

(1) * * *

(v) Any change in the purpose of the charter of the national bank or Federal savings association as described in § 5.20(l)(2).

(d) * * *

(3) * * *

(ii) *Additional factors.* The OCC's review of any substantial asset change that involves the purchase or other acquisition or other expansions of the bank's or savings association's operations or that involves a change in the purpose of the bank's or association's charter, as described in § 5.20(l)(2), will include, in addition to the foregoing factors, the factors governing the organization of a bank or savings association under § 5.20.

* * * * *

■ 12. Section 5.66 is amended by adding a sentence between the first and second sentences to read as follows:

§ 5.66 Dividends payable in property other than cash.

* * * A national bank shall submit a request for prior approval of a noncash dividend to the appropriate OCC licensing office. * * *

PART 7—ACTIVITIES AND OPERATIONS

■ 13. The authority citation for part 7 is revised to read as follows:

Authority: 12 U.S.C. 1 *et seq.,* 25b, 29, 71, 71a, 92, 92a, 93, 93a, 95(b)(1), 371, 371d, 481, 484, 1463, 1464, 1465, 1818, 1828(m) and 5412(b)(2)(B).

■ 14. Section 7.2008 is amended by revising paragraphs (b) and (c) to read as follows:

§ 7.2008 Oath of directors.

* * * * *

(b) *Execution of the oath.* Each director shall execute either a joint or individual oath at the first meeting of the board of directors that the director attends after the director is appointed or elected. A director shall take another oath upon re-election, notwithstanding uninterrupted service. Appropriate sample oaths may be found in the Charter Booklet of the Comptroller's Licensing Manual available at *www.occ.gov.*

(c) *Filing and recordkeeping.* A national bank must file the original executed oaths of directors with the appropriate OCC licensing office, as defined in 12 CFR 5.3(c), and retain a copy in the bank's records.

■ 15. Section 7.2013 is amended by:
■ a. Revising paragraph (a) and paragraph (b) introductory text; and
■ b. In paragraph (b)(4), by adding the phrase ''or savings association'' after the word ''bank''.

The revisions read as follows:

§ 7.2013 Fidelity bonds covering officers and employees.

(a) *Adequate coverage.* All officers and employees of a national bank or Federal savings association must have adequate fidelity bond coverage. The failure of directors to require bonds with adequate sureties and in sufficient amount may make the directors liable for any losses that the bank or savings association sustains because of the absence of such bonds. Directors should not serve as sureties on such bonds. Directors should consider whether agents who have access to assets of the bank or savings association should also have fidelity bond coverage.

(b) *Factors.* The board of directors of the national bank or Federal savings association, or a committee thereof, must determine the amount of such coverage, premised upon a consideration of factors, including:

* * * * *

PART 8—ASSESSMENT OF FEES

■ 16. The authority citation for part 8 is revised to read as follows:

Authority: 12 U.S.C. 16, 93a, 481, 482, 1467, 1831c, 1867, 3102, 3108, and 5412(b)(2)(B); and 15 U.S.C. 78c and 78*l.*

■ 17. Section 8.6 is amended by revising paragraph (c)(3)(iv) to read as follows:

§ 8.6 Fees for special examinations and investigations.

* * * * *

(c) * * *

(3) * * *

(iv) *Full-service Federal savings association* is a Federal savings association that generates more than 50% of its interest and non-interest income from activities other than credit card operations or trust activities and is authorized according to its charter to engage in all types of activities

permissible for Federal savings associations.

* * * * *

PART 9—FIDUCIARY ACTIVITIES OF NATIONAL BANKS

■ 18. The authority citation for part 9 continues to read as follows:

Authority: 12 U.S.C. 24 (Seventh), 92a, and 93a; 15 U.S.C. 78q, 78q–1, and 78w.

■ 19. Section 9.13 is amended by adding a sentence at the end of paragraph (a) to read as follows:

§ 9.13 Custody of fiduciary assets.

(a) * * * A bank that is deemed a fiduciary based solely on its capacity as investment advisor, as that capacity is defined in § 9.101(a), and has no other fiduciary capacity as enumerated in § 9.2(e) is not required to serve as custodian when offering those fiduciary services.

* * * * *

§ 9.14 [Amended]

■ 20. Section 9.14 is amended in paragraph (a) by adding the phrase ''or Federal Home Loan Bank'' after the phrase ''with the Federal Reserve Bank''.

■ 21. Section 9.18 is amended:

■ a. In paragraph (b)(1) by revising the second sentence; and

■ b. In paragraph (c)(2) by:

■ i. Removing ''$1,000,000'' and adding in its place ''$1,500,000''; and

■ ii. Adding a sentence at the end.

The revision and addition reads as follows:

§ 9.18 Collective investment funds.

* * * * *

(b) * * *

(1) * * * The bank shall make a copy of the Plan available either for public inspection at its main office during all banking hours or on its Web site and shall provide a written or electronic copy of the Plan to any person who requests it. * * *

* * * * *

(c) * * *

(2) * * * The OCC shall adjust this $1,500,000 threshold amount on January 1 of every year by the percentage increase in the Consumer Price Index for Urban Wage Earners and Clerical Workers (CPI–W) that was in effect on the preceding June 1, rounded to the nearest $100 increment, and make this adjusted amount available to the public.

* * * * *

PART 10—MUNICIPAL SECURITIES DEALERS

■ 22. The authority citation for part 10 is revised to read as follows:

Authority: 12 U.S.C. 93a, 481, 1462a, 1463, 1464(c), 1818, and 5412(b)(2)(B); 15 U.S.C. 78o–4(c)(5) and 78q–78w.

■ 23. Amend § 10.1 by:

■ a. Adding the phrase ''or Federal savings association'' after the word ''bank'', wherever it appears;

■ b. In paragraph (b), removing the phrase ''to be'' and adding in its place the phrase ''will be'';

■ c. In paragraph (b), removing footnote 1; and

■ d. Adding a sentence at the end of paragraph (b).

The addition reads as follows.

§ 10.1 Scope.

* * * * *

(b) * * * MSRB rules may be obtained at *www.msrb.org.*

§ 10.2 [Amended]

■ 24. Amend § 10.2 by:

■ a. In paragraph (a):

■ i. Adding ''or Federal savings association'' after the phrase ''national bank'', wherever it appears; and

■ ii. Removing the phrase ''Rule G–7(b)(i)–(x)'' and adding in its place the phrase ''Rule G–7(b)'';

■ b. In paragraph (b):

■ i. Removing the word ''must'' and adding in its place the phrase ''or Federal savings association shall''; and

■ ii. Removing the phrase ''the bank as a municipal'' and adding in its place the phrase ''the national bank or Federal savings association as a municipal''; and

■ c. In paragraph (c), removing the phrase ''by contacting the OCC at 400 7th Street, SW., Washington, DC 20219, Attention: Bank Dealer Activities'' and adding in its place ''at *http://www.banknet.gov/*''.

PART 11—SECURITIES EXCHANGE ACT DISCLOSURE RULES

■ 25. The authority citation for part 11 is revised to read as follows:

Authority: 12 U.S.C. 93a, 1462a, 1463, 1464 and 5412(b)(2)(B); 15 U.S.C. 78j–1(m), 78m, 78n, 78p, 78w, 78l, 7241, 7242, 7243, 7244, 7261, 7262, 7264, and 7265.

■ 26. Section 11.1 is revised to read as follows:

§ 11.1 Authority.

The Office of the Comptroller of the Currency (OCC) is vested with the powers, functions, and duties otherwise vested in the Securities and Exchange Commission (SEC) to administer and enforce the provisions of sections 10A(m), 12, 13, 14(a), 14(c), 14(d), 14(f), and 16 of the Securities Exchange Act of 1934, as amended (Exchange Act) (15 U.S.C. 78j–1(m), 78l, 78m, 78n(a), 78n(c), 78n(d), 78n(f), and 78p), and sections 302, 303, 304, 306, 401(b), 404, 406, and 407 of the Sarbanes-Oxley Act of 2002 (Sarbanes-Oxley Act), as amended (15 U.S.C. 7241, 7242, 7243, 7244, 7261, 7262, 7264, and 7265), for national banks and Federal savings associations with one or more classes of securities subject to the registration provisions of sections 12(b) and (g) of the Exchange Act (registered national banks or registered Federal savings associations). Further, the OCC has general rulemaking authority under 12 U.S.C. 93a, 1462a, 1463, and 1464, to promulgate rules and regulations concerning the activities of national banks and Federal savings associations.

■ 27. Section 11.2 is revised to read as follows:

§ 11.2 Reporting requirements for registered national banks and Federal savings associations.

(a) *Filing, disclosure and other requirements*—(1) *General.* Except as otherwise provided in this section, a national bank or Federal savings association whose securities are subject to registration pursuant to section 12(b) or section 12(g) of the Exchange Act (15 U.S.C. 78l(b) and (g)) shall comply with the rules, regulations, and forms adopted by the SEC pursuant to:

(i) Sections 10A(m), 12, 13, 14(a), 14(c), 14(d), 14(f), and 16 of the Exchange Act (15 U.S.C. 78j–1(m), 78l, 78m, 78n(a), (c), (d) and (f), and 78p); and

(ii) Sections 302, 303, 304, 306, 401(b), 404, 406, and 407 of the Sarbanes-Oxley Act (codified at 15 U.S.C. 7241, 7242, 7243, 7244, 7261, 7262, 7264, and 7265).

(2) [Reserved]

(b) *References to the Securities Exchange Commission, SEC, or Commission.* Any references to the ''Securities and Exchange Commission,'' the ''SEC,'' or the ''Commission'' in the rules, regulations and forms described in paragraph (a)(1) of this section with respect to securities issued by registered national banks or registered Federal savings associations shall be deemed to refer to the OCC unless the context otherwise requires.

(c) *References to registration requirements.* For national banks and Federal savings associations, any references to registration requirements under the Securities Act of 1933 and its accompanying rules in the rules, regulations, and forms described in paragraph (a)(1) of this section mean the

registration requirements in 12 CFR part 16.

