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Rules and Regulations

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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents.

OFFICE OF GOVERNMENT ETHICS

5 CFR Parts 2634 and 2636

RIN 3209–AA38

Civil Monetary Penalties Inflation Adjustments for Ethics in Government Act Violations

AGENCY: Office of Government Ethics.

ACTION: Final rule.

SUMMARY: In accordance with the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, the U.S. Office of Government Ethics (OGE) is issuing this final rule to make the 2018 annual adjustments to the Ethics in Government Act civil monetary penalties.

DATES: *Effective date:* This final rule is effective January 17, 2018. *Applicability date:* This final rule is applicable January 15, 2018.

FOR FURTHER INFORMATION CONTACT: Kimberly L. Sikora Panza, Associate Counsel, General Counsel and Legal Policy Division, Office of Government Ethics, Telephone: 202–482–9300; TTY: 800–877–8339; FAX: 202–482–9237.

SUPPLEMENTARY INFORMATION:

I. Background

In November 2015, Congress passed the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Sec. 701 of Pub. L. 114–74) (the 2015 Act), which further amended the Federal Civil Penalties Inflation Adjustment Act of 1990 (Pub. L. 101–410). The 2015 Act required Federal agencies to make inflationary adjustments to the civil monetary penalties (CMPs) within their jurisdiction with an initial ''catch-up'' adjustment through an interim final rule effective no later than August 1, 2016, and further mandates that Federal agencies make subsequent annual inflationary adjustments of their CMPs, to be effective no later than January 15 of each year.

The Ethics in Government Act of 1978 as amended, 5 U.S.C. appendix (the Ethics Act) provides for five CMPs.[1] Specifically, the Ethics Act provides for penalties that can be assessed by an appropriate United States district court, based upon a civil action brought by the Department of Justice, for the following five types of violations:

(1) Knowing and willful failure to file, report required information on, or falsification of a public financial disclosure report, 5 U.S.C. appendix 104(a), 5 CFR 2634.701(b);

(2) knowing and willful breach of a qualified trust by trustees and interested parties, 5 U.S.C. appendix 102(f)(6)(C)(i), 5 CFR 2634.702(a);

(3) negligent breach of a qualified trust by trustees and interested parties, 5 U.S.C. appendix 102(f)(6)(C)(ii), 5 CFR 2634.702(b);

(4) misuse of a public report, 5 U.S.C. appendix 105(c)(2), 5 CFR 2634.703; and

(5) violation of outside employment/activities provisions, 5 U.S.C. appendix 504(a), 5 CFR 2636.104(a).

In compliance with the 2015 Act and guidance issued by the Office of Management and Budget (OMB), on June 28, 2016, the U.S. Office of Government Ethics (OGE) published in the **Federal Register** an interim final rule, 81 FR 41787 (June 28, 2016), that made the ''catch up'' inflationary adjustments to the five Ethics Act CMPs. On January 24, 2017, OGE published in the **Federal Register** a rule adopting as final that interim regulation, and also making the 2017 annual inflationary adjustments to the Ethics Act CMPs. See 82 FR 8131 (Jan. 24, 2017).

This rulemaking effectuates the 2018 annual inflationary adjustments to the Ethics Act CMPs. In accordance with the 2015 Act, these adjustments are based on the percent change between the Consumer Price Index for all Urban Consumers (CPI–U) for the month of October preceding the date of the adjustment, and the prior year's October CPI–U. Pursuant to OMB guidance, the cost-of-living adjustment multiplier for 2018, based on the CPI–U for October 2017, not seasonally adjusted, is 1.02041. To calculate the 2018 annual adjustment, agencies must multiply the most recent penalty by the 1.02041 multiplier, and round to the nearest dollar.

Applying the formula established by the 2015 Act and OMB guidance, OGE is amending the Ethics Act CMPs through this rulemaking to:

(1) Increase the three penalties reflected in 5 CFR 2634.702(a), 5 CFR 2634.703, and 5 CFR 2636.104(a)—which were previously adjusted to a maximum of $19,246—to a maximum of $19,639;

(2) Increase the penalty reflected in 5 CFR 2634.702(b)—which was previously adjusted to a maximum of $9,623—to a maximum of $9,819; and

(3) Increase the penalty reflected in 5 CFR 2634.701(b)—which was previously adjusted to a maximum of $57,847—to a maximum of $59,028.

These adjusted penalty amounts will apply to penalties assessed after January 15, 2018 (the applicability date of this final rule) whose associated violations occurred after November 2, 2015.

OGE will continue to make future annual inflationary adjustments to the Ethics Act CMPs in accordance with the statutory formula set forth in the 2015 Act and OMB guidance.

II. Matters of Regulatory Procedure

Administrative Procedure Act

Pursuant to 5 U.S.C. 553(b), as Acting Director of the Office of Government Ethics, I find that good cause exists for waiving the general notice of proposed rulemaking and public comment procedures as to these technical amendments. The notice and comment procedures are being waived because these amendments, which concern matters of agency organization, procedure and practice, are being adopted in accordance with statutorily mandated inflation adjustment procedures of the 2015 Act, which specifies that agencies shall adjust civil monetary penalties notwithstanding Section 553 of the Administrative Procedure Act. It is also in the public interest that the adjusted rates for civil monetary penalties under the Ethics in Government Act become effective as

[1] OGE has previously determined, after consultation with the Department of Justice, that the $200 late filing fee for public financial disclosure reports that are more than 30 days overdue (see section 104(d) of the Ethics Act, 5 U.S.C. appendix, 104(d), and 5 CFR 2634.704 of OGE's regulations thereunder) is not a CMP as defined under the Federal Civil Penalties Inflation Adjustment Act, as amended. Therefore, that fee is not being adjusted in this rulemaking (nor was it adjusted by OGE in previous CMP rulemakings), and will remain at its current amount of $200.

soon as possible in order to maintain their deterrent effect.

Regulatory Flexibility Act

As the Acting Director of the Office of Government Ethics, I certify under the Regulatory Flexibility Act (5 U.S.C. chapter 6) that this final rule would not have a significant economic impact on a substantial number of small entities because it primarily affects current Federal executive branch employees.

Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. chapter 35) does not apply because this regulation does not contain information collection requirements that require approval of the Office of Management and Budget.

Unfunded Mandates Reform Act

For purposes of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. chapter 5, subchapter II), this rule would 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) in any one year.

Executive Order 13563 and Executive Order 12866

Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select the regulatory approaches that maximize net benefits (including 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. The Office of Management and Budget has determined that rulemakings such as this implementing annual inflationary adjustments under the 2015 Act are not significant regulatory actions under Executive Order 12866.

Executive Order 12988

As Acting Director of the Office of Government Ethics, I have reviewed this rule in light of section 3 of Executive Order 12988, Civil Justice Reform, and certify that it meets the applicable standards provided therein.

List of Subjects

5 CFR Part 2634

Certificates of divestiture, Conflict of interests, Government employees, Penalties, Reporting and recordkeeping requirements, Trusts and trustees.

5 CFR Part 2636

Conflict of interests, Government employees, Penalties.

Dated: January 11, 2018.

David J. Apol,

Acting Director, U.S. Office of Government Ethics.

For the reasons set forth in the preamble, the U.S. Office of Government Ethics is amending 5 CFR parts 2634 and 2636 as follows:

PART 2634—EXECUTIVE BRANCH FINANCIAL DISCLOSURE, QUALIFIED TRUSTS, AND CERTIFICATES OF DIVESTITURE

■ 1. The authority citation for part 2634 continues to read as follows:

Authority: 5 U.S.C. App. (Ethics in Government Act of 1978); 26 U.S.C. 1043; Pub. L. 101–410, 104 Stat. 890, 28 U.S.C. 2461 note (Federal Civil Penalties Inflation Adjustment Act of 1990), as amended by Sec. 31001, Pub. L. 104–134, 110 Stat. 1321 (Debt Collection Improvement Act of 1996) and Sec. 701, Pub. L. 114–74 (Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015); E.O. 12674, 54 FR 15159, 3 CFR, 1989 Comp., p. 215, as modified by E.O. 12731, 55 FR 42547, 3 CFR, 1990 Comp., p. 306.

■ 2. Section 2634.701 is amended by revising paragraph (b) to read as follows:

§ 2634.701 Failure to file or falsifying reports.

* * * * *

(b) *Civil action.* The Attorney General may bring a civil action in any appropriate United States district court against any individual who knowingly and willfully falsifies or who knowingly and willfully fails to file or report any information required by filers of public reports under subpart B of this part. The court in which the action is brought may assess against the individual a civil monetary penalty in any amount, not to exceed the amounts set forth below, as provided by section 104(a) of the Act, as amended, and as adjusted in accordance with the inflation adjustment procedures prescribed in the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended:

Date of violation	Penalty
Violation occurring between Sept. 14, 2007 and Nov. 2, 2015	$50,000
Violation occurring after Nov. 2, 2015	59,028

* * * * *

■ 3. Section 2634.702 is revised to read as follows:

§ 2634.702 Breaches by trust fiduciaries and interested parties.

(a) The Attorney General may bring a civil action in any appropriate United States district court against any individual who knowingly and willfully violates the provisions of § 2634.408(d)(1) or (e)(1). The court in which the action is brought may assess against the individual a civil monetary penalty in any amount, not to exceed the amounts set forth below, as provided by section 102(f)(6)(C)(i) of the Act and as adjusted in accordance with the inflation adjustment procedures prescribed in the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended:

Date of violation	Penalty
Violation occurring between Sept. 29, 1999 and Nov. 2, 2015	$11,000
Violation occurring after Nov. 2, 2015	19,639

(b) The Attorney General may bring a civil action in any appropriate United States district court against any individual who negligently violates the provisions of § 2634.408(d)(1) or (e)(1). The court in which the action is brought may assess against the individual a civil monetary penalty in any amount, not to exceed the amounts set forth below, as provided by section 102(f)(6)(C)(ii) of the Act and as adjusted in accordance with the inflation adjustment procedures of the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended:

Date of violation	Penalty
Violation occurring between Sept. 29, 1999 and Nov. 2, 2015	$5,500
Violation occurring after Nov. 2, 2015	9,819

■ 4. Section 2634.703 is revised to read as follows:

§ 2634.703 Misuse of public reports.

(a) The Attorney General may bring a civil action against any person who obtains or uses a report filed under this part for any purpose prohibited by section 105(c)(1) of the Act, as incorporated in § 2634.603(f). The court in which the action is brought may assess against the person a civil monetary penalty in any amount, not to exceed the amounts set forth below, as provided by section 105(c)(2) of the Act and as adjusted in accordance with the

inflation adjustment procedures prescribed in the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended:

Date of violation	Penalty
Violation occurring between Sept. 29, 1999 and Nov. 2, 2015	$11,000
Violation occurring after Nov. 2, 2015	19,639

(b) This remedy shall be in addition to any other remedy available under statutory or common law.

PART 2636—LIMITATIONS ON OUTSIDE EARNED INCOME, EMPLOYMENT AND AFFILIATIONS FOR CERTAIN NONCAREER EMPLOYEES

■ 5. The authority citation for part 2636 continues to read as follows:

Authority: 5 U.S.C. App. (Ethics in Government Act of 1978); Pub. L. 101–410, 104 Stat. 890, 28 U.S.C. 2461 note (Federal Civil Penalties Inflation Adjustment Act of 1990), as amended by Sec. 31001, Pub. L. 104–134, 110 Stat. 1321 (Debt Collection Improvement Act of 1996) and Sec. 701, Pub. L. 114–74 (Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015); E.O. 12674, 54 FR 15159, 3 CFR, 1989 Comp., p. 215, as modified by E.O. 12731, 55 FR 42547, 3 CFR, 1990 Comp., p. 306.

■ 6. Section 2636.104 is amended by revising paragraph (a) to read as follows:

§ 2636.104 Civil, disciplinary and other action.

(a) *Civil action.* Except when the employee engages in conduct in good faith reliance upon an advisory opinion issued under § 2636.103, an employee who engages in any conduct in violation of the prohibitions, limitations and restrictions contained in this part may be subject to civil action under 5 U.S.C. app. 504(a) and a civil monetary penalty of not more than the amounts set forth below, as adjusted in accordance with the inflation adjustment procedures prescribed in the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended, or the amount of the compensation the individual received for the prohibited conduct, whichever is greater.

Date of violation	Penalty
Violation occurring between Sept. 29, 1999 and Nov. 2, 2015	$11,000
Violation occurring after Nov. 2, 2015	19,639

* * * * *

[FR Doc. 2018–00688 Filed 1–16–18; 8:45 am]

BILLING CODE 6345–03–P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 50

[NRC–2012–0059]

RIN 3150–AJ13

Approval of American Society of Mechanical Engineers' Code Cases

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is amending its regulations to incorporate by reference (IBR) the latest revisions of three regulatory guides (RGs) approving new, revised, and reaffirmed Code Cases published by the American Society of Mechanical Engineers (ASME). This action allows nuclear power plant licensees and applicants for construction permits, operating licenses, combined licenses, standard design certifications, standard design approvals and manufacturing licenses to voluntarily use the Code Cases listed in these RGs as alternatives to engineering standards for the construction, inservice inspection (ISI), and inservice testing (IST) of nuclear power plant components. These engineering standards are set forth in the ASME's Boiler and Pressure Vessel (BPV) Codes and ASME Operation and Maintenance (OM) Codes, which are currently incorporated by reference into the NRC's regulations. This final rule announces the availability of the final versions of the three RGs that are being incorporated by reference. Further, the final rule announces the availability of a related RG, not incorporated by reference into the NRC's regulations that lists Code Cases that the NRC has not approved for use.

DATES: This final rule is effective on February 16, 2018. The incorporation by reference of certain publications listed in the regulation is approved by the Director of the Federal Register as of February 16, 2018.

ADDRESSES: Please refer to Docket ID NRC–2012–0059 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 Website:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2012–0059. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *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.* For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in the ''Availability of Documents'' section.
- *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.

FOR FURTHER INFORMATION CONTACT: Jennifer Tobin, Office of Nuclear Reactor Regulation, telephone: 301–415–2328, email: *Jennifer.Tobin@nrc.gov;* or Giovanni Facco, Office of Nuclear Regulatory Research, telephone: 301–415–6337; email: *Giovanni.Facco@nrc.gov.* Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

Executive Summary

The purpose of this regulatory action is to incorporate by reference into the NRC's regulations the latest revisions of three RGs. The three RGs identify new, revised, and reaffirmed Code Cases published by the ASME, which the NRC has determined are acceptable for use as alternatives to certain provisions of the ASME BPV Codes and ASME OM Codes, currently incorporated by reference into the NRC's regulations. The three RGs that the NRC is incorporating by reference are RG 1.84, ''Design, Fabrication, and Materials Code Case Acceptability, ASME Section III,'' Revision 37; RG 1.147, ''Inservice Inspection Code Case Acceptability, ASME Section XI, Division 1,'' Revision 18; and RG 1.192, ''Operation and Maintenance Code Case Acceptability, ASME OM Code,'' Revision 2. This regulatory action allows nuclear power plant licensees and applicants for construction permits, operating licenses, combined licenses, standard design certifications, standard design approvals, and manufacturing licenses to voluntarily use the Code Cases, newly listed in these revised RGs, as

alternatives to engineering standards for the design, construction, ISI, and IST, and repair/replacement of nuclear power plant components. In this notice, the NRC also notifies the public of the availability of RG 1.193, ''ASME Code Cases Not Approved for Use,'' Revision 5. The regulatory guide lists Code Cases that the NRC has not approved for generic use, and will not be incorporated by reference into the NRC's regulations.

The NRC prepared a regulatory analysis (ADAMS Accession No. ML16285A013) to identify the benefits and costs associated with this final rule. The regulatory analysis prepared for this rulemaking was used to determine if the rule is cost-effective, overall, and to help the NRC evaluate potentially costly conditions placed on specific provisions of the ASME Code Cases, which are the subject of this rulemaking.

TABLE 1—COST-BENEFIT SUMMARY

Objective	Alternative 2—the rule alternative net benefits (costs) (net present value, 7% discount rate) ($ million)
Industry	2.42
NRC	2.52
Net Benefit	4.94

Table 1 summarizes the benefits and costs for the alternative of proceeding with the final rule (Alternative 2) and shows that the final rule is quantitatively cost-beneficial with a net benefit of $4.94 million to both the industry and the NRC when compared to the regulatory baseline (Alternative 1). The regulatory analysis shows that implementing the final rule is quantitatively cost-effective and an efficient use of the NRC's and Industry's resources. Uncertainty analysis shows that the net benefit ranges from $2.86 million to $6.90 million with a mean of $4.94 million. Because the rulemaking alternative is cost-effective, the rulemaking approach is recommended.

There are several benefits associated with this final rule. Under this final rule, a licensee of a nuclear power plant would no longer be required to submit a Code Case alternative request under the new § 50.55a(z) of Title 10 of the *Code of Federal Regulations* (10 CFR), which would provide an averted cost of $7.75 million (7-percent net present value) to the licensee. Additionally, the NRC would not receive Code Case alternative request submittals, which would provide an averted cost of $2.52 million (7-percent net present value) to the NRC.

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I. Background

The ASME develops and publishes the ASME BPV Code, which contains requirements for the design, construction, and ISI and examination of nuclear power plant components, and ASME's Nuclear Power Plants (OM) Code,[1] which contains requirements for IST of nuclear power plant components. In response to BPV Code and OM Code user requests, the ASME develops Code Cases that provide alternatives to BPV Code and OM Code requirements under special circumstances.

The NRC approves and can mandate the use of the ASME BPV Codes and OM Codes in § 50.55a, ''Codes and standards,'' through the process of incorporation by reference. As such, each provision of the ASME Codes incorporated by reference into and mandated by § 50.55a constitutes a legally-binding NRC requirement imposed by the regulations. As noted previously, ASME Code Cases, for the most part, represent alternative approaches for complying with provisions of the ASME BPV Codes and OM Codes. Accordingly, the NRC periodically amends § 50.55a to incorporate by reference the NRC's RGs listing approved ASME Code Cases that may be used as alternatives to the BPV Codes and OM Codes.[2]

This rulemaking is the latest in a series of rulemakings that incorporates by reference new versions of several RGs identifying new, revised, and reaffirmed,[3] and unconditionally or conditionally acceptable ASME Code Cases that the NRC approves for use. In developing these RGs, the staff reviews ASME BPV and OM Code Cases, determines the acceptability of each Code Case, and publishes its findings in the RGs. The RGs are revised periodically, as new Code Cases and are published by the ASME. The NRC incorporates by reference the RGs, listing acceptable and conditionally acceptable ASME Code Cases into § 50.55a. Currently, NRC RG 1.84, ''Design, Fabrication, and Materials Code Case Acceptability, ASME Section III,'' Revision 36; RG 1.147, ''Inservice Inspection Code Case Acceptability, ASME Section XI, Division 1,'' Revision 17; and RG 1.192, ''Operation and Maintenance Code Case Acceptability, ASME OM Code,'' Revision 1, are incorporated into the NRC's regulations in § 50.55a.

II. Discussion

This rule incorporates by reference the latest revisions of the NRC RGs that list ASME BPV and OM Code Cases that the NRC finds to be acceptable, or acceptable with NRC-specified conditions (''conditionally acceptable''). Regulatory Guide 1.84, Revision 37, supersedes Revision 36; RG 1.147, Revision 18, supersedes Revision 17; and RG 1.192, Revision 2, supersedes Revision 1. The NRC also publishes a document (RG 1.193, ''ASME Code Cases Not Approved for Use'') that lists Code Cases that the NRC has not approved for generic use. The RG 1.193 is not incorporated by reference into the NRC's regulations; however, in this final rule, the NRC notes the availability of RG 1.193, Revision 5.

The ASME Code Cases that are the subject of this rulemaking are the new, revised, and reaffirmed Section III and Section XI Code Cases listed in

[1] The editions and addenda of the ASME Code for Operation and Maintenance of Nuclear Power Plants have had different titles from 2005 to 2012, and are referred to collectively in this rule as the ''OM Code.''

[2] See **Federal Register** notice, ''Incorporation by Reference of ASME BPV and OM Code Cases'' (68 FR 40469; July 8, 2003).

[3] Code Cases are categorized by ASME as one of three types: new, revised, or reaffirmed. A new Code Case provides for a new alternative to specific ASME Code provisions or addresses a new need. The ASME defines a revised Code Case to be a revision (modification) to an existing Code Case to address, for example, technological advancements in examination techniques or to address NRC conditions imposed in one of the RGs that have been incorporated by reference into § 50.55a. The ASME defines ''reaffirmed'' as an OM Code Case to be one that does not have any change to technical content, but includes editorial changes.

Supplement 11 to the 2007 BPV Code through Supplement 10 to the 2010 BPV Code, and the OM Code Cases published with the 2009 Edition through the 2012 Edition.

The latest editions and addenda of the ASME BPV and OM Codes that the NRC has approved for use are referenced in § 50.55a. The ASME also publishes Code Cases that provide alternatives to existing Code requirements that the ASME developed and approved. This rule incorporates by reference the latest revisions of RGs 1.84, 1.147, and 1.192. This rule allows nuclear power plant licensees and applicants for construction permits, operating licenses, combined licenses, standard design certifications, standard design approvals, and manufacturing licenses, under the regulations that govern license certifications, to voluntarily use the Code Cases listed in these RGs as suitable alternatives to certain provisions of the ASME BPV and OM Codes for the construction, ISI, and IST of nuclear power plant components. This action is consistent with the provisions of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, which encourages Federal regulatory agencies to consider adopting industry consensus standards as an alternative to *de novo* agency development of standards affecting an industry. This action is also consistent with the NRC policy of evaluating the latest versions of consensus standards, in terms of their suitability for endorsement by regulations or regulatory guides.

The NRC follows a three-step process to determine acceptability of new, revised, and reaffirmed Code Cases, and the need for regulatory positions on the use of these Code Cases. This process was employed in the review of the Code Cases in Supplement 11 to the 2007 Edition through Supplement 10 to the 2010 Edition of the BPV Code and the 2009 Edition through the 2012 Edition of the OM Code. The Code Cases in these supplements and OM Editions and Addenda are the subject of this rule. First, the ASME develops Code Cases through a consensus development process, as administered by the American National Standards Institute (ANSI), which ensures that the various technical interests (*e.g.,* utility, manufacturing, insurance, regulatory) are represented on standards development committees and that their view points are addressed fairly. The NRC staff actively participates in discussions and technical debates of the task groups, working groups, subgroups, and standards committees regarding the development of new and revised standards. The Code Case process includes the development of a technical justification in support of each new or revised Code Case. The ASME committee meetings are open to the public and attendees are encouraged to participate. Task groups, working groups, and subgroups report to respective standards committees. The standards committee is the decisive consensus committee in that it ensures that the development process fully complies with the ANSI consensus process.

Second, the standards committee transmits a first consideration letter ballot to every member of the standards committee, requesting comment or approval of new and revised Code Cases. Code Cases are approved by the standards committee from the first consideration letter ballot when: (1) At least two thirds of the eligible consensus committee membership vote approved; (2) there are no disapprovals from the standards committee; and (3) no substantive comments are received from the ASME oversight committees such as the Technical Oversight Management Committee (TOMC). The TOMC's duties, in part, are to oversee various standards committees to ensure technical adequacy and to provide recommendations in the development of codes and standards, as required. Code Cases that were disapproved or received substantive comments from the first consideration ballot are reviewed by the working level group(s) responsible for their development to consider the comments received. These Code Cases are approved by the standards committee on second consideration when at least two thirds of the eligible consensus committee membership vote approved, and there are no more than three disapprovals from the consensus committee.

Third, the NRC reviews new, revised, and reaffirmed Code Cases to determine their acceptability for incorporation by reference in § 50.55a through the subject RGs. This rulemaking process, when considered together with the ANSI process for developing and approving the ASME codes and standards, and Code Cases, constitutes the NRC's basis that the Code Cases (with conditions as necessary) provide reasonable assurance of adequate protection to public health and safety.

The staff concludes, in accordance with the process described, that the Code Cases are technically adequate (with conditions as necessary) and consistent with current NRC regulations, and the staff is referencing these Code Cases in the applicable RGs, thereby approving them for voluntary use, without conditions as addressed in Section A of this document; subject to the specified conditions, or as identified in Section B of this document. The staff reviewed the new, revised, and reaffirmed Code Cases identified in the three RGs being incorporated by reference into § 50.55a in this rulemaking. Therefore, the NRC approves revising the § 50.55a regulations to incorporate by reference the latest revisions of RGs 1.84, 1.147, and 1.192. Additionally, the NRC announces the availability of the latest revision of RG 1.193.

A. ASME Code Cases Approved for Unconditional Use

The Code Cases that are discussed in Table I are new, revised, or reaffirmed Code Cases that the NRC is approving for use without conditions. The NRC concludes, in accordance with the process described for review of ASME Code Cases, that each of the ASME Code Cases listed in Table I are acceptable for use without conditions. Therefore, the NRC is approving for unconditional use the Code Cases listed in Table I. This table identifies the regulatory guide the applicable Code Case that the NRC is approving for use.

The NRC revised RG 1.147, Revision 18 to approve Code Case N–786–1 in Table 1 to address inconsistencies that were identified between the NRC's position in the proposed rule regarding the acceptability of Code Case N–786 and several licensee requests for alternatives to ASME Code requirements, in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 50.55a(z), that have utilized Code Case N–786. The NRC had authorized the use of Code Case N–786 with modifications. The NRC erred in not listing N–786 in DG–1296, Table 2 ''Conditionally Acceptable Section XI Code Cases'' with appropriate conditions, in order to be consistent with modifications that the NRC has required for requested alternatives based on Code Case N–786. In response to modifications to N–786 by licensees requesting to use this code case as an alternative to ASME Code, ASME revised the code case. The revised Code Case, N–786–1 ''Alternative Requirements for Sleeve Reinforcement of Class 2 and 3 Moderate-Energy Carbon Steel Piping Section XI, Division 1,'' includes modifications that address all of the NRC's concerns that the NRC identified in previously approved alternatives that were based on N–786. Therefore, the NRC has listed Code Case N–786–1 in Table 1 of RG 1.147 Revision 18 in lieu of code Case N–786. There were no public comments

received on the inclusion of N–786 in the RG. Code Case N–786–1 is included in this final rule because it includes the latest ASME guidance and the NRC conditions on the use of this method of repair.

TABLE I—ASME CODE CASES APPROVED FOR UNCONDITIONAL USE

Code Case No.	Supplement	Title
Boiler and Pressure Vessel Code Section III (addressed in RG 1.84, Revision 37, Table 1)		
N–284–3	7 (10 Edition)	Metal Containment Shell Buckling Design Methods, Class MC, TC, and SC Construction, Section III, Divisions 1 and 3.
N–500–4	8 (10 Edition)	Alternative Rules for Standard Supports for Classes 1, 2, 3, and MC, Section III, Division 1.
N–520–5	10 (10 Edition)	Alternative Rules for Renewal of Active or Expired N-type Certificates for Plants Not in Active Construction, Section III, Division 1.
N–594–1	8 (10 Edition)	Repairs to P–4 and P–5A Castings without Postweld Heat Treatment Class 1, 2, and 3 Construction, Section III, Division 1.
N–637–1	3 (10 Edition)	Use of 44Fe–25Ni–21Cr–Mo (Alloy UNS N08904) Plate, Bar, Fittings, Welded Pipe, and Welded Tube, Classes 2 and 3, Section III, Division 1.
N–655–2	4 (10 Edition)	Use of SA–738, Grade B, for Metal Containment Vessels, Class MC, Section III, Division 1.
N–763	2 (10 Edition)	ASTM A 709–06, Grade HPS 70W (HPS 485W) Plate Material Without Postweld Heat Treatment as Containment Liner Material or Structural Attachments to the Containment Liner, Section III, Division 2.
N–777	4 (10 Edition)	Calibration of C_v Impact Test Machines, Section III, Divisions 1, 2, and 3.
N–785	11 (07 Edition)	Use of SA–479/SA–479M, UNS S41500 for Class 1 Welded Construction, Section III, Division 1.
N–811	7 (10 Edition)	Alternative Qualification Requirements for Concrete Level III Inspection Personnel, Section III, Division 2.
N–815	8 (10 Edition)	Use of SA–358/SA–358M Grades Fabricated as Class 3 or Class 4 Welded Pipe, Class CS Core Support Construction, Section III, Division 1.
N–816	8 (10 Edition)	Use of Temper Bead Weld Repair Rules Adopted in 2010 Edition and Earlier Editions, Section III, Division 1.
N–817	8 (10 Edition)	Use of Die Forgings, SB–247, UNS A96061 Class T6, With Thickness ≤ 4.000 in. Material, Class 2 Construction (1992 Edition or Later), Section III, Division 1.
N–819	8 (10 Edition)	Use of Die Forgings, SB–247, UNS A96061 Class T6, With Thickness ≤ 4.000 in. Material, Class 2 Construction (1989 Edition with the 1991 Addenda or Earlier), Section III, Division 1.
N–822	8 (10 Edition)	Application of the ASME Certification Mark, Section III, Divisions 1, 2, 3, and 5.
Boiler and Pressure Vessel Code Section XI (addressed in RG 1.147, Revision 18, Table 1)		
N–609–1	3 (10 Edition)	Alternative Requirements to Stress-Based Selection Criteria for Category B–J Welds, Section XI, Division 1.
N–613–2	4 (10 Edition)	Ultrasonic Examination of Full Penetration Nozzles in Vessels, Examination Category B–D, Reactor Nozzle-To-Vessel Welds, and Nozzle Inside Radius Section Figs. IWB–2500–7(a), (b), (c), and (d), Section XI, Division 1.
N–652–2	9 (10 Edition)	Alternative Requirements to Categorize B–G–1, B–G–2, and C–D Bolting Examination Methods and Selection Criteria, Section XI, Division 1.
N–653–1	9 (10 Edition)	Qualification Requirements for Full Structural Overlaid Wrought Austenitic Piping Welds, Section XI, Division 1.
N–694–2 [4]	1 (13 Edition)	Evaluation Procedure and Acceptance Criteria for [pressurized water reactors] (PWR) Reactor Vessel Head Penetration Nozzles, Section XI, Division 1.
N–730–1	10 (10 Edition)	Roll Expansion of Class 1 Control Rod Drive Bottom Head Penetrations in [boiling water reactors] BWRs, Section XI, Division 1.
N–769–2	10 (10 Edition)	Roll Expansion of Class 1 In-Core Housing Bottom Head Penetrations in BWRs, Section XI, Division 1.
N–771	7 (10 Edition)	Alternative Requirements for Additional Examinations of Class 2 or 3 Items, Section XI, Division 1.
N–775	2 (10 Edition)	Alternative Requirements for Bolting Affected by Borated Water Leakage, Section XI, Division 1.
N–776	1 (10 Edition)	Alternative to IWA–5244 Requirements for Buried Piping, Section XI, Division 1.
N–786–1	5 (10 Edition)	Alternative Requirements for Sleeve Reinforcement of Class 2 and 3 Moderate-Energy Carbon Steel Piping, Section XI, Division 1.

TABLE I—ASME CODE CASES APPROVED FOR UNCONDITIONAL USE—Continued

Code Case No.	Supplement	Title
N–798	4 (10 Edition)	Alternative Pressure Testing Requirements for Class 1 Piping Between the First and Second Vent, Drain, and Test Isolation Devices, Section XI, Division 1.
N–800	4 (10 Edition)	Alternative Pressure Testing Requirements for Class 1 Piping Between the First and Second Injection Valves, Section XI, Division 1.
N–803	5 (10 Edition)	Similar and Dissimilar Metal Welding Using Ambient Temperature Automatic or Machine Dry Underwater Laser Beam Welding (ULBW) Temper Bead Technique, Section XI, Division 1.
N–805	6 (10 Edition)	Alternative to Class 1 Extended Boundary End of Interval or Class 2 System Leakage Testing of the Reactor Vessel Head Flange O-Ring Leak-Detection System, Section XI, Division 1.
N–823	9 (10 Edition)	Visual Examination, Section XI, Division 1.
N–825 [5]	3 (13 Edition)	Alternative Requirements for Examination of Control Rod Drive Housing Welds, Section XI, Division 1.
N–845 [6]	6 (13 Edition)	Qualification Requirements for Bolts and Studs, Section XI, Division 1.
Operation and Maintenance Code (OM) (addressed in RG 1.192, Revision 2, Table 1)		
OMN–2	2012 Edition	Thermal Relief Valve Code Case, OM Code-1995, Appendix I.
OMN–5	2012 Edition	Testing of Liquid Service Relief Valves without Insulation.
OMN–6	2012 Edition	Alternative Rules for Digital Instruments.
OMN–7	2012 Edition	Alternative Requirements for Pump Testing.
OMN–8	2012 Edition	Alternative Rules for Preservice and Inservice Testing of Power-Operated Valves That Are Used for System Control and Have a Safety Function per OM–10, ISTC–1.1, or ISTA–1100.
OMN–13, Revision 2	2012 Edition	Performance-Based Requirements for Extending Snubber Inservice Visual Examination Interval at [light water reactor] LWR Power Plants.
OMN–14	2012 Edition	Alternative Rules for Valve Testing Operations and Maintenance, Appendix I: BWR [control rod drive] CRD Rupture Disk Exclusion.
OMN–15, Revision 2	2012 Edition	Performance-Based Requirements for Extending the Snubber Operational Readiness Testing Interval at LWR Power Plants.
OMN–17	2012 Edition	Alternative Rules for Testing ASME Class 1 Pressure Relief/Safety Valves.

B. ASME Code Cases Approved for Use With Conditions

The Code Cases that are discussed in Table II, below, are new, revised or reaffirmed Code Cases, which the NRC is approving for use with conditions. The NRC has determined that certain Code Cases, as issued by the ASME, are generally acceptable for use, but that the alternative requirements specified in those Code Cases must be supplemented in order to provide an acceptable level of quality and safety. Accordingly, the NRC is imposing conditions on the use of these Code Cases to modify, limit, or clarify their requirements. The conditions specify, for each applicable Code Case, the additional activities that must be performed, the limits on the activities specified in the Code Case, and the supplemental information needed to provide clarity. These ASME Code Cases with conditions are included in Table 2 of each RG (*i.e.,* RG 1.84, RG 1.147, and RG 1.192). It is noted that both RG 1.147 and RG 1.192 have new ASME Code Cases with conditions; however, there are no new ASME Code Cases with conditions for RG 1.84.

TABLE II—CODE CASES APPROVED FOR CONDITIONAL USE

Code Case No.	Supplement	Title
Boiler and Pressure Vessel Code Section III (addressed in RG 1.84, Revision 37, Table 2)		
No ASME Section III Code Cases are approved for conditional use in this rule.		
Boiler and Pressure Vessel Code Section XI (addressed in RG 1.147, Revision 18, Table 2)		
N–552–1	10 (10 Edition)	Alternative Methods—Qualification for Nozzle Inside Radius Section from the Outside Surface, Section XI, Division 1.
N–576–2	9 (10 Edition)	Repair of Class 1 and 2 SB–163, UNS N06600 Steam Generator Tubing, Section XI, Division 1.
N–593–2	8 (10 Edition)	Examination Requirements for Steam Generator Nozzle-to-Vessel Welds, Section XI, Division 1.

[4] Code Case published in Supplement 1 to the 2013 Edition; included at the request of ASME.

[5] Code Case published in Supplement 3 to the 2013 Edition; included at the request of ASME.

[6] Code Case published in Supplement 6 to the 2013 Edition; included at the request of ASME.

TABLE II—CODE CASES APPROVED FOR CONDITIONAL USE—Continued

Code Case No.	Supplement	Title
N–638–6	6 (10 Edition)	Similar and Dissimilar Metal Welding Using Ambient Temperature Machine GTAW Temper Bead Technique, Section XI, Division 1.
N–662–1	6 (10 Edition)	Alternative Repair/Replacement Requirements for Items Classified in Accordance with Risk-Informed Processes, Section XI, Division 1.
N–666–1	9 (10 Edition)	Weld Overlay of Classes 1, 2, and 3 Socket Welded Connections, Section XI, Division 1.
N–749	9 (10 Edition)	Alternative Acceptance Criteria for Flaws in Ferritic Steel Components Operating in the Upper Shelf Temperature Range, Section XI, Division 1.
N–754	6 (10 Edition)	Optimized Structural Dissimilar Metal Weld Overlay for Mitigation of PWR Class 1 Items, Section XI, Division 1.
N–778	6 (10 Edition)	Alternative Requirements for Preparation and Submittal of Inservice Inspection Plans, Schedules, and Preservice and Inservice Summary Reports, Section XI, Division 1.
N–789	6 (10 Edition)	Alternative Requirements for Pad Reinforcement of Class 2 and 3 Moderate Energy Carbon Steel Piping for Raw Water Service, Section XI, Division 1.
N–795	3 (10 Edition)	Alternative Requirements for BWR Class 1 System Leakage Test Pressure Following Repair/Replacement Activities, Section XI, Division 1.
N–799	4 (10 Edition)	Dissimilar Metal Welds Joining Vessel Nozzles to Components, Section XI, Division 1.
Operation and Maintenance Code (OM) (addressed in RG 1.192, Revision 2, Table 2)		
OMN–1 Revision 1	2012 Edition	Alternative Rules for Preservice and Inservice Testing of Active Electric Motor Operated-Valve Assemblies in Light-Water Reactor Power Plants.
OMN–3	2012 Edition	Requirements for Safety Significance Categorization of Components Using Risk Insights for Inservice Testing of LWR Power Plants.
OMN–4	2012 Edition	Requirements for Risk Insights for Inservice Testing of Check Valves at LWR Power Plants.
OMN–9	2012 Edition	Use of a Pump Curve for Testing.
OMN–12	2012 Edition	Alternative Requirements for Inservice Testing Using Risk Insights for Pneumatically and Hydraulically Operated Valve Assemblies in Light-Water Reactor Power Plants (OM-Code 1998, Subsection ISTC).
OMN–16 Revision 1	2012 Edition	Use of a Pump Curve for Testing.
OMN–18	2012 Edition	Alternate Testing Requirements for Pumps Tested Quarterly Within ±20% of Design Flow.
OMN–19	2012 Edition	Alternative Upper Limit for the Comprehensive Pump Test.
OMN–20	2012 Edition	Inservice Test Frequency.

The NRC's evaluation of the Code Cases and the reasons for the NRC's conditions are discussed in the following paragraphs. Notations have been made to indicate the conditions duplicated from previous versions of the RG.

ASME BPV Code, Section III Code Cases (RG 1.84)

There are no new or revised Section III Code Cases in Supplement 11 to the 2007 Edition through Supplement 10 to the 2010 Edition that the NRC is conditionally approving in Revision 37 of RG 1.84.

ASME BPV Code, Section XI Code Cases (RG 1.147)

Code Case N–552–1 [Supplement 10, 2010 Edition]

Type: Revised.

Title: Alternative Methods—Qualification for Nozzle Inside Radius Section from the Outside Surface, Section XI, Division 1.

The conditions on Code Case N–552–1 are identical to the conditions on N–552 that were approved by the NRC in Revision 16 of RG 1.147 in October 2010. The reasons for imposing these conditions in Code Case N–576 continue to apply to N–576–2. Therefore, these conditions have been retained for this Code Case in Revision 18 of RG 1.147.

Code Case N–576–2 [Supplement 9, 2010 Edition]

Type: Revised.

Title: Repair of Class 1 and 2 SB–163, UNS N06600 Steam Generator Tubing, Section XI, Division 1.

The conditions on Code Case N–576–2 are identical to the conditions on N–576–1 that were approved by the NRC in Revision 17 of RG 1.147 in October 2014. The reasons for imposing these conditions are not resolved by Code Case N–576–2 and, therefore, these conditions have been retained in Revision 18 of RG 1.147.

Public comments on N–576–2 requested that the NRC revise the proposed condition to follow IWA–4200 in their code of record. In response, the NRC revised the ''note'' in the condition in Revision 18 of RG 1.147 to eliminate the portion regarding reconciliation. The revised ''note'' will read: ''Note: Steam generator tube repair methods require prior NRC approval through the Technical Specifications. This Code Case does not address certain aspects of this repair, *e.g.,* the qualification of the inspection and plugging criteria necessary for staff approval of the repair method.''

Code Case N–593–2 [Supplement 8, 2010 Edition]

Type: Revised.

Title: Examination Requirements for Steam Generator Nozzle-to-Vessel Welds, Section XI, Division 1.

The first condition on Code Case N–593–2 is identical to the condition on Code Case N–593 that was first approved by the NRC in Revision 13 of RG 1.147 in June 2003. The condition stated that, ''Essentially 100 percent (not less than 90 percent) of the examination volume A–B–C–D–E–F–G–H [in Figure 1 of the Code Case] must be examined.'' The reasons for imposing this condition in Code Case N–593 continue to apply to Code Case N–593–2. Therefore, this condition has been retained for this Code Case in Revision 18 of RG 1.147.

The second condition on Code Case N–593–2 is new. Revision 2 of the Code Case reduces the weld examination volume by reducing the width examined on either side of the weld from $t_s/2$ to ½ in. The basis for this change in inspection volume is to revise the examination volume for steam generator nozzle-to-vessel welds (under Code Case N–593–2) to be consistent with that specified in Code Case N–613–1 for similar vessel nozzles.

The NRC identified an issue with respect to Code Case N–593–2 regarding its inconsistency with Code Case N–613–1. Code Case N–593–2 and Code Case N–613–1 address certain types of nozzle-to-vessel welds. Code Case N–613–1 states that ''. . . Category B–D nozzle-to-vessel welds previously ultrasonically examined using the examination volumes of Figs. IWB–2500–7(a), (b), and (c) may be examined using the reduced examination volume (A–B–C–D–E–F–G–H) of Figs. 1, 2, and 3.'' The keywords are ''previously examined.'' Code Case N–613–1 requires the larger volume to have been previously examined before examinations using the reduced volume can be performed. This ensures that there are no detrimental flaws in the component adjacent to the weld that would be missed if the inspection was performed only on the reduced volume. However, Code Case N–593–2 allows a licensee to immediately implement the reduced volume. Accordingly, the NRC is approving Code Case N–593–2 with a condition to require that the examination volume specified in Section XI, Table IWB–2500–1, Examination Category B–D, be used for the examination of steam generator nozzle-to-vessel welds at least once prior to use of the reduced volume, as allowed by the Code Case.

Code Case N–638–6 [Supplement 6, 2010 Edition]

Type: Revised.

Title: Similar and Dissimilar Metal Welding Using Ambient Temperature Machine GTAW Temper Bead Technique, Section XI, Division 1.

Code Case N–638–6 allows the use of the automatic or machine gas-tungsten arc welding (GTAW) temper bead technique. The GTAW is a proven method that can produce high-quality welds because it affords greater control over the weld area than many other welding processes.

The NRC first approved Code Case N–638 (Revision 0) in 2003 (Revision 13 of RG 1.147). Code Case N–638–4 was approved by the NRC in Revision 16 of RG 1.147 with two conditions. Code Case N–638–5 was not approved in RG 1.147 for generic use but has been approved through requests for an alternative to § 50.55a. Code Case N–638–6 resolves one of the NRC's concerns that were raised when Code Case N–638–4 was considered for approval and, therefore, the NRC is deleting that condition from RG 1.147.

Many of the provisions for developing and qualifying welding procedure specifications for the temper bead technique that were contained in earlier versions of the Code Case have been incorporated into ASME Section IX, ''Welding and Brazing Qualifications,'' QW–290, ''Temper Bead Welding.'' Code Case N–638–6 retains the provisions not addressed by QW–290 and references QW–290 in lieu of specifying them directly in the Code Case.

In addition to retaining one of the two conditions on Code Case N–638–4, the NRC considered adding a new condition to address technical issues raised by certain provisions of Code Case N–638–6.

The retained condition on Code Case N–638–6 pertains to the qualification of nondestructive evaluation (NDE) and is identical to the condition on N–638–4 that was approved by the NRC in Revision 17 of RG 1.147 in October 2014. The reasons for imposing this condition in Code Case N–638 continue to apply to N–638–6. Therefore, this condition has been retained in Revision 18 of RG 1.147.

The new proposed condition (2) states that section 1(b)(1) of the Code Case shall not be used. Section 1(b)(1) would allow through-wall circumferential repair welds to be made using the temper bead technique without heat treatment. Revisions 1 through 5 of N–638 limited the depth of the weld to one-half of the ferritic base metal thickness and the previously stated condition will limit repairs to this previously approved value. Repairs exceeding one-half of the ferritic base metal thickness may represent significant repairs (*e.g.,* replacement of an entire portion of the reactor coolant loop). At the time that this revision of the Code Case was approved by ASME, the NRC staff had concerns related to through-wall repairs. Subsequently, through further evaluation related to a separate rulemaking, the NRC resolved its concerns related to through-wall repairs. Therefore, the NRC determined that proposed Condition (2) is unnecessary and has removed this condition from the final RG 1.147, Revision 18.

Code Case N–662–1 [Supplement 6, 2010 Edition]

Type: Revised.

Title: Alternative Repair/Replacement Requirements for Items Classified in Accordance with Risk-Informed Processes, Section XI, Division 1.

The condition on Code Case N–662–1 is identical to the condition on N–662 that was approved by the NRC in Revision 16 of RG 1.147 in October 2010. The reasons for imposing this condition were not resolved by Code Case N–662–1. Therefore, this condition has been retained for this Code Case in Revision 18 of RG 1.147.

Code Case N–666–1 [Supplement 9, 2010 Edition]

Type: Revised.

Title: Weld Overlay of Classes 1, 2, and 3 Socket Welded Connections, Section XI, Division 1.

Code Case N–666 was unconditionally approved in Revision 17 of RG 1.147. The NRC approves Code Case N–666–1 with one condition.

The condition is that a surface examination must be performed on the completed weld overlay for Class 1 and Class 2 piping socket welds. Code Case N–666–1 contains provisions for the design, installation, evaluation, pressure testing, and examination of the weld overlays on Class 1, 2, and 3 socket welds. Section 5(a)(1) of the Code Case requires NDE of the completed weld overlay in accordance with the Construction Code. However, various Construction Codes have been used in the design and fabrication of the nuclear power plant fleet. The requirements for NDE have changed over the years, as more effective and reliable methods and techniques have been developed. In addition, Construction Code practices have evolved based on design and construction experience. The NRC is concerned that some of the Construction

Codes would not require a surface examination of the weld overlay and would, therefore, be inadequate for NDE of the completed weld overlay. The NRC believes that a VT–1 examination alone would not be adequate and that a surface or volumetric examination must be performed on the completed weld overlay for Class 1 and Class 2 piping socket welds. Fabrication defects must be dispositioned using the surface or volumetric examination criteria of the Construction Code, as identified in the Repair/Replacement Plan.

Public commenters requested that the words ''and seal weld'' be removed from the condition because the phrase implies that the seal weld requires surface examination in addition to surface examination of the final overlay. The Code Case requires a visual examination of the seal weld, remaining socket weld, and adjacent base material before the weld overlay can be applied, which the NRC has determined is the appropriate examination prior to the application of the weld overlay. Therefore, proposed Condition (1) has been revised to remove ''and seal weld.''

In the proposed rule, the NRC included a second condition, which required that if a surface or volumetric examination of the completed weld overlay was not required by the plant-specific Construction Code, that a VT–1 visual examination be performed of the weld overlay. Paragraph 5(a) of the Code Case requires ''visual and nondestructive examination of the final structural overlay weld.'' Paragraph 5(a)(1) of the Code Case specifically requires a VT–1 visual examination of the completed weld overlay. Public commenters requested that the NRC remove the second condition because it was redundant and unnecessary. The NRC staff agrees and thus Condition (2) has been removed from the final rule.

Code Case N–749 [Supplement 9, 2010 Edition]

Type: New.

Title: Alternative Acceptance Criteria for Flaws in Ferritic Steel Components Operating in the Upper Shelf Temperature Range, Section XI, Division 1.

The NRC has determined that instead of the upper shelf transition temperature, T_c, as defined in the Code Case, the following shall be used:

$T_c = 154.8\ °F + 0.82 \times RT_{NDT}$ (in U.S Customary Units), and

$T_c = 82.8\ °C + 0.82 \times RT_{NDT}$ (in International System (SI) Units).

T_c is the temperature above which the elastic plastic fracture mechanics (EPFM) method must be applied. Additionally, the NRC defines temperature T_{c1} below, which the linear elastic fracture mechanics (LEFM) method must be applied:

$T_{c1} = 95.36\ °F + 0.703 \times RT_{NDT}$ (in U.S Customary Units), and

$T_{c1} = 47.7\ °C + 0.703 \times RT_{NDT}$ (in International System (SI) Units).

Between T_{c1} and T_c, while the fracture mode is in transition from LEFM to EPFM, users should consider whether or not it is appropriate to apply the EPFM method. Alternatively, the licensee may use a different T_c value, if it can be justified by plant-specific Charpy curves.

Code Case N–749 provides acceptance criteria for flaws in ferritic components for conditions when the material fracture resistance will be controlled by upper-shelf toughness behavior. These procedures may be used to accept a flaw in lieu of the requirements in Section XI, paragraphs IWB–3610 and IWB–3620, which use LEFM to evaluate flaws that exceed limits of Section XI, paragraph IWB–3500. Code Case N–749 employs EPFM methods (J-integral) and is patterned after the fracture methodology and acceptance criteria that currently exist in Section XI, paragraph IWB–3730(b), and Section XI, Nonmandatory Appendix K, ''Assessment of Reactor Vessels with Upper Shelf Charpy Impact Energy Levels.'' The Code Case states that the proposed methodology is applicable if the metal temperature of the component exceeds the upper shelf transition temperature, T_c, which is defined as nil-ductility reference temperature (RT_{NDT}) plus 105 degrees F. The justification for this, as documented in the underlying White Paper, PVP2012–78190, ''Alternative Acceptance Criteria for Flaws in Ferritic Steel Components Operating in the Upper Shelf Temperature Range,'' is that the ASME BPV Code, Section XI, K_{1c} curve will give a ($T - RT_{NDT}$) value of 105 degrees F at K_{1c} of 200 ksi√inch.

Defining an upper shelf transition temperature purely based on LEFM data is not convincing because it ignores EPFM data and Charpy data and their relationship to the LEFM data. The NRC staff performed calculations on several randomly selected reactor pressure vessel surveillance materials with high upper-shelf energy values and low RT_{NDT} values from three plants and found that using T_c, as defined in the Code Case, is nonconservative because at the temperature of RT_{NDT} + 105 degrees F, the Charpy curves show that most of the materials will not reach their respective upper-shelf energy levels. The NRC staff's condition is based on a 2015 ASME Pressure Vessels and Piping Conference paper (PVP2015–45307) by Mark Kirk, Gary Stevens, Marjorie Erickson, William Server, and Hal Gustin entitled, ''Options for Defining the Upper Shelf Transition Temperature (Tc) for Ferritic Pressure Vessel Steels,'' where T_c and T_{c1} are defined as the intersections of specific toughness curves of LEFM data and EPFM data, as shown in that paper. Using the model in the 2015 PVP paper is justified because, in addition to its theoretically motivated approach in applying the temperature-dependent flow behavior of body-centered cubic materials, the model is also supported by numerous LEFM data and 809 EPFM data in the upper shelf region.

While the T_c proposed in Code Case N–749 is conservative based on the intersection of the mean curves of the two sets of data, the NRC determined that actual or bounding properties (on the conservative side) should be used instead of mean material properties for evaluating flaws detected in a ferritic component using the EPFM approach. This will prevent inaccurate component failure predictions using the EPFM approach, due to overestimated material properties. Further, the NRC's approach considers the temperature range for fracture mode transition between LEFM and EPFM. Based on the previous discussion, the NRC is imposing a condition on the use of Code Case N–749 that: (1) The two equations for T_c be used instead of T_c, as proposed in the Code Case for requiring EPFM application, when the temperature is above T_c, and (2) the two equations for T_{c1} be used for requiring LEFM application when temperature is below T_{c1}. Between T_{c1} and T_c, while the fracture mode is in transition between LEFM and EPFM, users should consider whether or not it is appropriate to apply the EPFM method.

Alternatively, the licensee may use a different T_c value, if it can be justified by plant-specific Charpy curves.

Code Case N–754 [Supplement 6, 2010 Edition]

Type: New.

Title: Optimized Structural Dissimilar Metal Weld Overlay for Mitigation of PWR Class 1 Items, Section XI, Division 1.

The NRC approves Code Case N–754 with three conditions. Code Case N–754 provides requirements for installing optimized structural weld overlays (OWOL) on the outside surface of ASME Class 1 heavy-wall, large-diameter piping composed of ferritic, austenitic stainless steel, and nickel based alloy materials in pressurized water reactors

(PWRs) as a mitigation measure, where no known defect exists or the defect depth is limited to 50 percent through wall. The upper 25 percent of the original pipe wall thickness is credited as a part of the OWOL design in the analyses performed, in support of these repairs. The technical basis supporting the use of OWOLs is provided in the Electric Power Research Institute (EPRI) Materials Reliability Project (MRP) Report MRP–169, Revision 1–A, entitled, ''Technical Basis for Preemptive Weld Overlays for Alloy 82/182 Butt Welds in PWRs.'' By letter dated August 9, 2010 (ADAMS Accession No. ML101620010), the NRC informed the Nuclear Energy Institute (NEI) that the staff found that MRP–169, Revision 1, as revised by letter dated February 3, 2010, adequately described: (1) Methods for the weld overlay design; (2) the supporting analyses of the design; (3) the experiments that verified the analyses; and (4) the inspection requirements of the dissimilar metal welds to be overlaid. However, the NRC identified the following conditions.

The first condition requires that the conditions imposed on the use of OWOLs contained in the NRC final safety evaluation for MRP–169, Revision 1–A, must be satisfied. Eighteen limitations and conditions are described in the final safety evaluation that address issues such as fatigue crack growth rates, piping loads, design life of the weld overlay, and reexamination frequencies. The imposition of the conditions in the safety evaluation provide reasonable assurance that the structural integrity of the pipes repaired through the use of weld overlays will be maintained.

Code Case N–754 references Code Case N–770–2, ''Alternative Examination Requirements and Acceptance Standards for Class 1 Pressure Water Reactor (PWR) Piping and Vessel Nozzle Butt Welds Fabricated With UNS N06082 or UNS W86182 Weld Filler Material With or Without Application of Listed Mitigation Activities, Section XI, Division 1.'' The reference to Code Case N–770–2 provides the ASME requirements for the performance of the preservice and ISI examinations of OWOLs, with additional requirements if the ultrasonic examination is qualified for axial flaws. The NRC approved Code Case N–770–2 with conditions in § 50.55a(g)(6)(ii)(F) on July 18, 2017 (82 FR 32934). Accordingly, the second condition on the use of Code Case N–754 is that the preservice and inservice inspections of OWOLs must satisfy § 50.55a(g)(6)(ii)(F), *i.e.,* meet the provisions of Code Case N–770–2.

The third condition addresses a potential implementation issue in Code Case N–754 with respect to the deposition of the first layer of weld metal. The second sentence in paragraph 1.2(f)(2) states that ''The first layer of weld metal deposited may not be credited toward the required thickness, but the presence of this layer shall be considered in the design analysis requirements in 2(b).'' The NRC found that, among licensees, there can be various interpretations of the words used in the ASME BPV Code and Code Cases. In this instance, the NRC determined that the word ''may'' needed to be changed to ''shall'' in the second sentence in paragraph 1.2(f)(2), as a condition for use of this Code Case. Accordingly, the NRC is adding a third condition to clarify that the first layer shall not be credited toward the required OWOL thickness unless the chromium content of the first layer is at least 24 percent.

Code Case N–778 [Supplement 6, 2010 Edition]

Type: New.

Title: Alternative Requirements for Preparation and Submittal of Inservice Inspection Plans, Schedules, and Preservice and Inservice Summary Reports, Section XI, Division 1.

The NRC is approving Code Case N–778 with two conditions. Section XI, paragraph IWA–1400(d), in the editions and addenda currently used by the operating fleet, requires licensees to submit plans, schedules, and preservice and ISI summary reports to the enforcement and regulatory authorities having jurisdiction at the plant site. In the licensees' pursuit to decrease burden, they have alluded to the resources associated with the requirement to submit the items previously listed. Code Case N–778 was developed to provide an alternative to the requirements in the ASME BPV Code, in that the items previously listed would only have to be submitted if specifically required by the regulatory and enforcement authorities.

The NRC reviewed its needs with respect to the submittal of the subject plans, schedules, and reports, and determined that it is not necessary to require the submittal of plans and schedules. The NRC made this determination because the latest up-to-date plans and schedules are available at the plant site and can be requested by the NRC at any time. However, the NRC determined that summary reports still need to be submitted. Summary reports provide valuable information regarding examinations that have been performed, conditions noted during the examinations, the corrective actions performed, and the status of the implementation of the ISI program. Accordingly, the NRC is approving Code Case N–778 with conditions to require that licensees continue to submit summary reports in accordance with paragraph IWA–6240 of the 2009 Addenda of ASME Section XI, as addressed below.

The two conditions are modeled on the requirements currently in paragraph IWA–6240 of the 2009 Addenda, Section XI. The requirements in Section XI do not specify when the reports are to be submitted to the regulatory authority; rather, the requirements only state that the reports shall be completed. The first condition requires that the preservice inspection summary report be submitted before the date of placement of the unit into commercial service. The second condition requires that the ISI summary report be submitted within 90 calendar days of the completion of each refueling outage. The conditions rely on the date of commercial service and the completion of a refueling outage to determine when the reports are needed to be submitted to the regulatory authority.

Code Case N–789 [Supplement 6, 2010 Edition]

Type: New.

Title: Alternative Requirements for Pad Reinforcement of Class 2 and 3 Moderate-Energy Carbon Steel Piping for Raw Water Service, Section XI, Division 1.

The NRC is approving Code Case N–789 with one condition. For certain types of degradation, the Code Case provides requirements for the temporary repair of degraded moderate energy Class 2 and Class 3 piping systems by external application of welded reinforcement pads. The Code Case does not require inservice monitoring for the pressure pad. However, the NRC determined that it is unacceptable to not monitor the pressure pad because there may be instances where an unexpected corrosion rate may cause the degraded area in the pipe to expand beyond the area that is covered by the pressure pad. This could lead to the pipe leaking and may challenge the structural integrity of the repaired pipe. Therefore, the NRC is approving Code Case N–789 with a condition to require a monthly visual examination of the installed pressure pad for evidence of leakage.

In the proposed rule, the NRC expressed concern that the corrosion rate specified in paragraph 3.1(1) of the Code Case may not address certain scenarios. That paragraph would allow

either a corrosion rate of two times the actual measured corrosion rate at the reinforcement pad installation location or four times the estimated maximum corrosion rate for the system. To ensure that a conservative corrosion rate is used to provide sufficient margin, the NRC considered adding a second condition that requires that the design of the pressure pad use the higher of the two corrosion rates calculated, based on the same degradation mechanism as the degraded location. However, as a result of a public comment, the NRC reconsidered and determined that using a corrosion rate of either two times the actual measured corrosion rate in that location, or four times the estimated maximum corrosion rate for the system, already provides a sufficiently conservative estimate of the corrosion rate; therefore, a condition is not needed.

Code Case N–795 [Supplement 3, 2010 Edition]

Type: New.

Title: Alternative Requirements for BWR Class 1 System Leakage Test Pressure Following Repair/Replacement Activities, Section XI, Division 1.

The NRC is approving Code Case N–795 with two conditions. The first condition addresses a prohibition against the production of heat through the use of a critical reactor core to raise the temperature of the reactor coolant and pressurize the reactor coolant pressure boundary (RCPB) (sometimes referred to as nuclear heat). The second condition addresses the duration of the hold time when testing non-insulated components to allow potential leakage to manifest itself during the performance of system leakage tests.

Code Case N–795 was intended to address concerns that performing the ASME-required pressure test for boiling water reactors (BWRs) under shutdown conditions, (1) places the unit in a position of significantly reduced margin, approaching the fracture toughness limits defined in the Technical Specification Pressure-Temperature (P–T) curves, and (2) requires abnormal plant conditions/alignments, incurring additional risks and delays, while providing little added benefit beyond tests, which could be performed at slightly reduced pressures under normal plant conditions. However, due to restrictions imposed by the pressure control systems, most BWRs cannot obtain reactor pressure corresponding to 100 percent rated power during normal startup operations at low power levels that would be conducive to performing examinations for leakage. The alternative test, provided by Code Case N–795, would be performed at slightly reduced pressures and normal plant conditions, which the NRC finds will constitute an adequate leak examination and would reduce the risk associated with abnormal plant conditions and alignments.

However, the NRC has had a long-standing prohibition against the production of heat through the use of a critical reactor core to raise the temperature of the reactor coolant and pressurize the RCPB. A letter dated February 2, 1990, from James M. Taylor, Executive Director for Operations, NRC, to Messrs. Nicholas S. Reynolds and Daniel F. Stenger, Nuclear Utility Backfitting and Reform Group (ADAMS Accession No. ML14273A002), established the NRC position with respect to use of a critical reactor core to raise the temperature of the reactor coolant and pressurize the RCPB. In summary, the NRC's position is that testing under these conditions involves serious impediments to careful and complete inspections, and therefore, inherent uncertainty with regard to assuring the integrity of the RCPB. Further, the practice is not consistent with basic defense-in-depth safety principles.

The NRC's position established in 1990, was reaffirmed in Information Notice No. 98–13, ''Post-Refueling Outage Reactor Pressure Vessel Leakage Testing Before Core Criticality,'' dated April 20, 1998. The Information Notice was issued in response to a licensee that had conducted an ASME BPV Code, Section XI, leakage test of the reactor pressure vessel and subsequently discovered that it had violated 10 CFR part 50, appendix G, IV.A.2.d. This regulation states that pressure tests and leak tests of the reactor vessel that are required by Section XI of the ASME Code must be completed before the core is critical. The Information Notice references NRC Inspection Report 50–254/97–27 (ADAMS Accession No. ML15216A276), which documents that licensee personnel performing VT–2 examinations of the drywell at one BWR plant covered 50 examination areas in 12 minutes, calling into question the adequacy of the VT–2 examinations.

The bases for the NRC's historical prohibition of pressure testing with the core critical can be summarized as follows:

1. Nuclear operation of a plant should not commence before completion of system hydrostatic and leakage testing to verify the basic integrity of the RCPB, a principal defense-in-depth barrier to the accidental release of fission products. In accordance with the defense-in-depth safety precept, the nuclear power plant design provides for multiple barriers to the accidental release of fission products from the reactor.

2. Hydrotesting must be done essentially water solid (*i.e.,* free of pockets of air, steam or other gases) so that stored energy in the reactor coolant is minimized during a hydrotest or leaktest.

3. The elevated reactor coolant temperatures, associated with critical operation, result in a severely uncomfortable and difficult working environment in plant spaces where the system leakage inspections must be conducted. The greatly increased stored energy in the reactor coolant, when the reactor is critical, increases the hazard to personnel and equipment in the event of a leak. As a result, the ability for plant workers to perform a comprehensive and careful inspection becomes greatly diminished.

However, the NRC staff has determined that pressure testing with the core critical is acceptable, if performed after repairs of a limited scope, where only a few locations or a limited area needs to be examined, and when ASME Code Section XI, Table IWB–2500–1, Category B–P (the pressure test required once per cycle of the entire RCPB), has been recently performed, thus verifying the integrity of the overall RCPB. The NRC also notes that Code Case N–795 does not allow for the use of the alternative test pressure following repairs/replacements on the RPV, therefore it does not violate 10 CFR part 50, Appendix G. The NRC determined that the risk associated with nuclear heat at low power is comparable with the risk to the plant, when the test is performed without nuclear heat (with the core subcritical) during mid-cycle outages, when decay heat must be managed. Performing the pressure test under shutdown conditions at full operating pressure without nuclear heat requires securing certain key pressure control, heat removal, and safety systems. Under such conditions, it is more difficult to control temperature and pressure, when there is significant decay heat production, such as after a mid-cycle outage, which may reduce the margin available to prevent exceeding the plant pressure-temperature limits.

The scope of repairs should be relatively small, when the pressure test is conducted using nuclear heat, in order to minimize the personnel safety risk and to avoid rushed examinations. Code Case N–795 does not place any restrictions on the size or scope of the repairs for which the alternative may be used, other than the alternative test pressure may not be used to satisfy

pressure test requirements following repair/replacement activities on the reactor vessel. It is impractical to specify a particular number of welded or mechanical repairs that would constitute a ''limited scope.'' However, if the plant is still in a refueling outage and has already performed the ASME Section XI Category B–P pressure test of the entire RCPB, it is likely that subsequent repairs would be performed only on an emergent basis, and would generally be of a limited scope. Additionally, the overall integrity of the RCPB will have been recently confirmed via the Category B–P test. For mid-cycle maintenance outages, the first condition allows the use of nuclear heat to perform the test, if the outage duration is fourteen (14) days or less. This would tend to limit the scope of repairs, and also limit use of the Code Case to outages when decay heat was a significant problem. Therefore, the first condition on Code Case N–795 states:

''The use of nuclear heat to conduct the BWR Class 1 system leakage test is prohibited (*i.e.,* the reactor must be in a non-critical state), except during refueling outages in which the ASME Section XI Category B–P pressure test has already been performed, or at the end of mid-cycle maintenance outages fourteen (14) days or less in duration.''

With respect to the second condition and adequate pressure test hold time, the technical analysis supporting Code Case N–795 indicates that the lower test pressure provides more than 90 percent of the flow, which would result from the pressure corresponding to 100 percent power. However, a reduced pressure means a lower leakage rate, so additional time is required in order for there to be sufficient leakage to be observed by inspection personnel. Section XI, paragraph IWA–5213, ''Test Condition Holding Time,'' does not require a holding time for Class 1 components, once test pressure is obtained. To account for the reduced pressure, Code Case N–795 would require a 15-minute hold time for non-insulated components. The NRC has determined that 15 minutes does not allow for an adequate examination, because it is not possible to predict the entire range of scenarios or types of defects that could result in leakage. While some types of defects could result in immediate leakage, such as an improperly torqued bolted connection; other types of defects, such as weld defects or tight cracks could represent a more torturous path for leakage and may result in delayed leakage. The staff determined that, due to the uncertainty in the time required for leakage to occur to an extent, it would be readily detectable by visual examination, hence, it is appropriate to conservatively specify a longer hold time of 1 hour for non-insulated components. Therefore, the final rule retains the one hour hold time for non-insulated components.

Code Case N–799 [Supplement 4, 2010 Edition]

Type: New.

Title: Dissimilar Metal Welds Joining Vessel Nozzles to Components, Section XI, Division 1.

The NRC approves Code Case N–799 with four conditions. Code Case N–799 is a new Code Case developed to provide examination requirements for the steam generator primary nozzle to pump casing attachment weld for AP–1000 plants and dissimilar metal welds joining vessel nozzles to pumps used in recent reactor designs (*e.g.,* AP–1000, Advanced BWR). Nuclear power plant pump casings are typically manufactured from cast austenitic stainless steel (CASS) materials. The NRC is approving the Code Case with conditions to address the shortcomings in the Code Case with respect to requirements for ultrasonic examination.

The CASS is an anisotropic and inhomogeneous material. The manufacturing process can result in varied and mixed structures. The large size of the anisotropic grains affects the propagation of ultrasound by causing severe attenuation, changes in velocity, and scattering of ultrasonic energy. Refraction and reflection of the sound beam occurs at the grain boundaries, which can result in specific volumes of material not being examined, or defects being missed or mischaracterized. The grain structure of the associated weldments also impacts the effectiveness and reliability of the examinations. Accordingly, it is paramount that robust examination techniques be used.

Research has been conducted by several domestic and international organizations attempting to address the shortcomings associated with the use of conventional methods for the inspection of CASS materials. The results of a study at Pacific Northwest National Laboratory (PNNL) were published in NUREG/CR–6933, ''Assessment of Crack Detection in Heavy-Walled Cast Stainless Steel Piping Welds Using Advanced Low-Frequency Ultrasonic Methods'' (ADAMS Accession No. ML071020409). The study demonstrated that additional measures were required to reliably detect and characterize flaws in CASS materials and their associated weldments.

Performance demonstration requirements for CASS components and associated weldments have not yet been developed by the industry. To ensure that effective and reliable examinations are performed, the NRC is adopting the following four conditions on the Code Case.

The first condition addresses the gap between the probe and component surface. Industry experience shows that effective ultrasonic examinations depend, to a great extent, on limiting the gap between the probe and component surface to less than 0.032-inch. The BPV Code does not have any requirements with respect to surface smoothness and waviness. It has been demonstrated that reduced coupling and probe lift-off on ''rough'' surfaces have the potential to present a scattering effect at an interface where an acoustic beam impinges, to redirect and mode convert some energy, which when returned to the probe can be the source of spurious signals, or cause flaws to be mis-characterized or missed altogether. Accordingly, the first condition requires that the scanning surfaces have a gap less than 0.032-inch beneath the ultrasonic testing probe. Gaps greater than 0.032-inch must be considered to be unexamined, unless it can be demonstrated, on representative mockups, that a Section XI, Appendix VIII, Supplement 10, demonstration can be passed.

The second condition (No. 2a in DG–1296) is that the examination requirements of Section XI, Mandatory Appendix I, paragraph I–3200(c) must be applied. Code Case N–799 does not contain specific requirements regarding examination techniques. Paragraph I–3200(c) contains specific requirements that can be applied.

The third condition (No. 2c in DG–1296) is that ultrasonic depth and sizing qualifications for CASS components must use the ASME BPV Code requirements in Section XI, Appendix VIII, Supplement 10. Supplement 10 contains qualification requirements for dissimilar metal welds, and the use of these requirements will ensure that robust techniques are applied.

The fourth condition (No. 2e in DG–1296) is that cracks that are detected but cannot be depth-sized with performance-based procedures, equipment, and personnel qualifications consistent with ASME Code Section XI, Appendix VIII, shall be repaired or removed.

OM Code Cases (RG 1.192)

Code Case OMN–1, Revision 1 [2012 Edition]

Type: Revised.

Title: Alternative Rules for Preservice and Inservice Testing of Active Electric

Motor-Operated Valve Assemblies in Light-Water Reactor Power Plants.

The conditions on Code Case OMN–1, Revision 1 [2012 Edition] are identical to the conditions on OMN–1 [2006 Addenda] that were approved by the NRC in Revision 1 of RG 1.192 in October 2014. The reasons for imposing these conditions are not resolved by Code Case OMN–1, Revision 1 [2012 Edition] and, therefore, these conditions have been retained in Revision 2 of RG 1.192.

Code Case OMN–3 [2012 Edition]

Type: Reaffirmed.

Title: Requirements for Safety Significance Categorization of Components Using Risk Insights for Inservice Testing of LWR Power Plants.

The conditions on Code Case OMN–3 [2012 Edition] are identical to the conditions on OMN–3 [2004 Edition] that were approved by the NRC in Revision 1 of RG 1.192 in October 2014. The reasons for imposing these conditions are not resolved by Code Case OMN–3 [2012 Edition] and, therefore, these conditions have been retained in Revision 2 of RG 1.192.

Code Case OMN–4 [2012 Edition]

Type: Reaffirmed.

Title: Requirements for Risk Insights for Inservice Testing of Check Valves at LWR Power Plants.

The conditions on Code Case OMN–4 [2012 Edition] are identical to the conditions on OMN–4 [2004 Edition] that were approved by the NRC in Revision 1 of RG 1.192 in October 2014. The reasons for imposing these conditions are not resolved by Code Case OMN–4 [2012 Edition] and, therefore, these conditions have been retained in Revision 2 of RG 1.192.

Code Case OMN–9 [2012 Edition]

Type: Reaffirmed.

Title: Use of a Pump Curve for Testing.

The conditions on Code Case OMN–9 [2012 Edition] are identical to the conditions on OMN–9 [2004 Edition] that were approved by the NRC in Revision 1 of RG 1.192 in October 2014. The reasons for imposing these conditions are not resolved by Code Case OMN–9 [2012 Edition] and, therefore, these conditions have been retained in Revision 2 of RG 1.192.

Code Case OMN–12 [2012 Edition]

Type: Reaffirmed.

Title: Alternative Requirements for Inservice Testing Using Risk Insights for Pneumatically and Hydraulically Operated Valve Assemblies in Light-Water Reactor Power Plants (OM-Code 1998, Subsection ISTC).

The conditions on Code Case OMN–12 [2012 Edition] are identical to the conditions on OMN–12 [2004 Edition] that were approved by the NRC in Revision 1 of RG 1.192 in October 2014. The reasons for imposing these conditions are not resolved by Code Case OMN–12 [2012 Edition] and, therefore, these conditions have been retained in Revision 2 of RG 1.192.

Code Case OMN–16, Revision 1 [2012 Edition]

Type: Revised.

Title: Use of a Pump Curve for Testing.

Code Case OMN–16, 2006 Addenda, was approved by the NRC in Regulatory Guide 1.192, Revision 1. With respect to Code Case OMN–16, Revision 1, 2012 Edition, there was an editorial error in the publishing of this Code Case in that Figure 1 from the original Code Case (*i.e.,* Rev. 0, 2006 Addenda) was omitted. Accordingly, the NRC approves OMN–16, Revision 1, with a condition requiring that Figure 1 from the original Code Case be used when implementing OMN–16, Revision 1.

Code Case OMN–18 [2012 Edition]

Type: Reaffirmed.

Title: Alternate Testing Requirements for Pumps Tested Quarterly Within ±20% of Design Flow.

The ASME OM Code defines Group A pumps as those pumps that are operated continuously or routinely during normal operation, cold shutdown, or refueling operations. The OM Code specifies that each Group A pump undergoes a Group A test quarterly and a comprehensive test biennially. The OM Code requires that the reference value for a comprehensive test to be within 20 percent of pump design flow, while the reference value for a Group A test needs to be within 20 percent of the pump design flow, if practicable. The biennial comprehensive test was developed (first appeared in the 1995 Edition of the OM Code) because pump performance concerns demonstrated that more stringent periodic testing was needed at a flow rate within a more reasonable range of the pump design flow rate, than typically performed during the pump IST in the past.

Currently, when performing either the quarterly Group A test or the biennial comprehensive pump test, licensees must comply with certain limits for the flow Acceptable Range, the flow Required Action Range, the differential pressure (or discharge pressure) Acceptable Range, and the differential pressure (or discharge pressure) Required Action Range. The limits for the quarterly Group A test are obtained by using a factor of 1.10 times the flow reference value (Q_r) or the differential or discharge pressure reference value (ΔP_r or P_r), as applicable to the pump type. The limits for the biennial comprehensive pump test are obtained by using the factor of 1.03 times Q_r or ΔP_r (or P_r), as applicable to the pump type, providing more restrictive test ranges and higher quality data.

Code Case OMN–18, 2012 Edition, would remove the Code requirement to perform a biennial comprehensive pump test, where the quarterly Group A pump test is performed within ±20 percent of the pump design flow rate, with instruments having the ability to obtain the accuracies required for the comprehensive pump test. The NRC finds the performance of a quarterly Group A pump test, at flow within ±20 percent of the pump design flow rate, will be sufficient to detect mechanical and hydraulic degradation of the tested pump. The NRC finds that this will satisfy the intent of the biennial comprehensive pump test, with the exception that the test acceptable ranges and required action ranges are less precise than required for the comprehensive test. Therefore, the NRC approves Code Case OMN–18, 2012 Edition, with a condition to specify the use of a factor of 1.06 for the Group A test parameters, to be consistent with the test ranges for the comprehensive test. The NRC concludes that the factor of 1.06 will provide a reasonable test range, when applying Code Case OMN–18 to Group A pumps tested quarterly, within ±20 percent of the pump design flow rate. The NRC finds that the quarterly Group A test for pumps within ±20 percent of the pump design flow rate, combined with the provisions in the Code Case OMN–18 for the pump instrumentation and the conditions in RG 1.192 for the test ranges, will provide reasonable assurance of the operational readiness of these pumps, as an acceptable alternative to the comprehensive pump test provisions in the ASME OM Code.

Code Case OMN–19 [2012 Edition]

Type: Reaffirmed.

Title: Alternative Upper Limit for the Comprehensive Pump Test.

A requirement for a periodic pump verification test was added in Mandatory Appendix V, ''Pump Periodic Verification Test Program,'' to the 2012 Edition of the OM Code. The mandatory appendix is based on the determination by the ASME that a pump periodic verification test is needed to confirm that a pump can meet the required (differential or discharge) pressure as applicable, at its highest

design basis accident flow rate. Code Case OMN–19, 2012 Edition, would allow an applicant or licensee to use a multiplier of 1.06 times the reference value in lieu of the 1.03 multiplier for the comprehensive pump test's upper Acceptable Range criteria and Required Action Range, High criteria reference in the ISTB test acceptance criteria tables. The NRC considers Code Case OMN–19 to be acceptable where the provisions of Appendix V for a pump periodic verification test as referenced by ISTB–1400 are also satisfied to detect mechanical and hydraulic degradation. Therefore, the NRC approves Code Case OMN–19, 2012 Edition, with the condition that the provisions in paragraph ISTB–1400 and Mandatory Appendix V be applied when implementing the Code Case.

Code Case OMN–20 [2012 Edition]

Type: New.

Title: Inservice Testing Frequency.

Surveillance Requirement (SR) 3.0.3 from Technical Specification (TS) 5.5.6, ''Inservice Testing Program,'' allows licensees to apply a delay period before declaring the SR for TS equipment ''not met,'' if a licensee inadvertently exceeds or misses the time limit for performing the TS surveillance. Licensees have been applying SR 3.0.3 to inservice tests performed in accordance with the ASME Codes. The NRC has determined that licensees cannot use TS 5.5.6 to apply SR 3.0.3 to inservice tests under § 50.55a(f) that are not associated with a TS surveillance. To invoke SR 3.0.3, the licensee must first discover that a TS surveillance was not performed at its specified frequency. Therefore, the delay period that SR 3.0.3 provides does not apply to non-TS support components tested under § 50.55a(f). The OM Code does not provide for inservice test frequency reductions or extensions. In order to provide inservice test frequency reductions or extensions that cannot be provided by SR 3.0.3 from TS 5.5.6, ASME developed OM Code Case OMN–20. The NRC has reviewed OM Code Case OMN–20 and has found it acceptable for use. The NRC determined that OM Code Case OMN–20 may be applied to editions and addenda of the OM Code that are listed in § 50.55a(a)(1)(iv). Therefore, the NRC has included a condition in RG 1.192, specifying that Code Case OMN–20 is applicable to editions and addenda of the OM Code listed in § 50.55a(a)(1)(iv).

C. ASME Code Cases Not Approved for Use (RG 1.193)

The ASME Code Cases that are currently issued by the ASME, but not approved for generic use by the NRC are listed in RG 1.193, ''ASME Code Cases not Approved for Use.'' In addition to the ASME Code Cases that the NRC has found to be technically or programmatically unacceptable, RG 1.193 includes Code Cases on reactor designs for high-temperature gas-cooled reactors and liquid metal reactors, reactor designs not currently licensed by the NRC, and certain requirements in Section III, Division 2, for submerged spent fuel waste casks, that are not endorsed by the NRC. Regulatory Guide 1.193 complements RGs 1.84, 1.147, and 1.192; RG 1.193 confirms the Code Cases that are not approved for use. The NRC is not adopting any of the Code Cases listed in RG 1.193.

III. Opportunities for Public Participation

The proposed rule and draft RGs were published in the **Federal Register** on March 2, 2016 (81 FR 10780), for a 75-day comment period. The public comment period closed on May 16, 2016.

After the close of the public comment period, the NRC held a public meeting on August 22, 2016, to discuss the status of this proposed rule. The public meeting summary is available in ADAMS under Accession No. ML16265A001.

IV. Public Comment Analysis

The NRC received a total of seven comment submissions on the proposed rule and draft RGs. Table III lists the commenters, their affiliation, and the ADAMS Accession Number for each submission.

TABLE III—COMMENT SUBMISSIONS RECEIVED ON THE PROPOSED RULE AND DRAFT RGS

Submission ID	Commenter name	Affiliation	ADAMS accession No.
1	Paul Donavin	Private Citizen	ML16063A509
2	Gregory Frederick and Dan Patten	Electric Power Research Institute	ML16126A524
3	Anonymous	Unknown	ML16133A422
4	Charles Pierce	Southern Nuclear Operating Company	ML16137A857
5	Ralph Hill III	ASME	ML16138A835
6	Mark Gowin	Private Citizen	ML16139A798
7	David Helker	Exelon Generation Company, LLC	ML16153A432

The NRC reviewed every comment submission and identified 32 unique comments requiring the NRC's consideration and response. Comment summaries and the NRC's responses are presented in this section. At the end of each summary, the individual comments represented by the summary are identified in the form [XX–YY] where XX represents the Submission ID in Table III and YY represents the sequential comment within the submission.

Public Comments on Draft Regulatory Guides

Regulatory Guide 1.84, Revision 37 (DG–1295)

No public comments were submitted regarding Regulatory Guide 1.84, Revision 37 (Draft Guide (DG)–1295), therefore no NRC response is needed.

Regulatory Guide 1.147, Revision 18 (DG–1296)

Code Case N–552–1

Comment: The proposed conditions on N–552–1 were incorporated into the ASME BPV Code, Section XI, 2005 Addenda when Code Case N–552 was incorporated into the code. However, these conditions have never been incorporated into the Code Case itself. The proposed conditions are identical to those imposed on Code Case N–552 in Revision 16 of RG 1.147. ASME does not object to these conditions. [ASME 5–2]

NRC Response: The NRC agrees with this comment.

No change was made to the final rule as a result of this comment.

Code Case N–576–2

Comment: Because the NRC has adopted the 2008 Addenda with no conditions on IWA–4200, ASME recommends that the proposed

condition be revised to state ''. . . is to be performed in accordance with IWA–4200 of the code of record for the current ISI Program.'' [ASME 5–3]

NRC Response: The NRC agrees, in part, with this comment. The NRC staff has adopted the 2008 Addenda with no conditions on IWA–4200. However, the staff does not agree that the proposed condition/note in Regulatory Guide 1.147 should be revised to state ''. . . is to be performed in accordance with IWA–4200 of the code of record for the current ISI program'', because there may be licensees whose code of record is prior to 2008 and such a condition is not necessary because licensees would be required to follow IWA–4200 in their code of record, if they were to adopt this Code Case. As a result, because use of the repair method described in this Code Case (N–576–2) requires the NRC's review and approval prior to implementation and licensees will be required to follow IWA–4200 in their code of record, the NRC modified the ''note'' on this Code Case to eliminate the portion of the ''note'' regarding reconciliation. The revised ''note'' now reads:

''Note: Steam generator tube repair methods require prior NRC approval through the Technical Specifications. This Code Case does not address certain aspects of this repair, *e.g.,* the qualification of the inspection and plugging criteria necessary for staff approval of the repair method.''

Code Case N–638–6

Comment: Condition 1 was incorporated into IWA–4673(a)(2) of the 2013 Edition when N–638–6 was incorporated into the Code. This condition has also been incorporated into N–638–8, which has been published in the 2015 Code Case Book. Condition (2) was incorporated into IWA–4671(b)(1) of the 2013 Edition when N–638–6 was incorporated into the Code. Because there were no conditions imposed on the use of IWA–4673(a)(2) or IWA–4671(b)(1) in the draft rule, to incorporate by reference the 2013 Edition of the ASME BPV Code, Section XI, ASME recommends that both of the proposed conditions be removed and Code Case N–638–6 be moved to Table 1 of RG 1.147, Revision 18. [ASME 5–4]

NRC Response: The NRC agrees, in part, with this comment. Regarding proposed Condition (1), the staff agrees that Condition (1) was incorporated into IWA–4673(a)(2) of the 2013 Edition of ASME BPV Code, Section XI, when ASME incorporated Code Case N–638–6 into the Section XI. Proposed Condition (1) was also addressed in Code Case N–638–8. However, Code Case N–638–6 does not address proposed Condition (1) and this version of the Code Case will be available for use by licensees who will not adopt the 2013 Edition of Section XI for several years. Therefore, the NRC determined that it is appropriate to include proposed Condition (1) in RG 1.147, Revision 18.

Regarding proposed Condition (2), Paragraph 1(b)(1) of Code Case N–638–6 contains changes from the previous version of the Code Case, which allows through-wall circumferential welds and includes additional requirements when performing repairs that utilize through-wall circumferential welds. At the time that this revision of the Code Case was approved by the ASME, the staff had concerns related to through-wall repairs. Subsequently, the NRC resolved its concerns. Therefore, the NRC determined that proposed Condition (2) is unnecessary.

The NRC has removed proposed Condition (2) on Code Case N–638–6 from the final RG 1.147, Revision 18.

No change was made to the final rule as a result of this comment.

Code Cases N–666 and N–666–1

Comment: A new condition has been added to N–666, which is listed as a Superseded Code Case: A surface (magnetic particle or liquid penetrant) examination must be performed after installing the seal weld and weld overlay on Class 1 and 2 piping socket welds. The fabrication defects, if detected, must be dispositioned using the surface examination acceptance criteria of the Construction Code identified in the Repair/Replacement Plan.

As stated in our comment on N–666–1, the phrase ''seal weld and'' should be removed from the first sentence. Also, the addition of a new condition to a Code Case that was previously unconditionally approved in the Reg. Guide, and is now superseded, seems inappropriate. Several plants would likely have this version of the Code Case in their Section XI ''tool box'' until the end of their current Inspection Interval, and would be apparently (but not obviously) bound by the new condition, upon issuance of the new revision to Regulatory Guide. The third paragraph under Section B. DISCUSSION, in the draft RG, includes the statement ''If a Code Case is implemented by a licensee and a later version of the Code Case is incorporated by reference into 10 CFR 50.55a and listed in Tables 1 and 2 during the licensee's present 120-month ISI program interval, that licensee may use either the later version or the previous version. An exception to this provision would be the inclusion of a limitation or condition on the use of the Code Case that is necessary, for example, to enhance safety.'' Perhaps this could be supplemented with another sentence such as, ''In this case, the condition will be entered for the superseded Code Case under Table 5.'' [EPRI 2–4, Exelon 7–4]

NRC Response: The NRC agrees with this comment. The condition shown in Table 5 of DG–1295 for Code Case N–666 was in error.

The condition on Code Case N–666 in Table 5 from the final RG 1.147, Revision 18 has been removed.

No change was made to the final rule as a result of this comment.

Comment: Condition 1—The construction code may not always require a surface examination (depending on the construction code) on socket welds. This condition is appropriate. However, the words ''and seal weld'' in the first sentence should be removed from the condition because it is inappropriate to require surface examination of non-structural seal welds whose only function is to seal a leak. The ASME recommends revising this condition to remove the words ''and seal weld'' in the first sentence. Condition 2—This condition should be removed as 5(a)(1) already required a Visual VT–1 examination of completed weld overlays irrespective of the class of the joint. This condition is redundant and only causes confusion. ASME recommends removing this proposed condition. [EPRI 2–1, ASME 5–5]

NRC Response: The NRC agrees with this comment. The function of the seal weld is to seal a leak so that sound weldment for the overlay can be applied. The code case requires a visual examination of the seal weld, remaining socket weld, and adjacent base material before the weld overlay can be applied, which the NRC has determined is the appropriate examination prior to the application of the weld overlay. Therefore, Condition 1 has been revised to remove ''and seal weld.'' Regarding Condition 2, the NRC agrees with the commenter. The code case requires a visual examination of the seal pass and the completed weld overlay and provides appropriate acceptance criteria. Therefore, the condition is redundant and unnecessary. Condition 2 has been removed from Code Case N–666 in Table 2 from the final RG 1.147, Revision 18.

No change was made to the final rule as a result of this comment.

Code Case N–711

Comment: ASME recommends that this Code Case N–711 be removed from RG 1.193, Table 2 and added to Table 2 of RG 1.147 with appropriate conditions to address NRC technical concerns with the use of this case. [ASME 5–10]

NRC Response: The NRC disagrees with this comment. The NRC declines at this time to adopt the recommended changes to the regulatory guides. It would not be appropriate to include the Code Case in RG 1.147 without first having sought public comment on the adoption of the Code Case. Nonetheless, the NRC has reviewed the information provided by ASME and will consider approval of the Code Case in future rulemaking activities.

No change was made to the final rule as a result of this comment.

Code Case N–722–2

Comment: ASME requests that the NRC identify any technical concerns with N–722–2 and list these concerns in R.G. 1.193, Table 2. [ASME 5–11]

NRC Response: The NRC disagrees with this comment. The NRC disagrees with the comment because the NRC does not provide comments in the Regulatory Guide 1.193 on ASME Code Cases, which the NRC mandates for use as augmented inservice inspection programs under § 50.55a(g)(6)(ii). Any conditions that the NRC finds necessary to require are included under the particular section of § 50.55a(g)(6)(ii)(D), (E) or (F), as applicable. This is to avoid confusion such that a stakeholder does not use versions of these ASME Code Cases in lieu of the mandated versions of the ASME Code Case in § 50.55a(g)(6)(ii). However, in order to be responsive to the stakeholder comment, the NRC will provide the current concerns with the implementation of ASME Code Case N–722–2, as a response to this comment to be included in the **Federal Register** notice.

The NRC currently finds ASME Code Case N–722–2 unacceptable as written due to the following main issues. First, the basis for the removal of the Parts Examined from N–722–1 was found to be in error. According to an ASME Code interpretation, XI–1–13–27, not all items removed in N–722–2 were covered by the inspection requirements of ASME Code Case N–770–1. The ASME Code Case N–722 will need to be revised with a new basis for the removal of Parts Examined to be considered for approval by the NRC. Second, Note 11 is not acceptable. The bases for this concern is the same basis as § 50.55a(g)(6)(ii)(F)(2), which restricts the application of this material condition to exempt volumetric and visual examination requirements in N–770–1. The NRC is concerned that the wording of this exemption may allow insufficiently mitigated items to be exempt from currently required visual inspection requirements for components containing alloy 600/82/182 to maintain structural and leak-tight integrity. Once again though, it is not the intent of the NRC to include these items as conditions or limitations in the regulatory guide. The current wording to redirect the user to the applicable section of § 50.55a(g)(6)(ii)(E) will remain, because versions of this ASME Code Case, as well as N–729 and N–770, are not alternatives to the Code requirements, but are mandated by § 50.55a as augmented ISI requirements. For these reasons the NRC disagrees with the comment.

No change was made to the final rule as a result of this comment.

Code Case N–749

Comment: Public comment 5–6 raised two main points:

1. The comment takes issue with the temperature, T_c, above which the staff suggests that EPFM techniques should be used. The formula for T_c, given in the staff's condition, differs from that proposed in Code Case N–749.