(d) *Emerging growth company eligibility*—(1) *General.* A national bank or Federal savings association that meets the criteria to qualify as an emerging growth company under section 3(a)(80) of the Exchange Act (15 U.S.C. 78c(a)(80)) shall be eligible for treatment as an emerging growth company for purposes of any rule, regulation or form described in paragraph (a)(1) of this section, except as provided in paragraph (d)(3) of this section.

(2) *Opt-in right.* With respect to an exemption provided to a national bank or Federal savings association that is an emerging growth company under this part, the bank or savings association may choose to forgo such exemption and instead comply with the requirements that apply to a bank or savings association that is not an emerging growth company.

(3) *Exclusions.* A national bank or Federal savings association that otherwise meets the definition of emerging growth company in section 3(a)(80) of the Exchange Act (15 U.S.C. 78c(a)(80)) shall not be considered an emerging growth company for purposes of this part if:

(i) The first sale of its common equity securities pursuant to an effective registration statement or offering circular occurred on or before December 8, 2011; or

(ii) It has reached the last day of its fiscal year following the fifth anniversary of the date of the first sale of its common equity securities pursuant to an effective registration statement or offering circular.

■ 28. Section 11.3 is amended by:

■ a. Revising paragraphs (a)(1) and (a)(3)(i) and the heading to paragraph (a)(3)(ii);

■ b. Adding a paragraph (a)(3)(iii);

■ c. Removing paragraph (a)(4); and

■ d. Removing the phrase ‘‘, at the address listed in paragraph (a) of this section’’ in paragraph (b) and adding in its place the phrase ‘‘, at the address listed on *www.occ.gov.*’’.

The revisions read as follows:

§ 11.3 Filing requirements and inspection of documents.

(a) *Filing requirements*—(1)(i) *In general.* Except as otherwise provided in this section, all papers required to be filed with the OCC pursuant to the Exchange Act or regulations thereunder shall be submitted to the Securities and Corporate Practices Division of the OCC electronically at *http://www.banknet.gov/.* Documents may be signed electronically using the signature provision in SEC Rule 12b–11 (17 CFR 240.12b–11).

(ii) *Electronic filing exception.* If a national bank or Federal savings association experiences unanticipated technical difficulties preventing the timely preparation and submission of an electronic filing, other than the filings described in paragraph (a)(3)(ii) of this section, the bank may, upon notice to the OCC's Securities and Corporate Practices Division, file the subject filing in paper format no later than one business day after the date on which the filing was to be made. Paper filings should be submitted to the Securities and Corporate Practices Division, Office of the Comptroller of the Currency at the address provided at *www.occ.gov.*

* * * * *

(3) *Date of filing*—(i) *General.* The date of filing is the date the OCC receives the filing, provided the person, bank, or savings association submitting the filing has complied with all applicable requirements. An electronic filing that is submitted on a business day by direct transmission commencing on or before 5:30 p.m. Eastern Standard or Daylight Savings Time, whichever is currently in effect, would be deemed received by the OCC on the same business day. An electronic filing that is submitted by direct transmission commencing after 5:30 p.m. Eastern Standard or Daylight Savings Time, whichever is currently in effect, or on a Saturday, Sunday, or Federal holiday, would be deemed received by the OCC on the next business day.

(ii) *Beneficial ownership filings.*

* * *

(iii) *Adjustment of filing date.* If an electronic filer in good faith attempts to file a document pursuant to this part in a timely manner but the filing is delayed due to technical difficulties beyond the electronic filer's control, the electronic filer may request that the OCC adjust the filing date of such document. The OCC may grant the request if it appears that such adjustment is appropriate and consistent with the public interest and the protection of investors.

* * * * *

■ 29. Section 11.4 is amended by revising paragraph (b) to read as follows:

§ 11.4 Filing fees.

* * * * *

(b) Fees must be paid by check payable to the Comptroller of the Currency or by other means acceptable to the OCC.

PART 12—RECORDKEEPING AND CONFIRMATION REQUIREMENTS FOR SECURITIES TRANSACTIONS

■ 30. The authority citation for part 12 continues to read as follows:

Authority: 12 U.S.C. 24, 92a, and 93a.

§ 12.1 [Amended]

■ 31. Section 12.1 is amended:

■ a. In paragraph (c)(1) by removing the phrase ‘‘Securities and Exchange Commission’’ and adding in its place the phrase ‘‘Securities and Exchange Commission (SEC)’’; and

■ b. By removing the phrase ‘‘Securities and Exchange Commission’’ in paragraph (c)(2)(iii) and the phrase ‘‘Securities and Exchange Commission (SEC)’’ in paragraph (c)(2)(v) and adding ‘‘SEC’’ in their place.

■ 32. Section 12.2 is amended by:

■ a. In paragraph (g)(3), removing the phrase ‘‘Securities and Exchange Commission’’ and adding in its place ‘‘SEC’’; and

■ b. Revising paragraph (i)(3).

The revision reads as follows.

§ 12.2 Definitions.

* * * * *

(i) * * *

(3) A security that is an industrial development bond.

* * * * *

■ 33. Section 12.3 is amended by adding a sentence at the end of paragraph (b) to read as follows:

§ 12.3 Recordkeeping.

* * * * *

(b) * * * A national bank may contract with a third-party service provider to maintain the records, provided that the bank maintains effective oversight of the third-party service provider to ensure the records meet the requirements of this section.

■ 34. Section 12.4 is amended by revising paragraph (b) to read as follows:

§ 12.4 Content and time of notification.

* * * * *

(b) *Copy of the registered broker/dealer's confirmation.* A copy of the confirmation of a registered broker/dealer relating to the securities transaction, which the bank may direct the registered broker/dealer to send directly to the customer; and, if the customer or any other source will provide remuneration to the bank in connection with the transaction and a written agreement between the bank and the customer does not determine the remuneration, a statement of the source and amount of any remuneration that the customer or any other source is to provide the bank.

§ 12.7 [Amended]

■ 35. Section 12.7(d) is amended by removing the phrase ''Securities and Exchange Commission (SEC)'' adding in its place ''SEC''.

§ 12.9 [Amended]

■ 36. Section 12.9(b)(2) is amended by removing the phrase ''Securities and Exchange Commission (SEC)'' and adding in their place ''SEC''.

§§ 12.101 through 12.102 [Removed]

■ 37. The undesignated center heading ''Interpretations'' and §§ 12.101 and12.102 are removed.

PART 16—SECURITIES OFFERING DISCLOSURE RULES

■ 38. The authority citation for part 16 is revised to read as follows:

Authority: 12 U.S.C. 1 *et seq.,* 93a, 1462a, 1463, 1464, and 5412(b)(2)(B).

■ 39. Section 16.1 is amended by:
■ a. Revising paragraph (a); and
■ b. In paragraphs (b) and (c), removing the word ''bank'' wherever it appears and adding in its place the phrase ''national bank or Federal savings association''.

The revision reads as follows:

§ 16.1 Authority, purpose, and scope.

(a) *Authority.* This part is issued under the rulemaking authority of the Comptroller of the Currency (OCC) for national banks in 12 U.S.C. 1 *et seq.,* and 93a, and for Federal savings associations in 12 U.S.C. 1462a, 1463, 1464, and 5412(b)(2)(B).

* * * * *

■ 40. Section 16.2 is amended by:
■ a. In paragraph (a), removing the phrase ''Commission Rule'' and adding in its place ''SEC Rule'';
■ b. Removing paragraphs (b), (c), and (j) and redesignating paragraphs (d) through (f) as paragraphs (b) through (d), respectively; redesignating paragraphs (g) and (h) as paragraphs (f) and (g), respectively; and redesignating paragraphs (k) through (n) as paragraphs (j) through (m), respectively;
■ c. In newly designated paragraph (b), removing ''2(12)'' and ''77b(12))'' and adding ''2(a)(12)'' and ''77b(a)(12))'', respectively, in their places;
■ d. In newly redesignated paragraph (c), removing ''78a through 78jj'' and adding ''78a *et seq.*'' in its place;
■ e. Adding new paragraphs (e), (h), and (n);
■ f. In newly redesignated paragraph (g) and paragraph (i), removing the word ''bank'' and adding in its place the phrase ''national bank or Federal savings association'';
■ g. In newly redesignated paragraph (j):
■ i. Removing ''2(2)'' and ''77b(2))'' and adding ''2(a)(2)'' and ''77b(a)(2))'', respectively, in their places; and
■ ii. Removing the word ''bank'' and adding in its place the phrase ''national bank and a Federal savings association'';
■ h. In newly redesignated paragraph (m), removing ''2(3)'' and ''77b(3))'' and adding ''2(a)(3)'' and ''77b(a)(3))'', respectively, in their places;
■ i. In paragraph (o), removing ''through 77aa'' and adding ''*et seq.*'' in its place;
■ j. In paragraph (p), removing ''2(1)'' and ''77b(1))'' and adding ''2(a)(1)'' and ''77b(a)(1))'', respectively, in their places; and
■ k. In paragraph (q):
■ i. Removing ''77b(11))'' and adding ''77b(a)(11))'' in its place;
■ ii. Removing ''2(11)'' wherever it appears and adding ''2(a)(11)'' in its place; and
■ iii. Removing the phrase ''Commission Rules'' and adding in its place ''SEC Rules''.

The additions read as follows:

§ 16.2 Definitions.

* * * * *

(e) *Federal savings association* means an existing Federal savings association chartered under section 5 of the Home Owners' Loan Act (HOLA) (12 U.S.C. 1464 *et seq.*) or a Federal savings association in organization.

* * * * *

(h) *National bank* means an existing national bank, a national bank in organization, or a Federal branch or agency of a foreign bank.

* * * * *

(n) *SEC* means the Securities and Exchange Commission. When used in the rules, regulations, or forms of the SEC referred to in this part, the term ''SEC'' shall be deemed to refer to the OCC.

* * * * *

§ 16.3 [Amended]

■ 41. Section 16.3 is amended by:
■ a. In paragraphs (a) introductory text and (b) introductory text, removing the word ''bank'' and adding in its place the phrase ''national bank or Federal savings association''; and
■ b. In paragraph (c):
■ i. Removing ''Commission Rule'' and adding in its place ''SEC Rule'';
■ ii. Removing the citation ''section 4(3)'' and adding in its place the citation ''section 4(a)(3)''; and
■ iii. Removing the word ''bank'' and adding in its place the phrase ''national bank and Federal savings association''.