2. The comment takes issue with the part of the staff's condition stating that "*T_c is the temperature above which elastic plastic fracture mechanics (EPFM) must be applied.*" Item 4 of the public comment suggests adopting a permissive rather than a perspective condition by replacing the word "*must*" with the word "*may*" in the preceding sentence. [ASME 5–6]

NRC Response: The NRC disagrees with this comment. The staff's responses to these points are, as follows:

Concerning point 1, the technical bases for the staff's proposed equation for T_c are well documented, as discussed previously, and are well supported by data for RPV steels both before and after neutron irradiation. This documentation appears in PVP 2015–45307. Conversely, the T_c equation in the proposed Code Case relates only to the intersection of the ASME K_{Ic} curve with a fracture toughness (K_{Ic}) value of 220 MPa√m, a value that does not correspond well to any known materials data and, moreover, does not account for the effects of irradiation embrittlement. The NRC staff's proposal for T_c is thus better supported by materials data than is the Code Case value.

Concerning point 2, in order for a permissive condition to be acceptable (*e.g.*, the use of "may"), it would need to be demonstrated that application of LEFM approaches to flaw assessment on the upper shelf fracture behavior is always conservative relative to the more technically correct EPFM approach. This has not been demonstrated in either Code Case N–749 or in its supporting technical basis document. As one example, an approach to using LEFM on the upper shelf fracture behavior would be to continue to use the ASME K_{Ic} curve. At upper shelf temperatures, the K_{Ic} curve over-estimates the fracture toughness relative to the ductile fracture toughness (*i.e.*, J0.1 or J–R), which is non-conservative.

No change was made to the final rule as a result of this comment.

Code Case N–754

Comment: The third condition proposed for this Code Case inversely paraphrases existing statements in the Code Case, causing confusion to the user as to what the condition actually adds to the existing requirements. Further, by paraphrasing the requirements, essential technical requirements, such as chrome content in the dilution zone, are omitted which we do not believe is the intent of the condition. The **Federal Register** states that the reason for this condition is that "In this instance, the NRC felt the word "may" needed to be changed to "shall" in the second sentence in paragraph 1.2(f)(2) as a condition for use of this Code Case." In the English language, when the term "may" is followed by the word "not", the phrase means the same as "shall not." However, if this phrase is truly a concern for some, then the condition should be written exactly as the Code Case except change the one word "may" to "shall." [EPRI 2–2, ASME 5–7]

NRC Response: The NRC disagrees with this comment. Condition (3) addresses the following two statements in Paragraph 1.2(f)(2) of Code Case N–754 that reads: ". . . The first layer of weld metal deposited may not be credited toward the required thickness, but the presence of this layer shall be considered in the design analysis requirements in 2(b). Alternatively, a first diluted layer may be credited toward the required thickness, provided the layer and the associated dilution zone contain at least 24% Cr [chromium] . . ." The first sentence in Paragraph 1.2(f)(2) could be interpreted so that the first weld layer could be credited toward the required thickness because the word "may not" does not absolutely prohibit such action. In addition, the first sentence in the quoted statements does not have restriction on

the chromium contents for crediting the first weld layer toward the required thickness.

The second sentence in the above quote limits the chromium content of at least 24 percent; however, the second sentence began with the word ''Alternatively.'' The word ''Alternatively'' implies that the requirement in the second sentence is optional, *i.e.,* a licensee may choose to satisfy either the first sentence or the second sentence, but the licensee does not need to satisfy both.

For example, a licensee deposits a first weld layer that contains less than 24 percent chromium. The licensee could consider the first layer, as part of the required weld overlay thickness, based on the first sentence above because the first sentence does not identify a specific chromium content. Therefore, it does not restrict the consideration of the first layer for the required weld overlay thickness. The second sentence in the above quote does require the chromium content to be at least 24 percent. However, the licensee could interpret that the second sentence does not apply to this case because the second sentence is an alternate, optional requirement based on the word ''Alternatively.''

The staff finds that Condition (3) does not omit the essential technical requirements such as the chrome content in the dilution zone. Condition (3) requires that if the first weld layer cannot achieve a chromium content of at least 24 percent, it cannot be considered as part of the weld overlay thickness. The staff recognizes that Condition (3) provides the same requirements as in Paragraph 1.2(f)(2). However, the purpose of Condition (3) is to clarify the requirements in Paragraph 1.2(f)(2).

No change was made to the final rule as a result of this comment.

Code Case N–784

Comment: This Code Case enables personnel to receive credit for experience hours for laboratory practice beyond the required number of hours of laboratory training. For Level II certification, the total experience hours may be reduced from 800 to 400 if the experience consists of a combination of 80 hours of field experience and 320 hours laboratory practice by scanning specimens containing flaws in materials representative of those in actual power plant components. The field experience will likely be in nuclear plants but there is no requirement for UT examiners to obtain their experience in a nuclear plant. While the experience credited would be on samples and mockups, those samples would be required to contain actual flaws whereas over many hours of field experience, fewer flaws may be encountered. Further, to ensure the effectiveness of the laboratory practice, the Level II experience time would be credited only after the individual passed an Appendix VIII, Supplement 2 performance demonstration for length and depth sizing. Since other performance demonstrations are required for certification for vessels, ferritic piping and bolting, for example, it is considered reasonable to only require the Supplement 2 performance demonstration as a threshold for crediting the laboratory practice hours. EPRI will provide reports (Nondestructive Evaluation: Fast-Track NDE Work Force Enhancement, Volume 1; 1019119 and Nondestructive Evaluation: Fast-Track NDE Work Force Enhancement, Volume 2, 1021150) to the USNRC to support this Code Case and address the impact of the reduced experience. This case does not reduce the training hours. [ASME 5–12]

NRC Response: The NRC disagrees with this comment. The ASME BPV Code replaces field experience with training hours without a defined technical basis. While the NRC is open to evidence related to a technical basis for the substitution of laboratory experience as a substitute for hours of work experience, the impact of the substitution of laboratory hours for field experience and nuclear power plant familiarization is unknown. The two documents cited in the comment require 1,050 hours of hands-on practice with hundreds of hours of additional classwork, not only 320 hours of laboratory training. If future work showed that 320 hours would be sufficient or the Code Case was modified to be in line with these documents, the NRC would consider allowing the use of the Code Case.

No change was made to the final rule as a result of this comment.

Code Case N–789

Comment: The NRC Condition [2] does not allow the user to apply the actual corrosion rate for the pressure pad design. This reflects the staff position that the factors of 2 and 4 do not provide reasonable assurance that actual corrosion rate is bounded. However, the compensatory measures of inservice monitoring and the short acceptance period of one operating cycle verify and provide assurance that both structural and leak integrity will be maintained during the temporary acceptance period. Condition (2) is contrary to several NRC SERs that have evaluated and approved the Code Case for application at dozens of domestic plants. Those SERs require that the reinforcing pad be designed to accommodate twice the actual measured corrosion rate or *if unknown,* then 4 times the maximum experienced in that or a similar system at the same plant for the same degradation mechanism. Corrosion rates are dependent upon many system variables—one primary factor being the amount and frequency of fluid flow. To impose the rate that may occur on a seldom-used dead-leg of a system to an area of active flow, where the actual corrosion rate has been measured is technically inappropriate. Since the monthly monitoring imposed by Condition (1) was initiated for the same reason that this condition was proposed—namely, the potential for an unexpected corrosion rate—this condition should be removed. [EPRI 2–3, ASME 5–8]

NRC Response: The NRC agrees with this comment. The NRC determined that the current language in the Code Case, which requires using a corrosion rate of either two times the actual measured corrosion rate in that location, or four times the estimated maximum corrosion rate for the system, is reasonable and provides a conservative estimate of the corrosion rate. This conservatively estimated corrosion rate, coupled with proposed Condition (1) that requires enhanced inservice monitoring, provides reasonable assurance that should corrosion rates be more aggressive than originally predicted, there will be sufficient time to initiate corrective actions prior to excessive leakage or loss of structural integrity. Therefore, the NRC has determined that proposed Condition (2) is not necessary.

The NRC has removed proposed Condition (2) on Code Case N–789 from the final RG 1.147, Revision 18.

No change was made to the final rule as a result of this comment.

Comment: Paragraph 3.2(i) of Code Case N–789 has a typographic error where it states ''. . . piping designed to NC–2650, ND–3650. . . .'' NC–2650 should be NC–3650. Code Case N–789–2 corrected this statement to read ''. . . piping designed to NC–3650 or ND–3650. . . .'' The use of this Code Case N–789 should be conditioned to require using the corrected language for paragraph 3.2(i) in N–789–2. [Anonymous 3–1, Exelon 7–1]

NRC Response: The NRC agrees with the commenter. Code Case N–789 Paragraph 3.2(i) contains a typographical error. The code case references NC–2650 and the correct reference is NC–3650. NC–2650 does not exist in ASME Code Section III and

NC–3650 is the correct portion of the Code to use for the design of reinforcing pads. The NRC does not believe that this typographical error represents a safety concern. In order to prevent the delay of issuance of the final rule by including a new condition on the code case, the NRC will address this issue in a future rulemaking.

No change was made to the final rule as a result of this comment.

Code Case N–795

Comment: The commenters requested that one or both proposed conditions on the use of this Code Case in DG–1296 be removed: (1) Prohibition of use of nuclear heat to perform the leakage test; and (2) Hold time for noninsulated components must be 1 hour versus 15 minutes required by Code Case N–795. [Southern 4–1, ASME 5–9, and Exelon 7–2]

NRC Response: The NRC agrees, in part, with this comment. As discussed in detail in the proposed rule in 81 FR 10780, dated March 2, 2016, the historical prohibition of the use of nuclear heat for pressure testing is based on concerns about the quality of the VT–2 examinations performed with the core critical, due to the high temperatures in containment, which limit stay times for inspectors, and also concerns about personnel safety. However, the commenters emphasized that Code Case N–795 is only intended for use in the case of limited scope repairs, such as the replacement of a main steam relief valve pilot valve (involving a single mechanical joint) when the relief valve is found to be leaking during startup. Code Case N–795 states that the alternative test pressure may not be used to satisfy the requirements of Table IWB–2500–1, Category B–P (the pressure test required once per cycle of the entire reactor coolant pressure boundary). Code Case N–795 does not place any restrictions on the size or scope of the repairs for which the alternative may be used, other than the alternative test pressure may not be used to satisfy pressure test requirements, following repair/replacement activities on the reactor vessel.

However, upon review of the public comments, the staff has determined that the risk associated with performing the pressure test with nuclear heat at low power is comparable with the risk to the plant, when the test is performed without nuclear heat (with the core subcritical) during mid-cycle outages when decay heat must be managed. Performing the pressure test under shutdown conditions at full operating pressure without nuclear heat requires securing certain key pressure control, heat removal, and safety systems. Under such conditions, it is more difficult to control temperature and pressure, when there is significant decay heat production, such as after a mid-cycle outage, which may reduce the margin available to prevent exceeding the plant pressure-temperature limits.

The NRC considers it desirable that the scope of repairs be relatively small when the pressure test is conducted using nuclear heat, in order to minimize the personnel safety risk and to avoid rushed examinations. The staff considers it impractical to specify a particular number of welded or mechanical repairs that would constitute a ''limited scope.'' However, if the plant is still in a refueling outage and has already performed the ASME Section XI Category B–P pressure test of the entire RCPB, it is likely that subsequent repairs would be performed only on an emergent basis and would generally be of a limited scope. Additionally, the overall integrity of the RCPB will have been recently confirmed via the Category B–P test. For mid-cycle maintenance outages, the staff proposes to modify the condition to incorporate a limit on the outage duration of fourteen (14) days. This would tend to limit the scope of repairs, and also limit use of the Code Case to outages when decay heat was a significant problem. Therefore, the first condition on Code Case N–795 in Table 2 of DG–1296, which currently reads:

1. The use of nuclear heat to conduct the BWR Class 1 system leakage test is prohibited (*i.e.*, the reactor must be in a non-critical state).

a. This condition also applies to pressure testing of reactor coolant pressure boundary components repaired or replaced in accordance with Section XI, IWA–4000.

is modified to read:

1. The use of nuclear heat to conduct the BWR Class 1 system leakage test is prohibited (*i.e.*, the reactor must be in a non-critical state), except during refueling outages in which the ASME Section XI Category B–P pressure test has already been performed, or at the end of mid-cycle maintenance outages fourteen (14) days or less in duration.

With respect to the comment on the second condition, the NRC disagrees with this comment. A one hour hold time is not unreasonable for non-insulated components. Inspectors do not need to be in containment during the hold time. Comment 5–9 (ASME) discussed the technical basis for Code Case N–795, which stated that pressure testing at 87 percent of full operating pressure would only result in a 7 percent reduction in flow, while the hold time is being increased by 50 percent from 10 minutes to 15 minutes. However, it is not possible to predict the entire range of scenarios or types of defects that could result in leakage. While some types of defects could result in immediate leakage, such as an improperly torqued bolted connection, other types of defects, such as weld defects or tight cracks could represent a more torturous path for leakage and may result in delayed leakage. Because the visual examination may be conducted with the core critical, stay times for examiners in containment may be limited; therefore, it is desirable that any leakage be readily detectable. The staff determined that, due to the uncertainty in the time required for leakage to occur, to an extent that it would be readily detectable by visual examination, it is appropriate to conservatively specify a longer hold time of 1 hour for non-insulated components. Therefore, no changes are made to Condition (2) requiring a 1-hour hold time for non-insulated components.

No change was made to the final rule as a result of this comment.

Code Case N–799

Comment: This is a Code Case to define the examination volume/area where older Section XI codes (up through 2010 Edition) do not recognize the defined configuration. The conditions proposed in the Code Case are not included in the proposed rule to accept the 2013 Edition of Section XI and the Code Case configuration is defined in the 2013 Code Edition. Commenters believe that this results in inconsistent requirements for plants using older Code versions versus newer Code versions. The examination conditions proposed for this Code Case use are not appropriate for a volume of interest Code Case. If the NRC considers the conditions appropriate, commenters believe that they should be included in a revision to 10 CFR 50.55a to assure consistent application, regardless of Code year and Addenda being applied. Specifically Conditions (3) and (5) should be removed from the Code Case. [Southern 4–2, Southern 4–3, and Exelon 7–3]

NRC Response: The NRC agrees, in part, with this comment.

Regarding the removal of proposed Condition (3) from N–799, the NRC disagrees with the comment. The NRC doesn't find that the examination of the inner ⅓ of the component-to-component weld depicted in Figure 1 of Code Case N–799 provides reasonable assurance that the integrity of the component-to-component welds will be maintained throughout the operating life of the plant. Code Case N–799 was written to support new plant construction to provide examination requirements for a weld configuration, which did not exist in Section XI (*i.e.*, component-to-component welds). Specifically, the examination requirements described in Code Case N–

799 would apply to the steam generator nozzle-to-reactor coolant pump casing (SG-to-RCP) weld in the AP1000 design and the reactor vessel nozzle-to-recirculation pump weld in the Advanced Boiling Water Reactor (ABWR). The following discussion will focus on the AP1000 design, but the staff's overall concern is also applicable to the reactor vessel-to-reactor coolant pump connection for the ABWR design.

The AP1000 design is unique in that a reactor coolant pump is welded directly to each of the two outlet nozzles on the steam generator channel head. This SG-to-RCP weld is a dissimilar metal (low alloy steel to cast austenitic stainless steel with Alloy 52/152 weld metal) circumferential butt weld with a double sided weld joint configuration, similar to that of a reactor vessel shell weld. Also, this unique component-to-component weld is part of the reactor coolant pressure boundary and is, therefore, subject to the examination requirements of ASME Section XI, Subsection IWB.

ASME Section XI, IWB–2500 requires a full volume examination of all component welds, except those welds found in piping and those found in nozzles welded to piping. However, for the component-to-component welds in question, Code Case N–799 only requires a licensee to perform a volumetric examination of the inner ⅓ of the weld and a surface examination of the outer diameter. The staff notes that the requirements of Code Case N–799 are identical to those in ASME Section XI, Table IWB–2500–1, Examination Category B–F for welds between vessel nozzles larger than NPS 4 and piping. As such, the staff does not believe that examination requirements proposed in Code Case N–799 are appropriate for the component-to-component welds because the service conditions of the aforementioned welds are significantly different from those that would be experienced by a traditional vessel nozzle-to-piping/safe end butt weld. Specifically, in addition to the operating environment (RCS pressure, temperature, and exposure to coolant) and loads expected on a traditional nozzle-to-safe end weld, each SG-to-RCP weld will support the full weight of a reactor coolant pump with no other vertical or lateral supports. The SG-to-RCP welds will also be subject to pump rotational forces and vibration loads from both the steam generator and the reactor coolant pump during service. In the absence of operating experience for the weld in question or a bounding analysis, which demonstrates that a potential fabrication defect in the outer ⅔ of the weld will not experience subcritical crack growth, the effects of these additional operating loads and stresses are indeterminate. Absent either of the above, the staff finds that it is inappropriate to limit the examination volume to the inner ⅓ of the weld as typical of a piping weld at this time. When the examination volume that can be qualified by performance demonstration is less than 100 percent of the weld volume, a licensee should include an ultrasonic examination to examine the qualified volume and perform a flaw evaluation of the largest hypothetical crack that could exist in the volume not qualified for ultrasonic examination. No change was made to the rule as a result of this comment.

The NRC agrees that performing the examination in accordance with Section XI, Appendix VIII, Supplement 10, for detection and sizing would eliminate the need for the requirement to perform a flaw evaluation, based on the largest hypothetical flaw in the unqualified examination volume. However, the NRC determined a full volume examination of the entire weld and heat affected zone is required to provide reasonable assurance of structural integrity of the component-to component welds addressed by Code Case N–799. The NRC also determined that requiring the examination procedures to be qualified in accordance with Section XI, Appendix VIII, Supplement 10, would eliminate the need for several of the other conditions that were proposed for N–799. Therefore, the final regulatory guide was modified to specify only four conditions for Code Case N–799, as follows:

(i) Ultrasonic examination procedures, equipment, and personnel shall be qualified by performance demonstration in accordance with Section XI, Appendix VIII, Supplement 10. When applying the examination requirements of Figure IWB–2500–8, the examination volume shall be extended to include 100 percent of the weld.

(ii) Examination requirements of Section XI, Mandatory Appendix I, paragraph I–3200(c) must be applied.

(iii) Ultrasonic depth and sizing qualifications for cast austenitic stainless steel components must follow Appendix VIII, Supplement 10, using representative cast austenitic stainless steel mockups containing representative cracks and be independent of other Supplement 10 qualifications.

(iv) Cracks detected and not depth sized to Appendix VIII type performance-based procedures, equipment, and personnel qualifications shall be repaired or removed.

The NRC agrees with the examination requirement regarding the consistency between the Code Case and the codes, where the Code Case that has been incorporated should be consistent. The NRC disagrees with the statement that the proposed conditions are not appropriate for a volume of interest Code Case. The NRC is planning to include this topic in a future rulemaking.

Code Case N–806

Comment: ASME stated that it has taken action to address some of these concerns and has published Code Case N–806–1, providing additional requirements for determining wall thickness loss rates. The ASME recommends that the NRC consider developing conditions on the use of this case that would enable the endorsement of the case in Table 2 of RG 1.147. [ASME 5–13]

NRC Response: The NRC disagrees with this comment. The NRC recognizes that ASME has addressed the NRC's concerns regarding the derivation of the corrosion rate in predicting metal loss in piping and has incorporated the corrosion rate derivation in the published Code Case N–806–1. However, the current rulemaking is for Code Case N–806, which does not contain sufficient information regarding the corrosion rate. The ASME suggested that the NRC develop conditions on the use of the Code Case such that the NRC could approve the Code Case for RG 1.147. The NRC has determined that approval of Code Case N–806 with conditions would require too many conditions to address several open issues regarding the relationship to the derivation of the corrosion rate, which still need to be resolved. Therefore, the NRC cannot approve Code Case N–806 in this rulemaking.

No change was made to the final rule as a result of this comment.

Code Case N–813

Comment: This Code Case should be removed from Table 2 of Regulatory Guide 1.193 and added to Table 1 of Regulatory Guide 1.147 because of the following reasons.

1. The requirements of Code Case N–813 are identical to changes made in the 2013 Edition of Section XI, which are being considered under a separate draft 10 CFR 50.55a rule. The NRC has not proposed any conditions on these requirements in the 2013 Edition. It is inappropriate for the NRC to impose conditions on the same requirements in Case N–813 as the requirements in the 2013 Edition.

2. This Case permits acceptance of subsurface flaws detected during preservice examination using the same criteria applicable to flaws detected during inservice examination. There is no greater likelihood of subsurface flaws detected during preservice examination to grow unacceptably than there is for the same flaws to grow during inservice examination. Operating experience has

shown that the propensity for failure is increased by repairing such flaws, whereas leaving them in place has never been shown to be a precursor to failure. Without weld repair, there is no mechanism expected to produce unacceptable flaw growth, whereas repair welding itself has been repeatedly shown to cause flaws to grow to the point of failure. The provisions of this Case, and the identical provisions in the 2013 Edition, improve safety.

3. The technical basis for this Code Case and accompanying Code revision states that the action is being sought to prevent the unnecessary excavation and weld repair of subsurface indications, which can be analytically shown to be benign over the expected service lifetime of a component. Based on operating experience, it is known that weld repairs and their associated stress fields often serve as points of initiation for inservice degradation mechanisms (*e.g.*, intergranular stress corrosion cracking, primary water stress corrosion cracking, etc.). Hence, it is in the best interest of the long term safe operation of components being placed into service to eliminate the need for weld repairs where they are not necessary to correct fabrication problems, which will not challenge the operability of the component over its service lifetime. This can be achieved by permitting licensees to effectively utilize the flaw evaluation rules of IWB–3600 and IWC–3600, which are already accepted for the analysis of indications due to inservice degradation.

4. It is important to note that any preservice flaw that has been evaluated as acceptable is required to receive successive examinations under IWB–2420(b) or IWC–2420(c) so if the flaw does grow, it will be detected during these examinations. [ASME 5–14]

NRC Response: The NRC disagrees with this comment, in part. The NRC has recognized that the provisions in Code Case N–813 are identical to changes made in the 2013 Edition of the ASME BPV Code, Section XI. The NRC addressed the contents of the 2013 Edition of the ASME BPV Code, including the Code provisions identical to those allowed in Code Case N–813, in a separate rulemaking.

The NRC recognizes that operating experience has shown that repairing a weld that contains fabrication defects may cause the defect to grow in the future. On the other hand, permitting a weld that contains a known unacceptable fabrication defect prior to deployment is not appropriate and is contrary to the fundamental engineering principle of a good design. The fundamental engineering design is that a component should not contain defects before placing it into service. The staff has accepted the provision of ASME BPV Code, Section III that permits acceptable flaws (*i.e.*, small insignificant flaws) in a weld to exist before deployment. The staff's objection to Code Case N–813 is that the code case permits the existence of unacceptable flaws, which do not meet the ASME Code preservice acceptance criteria, in welds before their deployment. The code case allows these unacceptable flaws to be accepted by analytical evaluation. The code case places no limits on such flaws (*i.e.*, a weld could have more than one unacceptable flaw or numerous welds within a piping run could have flaws that did not meet the preservice acceptance criteria), whereas the original fleet of nuclear plants had no unacceptable preservice flaws. The staff concludes that it cannot approve Code Case N–813 in this rulemaking. The NRC will continue to evaluate operating experience relative to this type of flaw to further inform decisions on possible approval of this code case in future rulemakings.

No change was made to the final rule as a result of this comment.

Code Case N–818

Comment: Code Case N–818 should be removed from Regulatory Guide 1.193 and be allowed for use, as the reasons given in Regulatory Guide 1.193 to disallow Code Case N–818 have the following issues: (a) The fact that the examination will be difficult should not be a reason to prohibit it as Mandatory Appendix I requires that the technique(s) to be applied for the volumetric procedure be demonstrated on specimens simulating geometric, material and surface conditions to be encountered during implementation. (b) The discussion that ultrasound may have difficulties discerning between planar and volumetric flaws is not relevant. There is no requirement in the Code Case to characterize the flaw by type (*i.e.,* planar or volumetric). (c) The suggestion that its application should be limited to ferritic weldments defeats the purpose of Code Case N–818. [EPRI 2–5, Southern 4–4]

NRC Response: The NRC disagrees with this comment, in part. At present, the NRC has not received any supporting documents from the industry to address the NRC's concern regarding this Code Case, such as a demonstration of the adequacy of a full volume ultrasonic examination for fabrication flaws in austenitic welds. Therefore, the wording of the reasons given in RG 1.193 should not refer to the inspection being difficult for austenitic materials and dissimilar metal welds, but should instead refer to there not being an established technical basis for the use of ultrasound to find fabrication flaws in these materials. Additionally, the discussion of planar vs. volumetric flaws will be removed from RG 1.193, as the Code Case does not require the examiner to discriminate between these types of flaws. The revised wording for RG 1.193 is:

The NRC has been conducting research at Pacific Northwest National Laboratory on the examination of austenitic and ferritic welds. The work has shown that performing a full volume ultrasonic examination for fabrication flaws is significantly different from an inservice examination. For example, examination from two directions is necessary to detect certain circumferentially oriented fabrication flaws such as lack of fusion. The work has also shown that the second leg of a V-path can be applied to examine ferritic materials on a limited basis but to date the technical basis has not been established to show that these techniques will be effective on austenitic materials and dissimilar metal welds. Another finding is that surface conditions are critical with respect to detecting and characterizing fabrication flaws. In summary, the NRC finds that an analytical approach for the acceptance of certain fabrication flaws could be acceptable if appropriately justified and the scope limited to ferritic materials. The NRC finds that significant research will be required to demonstrate that full-volume ultrasonic examination for fabrication flaws is acceptable for austenitic and dissimilar metal welds.

Regulatory Guide 1.192, Revision 2 (DG–1297)

Code Case OMN–20

Comment: Allow the use of Code Case OMN–20 for those plants that implement ASME OM Code 2015 Edition and earlier editions and addenda. [Gowin 6–1]

NRC Response: The NRC agrees, in part, with this comment. Code Case OMN–20 cannot be implemented with the 2015 Edition of the ASME OM Code because the 2015 Edition has not been incorporated by reference into § 50.55a. Code Case OMN–20 is currently applicable to the 2009 Edition through the OMa–2011 Addenda and all earlier editions and addenda. Licensees who adopt the 2012 Edition of the ASME OM Code would not be able to use Code Case OMN–20, without submitting a relief request to the NRC for approval. For this reason, the NRC partially agrees with the comment. The NRC believes that Code Case OMN–20 should be allowed to be implemented with the 2012 Edition and earlier editions and addenda of the ASME OM Code. The RG 1.192 was updated to add a condition stating that Code Case OMN–20 is applicable to the editions and addenda of the ASME OM Code listed in § 50.55a(a)(1)(iv).

No change was made to the final rule as a result of this comment.

Public Comments on the Proposed Rule

Comment: The ASME Code is updated every year. Preparations are underway to publish the 2017 edition. NRC is working on 2010 Edition. It appears that NRC is not in compliance with National Technology Transfer and Advancement Act of 1995 (NTTAA) by passive non-compliance. Since NRC has many participants in the Code process, they should be prepared to act as soon as final standards votes are counted. [Donavin 1–1]

NRC Response: The NRC disagrees with this comment. The NRC appreciates the ASME's efforts to consider the NRC's concerns as addressed in conditions to § 50.55a. The NRC agrees that delays in approving new ASME Code editions and Code Cases can be counterproductive with respect to implementation of improvements in ASME Code requirements. The NRC continues to assess ways to improve the rulemaking process to find schedule efficiencies.

No change was made to the final rule as a result of this comment.

Comment: Many of the conditions are historical and are the result of a single reviewer's opinion. An example is the rules for the 1994 edition where I watched an NRC reviewer living in Washington, DC telling a PhD from Tokyo, Japan, that his seismic analysis defending the edition was non conservative. If there are legitimate questions, these should be separated from the ''not sufficiently conservative'' or ''insufficient information'' justifications. The Commission has set a precedent in CVR for SECY–15–0106. ASME has endeavored to address conditions with docketed letters and Code actions. [Donavin 1–2]

NRC Response: The NRC disagrees with this comment. Although a single reviewer may state a contrary position, NRC reviews all Code Cases and comments with appropriate staff and management. Code Cases that the NRC finds to be conditionally acceptable are also listed in RGs 1.84, 1.147, and 1.192, which are the subject of this rulemaking, together with the conditions that must be used if the Code Case is applied. The NRC determined that this rule complies with the NTTAA and OMB Circular A–119, despite these conditions. If the NRC did not conditionally accept ASME Code Cases, it would disapprove these Code Cases entirely.

No change was made to the final rule as a result of this comment.

Comment: ASME believes that it is not clear whether the word ''superseded'' applies to those Code Cases that are superseded by ASME or those Code Cases that are listed as superseded in Table 5 of Regulatory Guide 1.147.

ASME recommends revising the second sentence of this paragraph to clarify that ''The older or superseded version of the Code Case, if listed in Table 5, cannot be applied by the licensee or applicant for the first time.'' [ASME 5–1]

NRC Response: The NRC agrees with this comment. The proposed additional text will add clarity to the information presented in Table 5. The final RG 1.147 in the introductory paragraph to Table 5, has been revised to include the statement, ''The older or superseded version of the Code Case, if listed in Table 5, cannot be applied by the licensee or applicant for the first time.'' at the end of the explanatory text above Table 5.

No change was made to the final rule as a result of this comment.

Comment: The Code Case [N–711] would permit each licensee to independently determine when achievement of a coverage requirement is impractical, and when Code-required coverage is satisfied. As a result, application of the Code Case for similar configurations at different plants could result in potentially significant quantitative variations. Furthermore, application of the Code Case is inconsistent with NRC's responsibility for determining whether examinations are impractical, and eliminates the NRC's ability to take exception to a licensee's proposed action and impose additional measures where warranted in accordance with 10 CFR 50.55a(g)(6)(i).

ASME recommends that this case be removed from RG 1.193, Table 2 and added to Table 2 of RG 1.147 with appropriate conditions to address NRC technical concerns with the use of this case. [ASME 5–10]

NRC Response: The NRC agrees with this comment. However, this is a new proposal and cannot be included in this rulemaking because it was not provided for public comment. Rather than include the action in this rulemaking, the NRC intends to include it within the scope of the rulemaking that will incorporate by reference the 2015 edition of the ASME BPV Code.

No change was made to the final rule as a result of this comment.

Comment: In Section IV, ''Section-by-Section Analysis'' of the Proposed Rule dated March 2, 2016 (**Federal Register** Vol. 81, No. 41), ASME believes that it is not clear whether the word ''superseded'' applies to those Code Cases that are superseded by ASME or those Code Cases that are listed as superseded in Table 5 of Regulatory Guide 1.147 and in Table 5 of Regulatory Guide 1.84. [ASME 5–1 and ASME 5–15]

ASME provides the following recommendations:

i. ASME recommends that the NRC clarify the above concern in the final rule.

ii. ASME recommends that the NRC review requirements for superseded ASME Section III and OM Code Cases in RG 1.84 and RG 1.192 for similar clarification.

NRC Response: The NRC agrees with this comment as noted in the response to Comment 5–1. In addition to that clarifying text being added in the introduction to Table 5 in RG 1.147, it will also be added to the introduction of Table 5 in RG 1.84. The RG 1.192 does not contain a table of superseded Code Cases, therefore, no change will be made to the RG 1.192.

No change was made to the final rule as a result of this comment.

V. Section-by-Section Analysis

The following paragraphs in § 50.55a, which list the three RGs that are being incorporated by reference, are revised as follows:

Paragraphs (a)(3)(i): The reference to ''*NRC Regulatory Guide 1.84, Revision 36,*'' is amended to remove ''Revision 36'' and add in its place ''Revision 37.''

Paragraphs (a)(3)(ii): The reference to ''*NRC Regulatory Guide 1.147, Revision 17,*'' is amended to remove ''Revision 17'' and add in its place ''Revision 18.''

Paragraphs (a)(3)(iii): The reference to ''*NRC Regulatory Guide 1.192, Revision 1,*'' is amended to remove ''Revision 1'' and add in its place ''Revision 2.''

Overall Considerations on the Use of ASME Code Cases

This rulemaking amends § 50.55a to incorporate by reference RG 1.84, Revision 37, which supersedes Revision 36; RG 1.147, Revision 18, which supersedes Revision 17; and RG 1.192, Revision 2, which supersedes Revision 1. The following general guidance applies to the use of the ASME Code Cases approved in the latest versions of the RGs that are incorporated by reference into § 50.55a as part of this rulemaking.

The approval of a Code Case in the NRC RGs constitutes acceptance of its technical position for applications that are not precluded by regulatory or other requirements or by the recommendations in these or other RGs. The applicant and/or licensee are responsible for ensuring that use of the Code Case does not conflict with regulatory requirements or licensee

commitments. The Code Cases listed in the RGs are acceptable for use within the limits specified in the Code Cases. If the RG states an NRC condition on the use of a Code Case, then the NRC condition supplements the Code Case, and does not supersede any condition(s) specified in the Code Case, unless otherwise stated in the NRC condition.

The ASME Code Cases may be revised for many reasons (*e.g.*, to incorporate operational examination and testing experience and to update material requirements based on research results). On occasion, an inaccuracy in an equation is discovered or an examination, as practiced, is found not to be adequate to detect a newly discovered degradation mechanism. Hence, when an applicant or a licensee initially implements a Code Case, § 50.55a requires that the applicant or the licensee implement the most recent version of that Code Case, as listed in the RGs incorporated by reference. Code Cases superseded by revision are no longer acceptable for new applications, unless otherwise indicated.

Section III of the ASME BPV Code applies only to new construction (*i.e.*, the edition and addenda to be used in the construction of a plant are selected based on the date of the construction permit and are not changed thereafter, except voluntarily by the applicant or the licensee). Hence, if a Section III Code Case is implemented by an applicant or a licensee and a later version of the Code Case is incorporated by reference into § 50.55a and listed in the RGs, the applicant or the licensee may use either version of the Code Case (subject, however, to whatever change requirements apply to its licensing basis (*e.g.*, 10 CFR 50.59)).

A licensee's ISI and IST programs must be updated every 10 years to the latest edition and addenda of Section XI and the OM Code, respectively, that were incorporated by reference into § 50.55a and in effect 12 months prior to the start of the next inspection and testing interval. Licensees who were using a Code Case prior to the effective date of its revision may continue to use the previous version for the remainder of the 120-month ISI or IST interval. This relieves licensees of the burden of having to update their ISI or IST program each time a Code Case is revised by the ASME and approved for use by the NRC. Code Cases apply to specific editions and addenda, and Code Cases may be revised if they are no longer accurate or adequate, so licensees choosing to continue using a Code Case during the subsequent ISI or IST interval must implement the latest version incorporated by reference into § 50.55a and listed in the RGs.

The ASME may annul Code Cases that are no longer required, are determined to be inaccurate or inadequate, or have been incorporated into the BPV or OM Codes. If an applicant or a licensee applied a Code Case before it was listed as annulled, the applicant or the licensee may continue to use the Code Case until the applicant or the licensee updates its construction Code of Record (in the case of an applicant, updates its application) or until the licensee's 120-month ISI or IST update interval expires, after which the continued use of the Code Case is prohibited, unless NRC authorization is given under § 50.55a(z). If a Code Case is incorporated by reference into § 50.55a and later annulled by the ASME because experience has shown that the design analysis, construction method, examination method, or testing method is inadequate, the NRC will amend § 50.55a and the relevant RG to remove the approval of the annulled Code Case. Applicants and licensees should not begin to implement such annulled Code Cases in advance of the rulemaking.

A Code Case may be revised, for example, to incorporate user experience. The older or superseded version of the Code Case cannot be applied by the licensee or applicant for the first time.

If an applicant or a licensee applied a Code Case before it was listed as superseded, the applicant or the licensee may continue to use the Code Case until the applicant or the licensee updates its Construction Code of Record (in the case of an applicant, updates its application) or until the licensee's 120-month ISI or IST update interval expires, after which the continued use of the Code Case is prohibited, unless NRC authorization is given under § 50.55a(z). If a Code Case is incorporated by reference into § 50.55a and later a revised version is issued by the ASME because experience has shown that the design analysis, construction method, examination method, or testing method is inadequate; the NRC will amend § 50.55a and the relevant RG to remove the approval of the superseded Code Case. Applicants and licensees should not begin to implement such superseded Code Cases in advance of the rulemaking.

VI. Regulatory Flexibility Certification

Under the Regulatory Flexibility Act, 5 U.S.C. 605(b), the NRC certifies that this rule does not have a significant economic impact on a substantial number of small entities. This final rule affects only the licensing and operation of nuclear power plants. The companies that own these plants do not fall within the scope of the definition of ''small entities'' set forth in the Regulatory Flexibility Act or the size standards established by the NRC (§ 2.810).

VII. Regulatory Analysis

The NRC has prepared a final regulatory analysis on this regulation. The analysis examines the costs and benefits of the alternatives considered by the NRC. The total estimated net benefit of this rule is $4.94 million (7% discount rate) and $5.68 million (3% discount rate). The regulatory analysis is available as indicated in the ''Availability of Documents'' section of this document.

VIII. Backfitting and Issue Finality

The provisions in this rule allow licensees and applicants to voluntarily apply NRC-approved Code Cases, sometimes with NRC-specified conditions. The approved Code Cases are listed in the three RGs that are incorporated by reference into § 50.55a.

An applicant's or a licensee's voluntary application of an approved Code Case does not constitute backfitting, inasmuch as there is no imposition of a new requirement or new position. Similarly, voluntary application of an approved Code Case by a 10 CFR part 52 applicant or licensee does not represent NRC imposition of a requirement or action that is inconsistent with any issue finality provision in 10 CFR part 52. The NRC finds that this rule does not involve any provisions requiring the preparation of a backfit analysis or documentation demonstrating that one or more of the issue finality criteria in 10 CFR part 52 are met.

IX. Plain Writing

The Plain Writing Act of 2010 (Pub. L. 111–274) requires Federal agencies to write documents in a clear, concise, and well-organized manner. The NRC has written this document to be consistent with the Plain Writing Act as well as the Presidential Memorandum, ''Plain Language in Government Writing,'' published June 10, 1998 (63 FR 31883).

X. Environmental Assessment and Final Finding of No Significant Environmental Impact

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in subpart A of 10 CFR part 51, that this rule, if adopted, would not be a major Federal action significantly affecting the quality of the human environment; therefore, an

environmental impact statement is not required.

The determination of this environmental assessment is that there will be no significant effect on the quality of the human environment from this action. As alternatives to the ASME Code, NRC-approved Code Cases provide an equivalent level of safety. Therefore, the probability or consequences of accidents is not changed. There are also no significant, non-radiological impacts associated with this action because no changes would be made affecting non-radiological plant effluents and because no changes would be made in activities that would adversely affect the environment. The determination of this environmental assessment is that there will be no significant offsite impact to the public from this action.

XI. Paperwork Reduction Act

This final rule contains new or amended collections of information subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). The collection of information was approved by the Office of Management and Budget (approval number 3150–0011).

The burden to the public for these information collections is estimated to average a reduction of 380 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection.

The information collection is being conducted to document the plans for and the results of inservice inspection and inservice testing programs. The records are generally historical in nature and provide data on which future activities can be based. The practical utility of the information collection for the NRC is that appropriate records are available for auditing by NRC personnel to determine if ASME BPV and OM Code provisions for construction, inservice inspection, repairs, and inservice testing are being properly implemented in accordance with § 50.55a of the NRC regulations, or whether specific enforcement actions are necessary. Responses to this collection of information are generally mandatory under § 50.55a.

You may submit comments on any aspect of the information collection(s), including suggestions for reducing the burden, by the following methods:

- *Federal Rulemaking Website:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2012–0059.
- *Mail comments to:* Information Services Branch, Office of the Chief Information Officer, Mail Stop: T–2 F43, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001 or to Aaron Szabo, Desk Officer, Office of Information and Regulatory Affairs (3150–0011), NEOB–10202, Office of Management and Budget, Washington, DC 20503; telephone 202–395–3621, email: *oira_submission@omb.eop.gov.*

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement, unless the requesting document displays a currently valid OMB control number.

XII. Congressional Review Act

This final rule is a rule as defined in the Congressional Review Act (5 U.S.C. 801–808). However, the Office of Management and Budget has not found it to be a major rule, as defined in the Congressional Review Act.

XIII. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995, Public Law 104–113, requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies, unless using such a standard is inconsistent with applicable law or is otherwise impractical. In this rule, the NRC is continuing to use ASME BPV and OM Code Cases, which are ASME-approved alternatives to compliance with various provisions of the ASME BPV and OM Codes. The NRC's approval of the ASME Code Cases is accomplished by amending the NRC's regulations to incorporate by reference the latest revisions of the following, which are the subject of this rulemaking, into § 50.55a: RG 1.84, Revision 37; RG 1.147, Revision 18; and RG 1.192, Revision 2. These RGs list the ASME Code Cases that the NRC has approved for use. The ASME Code Cases are national consensus standards, as defined in the National Technology Transfer and Advancement Act of 1995 and OMB Circular A–119. The ASME Code Cases constitute voluntary consensus standards, in which all interested parties (including the NRC and licensees of nuclear power plants) participate.

XIV. Incorporation by Reference—Reasonable Availability to Interested Parties

The NRC is incorporating by reference three NRC Regulatory Guides that list new and revised ASME Code Cases, which the NRC has approved as alternatives to certain provisions of NRC-required Editions and Addenda of the ASME BPV Code and the ASME OM Code.

The NRC is required by law to obtain approval for incorporation by reference from the Office of the Federal Register (OFR). The OFR's requirements for incorporation by reference are set forth in 1 CFR part 51. On November 7, 2014, the OFR adopted changes to its regulations governing incorporation by reference (79 FR 66267). The OFR regulations require an agency to include, in a proposed rule, a discussion of the ways that the materials the agency proposes to incorporate by reference are reasonably available to interested parties or how it worked to make those materials reasonably available to interested parties. The discussion in this section complies with the requirement for final rules, as set forth in 1 CFR 51.5(b).

The NRC considers ''interested parties'' to include all potential NRC stakeholders, not only the individuals and entities regulated or otherwise subject to the NRC's regulatory oversight. These NRC stakeholders are not a homogenous group, so the considerations for determining ''reasonable availability'' vary by class of interested parties. The NRC identifies six classes of interested parties with regard to the material to be incorporated by reference in an NRC rule:

- Individuals and small entities regulated or otherwise subject to the NRC's regulatory oversight. This class includes applicants and potential applicants for licenses and other NRC regulatory approvals, and who are subject to the material to be incorporated by reference. In this context, ''small entities'' has the same meaning as set out in § 2.810.
- Large entities otherwise subject to the NRC's regulatory oversight. This class includes applicants and potential applicants for licenses and other NRC regulatory approvals, and who are subject to the material to be incorporated by reference. In this context, a ''large entity'' is one which does not qualify as a ''small entity'' under § 2.810.
- Non-governmental organizations with institutional interests in the matters regulated by the NRC.
- Other Federal agencies, states, local governmental bodies (within the meaning of § 2.315(c)).
- Federally-recognized and State-recognized [7] Indian tribes.

[7] State-recognized Indian tribes are not within the scope of 10 CFR 2.315(c). However, for purposes of the NRC's compliance with 1 CFR 51.5, ''interested

• Members of the general public (*i.e.*, individual, unaffiliated members of the public who are not regulated or otherwise subject to the NRC's regulatory oversight) and who need access to the materials that the NRC proposes to incorporate by reference in order to participate in the rulemaking.

The three regulatory guides being incorporated by reference in this rule are available without cost and can be read online, downloaded, or viewed, by appointment, at the NRC Technical Library, which is located at Two White Flint North, 11545 Rockville Pike, Rockville, Maryland 20852; telephone: 301–415–7000; e-mail: *Library.Resource@nrc.gov; url: www.nrc.gov/reading-rm/doc-collections/*.

Because access to the three regulatory guides are available in various forms and at no cost, the NRC determines that the three regulatory guides, RG 1.84, Revision 37; RG 1.147, Revision 18; and RG 1.192, Revision 2, once approved by the OFR for incorporation by reference, are reasonably available to all interested parties.

XV. Availability of Documents

The documents identified in the following table are available to interested persons through one or more of the following methods, as indicated.

TABLE IV—RULEMAKING RELATED DOCUMENTS

Document title	ADAMS accession No./ **Federal Register** citation/web link
Proposed Rule Documents:	
Proposed Rule—**Federal Register** notice, March 2, 2016	81 FR 10780.
Draft Regulatory Analysis	ML15041A816.
Draft RG 1.84, Revision 37 (DG–1295)	ML15027A002.
Draft RG 1.147, Revision 18 (DG–1296)	ML15027A202.
Draft RG 1.192, Revision 2 (DG–1297)	ML15027A330.
Final Rule Documents:	
Regulatory Analysis	ML16285A013.
RG 1.84, Revision 37	ML16321A335.
RG 1.147, Revision 18	ML16321A336.
RG 1.192, Revision 2	ML16321A337.
Related Documents:	
Draft RG 1.193, "ASME Code Cases Not Approved for Use," Revision 5. (DG–1298)	ML15028A003.
Federal Register notice—"Incorporation by Reference of American Society of Mechanical Engineers Codes and Code Cases," July 18, 2017.	82 FR 32934.
Federal Register notice—"Incorporation by Reference of American Society of Mechanical Engineers Codes and Code Cases," September 18, 2015.	80 FR 56820.
Federal Register notice—"Incorporation by Reference of ASME BPV and OM Code Cases," July 8, 2003.	68 FR 40469.
Federal Register notice—"Fracture Toughness Requirements for Light Water Reactor Pressure Vessels," December 19, 1995.	60 FR 65456.
Information Notice No. 98–13, "Post-Refueling Outage Reactor Pressure Vessel Leakage Testing Before Core Criticality," April 20, 1998.	ML031050237.
Inspection Report 50–254/97–27	ML15216A276.
Letter from James M. Taylor, Executive Director for Operations, NRC, to Messrs. Nicholas S. Reynolds and Daniel F. Stenger, Nuclear Utility Backfitting and Reform Group, February 2, 1990.	ML14273A002.
Materials Reliability Project Report MRP–169 Technical Basis for Preemptive Weld Overlays for Alloy 82/182 Butt Welds in PWRs (Revision 1), EPRI, Palo Alto, CA: 2012. 1025295.	ML101660468.
NUREG/CR–6933, "Assessment of Crack Detection in Heavy-Walled Cast Stainless Steel Piping Welds Using Advanced Low-Frequency Ultrasonic Methods".	ML071020409.
White Paper, PVP2012–78190, "Alternative Acceptance Criteria for Flaws in Ferritic Steel Components Operating in the Upper Shelf Temperature Range," 2012.	*http://proceedings.asmedigitalcollection.asme.org/proceeding.aspx?articleid=1723450.*
White Paper PVP2015–45307, "Options for Defining the Upper Shelf Transition Temperature (*Tc*) for Ferritic Pressure Vessel Steels," 2015.	*http://proceedings.asmedigitalcollection.asme.org/proceeding.aspx?articleid=2471884.*

List of Subjects in 10 CFR Part 50

Administrative practice and procedure, Antitrust, Classified information, Criminal penalties, Education, Fire prevention, Fire protection, Incorporation by reference, Intergovernmental relations, Nuclear power plants and reactors, Penalties, Radiation protection, Reactor siting criteria, Reporting and recordkeeping requirements, Whistleblowing.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to 10 CFR part 50:

PART 50—DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

■ 1. The authority citation for part 50 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 11, 101, 102, 103, 104, 105, 108, 122, 147, 149, 161, 181, 182, 183, 184, 185, 186, 187, 189, 223, 234 (42 U.S.C. 2014, 2131, 2132, 2133, 2134, 2135, 2138, 2152, 2167, 2169, 2201, 2231, 2232, 2233, 2234, 2235, 2236, 2237, 2239, 2273, 2282); Energy

parties" includes a broad set of stakeholders including State-recognized Indian tribes.

Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); Nuclear Waste Policy Act of 1982, sec. 306 (42 U.S.C. 10226); National Environmental Policy Act of 1969 (42 U.S.C. 4332); 44 U.S.C. 3504 note; Sec. 109, Pub. L. 96–295, 94 Stat. 783.

■ 2. In § 50.55a, revise paragraphs (a)(3)(i) through (iii) to read as follows:

§ 50.55a Codes and standards.

(a) * * *

(3) * * *

(i) *NRC Regulatory Guide 1.84, Revision 37.* NRC Regulatory Guide 1.84, Revision 37, ''Design, Fabrication, and Materials Code Case Acceptability, ASME Section III,'' dated March 2017, with the requirements in paragraph (b)(4) of this section.

(ii) *NRC Regulatory Guide 1.147, Revision 18.* NRC Regulatory Guide 1.147, Revision 18, ''Inservice Inspection Code Case Acceptability, ASME Section XI, Division 1,'' dated March 2017, which lists ASME Code Cases that the NRC has approved in accordance with the requirements in paragraph (b)(5) of this section.

(iii) *NRC Regulatory Guide 1.192, Revision 2.* NRC Regulatory Guide 1.192, Revision 2, ''Operation and Maintenance Code Case Acceptability, ASME OM Code,'' dated March 2017, which lists ASME Code Cases that the NRC has approved in accordance with the requirements in paragraph (b)(6) of this section.

* * * * *

Dated at Rockville, Maryland, this 2nd day of August 2017.

For the Nuclear Regulatory Commission.

Brian E. Holian,

Acting Director, Office of Nuclear Reactor Regulation.

Editorial note: This document was received for publication by the Office of the Federal Register on January 3, 2018.

[FR Doc. 2018–00112 Filed 1–16–18; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2017–0324; Product Identifier 2017–CE–004–AD; Amendment 39–19157; AD 2018–02–04]

RIN 2120–AA64

Airworthiness Directives; Aerospace Welding Minneapolis, Inc., Mufflers

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain Aerospace Welding Minneapolis, Inc. mufflers, part numbers A1754001–23 and A1754001–25, installed on airplanes. This AD was prompted by occurrences of cracks or broken welds in the connecting weld of the muffler body to muffler cuff that may allow carbon monoxide exhaust fumes into the cockpit heating system. This AD requires an inspection of the muffler for leaking to identify cracks and replacement of the muffler. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective February 21, 2018.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of February 21, 2018.

ADDRESSES: For service information identified in this final rule, contact Aerospace Welding Minneapolis, Inc. (AWI) 1045 Gemini Road, Eagan, Minnesota 55121; telephone: 651–379–9888; fax: 651–379–9889; internet: *www.awi-ami.com.* You may view this service information at the FAA, Policy and Innovation Division, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148. It is also available on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–0324.

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–2017–0324; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the regulatory evaluation, any comments received, and other information. The address for Docket Operations (phone: 800–647–5527) is Docket Operations, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Mark Grace, Aerospace Engineer, FAA, Chicago ACO Branch, 2300 East Devon Avenue, Des Plaines, IL 60018–4696; telephone: (847) 294–7377; fax: (847) 294–7834; email: *mark.grace@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Aerospace Welding Minneapolis, Inc. (AWI) mufflers, part numbers A1754001–23 and A1754001–25, installed on airplanes. The NPRM published in the **Federal Register** on April 18, 2017 (82 FR 18265). The NPRM was prompted by reports of broken or cracked welds in the connecting weld of the muffler body to muffler cuff. There have been 54 occurrences identified by maintenance and 2 occurrences identified by the carbon monoxide (CO) gas monitor warning system. The NPRM proposed to require an inspection of the muffler for leaking to identify cracks and replacement of the muffler. We are issuing this AD to correct the unsafe condition on these products.

Comments

We gave the public the opportunity to participate in developing this final rule. The following presents the comments received on the NPRM and the FAA's response to each comment.

Request To Expand the Applicability

An anonymous commenter requested we expand the applicability of the AD to include additional part number mufflers produced by the same manufacturer as the mufflers affected by this AD. The commenter thinks the additional part number mufflers may share some of the same materials, processes, and methods of assembly as the mufflers affected by this AD.

We do not agree with this comment. We addressed this concern during the investigation of the unsafe condition. We found that the unsafe condition is related to a design change and was applicable to one manufacturing lot. The unsafe condition applies to only the part numbers and serial numbers affected by this AD.

We have not changed this AD based on this comment.

Request To Prohibit the Installation of the Affected Muffler on Cessna 172R and 172S Airplanes

An anonymous commenter pointed out that that all 10 SDRs address the Models 172R and 172S airplanes. This commenter also asks how many of the 56 parts were installed on Cessna Models C172R and C172S airplanes. The commenter explains that (AWI) mufflers, part numbers A1754001–23 and A1754001–25, lack the reinforced ends and high temperature corrosion resistant material specified in FAR Part 23.1125(a)(1). The material substitution

makes it less resistant to high temperature and corrosion than the original type-certificated product. Based on the comments, the FAA infers that the commenter wants the AD to prohibit the installation of the affected parts, regardless of serial number, specifically on the Cessna Models 172R and 172S airplanes.

We do not agree with the implication that the installation prohibition should apply to all produced parts or only apply to the Cessna Model 172R and 172S airplanes. The unsafe condition resulted from a design change with a limited serial number effectivity and that is approved for installation on other models. We don't know how many parts are installed or could be installed in the future on the Cessna Models C172R and C172S airplanes. The current applicability captures all the potentially unsafe parts in the field. Concerns about material substitutions complying with 14 CFR 23.1125(a)(1) goes beyond the scope of this AD.

We have not changed this AD based on this comment.

Request We Add an Exhaust Systems Inspection

An anonymous commenter requested we issue an AD similar to a Transport Canada AD which requires an ongoing periodic pressure testing of the exhaust systems to help identify and reduce the risk of CO entering the cabin area.

We do not agree with this comment. This AD addresses the identified unsafe condition on the affected mufflers by requiring removal of the affected mufflers from airplanes. A more general pressure testing of exhaust systems is beyond the scope of this AD.

We have not changed this AD based on this comment.

Request To Make Spot Weld Procedures More Rigid

An anonymous commenter requested we require parts manufacturer approval (PMA) spot weld procedures to be more rigid. The commenter stated that manually operated spot welding machines do not consistently control pressure, time, or frequency as required by weld schedules because the human operator controls those factors. It is almost impossible to meet the weld code without a computer aided machine.

We do not agree with this comment. Regulating how spot welds are done goes beyond the scope of this AD. This AD addresses the identified unsafe condition on the affected mufflers by requiring removal of the affected mufflers from airplanes.

We have not changed this AD based on this comment.

Request We Prohibit the Use of Less Heat Resistant Material

An anonymous commenter requested we not allow the substitution of less heat resistant material for higher heat resistant material. There are a number of FAA-approved PMA articles in existence certified by Identicality or Test and Computation where less heat resistant materials have been substituted. In many cases these PMA articles are used as terminating action to ADs and undermine the basis of the AD.

We do not agree with this comment. An applicant for a PMA must demonstrate compliance with the applicable regulations before the PMA is granted. This AD addresses the unsafe condition on the affected mufflers by requiring removal of the affected mufflers from airplanes. Changing the PMA process goes beyond the scope of this AD.

We have not changed this AD based on this comment.

Request We Make Related Documents Available

David McGhee requested we ensure documents related to the AD are readily available. Although requested several times by telephone and email, the commenter was unable to obtain a copy of related service information. This made review and comment on the proposed AD difficult.

We agree with this comment. Related documents should be available for a timely review of the AD. The NPRM incorrectly cited the related AWI service bulletin as AWI Mandatory Service Bulletin No. 16063001, dated June 30, 2015. The correct citation should read AWI Mandatory Service Bulletin No. 15063001, dated June 30, 2015. We confirmed the availability of the related service bulletin with the document provider and confirmed the commenter received a copy prior to the close of the comment period.

We changed this AD to use the correct citation based on this comment.

Request a Change to the Cost of Compliance

David McGhee requested we add the cost to determine if the affected muffler is installed on the airplane to the estimated cost of the AD. The related service information estimated it would take 1 hour of labor to inspect the airplane to determine if the affected muffler is installed.

We do not agree with this comment. The estimated cost of the AD applies specifically to addressing and correcting the unsafe condition. The FAA process for determining the cost of compliance does not include the initial determination of applicability. Also, for many airplanes, a review of the maintenance records will identify if the affected muffler is installed.

We have not changed this AD based on this comment.

Request We Allow the Use of Other Service Information for Muffler Replacement

David McGhee requested we revise the AD to allow the use of other service information for installing a replacement muffler. Operators may choose to install an FAA-approved muffler from a source other than AWI. The service information proposed in the NPRM may not be appropriate for mufflers produced by a different manufacturer.

We agree with this comment. If an operator installs an FAA-approved muffler other than the AWI muffler, the installation instructions from that manufacturer should be used.

We have revised the language in this AD to allow the use of the manufacturer's installation instructions for the specific muffler that is being installed.

Request We Revise the Subject Heading

Thomas Nelson requested we revise the subject heading of the AD because it is not part of the company's name and implies the AD applies to all mufflers made by this company.

We partially agree with this comment. We agree the subject header could more clearly define the specific mufflers this AD applies to; however, we disagree with revising the subject header. The subject header is intended as a general header and is not intended to include details that address the specifics of applicability. The Office of the Federal Register develops the guidelines for the format and structure of rulemaking documents for all federal agencies to follow.

We have not changed this AD based on this comment.

Conclusion

We reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting this final rule with the changes described previously and minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM for correcting the unsafe condition; and

• Do not add any additional burden upon the public than was already proposed in the NPRM.

We also determined that these changes will not increase the economic burden on any operator or increase the scope of this final rule.

Related Service Information Under 1 CFR Part 51

We reviewed AWI Cessna 172 (Lycoming) Muffler Removal and Installation, Revision 01, January 17, 2017. The service information describes procedures for removing and replacing the affected mufflers. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Other Related Service Information

We reviewed AWI Mandatory Service Bulletin No. 15063001, dated June 30, 2015. The service bulletin describes how to identify the installation of an affected muffler.

Costs of Compliance

We estimate that this AD affects 171 mufflers installed on airplanes of U.S. registry.

We estimate the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspection of muffler	1 work-hour × $85 per hour = $85	Not applicable	$85	$14,535
Replacement of the muffler	4 work-hours × $85 per hour = $340	$350	690	117,990

This AD affects 171 mufflers with PMA; however, only 9 mufflers remain in service.

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

Authority for This Rulemaking

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

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

This AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to small airplanes, gliders, balloons, airships, domestic business jet transport airplanes, and associated appliances to the Director of the Policy and Innovation Division.

Regulatory Findings

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

For the reasons discussed above, I certify that this AD:

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

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

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

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2018–02–04 Aerospace Welding Minneapolis, Inc.: Amendment 39–19157; Docket No. FAA–2017–0324; Product Identifier 2017–CE–004–AD.

(a) Effective Date

This AD is effective February 21, 2018.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Aerospace Welding Minneapolis, Inc. (AWI) mufflers listed in figure 1 of paragraph (c) of this AD that are installed on but not limited to the airplanes listed in figure 2 of paragraph (c) of this AD.

Note 1 to paragraph (c) of this AD: You may use AWI Mandatory Service Bulletin No. 15063001, dated June 30, 2015, to identify if an affected muffler is installed on the airplane.

FIGURE 1 OF PARAGRAPH (c) OF THIS AD—AFFECTED MUFFLERS

Muffler part No.	Muffler serial Nos.
A1754001–23	33553 through 33557; 34721 through 34728; 35322 through 35329; 35670; 38481 through 38485; 38584 through 38586; and 38723 through 38727.
A1754001–25	32795 through 32800; 33558 through 33569; 33779 through 33790; 34636 through 34653; 34968 through 34984; 35159 through 35176; 37903 through 37906; 38174 through 38193; 38502 through 38506; 38566 through 38575; and 38817 through 38836.

FIGURE 2 OF PARAGRAPH (c) OF THIS AD—AFFECTED AIRPLANES

Muffler part No.	Textron Aviation Inc. (type certificate previously held by Cessna Aircraft Company) airplanes
A1754001–23	Model 172 Serial numbers (S/Ns) 17259224 and up; Model 172R S/Ns 80001 and up; and Model 172S S/Ns 8001 and up.
A1754001–25	Model 172 S/Ns 17256513 and up; Model 172R S/Ns 80001 and up; 172S S/N 8001 and up; and Model 177 S/N 1770001 and up.

(d) Subject

Joint Aircraft System Component (JASC)/Air Transport Association (ATA) of America Code 7820, Exhaust Noise Suppressor.

(e) Unsafe Condition

This AD was prompted by occurrences of cracks or broken welds in the connecting weld of the muffler body to muffler cuff that may allow carbon monoxide (CO) exhaust fumes into the cockpit heating system. We are issuing this AD to prevent cracks in the connecting weld of the muffler body to muffler cuff that may allow CO fumes to enter the cockpit heating system and possibly inhibit the pilot's ability to maintain control of the airplane.

(f) Compliance

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

(g) Inspection of the Muffler

(1) Within 5 hours time-in-service after February 21, 2018 (the effective date of this AD), inspect the affected muffler following the instructions listed in paragraphs (g)(1)(i) through (iii).

(i) Using a vacuum cleaner with the hose attached to the blowing side of the vacuum (with the filter installed), attach the vacuum to the airplane tailpipe and seal securely.

(ii) The vacuum will pressurize the system sufficiently for a soap solution to be brushed or applied from a spray bottle to the surface of the exhaust system.

(iii) Inspect for evidence of breaches (leakage) in the system from cracks.

(2) In lieu of doing the inspection required in paragraph (g)(1) of this AD, within 5 hours after February 21, 2018 (the effective date of this AD), you may remove the affected muffler following AWI Cessna 172 (Lycoming) Muffler Removal and Installation, Revision 01, January 17, 2017, and replace the affected muffler with an FAA-approved part that is not a muffler listed in figure 1 of paragraph (c) of this AD following the manufacturer's instructions.

(3) If replacement specified in paragraph (g)(2) of this AD is done instead of the inspection required in paragraph (g)(1) of this AD, then paragraph (h)(3) of this AD is the only additional requirement of this AD.

(h) Replacement of the Muffler

(1) If evidence of breaches (leakage) is found during the inspection required in paragraph (g) of this AD, before further flight, remove the affected muffler following AWI Cessna 172 (Lycoming) Muffler Removal and Installation, Revision 01, January 17, 2017, and replace the affected muffler with an FAA-approved part that is not a muffler listed in figure 1 of paragraph (c) of this AD following the manufacturer's instructions.

(2) If no evidence of breaches (leakage) is found during the inspection required in paragraph (g) of this AD, within the next 100 hours TIS after February 21, 2018 (the effective date of this AD) or at the next annual inspection after February 21, 2018 (the effective date of this AD), whichever occurs later, remove and replace the affected muffler with an FAA-approved part that is not a muffler listed in figure 1 of paragraph (c) of this AD as described in (h)(1).

(3) After February 21, 2018 (the effective date of this AD), do not install on any airplane an affected muffler listed in figure 1 of paragraph (c) of this AD.

(i) Alternative Methods of Compliance (AMOCs)

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

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

(j) Related Information

For more information about this AD, contact Mark Grace, Aerospace Engineer, FAA, Chicago ACO Branch, 2300 East Devon Avenue, Des Plaines, IL 60018–4696; telephone: (847) 294–7377; fax: (847) 294–7834; email: *mark.grace@faa.gov.*

(k) Material Incorporated by Reference

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

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) AWI Cessna 172 (Lycoming) Muffler Removal and Installation, Revision 01, January 17, 2017.

(ii) Reserved.

(3) For service information identified in this AD, contact Aerospace Welding Minneapolis, Inc. (AWI) 1045 Gemini Road, Eagan, Minnesota 55121; telephone: 651–379–9888; fax: 651–379–9889; internet: *www.awi-ami.com.*

(4) You may view this service information at FAA, Policy and Innovation Division, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Kansas City, Missouri, on January 8, 2018.

Melvin Johnson,

Deputy Director, Policy and Innovation Division, Aircraft Certification Service.

[FR Doc. 2018–00479 Filed 1–16–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2017–0895; Product Identifier 2017–SW–048–AD; Amendment 39–19161; AD 2018–02–08]

RIN 2120–AA64

Airworthiness Directives; Bell Helicopter Textron Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: We are adopting a new airworthiness directive (AD) for Bell Helicopter Textron (Bell) Model 204B, 205A, and 205A–1 helicopters with a Helicopter Technology Company (HTC) main rotor (M/R) blade installed. This AD requires cleaning and visually inspecting the M/R blades, and depending on the outcome of the inspection, repairing or replacing the M/R blades. This AD is prompted by a report of an M/R blade with a fatigue crack in the grip plate and doublers at the blade retention bolt hole. The actions of this AD are intended to correct an unsafe condition on these products.

DATES: This AD becomes effective February 1, 2018.

We must receive comments on this AD by March 19, 2018.

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

- *Federal eRulemaking Docket:* Go to *http://www.regulations.gov.* Follow the online instructions for sending your comments electronically.
- *Fax:* 202–493–2251.
- *Mail:* Send comments to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590–0001.
- *Hand Delivery:* Deliver to the ''Mail'' address 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–2017–0895; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the economic evaluation, any comments received, and other information. The street address for Docket Operations (telephone 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

For service information identified in this final rule, contact Bell Helicopter Textron, Inc., P.O. Box 482, Fort Worth, TX 76101; telephone (817) 280–3391; fax (817) 280–6466; or at *http://www.bellcustomer.com/files/.* You may review the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy, Room 6N–321, Fort Worth, TX 76177.

FOR FURTHER INFORMATION CONTACT: Galib Abumeri, Aerospace Engineer (Structures), Airframe Section, Los Angeles ACO Branch, Compliance and Airworthiness Division, FAA, 3960 Paramount Blvd., Lakewood, California 90712; telephone 562–627–5324; email *galib.abumeri@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

This AD is a final rule that involves requirements affecting flight safety, and we did not provide you with notice and an opportunity to provide your comments prior to it becoming effective. However, we invite you to participate in this rulemaking by submitting written comments, data, or views. We also invite comments relating to the economic, environmental, energy, or federalism impacts that resulted from adopting this AD. The most helpful comments reference a specific portion of the AD, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should send only one copy of written comments, or if comments are filed electronically, commenters should submit them only one time. We will file in the docket all comments that we receive, as well as a report summarizing each substantive public contact with FAA personnel concerning this rulemaking during the comment period. We will consider all the comments we receive and may conduct additional rulemaking based on those comments.

Discussion

We are adopting a new AD for Bell 204B, 205A and 205A–1 helicopters with an HTC M/R blade part number (P/N) 204P2100–101 installed. This AD requires repetitive inspections of the exposed areas of the lower grip pad and upper and lower grip plates of each M/R blade for a crack, corrosion, an edge void, loose or damaged adhesive squeeze-out, and an edge delamination.

The actions of this AD are the same as those required by AD 2016–22–07 (81 FR 74285, October 26, 2016), which applies to Bell Model 204B, 205A and 205A–1 helicopters with an M/R blade P/N 204–011–200–001 or P/N 204–011–250-(all dash numbers) installed. AD 2016–22–07 was prompted by a report of an M/R blade with multiple fatigue cracks around the retention bolt hole.

This AD is prompted by a report that during a ground inspection, a crack was discovered in the grip plate and doublers at the blade retention bolt hole of a UH–1B helicopter model. The blade, which HTC produced for restricted category and commercial model helicopters, had 926 hours TIS and is of the same design as the M/R blades in AD 2016–22–07. We are issuing this AD to detect or prevent a crack, which could lead to failure of an M/R blade and subsequent loss of helicopter control.

FAA's Determination

We are issuing 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 these same type designs.

Related Service Information

HTC has issued Service Notice No. 204–2100–1 on July 5, 2017, for affected helicopters with M/R blade P/N 204P2100–101, serial numbers A099 through A119 installed. This service notice specifies cleaning and visually inspecting the M/R blades and depending on the outcome, repairing or replacing the blades in accordance with AD 2016–23–09.

We also reviewed Bell Helicopter Alert Service Bulletin (ASB) No. UH–1H–13–09, dated January 14, 2013, for the Model UH–1H helicopter. ASB No. UH–1H–13–09 specifies a one-time visual inspection, within 10 hours time-in-service (TIS), of the lower grip pad and upper and lower grip plates for cracks, edge voids, and loose or damaged adhesive squeeze-out. ASB No. UH–1H–13–09 also specifies a repetitive and more detailed visual inspection, daily and at every 150 hours TIS, of the lower grip pad, upper and lower grip plates, and all upper and the lower doublers for cracks, corrosion, edge voids, and loose or damaged adhesive squeeze-out.

Lastly, we reviewed Bell Helicopter ASB No. 204–75–1 for Model 204B helicopters and ASB No. 205–75–5 for Model 205A–1 helicopters, both Revision C and both dated April 25, 1979. ASB No. 204–75–1 and ASB No. 205–75–5 specify visually inspecting

the M/R blades during each daily inspection. ASB No. 204–75–1 and ASB No. 205–75–5 also provide instructions for repetitively inspecting the blades every 1,000 hours of operation or every 12 months, whichever occurs first.

AD Requirements

This AD requires within 25 hours time-in-service (TIS) or 2 weeks, whichever occurs first, and thereafter at intervals not to exceed 25 hours TIS or 2 weeks, whichever occurs first, cleaning the upper and lower exposed surfaces of each M/R blade from an area starting at the butt end of the blade to three inches outboard of the doublers. Using a 3X or higher power magnifying glass and a light, this AD also requires visually inspecting various M/R blade parts for a crack or corrosion. If there is a crack, corrosion, an edge void, loose or damaged adhesive squeeze-out, or an edge delamination, before further flight, this AD requires repairing the M/R blade or replacing it with an airworthy M/R blade, depending on whether the condition is within maximum repair damage limits.

This AD also requires reporting information about any cracks found during the inspection to the FAA within 10 days.

Differences Between This AD and the Service Information

This AD requires all inspections every 25 hours TIS or 2 weeks, whichever occurs first. ASB 204–75–1 and ASB 205–75–5 call for daily visual inspections, and inspections, rework, and refinishing every 1,000 hours TIS or 12 months, whichever occurs first. The service information applies to Bell M/R blade P/N 204–011–250. This AD applies to HTC M/R blade P/N 204P2100–101.

Interim Action

We consider this AD to be an interim action. The notification of a crack in the M/R blade that is required by this AD may enable us to obtain better insight into the cause of the M/R blade cracking. This information may help us develop additional action to address this unsafe condition. Once this action is developed, approved, and available, we might consider additional rulemaking.

Costs of Compliance

We estimate that this AD affects 10 helicopters of U.S. Registry and that labor costs average $85 per work-hour. Based on these estimates, we expect the following costs:

- Cleaning and performing all inspections of a set of M/R blades (2 per helicopter) requires 0.5 work-hour for a cost of $43 per helicopter and $430 for the U.S. fleet per inspection cycle.
- Replacing an M/R blade requires 12 work-hours and parts cost $86,000 for a total cost of $87,020 per blade.
- Reporting the inspection results required by this AD will require about 0.5 work-hour for a cost of $43 per helicopter and $430 for the U.S. fleet per report.

Paperwork Reduction Act

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB control number. The control number for the collection of information required by this AD is 2120–0056. The paperwork cost associated with this AD has been detailed in the Costs of Compliance section of this document and includes time for reviewing instructions, as well as completing and reviewing the collection of information. Therefore, all reporting required by this AD is mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at 800 Independence Ave. SW, Washington, DC 20591. ATTN: Information Collection Clearance Officer, AES–200.

FAA's Justification and Determination of the Effective Date

Providing an opportunity for public comments prior to adopting these AD requirements would delay implementing the safety actions needed to correct this known unsafe condition. Therefore, we find that the risk to the flying public justifies waiving notice and comment prior to the adoption of this rule because the required corrective actions must be accomplished within two weeks.

Since an unsafe condition exists that requires the immediate adoption of this AD, we determined that notice and opportunity for prior public comment before issuing this AD are impracticable and that good cause exists to make this AD effective in less than 30 days.

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed, I certify that this AD:

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

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2018–02–08 Bell Helicopter Textron: Amendment 39–19161; Docket No.

FAA–2017–0895; Product Identifier 2017–SW–048–AD.

(a) Applicability

This AD applies to Bell Helicopter Textron (Bell) Model 204B, 205A, and 205A–1 helicopters with a Helicopter Technology Company (HTC) main rotor (M/R) blade part number 204P2100–101 installed, certificated in any category.

(b) Unsafe Condition

This AD defines the unsafe condition as a crack in an M/R blade, which could result in failure of an M/R blade and subsequent loss of helicopter control.

(c) Effective Date

This AD becomes effective February 1, 2018.

(d) Compliance

You are responsible for performing each action required by this AD within the specified compliance time unless it has already been accomplished prior to that time.

(e) Required Actions

(1) Within 25 hours time-in-service (TIS) or 2 weeks, whichever occurs first, and thereafter at intervals not to exceed 25 hours TIS or 2 weeks, whichever occurs first, clean the upper and lower exposed surfaces of each M/R blade from an area starting at the butt end of the blade to three inches outboard of the doublers. Using a 3X or higher power magnifying glass and a light, inspect as follows:

(i) Visually inspect the exposed areas of the lower grip pad and upper and lower grip plates of each M/R blade for a crack and any corrosion.

(ii) On the upper and lower exposed surfaces of each M/R blade from blade stations 24.5 to 35 for the chord width, visually inspect each layered doubler and blade skin for a crack and any corrosion. Pay particular attention for any cracking in a doubler or skin near or at the same blade station as the blade retention bolt hole (blade station 28).

(iii) Visually inspect the exposed areas of each bond line at the edges of the lower grip pad, upper and lower grip plates, and each layered doubler (bond lines) on the upper and lower surfaces of each M/R blade for the entire length and chord width for an edge void, any corrosion, loose or damaged adhesive squeeze-out, and an edge delamination. Pay particular attention to any crack in the paint finish that follows the outline of a grip pad, grip plate, or doubler, and to any loose or damaged adhesive squeeze-out, as these may be the indication of an edge void.

(2) If there is a crack, any corrosion, an edge void, loose or damaged adhesive squeeze-out, or an edge delamination during any inspection in paragraph (e)(1) of this AD, before further flight, do the following:

(i) If there is a crack in a grip pad or any grip plate or doubler, replace the M/R blade with an airworthy M/R blade.

(ii) If there is a crack in the M/R blade skin that is within maximum repair damage limits, repair the M/R blade. If the crack exceeds maximum repair damage limits, replace the M/R blade with an airworthy M/R blade.

(iii) If there is any corrosion within maximum repair damage limits, repair the M/R blade. If the corrosion exceeds maximum repair damage limits, replace the M/R blade with an airworthy M/R blade.

(iv) If there is an edge void in the grip pad or in a grip plate or doubler, determine the length and depth using a feeler gauge. Repair the M/R blade if the edge void is within maximum repair damage limits or replace the M/R blade with an airworthy M/R blade.

(v) If there is an edge void in a grip plate or doubler near the outboard tip, tap inspect the affected area to determine the size and shape of the void. Repair the M/R blade if the edge void is within maximum repair damage limits or replace the M/R blade with an airworthy M/R blade.

(vi) If there is any loose or damaged adhesive squeeze-out along any of the bond lines, trim or scrape away the adhesive without damaging the adjacent surfaces or parent material of the M/R blade. Determine if there is an edge void or any corrosion by lightly sanding the trimmed area smooth using 280 or finer grit paper. If there is no edge void or corrosion, refinish the sanded area.

(vii) If there is an edge delamination along any of the bond lines or a crack in the paint finish, determine if there is an edge void or a crack in the grip pad, grip plate, doubler, or skin by removing paint from the affected area by lightly sanding in a span-wise direction using 180–220 grit paper. If there are no edge voids and no cracks, refinish the sanded area.

(viii) If any parent material is removed during any sanding or trimming in paragraphs (e)(2)(vi) or (e)(2)(vii) of this AD, repair the M/R blade if the damage is within maximum repair damage limits or replace the M/R blade with an airworthy M/R blade.

(3) If there is a crack during any inspection in paragraph (e)(1) of this AD, within 10 days after completing the inspection, report the information requested in Appendix 1 to this AD by mail to the Los Angeles ACO Branch, Compliance and Airworthiness Division, FAA, 3960 Paramount Blvd., Lakewood, California 90712; attn. Galib Abumeri; or by email to *galib.abumeri@faa.gov.*

(f) Special Flight Permits

Special flight permits are prohibited.

(g) Paperwork Reduction Act Burden Statement

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2120–0056. Public reporting for this collection of information is estimated to be approximately 30 minutes per response, including the time for reviewing instructions, completing and reviewing the collection of information. All responses to this collection of information are mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at: 800 Independence Ave. SW, Washington, DC 20591, Attn: Information Collection Clearance Officer, AES–200.

(h) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Los Angeles ACO Branch, FAA, may approve AMOCs for this AD. Send your proposal to: Galib Abumeri, Aerospace Engineer (Structures), Airframe Section, Los Angeles ACO Branch, Compliance and Airworthiness Division, FAA, 3960 Paramount Blvd., Lakewood, California 90712; telephone 562–627–5324; email *galib.abumeri@faa.gov.*

(2) For operations conducted under a 14 CFR part 119 operating certificate or under 14 CFR part 91, subpart K, we suggest that you notify your principal inspector, or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office before operating any aircraft complying with this AD through an AMOC.

(i) Additional Information

HTC Service Notice No. 204–2100–1, dated July 5, 2017; Alert Service Bulletin (ASB) No. UH–1H–13–09, dated January 14, 2013; Bell ASB No. 204–75–1 and Bell ASB No. 205–75–5, both Revision C and both dated April 25, 1979, which are not incorporated by reference, contain additional information about the subject of this AD. For service information identified in this AD, contact Bell Helicopter Textron, Inc., P.O. Box 482, Fort Worth, TX 76101; telephone (817) 280–3391; fax (817) 280–6466; or at *http://www.bellcustomer.com/files/.* You may review this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177.

(j) Subject

Joint Aircraft Service Component (JASC) Code: 6210, Main Rotor Blades.

Issued in Fort Worth, Texas, on January 9, 2018.

James A. Grigg,

Acting Director, Compliance & Airworthiness Division, Aircraft Certification Service.

Appendix 1 to AD 2018–02–08

Please report the following information by mail to the Los Angeles ACO Branch, Compliance and Airworthiness Division, FAA, 3960 Paramount Blvd., Lakewood, California 90712; attn. Galib Abumeri; or by email to *galib.abumeri@faa.gov.*

(1) Date of inspection:

(2) Aircraft N-number:

(3) M/R blade serial number:

(4) M/R blade hours of time-in-service:

(5) Location of each crack:

(6) Dimension of each crack:

(7) Primary operating location of the M/R blade:

[FR Doc. 2018–00660 Filed 1–16–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2017–0894; Product Identifier 2017–SW–044–AD; Amendment 39–19160; AD 2018–02–07]

RIN 2120–AA64

Airworthiness Directives; Various Restricted Category Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: We are adopting a new airworthiness directive (AD) for Model TH–1F, UH–1B, UH–1F, UH–1H, and UH–1P helicopters with a Helicopter Technology Company (HTC) main rotor (M/R) blade installed. This AD requires cleaning and visually inspecting the M/R blades and, depending on the outcome of the inspection, repairing or replacing the M/R blades. This AD is prompted by a report of an M/R blade with a fatigue crack in the grip plate and doublers at the blade retention bolt hole. The actions of this AD are intended to correct an unsafe condition on these products.

DATES: This AD becomes effective February 1, 2018.

We must receive comments on this AD by March 19, 2018.

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

- *Federal eRulemaking Docket:* Go to *http://www.regulations.gov.* Follow the online instructions for sending your comments electronically.
- *Fax:* 202–493–2251.
- *Mail:* Send comments to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590–0001.
- *Hand Delivery:* Deliver to the ''Mail'' address 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–2017–0894; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the economic evaluation, any comments received, and other information. The street address for Docket Operations (telephone 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

For service information identified in this final rule, contact Bell Helicopter Textron, Inc., P.O. Box 482, Fort Worth, TX 76101; telephone (817) 280–3391; fax (817) 280–6466; or at *http://www.bellcustomer.com/files/.* You may review the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177.

FOR FURTHER INFORMATION CONTACT: Galib Abumeri, Aerospace Engineer (Structures), Los Angeles ACO Branch, Compliance and Airworthiness Division, FAA, 3960 Paramount Blvd., Lakewood, California 90712; telephone 562–627–5324; email *galib.abumeri@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

This AD is a final rule that involves requirements affecting flight safety, and we did not provide you with notice and an opportunity to provide your comments prior to it becoming effective. However, we invite you to participate in this rulemaking by submitting written comments, data, or views. We also invite comments relating to the economic, environmental, energy, or federalism impacts that resulted from adopting this AD. The most helpful comments reference a specific portion of the AD, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should send only one copy of written comments, or if comments are filed electronically, commenters should submit them only one time. We will file in the docket all comments that we receive, as well as a report summarizing each substantive public contact with FAA personnel concerning this rulemaking during the comment period. We will consider all the comments we receive and may conduct additional rulemaking based on those comments.

Discussion

We are adopting a new AD for restricted category Model TH–1F, UH–1B, UH–1F, UH–1H, and UH–1P helicopters with an HTC M/R blade part number (P/N) 204P2100–101 installed. This AD requires repetitive inspections of the exposed areas of the lower grip pad and upper and lower grip plates of each M/R blade for a crack, corrosion, an edge void, loose or damaged adhesive squeeze-out, and an edge delamination. The type certificate holders for these model helicopters are: Arrow Falcon Exporters Inc.; AST, Inc.; California Department of Forestry; Global Helicopter Technology, Inc.; Hagglund Helicopters, LLC; International Helicopters, Inc.; JJASPP Engineering Services, LLC; Northwest Rotorcraft, LLC; OAS Parts LLC; Red Tail Flying Services, LLC; Richards Heavylift Helo, Inc.; Robinson Air Crane, Inc.; Rotorcraft Development Corporation; San Joaquin Helicopters; Southwest Florida Aviation International, Inc.; and Tamarack Helicopters, Inc.

The actions of this AD are the same as those required by AD 2016–23–09 (81 FR 83660, November 22, 2016), which applies to various restricted category helicopters with an M/R blade P/N 204–011–250–005 or P/N 204–011–250–113 installed. AD 2016–23–09 was prompted by a report of an M/R blade with multiple fatigue cracks around the retention bolt hole.

This AD is prompted by a report that during a ground inspection, a crack was discovered in the grip plate and doublers at the blade retention bolt hole of a UH–1B helicopter model. The blade, which HTC produced for restricted category and commercial model helicopters, had 926 hours TIS and is of the same design as the M/R blades in AD 2016–23–09. We are issuing this AD to detect or prevent a crack, which could lead to failure of an M/R blade and subsequent loss of helicopter control.

FAA's Determination

We are issuing 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 these same type designs.

Related Service Information

We reviewed Bell Helicopter Alert Service Bulletin (ASB) No. UH–1H–13–09, dated January 14, 2013, for the Model UH–1H helicopter. ASB No. UH–1H–13–09 specifies a one-time visual inspection, within 10 hours time-in-service (TIS), of the lower grip pad and upper and lower grip plates for cracks, edge voids, and loose or damaged adhesive squeeze-out. ASB No. UH–1H–13–09 also specifies a repetitive and more detailed visual inspection, daily and at every 150 hours TIS, of the lower grip pad, upper and lower grip plates, and all upper and the lower doublers for cracks, corrosion, edge voids, and loose or damaged adhesive squeeze-out.

We also reviewed HTC Service Notice No. 204–2100–1, dated July 5, 2017, for

affected helicopters with M/R blade P/N 204P2100–101, serial numbers A099 through A119 installed. This service notice specifies cleaning and visually inspecting the M/R blades and depending on the outcome, repairing or replacing the blades, in accordance with AD 2016–23–09.

AD Requirements

This AD requires within 25 hours time-in-service (TIS) or 2 weeks, whichever occurs first, and thereafter at intervals not to exceed 25 hours TIS or 2 weeks, whichever occurs first, cleaning the upper and lower exposed surfaces of each M/R blade from an area starting at the butt end of the blade to three inches outboard of the doublers. Using a 3X or higher power magnifying glass and a light, this AD also requires inspecting the M/R blade parts for a crack or corrosion. If there is a crack, corrosion, an edge void, loose or damaged adhesive squeeze-out, or an edge delamination, before further flight, this AD requires repairing the M/R blade or replacing it with an airworthy M/R blade, depending on whether the condition is within maximum repair damage limits.

This AD also requires reporting information about any cracks found during the inspection to the FAA within 10 days.

Differences Between This AD and the Service Information

ASB No. UH–1H–13–09 specifies a one-time inspection and then a second repetitive inspection daily and at every 150 hours TIS. This AD requires all inspections at intervals not to exceed 25 hours TIS or two weeks, whichever occurs first. This AD contains more detailed inspection requirements and a more specific inspection area than the instructions in ASB No. UH–1H–13–09. Lastly, ASB No. UH–1H–13–09 applies to Model UH–1H helicopters with M/R blade P/N 204–011–250–113, while this AD applies to Model UH–1H, TH–1F, UH–1B, UH–1F, and UH–1P helicopters with HTC M/R blade part number (P/N) 204P2100–101.

Interim Action

We consider this AD to be an interim action. The notification of a crack in the M/R blade that is required by this AD may enable us to obtain better insight into the cause of the M/R blade cracking. This information may help us develop additional action to address this unsafe condition. Once this action is developed, approved, and available, we might consider additional rulemaking.

Costs of Compliance

We estimate that this AD affects 10 helicopters of U.S. Registry and that labor costs average $85 per work-hour. Based on these estimates, we expect the following costs:

- Cleaning and performing all inspections of a set of M/R blades (2 per helicopter) requires 0.5 work-hour for a cost of $43 per helicopter and $430 for the U.S. fleet per inspection cycle.
- Replacing an M/R blade requires 12 work-hours and parts cost $86,000 for a total cost of $87,020 per blade.
- Reporting the inspection results required by this AD will require about 0.5 work-hour for a cost of $43 per helicopter and $430 for the U.S. fleet.

Paperwork Reduction Act

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB control number. The control number for the collection of information required by this AD is 2120–0056. The paperwork cost associated with this AD has been detailed in the Costs of Compliance section of this document and includes time for reviewing instructions, as well as completing and reviewing the collection of information. Therefore, all reporting required by this AD is mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at 800 Independence Ave. SW, Washington, DC 20591. ATTN: Information Collection Clearance Officer, AES–200.

FAA's Justification and Determination of the Effective Date

Providing an opportunity for public comments prior to adopting these AD requirements would delay implementing the safety actions needed to correct this known unsafe condition. Therefore, we find that the risk to the flying public justifies waiving notice and comment prior to the adoption of this rule because the required corrective actions must be accomplished within two weeks.

Since an unsafe condition exists that requires the immediate adoption of this AD, we determined that notice and opportunity for prior public comment before issuing this AD are impracticable and that good cause exists to make this AD effective in less than 30 days.

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed, I certify that this AD:

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

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2018–02–07 Various Restricted Category Helicopters: Amendment 39–19160; Docket No. FAA–2017–0894; Product Identifier 2017–SW–044–AD.

(a) Applicability

This AD applies to the following helicopters, certificated in the restricted category, with a Helicopter Technology Company (HTC) main rotor (M/R) blade part number 204P2100–101 installed:

(1) Arrow Falcon Exporters Inc.; Global Helicopter Technology, Inc.; Hagglund Helicopters, LLC; JJASPP Engineering Services, LLC; Northwest Rotorcraft, LLC; OAS Parts, LLC; Richards Heavylift Helo, Inc.; Rotorcraft Development Corporation; Southwest Florida Aviation International, Inc.; and Tamarack Helicopters, Inc., Model UH–1H helicopters;

(2) International Helicopters, Inc.; OAS Parts, LLC; Red Tail Flying Services, LLC; Richards Heavylift Helo, Inc.; Rotorcraft Development Corporation; San Joaquin Helicopters; and Southwest Florida Aviation International, Inc., Model UH–1B helicopters;

(3) Robinson Air Crane, Inc.; Rotorcraft Development Corporation; and Tamarack Helicopters, Inc., Model TH–1F helicopters;

(4) AST, Inc.; California Department of Forestry, Robinson Air Crane, Inc.; Rotorcraft Development Corporation; and Tamarack Helicopters, Inc., Model UH–1F helicopters; and

(5) Robinson Air Crane, Inc., and Rotorcraft Development Corporation, Model UH–1P helicopters.

(b) Unsafe Condition

This AD defines the unsafe condition as a crack in an M/R blade, which could result in failure of the M/R blade and subsequent loss of helicopter control.

(c) Effective Date

This AD becomes effective February 1, 2018.

(d) Compliance

You are responsible for performing each action required by this AD within the specified compliance time unless it has already been accomplished prior to that time.

(e) Required Actions

(1) Within 25 hours time-in-service (TIS) or 2 weeks, whichever occurs first, and thereafter at intervals not to exceed 25 hours TIS or 2 weeks, whichever occurs first, clean the upper and lower exposed surfaces of each M/R blade from an area starting at the butt end of the blade to three inches outboard of the doublers. Using a 3X or higher power magnifying glass and a light, inspect as follows:

(i) Visually inspect the exposed areas of the lower grip pad and upper and lower grip plates of each M/R blade for a crack and any corrosion.

(ii) On the upper and lower exposed surfaces of each M/R blade from blade stations 24.5 to 35 for the chord width, visually inspect each layered doubler and blade skin for a crack and any corrosion. Pay particular attention for any cracking in a doubler or skin near or at the same blade station as the blade retention bolt hole (blade station 28).

(iii) Visually inspect the exposed areas of each bond line at the edges of the lower grip pad, upper and lower grip plates, and each layered doubler (bond lines) on the upper and lower surfaces of each M/R blade for the entire length and chord width for an edge void, any corrosion, loose or damaged adhesive squeeze-out, and an edge delamination. Pay particular attention to any crack in the paint finish that follows the outline of a grip pad, grip plate, or doubler, and to any loose or damaged adhesive squeeze-out, as these may be the indication of an edge void.

(2) If there is a crack, any corrosion, an edge void, loose or damaged adhesive squeeze-out, or an edge delamination during any inspection in paragraph (e)(1) of this AD, before further flight, do the following:

(i) If there is a crack in a grip pad or any grip plate or doubler, replace the M/R blade with an airworthy M/R blade.

(ii) If there is a crack in the M/R blade skin that is within maximum repair damage limits, repair the M/R blade. If the crack exceeds maximum repair damage limits, replace the M/R blade with an airworthy M/R blade.

(iii) If there is any corrosion within maximum repair damage limits, repair the M/R blade. If the corrosion exceeds maximum repair damage limits, replace the M/R blade with an airworthy M/R blade.

(iv) If there is an edge void in the grip pad or in a grip plate or doubler, determine the length and depth using a feeler gauge. Repair the M/R blade if the edge void is within maximum repair damage limits or replace the M/R blade with an airworthy M/R blade.

(v) If there is an edge void in a grip plate or doubler near the outboard tip, tap inspect the affected area to determine the size and shape of the void. Repair the M/R blade if the edge void is within maximum repair damage limits or replace the M/R blade with an airworthy M/R blade.