§ 16.4 [Amended]

■ 42. Section 16.4 is amended by removing the phrase ''Commission Rule'' and adding in its place the phrase ''SEC Rule'' wherever it occurs.

■ 43. Section 16.5 is amended by:
■ a. Revising the introductory text and paragraphs (a), (b), and (e);
■ b. In paragraph (f), removing the phrase ''Commission Rule'' and adding in its place the phrase ''SEC Rule''; and
■ c. In paragraph (g), removing the phrase ''Commission Regulation'' and adding in its place the phrase ''SEC Regulation''.

The revisions read as follows.

§ 16.5 Exemptions.

The registration statement and prospectus requirements of § 16.3 do not apply to an offer or sale of national bank or Federal savings association securities:

(a) If the securities are exempt from registration under section 3 of the Securities Act (15 U.S.C. 77c), but only by reason of an exemption other than section 3(a)(2) (exemption for bank securities), section 3(a)(5) (exemption for savings association securities), section 3(a)(11) (exemption for intrastate offerings), and section 3(a)(12) (exemption for bank holding company formation) of the Securities Act.

(b) In a transaction exempt from registration under section 4 of the Securities Act (15 U.S.C. 77d). SEC Rules 152 and 152a (17 CFR 230.152 and 230.152a) (which apply to sections 4(a)(2) and 4(a)(1) of the Securities Act) apply to this part;

* * * * *

(e) In a transaction that satisfies the requirements of SEC Rule 144, 144A, or 236 (17 CFR 230.144, 230.144A, or 230.236);

* * * * *

■ 44. Section 16.6 is amended by:
■ a. In paragraph (a) introductory text, removing the word ''bank'' and adding in its place the phrase ''national bank or Federal savings association'';
■ b. Revising paragraphs (a)(1) and (5);
■ c. In paragraph (a)(3), removing the word ''bank'' and adding in its place the phrase ''national bank or Federal savings association''; and
■ d. In paragraph (b), removing the phrase ''Commission Rule'' and adding in its place the phrase ''SEC Rule'', wherever it appears.

The revisions read as follows:

§ 16.6 Sales of nonconvertible debt.

(a) * * *

(1) The national bank or Federal savings association issuing the debt has securities registered under the Exchange Act or is a subsidiary of a holding

company that has securities registered under the Exchange Act;

* * * * *

(5) Prior to or simultaneously with the sale of the debt, each purchaser receives an offering document that contains a description of the terms of the debt, the use of proceeds, and method of distribution, and incorporates the national bank's or Federal savings association's latest Consolidated Reports of Condition and Income (Call Report) and the national bank's, Federal savings association's, or the holding company's Forms 10–K, 10–Q, and 8–K (17 CFR part 249) filed under the Exchange Act; and

* * * * *

§ 16.7 [Amended]

■ 45. Section 16.7 is amended by:
■ a. Removing the phrase ''Commission Regulation'' and adding in its place the phrase ''SEC Regulation'', wherever it appears;
■ b. In paragraphs (a) introductory text, removing the word ''bank'' and adding in its place the phrase ''national bank or Federal savings association'';
■ c. In paragraph (b):
■ i. Removing the word ''bank'' and adding in its place the phrase ''national bank or Federal savings association''; and
■ ii. Removing the phrase ''Commission Rule'' and adding in its place the phrase ''SEC Rule''; and
■ d. In paragraph (c), removing the word ''bank'' and adding in its place the phrase ''national bank or Federal savings association''.

§ 16.8 [Amended]

■ 46. Section 16.8 is amended:
■ a. By removing the phrase ''Commission Regulation'' and adding in its place the phrase ''SEC Regulation'', wherever it appears;
■ b. In paragraph (a), by removing the word ''bank'' and adding in its place the phrase ''national bank or Federal savings association''; and
■ c. In paragraph (b), by removing the word ''Commission's'' and adding in its place the word ''SEC's''.

■ 47. Section 16.9 is amended by:
■ a. Revising paragraph (a); and
■ b. In the introductory text and paragraphs (b) through (d), removing the word ''bank'' and adding in its place the phrase ''national bank or Federal savings association'', wherever it appears.

The revision reads as follows:

§ 16.9 Securities offered and sold in holding company dissolution.

* * * * *

(a) The offer and sale of national bank or Federal savings association issued securities occurs solely as part of a dissolution in which the security holders exchange their shares of stock in a holding company that had no significant assets other than securities of the bank or savings association, for bank or savings association stock;

* * * * *

■ 48. Section 16.10 is added to read as follows:

§ 16.10 Sales of securities at an office of a Federal savings association.

Sales of securities of a Federal savings association or its affiliates at an office of a Federal savings association may be made only in accordance with the provisions of 12 CFR 163.76. For the purpose of this section, ''affiliate'' has the same meaning as in 12 CFR 161.4.

§ 16.15 [Amended]

■ 49. Section 16.15 is amended by:
■ a. In paragraph (a):
■ i. Removing the word ''Commission's'' and adding in its place the word ''SEC's'';
■ ii. Removing the phrase ''Commission regulations'' and adding in its place the phrase ''SEC regulations''; and
■ iii. Removing the word ''bank'' and adding in its place the phrase ''national bank or Federal savings association'';
■ b. In paragraph (b), removing the phrase ''Commission Regulation'' and adding in its place the phrase ''SEC Regulation'';
■ c. In paragraph (d), removing the word ''bank'' and adding in its place the phrase ''national bank or Federal savings association''; and
■ d. In paragraph (e), adding the phrase ''or Federal savings association'' after the word ''bank'', wherever it appears.

§ 16.16 [Amended]

■ 50. Section 16.16 is amended in paragraph (a) by removing the phrase ''Commission Regulation'' and adding in its place the phrase ''SEC Regulation''.

■ 51. Section 16.17 is revised to read as follows:

§ 16.17 Filing requirements and inspection of documents.

(a) Except as otherwise provided in this section, all registration statements, offering documents, amendments, notices, or other documents must be filed with the OCC's Securities and Corporate Practices Division electronically at *http://www.banknet.gov/.* Documents may be signed electronically using the signature provision in SEC Rule 402 (17 CFR 230.402).

(b) All registration statements, offering documents, amendments, notices, or other documents relating to a national bank or Federal savings association in organization must be filed with the appropriate district office of the OCC at *http://www.banknet.gov/.*

(c) Where this part refers to a section of the Securities Act or the Exchange Act or an SEC rule that requires the filing of a notice or other document with the SEC, that notice or other document must be filed with the OCC.

(d) Provided the person filing the document has complied with all requirements regarding the filing, including the submission of any fee required under § 16.33, the date of filing of the document is the date the OCC receives the filing. An electronic filing that is submitted on a business day by direct transmission commencing on or before 5:30 p.m. Eastern Standard or Daylight Savings Time, whichever is currently in effect, would be deemed received by the OCC on the same business day. An electronic filing that is submitted by direct transmission commencing after 5:30 p.m. Eastern Standard or Daylight Savings Time, whichever is currently in effect, or on a Saturday, Sunday, or Federal holiday, would be deemed received by the OCC on the next business day. If an electronic filer in good faith attempts to file a document with the OCC in a timely manner but the filing is delayed due to technical difficulties beyond the electronic filer's control, the electronic filer may request that the OCC adjust the filing date of such document. The OCC may grant the request if it appears that such adjustment is appropriate and consistent with the public interest and the protection of investors.

(e) Notwithstanding paragraph (d) of this section, any registration statement or any post-effective amendment thereto filed pursuant to SEC Rule 462(b) (17 CFR 230.462(b)) shall be deemed received by the OCC on the same business day if its submission commenced on or before 10 p.m. Eastern Standard Time or Eastern Daylight Savings Time, whichever is currently in effect, and on the next business day if its submission commenced after 10 p.m. Eastern Standard or Daylight Savings Time, whichever is currently in effect, or any time on a Saturday, Sunday, or Federal holiday.

(f) If a national bank or Federal savings association experiences unanticipated technical difficulties preventing the timely preparation and submission of an electronic filing, the bank or savings association may, upon notice to the OCC's Securities and

Corporate Practices Division or district office, as appropriate, file the subject filing in paper format no later than one business day after the date on which the filing was to be made. Paper filings should be submitted to the OCC's Securities and Corporate Practices Division or appropriate district office, at the address provided at *www.occ.gov.*

(g) Any filing of amendments or revisions must include two copies, one of which must be marked to indicate clearly and precisely, by underlining or in some other appropriate manner, the changes made.

(h) The OCC will make available for public inspection copies of the registration statements, offering documents, amendments, exhibits, notices or reports filed pursuant to this part at the address identified in § 4.14 of this chapter.

■ 52. Section 16.30 is amended by revising paragraph (a) to read as follows:

§ 16.30 Request for interpretive advice or no-objection letter.

* * * * *

(a) File a copy of the request, including any supporting attachments, with the OCC's Securities and Corporate Practices Division at the address provided at *www.occ.gov;*

* * * * *

■ 53. Section 16.32 is amended:

■ a. By revising the section heading;

■ b. In paragraphs (a) introductory text and (a)(3), removing the word ''bank'' and adding in its place the phrase ''national bank or Federal savings association''; and

■ c. In paragraph (d), removing the phrase ''Commission Rule'' and adding in its place the phrase ''SEC Rule''.

The revision reads as follows.

§ 16.32 Fraudulent transactions and unsafe or unsound practices.

* * * * *

■ 54. Section 16.33 is revised to read as follows:

§ 16.33 Filing fees.

(a) The OCC may require filing fees to accompany certain filings made under this part before it will accept those filings. The OCC provides an applicable fee schedule in the *Notice of Comptroller of the Currency Fees* published pursuant to § 8.8 of this chapter.

(b) Filing fees must be paid by check payable to the Comptroller of the Currency or by other means acceptable to the OCC.

PART 18 [REMOVED]

■ 55. Remove part 18.

PART 31—EXTENSIONS OF CREDIT TO INSIDERS AND TRANSACTIONS WITH AFFILIATES

■ 56. The authority citation for part 31 is revised to read as follows:

Authority: 12 U.S.C. 93a, 375a(4), 375b(3), 1463, 1467a(d), 1468, 1817(k), and 5412(b)(2)(B).

■ 57. Section 31.1 is revised to read as follows:

§ 31.1 Authority.

This part is issued pursuant to 12 U.S.C. 93a, 375a(4), 375b(3), 1463, 1467a(d), 1468, 1817(k), and 5412(b)(2)(B), as amended.

§ 31.2 [Amended]

■ 58. Section 31.2 is amended by:

■ a. In paragraph (a):

■ i. Removing the phrase ''A national bank and its'' and adding in its place the phrase ''National banks, Federal savings associations, and their''; and

■ ii. Adding ''(Regulation O)'' to the end of the sentence; and

■ b. In paragraph (b), adding '', Federal savings associations,'' after the word ''banks''.

■ 59. Add § 31.3 to read as follows:

§ 31.3 Affiliate transactions requirements.

(a) *General rule.* National banks and Federal savings associations shall comply with the provisions contained in 12 CFR part 223 (Regulation W).

(b) *Enforcement.* The Comptroller of the Currency administers and enforces affiliate transactions requirements as they apply to national banks and Federal savings associations.

(c) *Standard for exemptions.* The OCC may, by order, exempt transactions or relationships of a national bank or Federal savings association from the requirements of section 23A and section 11 of the Home Owners' Loan Act (HOLA), as applicable, and 12 CFR part 223 if:

(1) The OCC, jointly with the Federal Reserve Board, finds the exemption to be in the public interest and consistent with the purposes of section 23A or section 11 of the HOLA, as applicable; and

(2) The FDIC, within 60 days of receiving notice of such joint finding, does not object in writing to the finding based on a determination that the exemption presents an unacceptable risk to the Deposit Insurance Fund.

(d) *Procedures for exemptions.* A national bank or Federal savings association may request an exemption from the requirements of section 23A or section 11 of the HOLA, as applicable, and 12 CFR part 223 for a national bank or Federal savings association by submitting a written request to the Deputy Comptroller for Licensing with a copy to the appropriate Federal Reserve Bank. Such a request must:

(1) Describe in detail the transaction or relationship for which the national bank or Federal savings association seeks exemption;

(2) Explain why the OCC should exempt the transaction or relationship;

(3) Explain how the exemption would be in the public interest and consistent with the purposes of section 23A or section 11 of the HOLA, as applicable; and

(4) Explain why the exemption does not present an unacceptable risk to the Deposit Insurance Fund.

60. Appendix B to part 31 is amended by:

a. Revising the appendix heading and introductory note;

b. Removing the references ''part 31'', ''Part 31'', and ''Parts 31 and 32'' and adding in their place the references ''part 215'', ''Part 215'', and ''parts 32 and 215'', respectively, wherever they appear;

c. Under the heading ''Definition of 'Loan or Extension of Credit''', in the first sentence under ''Renewals'', removing the phrase ''will be applied in the same manner'' and adding in its place the phrase ''are equivalent''; and

d. Under the heading ''Combination/Attribution Rules'', in the fourth sentence, under ''Loans to corporate groups'', removing the word ''until'' and adding in its place the word ''unless''.

The revisions read as follows:

Appendix B to Part 31—Comparison of Selected Provisions of Parts 32 and 215

Note: This appendix compares certain provisions of 12 CFR part 32 with those of 12 CFR part 215. As used in this appendix, the term ''bank'' refers to both national banks and Federal savings associations.

* * * * *

PART 150—FIDUCIARY POWERS OF FEDERAL SAVINGS ASSOCIATIONS

■ 61. The authority citation for part 150 continues to read as follows:

Authority: 12 U.S.C. 1462a, 1463, 1464, 5412(b)(2)(B).

■ 62. Section 150.245 is added to read as follows:

§ 150.245 When is a fiduciary not required to maintain custody or control of fiduciary assets?

If you are deemed a fiduciary based solely on your capacity as investment advisor, as that capacity is defined in § 9.101(a) of this chapter, and have no other fiduciary capacity as enumerated in § 150.30, you are not required to

maintain custody or control of fiduciary assets as set forth in § 150.220 or § 150.240.

PART 151—RECORDKEEPING AND CONFIRMATION REQUIREMENTS FOR SECURITIES TRANSACTIONS

■ 63. The authority citation for part 151 continues to read as follows:

Authority: 12 U.S.C. 1462a, 1463, 1464, 5412(b)(2)(B).

■ 64. Section 151.40 is amended by revising paragraph (3) of the definition of *Municipal security* to read as follows:

§ 151.40 What definitions apply to this part?

* * * * *

Municipal security * * *

(3) A security that is an industrial development bond.

* * * * *

■ 65. Section 151.60 is revised to read as follows:

§ 151.60 How must I maintain my records?

(a) *In general.* The records required by § 151.50 must clearly and accurately reflect the information required and provide an adequate basis for the audit of the information. Record maintenance may include the use of automated or electronic records provided the records are easily retrievable, readily available for inspection, and capable of being reproduced in a hard copy.

(b) *Use of third party.* You may contract with third-party service providers to maintain the records required by this section, provided that you maintain effective oversight of the third-party vendor to ensure records meet the requirements of § 150.50 and this section.

■ 66. Revise § 151.80(b) to read as follows:

§ 151.80 How do I provide a registered broker-dealer confirmation?

* * * * *

(b) Unless you have determined remuneration in a written agreement with the customer, if you have received or will receive remuneration from any source, including the customer, in connection with the transaction, you must provide a statement of the source and amount of the remuneration in addition to the registered broker-dealer confirmation described in paragraph (a) of this section.

§ 151.110 [Removed]

■ 67. Section 151.110 is removed.

■ 68. Part 155 is revised to read as follows:

PART 155—ELECTRONIC OPERATIONS OF FEDERAL SAVINGS ASSOCIATIONS

Sec.

Authority: 12 U.S.C. 1462a, 1463, 1464, 5412(b)(2)(B).

§ 155.100 Scope.

This part describes how a Federal savings association may provide products and services through electronic means and facilities.

§ 155.200 Use of electronic means and facilities.

(a) *General.* A Federal savings association may use, or participate with others to use, electronic means or facilities to perform any function, or provide any product or service, as part of an authorized activity. Electronic means or facilities include, but are not limited to, automated teller machines, automated loan machines, personal computers, the internet, telephones, and other similar electronic devices.

(b) *Other.* To optimize the use of resources, a Federal savings association may market and sell, or participate with others to market and sell, electronic capacities and by-products to third-parties, if the savings association acquired or developed these capacities and by-products in good faith as part of providing financial services.

§ 155.210 Requirements for using electronic means and facilities.

To use electronic means and facilities under this subpart, a Federal savings association's management must:

(a) Identify, assess, and mitigate potential risks and establish prudent internal controls; and

(b) Implement security measures designed to ensure secure operations. Such measures must be adequate to:

(1) Prevent unauthorized access to the savings association's records and its customers' records;

(2) Prevent financial fraud through the use of electronic means or facilities; and

(3) Comply with applicable security devices requirements of part 168 of this chapter.

■ 69. Part 162 is revised to read as follows:

PART 162—ACCOUNTING AND DISCLOSURE STANDARDS

Sec.

Authority: 12 U.S.C. 1463, 5412(b)(2)(B).

§ 162.1 Accounting and disclosure standards.

A Federal savings association shall follow U.S. generally accepted accounting principles (GAAP) and the disclosure standards included therein when complying with all applicable regulations, unless otherwise required by statute, regulation, or the OCC.

PART 163—SAVINGS ASSOCIATIONS—OPERATIONS

■ 70. The authority citation for part 163 continues to read as follows:

Authority: 12 U.S.C. 1462a, 1463, 1464, 1467a, 1817, 1820, 1828, 1831o, 3806, 5101 *et seq.,* 5412(b)(2)(B); 31 U.S.C. 5318; 42 U.S.C. 4106.

§ 163.41 [Removed]

■ 71. Remove § 163.41.

§ 163.43 [Removed]

■ 72. Remove § 163.43.

§ 163.161 [Removed]

■ 73. Remove § 163.161.

■ 74. Section 163.172 is amended by:

■ a. In paragraph (a), revising the paragraph heading and removing the word ''commitments'' and adding the word ''contracts'' in its place;

■ b. Revising paragraph (b), the heading to paragraph (c) and paragraph (c)(1);

■ c. In paragraph (c)(2):

■ i. Removing the word ''you'' and adding in its place the phrase ''a savings association''; and

■ ii. Removing the word ''Your'' and adding in its place the word ''The'';

■ d. In paragraphs (c)(3) introductory text and (c)(4), removing the word ''Your'' wherever it appears and adding in its place the word ''The'';

■ e. In paragraph (c)(3)(ii), removing the word ''your'' and adding in its place the phrase ''the savings association's'';

■ f. Revising the heading to paragraph (d);

■ g. In paragraph (d)(1), removing the word ''Management'' and adding in its place the phrase ''The management of a Federal savings association''; and

■ h. Revising paragraph (e).

The revisions read as follows:

§ 163.172 Financial derivatives.

(a) *Definition.* * * *

(b) *Permissible financial derivatives transactions.* A Federal savings association may engage in a transaction involving a financial derivative if the savings association is authorized to invest in the assets underlying the financial derivative, the transaction is safe and sound, and the requirements in paragraphs (c) through (e) of this section are met. In general, a Federal savings

association that engages in a transaction involving a financial derivative should do so to reduce its risk exposure.

(c) *Board of directors' responsibilities.* (1) A Federal savings association's board of directors is responsible for effective oversight of financial derivatives activities.

* * * * *

(d) *Management responsibilities.*

* * *

(e) *Recordkeeping requirement.* A Federal savings association must maintain records adequate to demonstrate compliance with this section and with its board of directors' policies and procedures on financial derivatives.

§ 163.180 [Amended]

■ 75. Section 163.180 is amended by removing and reserving paragraphs (a) and (c).

§ 163.190 [Removed]

■ 76. Remove § 163.190.

§ 163.191 [Removed]

■ 77. Remove § 163.191.

PART 193 [REMOVED]

■ 78. Remove part 193.