(vi) If there is any loose or damaged adhesive squeeze-out along any of the bond lines, trim or scrape away the adhesive without damaging the adjacent surfaces or parent material of the M/R blade. Determine if there is an edge void or any corrosion by lightly sanding the trimmed area smooth using 280 or finer grit paper. If there is no edge void or corrosion, refinish the sanded area.

(vii) If there is an edge delamination along any of the bond lines or a crack in the paint finish, determine if there is an edge void or a crack in the grip pad, grip plate, doubler, or skin by removing paint from the affected area by lightly sanding in a span-wise direction using 180–220 grit paper. If there are no edge voids and no cracks, refinish the sanded area.

(viii) If any parent material is removed during any sanding or trimming in paragraphs (e)(2)(vi) or (e)(2)(vii) of this AD, repair the M/R blade if the damage is within maximum repair damage limits or replace the M/R blade with an airworthy M/R blade.

(3) If there is a crack during any inspection in paragraph (e)(1) of this AD, within 10 days after completing the inspection, report the information requested in Appendix 1 to this AD by mail to the Los Angeles ACO Branch, Compliance and Airworthiness Division, FAA, 3960 Paramount Blvd., Lakewood, California 90712; attn. Galib Abumeri; or by email to *galib.abumeri@faa.gov.*

(f) Special Flight Permits

Special flight permits are prohibited.

(g) Paperwork Reduction Act Burden Statement

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2120–0056. Public reporting for this collection of information is estimated to be approximately 30 minutes per response, including the time for reviewing instructions, completing and reviewing the collection of information. All responses to this collection of information are mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at: 800 Independence Ave. SW, Washington, DC 20591, Attn: Information Collection Clearance Officer, AES–200.

(h) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Los Angeles ACO Branch, FAA, may approve AMOCs for this AD. Send your proposal to: Galib Abumeri, Aerospace Engineer (Structures), Airframe Section, Los Angeles ACO Branch, Compliance and Airworthiness Division, FAA, 3960 Paramount Blvd., Lakewood, California 90712; telephone 562–627–5324; email *galib.abumeri@faa.gov.*

(2) For operations conducted under a 14 CFR part 119 operating certificate or under 14 CFR part 91, subpart K, we suggest that you notify your principal inspector, or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office before operating any aircraft complying with this AD through an AMOC.

(i) Additional Information

HTC Service Notice No. 204–2100–1, dated July 5, 2017, and Bell Alert Service Bulletin No. UH–1H–13–09, dated January 14, 2013, which are not incorporated by reference, contain additional information about the subject of this AD. For service information identified in this AD, contact Bell Helicopter Textron, Inc., P.O. Box 482, Fort Worth, TX 76101; telephone (817) 280–3391; fax (817) 280–6466; or at *http://www.bellcustomer.com/files/.* You may review this service information at the FAA, Office of the Regional Counsel, Southwest

Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177.

(j) Subject

Joint Aircraft Service Component (JASC) Code: 6210, Main Rotor Blades.

Issued in Fort Worth, Texas, on January 9, 2018.

James A. Grigg,

Acting Director, Compliance & Airworthiness Division, Aircraft Certification Service.

Appendix 1 to AD 2018–02–07

Please report the following by mail to the Los Angeles ACO Branch, Compliance and Airworthiness Division, FAA, 3960 Paramount Blvd., Lakewood, California 90712; attn. Galib Abumeri; or by email to *galib.abumeri@faa.gov.*

(1) Date of inspection:
(2) Aircraft N-number:
(3) M/R blade serial number:
(4) M/R blade hours of time-in-service:
(5) Location of each crack:
(6) Dimension of each crack:
(7) Primary operating location of the M/R blade:

[FR Doc. 2018–00658 Filed 1–16–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2017–1249; Product Identifier 2013–NM–104–AD; Amendment 39–19156; AD 2018–02–03]

RIN 2120–AA64

Airworthiness Directives; Fokker Services B.V. Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: We are adopting a new airworthiness directive (AD) for all Fokker Services B.V. Model F28 Mark 0070 and Mark 0100 series airplanes. This AD requires contacting the FAA to obtain instructions for addressing the unsafe condition on these products, and doing the actions specified in those instructions. This AD was prompted by an erroneous radio altimeter reading, which caused certain systems to respond in a way that led to loss of speed. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD becomes effective February 15, 2018.

We must receive comments on this AD by March 5, 2018.

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:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

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–2017–1249; or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Tom Rodriguez, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 1601 Lind Avenue SW, Renton, WA 98057–3356; telephone: 425–227–1137; fax: 425–227–1149.

SUPPLEMENTARY INFORMATION:

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2013–0112, dated May 28, 2013 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for all Fokker Services B.V. Model F28 Mark 0070 and Mark 0100 series airplanes. The MCAI states:

> Following an accident * * * [of an] aeroplane on final approach, the investigating body determined that an important contributing factor to the accident was an erroneous reading of -7 to -8 feet from the left Radio Altimeter (RA). The responses of the autothrottle and autopilot systems to this erroneous RA system reading led to speed loss and, in combination with operational factors, caused the aeroplane to hit the ground before reaching the runway.
>
> Fokker Services conducted an evaluation of the effects of un-flagged erroneous low RA system indications in response to the recommendations in the investigator's report. The result of the evaluation was a new ''ERRONEOUS RADIO ALTIMETER INDICATION'' abnormal procedure in the Airplane Flight Manual (AFM). This new procedure includes pulling the circuit breaker of a failed RA system, and in support of this, new yellow identification collars to the RA circuit breakers are to be introduced to improve instantaneous recognition, both visual and tactile, in low illumination and under increased workload conditions.
>
> In order to prevent an unsafe condition, similar to the one that contributed to the accident described above, this [EASA] AD requires incorporation of the new abnormal procedure in the AFM and installation of the new yellow RA circuit breaker identification collars.

You may examine the MCAI on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–1249.

FAA's Determination and Requirements of This AD

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

FAA's Determination of the Effective Date

Since there are currently no domestic operators of this product, we find good cause that notice and opportunity for prior public comment are unnecessary. In addition, for the reason(s) stated above, we find that good cause exists for making this amendment effective in less than 30 days.

Comments Invited

This AD is a final rule that involves requirements affecting flight safety, and we did not precede it by notice and opportunity for public comment. We invite you to send any written relevant data, views, or arguments about this AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2017–1249; Product Identifier 2013–NM–104–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this AD. We will consider all comments received by the closing date and may amend this AD based on those comments.

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

Costs of Compliance

Currently, there are no affected U.S.-registered airplanes. This AD requires contacting the FAA to obtain instructions for addressing the unsafe condition, and doing the actions specified in those instructions. Based on the actions specified in the MCAI AD, we are providing the following cost estimates for an affected airplane that is placed on the U.S. Register in the future:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product
Modification	1 work-hour × $85 per hour = $85	$9	$94

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.

This AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to transport category airplanes to the Director of the System Oversight Division.

Regulatory Findings

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

For the reasons discussed above, I certify that this AD:

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

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

3. Will not affect intrastate aviation in Alaska; and

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2018–02–03 Fokker Services B.V.: Amendment 39–19156; Docket No. FAA–2017–1249; Product Identifier 2013–NM–104–AD.

(a) Effective Date

This AD becomes effective February 1, 2018.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Fokker Services B.V. Model F28 Mark 0070 and Mark 0100 series airplanes, certificated in any category, all serial numbers.

(d) Subject

Air Transport Association (ATA) of America Code 34, Navigation.

(e) Reason

This AD was prompted by an erroneous radio altimeter (RA) reading, which caused certain systems to respond in a way that led to loss of speed. We are issuing this AD to ensure the flight crew has procedures for detecting erroneous RA readings. Erroneous RA readings could cause the autothrottle and autopilot systems to respond by causing a loss of speed, which, in combination with operational factors, could cause an airplane to hit the ground before reaching the runway.

(f) Compliance

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

(g) Required Action(s)

Within 30 days after the effective date of this AD, request instructions from the Manager, International Section, Transport Standards Branch, FAA, to address the unsafe condition specified in paragraph (e) of this AD; and accomplish the action(s) at the times specified in, and in accordance with, those instructions. Guidance can be found in Mandatory Continuing Airworthiness Information (MCAI) European Aviation Safety Agency (EASA) AD 2013–0112, dated May 28, 2013.

(h) Alternative Methods of Compliance (AMOCs)

The Manager, International Section, Transport Standards Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Section, send it to the attention of the person identified in paragraph (i)(2) of this AD. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(i) Related Information

(1) Refer to MCAI EASA AD 2013–0112, dated May 28, 2013, for related information. You may examine the MCAI on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–1249.

(2) For more information about this AD, contact Tom Rodriguez, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 1601 Lind Avenue SW, Renton, WA 98057–3356; telephone: 425–227–1137; fax: 425–227–1149.

(j) Material Incorporated by Reference

None.

Issued in Renton, Washington, on January 5, 2018.

Michael Kaszycki,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2018–00656 Filed 1–16–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2017–0141; Product Identifier 2016–SW–067–AD; Amendment 39–19154; AD 2018–02–01]

RIN 2120–AA64

Airworthiness Directives; The Enstrom Helicopter Corporation Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are superseding Airworthiness Directive (AD) 2015–08–51 for the Enstrom Helicopter Corporation (Enstrom) Model F–28A, 280, F–28C, F–28C–2, F–28C–2R, 280C, F–28F, F–28F–R, 280F, 280FX, and 480 helicopters. AD 2015–08–51 required an inspection of the main rotor spindle (spindle) and reporting the inspection results to the FAA. This new AD was prompted by additional reports of cracked spindles and requires establishing a life limit and a recurring inspection. The actions of this AD are intended to prevent the unsafe condition on these products.

DATES: This AD is effective February 21, 2018.

ADDRESSES: For service information identified in this final rule, contact Enstrom Helicopter Corporation, 2209 22nd Street, Menominee, MI; telephone (906) 863–1200; fax (906) 863–6821; or at *www.enstromhelicopter.com.* You may view this referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177.

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov in* Docket No. FAA–2017–0141; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the economic evaluation, any comments received, and other information. The address for the Docket Office (phone: 800–647–5527) is Document Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Manzoor Javed, Senior Aerospace Engineer, Chicago ACO Branch, Compliance and Airworthiness Division, FAA, 2300 East Devon Ave., Des Plaines, IL 60018; telephone (847) 294–8112; email *manzoor.javed@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to remove AD 2015–08–51, Amendment 39–18160 (80 FR 28172, May 18, 2015) (AD 2015–08–51) and add a new AD. AD 2015–08–51 applied to Enstrom Model F–28A, 280, F–28C, F–28C–2, F–28C–2R, 280C, F–28F, F–28F–R, 280F, 280FX, and 480 helicopters with a spindle part number (P/N) 28–14282–11 or 28–14282–13 installed. AD 2015–08–51 required conducting a one-time magnetic particle inspection (MPI) of the spindle for cracks and reporting the inspection results to the FAA. AD 2015–08–51 was prompted by a fatal accident and reports of spindles with cracks. AD 2015–08–51 was issued as an interim action and was intended to detect a crack in a spindle and prevent loss of a main rotor blade and subsequent loss of control of the helicopter.

The NPRM published in the **Federal Register** on March 2, 2017 (82 FR 12308). The NPRM was prompted by additional reports of cracked spindles. Based on review of in-service data and a fatigue analysis, the FAA determined a life limit and recurring MPIs are necessary to reduce the risk of a crack developing in a spindle. We also determined the reporting requirement in AD 2015–08–51 is no longer necessary. Accordingly, the NPRM proposed to require an MPI of the spindle every 500 hours time-in-service (TIS) until the spindle reaches its new life limit of 1,500 hours TIS.

Since the NPRM was issued, the FAA's Aircraft Certification Service has changed its organizational structure. The new structure replaces product directorates with functional divisions. We have revised some of the office titles and nomenclature throughout this Final rule to reflect the new organizational changes. Additional information about the new structure can be found in the Notice published on July 25, 2017 (82 FR 34564).

Comments

After our NPRM was published, we received comments from 50 commenters.

A. Support for the NPRM

One commenter supported the 500-hour repetitive inspection proposed by the NPRM.

B. Comments Regarding the FAA's Justification of the Unsafe Condition

Many commenters, including Enstrom, disagreed with the FAA's determination that an unsafe condition exists and requested the FAA provide more information about the additional cracks that prompted this AD.

Request: A few commenters noted the entire fleet has been inspected in accordance with AD 2015–08–51 and no additional cracks were found. Other commenters stated no additional cracks have been found in the area of a spindle where a failure could cause a catastrophic accident. A few commenters, including Enstrom, stated no additional cracking has been reported in the same location as that of the accident spindle.

Other commenters requested the FAA provide information about the number of additional reported cracks and whether there is any correlation between cracks and manufacturing dates or suppliers. Enstrom stated the cracked spindles discovered after the accident were manufactured between 1975 to 1980 by two specific suppliers.

FAA Response: We agree to provide information about the cracks that prompted this AD. Contrary to the public comments stating there were no additional cracks found by the inspections required by AD 2015–08–51, those inspection results revealed 34 cracked spindle assemblies. The commenters are correct that the additional cracking was not in the same location as that of the accident spindle. The location of the additional 34 spindle cracks was at the hole for the cotter pin securing the lamiflex bearing nut. However, we disagree that the additional cracks were not in an area where a failure could cause a catastrophic accident. A spindle assembly is a primary structural element and a critical part. Flight with any known crack is prohibited in primary

structural elements including spindle assemblies. Regardless of the location of the crack, failure of a spindle assembly could result in loss of a main rotor blade.

We agree with Enstrom's comment that the cracked spindles discovered after the accident were manufactured between 1975 to 1980 by two specific suppliers. However, the accident helicopter had two cracked and one failed spindle that were manufactured in 1984 by a third manufacturer. The identities of the manufacturers are unknown. The parts were marked differently with a letter designation at the end depending on the manufacturer, but no manufacturing records exist to indicate which letter corresponds to which manufacturer. Therefore, no investigation could be conducted as to what manufacturing processes or specifications used by these suppliers may have resulted in the cracking. Accordingly, we cannot draw a conclusion as to whether the manufacturer and date range are causal factors in the accident.

Request: One commenter questioned whether the FAA investigated the possibility that the cracked spindle resulted from improper maintenance action or procedures.

FAA's Response: As part of the accident investigation, the NTSB lab inspected the three spindles from the accident aircraft for any tool marks that might indicate an initiation point that was maintenance related. They were unable to find such marks. Based on the number of cracks found in the field and the fact that they were not all maintained by the same organization, there is no data to suggest that this resulted from improper maintenance.

C. Comments Regarding the Required Actions

Request: Thirty-eight commenters, including Enstrom, requested the AD not require the 1,500-hour life limit because it would be burdensome and unnecessary. Most of these commenters also stated that the repetitive inspections specified by Enstrom would be effective in identifying cracks and removing any cracked spindles from service. Four commenters requested the life limit be higher than 1,500 hours, and proposed alternative life limits of 4,000 hours, 6,750 hours, between 8,000 and 9,000 hours, and 15,000 hours.

FAA Response: We disagree. The corrective action outlined in the Enstrom service information did not reduce the risk to an acceptable level. Consequently, we used the crack data to conduct a risk assessment in accordance with the FAA's Rotorcraft Risk Analysis Handbook, Revision 3, dated September 10, 2014. The accident investigation and inspection results from AD 2015–08–51 show cracked spindles from 1,800 hours up to 9,300 hours (on the accident helicopter). A Weibull analysis identified a life limit of approximately 800 hours. But the goodness of fit was not high as the times on these parts historically have not been tracked, so we assumed the part time to be the time on the airframe, which may not be accurate. We therefore applied an additional method to determine an appropriate life limit. We used inspection results as baseline data to conduct a fatigue analysis using standard fatigue methodology and scatter factors found in Advisory Circular (AC) 23–13A, ''Fatigue, Fail-Safe, and Damage Tolerance Evaluation of Metallic Structure For Normal, Utility, Acrobatic, and Commuter Category Airplanes.'' While this AC was written for small aircraft, its approach for establishing a life limit is conventional and was the most computationally valid method considered. This analysis resulted in a life limit of 1,500 hours. We also reviewed the potential for higher life limits, but these resulted in unacceptably short inspection intervals. For example, a retirement age of 10,000 hours with an initial inspection at 1,500 hours would require repetitive inspections every 75 hours to maintain an acceptable level of risk. We rejected these short inspection frequencies because of the potential for increased maintenance errors. Additionally, we considered the life limit of 1,500 hours is similar to those for spindles used in other rotorcraft.

Request: Twenty-three commenters, including Enstrom, disagreed with the compliance time for the 500-hour initial inspection. To support this disagreement, most of these commenters stated no cracks have been reported on spindles with less than 1,800 hours TIS. The commenters requested that the AD require the initial inspection within 1,500 hours as specified in Enstrom's service information.

FAA Response: We disagree. While the commenters are correct that no cracks have been reported on spindles with less than 1,800 hours TIS, this factor is less significant than those discussed above. Standard practice in addressing fatigue and life limits require inspection intervals that provide two inspection opportunities to detect a crack before a life limit is reached. Because the FAA determined a life limit of 1,500 hours TIS is required for the spindles, it follows that at a minimum initial and repetitive inspections every 500 hours TIS are necessary.

Request: One commenter requested the AD require the spindle life limit of 7,500 cycles instead of 1,500 flight hours.

FAA Response: We disagree. All data considered and analysis conducted for this AD has been determined using flight hours. The commenter states he used figure AC 27 MG 11–9 from AC 27–1B, ''Certification of Normal Category Rotorcraft,'' for his conversion. The spectrum in that figure is an example and therefore we do not find the commenter's conversion the most appropriate in this case.

Request: Two commenters disagreed with the AD because of the service history of their helicopters and Enstrom's history in general.

FAA Response: The fact that the individual helicopters owned or operated by some commenters have not experienced cracking does not negate the existence of an unsafe condition. The risk analysis used to support the requirements of this AD was based on in-service data reported as a result of AD 2015–04–51. This data represents the actual service state of the current Enstrom fleet, which is more accurate than the factors mentioned by the commenters.

D. Requests To Allow Alternative Actions

Request: Many commenters, including Airwolf Aerospace (Airwolf), requested the AD allow installing an Airwolf tension-torsion strap assembly (TT strap) as a means of complying with or terminating the AD. In support of this request, Airwolf stated that TT strap installation completely removes the threaded area of the spindle, leaving nothing left to inspect.

FAA Response: We disagree. The commenter's request is unnecessary. The Airwolf TT strap installation modifies the helicopter and the spindle, changing the P/N of the spindle, such that the AD would no longer apply.

Request: One commenter requested that instead of a life limit, the AD require a visual inspection of the cotter pin hole at each 100-hour or annual inspection. No technical data supporting this request was provided by the commenter.

FAA Response: We disagree. As explained above, the FAA has determined a life limit is required to correct the unsafe condition. Inspection programs alone are not sufficient to lower the risk to an acceptable level.

Request: Four commenters stated they have already inspected the spindles in accordance with AD 2015–08–51. One

commenter requested the AD allow a 300-hour grace period for spindles that have already been inspected.

FAA Response: We disagree. Providing a grace period within which to comply with a life limit essentially extends the life limit and would not be appropriate.

E. Comments Regarding Costs of Compliance With This AD

Request: Many commenters stated that the cost to comply with this AD is underestimated or inaccurate. These commenters stated the cost should include the costs associated with loss of utility; should reflect a replacement cost of $24,492 for three spindles; and should increase the labor rate.

FAA's Response: We disagree. The cost analysis in AD rulemaking actions typically includes only the costs associated with complying with the AD, which does not include indirect costs such as down-time and loss of revenue.

The parts costs for this AD were provided by the manufacturer. We do not control any price differences or retail pricing.

The labor rate of $85 per hour is provided by the FAA Office of Aviation Policy and Plans for the FAA to use when estimating the labor costs of complying with AD requirements.

Request: Several commenters requested the FAA not issue the AD because the extremely high cost will cause small operators to cease operations.

FAA's Response: We disagree. Although the FAA sympathizes with owners and the economic impact this AD may have, it does not negate the need to correct the identified unsafe condition. The applicable spindles in this design are critical for safe flight.

FAA's Determination

We have reviewed the relevant information and determined that an unsafe condition exists and is likely to exist or develop on other helicopters of these same type designs and that air safety and the public interest require adopting the AD requirements as proposed.

Related Service Information

We reviewed Enstrom Service Directive Bulletin No. 0119, Revision 3, dated June 24, 2016, for Model F–28A, F–28C, F–28F, 280, 280C, 280F, and 280FX helicopters with a spindle P/N 28–14282–11 or 28–14282–13. We also reviewed Enstrom Service Directive Bulletin No. T–050, Revision 3, dated June 24, 2016, for Model 480 helicopters, serial numbers 5001 through 5004 and 5006, and with a spindle P/N 28–14282–13, except those aircraft modified with tension-torsion straps. Both service directive bulletins specify sending the spindle to Enstrom for an MPI before the spindle reaches 1,500 hours TIS, or within 5 hours TIS for those spindles with 1,500 or more hours TIS. Thereafter, the service directive bulletins specify returning the spindle to Enstrom for an MPI every 500 hours.

Differences Between This AD and the Service Information

This AD requires establishing a spindle life limit of 1,500 hours TIS. The service information does not specify a life limit.

This AD requires that the MPI be conducted by a Level II or Level III inspector or equivalent. The service information specifies sending the spindle to Enstrom for an MPI.

This AD requires an initial MPI before further flight for a spindle with 500 or more hours TIS, unless an MPI has been done within the last 500 hours TIS. The service information specifies an initial MPI compliance time of within 5 hours TIS for a spindle with 1,500 or more hours TIS.

Costs of Compliance

We estimate that this AD affects 323 helicopters of U.S. Registry. We estimate that operators may incur the following costs in order to comply with this AD. Labor costs are estimated at $85 per work-hour. Inspecting the spindles takes about 15 work-hours for an estimated cost of $1,275 per helicopter and $411,825 for the U.S. fleet per inspection cycle. Replacing a cracked spindle costs $8,164 for parts and no additional work-hours. Replacing a set of three spindles that have reached their life limit takes about 14 work-hours and parts will cost $17,500 for a total cost of $18,690 per helicopter.

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

For the reasons discussed above, I certify that this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866;

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

(3) Will not affect intrastate aviation in Alaska to the extent that a regulatory distinction is required; 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.

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing Airworthiness Directive (AD) 2015–08–51, Amendment 39–18160 (80 FR 28172, May 18, 2015), and adding the following new AD:

2018–02–01 The Enstrom Helicopter Corporation (Enstrom): Amendment 39–19154; Docket No. FAA–2017–0141; Product Identifier 2016–SW–067–AD.

(a) Applicability

This AD applies to Enstrom Model F–28A, 280, F–28C, F–28C–2, F–28C–2R, 280C, F–28F, F–28F–R, 280F, and 280FX helicopters, all serial numbers; and Enstrom Model 480 helicopters, serial numbers 5001 through 5006; with a main rotor spindle (spindle) part number (P/N) 28–14282–11 or 28–14282–13, installed, certificated in any category.

(b) Unsafe Condition

This AD defines the unsafe condition as a crack in a spindle, which, if not detected, could result in loss of a main rotor blade and subsequent loss of control of the helicopter.

(c) Affected ADs

This AD supersedes AD 2015–08–51, Amendment 39–18160 (80 FR 28172, May 18, 2015).

(d) Effective Date

This AD becomes effective February 21, 2018.

(e) Compliance

You are responsible for performing each action required by this AD within the specified compliance time unless it has already been accomplished prior to that time.

(f) Required Actions

(1) Before further flight, remove from service any spindle P/N 28–14282–11 or 28–14282–13 that has 1,500 or more hours time-in-service (TIS). If the hours TIS of a spindle is unknown, use the TIS of the helicopter. Thereafter, remove from service any spindle P/N 28–14282–11 or 28–14282–13 before accumulating 1,500 hours TIS.

(2) For each spindle with 500 or more hours TIS, using the hours TIS of the helicopter if the hours TIS of the spindle is unknown:

(i) Before further flight, unless already done within the last 500 hours TIS, conduct a magnetic particle inspection (MPI) of the spindle for a crack, paying particular attention to the threaded portion of the spindle. The MPI of the spindle must be conducted by a Level II or Level III inspector qualified in the MPI in the Aeronautics Sector according to the EN4179 or NAS410 standard or equivalent. If there is a crack in the spindle, replace it with an airworthy spindle before further flight.

(ii) Thereafter at intervals not to exceed 500 hours TIS, repeat the MPI specified in paragraph (f)(2)(i) of this AD.

(g) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Chicago ACO Branch, FAA, may approve AMOCs for this AD. Send your proposal to: Manzoor Javed, Senior Aerospace Engineer, Chicago ACO Branch, Compliance and Airworthiness Division, FAA, 2300 East Devon Ave., Des Plaines, IL 60018; telephone (847) 294–8112; email *manzoor.javed@faa.gov.*

(2) For operations conducted under a 14 CFR part 119 operating certificate or under 14 CFR part 91, subpart K, we suggest that you notify your principal inspector, or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office, before operating any aircraft complying with this AD through an AMOC.

(h) Additional Information

Enstrom Service Directive Bulletin Nos. 0119 and T–050, both Revision 3 and both dated June 24, 2016, which are not incorporated by reference, contain additional information about the subject of this AD. For service information identified in this AD, contact Enstrom Helicopter Corporation, 2209 22nd Street, Menominee, MI; telephone (906) 863–1200; fax (906) 863–6821; or at *www.enstromhelicopter.com.* You may review a copy of the service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177.

(i) Subject

Joint Aircraft Service Component (JASC) Code: 6220, Main Rotor Head.

Issued in Fort Worth, Texas, on January 8, 2018.

James A. Grigg,

Acting Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2018–00659 Filed 1–16–18; 8:45 am]

BILLING CODE 4910–13–P

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 232

[Release Nos. 33–10444; 34–82246; 39–2519; IC–32938]

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 EDGAR system is scheduled to be upgraded on December 11, 2017.

DATES: Effective January 17, 2018. The incorporation by reference of the EDGAR Filer Manual is approved by the Director of the Federal Register as of January 17, 2018.

FOR FURTHER INFORMATION CONTACT: In the Division of Investment Management, for questions concerning Form N–LIQUID and additional data submission protocols for Form N–CEN, contact Heather Fernandez at (202) 551–6708; and in the Division of Corporation Finance, for questions concerning the combined Form 10–D/ABS–EE submission protocols or the new CERT submission form type, contact Heather Macintosh at (202) 551–8111.

SUPPLEMENTARY INFORMATION: We are adopting an updated EDGAR Filer Manual, 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 website.

The revisions to the Filer Manual reflect changes within Volume II, entitled EDGAR Filer Manual, Volume II: ''EDGAR Filing,'' Version 44 (December 2017). 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 17.4 on December 11, 2017 and will introduce the changes referenced below.

EDGAR Release 17.4 will update EDGAR to allow, but not require, asset-backed securities filers to submit a combined Form 10–D and Form ABS–EE. The combined submission would allow filers to concurrently submit and create hyperlinks in Form 10–D to the Form ABS–EE exhibits incorporated by reference into the Form 10–D.[4] The combined submission will be subject to a size limitation of 800MB, with 600MB for the Form ABS–EE submission and 200MB for the Form 10–D submission. Corresponding changes will be made to Chapter 5 (Constructing Attached Documents and Document Types) and Chapter 7 (Preparing and Transmitting EDGARLink Online Submissions) of the EDGAR Filer Manual, Volume II.

EDGAR Release 17.4 will update EDGAR to allow, but not require, national securities exchanges to submit a new certification form type on EDGAR to evidence the approval of securities for listing on an exchange. EDGAR Release 17.4 will introduce submission

[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 13, 2017. *See* Release No. 33–10413 (September 13, 2017) [82 FR 45434].

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

[3] *See* Release No. 33–10385 (July 6, 2017) [82 FR 35062] (implementing revisions to reflect EDGAR Release 17.2. For additional history of EDGAR Filer Manual revisions, please see the citations therein).

[4] The Commission previously adopted amendments requiring registrants to include a hyperlink to each exhibit listed in the exhibit index of certain filings, including filings on Form 10–D. *See* Release Nos. 33–10322, 34–80132 (March 1, 2017) [82 FR 14130 (March 17, 2017)].

form type CERT, a new EDGARLink Online submission form type. Instructions for making submissions of form type CERT will be added to Chapter 5 (Constructing Attached Documents and Document Types) and Chapter 7 (Preparing and Transmitting EDGARLink Online Submissions) of the EDGAR Filer Manual, Volume II.

In Release No. 33–10233 (October 13, 2016) [81 FR 82142], the Commission adopted changes to the reporting requirements for open-end management investment companies. Among the changes was the adoption of new Form N–LIQUID, which requires all registered open-end funds (except money market funds) to confidentially notify the Commission when certain events related to their liquidity occur. EDGAR Release 17.4 will update EDGAR to provide a means of submitting information regarding liquidity events using the following form types:

- Current Report Open-End Management Investment Company Liquidity on Form N–LIQUID (N–LIQUID); and
- Amended Current Report Open-End Management Investment Company Liquidity Form N–LIQUID (N–LIQUID/A).

Changes will be made to Chapter 3 (Index to Forms) and Chapter 7 (Preparing and Transmitting Online Submissions) of the EDGAR Filer Manual, Volume II.

In Release No. 33–10231 the Commission also adopted Form N–CEN, which will require investment companies, other than face amount certificate companies, to provide an annual report of census-type information in a structured format. EDGAR Release 17.3 added Form N–CEN and its related submission form types to EDGAR.[5] As part of EDGAR Release 17.4, Chapter 7 (Preparing and Transmitting Online Submissions) of the EDGAR Filer Manual, Volume II will be revised to provide clarifying instructions for filers on how to submit an amended Form N–CEN that contains data from a previously accepted filing on Form N–CEN or N–CEN/A covering the same period-end.

Finally, clarifying changes to the instructions for preparing documents that contain interactive data will be made to Chapter 5 (Constructing Attached Documents and Document Types) and Chapter 6 (Interactive Data) of the EDGAR Filer Manual, Volume II.

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 website 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 a.m. and 3 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'').[6] It follows that the requirements of the Regulatory Flexibility Act[7] do not apply.

The effective date for the updated Filer Manual and the rule amendments is January 17, 2018. In accordance with the APA,[8] 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 17.4 is scheduled to become available on December 11, 2017. 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,[9] Sections 3, 12, 13, 14, 15, 23, and 35A of the Securities Exchange Act of 1934,[10] Section 319 of the Trust Indenture Act of 1939,[11] and Sections 8, 30, 31, and 38 of the Investment Company Act of 1940.[12]

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:

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. 77c, 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, unless otherwise noted.

* * * * *

■ 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 forth 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 29 (September 2017). The requirements for filing on EDGAR are set forth in the updated EDGAR Filer Manual, Volume II: ''EDGAR Filing,'' Version 44 (December 2017). Additional provisions applicable to Form N–SAR filers are set forth in the EDGAR Filer Manual, Volume III: ''N–SAR Supplement,'' Version 6 (January 2017). 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 website 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: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

By the Commission.

[5] *See* Release No. 33–10413 (adopting updates to reflect EDGAR Release 17.3).

[6] 5 U.S.C. 553(b)(A).

[7] 5 U.S.C. 601–612.

[8] 5 U.S.C. 553(d)(3).

[9] 15 U.S.C. 77f, 77g, 77h, 77j, and 77s(a).

[10] 15 U.S.C. 78c, 78*l,* 78m, 78n, 78o, 78w, and 78*ll.*

[11] 15 U.S.C. 77sss.

[12] 15 U.S.C. 80a–8, 80a–29, 80a–30, and 80a–37.

Dated: December 8, 2017.

Brent J. Fields,

Secretary.

[FR Doc. 2018–00625 Filed 1–16–18; 8:45 am]

BILLING CODE 8011–01–P

LIBRARY OF CONGRESS

Copyright Office

37 CFR Part 202

[Docket No. 2017–9]

Simplifying Deposit Requirements for Certain Literary Works and Musical Compositions

AGENCY: U.S. Copyright Office, Library of Congress.

ACTION: Final rule.

SUMMARY: The United States Copyright Office is issuing a final rule, amending regulations that govern the deposit requirements for certain types of literary works and musical compositions. The final rule is adopted as proposed in the notice of proposed rulemaking, though the Office provides some clarification regarding the rule's application.

DATES: Effective February 16, 2018.

FOR FURTHER INFORMATION CONTACT: Sarang V. Damle, General Counsel and Associate Register of Copyrights, by email at *sdam@loc.gov;* Robert J. Kasunic, Associate Register of Copyrights and Director of Registration Policy and Practice, by email at *rkas@loc.gov;* Erik Bertin, Deputy Director of Registration Policy and Practice, by email at *ebertin@loc.gov;* or Cindy Abramson, Assistant General Counsel, by email at *ciab@loc.gov.* All can be reached by telephone by calling 202–707–8040.

SUPPLEMENTARY INFORMATION: On August 16, 2017, the Copyright Office published a notice of proposed rulemaking (''NPRM'') to amend the regulations governing the deposit requirements for certain types of literary works (specifically, literary monographs) and musical compositions that are published in print formats.

Under the previous regulations, two copies of the best edition were generally needed to register these types of works and to comply with the mandatory deposit requirement. Under the new rule, copyright owners will be able to satisfy both registration deposit and mandatory deposit requirements by submitting one copy of the best edition of the work. In the case of literary monographs, the Office will retain the right to demand a second copy under the mandatory deposit provision should the Library need it.

As part of these changes, the rule also clarifies the deposit requirements for musical compositions published *both* in print and phonorecord formats, requiring the submission of the print version for purposes of copyright registration. If, however, the musical composition is published only as a phonorecord, the applicant should submit a copy of the phonorecord.

All of these changes will improve the efficiency of registration and mandatory deposit for both the Office and copyright owners alike, ensuring that the Office has an adequate registration record and continuing to make these works available to the Library of Congress when needed for use in its collections or other disposition.

The NPRM explained in detail the rationale for the rule changes.[1] The Office solicited and received five comments, only two of which were substantive. Having reviewed and carefully considered the comments, the Copyright Office now issues a final rule identical to the proposed rule. While the Office does not believe the comments require any alteration to the rule itself, it does believe that some clarification would be helpful to both the commenters and copyright owners, and is provided here.

The Association of American Publishers (''AAP'') filed a comment regarding the proposed rule as it relates to the deposit of literary monographs. While the comment appreciates that the rule ''could reduce the financial burdens of publishers with respect to deposit regulations,'' it nevertheless does not support the rule because it takes issue with the Library's disposition of surplus works. AAP Comments at 2.

AAP appears to believe that there is no authority in the Copyright Act for the Library's disposition of surplus works and that the only authority comes from the Library's own regulations. AAP Comments at 6–7. But as discussed in the NPRM, section 704 of the Copyright Act explicitly states that ''[i]n the case of published works, all copies, phonorecords, and identifying material deposited are available to the Library of Congress for its collections, *or for exchange or transfer to any other library.*'' 17 U.S.C. 704(b) (emphasis added). Furthermore, AAP's concern about the Library's disposition of surplus books would be diminished by adoption of the rule, which limits the volume of works (and thereby any surplus) coming in to the Library in the first place. AAP concedes that the rule should have that result. AAP Comments at 2. In part, a primary goal of the rule is to lessen the burden for publishers. Accordingly, the Office chooses to move forward with the rule as is and anticipates that AAP's members will benefit significantly from the rule.

The National Music Publishers' Association (''NMPA'') filed a comment in support of the rule, subject to certain clarifications pertaining to the deposit of musical compositions. Specifically, NMPA wanted to clarify that ''where musical works are originally published solely as phonorecords, and such musical works are properly deposited and registered in accordance with the statutory and regulatory directives . . . that the later publication of the same musical work in the form of a 'copy' does not create an additional burden to subsequently deposit and register the work in 'copy' form.'' NMPA Comments at 2. The Office confirms that a later publication in the form of a ''copy'' does not create an additional deposit requirement.

As NMPA correctly points out, the Copyright Act defines ''best edition'' as ''the edition, published in the United States *at any time before the date of deposit,* that the Library of Congress determines to be most suitable for its purposes.'' 17 U.S.C. 101 (emphasis added); NMPA Comments at 4. NMPA believes, and the Office agrees, that this definition limits a ''best edition'' to published works at the time of deposit—that is, at the time the deposit for copyright registration or mandatory deposit is made. NMPA Comments at 4–5. Therefore, if only a phonorecord is published at the time of deposit, a subsequently published ''copy'' would not be a ''best edition'' and not be required for deposit.

NMPA proposes language to the rule to clarify any confusion regarding subsequent publication of ''copies.'' The Office believes that the rule in its current form along with the current definition of ''best edition'' is sufficient and no changes need to be made to the rule.

List of Subjects in 37 CFR Part 202

Copyright, Preregistration and registration of claims to copyright.

Final Regulations

For the reasons set forth in the preamble, the Copyright Office amends 37 CFR part 202 as follows:

PART 202—GENERAL PROVISIONS

■ 1. The authority citation for part 202 continues to read as follows:

[1] 82 FR 38859 (Aug. 16, 2017).

Authority: 17 U.S.C. 408(f), 702.

■ 2. Amend § 202.19 as follows:

■ a. Add paragraph (b)(5).

■ b. In paragraph (d)(2)(v), remove the words ''in copies only,'' and add in their place ''solely in copies,'' and remove the words ''if the only publication of copies in the United States took place by rental, lease, or lending,''.

■ c. Add paragraph (d)(2)(ix).

The additions read as follows:

§ 202.19 Deposit of published copies or phonorecords for the Library of Congress.

* * * * *

(b) * * *

(5) The term *literary monograph* means a literary work published in one volume or a finite number of volumes. This category does not include serials, nor does it include legal publications that are published in one volume or a finite number of volumes that contain legislative enactments, judicial decisions, or other edicts of government.

* * * * *

(d) * * *

(2) * * *

(ix) In the case of published literary monographs, the deposit of one complete copy of the best edition of the work will suffice in lieu of the two copies required by paragraph (d)(1) of this section, unless the Copyright Office issues a demand for a second copy pursuant to 17 U.S.C. 407(d).

* * * * *

■ 3. Amend § 202.20 as follows:

■ a. Revise paragraph (b)(3).

■ b. Remove paragraph (b)(4).

■ c. Redesignate paragraph (b)(5) as paragraph (b)(4).

■ d. In paragraphs (c)(2)(i)(A) through (D), remove the semicolon and add a period in its place at the end of each sentence.

■ e. Revise paragraph (c)(2)(i)(E).

■ f. In paragraphs (c)(2)(i)(F) through (I), remove the semicolon and add a period in its place at the end of the sentence.

■ g. In paragraph (c)(2)(i)(J), remove ''; and'' and add a period in its place at the end of the sentence.

■ h. Add paragraph (c)(2)(i)(L).

■ i. In paragraphs (c)(2)(viii)(A) through (D), remove the semicolon and add a period in its place at the end of the sentence.

■ j. In paragraphs (c)(2)(viii)(C) and (D), remove ''an audiocassette or other'' and add in its place ''a''.

The revisions and additions read as follows:

§ 202.20 Deposit of copies and phonorecords for copyright registration.

* * * * *

(b) * * *

(3) The terms *secure test* and *literary monograph* have the meanings set forth in §§ 202.13(b) and 202.19(b)(5).

* * * * *

(c) * * *

(2) * * *

(i) * * *

(E) Musical compositions published solely in copies or in both copies and phonorecords, provided that one complete copy (rather than a phonorecord) is deposited.

* * * * *

(L) Published literary monographs.

* * * * *

Dated: December 14, 2017.

Karyn Temple Claggett,

Acting Register of Copyrights and Director of the U.S. Copyright Office.

Carla D. Hayden,

Librarian of Congress.

[FR Doc. 2018–00701 Filed 1–16–18; 8:45 am]

BILLING CODE 1410–30–P

Proposed Rules

Federal Register
Vol. 83, No. 11
Wednesday, January 17, 2018

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 Part 205

[Document Number AMS–NOP–17–0057; NOP–17–08]

Meeting of the National Organic Standards Board

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Public meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, as amended, the Agricultural Marketing Service (AMS), U.S. Department of Agriculture (USDA), is announcing a meeting of the National Organic Standards Board (NOSB) to assist the USDA in the development of standards for substances to be used in organic production and to advise the Secretary of Agriculture on any other aspects of the implementation of the Organic Foods Production Act.

DATES: The Board will receive public comments via webinars on April 17 and 19, 2018, from 1:00 p.m. to approximately 4:00 p.m. Eastern Time (ET). An in-person meeting will be held April 25–27, 2018, from 8:30 a.m. to approximately 6:00 p.m. Mountain Time. In-person oral comments will be heard on Wednesday, April 25, and Thursday, April 26, 2018. The deadline to submit written comments and/or sign up for oral comment at either the webinar or face-to-face meeting is 11:59 p.m. ET, April 4, 2018.

ADDRESSES: The webinars are virtual and will be accessed via the internet and/or phone. Access information will be available on the AMS website prior to the webinars. The in-person meeting will take place at the Tucson University Park Hotel, 880 East Second Street, Tucson, Arizona 85719, United States. Detailed information pertaining to the webinars and in-person meeting can be found at *www.ams.usda.gov/NOSBMeetings.*

FOR FURTHER INFORMATION CONTACT: Ms. Michelle Arsenault, Advisory Committee Specialist, National Organic Standards Board, USDA–AMS–NOP, 1400 Independence Ave. SW, Room 2642–S, Mail Stop 0268, Washington, DC 20250–0268; Phone: (202) 720–3252; Email: *nosb@ams.usda.gov.*

SUPPLEMENTARY INFORMATION: The NOSB makes recommendations to the Department of Agriculture about whether substances should be allowed or prohibited in organic production and/or handling, assists in the development of standards for organic production, and advises the Secretary on other aspects of the implementation of the Organic Foods Production Act. The NOSB is holding a public meeting to discuss and vote on proposed recommendations to the USDA, receive updates from the USDA National Organic Program (NOP) on issues pertaining to organic agriculture, and receive comments from the organic community. The meeting and webinars are open to the public. All meeting documents, including the meeting agenda, NOSB proposals and discussion documents, instructions for submitting and viewing public comments, and instructions for requesting time for oral comments, will be available on the AMS website at *www.ams.usda.gov/NOSBMeetings.* Please check the website periodically for updates. Meeting topics will encompass a wide range of issues, including substances petitioned for addition to or deletion from the National List of Allowed and Prohibited Substances (National List), substances on the National List that are under sunset review, and guidance on organic policies. Participants and attendees may take photos and video at the meeting, but not in a manner that disturbs the proceedings.

Public Comments: Comments should address specific topics noted on the meeting agenda.

Written Comments: Written public comments will be accepted on or before 11:59 p.m. ET on April 4, 2018, via *http://www.regulations.gov:* Document #AMS–NOP–17–0057. Comments submitted after this date will be provided to the NOSB, but Board members may not have adequate time to consider those comments prior to making recommendations. The NOP strongly prefers comments to be submitted electronically. However, written comments may also be submitted (*i.e.,* postmarked) via mail to the person listed under **FOR FURTHER INFORMATION CONTACT** by or before the deadline.

Oral Comments: The NOSB is providing the public multiple dates and opportunities to provide oral comments and will accommodate as many individuals and organizations as time permits. Persons or organizations wishing to make oral comments must pre-register by 11:59 p.m. ET, April 4, 2018, and can register for only one speaking slot: Either during the webinars scheduled for April 17 and 19, or at the in-person meeting, scheduled for April 25–27, 2018. Due to the limited time allotted for in-person public comments during the in-person meeting, commenters are strongly encouraged to comment during the webinar(s). Instructions for registering and participating in the webinar can be found at *www.ams.usda.gov/NOSBMeetings.*

Meeting Accommodations: The meeting hotel is ADA Compliant, and the USDA provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in this public meeting, please notify the person listed under **FOR FURTHER INFORMATION CONTACT**. Determinations for reasonable accommodation will be made on a case-by-case basis.

Dated: December 26, 2017.

Bruce Summers,

Acting Administrator, Agricultural Marketing Service.

[FR Doc. 2017–28170 Filed 1–16–18; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2017–1247; Product Identifier 2017–NM–085–AD]

RIN 2120–AA64

Airworthiness Directives; Bombardier, Inc., Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain Bombardier, Inc., Model BD–100–1A10 airplanes. This proposed AD was prompted by a report indicating that certain lanyards for the passenger oxygen masks located in the airplane's entry area are too long. This proposed AD would require replacement of certain oxygen mask lanyards with shorter lanyards. We are proposing this AD to address the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by March 5, 2018.

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

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

For service information identified in this NPRM, contact Bombardier, Inc., 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone: 514–855–5000; fax: 514–855–7401; email: *thd.crj@aero.bombardier.com;* internet: *http://www.bombardier.com.* You may view this referenced service information at the FAA, Transport Standards Branch, 1601 Lind Avenue SW, Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–1247; 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 NPRM, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Cesar Gomez, Aerospace Engineer, Airframe and Mechanical Systems Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone: 516–228–7318; fax: 516–794–5531.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2017–1247; Product Identifier 2017–NM–085–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this NPRM. We will consider all comments received by the closing date and may amend this NPRM based on those comments.

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

Discussion

Transport Canada Civil Aviation (TCCA), which is the aviation authority for Canada, has issued Canadian AD CF–2017–22, dated June 23, 2017 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for certain Bombardier, Inc., Model BD–100–1A10 airplanes. The MCAI states:

> Bombardier, Inc., has discovered that the entry area passenger oxygen mask lanyards are too long. Upon deployment during an emergency, this may result in difficulties to start the oxygen flow for tall individuals. This [Canadian] AD mandates the replacement of the existing entry area passenger oxygen mask lanyards with shorter ones for proper operation.