PART 194—[REMOVED]

■ 79. Remove part 194.

PART 197 [REMOVED]

■ 80. Remove part 197.

Dated: December 13, 2016.

Thomas J. Curry,

Comptroller of the Currency.

[FR Doc. 2016–30502 Filed 1–19–17; 8:45 am]

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Part VII

The President

Executive Order 13764—Amending the Civil Service Rules, Executive Order 13488, and Executive Order 13467 To Modernize the Executive Branch-Wide Governance Structure and Processes for Security Clearances, Suitability and Fitness for Employment, and Credentialing, and Related Matters

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Presidential Documents

Title 3—

The President

Executive Order 13764 of January 17, 2017

Amending the Civil Service Rules, Executive Order 13488, and Executive Order 13467 To Modernize the Executive Branch-Wide Governance Structure and Processes for Security Clearances, Suitability and Fitness for Employment, and Credentialing, and Related Matters

By the authority vested in me as President by the Constitution and the laws of the United States of America, and as part of continuing efforts to modernize the overarching executive branch enterprise to ensure that all persons performing work for or on behalf of the Government are and continue to be loyal to the United States, reliable, trustworthy, and of good conduct and character, and by using mutually consistent standards and procedures, it is hereby ordered as follows:

Section 1. *Amendments to the Civil Service Rules.* (a) Civil Service Rule II is amended as follows:

(i) The title to 5 CFR Part 2 is revised to read as follows:

''PART 2—APPOINTMENT THROUGH THE COMPETITIVE SERVICE; RELATED MATTERS (RULE II)''

(ii) The title to 5 CFR 2.1 is revised to read as follows:

''§ 2.1 Competitive examinations and eligible registers; suitability and fitness for civil service employment.''

(iii) 5 CFR 2.1(a) is revised to read as follows:

''(a) OPM shall be responsible for:

''(i) Open competitive examinations for admission to the competitive service that will fairly test the relative capacity and fitness of the persons examined for the position to be filled.

''(ii) Standards with respect to citizenship, age, education, training and experience, physical and mental fitness, and for residence or other requirements that applicants must meet to be admitted to or rated in examinations.

''(iii) Standards of suitability based on character and conduct for appointment to a position in the competitive service, for appointment to a position in the excepted service where the incumbent can be noncompetitively converted to the competitive service, and for career appointment to a position in the Senior Executive Service.

''(iv) Minimum standards of fitness based on character and conduct for appointment in any other position in the excepted service of the executive branch, except for (A) positions in any element of the intelligence community as defined in the National Security Act of 1947, as amended, to the extent they are not otherwise subject to OPM appointing authorities, and (B) positions where OPM is statutorily precluded from prescribing such standards.''

(b) Civil Service Rule V is amended as follows:

(i) 5 CFR 5.2(a) is revised to read as follows:

''(a) Investigating the qualifications, suitability, and fitness of applicants for positions in the competitive service, positions in the excepted service where the incumbent can be noncompetitively converted to the competitive service, career appointments to positions in the Senior Executive Service,

and any other positions in the excepted service of the executive branch for which the Director has standard-setting responsibility under Civil Service Rule II.

''(i) The Director may require appointments to be made subject to investigation to enable the Director to determine, after appointment, that the requirements of law or the Civil Service Rules and Regulations have been met.

''(ii) The Director may cause positions to be designated based on risk to determine the appropriate level of investigation, and may prescribe investigative standards, policies, and procedures.

''(iii) The Director may prescribe standards for reciprocal acceptance by agencies of investigations and adjudications of suitability and fitness, except to the extent authority to apply additional fitness standards is vested by statute in an agency.''

(ii) 5 CFR 5.3(a)(1) is revised by striking ''disqualified for Federal employment'' and inserting in lieu thereof ''disqualified or unsuitable for Federal employment.''

(c) Civil Service Rule VI is amended as follows:

(i) 5 CFR 6.3(b) is revised to read as follows:

''(b) To the extent permitted by law and the provisions of this part, and subject to the suitability and fitness requirements of the applicable Civil Service Rules and Regulations, appointments and position changes in the excepted service shall be made in accordance with such regulations and practices as the head of the agency concerned finds necessary.''

Sec. 2. *Amendment to Executive Order 13488 of January 16, 2009.* (a) Section 1(a) of Executive Order 13488 is revised to read as follows:

''**Section 1**. *Policy.* (a) When agencies conduct fitness determinations, prior favorable fitness or suitability determinations shall be granted reciprocal recognition, to the extent practicable.''

(b) Section 2 of Executive Order 13488 is revised to read as follows:

''(a) 'Agency' means an executive agency as defined in section 105 of title 5, United States Code, but does not include the Government Accountability Office.

''(b) 'Contractor employee' means an individual who performs work for or on behalf of any agency under a contract and who, in order to perform the work specified under the contract, will require access to space, information, information technology systems, staff, or other assets of the Federal Government, and who could, by the nature of his or her access or duties, adversely affect the integrity or efficiency of the Government. Such contracts, include, but are not limited to:

''(i) personal services contracts;

''(ii) contracts between any non-Federal entity and any agency; and

''(iii) sub-contracts between any non-Federal entity and another non-Federal entity to perform work related to the primary contract with the agency.

''(c) 'Excepted service' has the meaning provided in section 2103 of title 5, United States Code, but does not include those positions in any element of the intelligence community as defined in the National Security Act of 1947, as amended, to the extent they are not otherwise subject to Office of Personnel Management appointing authorities.

''(d) 'Fitness' is the level of character and conduct determined necessary for an individual to perform work for or on behalf of a Federal agency as an employee in the excepted service (other than a position subject to suitability), as a contractor employee, or as a nonappropriated fund employee.

''(e) 'Fitness determination' means a decision by an agency that an individual has or does not have the required level of character and conduct

necessary to perform work for or on behalf of a Federal agency as an employee in the excepted service (other than a position subject to suitability), as a contractor employee, or as a nonappropriated fund employee. A favorable fitness determination is not a decision to appoint or contract with an individual.

''(f) 'Nonappropriated fund employee' means an employee paid from nonappropriated funds of an instrumentality of the United States under the jurisdiction of the Armed Forces conducted for the comfort, pleasure, contentment, and mental and physical improvement of personnel of the Armed Forces as described in section 2105 of title 5, United States Code.

''(g) 'Position of Public Trust' has the meaning provided in 5 CFR Part 731.

''(h) 'Suitability' has the meaning and coverage provided in 5 CFR Part 731.

(c) Section 3 of Executive Order 13488 is revised to read as follows:

''OPM and Agency Authority.

''(a) *Adjudications for determining fitness for contractual or nonappropriated fund employment.* While the Office of Personnel Management establishes the minimum adjudicative criteria for suitability and fitness determinations for employment in the civil service pursuant to the Civil Service Rules, the heads of agencies retain the discretion to establish adjudicative criteria for determining fitness to perform work as a contractor employee or as a nonappropriated fund employee. Such discretion shall be exercised with due regard to the regulations and guidance prescribed by the Office of Personnel Management for the civil service and, for contractual work, subject to applicable regulations and directives of the Office of Management and Budget.

''(b) *Investigations for determining fitness for contractual or nonappropriated fund employment.* Contractor employee fitness or nonappropriated fund employee fitness is subject to the same position designation requirements and investigative standards, policies, and procedures as fitness determinations for civil service employees, as prescribed by the Office of Personnel Management under the Civil Service Rules.

''(c) *Reciprocity.* Fitness determinations and investigations for fitness determinations for contractor employees and for nonappropriated fund employees are subject to the same reciprocity requirements as those for employment in the civil service, as prescribed by the Office of Personnel Management under the Civil Service Rules.''

(d) Executive Order 13488 is revised by striking section 4 in its entirety, and redesignating sections 5 through 8 as sections 4 through 7, respectively.

Sec. 3. *Amendments to Executive Order 13467 of June 30, 2008, as amended.* (a) The preamble to Executive Order 13467 is revised to read as follows:

''By the authority vested in me as President by the Constitution and the laws of the United States of America, including sections 3301, 7103(b), and 7301 of title 5, United States Code, and in order to strengthen and ensure a secure, efficient, timely, reciprocal, and aligned system for investigating and determining suitability or fitness for Government employment, fitness to work as a contractor or a nonappropriated fund employee, eligibility for access to classified information or to hold a sensitive position, and authorization to be issued a Federal credential, while providing fair, impartial, and equitable treatment, and protecting individual rights under the Constitution and laws of the United States, and taking appropriate account of title III of Public Law 108–458, it is hereby ordered as follows:''

(b) Section 1.1 of Executive Order 13467 is revised to read as follows:

''**Section 1.1**. *Policy.* (a) Executive branch vetting policies and procedures relating to suitability, contractor or Federal employee fitness, eligibility to hold a sensitive position, authorization to be issued a Federal credential for access to federally controlled facilities and information systems, and

eligibility for access to classified information shall be aligned using consistent standards to the extent possible, shall provide for reciprocal recognition, and shall ensure cost-effective, timely, and efficient protection of the national interest, while providing fair treatment to those upon whom the Federal Government relies to conduct our Nation's business and protect national security.

''(b) The Government's tools, systems, and processes for conducting these background investigations and managing sensitive investigative information should keep pace with technological advancements, regularly integrating current best practices to better anticipate, detect, and counter malicious activities, and threats posed by external or internal actors who may seek to do harm to the Government's personnel, property, and information. To help fulfill these responsibilities, there shall be a primary executive branch investigative service provider whose mission is to provide effective, efficient, and secure background investigations for the Federal Government.

''(c) Executive branch vetting policies and procedures shall be sustained by an enhanced risk-management approach that facilitates early detection of issues by an informed, aware, and responsible Federal workforce; results in quality decisions enabled by improved vetting capabilities; and advances Government-wide capabilities through enterprise approaches.

''(d) The appointment or retention of each covered individual shall be subject to an investigation. Federal investigative standards established pursuant to this order shall be designed to develop information as to whether the employment or retention in employment in the Federal service of the person being investigated is clearly consistent with the interests of the national security, and the scope of the investigation shall be determined in the first instance according to the degree of material adverse effect the occupant of the position sought to be filled could bring about, by virtue of the nature of the position, on the national security.''