You may examine the MCAI in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–1247.

Related Service Information Under 1 CFR Part 51

Bombardier, Inc., has issued Service Bulletin 100–35–08, dated April 11, 2017. This service information describes procedures for replacing the lanyards in the passenger oxygen masks located in the passenger entry area. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination and Requirements of This Proposed AD

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

Costs of Compliance

We estimate that this proposed AD affects 187 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	1 work-hour × $85 per hour = $85	(1)	$85	$15,895

[1] We have received no definitive data that would enable us to provide cost estimates for the required parts.

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

Authority for This Rulemaking

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

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

This proposed AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to transport category airplanes to the Director of the System Oversight Division.

Regulatory Findings

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

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

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

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

3. Will not affect intrastate aviation in Alaska; and

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Bombardier, Inc.: Docket No. FAA–2017–1247; Product Identifier 2017–NM–085–AD.

(a) Comments Due Date

We must receive comments by March 5, 2018.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Bombardier, Inc., Model BD–100–1A10 airplanes, certificated in any category, serial numbers 20003 through 20424 inclusive and 20426 through 20500 inclusive.

(d) Subject

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

(e) Reason

This AD was prompted by a report indicating that certain lanyards for the passenger oxygen masks located in the airplane's entry area are too long. The length of the oxygen mask lanyard might cause the safety pin tethered to the opposite end of the lanyard to remain engaged in the oxygen flow mechanism when the mask is pulled to the passenger's face. We are issuing this AD to detect and correct lanyards that are too long, which might result in difficulties starting the flow of oxygen in an emergency.

(f) Compliance

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

(g) Lanyard Replacement

Within 36 months after the effective date of this AD: For any entry area passenger oxygen mask dispensing unit (POMDU) having part number (P/N) 833–830–01, replace the lanyards in the POMDU with new lanyards having P/N 289–65–10, in accordance with the Accomplishment Instructions of Bombardier Service Bulletin 100–35–08, dated April 11, 2017.

(h) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, New York ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone: 516–228–7300; fax: 516–794–5531. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, New York ACO Branch, FAA; or Transport Canada Civil Aviation (TCCA); or Bombardier, Inc.'s TCCA Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

(i) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) Canadian AD CF–2017–22, dated June 23, 2017, for related information. This MCAI may be found in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–1247.

(2) For more information about this AD, contact Cesar Gomez, Aerospace Engineer, Airframe and Mechanical Systems Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone: 516–228–7318; fax: 516–794–5531.

(3) For service information identified in this AD, contact Bombardier, Inc., 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone: 514–855–5000; fax: 514–855–7401; email: *thd.crj@aero.bombardier.com;* internet: *http://www.bombardier.com.* You may view this referenced service information at the FAA, Transport Standards Branch, 1601 Lind Avenue SW, Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on January 5, 2018.

Michael Kaszycki,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2018–00664 Filed 1–16–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2017–1248; Product Identifier 2017–NM–162–AD]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for all The Boeing Company Model 737–100, –200, –200C, –300, –400, and –500 series airplanes. This proposed AD was prompted by reports of cracks found in the main landing gear (MLG) beam forward support fitting. This proposed AD would require repetitive inspections for cracking of the MLG beam forward support fitting, and applicable on-condition actions. We are proposing this AD to address the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by March 5, 2018.

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

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

For service information identified in this NPRM, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; internet *https://www.myboeingfleet.com.* You may view this referenced service information at the FAA, Transport Standards Branch, 1601 Lind Avenue SW, Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221. It is also available on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–1248.

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–2017–1248; 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 NPRM, 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: Payman Soltani, Aerospace Engineer, Airframe Section, FAA, Los Angeles ACO Branch, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5313; fax: 562–627–5210; email: *payman.soltani@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–2017–1248; Product Identifier 2017–NM–162–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this NPRM. We will consider all comments received by the closing date and may amend this NPRM because of those comments.

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

Discussion

We have received reports indicating that a crack was found in the MLG beam forward support fitting around the fastener locations common to the rear spar web, below the upper chord on the inboard side of the wing buttock line (WBL) 157 rib. Cracks were found on airplanes having 62,706 to 65,827 total flight hours and 50,152 to 53,039 total flight cycles. Because cracks in the MLG beam forward support fitting at this location are entirely hidden—the forward side of the fitting (inside fuel tanks) by sealant, and the aft side by the rear spar web and MLG beam—they cannot be detected reliably during normal maintenance and therefore require additional inspections. This cracking of the MLG beam forward support fitting, if not corrected, could lead to a fuel leak, the inability of a principal structural element to carry limit load, or an MLG collapse that could prevent continued safe flight and landing.

Related Service Information Under 1 CFR Part 51

We reviewed Boeing Alert Service Bulletin 737–57A1334, dated September 26, 2017. The service information describes procedures for repetitive high frequency eddy current (HFEC) inspections for cracking of the MLG beam forward support fitting around the fastener locations common to the rear spar web, below the upper chord on the inboard side of the WBL 157 rib, and applicable on-condition actions (*e.g.,* repair). This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

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 accomplishment of the actions identified as ''RC'' (required for compliance) in the Accomplishment Instructions of Boeing Alert Service Bulletin 737–57A1334, dated September 26, 2017, described previously, except for any differences identified as exceptions in the regulatory text of this proposed AD.

For information on the procedures and compliance times, see this service information at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–1248.

Explanation of Applicability

Model 737 airplanes having line numbers 1 through 291 have a limit of validity (LOV) of 34,000 total flight cycles, and the actions proposed in this NPRM, as specified in Boeing Alert Service Bulletin 737–57A1334, dated September 26, 2017, would be required at a compliance time occurring after that LOV. Although operation of an airplane beyond its LOV is prohibited by 14 CFR 121.1115 and 129.115, this NPRM would include those airplanes in the applicability so that these airplanes are tracked in the event the LOV is extended in the future.

Costs of Compliance

We estimate that this proposed AD affects 160 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
HFEC inspections	Up to 81 work-hours × $85 per hour = Up to $6,885 per inspection cycle.	$0	Up to $6,885 per inspection cycle.	Up to $1,101,600 per inspection cycle.

We have received no definitive data that would enable us to provide cost estimates for the on-condition actions specified in this proposed AD. Because the number of work-hours can vary widely, depending on the inspection findings, these figures were not included in the service information.

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.

This proposed AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to transport category airplanes to the Director of the System Oversight Division.

Regulatory Findings

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

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

The Boeing Company: Docket No. FAA–2017–1248; Product Identifier 2017–NM–162–AD.

(a) Comments Due Date

We must receive comments by March 5, 2018.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all The Boeing Company Model –100, –200, –200C, –300, –400, and –500 series airplanes, certificated in any category.

(d) Subject

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

(e) Unsafe Condition

This AD was prompted by the report of a crack indication in the main landing gear (MLG) beam forward support fitting on the inboard side of the wing buttock line (WBL) 157 rib, and multiple reports of similar crack findings on other airplanes. We are issuing this AD to detect and correct cracking of the MLG beam forward support fitting on the inboard side of the WBL 157 rib. Undetected cracks could lead to a fuel leak, the inability of a principal structural element to carry limit load, or an MLG collapse that could prevent continued safe flight and landing.

(f) Compliance

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

(g) Required Actions

(1) For Group 1 airplanes identified in Boeing Alert Service Bulletin 737–57A1334, dated September 26, 2017: Within 120 days after the effective date of this AD, inspect the airplane and do all applicable corrective actions using a method approved in accordance with the procedures specified in paragraph (i) of this AD.

(2) For Group 2 airplanes identified in Boeing Alert Service Bulletin 737–57A1334, dated September 26, 2017: Except as required by paragraph (h) of this AD, at the applicable times specified in paragraph 1.E., ''Compliance,'' of Boeing Alert Service Bulletin 737–57A1334, dated September 26, 2017, do all applicable actions identified as ''RC'' (required for compliance) in, and in accordance with, the Accomplishment Instructions of Boeing Alert Service Bulletin 737–57A1334, dated September 26, 2017.

(h) Exceptions to Service Information Specifications

(1) Where Boeing Alert Service Bulletin 737–57A1334, dated September 26, 2017, uses the phrase ''after the original issue date of this service bulletin,'' for purposes of determining compliance with the requirements of this AD, the phrase ''after the effective date of this AD'' must be used.

(2) Where Boeing Alert Service Bulletin 737–57A1334, dated September 26, 2017, specifies contacting Boeing, and specifies that action as RC: This AD requires using a method approved in accordance with the procedures specified in paragraph (i) of this AD.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Los Angeles ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (j)(1) of this AD. Information may be emailed to: *9-ANM-LAACO-AMOC-Requests@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector,

or lacking a principal inspector, the manager of the local flight standards district office/ certificate holding district office.

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

(4) Except as required by paragraph (h)(2) of this AD: For service information that contains steps that are labeled as RC, the provisions of paragraphs (i)(4)(i) and (i)(4)(ii) of this AD apply.

(i) The steps labeled as RC, including substeps under an RC step and any figures identified in an RC step, must be done to comply with the AD. If a step or substep is labeled ''RC Exempt,'' then the RC requirement is removed from that step or substep. An AMOC is required for any deviations to RC steps, including substeps and identified figures.

(ii) Steps not labeled as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the RC steps, including substeps and identified figures, can still be done as specified, and the airplane can be put back in an airworthy condition.

(j) Related Information

(1) For more information about this AD, contact Payman Soltani, Aerospace Engineer, Airframe Section, FAA, Los Angeles ACO Branch, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5313; fax: 562–627–5210; email: *payman.soltani@faa.gov.*

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; internet *https://www.myboeingfleet.com.* You may view this referenced service information at the FAA, Transport Standards Branch, 1601 Lind Avenue SW, Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on January 5, 2018.

Michael Kaszycki,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2018–00662 Filed 1–16–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–9523; Product Identifier 2016–NM–134–AD]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

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

SUMMARY: We are revising an earlier proposal to supersede Airworthiness Directive (AD) 2014–12–13, which applies to all The Boeing Company Model 737–100, –200, –200C, –300, –400, and –500 series airplanes. The first SNPRM proposed to revise the proposal by expanding the inspection area, and terminating, rather than superseding, the requirements of AD 2014–12–13, after accomplishment of the initial inspections. This action proposes to again revise the proposal by requiring the installation of standard-size fasteners for a certain configuration. We are proposing this AD to address the unsafe condition on these products. Since these actions impose an additional burden over that proposed in the first SNPRM, we are reopening the comment period to allow the public the chance to comment on these proposed changes.

DATES: The comment period for the SNPRM published in the **Federal Register** on August 11, 2017 (82 FR 37549), is reopened.

We must receive comments on this SNPRM by March 5, 2018.

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

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

For service information identified in this SNPRM, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740; telephone 562–797–1717; internet *https://www.myboeingfleet.com.* You may view this referenced service information at the FAA, Transport Standards Branch, 1601 Lind Avenue SW, Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221. It is also available on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–9523.

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–2016–9523; 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 SNPRM, 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: Payman Soltani, Aerospace Engineer, Airframe Section, FAA, Los Angeles ACO Branch, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5313; fax: 562–627–5210; email: *payman.soltani@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–2016–9523; Product Identifier 2016–NM–134–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this SNPRM. We will consider all comments received by the closing date and may amend this SNPRM because of those comments.

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

Discussion

We issued AD 2014–12–13, Amendment 39–17874 (79 FR 39300, July 10, 2014) (''AD 2014–12–13''). AD 2014–12–13 requires actions to address an unsafe condition on all The Boeing Company Model 737–100, –200, –200C,

–300, –400, and –500 series airplanes. AD 2014–12–13 requires repetitive inspections for cracking of the aft support fitting for the main landing gear (MLG) beam, and the rear spar upper chord and rear spar web; and repair if necessary.

We issued an NPRM to amend 14 CFR part 39 by adding an AD to supersede AD 2014–12–13 that would apply to all The Boeing Company Model 737–100, –200, –200C, –300, –400, and –500 series airplanes. The NPRM published in the **Federal Register** on January 5, 2017 (82 FR 1254) (''the NPRM''). The NPRM was prompted by reports of cracking in locations outside the inspection area identified in AD 2014–12–13, in the inspar upper skin at Wing Buttock Line (WBL) 157 and in the skin at two holes common to the rear spar in the same area, and in the rear spar web on both wings. Subsequent inspections revealed that the right rear spar upper chord was almost completely severed and the left rear spar upper chord was completely severed. The NPRM proposed to expand the inspection area and add applicable related investigative and corrective actions.

We subsequently issued an SNPRM, which was published in the **Federal Register** on August 11, 2017 (82 FR 37549) (''the first SNPRM''). The first SNPRM was prompted by reports of additional cracking in the inspar upper skin at WBL 157 and in the skin at two holes common to the rear spar in the same area, and rear spar web cracks were also noted on both wings. The first SNPRM proposed to expand the inspection area and terminate (rather than supersede) the requirements of AD 2014–12–13, after accomplishment of the initial inspections.

Actions Since the First SNPRM Was Issued

Since we issued the first SNPRM, we have determined that standard-size fasteners are required for installation for a certain configuration, as explained below under ''Request to Install Standard-Size Fasteners.''

Related Service Information Under 1 CFR Part 51

We reviewed Boeing Alert Service Bulletin 737–57A1318, Revision 1, dated July 22, 2016. The service information describes procedures for repetitive high frequency eddy current (HFEC) open hole inspections for any cracking in the forward support fitting, the aft support fitting, the rear spar upper chord, and the rear spar web at the 12 fastener holes (locations 1–12). The service information also describes procedures for optional HFEC open hole inspections for any cracking in the forward support fitting, the aft support fitting, the rear spar upper chord, and the rear spar web, and HFEC surface inspections for any cracking in the rear spar upper chord and rear spar upper web, as applicable. The service information also describes procedures for related investigative and corrective actions.

We also reviewed Boeing Alert Service Bulletin 737–57A1328, dated July 22, 2016. The service information describes procedures for repetitive eddy current inspections of the left and right wing for any cracking in the inspar upper skin and at the repair parts if applicable, and related investigative and corrective actions.

This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Comments

We gave the public the opportunity to comment on the first SNPRM. The following presents the comments received on the first SNPRM and the FAA's response to each comment.

Request To Install Standard-Size Fasteners

Boeing requested that standard-size fasteners be used for installation on the airplane instead of same-type and same-size fasteners. Boeing stated that for Group 7, Configuration 1 airplanes specified in Boeing Alert Service Bulletin 737–57A1318, Revision 1, dated July 22, 2016, the service information specifies to install standard-size fasteners (not oversize) and specifies a loose-fit design feature common to the aft fitting at fastener #5. Boeing commented that the loose-fit design feature is consistent with the type design and decreases the potential for future cracking. Boeing also stated that if the actions of Boeing Special Attention Service Bulletin 737–57–1318, dated May 15, 2013, have been done, it is possible that the fasteners have already been oversized and the loose-fit design feature has already been eliminated. Boeing commented that this recommendation will allow the opportunity to restore the fastener #5 location to the intended fastener fit (*i.e.,* loose fit in the aft fitting and tight fit in the forward fitting, web and chord).

We agree with the commenter for the reasons provided above. We have revised paragraph (h)(2) of this proposed AD to require the installation of standard-size fasteners, and if the existing fastener holes exceed the permitted hole diameter, operators must do a repair before further flight using a method approved in accordance with the procedures specified in paragraph (l) of this proposed AD.

Request for Credit for Previous Actions

All Nippon Airlines (ANA) requested credit for previous actions specified in paragraph (h) of the proposed AD (in the first SNPRM). ANA stated that credit should be provided if those actions were performed before the effective date of the AD using option 1 or 2 of Boeing Special Attention Service Bulletin 737–57–1318, dated May 15, 2013, and the HFEC open hole inspection for the forward support fitting should be done at the same time as the existing inspection within a shortened inspection interval.

ANA commented that based on the current descriptions of the proposed AD (in the first SNPRM), all operators must do the initial inspection even if they have chosen option 1 or 2 of Boeing Special Attention Service Bulletin 737–57–1318, dated May 15, 2013. Since AD 2014–12–13 has been effective since July 25, 2014, ANA believes many operators have already completed the initial inspection and started the repetitive inspection in accordance with Boeing Special Attention Service Bulletin 737–57–1318, dated May 15, 2013. ANA questioned the reasonableness of the requirement for operators who have chosen option 1 or 2 of Boeing Special Attention Service Bulletin 737–57–1318, dated May 15, 2013, to do the initial inspection again within the compliance time specified in table 2 through table 9 of paragraph 1.E., ''Compliance,'' of Boeing Alert Service Bulletin 737–57A1318, Revision 1, dated July 22, 2016.

We disagree with the commenter's request. Paragraph (h) of the proposed AD (in the first SNPRM) includes a requirement to do the HFEC open hole inspection of the forward fitting in addition to the inspections that were previously required by AD 2014–12–13 with updated service information, Boeing Alert Service Bulletin 737–57A1318, Revision 1, dated July 22, 2016. Since AD 2014–12–13 was issued, there have been reports of cracks found in the forward fitting. Therefore, Boeing Alert Service Bulletin 737–57A1318, Revision 1, dated July 22, 2016, has added an inspection of the forward fitting. Paragraph (l) of this proposed AD would allow operators to request approval of an alternative method of compliance (AMOC) if they previously performed the HFEC open hole inspection of this stack up, including the forward fitting, and they have documentation that the inspection of

the forward fitting was done. We have not changed this proposed AD regarding this issue.

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. Certain changes described above expand the scope of the first SNPRM. As a result, we have determined that it is necessary to reopen the comment period to provide additional opportunity for the public to comment on this second SNPRM.

Proposed Requirements of This SNPRM

This SNPRM would require accomplishing the actions specified in the service information described previously, except as discussed under ''Differences Between this Proposed AD and the Service Information.'' For information on the procedures and compliance times, see this service information at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–9523.

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

The phrase ''corrective actions'' is used in this SNPRM. Corrective actions correct or address any condition found. Corrective actions in an AD could include, for example, repairs.

Differences Between This SNPRM and the Service Information

Boeing Alert Service Bulletin 737–57A1318, Revision 1, dated July 22, 2016; and Boeing Alert Service Bulletin 737–57A1328, dated July 22, 2016; specify to contact the manufacturer for certain instructions, but this proposed AD would require accomplishment of repair methods, modification deviations, and alteration deviations in one of the following ways:

- In accordance with a method that we approve; or
- Using data that meet the certification basis of the airplane, and that have been approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) whom we have authorized to make those findings.

Costs of Compliance

We estimate that this proposed AD affects 471 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
HFEC open hole inspections.	82 work-hours × $85 per hour = $6,970 per inspection cycle.	$0	$6,970 per inspection cycle.	$3,282,870 per inspection cycle.
Eddy current inspection	14 work-hours × $85 per hour = $1,190 per inspection cycle.	0	$1,190 per inspection cycle.	$560,490 per inspection cycle.

ESTIMATED COSTS FOR OPTIONAL ACTIONS

Action	Labor cost	Parts cost	Cost per product
Inspection	Up to 41 work-hours × $85 per hour = $3,485 per inspection cycle.	$0	Up to $1,641,435 per inspection cycle.

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

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.

This proposed AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to transport category airplanes to the Director of the System Oversight Division.

Regulatory Findings

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

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator,

the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

The Boeing Company: Docket No. FAA–2016–9523; Product Identifier 2016–NM–134–AD.

(a) Comments Due Date

The FAA must receive comments on this AD action by March 5, 2018.

(b) Affected ADs

This AD affects AD 2014–12–13, Amendment 39–17874 (79 FR 39300, July 10, 2014) (''AD 2014–12–13''), and AD 2015–21–08, Amendment 39–18301 (80 FR 65921, October 28, 2015) (''AD 2015–21–08'').

(c) Applicability

(1) This AD applies to all The Boeing Company Model 737–100, –200, –200C, –300, –400, and –500 series airplanes, certificated in any category.

(2) Installation of Supplemental Type Certificate (STC) ST01219SE does not affect the ability to accomplish the actions required by this AD. Therefore, for airplanes on which STC ST01219SE is installed, a ''change in product'' alternative method of compliance (AMOC) approval request is not necessary to comply with the requirements of 14 CFR 39.17.

(d) Subject

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

(e) Unsafe Condition

This AD was prompted by reports of additional cracking in the inspar upper skin at Wing Buttock Line (WBL) 157 and in the skin at two holes common to the rear spar in the same area, and rear spar web cracks were also noted on both wings. Subsequent inspections revealed that the right rear spar upper chord was almost completely severed and the left rear spar upper chord was completely severed. We are issuing this AD to detect and correct cracking of the forward and aft support fittings for the main landing gear (MLG) beam, and the rear spar upper chord and rear spar web in the area of rear spar station (RSS) 224.14, which could grow and result in a fuel leak and possible fire.

(f) Compliance

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

(g) Required Actions for Group 1 Airplanes (MLG Support Fittings and Rear Spar)

For airplanes identified as Group 1 in Boeing Alert Service Bulletin 737–57A1318, Revision 1, dated July 22, 2016: At the applicable time specified in table 1 of paragraph 1.E., ''Compliance,'' of Boeing Alert Service Bulletin 737–57A1318, Revision 1, dated July 22, 2016, do applicable inspections and corrective actions using a method approved in accordance with the procedures specified in paragraph (l) of this AD.

(h) Required Actions for Groups 2–7 Airplanes (MLG Support Fittings and Rear Spar)

For airplanes identified as Groups 2–7 in Boeing Alert Service Bulletin 737–57A1318, Revision 1, dated July 22, 2016: At the applicable time specified in table 2 through table 9 of paragraph 1.E., ''Compliance,'' of Boeing Alert Service Bulletin 737–57A1318, Revision 1, dated July 22, 2016, except as required by paragraph (j)(3) of this AD, do high frequency eddy current (HFEC) open hole inspections for any cracking in the forward support fitting, the aft support fitting, the rear spar upper chord, and the rear spar web at the 12 fastener holes (locations 1–12); or HFEC open hole inspections for any cracking in the forward support fitting, the aft support fitting, the rear spar upper chord, and the rear spar web, and an HFEC surface inspection for any cracking in the rear spar upper chord and rear spar upper web; as applicable; and do all applicable related investigative and corrective actions; in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 737–57A1318, Revision 1, dated July 22, 2016, except as provided by paragraph (h)(1) of this AD, and except as required by paragraphs (h)(2) and (j)(1) of this AD. Do all applicable related investigative and corrective actions before further flight. Thereafter, repeat the HFEC inspection at the applicable time specified in table 2 through table 9 of paragraph 1.E., ''Compliance,'' of Boeing Alert Service Bulletin 737–57A1318, Revision 1, dated July 22, 2016.

(1) Options provided in Boeing Alert Service Bulletin 737–57A1318, Revision 1, dated July 22, 2016, for accomplishing the inspection are acceptable for the corresponding requirements in the introductory text of paragraph (h) of this AD, provided that the inspections are done at the applicable times in paragraph 1.E., ''Compliance,'' of Boeing Alert Service Bulletin 737–57A1318, Revision 1, dated July 22, 2016.

(2) For Group 7, Configuration 1, airplanes identified in Boeing Alert Service Bulletin 737–57A1318, Revision 1, dated July 22, 2016: Install standard-size fasteners in accordance with figures 29 and 30 of Boeing Alert Service Bulletin 737–57A1318, Revision 1, dated July 22, 2016. If the existing fastener holes exceed the permitted hole diameter, repair before further flight using a method approved in accordance with the procedures specified in paragraph (l) of this AD.

(i) Eddy Current Inspection (Inspar Upper Skin)

For airplanes identified in Boeing Alert Service Bulletin 737–57A1328, dated July 22, 2016: At the applicable time specified in table 1 and table 2 of paragraph 1.E., ''Compliance,'' of Boeing Alert Service Bulletin 737–57A1328, dated July 22, 2016, except as required by paragraph (j)(2) of this AD, do an eddy current inspection of the left and right wings for any cracking in the inspar upper skin, and at the repair parts if installed, and do all applicable related investigative and corrective actions, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 737–57A1328, dated July 22, 2016, except as required by paragraph (j)(1) of this AD. Do all related investigative and corrective actions before further flight. Thereafter, repeat the eddy current inspection at the applicable time specified in table 1 and table 2 of paragraph 1.E., ''Compliance,'' of Boeing Alert Service Bulletin 737–57A1328, dated July 22, 2016.

(j) Exceptions to the Service Information

(1) If any cracking is found during any inspection required by this AD, and Boeing Alert Service Bulletin 737–57A1318, Revision 1, dated July 22, 2016; or Boeing Alert Service Bulletin 737–57A1328, dated July 22, 2016; specifies to contact Boeing for appropriate action: Before further flight, repair using a method approved in accordance with the procedures specified in paragraph (l) of this AD.

(2) Where Boeing Alert Service Bulletin 737–57A1328, dated July 22, 2016, specifies a compliance time ''after the Original Issue date of this service bulletin,'' this AD requires compliance within the specified compliance time after the effective date of this AD.

(3) Where Boeing Alert Service Bulletin 737–57A1318, Revision 1, dated July 22, 2016, specifies a compliance time ''after the Revision 1 date of this service bulletin, whichever occurs later,'' this AD requires compliance within the specified compliance time after the effective date of this AD.

(k) Terminating Action

(1) Accomplishing the initial inspections and applicable related investigative and corrective actions required by paragraphs (g), (h), and (i) of this AD, as applicable, terminates all requirements of AD 2015–21–08.

(2) Accomplishing the initial inspections and applicable related investigative and corrective actions required by paragraphs (g) and (h) of this AD, as applicable, terminates all requirements of AD 2014–12–13.

(l) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Los Angeles ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (m)(1) of this AD. Information may be emailed to: *9-ANM-LAACO-AMOC-Requests@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager

of the local flight standards district office/ certificate holding district office.

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

(4) AMOCs approved previously for AD 2014–12–13 are approved as AMOCs for the corresponding provisions of paragraphs (g) and (h) of this AD.

(5) Except as required by paragraph (j)(1) of this AD: For service information that contains steps that are labeled as Required for Compliance (RC), the provisions of paragraphs (l)(5)(i) and (l)(5)(ii) of this AD apply.

(i) The steps labeled as RC, including substeps under an RC step and any figures identified in an RC step, must be done to comply with the AD. If a step or sub-step is labeled ''RC Exempt,'' then the RC requirement is removed from that step or sub-step. An AMOC is required for any deviations to RC steps, including substeps and identified figures.

(ii) Steps not labeled as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the RC steps, including substeps and identified figures, can still be done as specified, and the airplane can be put back in an airworthy condition.

(m) Related Information

(1) For more information about this AD, contact Payman Soltani, Aerospace Engineer, Airframe Section, FAA, Los Angeles ACO Branch, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5313; fax: 562–627–5210; email: *payman.soltani@faa.gov.*

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740; telephone 562–797–1717; internet *https://www.myboeingfleet.com.* You may view this referenced service information at the FAA, Transport Standards Staff, 1601 Lind Avenue SW, Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on December 28, 2017.

John P. Piccola, Jr.,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2018–00109 Filed 1–16–18; 8:45 am]

BILLING CODE 4910–13–P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Chapter II

[Docket No. CPSC–2017–0044]

Clothing Storage Unit Tip Overs; Extension of Comment Period

AGENCY: Consumer Product Safety Commission.

ACTION: Advance notice of proposed rulemaking; extension of comment period.

SUMMARY: The Consumer Product Safety Commission (Commission or CPSC) published an advance notice of proposed rulemaking (ANPR) regarding clothing storage unit (CSU) tip overs in the **Federal Register** on November 30, 2017. The ANPR invited the public to submit written comments during a 60-day comment period, beginning on the ANPR publication date. In response to a request for an extension of the comment period, the Commission is extending the comment period by 75 days.

DATES: Submit comments by April 14, 2018.

ADDRESSES: You may submit comments, identified by Docket No. CPSC–2017–0044, electronically or in writing:

Electronic Submissions: You may submit electronic comments to the Federal eRulemaking Portal at: *http://www.regulations.gov,* by following the instructions for submitting comments. The Commission does not accept comments submitted by electronic mail (email), except through *www.regulations.gov.*

Written Submissions: You may submit written comments by mail, hand delivery, or courier to: Office of the Secretary, Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504–7923.

Instructions: All submissions must include the agency name and docket number for this notice. All comments may be posted to: *http://www.regulations.gov* without change, including any personal identifiers, contact information, or other personal information. Do not submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If you submit such information, the Commission recommends that you do so by mail, hand delivery, or courier.

Docket: To read background documents or comments regarding this rulemaking, go to: *http://www.regulations.gov,* insert docket number CPSC–2017–0044 in the ''Search'' box, and follow the prompts.

SUPPLEMENTARY INFORMATION: On November 30, 2017, the Commission published an ANPR in the **Federal Register**, initiating rulemaking under the Consumer Product Safety Act (15 U.S.C. 2051–2089) and seeking comments and information regarding the risk of injury associated with CSU tip overs. 82 FR 56752. The ANPR provided a 60-day comment period, which will close on January 29, 2018. The American Home Furnishings Alliance (AHFA) has requested that the Commission extend the comment period an additional 75 days, given AHFA's pending Freedom of Information Act (5 U.S.C. 552) request for the raw data underlying the ANPR; the numerous subjects on which the ANPR seeks comments; and the time necessary to analyze the preliminary findings, complex issues, and substantial amount of data in the ANPR.

The Commission grants this request, extending the comment period for an additional 75 days, until April 14, 2018.

Alberta E. Mills,

Acting Secretary, Consumer Product Safety Commission.

[FR Doc. 2018–00552 Filed 1–16–18; 8:45 am]

BILLING CODE 6355–01–P

TENNESSEE VALLEY AUTHORITY

18 CFR Part 1304

RIN 3316–AA23

Floating Cabin Regulation

AGENCY: Tennessee Valley Authority.

ACTION: Proposed rule.

SUMMARY: The Tennessee Valley Authority (TVA) is proposing to amend its regulations that govern floating cabins located on the Tennessee River and its tributaries. The mooring of floating cabins on the TVA reservoir system has increased, and TVA has determined that this poses an unacceptable risk to navigation, safety, and the environment. Left unaddressed, floating cabins convert the public waters under TVA's management to private use. The proposed amendments would re-define nonnavigable houseboats and floating cabins using one term—''floating cabins''—and prohibit new floating cabins on TVA-managed reservoirs after December 16, 2016. The proposed amendments also include limited mooring standards, limitations on expansions of floating cabins, and requirements for owners to register their

floating cabins. Additional health, safety, and environmental standards for floating cabins will be addressed in a later rulemaking once TVA has had the opportunity to discuss such standards with various stakeholders.

In addition, and separate from the updated rule amendments for floating cabins, these proposed amendments contain a minor changes to clarify when TVA will allow some water-use facilities (*e.g.,* docks) to be as large as 1,800 square feet.

DATES: Written comments must be received on or before March 19, 2018.

ADDRESSES: Send comments by mail or hand delivery to David B. Harrell, Program Manager, Floating Cabins, Tennessee Valley Authority, 260 Interchange Park Drive, Lenoir City, TN 37772 or by email to *dbharrell@tva.gov.*

FOR FURTHER INFORMATION CONTACT: David B. Harrell, 865–632–1327.

SUPPLEMENTARY INFORMATION:

Legal Authority

These proposed amendments are promulgated under the authority of the TVA Act, as amended, 16 U.S.C. 831–831ee, Title V of the Independent Offices Appropriations Act of 1955, 31 U.S.C. 9701, and OMB Circular No. A–25. Under Section 26a of the TVA Act, no obstructions affecting navigation, flood control, or public lands or reservations shall be constructed, operated, or maintained across, along, or in the Tennessee River System without TVA's approval. TVA has long considered nonnavigable structures such as floating cabins to be obstructions that require its approval. In addition, Section 9b of the TVA Act provides that TVA ''may establish regulations to prevent the construction of new floating cabins.'' 16 U.S.C. 831h–3(e).

Background and Proposed Amendments

TVA is a multi-purpose federal agency that has been charged by Congress with promoting the wise use and conservation of the resources of the Tennessee Valley region, including the Tennessee River System. In carrying out this mission, TVA operates a system of dams and reservoirs on the Tennessee River and its tributaries for the purpose of navigation, flood control, and power production. Consistent with those purposes, TVA uses the system to improve water quality and water supply and to provide a wide range of public benefits including recreation.

To promote the unified development and regulation of the Tennessee River System, Congress directed TVA to approve obstructions across, along, or in the river system under Section 26a of the TVA Act, as amended. ''Obstruction'' is a broad term that includes, by way of example, boat docks, piers, boathouses, buoys, floats, boat launching ramps, fills, water intakes, devices for discharging effluents, bridges, aerial cables, culverts, pipelines, fish attractors, shoreline stabilization projects, channel excavations, and nonnavigable houseboats. TVA also owns, as agent for the United States, much of the shoreline and inundated land along and under its Reservoir System.

Since 1971, TVA has used its authority under Section 26a to prohibit the mooring on the Tennessee River System of new nonnavigable houseboats that are used primarily for habitation or occupation and not for navigation or water transportation. In particular, TVA amended its regulations in 1971 to prohibit the mooring or anchoring of new nonnavigable houseboats except for those in existence before November 21, 1971. Criteria were established then to identify when a houseboat was considered ''navigable'' and the conditions under which existing nonnavigable houseboats would be allowed to remain. These criteria were characteristics that TVA determined were indicative of real watercraft; *i.e.,* boats or vessels that are designed and used primarily to traverse water. Since 1971, TVA has made minor changes to its regulations affecting nonnavigable houseboats, most notably in 1978 when TVA updated the prohibited mooring of nonnavigable houseboats on its reservoir system except for those in existence on or before February 15, 1978. The navigability criteria, however, largely have remained unchanged.

A ''nonnavigable houseboat'' under TVA's current regulations is identified as any houseboat not in compliance with the following criteria:

Built on a boat hull or on two or more pontoons;

Equipped with a motor and rudder controls located at a point on the houseboat from which there is forward visibility over a 180-degree range;

Compliant with all applicable state and federal requirements relating to vessels;

Registered as a vessel in the state of principal use; and

State registration numbers clearly displayed on the vessel.

Despite the nonnavigable houseboat prohibition, new nonnavigable houseboats in the form of floating cabins have been moored on TVA reservoirs. TVA estimates that approximately 2000 floating cabins and older nonnavigable houseboats are now moored on TVA reservoirs. Some developers and owners of these floating cabins have asserted that they are not nonnavigable houseboats because they have been designed to meet the criteria for navigability in TVA's regulations. Whether or not this is true, these floating cabins are designed and used primarily for human habitation at a fixed location rather than for transportation or navigation. These floating cabins are a modern version of the pre-1978 nonnavigable houseboats that TVA addressed in its 1971 and 1978 regulatory actions. They are not in any real sense watercraft, and absent action by TVA, the mooring of floating cabins on TVA reservoirs will continue to increase. Until now, TVA has discouraged the increased mooring of floating cabins without using the full scope of its regulatory authority under the TVA Act.

In determining what action to take, TVA prepared an Environmental Impact Statement (EIS) in accordance with the National Environmental Policy Act. This EIS assesses the environmental and socioeconomic impacts of different policies to address the proliferation of floating cabins and nonnavigable houseboats on TVA's reservoirs. TVA released a draft of this EIS for public comment in June 2015 and held four public meetings and a webinar to provide information about its analyses and to facilitate public involvement. Public reaction to this situation widely varied.

Many members of the general public urged TVA to require the removal of all floating cabins because TVA's reservoirs are public resources and owners of floating cabins are occupying public areas. Floating cabin owners generally supported additional reasonable regulation of their structures but argued against policies requiring their removal because of the investments they have made in the structures. Other commenters had concerns about discharges of black (sewage) and gray (showers, sinks, etc.) water from floating cabins and shock and electrocution risks associated with the electrical connections to floating cabins. Commenting agencies consistently supported better regulation of floating cabins. The final EIS and associated documents can be found at *https://www.tva.com/Environment/Shoreline-Construction/Floating-Cabins.*

After considering the comments it received during the EIS process and its analyses of impacts, TVA identified as its preferred policy one that establishes standards for floating cabins to enhance compliance with applicable water

quality discharge requirements set by other agencies, adherence to electrical safety codes, and location of floating cabins within identified harbor limits of commercial marinas. Under the preferred policy, the mooring of additional floating cabins would be prohibited on the TVA River System of which TVA reservoirs are a part. All existing floating cabins, including nonnavigable houseboats, would have to be removed from the Tennessee River System by January 1, 2036, and be subject to a regulatory program in the interim. On May 5, 2016, the TVA Board of Directors adopted the preferred policy with one exception—the Board changed the removal date to May 5, 2046.

On December 16, 2016, the Water Infrastructure Improvements for the Nation Act (WIIN Act) was enacted by the United States Congress. Title IV Section 5003 related to floating cabins and amended the TVA Act to include Section 9b. This new section of the TVA Act specifically addresses floating cabins and provides that TVA may allow the use of floating cabins where the structure was located on waters under TVA's jurisdiction as of December 16, 2016; and where the owner maintains the structure in accordance with reasonable health, safety, and environmental standards set by the TVA Board of Directors. Section 9b also states that TVA may establish regulations to prevent the construction of new floating cabins and may levy fees to ensure compliance.

Section 9b provides the circumstances under which TVA may require the removal of existing floating cabins; *i.e.,* those located on waters under TVA's jurisdiction as of December 16, 2016. For floating cabins that have a TVA permit as of December 16, 2016, TVA may not require their removal for 15 years; *i.e.,* until December 16, 2031. For those without permits on December 16, 2016, TVA may not require their removal for five years; *i.e.,* until December 16, 2021. During these 15- and 5-year periods, however, TVA may levy necessary and reasonable fees to ensure compliance with TVA's regulations. The new legislation also provides that, with respect to existing floating cabins, TVA ''shall approve and allow the use of the floating cabin on waters under the jurisdiction of [TVA] at such time and for such duration as (i) The floating cabin meets the requirements of [16 U.S.C. 831h–3(b)]; and (ii) the owner of the floating cabin has paid any fee assessed pursuant to [16 U.S.C. 831h–3(c)].'' 16 U.S.C. 831h–3(d)(1)(B).

Section 9b of the TVA Act defines ''floating cabin'' as a watercraft or other floating structure (1) primarily designed and used for human habitation or occupation; and (2) not primarily designed or used for navigation or transportation on the water. This proposed rule clarifies the type of structure that TVA will regulate as a floating cabin and updates TVA's regulations to clarify that floating cabins placed on TVA waters after December 16, 2016, are prohibited. The proposed rule also establishes limited mooring requirements; clarifies limitations on expansions; and requires all owners of floating cabins to register their structures with TVA by January 1, 2019, regardless of whether they already have a Section 26a permit. Although this deadline allows plenty of time for owners to register their floating cabins, TVA would encourage owners to begin the registration process without delay. A subsequent rulemaking will address: (1) The permitting process for existing floating cabins; (2) health, safety, and environmental standards; and (3) fees.

Floating Cabins

To more clearly describe the type of floating structure that TVA regulates, the term ''nonnavigable houseboat'' would be replaced in TVA's Section 26a regulations with the term ''floating cabin,'' the term adopted by Congress in the WIIN Act. Floating cabins are structures determined by TVA, in its sole judgment, to be designed and used primarily for human habitation or occupation and not designed or used primarily for navigation or transportation on the water. TVA's judgment will be guided by, but not limited to, the following factors:

1. Whether the structure is usually kept at a fixed mooring point;
2. Whether the structure is actually used on a regular basis for transportation or navigation;
3. Whether the structure has a permanent or continuous connection to the shore for electrical, plumbing, water, or other utility service;
4. Whether the structure has the performance characteristics of a vessel typically used for navigation or transportation on the water;
5. Whether the structure can be readily removed from the water;
6. Whether the structure is used for intermittent or extended human-habitation or occupancy;
7. Whether the structure clearly has a means of propulsion and appropriate power/size ratio;
8. Whether the structure is safe to navigate or use for transportation purposes.

Mooring

Existing floating cabins, *i.e.,* those located on the TVA River System on or before December 16, 2016, may continue to be moored within harbor limits of a commercial marina or, if the floating cabin is not associated with a marina, along shoreline approved in writing by TVA on or before December 16, 2016. However, to prevent sprawl and to better contain the impacts of floating cabins, TVA would not allow an existing floating cabin to relocate except to the harbor limits of a commercial marina that complies with 18 CFR 1304.404, the TVA regulation governing commercial marina harbor limits. Existing floating cabins without TVA permits would have to be moored within identified and approved harbor limits of commercial marinas that comply with 1304.404. In some cases, existing floating cabins moored at a commercial marina are located outside of the designated harbor limits or the marina's land ownership has changed since the harbor limits were originally designated. In these and other situations, TVA may require a floating cabin to relocate to another location within the marina's harbor limits. Relocations to alternate marinas would require advance approval from TVA in the form of a new permit.

Dock Size

Separate from the proposed amendments to regulations concerning floating cabins, the proposal would result in a minor change to clarify TVA's intent concerning the size of some water-use facilities (*e.g.,* docks). The current regulation requires water-use facilities to be sited within a 1000-square-foot rectangular or square area. The proposed change would allow some water-use facilities to be as large as 1800 square feet, but only in one of two circumstances (1) where the water-use facility will be located in a subdivision recorded before November 1, 1999, and TVA permitted at least one water-use facility in the subdivision prior to November 1, 1999; or (2) if there is no subdivision, where the water-use facility will be located within a quarter-mile radius of another water-use facility that TVA permitted prior to November 1, 1999. TVA's current waiver or variance provisions, set forth in 1304.212 and 1304.408 respectively, may allow even larger facilities where an applicant requests and justifies a waiver or variance, but such allowances shall be made in TVA's discretion and on a case-by-case basis.

Administrative Requirements

A. Unfunded Mandates Reform Act and Various Executive Orders Including E.O. 12866, Regulatory Planning and Review; E.O. 12898, Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations; E.O. 13045, Protection of Children From Environmental Health Risks; E.O. 13132, Federalism; E.O. 13175, Consultation and Coordination With Indian Tribal Governments; E.O. 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, and Use; E.O. 12988, Civil Justice Reform Act; and the Presidential Executive Order on Reducing Regulation and Controlling Regulatory Costs Dated January 30, 2017

This proposal contains no federal mandates for state, local, or tribal government or for the private sector. TVA has determined it will not have a significant annual effect of $100 million or more or result in expenditures of $100 million in any one year by state, local, or tribal governments or by the private sector. The proposal will not have a substantial direct effect on the States or Indian tribes, on the relationship between the Federal Government and the States or Indian tribes, or on the distribution of power and responsibilities between the federal Government and States or Indian tribes. Nor will the proposal have concerns for environmental health or safety risks that may disproportionately affect children, have significant effect on the supply, distribution, or use of energy, or disproportionally impact low-income or minority populations. Unified development and regulation of the Tennessee River System through an approval process for obstructions across, along, or in the river system, and management of United States-owned land entrusted to TVA are federal functions for which TVA is responsible under the TVA Act. In general, the proposal updates or clarifies TVA's regulations to align them with the status quo. First, the proposal clarifies that no new structures are allowed and codifies (1) an updated definition for floating, habitable structures that are allowable on TVA reservoirs; (2) where such structures may be located; and (3) the types of modifications that are allowed. The proposal also amends TVA's regulations to align better with its policy for allowing some obstructions, usually docks, to be larger than 1,000 square feet. Accordingly, the proposal has no implications for any of the referenced authorities, including the Presidential Executive Order on Reducing Regulation and Controlling Regulatory Costs dated January 30, 2017, which affects only ''significant regulatory actions'' as defined by Executive Order 12866.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act, 5 U.S.C. 605, TVA is required to prepare a regulatory flexibility analysis unless the head of the agency certifies that the proposal will not have a significant economic impact on a substantial number of small entities. The statute defines ''small entity'' as a ''small business,'' ''small organization'' (further defined as a ''not-for-profit enterprise''), or a ''small governmental jurisdiction.'' Most applications for water-use facilities are submitted by residential landowners for personal use. Since residential landowners are not businesses, not-for-profit enterprises, or small governmental jurisdictions, there are relatively few ''small entities'' affected by TVA's proposal. Moreover, nothing in this proposal significantly adds to the cost of applying for and constructing any regulated facility. Accordingly, this rule will not have a significant impact on a substantial number of small entities; no regulatory flexibility analysis is required; and TVA's Chief Executive Officer has made the requisite certification.

C. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), this notice announces TVA's intent to request approval from the Office of Management and Budget (OMB) for amendment of a currently approved information collection. The information collection requirements proposed under this rule for registration of floating cabins will be included within the Section 26a Permit Application information collection. For this information collection, we estimate an increase in the number of responses and the burden hours in the first year of the floating cabin registration process. The number of responses is estimated to increase from 1,500 to 3,700 in the first year, then return to close to the previous number in following years. The estimated burden per response remains at 2 hours. Therefore in the first year, the estimated burden will increase from 3,000 hours to 7,400 hours. The estimated overall burden for the information collection will return to about 3,000 hours in following years.

Title of Information Collection: Section 26a Permit Application.

Current OMB Approval Number: 3316–0060.

Type of Affected Public: Individuals or households, state or local governments, farms, businesses, or other for-profit organizations, federal agencies or employees, non-profit institutions, small businesses or organizations.

Small Businesses or Organizations Affected: Yes.

Federal Budget Functional Category Code: 452.

Estimated Number of Annual Responses: 3,700.

Estimated Total Annual Burden Hours: 7,400.

Estimated Average Burden Hours per Response: 2.0.