''(e) Investigative agencies shall control the reports, information, and other investigative materials that are developed during the vetting process. Recipient departments and agencies may retain and use the received reports, information, and other investigative material within that recipient for authorized purposes (including, but not limited to, adjudications, hearings and appeals, continuous evaluation, inspector general functions, counterintelligence, research, and insider threat programs), in compliance with the Privacy Act of 1974, as amended (section 552a of title 5, United States Code). Investigative agencies shall ensure that their applicable System of Records Notices include, at a minimum, the authorized uses of the recipient departments and agencies such as those set forth above. Recipient departments and agencies shall not make any external releases of received information, other than to an investigative subject for the purpose of providing procedural rights or administrative due process; and shall direct any other requests for external releases of copies of the reports, information, and other investigative materials to the investigative agency. In the event redisclosure by the recipient agency is required by compulsory legal process, the recipient agency shall consult with the investigating agency. The investigative agency shall maintain the reports, information, and other investigative material in a system of records subject to the Privacy Act and ensure that any re-disclosure does not violate statutory restrictions or result in the unauthorized disclosure of: classified information, information subject to a claim of privilege, or information that is otherwise lawfully exempt from disclosure. Subject to Security Executive Agent authorizations consistent with section 3341(e)(5) of title 50, United States Code, the investigative agencies shall make reports, information, and other investigative material available, as necessary, to carry out the responsibilities set forth in this order, including but not limited to, authorized executive branch-sponsored research and initiatives for enterprise-wide continuous performance improvement of vetting policy and procedures, as permitted by law.''

(c) Section 1.2 of Executive Order 13467 is revised to read as follows:

''**Sec. 1.2**. *Applicability.* (a) This order applies to vetting of all covered individuals as defined in section 1.3(h), except that:

''(i) the provisions regarding eligibility for physical access to federally controlled facilities and logical access to federally controlled information systems do not apply to individuals exempted in accordance with guidance pursuant to the Federal Information Security Management Act (title III of Public Law 107–347) and Homeland Security Presidential Directive 12 of August 27, 2004; and

''(ii) the qualification standards for enlistment, appointment, and induction into the Armed Forces pursuant to title 10, United States Code, are unaffected by this order.

''(b) This order also applies to vetting for employees of agencies working in or for the legislative or judicial branches when the vetting is conducted by the executive branch.''

(d) Section 1.3(a) of Executive Order 13467 is revised to read as follows:

''(a) 'Adjudication' means the evaluation of pertinent data in a background investigation, as well as any other available information that is relevant and reliable, to determine whether a covered individual is:

''(i) suitable for Government employment;

''(ii) eligible for logical and physical access;

''(iii) eligible for access to classified information;

''(iv) eligible to hold a sensitive position; or

''(v) fit to perform work for or on behalf of the Government as a Federal employee, contractor, or nonappropriated fund employee.''

(e) Sections 1.3(c) and 1.3(d) of Executive Order 13467 are revised to read as follows:

''(c) 'Classified information' means information that has been determined pursuant to Executive Order 13526 of December 29, 2009, or a successor or predecessor order, or the Atomic Energy Act of 1954 (42 U.S.C. 2011 *et seq.*) to require protection against unauthorized disclosure.

''(d) 'Continuous evaluation (CE)' means a vetting process to review the background of an individual who has been determined to be eligible for access to classified information or to hold a sensitive position at any time during the period of eligibility. CE leverages a set of automated record checks and business rules to assist in the on-going assessment of an individual's continued eligibility. CE is intended to complement continuous vetting efforts.''

(f) Section 1.3(f) of Executive Order 13467 is deleted.

(g) Sections 1.3(j), (k), (l), and (m) are redesignated as sections 1.3(m), (n), (o), and (p); sections 1.3(g), (h), and (i) are redesignated as sections 1.3(h), (i), and (j); and section 1.3(e) is redesignated as section 1.3(g).

(h) New sections 1.3(e) and 1.3(f) are added to Executive Order 13467 to read as follows:

''(e) 'Continuous performance improvement' means assessing national policy and operations, adverse events, and emerging trends and technology throughout the Government's end-to-end vetting program. It relies on research to generate data-driven decisions and uses outcome-based measurements to adjust policy and operations.

''(f) 'Continuous vetting' means reviewing the background of a covered individual at any time to determine whether that individual continues to meet applicable requirements.''

(i) Redesignated section 1.3(h) of Executive Order 13467 is revised to read as follows:

''(h) 'Covered individual' means a person who performs, or who seeks to perform, work for or on behalf of the executive branch (*e.g.,* Federal employee, military member, or contractor), or otherwise interacts with

the executive branch such that the individual must undergo vetting, but does not include:

''(i) the President or (except to the extent otherwise directed by the President) employees of the President under section 105 or 107 of title 3, United States Code;

''(ii) the Vice President or (except to the extent otherwise directed by the Vice President) employees of the Vice President under section 106 of title 3, United States Code, or annual legislative branch appropriations acts; or

''(iii) with respect to background investigations only, duly elected or appointed governor of a State or territory, or an official who has succeeded to that office under applicable law in accordance with Executive Order 13549 of August 18, 2010, and its implementing directive.''

(j) New sections 1.3(k) and 1.3(l) are added to Executive Order 13467 to read as follows:

''(k) 'Fitness' means the level of character and conduct determined necessary for an individual to perform work for or on behalf of a Federal agency as an employee in the excepted service (other than a position subject to suitability), or as a 'contractor employee' or a 'nonappropriated fund employee' as those terms are defined in Executive Order 13488 of January 16, 2009, as amended.

''(l) 'Investigation' means the collection and analysis of pertinent facts and data to support a determination of whether a covered individual is, and continues to be:

''(i) eligible for access to classified information;

''(ii) eligible to hold a sensitive position;

''(iii) suitable or fit for Federal employment;

''(iv) fit to perform work for or on behalf of the Federal Government as a contractor or nonappropriated fund employee; or

''(v) authorized to be issued a Federal credential.''

(k) Redesignated section 1.3(n) of Executive Order 13467 is revised to read as follows:

''(n) 'National Background Investigations Bureau' (NBIB) means the National Background Investigations Bureau, established within the Office of Personnel Management under section 1103(a)(3) of title 5, United States Code, or a successor entity, with responsibility for conducting effective, efficient, and secure personnel background investigations pursuant to law, rule, regulation, or Executive Order.''

(l) Redesignated section 1.3(o) of Executive Order 13467 is revised to read as follows:

''(o) 'Sensitive Position' means any position within or in support of a department or agency, the occupant of which could bring about, by virtue of the nature of the position, a material adverse effect on the national security, regardless of whether the occupant has access to classified information, and regardless of whether the occupant is an employee, a military service member, or a contractor.

(m) New section 1.3(q) is added to Executive Order 13467 to read as follows:

''(q) 'Vetting' is the process by which covered individuals undergo investigation, evaluation, and adjudication of whether they are, and remain over time, suitable or fit for Federal employment, eligible to occupy a sensitive position, eligible for access to classified information, eligible to serve as a nonappropriated fund employee or a contractor, eligible to serve in the military, or authorized to be issued a Federal credential. Vetting includes all steps in the end-to-end process, including determining need (appropriate position designation), validating need (existence of a current investigation or adjudication), collecting background information

via standard forms, investigative activity, adjudication, providing administrative due process or other procedural rights, and ongoing assessments to ensure that individuals continue to meet the applicable standards for the position for which they were favorably adjudicated.''

(n) The title to Part 2 of Executive Order 13467 is revised to read as follows:

''PART 2—VETTING ENTERPRISE, RECIPROCITY, CONTINUOUS PERFORMANCE IMPROVEMENT, AND GOVERNANCE''

(o) Section 2.1 of Executive Order 13467 is revised to read as follows:

''**Sec. 2.1.** *Vetting Enterprise.* (a) The executive branch-wide vetting enterprise shall use, to the greatest extent practicable, aligned and consistent vetting policies, procedures, and standards, as determined by the Council and the Executive Agents. The Executive Agents shall issue guidance to implement this provision.

''(b) The aligned executive branch-wide vetting enterprise shall employ modern and consistent standards and methods, enable innovations with enterprise information technology capabilities and end-to-end automation to the extent practicable, and ensure that relevant information maintained by agencies can be accessed and shared rapidly across the executive branch, while protecting national security, protecting privacy-related information, protecting civil rights and civil liberties, ensuring resulting decisions are in the national interest and in accordance with due process requirements, and providing the Federal Government with an effective trusted workforce.

''(c) The investigative and adjudicative standards for fitness shall, to the extent practicable, be consistent with the standards for suitability. The Executive Agents shall establish in Federal investigative standards the elements of the level of investigation necessary for vetting for fitness.

''(d) All covered individuals shall be subject to continuous vetting under standards (including, but not limited to, the frequency of such vetting) as determined by the Security Executive Agent or the Suitability and Credentialing Executive Agent exercising its Suitability Executive Agent functions, as applicable.

''(e) Vetting shall include a search of records of the Federal Bureau of Investigation, including a fingerprint-based search, and any other appropriate biometric or database searches not precluded by law.''

(p) Sections 2.2, 2.3, 2.4, and 2.5 of Executive Order 13467 are redesignated as sections 2.4, 2.5, 2.6, and 2.7.

(q) New sections 2.2 and 2.3 are added to Executive Order 13467 to read as follows:

''**Sec. 2.2**. *Reciprocity.* Except as otherwise authorized by law or policy issued by the applicable Executive Agent, agencies shall accept background investigations and adjudications conducted by other authorized agencies unless an agency determines that a particular background investigation or adjudication does not sufficiently address the standards used by that agency in determining the fitness of its excepted service employees who cannot be noncompetitively converted to the competitive service. Except as described above and except to the extent authority to apply additional requirements is vested by statute in an agency, an agency may not establish additional investigative or adjudicative requirements (other than requirements for the conduct of a polygraph examination consistent with law, directive, or regulation) that exceed existing requirements without the approval of the Suitability and Credentialing Executive Agent exercising its Suitability Executive Agent functions or Security Executive Agent, as appropriate. Any additional requirements approved by the appropriate Executive Agent shall be limited to those that are necessary to address significant needs unique to the agency involved, to protect national security, or to satisfy a requirement imposed by law.''