Need for and Use of Information: TVA Land Management activities and Section 26a of the Tennessee Valley Authority Act of 1933, as amended, require TVA to collect information relevant to projects that will impact TVA land and land rights and review and approve plans for the construction, operation, and maintenance of any dam, appurtenant works, or other obstruction affecting navigation, flood control, or public lands or reservations across, along, or in the Tennessee River or any of its tributaries. The information is collected via paper forms and/or electronic submissions and is used to assess the impact of the proposed project on TVA land or land rights and statutory TVA programs to determine if the project can be approved. Rules for implementation of TVA's Section 26a responsibilities are published in 18 CFR part 1304.

The information collection requirements in this proposed rule have been submitted for review by OMB under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

An Information Collection Request (ICR) document has been prepared by TVA, and a copy may be obtained from the Senior Privacy Program Manager: Christopher A. Marsalis, Tennessee Valley Authority, 400 W. Summit Hill Dr. (WT 5D), Knoxville, Tennessee 37902–1401; telephone (865) 632–2467 or by email at *camarsalis@tva.gov;* or to the Agency Clearance Officer: Philip D. Propes, Tennessee Valley Authority, 1101 Market Street (MP 2C), Chattanooga, Tennessee 37402–2801; telephone (423) 751–8593 or email at *pdpropes@tva.gov.*

Under the Paperwork Reduction Act, TVA is soliciting public comment before the ICR is submitted to OMB for final review and approval. We are soliciting comment to:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Comments on the ICR must be submitted to TVA by the date indicated above. Comments must be submitted by mail or hand delivery to David B. Harrell, Program Manager, Floating Cabins, Tennessee Valley Authority, 260 Interchange Park Drive, Lenoir City, TN 37772 or by email to *dbharrell@tva.gov.*

Comments may also be sent to OMB at: Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503, marked ''Attention: Desk Officer for Tennessee Valley Authority, OMB #3316–0060.'' Comments on the ICR will be summarized and included in the request for OMB approval.

List of Subjects in 18 CFR Part 1304

Administrative practice and procedure, Natural resources, Navigation (water), Rivers, Water pollution control.

For the reasons set out in the preamble, the Tennessee Valley proposes to amend 18 CFR part 1304 of the Code of Federal Regulations as follows:

PART 1304—APPROVAL OF CONSTRUCTION IN THE TENNESSEE RIVER SYSTEM AND REGULATION OF STRUCTURES AND OTHER ALTERATIONS

■ 1. The authority citation for 18 CFR part 1304 continues to read as follows:

Authority: 16 U.S.C 831–831ee.

■ 2. Amend § 1304.1 by revising the third sentence to read as follows:

§ 1304.1 Scope and intent.

* * * By way of example only, such obstructions may include boat docks, piers, boathouses, buoys, floats, boat launching ramps, fills, water intakes, devices for discharging effluent, bridges, aerial cables, culverts, pipelines, fish attractors, shoreline stabilization projects, channel excavations, and floating cabins as described in § 1304.101.

* * * * *

Subpart B—Regulation of Floating Cabins

■ 3. Revise the subpart B heading to read as set forth above.

■ 4. Revise § 1304.100 to read as follows:

§ 1304.100 Scope and intent.

This subpart prescribes requirements for floating cabins on the Tennessee River System. Floating cabins as applied to this subpart include existing nonnavigable houseboats approved by TVA on or before December 16, 2016, and other existing structures whose design and use is primarily for human habitation or occupation, not for navigation or transportation on the water. Floating cabins that were not located or moored on the Tennessee River System on or before December 16, 2016, shall be deemed new floating cabins. New floating cabins are prohibited and subject to the removal provisions of this part and Section 9b of the TVA Act. No new floating cabins shall be moored, anchored, or installed on the Tennessee River System. Floating cabins that were located or moored in the Tennessee River System on or before December 16, 2016 shall be deemed existing floating cabins. Existing floating cabins may remain moored on the Tennessee River System provided they remain in compliance with the rules in this part.

■ 5. Amend § 1304.101:

■ a. By revising the section heading and paragraphs (a) and (b);

■ b. In paragraphs (c) introductory text and (c)(1) and (2) by removing the words ''nonnavigable houseboat'' and ''nonnavigable houseboats'' and adding in their place the words ''floating cabin'' and ''floating cabins'', respectively;

■ c. By revising paragraph (d);

■ d. In paragraph (e) by removing the words ''nonnavigable houseboats'' and adding in their place the words ''floating cabins'';

■ e. In paragraph (f) by removing the words ''nonnavigable houseboat'' and adding in their place the words ''floating cabin''; and

■ f. By adding paragraph (g).

The revisions and additions read as follows:

§ 1304.101 Floating cabins.

(a)(1)Floating cabins include nonnavigable houseboats approved by TVA on or before December 16, 2016, and other floating structures determined by TVA in its sole discretion to be designed and used primarily for human habitation or occupation and not designed and used primarily for navigation or transportation on the water. TVA's judgment will be guided by, but not limited to, the following factors:

(i) Whether the structure is usually kept at a fixed mooring point;

(ii) Whether the structure is actually used on a regular basis for transportation or navigation;

(iii) Whether the structure has a permanent or continuous connection to the shore for electrical, plumbing, water, or other utility service;

(iv) Whether the structure has the performance characteristics of a vessel typically used for navigation or transportation on water;

(v) Whether the structure can be readily removed from the water;

(vi) Whether the structure is used for intermittent or extended human-habitation or occupancy;

(vii) Whether the structure clearly has a means of propulsion, and appropriate power/size ratio;

(viii) Whether the structure is safe to navigate or use for transportation purposes.

(2) That a structure could occasionally move from place to place, or that it qualifies under another federal or state regulatory program as a vessel or boat, are factors that TVA also will consider but would not be determinative. Floating cabins are not recreational vessels to which § 1304.409 applies.

(b)(1) Owners of floating cabins are required to register the floating cabin with TVA before January 1, 2019. Floating cabin owners must submit certain required information with their registration. Registration shall include the following information: Clear and current photographs of the structure; a drawing or drawings showing in reasonable detail the size and shape of the floating cabin (length, width, and height) and attached structures, such as decks or slips (length, width, and height); and a completed and signed TVA registration form. The completed TVA registration form shall include the mailing and contact information of the owner(s); the TVA permit or TVA-issued numbers (when applicable); the mooring location of the floating cabin; how the floating cabin is moored; how electrical service is provided; how waste water and sewage is managed; and an owner's signature.

(2) Existing floating cabins may remain on TVA reservoirs provided they stay in compliance with the rules contained in this part and pay any necessary and reasonable fees levied by TVA to ensure compliance with TVA's

regulations. Existing floating cabins must be moored within the designated and approved harbor limits of a commercial marina that comply with § 1304.404. Alternatively, provided the owner obtained written approval from TVA pursuant to subpart A of this part authorizing mooring at such location on or before December 16, 2016, floating cabins may be moored to the bank of the reservoir at locations where the owner of the floating cabin is the owner or lessee (or the licensee of such owner or lessee) of the proposed mooring location, and at locations described by § 1304.201(a)(1), (2), and (3). Existing floating cabins that have not been permitted by TVA must moor within designated and approved harbor limits of a commercial marina that complies with § 1304.404. As provided in § 1304.404, TVA may adjust harbor limits and require relocation of an existing floating cabin within the harbor limits.

(3) All floating cabins must be moored in such a manner as to:

(i) Avoid obstruction of or interference with navigation, flood control, public lands or reservations;

(ii) Avoid adverse effects on public lands or reservations;

(iii) Prevent the preemption of public waters when moored in permanent locations outside of the approved harbor limits of commercial marinas;

(iv) Protect land and landrights owned by the United States alongside and subjacent to TVA reservoirs from trespass and other unlawful and unreasonable uses; and

(v) Maintain, protect, and enhance the quality of the human environment.

* * * * *

(d) Existing floating cabins shall be maintained in a good state of repair and may be maintained without additional approval from TVA. Existing floating cabins may be rebuilt without TVA approval; but owners are required to notify TVA and submit their proposed plans for rebuilding the floating cabin and submit a photo of the rebuilt floating cabin for TVA's records. Plans for any structural modification that alters the length, width or height of the floating cabin or any attached structures (such as decks or walkways) shall be submitted to TVA for review and approval pursuant to the requirements of subpart A of this part authorizing such construction. TVA will determine if modifying or rebuilding a floating cabin requires a new Section 26a permit and any new fees.

* * * * *

(g) All floating cabins not in compliance with this part are subject to the applicable removal provisions of § 1304.406 and Section 9b of the TVA Act.

■ 6. Amend § 1304.102 by removing the words ''nonnavigable houseboat'' and ''nonnavigable houseboats'' and adding in their place the words ''floating cabin'' and ''floating cabins'', respectively, wherever they appear, and by adding a sentence to the end of paragraph (a) and revising paragraph (c).

The addition and revision read as follows:

§ 1304.102 Numbering of floating cabins and transfer of ownership.

(a) * * * If TVA provided a placard or tag, the tag must be displayed on a readily visible part of the outside of the floating cabin.

* * * * *

(c) A floating cabin moored at a location approved pursuant to the regulations in this subpart shall not be relocated and moored at a different location without prior approval by TVA, except for movement to a new location within the designated harbor limits of the same commercial dock or marina.

§ 1304.103 [Removed and Reserved]

■ 7. Remove and reserve § 1304.103.

■ 8. Amend § 1304.204 by revising paragraphs (a), (b), and (n) to read as follows:

§ 1304.204 Docks, piers, and boathouses.

* * * * *

(a) Docks, piers, boathouses, and all other residential water-use facilities shall not exceed a total footprint area of greater than 1,000 square feet, unless the proposed water-use facility will be located in an area of preexisting development. For the purpose of this regulation, ''preexisting development'' means either (1) the water-use facility will be located in a subdivision recorded before November 1, 1999, and TVA permitted at least one water-use facility in the subdivision prior to November 1, 1999; or (2) if there is no subdivision, where the water-use facility will be located within a quarter-mile radius of another water-use facility that TVA permitted prior to November 1, 1999. TVA may allow even larger facilities where an applicant requests and justifies a waiver or variance, set forth in 1304.212 and 1304.408 respectively, but such waivers or variances shall be made in TVA's discretion and on a case-by-case basis.

(b) Docks, boatslips, piers, and fixed or floating boathouses are allowable. These and other water-use facilities associated with a lot must be sited within a 1,000- or 1,800-square-foot rectangular or square area as required by § 1304.204(a) at the lakeward end of the access walkway that extends from the shore to the structure. Access walkways to the water-use structure are not included in calculating the 1,000- or 1,800-square foot area.

* * * * *

(n) Except for floating cabins approved in accordance with subpart B of this part, toilets and sinks are not permitted on water-use facilities.

* * * * *

§ 1304.406 [Amended]

■ 9. Amend § 1304.406 in the first sentence by removing the words ''nonnavigable houseboat'' and adding in their place the words ''floating cabin''.

■ 10. Amend § 1304.412 by:

■ a. Adding in alphabetical order definitions for ''Existing floating cabin'' and ''New floating cabin'';

■ b. Removing the definition of ''Nonnavigable houseboat''; and

■ c. Adding in alphabetical order definitions for ''Rebuilding'' and ''Tennessee River''.

The additions read as follows:

§ 1304.412 Definitions.

* * * * *

Existing floating cabin means a floating cabin that was located or moored on the Tennessee River System on or before December 16, 2016.

* * * * *

New floating cabin means a floating cabin that was not located or moored on the Tennessee River System on or before December 16, 2016.

* * * * *

Rebuilding means replacement of all or a significant portion of a floating cabin to the same approved plans, standards and conditions of the Section 26a permit.

* * * * *

Tennessee River System means TVA reservoirs, the Tennessee River or any of the Tennessee River's tributaries.

* * * * *

David L. Bowling,

VP Land & River Management.

[FR Doc. 2018–00323 Filed 1–16–18; 8:45 am]

BILLING CODE 8120–08–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 10 and 800

[Docket No. FDA–2016–N–2378]

RIN 0910–AH37

Internal Agency Review of Decisions; Requests for Supervisory Review of Certain Decisions Made by the Center for Devices and Radiological Health

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to implement regulations regarding internal agency supervisory review of certain decisions related to devices regulated by the Center for Devices and Radiological Health (CDRH) under the Federal Food, Drug, and Cosmetic Act (FD&C Act) to conform to the applicable provisions in the Food and Drug Administration Safety and Innovation Act (FDASIA) and the 21st Century Cures Act (Cures Act). FDA is taking this action to codify the procedures and timeframes for supervisory review of significant decisions pertaining to devices within CDRH. FDA is also proposing regulations to provide new procedural requirements for requesting internal agency supervisory review within CDRH of other types of decisions made by CDRH not addressed in FDASIA and the Cures Act. This action is also part of FDA's implementation of Executive Orders (EOs) 13771 and 13777. Under these EOs, FDA is comprehensively reviewing existing regulations to identify opportunities for repeal, replacement, or modification that will result in meaningful burden reduction, while allowing the Agency to achieve its public health mission and fulfill statutory obligations.

DATES: Submit either electronic or written comments by April 17, 2018. See section V of this document for the proposed effective date of a final rule that may issue based on this proposal.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 17, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of April 17, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal Rulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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 Docket No. FDA–2016–N–2378 for ''Internal Agency Review of Decisions; Requests for Supervisory Review of Certain Decisions Made by the Center for Devices and Radiological Health.'' Received comments, those filed in a timely manner (see **ADDRESSES**) will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff 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 *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. 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: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Adaeze Teme, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5574, Silver Spring, MD 20993–0002, 240–402–0768; or the Ombudsman for the Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4282, Silver Springs, MD 20993–0002, 301–796–5669, or *CDRHOmbudsman@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Purpose of the Proposed Rule

The purpose of this proposed rule is to implement regulations on the procedures regarding internal agency supervisory review of certain decisions made by CDRH under the FD&C Act. Section 603 of FDASIA added new section 517A to the FD&C Act (21 U.S.C. 360g–1), which was amended by

sections 3051 and 3058 of the Cures Act. These provisions established procedures and timeframes for supervisory review under § 10.75 (21 CFR 10.75) of significant decisions by CDRH pertaining to devices. After the enactment of FDASIA, FDA issued a guidance document entitled ''Center for Devices and Radiological Health Appeals Processes: Questions and Answers About 517A—Guidance for Industry and Food and Drug Administration Staff'' (Q&A Guidance) to provide interpretation of key provisions of section 517A, including those that pertain to requests for supervisory review of significant decisions by CDRH (Ref. 1). FDA is proposing this regulation to codify (1) the procedures and timeframes for § 10.75 appeals of ''significant decisions'' by CDRH established under section 517A and (2) the interpretation of key provisions of section 517A of the FD&C Act regarding supervisory review. In addition, the proposed regulations would introduce new procedural requirements for supervisory review within CDRH of other CDRH decisions that were not addressed in FDASIA and the Cures Act.

The proposed regulations will provide transparency and clarity for internal and external stakeholders on CDRH's process for supervisory review of decisions and will give requesters new predictability through binding deadlines for FDA action on a request for supervisory review within CDRH and the Center's internal agency review of ''significant decisions.'' Furthermore, this proposal, when finalized, will codify the types of decisions that are considered ''significant decisions,'' for which the timeframes apply. The proposed regulations will also codify the timeframe for submission of requests for the review of other decisions within CDRH.

B. Summary of the Major Provisions of the Proposed Rule

FDA proposes to amend part 10 (21 CFR part 10) by adding § 10.75(e). Section 10.75 currently provides that an interested person outside the Agency may request internal agency review of a decision of an FDA employee. FDA proposes to amend § 10.75 to add paragraph (e), which would require that requests for internal agency supervisory review within CDRH of a decision also comply with proposed § 800.75 (21 CFR 800.75). This proposed change to the regulations would encompass both significant decisions under section 517A of the FD&C Act and other decisions by CDRH employees.

The proposed rule would also add new § 800.75 to part 800 (21 CFR part 800). Proposed § 800.75 would incorporate in the regulations the provisions of section 517A of the FD&C Act for review of ''significant decisions'' related to devices regulated under the FD&C Act by CDRH. Proposed § 800.75 would define ''significant decisions.'' Section 800.75 would also include the timeframes for submission of requests for internal agency review of significant decisions within CDRH and for responses to such requests.

Proposed § 800.75 would further address requests for supervisory review within CDRH of decisions other than section 517A decisions and would indicate the timeframe for submission of these requests for internal agency review.

C. Legal Authority

FDA's legal authority to implement requirements pertaining to the process and timelines for § 10.75 appeals of decisions within CDRH derives from sections 510(k), 515, 515C, 517A, and 520(g) of the FD&C Act (21 U.S.C. 360(k), 360e, 360e–3, 360g–1, and 360j) and other provisions under which a decision might be appealed, and 701(a) of the FD&C Act (21 U.S.C. 371(a)). Section 701(a) of the FD&C Act gives FDA general rulemaking authority to issue regulations for the efficient enforcement of the FD&C Act.

D. Costs and Benefits

We expect the costs and benefits of the proposed rule to be negligible.

II. Background

A. Regulations on Internal Agency Review

FDA has long provided a path for outside parties to request internal agency review of decisions. A procedure for this type of review was first published as a proposed regulation in 1975 (40 FR 40682, September 3, 1975) (Ref. 2). In the preamble for the proposed rule, the Agency recognized that a process for administrative review of Agency decisions would advise outside parties how they should pursue matters that interest and concern them (40 FR 40682 at 40693). A final rule published in 1977 incorporated these provisions into the Code of Federal Regulations at 21 CFR 2.17 (42 FR 4680, January 25, 1977) (Ref. 3).

These regulations provided that any decision of an FDA employee, other than the Commissioner, on any matter was subject to review by the employee's supervisor under any of the following circumstances: (1) At the request of the employee, (2) on the initiative of the supervisor, (3) at the request of any interested person outside of the Agency, or (4) as required by duly promulgated delegations of authority. The review shall be accomplished by consultation between the employee and the supervisor, by review of the administrative file, or both. The review shall ordinarily follow established Agency channels of supervision. Internal agency review shall be based on the data and information available in the administrative file. If an interested person presents new data or information not contained in the administrative file, then the matter shall be returned to the appropriate lower level within the Agency for a reevaluation based upon the new information (§ 2.17 (1977)).

The following year, in 1978, a proposed rule was published to reorganize and revise the Agency's administrative practices and procedures regulations (43 FR 51966, November 7, 1978) (Ref. 4). When the final rule for this action was published, the regulations for internal agency review were moved from § 2.17 and redesignated as § 10.75 (44 FR 22318, April 13, 1979) (Ref. 5), where these regulations remain today.

In 1998, § 10.75 was amended to add provisions allowing a sponsor, applicant, or manufacturer of a drug or device to request review of a scientific controversy by an appropriate scientific advisory panel or advisory committee (63 FR 63978, November 18, 1998). Aside from the specific situation addressed by the amendment, the elements of internal agency review under § 10.75 relating to who may request the review and the information on which the review must be based remained unchanged.

Section 10.75 contains regulations that establish an orderly process for internal agency review of decisions, based on information in the FDA administrative file. Section 10.75 applies to requests for review of decisions made by any FDA employee, other than decisions by the Commissioner of Food and Drugs. Section 10.75 does not establish timelines for requests for Agency review or for the Agency to act upon these requests. The FDA guidance document entitled ''Center for Devices and Radiological Health Appeals Processes—Guidance for Industry and Food and Drug Administration Staff'' describes the § 10.75 appeal processes available to outside stakeholders to request review of decisions or actions by CDRH employees (Ref. 6).

B. Agency Documentation and Review of Significant Decisions Regarding Devices Under Section 517A of the Federal Food, Drug, and Cosmetic Act

On July 9, 2012, the FD&C Act (21 U.S.C. 301 *et seq.*) was amended by FDASIA. Section 603 of FDASIA added new section 517A to the FD&C Act, which specifies procedures and timeframes for the supervisory review of significant decisions pertaining to devices regulated by CDRH.

On December 13, 2016, the FD&C Act (21. U.S.C. 301 *et seq.*) was further amended by the Cures Act. Section 3051 of the Cures Act, ''Breakthrough Devices,'' added section 515C to the FD&C Act and amended section 517A(a)(1) to include any significant decision by CDRH regarding a request for designation as a breakthrough device under section 515C.

In addition, section 3058, ''Least Burdensome Device Review,'' of the Cures Act amended section 517A(a) by adding subsection (3), which requires that the substantive summary include a brief statement of how the least burdensome requirements were considered and applied consistent with sections 513(i)(1)(D), 513(a)(3)(D), and 515(c)(5) of the FD&C Act, as applicable.

Section 517A of the FD&C Act provides that any person may request a supervisory review of any significant decision of CDRH regarding the submission or review of a report under section 510(k), an application under section 515, a request for designation under section 515C, or an application for an exemption under section 520(g) of the FD&C Act. Any person may request such review, which may be conducted at the next supervisory level or higher above the individual who made the significant decision. Where the request for supervisory review was made at the organizational level, any person may request a supervisory review to the next organizational level or higher above the level at which the decision was made. In addition, the Office or Center Director may designate a Deputy Director to be their representative as the authority for a request made to that level. In this situation, a request for review heard by a Deputy is rendered on behalf of the Director and constitutes a review by that level of the organization (Ref. 6).

Section 517A of the FD&C Act includes specific timeframes both for the person requesting review and for FDA to respond to such a request. A request for review of a significant decision is required to be submitted to FDA not later than 30 days after such decision. In responding to this request, if the requester seeks an in-person meeting or a teleconference review, FDA is required to schedule the requested interaction not later than 30 days after the request is made. FDA is required to issue a decision not later than 30 days after the interaction, or, in the case of a person who does not seek an in-person meeting or teleconference review, FDA is required to issue a decision no later than 45 days after the request for supervisory review is received by FDA. An exception to the timeframes related to scheduling an in-person meeting or teleconference review, and to FDA's decision on a request for supervisory review of the significant decision, is provided in cases that are referred to experts outside of FDA. Although the procedures and timeframes in section 517A of the FD&C Act apply to an initial request for supervisory review of a significant decision by CDRH, CDRH has chosen to enhance transparency and predictability and apply those procedures and timeframes as well to sequential requests for supervisory review of significant decisions that are submitted to CDRH.

III. Legal Authority

We are proposing to codify the procedures and timeframes in section 517A of the FD&C Act, added by section 603 of FDASIA and amended by the Cures Act, for § 10.75 appeals of ''significant decisions'' regarding the submission or review of a report under section 510(k), an application under section 515, a request for designation under section 515C, or an application for an exemption under section 520(g) of the FD&C Act.

We are also proposing additional procedural requirements for § 10.75 appeals submitted to CDRH of other types of CDRH decisions not addressed in the FDASIA and the Cures Act.

FDA's legal authority to implement requirements pertaining to the process and timelines for § 10.75 appeals submitted to CDRH derives from sections 510(k), 515, 515C, 517A, and 520(g) of the FD&C Act and other provisions under which a decision might be appealed, and 701(a) of the FD&C Act. Section 701(a) of the FD&C Act gives FDA general rulemaking authority to issue regulations for the efficient enforcement of the FD&C Act.

IV. Description of the Proposed Rule

The proposed rule would, if finalized, incorporate the procedures and timeframes in section 517A to an initial or sequential request for supervisory review within CDRH of ''significant decisions'' by CDRH into FDA's regulations. The proposed regulations would also introduce new procedural requirements for requests for supervisory review within CDRH under § 10.75 of decisions that do not fall under ''significant decisions'' under section 517A of the FD&C Act.

FDA proposes to amend part 10 by adding § 10.75(e). Section 10.75 currently provides that an interested person outside the Agency may request internal agency review of a decision of an FDA employee. FDA proposes to amend § 10.75 to add paragraph (e), which would require that requests for internal agency supervisory review within CDRH also comply with proposed § 800.75. This proposed change to the regulations would encompass both significant decisions under section 517A of the FD&C Act and other types of decisions.

The proposed rule would add new § 800.75 to part 800. Proposed § 800.75 would incorporate, into the regulations, the provisions of section 517A of the FD&C Act for review of significant decisions related to devices regulated under the FD&C Act by CDRH. Proposed § 800.75 would define ''significant decisions.'' Section 800.75 would also include the timeframes for submission of requests for internal agency review of significant decisions within CDRH and for responses to such requests.

Proposed § 800.75 would further address the review of decisions other than 517A decisions and would indicate the timeframe for submission of these requests for internal agency review within CDRH.

A. Proposed Revisions to § 10.75

Part 10 would be amended to add § 10.75(e). FDA proposes to add language to clarify that requests by interested persons outside the Agency for internal agency review of a decision within CDRH must also comply with proposed § 800.75. Proposed § 10.75(e) would not be limited to significant decisions under section 517A of the FD&C Act. Rather, proposed § 10.75(e) would also encompass review of decisions other than 517A decisions made by CDRH.

B. Proposed § 800.75

Section 517A of the FD&C Act establishes procedural requirements, including timeframes for a request for internal agency review of a ''significant decision'' by CDRH. ''Significant decision'' is not defined in the statutory provision. FDA is proposing to define ''significant decision,'' to provide greater clarity regarding which decisions fall within this statutory term.

A ''517A decision'' would be defined as a significant decision regarding a device as set forth in section 517A of the

FD&C Act. We are proposing to use the term ''517A decision'' rather than the term ''significant decision'' because we do not want to imply that all other decisions of the Agency that do not fall within section 517A of the FD&C Act are not significant. Similarly, we did not want to use the term ''non-significant decision'' when speaking of decisions outside of the scope of section 517A, as that might imply some unintended assessment on our part concerning the importance of these types of decisions. In addition, because we are proposing these regulations to include regulatory decisions by CDRH besides those set forth in section 517A, we wanted to avoid any confusion that might occur in distinguishing between these two categories of decisions. For these reasons, we instead are proposing to use the term ''517A decision'' for those decisions that are identified under section 517A as significant decisions, and to refer to other decisions by CDRH as ''non-517A decisions.''

The review procedures under section 517A of the FD&C Act apply only to a request for review of a significant decision by CDRH regarding submission or review of a report under section 510(k) (Premarket Notification), an application under section 515 (Premarket Approval or ''PMA''/ Humanitarian Device Exemption or ''HDE''), a request for designation under section 515C (Breakthrough Devices), or an application for an exemption under section 520(g) of the FD&C Act (Investigational Device Exemption or ''IDE''). CDRH is proposing that only the following decisions be considered significant decisions under section 517A of the FD&C Act and, thus, defined for purposes of this proposed rule as ''517A decisions'':

- 510(k): Not substantially equivalent; Substantially equivalent.
- PMA/HDE: Not approvable; Approvable; Approval; Denial.
- Breakthrough Devices: Expedited access pathway (Ref. 7) program request for breakthrough designation for devices subject to premarket notification, premarket approval, or de novo requests. Grant; Denial of request for breakthrough designation.
- IDE: Disapproval; Approval.
- Failure to reach agreement on protocol under section 520(g)(7) of the FD&C Act.
- ''Clinical Hold'' determinations under section 520(g)(8) of the FD&C Act.

In proposing § 800.75, we are mindful that outside parties may use § 10.75 to request review of decisions other than 517A decisions. For this reason, we are also proposing new procedural requirements for internal agency supervisory review within CDRH under § 10.75 of non-517A decisions made by CDRH employees. A request for supervisory review of a CDRH decision other than a 517A decision is to be received no later than 60 days after the date of the decision that is subject to review. Any request received after 60 days in these cases will be denied as untimely, unless CDRH, for good cause related to circumstances beyond the control of the submitter, such as snow emergency, Federal Government shutdown, or other unforeseen emergency event, permits the request to be filed after 60 days.

Section 800.75 proposes that requests for CDRH review of 517A decisions and non-517A decisions must be addressed to the next organizational level or higher above the individual who made the decision. Requests to elevate the review of such decisions should include a rationale. The decision to collapse two or more levels of review or to elevate a review would solely be at CDRH's discretion. In addition, requesters should have exhausted review through the supervisory chain below the Center Director level prior to request for review at the Center Director level.

As provided in the FDA guidance, entitled ''eCopy Program for Medical Device Submissions—Guidance for Industry and Food and Drug Administration Staff'' (eCopy guidance), appeals to submission types identified under section 745A(b) of the FD&C Act are subject to the electronic format requirements. (Ref. 8). Therefore, 10.75 requests for supervisory review of 517A decisions within CDRH, and certain decisions other than 517A decisions, must be submitted in accordance with section 745A(b) and the standards established by the eCopy guidance, when applicable. In addition, requests for breakthrough designation under section 515C of the FD&C Act for devices under sections 510(k), 513(f)(2), and 515(c) of the FD&C Act would be considered ''presubmissions'' to those submission types as identified under section 745A, and, therefore, requests for breakthrough designation would be subject to section 745A(b), and likewise, § 10.75 requests for review within CDRH.

Further, § 800.75 proposes that requests for supervisory review of CDRH decisions other than 517A decisions must be sent to the CDRH Ombudsman, and those decisions, other than 517A decisions not subject to section 745A, are to be submitted in electronic format. Further instructions will be provided regarding submission of such requests in electronic format.

V. Proposed Effective Date

FDA is proposing that any final rule based on this proposal become effective 90 days after the date of publication of a final rule in the **Federal Register** or at a later date if stated in the final rule.

VI. Economic Analysis of Impacts

We have examined the impacts of the proposed rule under E.O. 12866, E.O. 13563, E.O. 13771, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). E.O. 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). E.O. 13771 requires that the costs associated with significant new regulations ''shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.'' We believe that this proposed rule is not a significant regulatory action as defined by E.O. 12866. It has been determined that this proposed rule is an action that does not impost more than de minimis costs.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because we anticipate that the costs of the rule would be de minimis, we propose to certify that the proposed rule will not 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 $148 million, using the most current (2016) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount. We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the proposed rule.

The proposed rule would (1) define ''517A decision,'' (2) apply to requests submitted to CDRH for review of 517A

decisions and decisions other than 517A decisions made by CDRH, and (3) establish timelines and procedures for an interested person to request supervisory review of these decisions by CDRH. By setting specific timelines for persons to submit requests for supervisory review, the proposed rule would help clarify the supervisory review process and provide firms with an incentive to promptly submit review requests. The proposed rule would also establish timelines for CDRH review of 517A decisions, reducing uncertainty about when interested persons would know the outcome of their requests for supervisory review. Because the proposed rule would not change the effort needed to prepare and submit a request for supervisory review, we anticipate that affected interested persons would incur only negligible costs to read and learn about the provisions of the proposed rule. We do not expect additional costs for FDA.

We received 42 requests for review in 2013, 28 requests for review in 2014, 20 requests for review in 2015, and 20 requests for review in 2016. We estimate that each request for review required 70 hours of CDRH staff time. One possible benefit of the proposed rule, if finalized, is that it may reduce the number of hours required per request for review. If firms have more clarity about the request for review process, they may not have to spend as much time navigating the process, and we may not need to spend as much time guiding them through the process.

VII. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Paperwork Reduction Act of 1995

This proposed rule refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information regarding the appeals process for devices in the guidance document entitled ''Center for Devices and Radiological Health Appeals Processes'' have been approved under OMB control number 0910–0738; the collections of information in 21 CFR part 807, subpart E (premarket notification) have been approved under OMB control number 0910–0120; the collections of information for De Novo classification requests have been approved under the OMB control number 0910–0844; the collections of information in 21 CFR part 812 (investigational device exemption) have been approved under OMB control number 0910–0078; the collections of information in 21 CFR part 814 (premarket approval) have been approved under OMB control number 0910–0231; and the collections of information in 21 CFR part 814, subpart H (humanitarian use devices) have been approved under OMB control number 0910–0332.

IX. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that the proposed rule does 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, we conclude 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.

X. References

The following references are on display in the Dockets Management Staff (see **ADDRESSES**) and is 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 website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. ''Center for Devices and Radiological Health Appeals Processes: Questions and Answers About 517A—Guidance for Industry and Food and Drug Administration Staff,'' July 30, 2014, available at: *http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM352254.pdf.*
2. 40 FR 40682, September 3, 1975 *http://heinonline.org/HOL/PDFsearchable?handle=hein.fedreg/040171&collection=fedreg&section=0&id=179&print=1&sectioncount=1&ext=.pdf&nocover=.*
3. 42 FR 4680, January 25, 1977 *http://heinonline.org/HOL/PDFsearchable?handle=hein.fedreg/042016&collection=fedreg&section=0&id=250&print=1&sectioncount=1&ext=.pdf&nocover=.*
4. 43 FR 51966, November 7, 1978 *http://heinonline.org/HOL/PrintRequest?collection=fedreg&nocover=&handle=hein.fedreg%2F043216&id=186&section=&skipstep=1&fromid=186&toid=238&format=PDFsearchable&submitx=Print%2FDownload&submit1=Print%2FDownload+Custom+Range.*
5. 44 FR 22318, April 13, 1979 *http://heinonline.org/HOL/PrintRequest?collection=fedreg&nocover=&handle=hein.fedreg%2F044073&id=258&section=&skipstep=1&fromid=258&toid=376&format=PDFsearchable&submitx=Print%2FDownload&submit1=Print%2FDownload+Custom+Range.*
6. ''Center for Devices and Radiological Health Appeals Processes—Guidance for Industry and Food and Drug Administration Staff,'' May 17, 2013, available at: *http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM284670.pdf.*
7. ''Expedited Access for Premarket Approval and *De Novo* Medical Devices Intended for Unmet Medical Need for Life Threatening or Irreversibly Debilitating Diseases or Conditions—Guidance for Industry and Food and Drug Administration Staff,'' April 13, 2015, available at: *http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm393978.pdf.*
8. ''eCopy Program for Medical Device Submissions—Guidance for Industry and Food and Drug Administration Staff,'' December 3, 2015, available at: *http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm313794.pdf.*

List of Subjects

21 CFR Part 10

Administrative practice and procedure, News media.

21 CFR Part 800

Administrative practice and procedure, Medical devices, Ophthalmic goods and services, Packaging and containers, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 10 and 800 be amended as follows:

PART 10—ADMINISTRATIVE PRACTICES AND PROCEDURES

■ 1. The authority citation for part 10 continues to read as follows:

Authority: 5 U.S.C. 551–558, 701–706; 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–397, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264.

■ 2. In § 10.75, add paragraph (e) to read as follows:

§ 10.75 Internal agency review of decisions.

* * * * *

(e) Each request by an interested person for review of a decision within the Center for Devices and Radiological Health shall also comply with § 800.75 of this chapter.

PART 800—GENERAL

■ 3. The authority citation for part 800 is revised to read as follows:

Authority: 5 U.S.C. 551–559; 21 U.S.C. 301–399f.

■ 4. In part 800, add § 800.75 to subpart C to read as follows:

§ 800.75 Requests for supervisory review of certain decisions made by the Center for Devices and Radiological Health.

(a) The following definitions shall apply to this section:

(1) *FDA* means the Food and Drug Administration.

(2) *517A decision* means a significant decision made by the Center for Devices and Radiological Health, as set forth in section 517A of the Federal Food, Drug, and Cosmetic Act, and includes one of the following decisions:

(i) A substantially equivalent order under § 807.100(a)(1) of this chapter, or a not substantially equivalent order under § 807.100(a)(2) of this chapter;

(ii) An approval order under § 814.44(d) of this chapter, an approvable letter under § 814.44(e) of this chapter, a not approvable letter under § 814.44(f) of this chapter, or an order denying approval under § 814.45 of this chapter;

(iii) An approval order under § 814.116(b) of this chapter, an approvable letter under § 814.116(c) of this chapter, a not approvable letter under § 814.116(d) of this chapter, or an order denying approval under § 814.118 of this chapter;

(iv) A grant or denial of a request for breakthrough device designation under section 515C of the Federal Food, Drug, and Cosmetic Act;

(v) An approval order under § 812.30(a) of this chapter or a disapproval order under § 812.30(c) of this chapter;

(vi) A failure to reach agreement letter under section 520(g)(7) of the Federal Food, Drug, and Cosmetic Act; or

(vii) A clinical hold determination under section 520(g)(8) of the Federal Food, Drug, and Cosmetic Act.

(3) *CDRH* means the Center for Devices and Radiological Health.

(b) Submission of request.

(1) Review of 517A decisions.

(i) An initial or sequential request for supervisory review within CDRH of a 517A decision under § 10.75 of this chapter must be addressed to the next organizational level or higher above the individual who made the decision; submitted in electronic format in accordance with section 745A(b) of the Federal Food, Drug, and Cosmetic Act; marked ''Appeal: Request for Supervisory Review;'' and received by CDRH no later than 30 days after the date of the decision involved. Any such request for supervisory review not received by CDRH within 30 days after the date of the decision involved is not eligible for review. Except as provided in paragraph (b)(1)(ii) or (iii) of this section, FDA will render a decision within 45 days of the request for supervisory review.

(ii) A person requesting supervisory review under paragraph (b)(1)(i) may request an in-person meeting or teleconference with the supervisor reviewing the request for supervisory review. Except as provided in paragraph (b)(1)(iii) of this section, if a request for in-person meeting or teleconference is included in the request for supervisory review to CDRH, CDRH will schedule the meeting or teleconference to occur within 30 days of receipt of the request. Except as provided in paragraph (b)(1)(iii) of this section, a decision will be rendered within 30 days of such meeting or teleconference.

(iii) The timeframes for CDRH to render a decision provided in (b)(1)(i) and (ii), and the timeframe to schedule an in-person meeting or teleconference review in (b)(1)(ii) of this section do not apply, if a matter related to the 517A decision under review is referred by CDRH to external experts, such as an advisory committee, as provided in § 10.75(b) of this chapter.

(2) An initial or sequential request for supervisory review within CDRH under § 10.75 of this chapter of a decision other than a 517A decision that is not received by CDRH within 60 days after the date of the decision involved will be denied as untimely, unless CDRH, for good cause, permits the request to be filed after 60 days. An initial or sequential request for supervisory review within CDRH of a decision other than a 517A decision must be addressed to the next organizational level or higher above the individual who made the decision; submitted in electronic format in accordance with section 745A(b) of the Federal Food, Drug, and Cosmetic Act, when applicable; marked, ''Appeal: Request for Supervisory Review'' in the subject line of the electronic request; and sent to the CDRH Ombudsman at *CDRHOmbudsman@fda.hhs.gov.*

Dated: January 10, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–00646 Filed 1–16–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. FDA–2017–N–0763]

RIN 0910–AH43

Food Labeling: Health Claims; Soy Protein and Coronary Heart Disease; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the comment period for the proposed rule that appeared in the **Federal Register** of October 31, 2017. We are taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the proposed rule published on October 31, 2017 (82 FR 50324). Submit either electronic or written comments by March 19, 2018.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before March 19, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of March 19, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, 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–N–0763 for ''Food Labeling: Health Claims; Soy Protein and Coronary Heart Disease.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff 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 *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. 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: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Crystal Rivers, Center for Food Safety and Applied Nutrition (HFS–830), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1444.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 31, 2017, FDA published a proposed rule to revoke our regulation authorizing the use of health claims on the relationship between soy protein and coronary heart disease on the label or in the labeling of foods. We proposed this action based on our review of the totality of publicly available scientific evidence currently available and our tentative conclusion that such evidence does not support our previous determination that there is significant scientific agreement among qualified experts for a health claim regarding the relationship between soy protein and reduced risk of coronary heart disease. We provided a 75-day comment period for the proposed rule.

We have received requests for a 60-day extension of the comment period for the proposed rule. Each request conveyed concern that the current comment period does not allow sufficient time to develop a meaningful or thoughtful response to the proposed rule.

FDA has considered the requests and is extending the comment period for the proposed rule until March 19, 2018. We believe that this extension allows adequate time for interested persons to submit comments without significantly delaying rulemaking on these important issues.

Dated: January 11, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–00683 Filed 1–12–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2017–1058]

RIN 1625–AA00

Safety Zone; Lower Mississippi River, New Orleans, LA

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish two temporary safety zones for multiple locations and dates within the Captain of the Port Sector New Orleans Zone. These safety zones are necessary to protect persons and vessels from potential safety hazards associated with fireworks displays on or over navigable waterways. Entry into these zones is prohibited unless specifically authorized by the Captain of the Port Sector New Orleans (COTP) or a designated representative. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before March 19, 2018.

ADDRESSES: You may submit comments identified by docket number USCG–2017–1058 using the Federal eRulemaking Portal at *http://www.regulations.gov.* See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email Lieutenant Commander (LCDR) Howard Vacco, Sector New Orleans, US Coast Guard; telephone 504–365–2281, email *Howard.K.Vacco@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port Sector New Orleans
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section

U.S.C. United States Code

II. Background, Purpose, and Legal Basis

The Coast Guard proposes to establish temporary safety zones for the following fireworks displays:

(1) On November 7, 2017, the New Orleans Tourism & Marketing Corporation notified the Coast Guard that it would be conducting a fireworks display from 7:45 p.m. through 8:45 p.m. on May 25, 2018. The fireworks are to be launched from a barge on the Lower Mississippi River at approximate mile marker (MM) 95.9, above Head of Passes, New Orleans, LA.

(2) On March 14, 2017, the NOLA 2018 Foundation notified the Coast Guard that it would be conducting a fireworks display from 8 p.m. through 8:20 p.m. on May 6, 2018. The fireworks are to be launched from a barge on the Lower Mississippi River at approximate MM 95.4, above Head of Passes, New Orleans, LA.

The purpose of this rulemaking is to ensure the safety of vessels on the navigable waters within a one-mile range of the fireworks barge before, during, and after the scheduled event. The Coast Guard proposes this rulemaking under authority in 33 U.S.C. 1231.

III. Discussion of Proposed Rule

The COTP proposes to establish two temporary safety zones within the Captain of the Port Sector New Orleans (COTP) Zone on two different dates and locations. Both safety zones will encompass a one-mile stretch of river with a duration lasting no more than one hour. The duration of the zones is intended to ensure the safety of vessels on these navigable waters before, during, and after the scheduled fireworks displays. No vessel or person would be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative. The proposed zones are as follows:

(1) Bayou Country Music Fest: a safety zone from 7:45 p.m. through 8:45 p.m. on May 25, 2018. The safety zone would cover all navigable waters of the Lower Mississippi River between MM 95.4 and MM 96.4, above Head of Passes.

(2) NOLA Tricentennial 2018 Jazz and Heritage Fest: A safety zone from 8 p.m. through 9 p.m. on May 6, 2018. This safety zone would cover all navigable waters of the Lower Mississippi River between MM 95 and MM 96, above Head of Passes.

IV. Regulatory Analyses

We developed this proposed rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 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. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This NPRM has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, the NPRM has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the size and short duration of the waterway closure, which would remain in effect for one hour on a one-mile section of the waterway. In addition, vessel traffic seeking to transit the areas would be able to seek permission from the COTP or his designated representative to do so.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section IV.A above, this proposed rule would not have a significant economic impact on any vessel owner or operator.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this proposed rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this proposed rule does not have tribal implications under Executive Order 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. If you believe this proposed rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

E. 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 proposed rule would not result in such an expenditure, we do discuss the

effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this proposed rule under Department of Homeland Security Management Directive 023–01, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and 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. This proposed rule involves two safety zones lasting one hour that would prohibit entry within a one-mile section of the Lower Mississippi River. They are categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 01. A preliminary Record of Environmental Consideration supporting this determination is available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

G. Protest Activities

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

V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking, and 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.

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, visit *http://www.regulations.gov/privacyNotice.*

Documents mentioned in this NPRM as being available in the docket, and all public comments, will be in our online docket at *http://www.regulations.gov* and can be viewed by following that website'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.

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T08–1058 to read as follows:

§ 165.T08–1058 Safety Zones; Lower Mississippi River, New Orleans, LA

(a) *Safety Zones.* The following areas are a safety zone:

(1) Bayou Country Music Fest, New Orleans, LA.

(i) *Location:* All navigable waters of the Lower Mississippi River between mile marker (MM) 95.4 and MM 96.4, above Head of Passes.

(ii) *Effective Period:* This rule is effective from 7:45 p.m. through 8:45 p.m. on May 25, 2018.

(2) NOLA Tricentennial 2018 Jazz and Heritage Fest.

(i) *Location:* All navigable waters of the Lower Mississippi River between mile marker (MM) 94 and MM 95, above Head of Passes.

(ii) *Effective Period:* This rule is effective from 8 p.m. through 9 p.m. on May 6, 2018.

(b) *Regulations.* (1) In accordance with the general regulations in § 165.23 of this part, entry into these zones is prohibited unless specifically authorized by the Captain of the Port Sector New Orleans (COTP) or a designated representative. A designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard assigned to units under the operational control of USCG Sector New Orleans.

(2) Vessels requiring entry into this safety zone must request permission from the COTP or a designated representative. They may be contacted on VHF–FM Channel 16 or 67.

(3) Persons and vessels permitted to enter these safety zones must transit at their slowest safe speed and comply with all lawful directions issued by the COTP or the designated representative.

(c) *Information broadcasts.* The COTP or a designated representative will inform the public through Broadcast Notices to Mariners of any changes in the planned schedule.

Dated: January 11, 2018.

Wayne R. Arguin,

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

[FR Doc. 2018–00652 Filed 1–16–18; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900–AP02

Civilian Health and Medical Program of the Department of Veterans Affairs

AGENCY: Department of Veterans Affairs.

ACTION: Proposed rule.

SUMMARY: The Department of Veterans Affairs (VA) proposes to amend its regulations governing the Civilian Health and Medical Program of the Department of Veterans Affairs (CHAMPVA). The proposed revisions would clarify and update these regulations to conform to changes in law and policy that control the administration of CHAMPVA and would include details concerning the administration of CHAMPVA that are not reflected in current regulations. The proposed revisions would also expand covered services and supplies to include certain preventive services and eliminate cost-share amounts and deductibles for certain covered services.