''**Sec. 2.3**. *Continuous Performance Improvement.* Executive branch vetting policies, processes, and procedures shall be supported by institutionalized enterprise-wide continuous performance improvement, which shall align with and support process improvements.''

(r) Redesignated section 2.4 of Executive Order 13467 is revised to read as follows:

''**Sec. 2.4**. *Establishment and Functions of Performance Accountability Council.* (a) There is hereby established a Security, Suitability, and Credentialing Performance Accountability Council (Council).

''(b) The Deputy Director for Management, Office of Management and Budget, shall serve as Chair of the Council and shall have authority, direction, and control over the Council's functions. Membership on the Council shall include the Suitability and Credentialing Executive Agent, the Security Executive Agent, and the Under Secretary of Defense for Intelligence. These four officials collectively shall constitute 'the Security, Suitability, and Credentialing Performance Accountability Council Principals.' The Director of the National Background Investigations Bureau shall also serve as a member of the Council. The Chair shall select a Vice Chair to act in the Chair's absence. The Chair shall have authority to designate officials from additional agencies who shall serve as members of the Council. Council membership shall be limited to Federal Government employees in leadership positions.

''(c) The Council shall be accountable to the President to achieve, consistent with this order, the goals of the executive branch vetting enterprise, and is responsible for driving implementation of reform efforts and enterprise development, ensuring accountability by agencies, ensuring the Executive Agents align their respective processes, and sustaining continuous performance improvement and reform momentum.

''(d) The Council shall:

''(i) ensure enterprise-wide alignment of suitability, security, credentialing, and as appropriate, fitness processes;

''(ii) hold agencies accountable for the implementation of suitability, security, fitness, and credentialing processes and procedures;

''(iii) define requirements for enterprise-wide reciprocity management information technology, and develop standards for enterprise-wide information technology;

''(iv) work with agencies to implement continuous performance improvement programs, policies, and procedures; establish annual goals and progress metrics; and prepare annual reports on results;

''(v) ensure and oversee the development of tools and techniques for enhancing background investigations and adjudications;

''(vi) enable discussion and consensus resolution of differences in processes, policies, and procedures among the Council Principals, and other agencies as appropriate;

''(vii) share best practices;

''(viii) advise the Executive Agents on policies affecting the alignment of investigations and adjudications;

''(ix) work with agencies to develop agency policies and procedures to enable sharing of vetting information consistent with the law and the protection of privacy and civil liberties and to the extent necessary for enterprise-wide efficiency, effectiveness, and security;

''(x) monitor performance to identify and drive enterprise-level process enhancements, and make recommendations for changes to executive branch-wide guidance and authorities to resolve overlaps or close policy gaps where they may exist;

''(xi) promote data-driven, transparent, and expeditious policy-making processes; and

''(xii) develop and continuously reevaluate and revise outcome-based metrics that measure the quality, efficiency and effectiveness of the vetting enterprise.

''(e) The Chair shall, to further the goals of the vetting enterprise and to the extent consistent with law, establish subordinate entities, mechanisms, and policies to support and assist in exercising the Council's authorities and responsibilities, and facilitate, consistent with the executive branch's enterprise strategy, adoption of enterprise-wide standards and solutions to ensure security, quality, reciprocity, efficiency, effectiveness, and timeliness. The Chair may assign, in whole or in part, to the head of any agency (solely or jointly) any function within the Council's authority or responsibilities pursuant to this order.''

(s) Redesignated section 2.5 of Executive Order 13467 is revised to read as follows:

''**Sec. 2.5**. *Establishment, Designation, and Functions of Executive Agents.* (a) There are hereby established a Suitability and Credentialing Executive Agent and a Security Executive Agent.

''(b) The Director of the Office of Personnel Management shall serve as the Suitability and Credentialing Executive Agent. With respect to the Suitability Executive Agent functions, the Director:

''(i) shall, pursuant to sections 1103 and 1104 of title 5, United States Code, and the Civil Service Rules, be responsible for suitability and fitness by prescribing suitability standards and minimum standards of fitness for employment; prescribing position designation requirements with regard to the risk to the efficiency and integrity of the service; prescribing applicable investigative standards, policies, and procedures for suitability and fitness; prescribing suitability and fitness reciprocity standards; making suitability determinations; and taking suitability actions;

''(ii) shall issue regulations, guidance, and standards to fulfill the Director's responsibilities related to suitability and fitness under Executive Order 13488 of January 16, 2009, as amended;

''(iii) shall promote reciprocal recognition of suitability or fitness determinations among the agencies, including acting as the final authority to arbitrate and resolve disputes among the agencies involving the reciprocity of investigations and adjudications of suitability and fitness;

''(iv) shall continue to initially approve, and periodically review for renewal, agencies' requests to administer polygraphs in connection with appointment in the competitive service, in consultation with the Security Executive Agent as appropriate;

''(v) shall make a continuing review of agency programs for suitability and fitness vetting to determine whether they are being implemented according to this order;

''(vi) may issue guidelines and instructions to the heads of agencies to promote appropriate uniformity, centralization, efficiency, effectiveness, reciprocity, timeliness, and security in processes relating to determining suitability or fitness; and

''(vii) shall, pursuant to section 1104 of title 5, United States Code, prescribe performance standards and a system of oversight for any suitability or fitness function delegated by the Director to the head of another agency, including uniform and consistent policies and procedures to ensure the effective, efficient, timely, and secure completion of delegated functions.

''(c) With respect to the Credentialing Executive Agent functions, the Director of the Office of Personnel Management:

''(i) shall develop standards for investigations, reinvestigations, and continuous vetting for a covered individual's eligibility for a personal identity verification credential permitting logical and physical access to federally controlled facilities and federally controlled information systems (PIV credential);

''(ii) shall develop adjudicative guidelines for a covered individual's eligibility for a PIV credential;

''(iii) shall develop guidelines on reporting and recording determinations of eligibility for a PIV credential;

''(iv) shall develop standards for unfavorable determinations of eligibility for a PIV credential, including procedures for denying and revoking the eligibility for a PIV credential, for reconsideration of unfavorable determinations, and for rendering the PIV credential inoperable;

''(v) shall develop standards and procedures for suspending eligibility for a PIV credential when there is a reasonable basis to believe there may be an unacceptable risk pending an inquiry or investigation, including special standards and procedures for imminent risk;

''(vi) shall be responsible for developing uniform and consistent policies and procedures to ensure the effective, efficient, timely, and secure completion of investigations and adjudications relating to eligibility for a PIV credential;

''(vii) may develop guidelines and instructions to the heads of agencies as necessary to ensure appropriate uniformity, centralization, efficiency, effectiveness, and timeliness in processes relating to eligibility for a PIV credential;

''(viii) shall monitor and make a continuing review of agency programs for determining eligibility for a PIV credential to determine whether they are being implemented according to this order; and

''(ix) shall consult to the extent practicable with other agencies with responsibilities related to PIV credentials to ensure that policies and procedures are consistent with law including:

''(A) the Office of Management and Budget, in exercising its responsibilities under section 11331 of title 40, United States Code, section 3553(a) of title 44, United States Code, division A, sections 1086(b)(2) and (b)(3) of Public Law 114–92, and Homeland Security Presidential Directive 12 of August 27, 2004;

''(B) the Department of Homeland Security, in exercising its responsibilities under sections 3553(b), (f), and (g) of title 44, United States Code;

''(C) the Department of Defense, in exercising its responsibilities under section 3553(e) of title 44, United States Code, and division A, sections 1086(a)(1)(E), (b)(1), and (b)(2) of Public Law 114–92;

''(D) the Office of the Director of National Intelligence, in exercising its responsibilities under section 3553(e) of title 44, United States Code, and division A, section 1086(b)(2) of Public Law 114–92;

''(E) the Department of Commerce and the National Institute of Standards and Technology, in exercising their responsibilities under section 278g–3 of title 15, United States Code, and Homeland Security Presidential Directive 12 of August 27, 2004;

''(F) the General Services Administration, in exercising its responsibilities under division A, section 1086(b)(2) of Public Law 114–92; and

''(G) the Federal Acquisition Regulation agencies, in exercising their responsibilities under chapter 137 of title 10, section 121(c) of title 40, and section 20113 of title 51, United States Code.

''(d) In fulfilling the Credentialing Executive Agent function of developing policies and procedures for determining eligibility for a PIV credential and to protect the national security, the Director of the Office of Personnel Management shall coordinate with and obtain the concurrence of the

other Council Principals. Agencies with authority to establish standards or guidelines or issue instructions related to PIV credentials shall retain the discretion as to whether to establish policies, guidelines, or instructions developed by the Credentialing Executive Agent.

''(e) The Director of National Intelligence shall serve as the Security Executive Agent. The Security Executive Agent:

''(i) shall direct the oversight of investigations, reinvestigations, adjudications, and, as applicable, polygraphs for eligibility for access to classified information or eligibility to hold a sensitive position made by any agency;

''(ii) shall make a continuing review of agencies' national security background investigation and adjudication programs to determine whether they are being implemented according to this order;

''(iii) shall be responsible for developing and issuing uniform and consistent policies and procedures to ensure the effective, efficient, timely, and secure completion of investigations, polygraphs, and adjudications relating to determinations of eligibility for access to classified information or eligibility to hold a sensitive position;

''(iv) may issue guidelines and instructions to the heads of agencies to ensure appropriate uniformity, centralization, efficiency, effectiveness, timeliness, and security in processes relating to determinations by agencies of eligibility for access to classified information or eligibility to hold a sensitive position, to include such matters as investigations, polygraphs, adjudications, and reciprocity;

''(v) may, if consistent with the national security, authorize exceptions to or waivers of national security investigative requirements, and may issue implementing or clarifying guidance as necessary;

''(vi) shall serve as the final authority to designate an agency or agencies, to the extent that it is not practicable to use the National Background Investigations Bureau, to conduct investigations of persons who are proposed for access to classified information or for eligibility to hold a sensitive position to ascertain whether such persons satisfy the criteria for obtaining and retaining access to classified information or eligibility to hold a sensitive position;

''(vii) shall serve as the final authority to designate an agency or agencies to determine eligibility for access to classified information or eligibility to hold a sensitive position in accordance with Executive Order 12968 of August 2, 1995, as amended;

''(viii) shall ensure reciprocal recognition of eligibility for access to classified information or eligibility to hold a sensitive position among the agencies, including acting as the final authority to arbitrate and resolve disputes among the agencies involving the reciprocity of investigations and adjudications of eligibility; and

''(ix) may assign, in whole or in part, to the head of any agency (solely or jointly) any of the functions detailed in (i) through (viii) of this subsection, with the agency's exercise of such assigned functions to be subject to the Security Executive Agent's oversight and with such terms and conditions (including approval by the Security Executive Agent) as the Security Executive Agent determines appropriate.

''(f) Nothing in this section shall be construed in a manner that would limit the authorities of the Director of the Office of Personnel Management, the Director of National Intelligence, or the Secretary of Defense under law.''

(t) Redesignated section 2.6 of Executive Order 13467 is revised to read as follows:

''**Sec. 2.6**. *Roles and Responsibilities of the National Background Investigations Bureau and the Department of Defense.*

''(a) The National Background Investigations Bureau shall:

''(1) serve as the primary executive branch service provider for background investigations for eligibility for access to classified information; eligibility to hold a sensitive position; suitability or, for employees in positions not subject to suitability, fitness for Government employment; fitness to perform work for or on behalf of the Government as a contractor; fitness to work as a nonappropriated fund employee, as defined in Executive Order 13488 of January 16, 2009, as amended; and authorization to be issued a Federal credential for logical and physical access to federally controlled facilities or information systems;

''(2) provide effective, efficient, and secure personnel background investigations for the Federal Government;

''(3) provide the Council information, to the extent permitted by law, on matters of performance, timeliness, capacity, information technology modernization, continuous performance improvement, and other relevant aspects of NBIB operations;

''(4) be headquartered in or near Washington, District of Columbia;

''(5) have dedicated resources, including but not limited to a senior privacy and civil liberties official;

''(6) institutionalize interagency collaboration and leverage expertise across the executive branch;

''(7) continuously improve investigative operations, emphasizing information accuracy and protection, and regularly integrate best practices, including those identified by subject matter experts from industry, academia, or other relevant sources;

''(8) conduct personnel background investigations in accordance with uniform and consistent policies, procedures, standards, and requirements established by the Security Executive Agent and the Suitability and Credentialing Executive Agent exercising its Suitability Executive Agent functions; and

''(9) conduct other personnel background investigations as authorized by law, rule, regulation, or Executive Order.''

''(b) The Secretary of Defense shall design, develop, deploy, operate, secure, defend, and continuously update and modernize, as necessary, vetting information technology systems that support all background investigation processes conducted by the National Background Investigations Bureau. Design and operation of the information technology systems for the National Background Investigations Bureau shall comply with applicable information technology standards and, to the extent practicable, ensure security and interoperability with other background investigation information technology systems. The Secretary of Defense shall operate the database in the information technology systems containing appropriate data relevant to the granting, denial, or revocation of eligibility for access to classified information or eligibility for a sensitive position pertaining to military, civilian, or Government contractor personnel, see section 3341(e) of title 50, United States Code, consistent with and following an explicit delegation from the Director of the Office of Personnel Management pursuant to section 1104 of title 5, United States Code.''

''(c) Delegations and designations of investigative authority in place on the date of establishment of the National Background Investigations Bureau shall remain in effect until amended or revoked. The National Background Investigations Bureau, through the Director of the Office of Personnel Management, shall be subject to the oversight of the Security Executive Agent in the conduct of investigations for eligibility for access to classified information or to hold a sensitive position; and to the oversight of the Suitability and Credentialing Executive Agent in the conduct of investigations of suitability or fitness and logical and physical access, as provided in section 2.5 of this order. The Council shall hold the National Background

Investigations Bureau accountable for the fulfillment of the responsibilities set forth in section 2.6(a) of this order.''

(u) Subsections (b) and (c) of redesignated section 2.7 of Executive Order 13467 are revised to read as follows:

''(b) Heads of agencies shall:

''(i) designate, or cause to be designated, as a 'sensitive position,' any position occupied by a covered individual in which the occupant could bring about by virtue of the nature of the position, a material adverse effect on the national security;

''(ii) establish and maintain within their respective agencies, an effective program to ensure that employment and retention of any covered individual within the agency is clearly consistent with the interests of national security and, as applicable, meets standards for eligibility for access to classified information or to hold a sensitive position, suitability, fitness, or credentialing, established by the respective Executive Agent;

''(iii) carry out any function assigned to the agency head by the Chair, and shall assist the Chair, the Council, the Executive Agents, the National Background Investigations Bureau, and the Department of Defense in carrying out any function under sections 2.4, 2.5, and 2.6 of this order;

''(iv) implement any policy or procedure established pursuant to this order;

''(v) to the extent permitted by law, make available to the Council, the Executive Agents, the National Background Investigations Bureau, and the Department of Defense such information as may be requested to implement this order, including information necessary to implement enterprise-wide vetting policies and procedures;

''(vi) except as authorized by section 3341(e)(5) of title 50, United States Code, promptly furnish, or cause to be promptly furnished, to the Office of Personnel Management the information deemed by the Executive Agents to be necessary for purposes of record keeping and reciprocity including, but not limited to, the date on which a background investigation is initiated, the date on which the background investigation is closed, and the specific adjudicative or access decision made. The Executive Agents shall determine the appropriate timeline pursuant to which this information must be reported to the Office of Personnel Management. The Executive Agents shall maintain discretion to determine the scope of information needed for record keeping and reciprocity purposes. The Office of Personnel Management shall regularly provide this information to the Director of National Intelligence for national security purposes.

''(vii) ensure that all actions taken under this order take account of the counterintelligence interests of the United States, as appropriate; and

''(viii) ensure that actions taken under this order are consistent with the President's constitutional authority to:

''(A) conduct the foreign affairs of the United States;

''(B) withhold information the disclosure of which could impair the foreign relations, the national security, the deliberative processes of the Executive, or the performance of the Executive's constitutional duties;

''(C) recommend for congressional consideration such measures as the President may judge necessary or expedient; and

''(D) supervise the unitary executive branch.

''(c) All investigations being conducted by agencies that develop information indicating that an individual may have been subjected to coercion, influence, or pressure to act contrary to the interests of the national security, or information that the individual may pose a counterintelligence or terrorist threat, or as otherwise provided by law, shall be referred to the Federal Bureau of Investigation for potential investigation, and may also be referred to other agencies where appropriate.''

(v) Section 3 of Executive Order 13467 is revised to read as follows:

''**Sec. 3**. *General Provisions.* (a) Executive Order 13381 of June 27, 2005, as amended, and Executive Order 10450 of April 27, 1953, as amended, are revoked. By revoking Executive Order 10450 of April 27, 1953, as amended, there is no intent to alter the requirement for an investigation for national security purposes or the ''clearly consistent with the interest of national security'' standard prescribed by that Executive Order for making the determinations referenced in section 2.7(b)(ii). Further, suitability, fitness, credentialing, and national security eligibility regulations, standards and guidance issued by, or interagency agreements entered into by, the Council, the Executive Agents, or any agency pursuant to Executive Order 10450 of April 27, 1953, as amended, shall remain valid until superseded. Nothing in this order shall:

''(i) supersede, impede, or otherwise affect:

''(A) Executive Order 10577 of November 23, 1954, as amended;

''(B) Executive Order 12333 of December 4, 1981, as amended;

''(C) Executive Order 12829 of January 6, 1993, as amended; or

''(D) Executive Order 13526 of December 29, 2009; or

''(ii) diminish or otherwise affect the denial and revocation procedures provided to individuals covered by Executive Order 10865 of February 20, 1960, as amended; or

''(iii) be applied in such a way as to affect any administrative proceeding pending on the date of this order.

''(b) Executive Order 12968 of August 2, 1995, is amended:

''(i) by inserting: 'Sec. 3.5. Continuous Evaluation. An individual who has been determined to be eligible for or who currently has access to classified information shall be subject to continuous evaluation as further defined by and under standards (including, but not limited to, the frequency of such evaluation) as determined by the Director of National Intelligence.'; and

''(ii) by striking 'the Security Policy Board shall make recommendations to the President through the Assistant to the President for National Security Affairs' in section 6.3(a) and inserting in lieu thereof 'the Director of National Intelligence shall serve as the final authority';

''(iii) by striking 'Security Policy Board' and inserting in lieu thereof 'Security Executive Agent' in each instance;

''(iv) by striking 'the Board' in section 1.1(j) and inserting in lieu thereof 'the Security Executive Agent'; and

''(v) by inserting 'or appropriate automated procedures' in section 3.1(b) after 'by appropriately trained adjudicative personnel'.

''(c) Provisions of Executive Order 12968 of August 2, 1995, as amended, that apply to eligibility for access to classified information shall apply to eligibility to hold any sensitive position regardless of whether that sensitive position requires access to classified information, subject to the Security Executive Agent issuing implementing or clarifying guidance regarding requirements for sensitive positions. Nothing in this order shall supersede, impede, or otherwise affect the remainder of Executive Order 12968 of August 2, 1995, as amended.

''(d) Nothing in this order shall be construed to impair or otherwise affect the:

''(i) authority granted by law to a department or agency, or the head thereof; or

''(ii) functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

''(e) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

''(f) Existing delegations of authority made pursuant to Executive Order 13381 of June 27, 2005, as amended, to any agency relating to granting eligibility for access to classified information shall remain in effect, subject to the exercise of authorities pursuant to this order to revise or revoke such delegation.

''(g) Existing delegations of authority made by the Office of Personnel Management to any agency relating to suitability or fitness shall remain in effect, subject to the exercise of authorities to revise or revoke such delegations.

''(h) If any provision of this order or the application of such provision is held to be invalid, the remainder of this order shall not be affected.

''(i) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.''

Sec. 4. *General Provisions.* (a) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(b) If any provision of this order or the application of such provision is held to be invalid, the remainder of this order shall not be affected.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

THE WHITE HOUSE,
January 17, 2017.

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