DATES: Written comments must be received on or before March 19, 2018.

ADDRESSES: Written comments may be submitted through *http://www.Regulations.gov;* by mail or hand-delivery to the Director, Regulation and Policy Management (00REG), Department of Veterans Affairs, 810 Vermont Avenue NW, Room 1068, Washington, DC 20420; or by fax to (202) 273–9026. Comments should indicate that they are submitted in

response to ''RIN 2900–AP02, Civilian Health and Medical Program of the Department of Veterans Affairs.'' Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1063B, between the hours of 8:00 a.m. and 4:30 p.m. Monday through Friday (except holidays). Please call (202) 461–4902 for an appointment. (This is not a toll-free number.) In addition, during the comment period, comments may be viewed online through the Federal Docket Management System at *http://www.Regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Joseph Duran, Director, Policy and Planning, Office of Community Care (OCC), 3773 Cherry Creek North Drive, Denver, Colorado 80209, *Joseph.Duran2@va.gov,* (303) 370–1637. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: The Civilian Health and Medical Program of the Department of Veterans Affairs (CHAMPVA) is a health benefits program in which the Department of Veterans Affairs (VA) shares the cost of covered medical care services and supplies with spouses, children, survivors, and certain caregivers of veterans who meet eligibility criteria under 38 U.S.C. 1781. CHAMPVA beneficiaries must not be eligible for TRICARE, a health care program administered by the Department of Defense (DoD) that is also authorized to provide health care to certain family members of veterans. Certain Primary Family Caregivers designated under 38 U.S.C. 1720G(a)(7)(A) are eligible under section 1781 as long as they are not entitled to services under a health-plan contract as that term is defined in 38 U.S.C. 1725(f).

Under section 1781, VA ''shall provide for medical care in the same or similar manner and subject to the same or similar limitations as medical care is furnished to certain dependents and survivors of active duty and retired members of the Armed Forces under chapter 55 of title 10 [United States Code] (CHAMPUS).'' 38 U.S.C. 1781(b). CHAMPUS was the original program administered by DoD to provide civilian health benefits for active duty military personnel, military retirees, and their dependents. 32 CFR 199.1. Although the CHAMPUS program is still referenced in DoD regulations, DoD effectively replaced the CHAMPUS program with what is commonly known as the ''TRICARE Standard'' plan (''TRICARE''). See 32 CFR 199.1(r), 199.17(a)(6)(ii)(C) (identifying ''TRICARE Standard'' as the basic CHAMPUS program). TRICARE's current benefit structure offers varying degrees of medical benefits under multiple plan options beyond its Standard plan, but we administer CHAMPVA in the same or similar manner as TRICARE Standard only, because that basic program is the one that is referenced by the CHAMPUS authority. Thus, all references in this rulemaking to ''TRICARE'' are to the TRICARE Standard plan, which we refer to simply as ''TRICARE'' throughout most of this rulemaking for ease of reference.

VA interprets the mandate in 38 U.S.C. 1781(b) to administer CHAMPVA in the ''same or similar manner . . . as medical care is furnished . . . under title 10 chapter 55 (CHAMPUS)'' to mean that we must generally administer CHAMPVA in a ''same or similar manner'' as the TRICARE Standard plan. The phrase ''same or similar manner'' does not require the programs to be administered in an identical manner. Rather, we broadly interpret this language as affording us needed flexibility to administer the program for CHAMPVA beneficiaries. For this reason, not every aspect of CHAMPVA will find a corollary in the TRICARE Standard Plan.

TRICARE has undergone changes in legal authority and policy that have prompted these proposed revisions to our CHAMPVA regulations. This rulemaking is intended to ensure that our regulations continue to be, again broadly speaking, the same or similar to the regulations and policies governing TRICARE. As noted throughout this proposed rule, there are necessary variations from TRICARE, particularly due to TRICARE's current benefit structure with varying degrees of medical benefits under multiple plan options, but we believe these variations satisfy the same or similar requirement in 38 U.S.C. 1781(b).

This rulemaking also proposes clarifications and revisions that will improve our ability to effectively administer CHAMPVA, as well as technical revisions to make our regulations more understandable.

17.270 General Provisions and Definitions

Current § 17.270(a) broadly discusses general administrative provisions of CHAMPVA, and current § 17.270(b) establishes certain definitions for the CHAMPVA regulations. We would revise the title of § 17.270 to clearly indicate that it contains both general provisions as well as definitions and would revise and reorganize the current definitions as well as add new definitions. Finally, we would add a new paragraph (c) to permit VA to waive, under certain circumstances, any requirements in the CHAMPVA regulations that are not otherwise required by statute, as is allowed under TRICARE. See 32 CFR 199.1(n). Waiver would be limited to very unusual and limited circumstances when waiver was determined to be in the best interests of VA; would not set a precedent for future decisions; and would not be used to deny any individual any right, benefit, or privilege provided to him or her by statute or these regulations.

Proposed § 17.270(a) would continue to provide an overview of CHAMPVA, including a general summary of the manner in which CHAMPVA is administered. We would refer to CHAMPUS, as we do in the current regulation, but would also reference TRICARE because the reference to CHAMPUS is outdated, as explained above, and may be misunderstood by CHAMPVA beneficiaries. Current § 17.270(a) states that CHAMPVA is administered by the ''Health Administration Center'' (HAC) (referred to now as the Office of Community Care (OCC)), which is located in Denver, Colorado. We propose to delete this statement because that fact is not substantively relevant to the regulations. These revisions are not substantively different from current § 17.270(a).

Proposed § 17.270(a)(1) would state that an authorized non-VA provider may provide medical services and supplies that are covered by CHAMPVA. This is current practice and would reflect in regulation VA's authority to provide CHAMPVA-covered services and supplies under 38 U.S.C. 1781(b)(2). As explained in greater detail below in connection with proposed § 17.272(b)(3), CHAMPVA-covered services and supplies are those provided by authorized non-VA providers who agree to provide covered services and supplies to CHAMPVA beneficiaries in exchange for payment of the CHAMPVA determined allowable amount. Proposed § 17.270(a)(2) would also reference VA's alternate authority under section 1781(b) to provide medical care to CHAMPVA beneficiaries through VA medical facilities equipped to provide the care and services if such resources are not being used for the care of eligible veterans. This initiative is called the CHAMPVA In-house Treatment Initiative (CITI) and would be referenced as such in proposed § 17.270(a)(2). CITI affords beneficiaries the same medical services available to veterans. CITI claims submitted to OCC are processed in the same manner as all other CHAMPVA claims. However, a monthly transfer of funds, or Transfer

Dispersing Authority (TDA), from OCC to the providing VA facility is used to reimburse CITI claims whereas electronic funds transfer or paper checks are used to reimburse beneficiaries and providers for non-CITI claims.

With regards to CHAMPVA beneficiaries receiving care in VA medical facilities through CITI, we have historically interpreted section 1781(b) to mean that such care may be provided only if the CHAMPVA beneficiary is not also eligible for Medicare benefits. We base this interpretation on the fact that CHAMPVA has always been the last payer for CHAMPVA-covered medical services and supplies when a CHAMPVA beneficiary has Medicare (included in this rulemaking's definition of ''other health insurance'' (OHI), see 38 U.S.C. 1781(d)(2)). The mandated coordination of benefits found in section 1781(d)(2) is essentially the same as the requirement in TRICARE codified at 32 CFR 199.8, which provides that if a TRICARE beneficiary is eligible for both Medicare and TRICARE, Medicare is the primary payer and TRICARE is the secondary payer. In addition, this policy limitation for CITI is reasonable because VA is a publicly funded health care system that cannot bill Medicare (see section 1814(c) and section 1835(d) of the Social Security Act, codified at 42 U.S.C. 1395f(c) and 1395n(d)). Moreover, Medicare is an entitlement program, whereas the provision of CHAMPVA medical benefits is subject to the availability of appropriations which, for any given time period, might or might not be sufficient to cover all CHAMPVA-covered medical services and supplies in a VA medical facility. Requiring beneficiaries to use their Medicare benefits first accomplishes our goal of protecting all patients' access to care. Therefore, we would further clarify in proposed § 17.270(a)(2) that any CHAMPVA beneficiary who is also eligible for Medicare benefits may not receive medical services and supplies through CITI.

Proposed § 17.270(a)(3) would newly indicate in regulation that outpatient prescription medications may be provided to certain CHAMPVA beneficiaries through Medications by Mail (MbM), administered by VA. Proposed paragraph (a)(3)(i) would further provide that VA's MbM provides prescription medications through the mail to CHAMPVA beneficiaries who do not have any OHI that pays for prescriptions, including Medicare Part D. This restriction largely is consistent with TRICARE policy on the provision of medications by mail, except that TRICARE covers prescribed medications for beneficiaries with OHI in two instances: When the prescribed medication is not covered by the OHI or when the beneficiary's OHI prescription benefit has been exhausted. See TRICARE Pharmacy Program Handbook (October 2015), pages 18–19. CHAMPVA is unable to duplicate these two exceptions due to system limitations, meaning that CHAMPVA will only provide prescription medications through the mail to beneficiaries who do not have any OHI prescription coverage. Despite this, CHAMPVA's inclusion of prescription medications is, broadly speaking, sufficiently similar to TRICARE that VA remains in substantial compliance with the requirements of section 1781(b).

Proposed paragraph (a)(3)(ii) would provide that smoking cessation pharmaceutical supplies are available only through MbM. Section 713 of the Duncan Hunter National Defense Authorization Act for Fiscal Year 2009, Public Law 110–417 (October 14, 2008) (''2009 NDAA'') required DoD to establish a smoking cessation program under TRICARE under which specified smoking cessation benefits are to be made available to beneficiaries who are not also eligible for Medicare. This TRICARE benefit is codified at 32 CFR 199.4(e)(30). As to the pharmaceutical component of this TRICARE benefit, smoking cessation pharmaceutical agents (which VA refers to as pharmaceutical supplies) are available only through Military Treatment Facility (MTF) pharmacies or the TRICARE Mail Order Program. See 32 CFR 199.4(e)(30)(ii)(A) and 199.21(h)(2)(iii). Similar to 32 CFR 199.4(e)(30)(i), proposed § 17.270(a)(3)(ii) would provide that the same smoking cessation supplies will be made available to CHAMPVA beneficiaries who are not eligible for Medicare. Additionally, smoking cessation pharmaceutical supplies would be available only through MbM. For purposes of CITI, we would not provide smoking cessation pharmaceutical supplies through VA facility pharmacies because it is administratively more efficient for CHAMPVA to provide these through MbM, and because, in complying with the requirements of section 1781(b), as discussed above, VA facility pharmacies would be required to administer any needed smoking cessation pharmaceutical supplies first to veterans before providing them to CHAMPVA beneficiaries. We would also remove the restriction on smoking cessation services and supplies in current § 17.272(a)(57), as discussed later in this proposed rule.

For clarity, we would establish abbreviations for the Civilian Health and Medical Program of the Department of Veterans Affairs as ''CHAMPVA'' and the Department of Veterans Affairs as ''VA.'' The current regulations refer to the part of VA that administratively handles CHAMPVA claims as the ''Center'' in several places (see current §§ 17.275–17.277), and to the ''Health Administration Center'' in other places (see current §§ 17.270, 17.275–17.276), and we believe that referring to ''VA'' is more appropriately descriptive and would eliminate ambiguity.

Proposed § 17.270(b) would establish definitions for the CHAMPVA regulations. We would define ''accepted assignment'' as the action of an authorized non-VA provider who accepts responsibility for the care of a CHAMPVA beneficiary and thereby agrees to accept the CHAMPVA determined allowable amount as full payment for services and supplies rendered to the beneficiary. This extinguishes the beneficiary's payment liability to the provider with the exception of applicable cost shares and deductibles. This definition is consistent with our explanation for proposed § 17.272(b)(3), which further outlines the necessity for defining ''accepted assignment.'' Our current regulations do not define the term ''authorized provider,'' but the term ''authorized provider'' (and variations thereof) is used throughout current § 17.272 to refer to an institutional or individual provider of CHAMPVA-covered services and supplies. The term is used to describe persons or institutions that are considered appropriately licensed or credentialed to competently provide medical services and supplies to CHAMPVA beneficiaries and that VA will pay to provide such services and supplies. In addition, an ''authorized provider'' has historically been interpreted in CHAMPVA to be a non-VA medical provider. To capture this historical interpretation in full, we would define an ''authorized non-VA provider'' to mean an individual or institutional non-VA provider of CHAMPVA-covered medical services and supplies who is licensed or certified by a State to provide the covered medical services and supplies, or is otherwise certified by an appropriate national or professional association that sets standards for the specific medical provider. This requirement for State licensure or other certification would be similar to TRICARE, which requires that its providers be either licensed or

certified by a State, or, where States do not offer licensure or certification, be otherwise certified by an appropriate national or professional association that sets standards for the specific medical provider. See TRICARE Policy Manual 6010.60–M, Chapter 11 (''Providers''), section 3.2 (''State Licensure And Certification''). (For general operational-type information, one can also refer to TRICARE Operations Manual 6010.59–M, Chapter 4, (''Provider Certification And Credentialing'') (April 1, 2015).)

We would define ''calendar year'' as the period of time between and including January 1 through December 31. This is plain language and is consistent with the generally understood meaning of the phrase ''calendar year.''

The term ''CHAMPVA beneficiary'' would be defined as a person enrolled for CHAMPVA under § 17.271. This would be a program-specific definition, but it is in plain language and is consistent with the generally understood meaning of the word ''beneficiary.'' To clarify, an individual is enrolled in CHAMPVA only after the individual has successfully completed the application process (*i.e.,* where the individual submits a completed VA Form 10–10d to VA, and VA has confirmed the individual's eligibility).

We would define ''CHAMPVA-covered services and supplies'' to mean those medical services and supplies that are medically necessary and appropriate for the treatment of a condition and that are not specifically excluded from coverage under proposed § 17.272(a)(1) through (84) (current § 17.272(a)(1) through (86)).

We would define ''CHAMPVA determined allowable amount'' by referencing the proposed paragraph that would relate to this term, proposed § 17.272(b)(1).

We would define ''CHAMPVA In-house Treatment Initiative (CITI)'' to mean the initiative under section 1781(b) under which participating VA medical facilities provide medical services and supplies to CHAMPVA beneficiaries who are not also eligible for Medicare, subject to availability of space and resources.

We would define the term ''child'' consistent with 38 U.S.C. 101, as we do in the current regulation at § 17.270(b).

We would define the term ''claim'' consistent with the current use and understanding of the term in the context of CHAMPVA, as a request by an authorized non-VA provider or CHAMPVA beneficiary for payment or reimbursement for medical services and supplies provided to a CHAMPVA beneficiary.

We would define ''fiscal year'' as the period of time starting on October 1 and ending on September 30. This is plain language and is consistent with the generally understood meaning of the phrase ''fiscal year'' as used within the Federal Government.

We would define ''Medications by Mail (MbM)'' to mean the initiative under which VA provides outpatient prescription medications through the mail to CHAMPVA beneficiaries.

We would define ''other health insurance'' (OHI) as a health insurance plan or program (to include Medicare) or third-party coverage that provides coverage to a CHAMPVA beneficiary for expenses incurred for medical services and supplies. The inclusion of Medicare is consistent with the TRICARE regulation related to double coverage. See 32 CFR 199.8(d)(1).

We would define the term ''payer'' to mean OHI, as defined in this rulemaking, that is obligated to pay for CHAMPVA-covered medical services and supplies. In a situation in which more than one insurer is responsible to pay for such services and supplies (*e.g.,* a ''double coverage'' situation), there would be a primary payer (*i.e.,* the payer obligated to pay first), a secondary payer (*i.e.,* the payer obligated to pay after the primary payer), etc. In double coverage situations, CHAMPVA would be the last payer, after payment by the primary payer and all other secondary payers.

Defining a ''payer'' and designating different payer types would not affect the administration of CHAMPVA because these concepts of relative payment responsibility are all accepted and understood by the insurance industry and current CHAMPVA beneficiaries and are an essential part of current CHAMPVA billing practices. For instance, Medicare would be the primary payer in situations governed by current § 17.271(b) (which remains unchanged by this proposed rulemaking). See 38 U.S.C. 1781(d)(2).

The definition of ''service-connected'' in current § 17.270(b) would be unchanged and given the same meaning as that term in 38 U.S.C. 101. However, the terms ''spouse'' and ''surviving spouse'' would no longer have the definitions of these same terms in 38 U.S.C. 101(31) and (3), respectively, as those definitions are outdated; instead, these terms would both be determined by operation of 38 U.S.C. 103(c).

Consistent with the waiver provisions of TRICARE, see 32 CFR 199.1(n), new proposed paragraph (c) would establish the discretionary authority of VA to waive, when it is deemed to be in the best interest of VA, any regulatory requirement of this part that is not required by 38 U.S.C. 1781 or otherwise imposed by statute. This discretionary waiver authority would be limited to very unusual and limited circumstances and would not set a precedent for future decisions. In addition, it would not be used to deny any individual any right, benefit, or privilege provided by statute or these regulations. This new provision would enable VA to allow payment under CHAMPVA in cases, for example, where, by operation of CHAMPVA rules, the claim is subject to complex administrative or accounting procedures that ultimately result in determination of the claim's technical noncompliance when the underlying claim is otherwise appropriate. Where a claimant's non-compliance with a purely policy or administrative-based technical requirement is both unintentional and harmless, we believe it would be in VA's best interest to have the authority to waive the regulatory requirement and allow payment.

17.271 Eligibility

Current § 17.271 identifies persons who may be eligible for CHAMPVA benefits. We would revise § 17.271(a) to recognize as CHAMPVA beneficiaries those individuals designated as Primary Family Caregivers under 38 CFR 71.25(f). This substantive addition to the eligibility criterion would be made pursuant to the Caregivers and Veterans Omnibus Health Services Act of 2010, Public Law 111–163, section 102, which amended 38 U.S.C. 1781(a) by adding a new subsection (a)(4) authorizing VA to provide CHAMPVA benefits to ''an individual designated as a primary provider of personal care services under [38 U.S.C. 1720G(a)(7)(A)] who is not entitled to care or services under a health-plan contract (as defined in [38 U.S.C. 1725(f)]).'' We amend CHAMPVA eligibility criteria to recognize these Primary Family Caregivers as CHAMPVA beneficiaries but not to establish substantive eligibility rules in the CHAMPVA regulations to determine whether an individual is a Primary Family Caregiver. (VA's regulations governing the Caregivers Benefits Program established by 38 U.S.C. 1720G are codified at 38 CFR part 71, and the specific rules governing the identification of such individuals are found at 38 CFR 71.15 through 71.25.) We would redesignate current § 17.271(a)(4) as § 17.271(a)(5) and add a new proposed § 17.271(a)(4) to state that a Primary Family Caregiver is eligible for CHAMPVA benefits if they are not entitled to care or services under a health-plan contract (as defined in 38 U.S.C. 1725(f)(2)). We note that VA is already providing CHAMPVA services

and supplies to these individuals pursuant to the statutory mandate in section 1720G(a)(3)(A)(ii)(IV) and under the Caregivers Benefits Program regulations. This revision would simply update the CHAMPVA regulations to conform to these laws.

17.272 Benefits Limitations/Exclusions

Current § 17.272 provides general information about what medical services and supplies are covered by CHAMPVA and lists coverage limitations along with the exclusions. The general information concerning coverage in current § 17.272(a) continues to be accurate, and we do not propose any changes to paragraph (a). Some of the coverage limitations and exclusions listed in the numbered paragraphs under § 17.272(a) require revision due to either changed standards in clinical practice or changes in TRICARE coverage.

Current § 17.272(a)(2) excludes the provision of services and supplies required as a result of an occupational disease or injury for which benefits are payable under workers' compensation or a similar protection plan. We propose to update the verbiage to clarify the exclusion for the reader.

Current § 17.272(a)(3) excludes the provision of services and supplies that are paid directly or indirectly by local, State, or Federal government agencies, with certain exceptions listed in § 17.272(a)(3)(i) and (ii) where CHAMPVA assumes primary payer status. We propose to add Indian Health Service and CHAMPVA supplemental policies as exceptions where CHAMPVA assumes primary payer status. This would be consistent with current CHAMPVA practice as well as the TRICARE regulation related to double coverage. See 32 CFR 199.8(b)(4)(ii) and (iv). We also propose to remove the ''(Medicaid excluded)'' parenthetical language in current § 17.272(a)(3), because § 17.272(a)(3)(i) already expressly excepts ''Medicaid'' from the general exclusion in § 17.272(a)(3).

Current § 17.272(a)(21) excludes dental care generally, with exceptions to such exclusion listed in paragraphs (a)(21)(i) through (xii). We would amend paragraph (a)(21)(ix) to clarify that the provision of initial imaging services for the treatment of temporomandibular joint disorder (TMD) could specifically include Computed Tomography (CT) and Magnetic Resonance Imaging (MRI) services. We believe the sole reference to ''initial radiographs'' in current § 17.272(a)(21)(ix) is outdated and that modern industry standards include the use of CT scans as well as MRIs for diagnosing TMD. A CT scan provides a more detailed image of the bones in the joint, and an MRI provides a more detailed image of the soft tissue to determine proper positioning as the jaw moves. We would also update § 17.272(a)(21)(ix) to refer to the more updated and clinically appropriate terminology ''temporomandibular joint disorder (TMD).'' These revisions would update CHAMPVA regulations with current standards of clinical practice for the benefit of CHAMPVA beneficiaries.

A majority of the remaining proposed changes to CHAMPVA coverage exclusions in proposed § 17.272(a)(1) through (82) are based on changes to TRICARE coverage and policy. Virtually all coverage limitations and exclusions in current § 17.272(a)(1)–(86), as shown in the chart below, are substantially identical to services and supplies excluded from, or limited under, TRICARE coverage under 32 CFR 199.4(g), or as otherwise noted in the chart.

LIST OF COMPARABLE CHAMPVA AND TRICARE EXCLUSIONS

CHAMPVA provision (identified paragraphs are from 38 CFR 17.272(a))	TRICARE provision (identified paragraphs are from 32 CFR 199.4(g), or as otherwise noted)
(1)	(11).
(2)	(23).
(3)	(13).
(4)	(1).
(5)	(2).
(6)	(3).
(7)	(4).
(8)	(5).
(9)	(6).
(10)	(7).
(11)	(8).
(12)	(9).
(13)	(14).
(14), (81)	(15).
(15)	(16).
(16)	(17).
(17)	(19).
(18)	(21).
(19), (82)	(24).
(20)	(26).
(21)	(27).
(22)	(28).
(23)	(29).
(24)	(30).
(25)	(31).
(27)	(33).
(28)	(34).
(29)	(35).
(30)	(36).
(31)	(37).
(32)	(38).
(33)	(39).
(34)	(40).
(35)	(41).
(36)	(20), (42).
(37)	(43).
(38)	(44).
(40)	(46).
(41)	(47).
(42)	(50).
(43)	(51).
(44)	(48).
(45)	(49).

LIST OF COMPARABLE CHAMPVA AND TRICARE EXCLUSIONS—Continued

CHAMPVA provision (identified paragraphs are from 38 CFR 17.272(a))	TRICARE provision (identified paragraphs are from 32 CFR 199.4(g), or as otherwise noted)
(46)	(52).
(47)	(53).
(48)	(54).
(49)	(55).
(50)	(56).
(51)	(57).
(52)	(58).
(53)	(60).
(54)	(61).
(55), (57)	(62).
(56)	(64).
(57)	(65).
(58)	(66).
(59)	(67).
(60)	(72).
(62)	32 CFR 199.4(a)(12) and (b)(10)(iv).
(63) through (65)	32 CFR 199.4(e)(4) and (h).
(66)	(73).
(67), (68)	32 CFR 199.2(b) and 199.4(e)(2).
(69)	32 CFR 199.4(c)(3)(ix) and 199.4(e)(4).
(70), (71)	32 CFR 199.4(e)(17).
(73)	32 CFR 199.4(g)(15)(iv).
(74)	(69).
(75)	32 CFR 199.4(a)(1).
(76)	32 CFR 199.4(g)(74).
(77)	(39), (42).
(78)	(25).
(79)	32 CFR 199.4(g)(15).
(80)	32 CFR 199.2(b) and 199.4(b)(2)(v), (b)(3)(iii), (b)(5)(v), (d)(3)(vi), (e)(11)(i).
(83)	32 CFR 199.4(c)(2), (c)(3), (e)(8)(i)(E).
(84)	32 CFR 199.4(e)(8).
(85), (86)	32 CFR 199.2(b), 199.4(e)(8), (g)(24).

We note that even where our current provisions are not identical to a TRICARE provision, our intent has consistently been to apply CHAMPVA comparable exclusions or limitations in the same or similar manner to their TRICARE counterpart in accordance with 38 U.S.C. 1781(b). The same is true for our proposed revisions below, which are consistent with changes in DoD's administration of TRICARE.

The first change we would make to our limitations and exclusions based on TRICARE regulatory and policy changes concerns current § 17.272(a)(26), which is not addressed in the chart above because it correlates with a provision that has been removed from TRICARE regulations. See 60 FR 12419 (March 7, 1995). Therefore, we propose to remove this exclusion from our regulations as well. Paragraph (a)(26) in current § 17.272 excludes coverage for services and supplies, including psychological testing, provided in connection with a specific developmental disorder. By removing this exclusion, CHAMPVA would now cover this service, and we would redesignate current

§ 17.272(a)(27) through (38) as § 17.272(a)(26) through (37), respectively.

Under section 711 of the 2009 NDAA, TRICARE must waive all beneficiary costs associated with certain preventive services, unless the beneficiary is also Medicare-eligible. TRICARE regulations were revised to delete from 32 CFR 199.4(g)(37) the list of preventive services not excluded from coverage, and these services were moved to new § 199.4(e)(28) so that they instead would be reflected as preventive services under TRICARE for which out-of-pocket costs are eliminated. See 76 FR 81368 (December 28, 2011). We would revise our current exclusion of preventive care in § 17.272(a)(31) (proposed to be redesignated as § 17.272(a)(30)) to except the same preventive services identified in paragraphs (d)(1)(A) through (F) of section 711 of the 2009 NDAA and, further, do so in a manner that, on the whole, reflects the manner in which these services are provided under TRICARE. Section 711 of the 2009 NDAA sets forth the following preventive services for which beneficiaries shall pay no associated costs: Colorectal cancer screening; breast cancer screening; cervical cancer screening; prostate cancer screening; annual physical exam; vaccinations. Current § 17.272(a)(31)(i) through (x) set forth exceptions to the general exclusion of certain specific preventive care. Respectively, the terms of current paragraphs (a)(31)(v) and (vi) already except ''[p]ap smears'' and ''[m]ammography tests'' and so effectively capture ''cervical cancer screening'' and ''breast cancer screening'' as referred to in the 2009 NDAA. However, because the singular terms ''mammography test'' and ''pap smear'' are outdated, we are updating to ''breast cancer screening'' and ''cervical cancer screening.'' Therefore, proposed § 17.272(a)(30) would revise the exceptions to the general exclusion of preventive care to include the four remaining preventive services specified in the 2009 NDAA, namely colorectal cancer screening; prostate cancer screening; annual physical examination; and vaccinations/immunizations.

We note that the TRICARE final rule that implemented the amendments made by section 711 of the 2009 NDAA does not include an annual physical exam benefit for all TRICARE beneficiaries; instead, such benefit is limited to certain dependents of Active Duty military personnel who are traveling outside the United States and for beneficiaries ages 5 through 11 who require such exams for school enrollment. This benefit is also not exempt from cost sharing requirements. See 76 FR 81368, and 32 CFR 199.4(e)(29). Broadly interpreting our mandate in section 1781(b), VA proposes to modify the current exclusion of preventive care in current § 17.272(a)(31) insofar as it defines that term to include annual physical examinations and create an exception permitting such exams. Despite the limited availability of such examinations under TRICARE, it is noteworthy that TRICARE nonetheless covers some preventive services that are typically provided as part of an annual physical examination such as blood pressure screening, cholesterol testing, and body measurements. See TRICARE Policy Manual 6010.60–M (''Medicine''), Chapter 7, section 2.1 (''Clinical Preventive Services-TRICARE Standard'') (April 1, 2015). To be paid for by TRICARE, however, these types of health promotion and disease prevention services must be billed in connection with another preventive service delineated in TRICARE's policy manual. Id. We do not believe limiting the provision of annual physical examinations to only a few select groups is appropriate from a clinical perspective. Further, in the exercise of our discretion, when broadly interpreting the mandate of section 1781(b), we conclude it lies within our discretion to determine that this benefit should be made available to all CHAMPVA beneficiaries. This is particularly the case given that some individual health promotion and disease prevention services that are typically provided as part of an annual physical examination would eventually be approved by TRICARE as long as they are coupled or associated with billing submitted for a covered service. (The nature and delivery of those services remains the same whether delivered as part of an annual examination or under the umbrella of another service for which TRICARE billing is permitted.) Furthermore, VA finds that annual physical examinations are beneficial for both CHAMPVA beneficiaries and VA, by serving to identify serious medical issues before they progress and their clinical management becomes more difficult and resource-intensive. Even though our proposed approach would include elements of an annual physical examination not otherwise included as an adjunct service provided under a covered benefit as described above, we believe our approach is sufficiently ''similar'' to TRICARE. Therefore, we propose to create an exception to the exclusion of preventive care, permitting an annual physical examination to be among the benefits available to all CHAMPVA beneficiaries.

We also note that we would except ''[v]accinations/immunizations'' from the general exclusion of preventive services. Although subsection (d)(1)(F) of section 711 of the 2009 NDAA exempts ''vaccination'' only, TRICARE's guidance on this issue additionally exempts immunizations. See TRICARE Reimbursement Manual 6010.61–M Chapter 2 (''Beneficiary Liability''), section 1 (''Cost-Shares And Deductibles'') (April 1, 2015). We believe these terms have identical meanings and would use both terms just to be clear that this preventive service is covered regardless of whether it is called an ''immunization'' or a ''vaccination.''

Current § 17.272(a)(39) excludes coverage for audiological services or speech therapy, except when prescribed by a physician and rendered as part of a treatment addressing a physical defect, which correlates with a provision not addressed in the chart above because it has been removed from TRICARE regulations. See 75 FR 50880 (August 18, 2010). Therefore, we propose to remove this exclusion from our regulations as well. By removing this exclusion, CHAMPVA would now cover this service, and we would redesignate current § 17.272(a)(40) through (56) as § 17.272(a)(38) through (54), respectively.

As stated earlier in this rulemaking, pursuant to section 713 of the 2009 NDAA, TRICARE must make available smoking cessation benefits, as specified in the law, to beneficiaries who are not also eligible for Medicare. The four categories of smoking cessation benefits available to these beneficiaries are set forth in TRICARE's regulations under 32 CFR 199.4(e)(30)(ii)(A)–(D). Hence, we would revise our regulations by removing our correlate restriction on smoking cessation services and supplies in current § 17.272(a)(57). In removing current § 17.272(a)(57), current paragraphs (a)(58) through (71) would be redesignated as paragraphs (a)(55) through (68), respectively.

Redesignated paragraphs (a)(57) through (59) would be revised to reference coverage of mental health benefits in a ''calendar year'' versus the current reference to ''fiscal year.'' We propose to change the yearly basis of this coverage because our beneficiaries and providers are more familiar with calendar year events, and the impact of the change from fiscal to calendar on the functioning of CHAMPVA would be minimal.

With the proposed removal of § 17.272(a)(57) and subsequent redesignations of paragraphs noted above, current paragraph (a)(67) would be redesignated as paragraph (a)(64). CHAMPVA would continue to exclude the performance of abortions, except when a physician certifies that the life of the mother would be endangered if the fetus were carried to term. This is the same restriction in current TRICARE regulations (see 32 CFR 199.4(e)(2)), although statute and TRICARE policy statements recently established an additional exception to the general ban on abortions. Specifically, section 704 of the National Defense Authorization Act for Fiscal Year 2013, Public Law 112–239 (2013 NDAA), amended 10 U.S.C. 1093(a) and (b) to expand the circumstances under which funds available to DoD and MTFs may be used to provide and perform abortions in cases of pregnancy resulting from an act of rape or incest. Despite the recent amendments to section 1093 of title 10 and TRICARE policy, we do not propose same or similar changes to CHAMPVA's current exclusion at this time because TRICARE regulations do not provide for it. Additionally, such changes would create an even greater disparity between the women's health care benefits afforded veterans and CHAMPVA beneficiaries.

Current § 17.272(a)(72) excludes from coverage drug maintenance programs where one addictive drug is substituted for another such as methadone substituted for heroin. A TRICARE final rule published on October 22, 2013, and effective November 21, 2013, removes a correlate restriction from TRICARE regulations, and so we propose to similarly remove § 17.272(a)(72). See 78 FR 62427 (October 22, 2013); 32 CFR 199.4(e)(4)(ii). We agree with the stated rationale in the related TRICARE proposed rule that the current restriction fails to recognize the accumulated medical evidence supporting certain maintenance programs as one component of the continuum of care necessary for the effective treatment of substance use disorders. See 76 FR 81899 (December 29, 2011). In removing current § 17.272(a)(72), current paragraphs (a)(73) through (86) would be redesignated as paragraphs (a)(69) through (82), respectively.

Current § 17.272(a)(80), as proposed to be redesignated as paragraph (a)(76), excludes from CHAMPVA benefits medications not requiring a prescription, except for insulin and related diabetic testing supplies and syringes. We would revise redesignated paragraph (a)(76) to instead exclude ''over-the-counter products'' and would additionally expand the exception to this exclusion to cover over-the-counter smoking cessation pharmaceutical supplies that are approved by the U.S. Food and Drug Administration (FDA), prescribed, and provided through MbM. These changes would be consistent with TRICARE regulations, which require a prescription from an authorized provider for smoking cessation pharmaceutical agents (even for FDA-approved over-the-counter smoking cessation agents). See 32 CFR 199.4(e)(30)(ii)(A).

Section 702 of the 2013 NDAA grants the Secretary of Defense the authority to add certain over-the-counter medications to the TRICARE formulary so that such medications may be administered as if they were prescription medications. CHAMPVA does not have a same or similar uniform formulary as DoD that could be altered to include certain over-the-counter medications, and we do not interpret section 702 as granting authority to alter VA's uniform formulary. Therefore, we would not amend our regulations in response to section 702 of the 2013 NDAA. Our regulation as revised and redesignated § 17.272(a)(76) would permit CHAMPVA to provide the same over-the-counter smoking cessation supplies as permitted in TRICARE policy.

Lastly, we would add two new exclusions to § 17.272. Proposed paragraph (a)(83) would exclude medications that are not approved by the FDA, excluding FDA exceptions to the approval requirement. Current CHAMPVA regulations are silent regarding the need for medications to meet FDA approval requirements; however, this has not been a problem as a matter of practice because applicable standards of care generally require prescribed medications to be FDA-approved or excluded as an exception from the approval requirement. Still, we wish to formally and expressly exclude medications that do not meet these requirements. In addition, to provide benefits in the same or similar manner and subject to the same or similar limitations as TRICARE, paragraph (a)(84) would establish exclusions for services and supplies related to the treatment of dyslexia. See 38 CFR 199.4(g)(32). This change merely reflects in regulation current CHAMPVA practice and policy.

Due to the multiple proposed deletions and additions in § 17.272(a)(1)–(86), we reiterate that we would redesignate most of the current paragraphs under § 17.272(a). With the proposed removal of current paragraph (a)(26), current paragraphs (a)(27) through (38) would be redesignated as (a)(26) through (37), respectively, with the substantive changes to redesignated (a)(30) as noted above. With the proposed removal of current paragraph (a)(39), current paragraphs (a)(40) through (56) would be redesignated as (a)(38) through (54), respectively, with no substantive changes. With the deletion of the current paragraphs (a)(57) and (72), current paragraphs (a)(58) through (86) would be redesignated as (a)(55) through (82), respectively, with the minor substantive changes as noted above to redesignated paragraphs (a)(57) through (59) and (a)(76). Lastly, we would add new paragraphs (a)(83) and (84).

Current § 17.272(b) establishes the ''CHAMPVA determined allowable amount,'' and paragraph (b)(1) states that the term ''allowable amount'' is the maximum amount that CHAMPVA will pay an authorized provider for a covered benefit, which is determined prior to cost sharing and the application of deductibles or OHI. (This means, for instance, that the cost-share would be a percentage of the entire CHAMPVA determined allowable amount.) However, this is merely a definition and not a statement of coverage limitation or exclusions. We would revise paragraph (b) to clearly indicate that amounts above the CHAMPVA determined allowable amount are excluded from CHAMPVA coverage. The actual payment methodology—the amount to which cost sharing and deductibles will be applied—is addressed in proposed § 17.274(e) and is discussed below.

Proposed § 17.272(b)(1) would explain that the CHAMPVA determined allowable amount is the maximum level of payment to an authorized non-VA provider for CHAMPVA-covered services and supplies and that this allowable amount is determined before cost sharing and the application of deductibles or OHI is considered. This is a restatement of current § 17.272(b)(1), except that we would use the term ''authorized non-VA provider'' to encompass all those providers listed in current § 17.272(b)(1) and include the term ''supplies'' after ''covered services'' to underscore they too can be covered. See current 38 CFR 17.272(b)(1) (referencing ''a hospital or other authorized institutional provider, a physician or other authorized individual professional provider, or other authorized provider for covered services''). We believe use of the one term ''authorized non-VA provider'' as defined in proposed § 17.270(b) properly captures all provider types now listed in § 17.272(b)(1) and

simplifies the regulatory reference to providers for the benefit of CHAMPVA beneficiaries. Proposed § 17.272(b)(1) would also clearly state that the CHAMPVA determined allowable amount is payment made by VA to an authorized non-VA provider for the provision of CHAMPVA-covered services and supplies to a CHAMPVA beneficiary.

Current § 17.272(b)(2) states that a Medicare-participating hospital must accept the CHAMPVA determined allowable amount for inpatient services as payment in full and references 42 CFR parts 489 and 1003. While this is a true statement of law under 42 CFR 489.25, the references to 42 CFR parts 489 and 1003 are vague, and part 1003 is not relevant to the issue of what amounts Medicare-participating hospitals must accept as payment in full from CHAMPVA. See 42 CFR part 1003 (describing civil money penalties, assessments, and exclusions generally for individuals who violate provisions of or agreements with Federal health care programs). Proposed § 17.272(b)(2) would state that inpatient services are ''provided to a CHAMPVA beneficiary'' and use a single, clarifying reference to 42 CFR 489.25.

Section 503 of The Caregivers and Veterans Omnibus Health Services Act of 2010, Public Law 111–163, revised 38 U.S.C. 1781 by adding new subsection (e), which states: ''Payment by the Secretary under this section on behalf of a covered beneficiary for medical care shall constitute payment in full and extinguish any liability on the part of the beneficiary for that care.'' Current § 17.272(b)(3) states that: ''An authorized provider of covered medical services or supplies must accept the CHAMPVA determined allowable amount as payment in full.'' Proposed § 17.272(b)(3) would state more clearly that ''accepted assignment'' refers to the action of an authorized non-VA provider who accepts responsibility for the care of a CHAMPVA beneficiary and thereby agrees to accept the CHAMPVA determined allowable amount as full payment for services and supplies rendered to the beneficiary. The provider's acceptance of the CHAMPVA determined allowable amount extinguishes the beneficiary's payment liability to the provider with the exception of applicable cost shares and deductibles. Proposed § 17.272(b)(3) would not be substantively different than current paragraph (b)(3) but would clarify that the action of accepting payment is the equivalent of accepting assignment. The term ''accepted assignment'' is used currently in the administration of CHAMPVA payments, and we believe using it in this regulation as described would increase clarity in payment practices for both CHAMPVA beneficiaries and authorized non-VA providers.

Current § 17.272(b)(4) provides that a provider who has collected and not made an appropriate refund, or attempts to collect from the beneficiary any amount in excess of the CHAMPVA determined allowable amount may be subject to exclusion from Federal benefit programs. The underlying authority for this rule is 42 CFR 1003.105, which establishes the terms for a health care provider's permissive or mandatory exclusion from participation in the Medicare program and other Federal health care programs. Exclusion may result, for instance, if a provider files false claims under these programs. We would move this information to proposed § 17.272(b)(3) for increased clarity and would remove mention of providers not making an appropriate refund of amounts collected from beneficiaries, as the purpose of 38 U.S.C. 1781(e) and proposed § 17.272(b)(3) is for these amounts to never be collected by the provider. By moving this information to proposed paragraph (b)(3), we would also remove current paragraph (b)(4).

17.273 Preauthorization

CHAMPVA preauthorization requirements for certain medical care and services are based on CHAMPVA needs and are substantially the same or similar as those required by TRICARE. See 32 CFR 199.4 *passim.* We propose to revise the preauthorization requirements by adding language to indicate when a beneficiary has ''other health insurance'' that provides primary coverage for the benefit, preauthorization requirements will not apply. TRICARE waives preauthorization requirements in all instances when OHI, to include Medicare, is the primary payer. See TRICARE Policy Manual 6010.60–M, Chapter 1 (''Administration''), section 6.1 (''Special Authorization Requirements'') (April 1, 2015). To provide benefits in a similar fashion, we would waive any requirement for preauthorization where OHI (as defined by this rulemaking) covers the benefit. We would also revise current § 17.273(d) to refer to dental coverage limitations in § 17.272(a)(21)(i)–(xii) to avoid a potential misconception that preauthorization is generally required for dental services. CHAMPVA clearly excludes all dental services, except for those listed in current § 17.272(a)(21)(i)–(xii). We would remove current § 17.273(e) and not require preauthorization for durable medical equipment as a covered service or supply. Removal of § 17.273(e) would be consistent with TRICARE policy. See TRICARE Policy Manual 6010.60–M, Chapter 8 (''Other Services''), section 2.1 (''Durable Medical Equipment: Basic Program'') (April 1, 2015). Based on this removal, we would redesignate current § 17.273(f) as § 17.273(e).

Finally, we would add new proposed § 17.273(f) to detail the reviews of medical necessity. Since CHAMPVA is a secondary payer, VA would be required to perform reviews of medical necessity on a retrospective basis. If during the coordination of benefits process it is determined that CHAMPVA would be the responsible payer for the services and supplies but CHAMPVA preauthorization was not obtained prior to delivery of the services or supplies, we would obtain the necessary information and perform a retrospective medical necessity review. We would also propose that any claims, where a retrospective review occurs, are filed within the appropriate one-year period.

17.274 Cost Sharing

Current § 17.274(a) provides in general that CHAMPVA is a cost sharing program in which the cost of CHAMPVA-covered services and supplies is shared with the beneficiary, with the exception of services obtained through VA medical facilities. This provision would remain substantively the same, but we would add new paragraphs (a)(1)(i) and (ii) to explicate, respectively, that the former language ''services obtained through VA facilities'' refers to services and supplies provided both through MbM and through CITI. That is, the exception to this cost-share requirement would extend specifically to each of these initiatives (as these initiatives would be defined by this proposed rulemaking).

Subsections (d)(1)(A) through (d)(1)(F) of section 711 of the 2009 NDAA, as discussed earlier, set forth certain preventive services for which TRICARE waives all out-of-pocket costs, even if the beneficiary has not paid the amount necessary to cover the beneficiary's deductible requirement for the year. We propose to revise § 17.274(a) to make clear that there will be no associated cost share for CHAMPVA beneficiaries for such services. (We address waiving the associated deductible requirement later in the discussion of proposed § 17.274(b)). We would add new paragraphs (a)(1)(iii)(A)–(G) to § 17.274 to waive CHAMPVA beneficiary cost-share requirements for the same preventive services identified in paragraphs (d)(1)(A) through (F) of

section 711 of the 2009 NDAA. Section 711 also authorizes, but does not require, the Secretary of Defense to extend the waiver of beneficiary costs to other preventive services. As such, we state in regulation that the list of services is not all-inclusive, enabling us to add supplemental items to the list in the future if needed, while enabling us to be sufficiently similar to TRICARE. See Public Law 110–417, section 711(d)(1)(G). TRICARE regulations and policy guidance extend this waiver to well-child visits for children under 6 years of age. See 32 CFR 199.4(e)(28)(iv), (f); TRICARE Reimbursement Manual 6010.61–M, Chapter 2 (''Beneficiary Liability''), section 1 (''Cost-Shares and Deductibles), 1.3.3.10.1.6 (Preventive Services''). We would include this same waiver in proposed paragraph (a)(1)(iii)(G) of § 17.274. We would waive any cost-share requirement for hospice services in proposed § 17.274(a)(1)(iv). This waiver is similar to the cost-share waiver for hospice services in TRICARE regulation. See 32 CFR 199.14(g)(9). Lastly, to remain similar to TRICARE, in § 17.274(a)(1)(v), we would add a waiver for other services as determined by the Secretary of Veterans Affairs.

For TRICARE, the waiver of beneficiary costs associated with preventive services in proposed § 17.274(a)(1)(iii)(A) through (G) do not apply to any TRICARE beneficiary who is also Medicare-eligible. See Public Law 110–417, section 711(b). We would not exclude Medicare-eligible beneficiaries from cost sharing waivers for preventive services as this would unfairly disadvantage them as compared to other CHAMPVA beneficiaries with OHI. By not including this waiver, CHAMPVA will treat all beneficiaries with OHI the same. Additionally, we believe most preventive services provided to Medicare-eligible beneficiaries will be paid in full by Medicare, and, therefore, CHAMPVA will not assume any payment responsibility. In the event a cost share or deductible is applied for preventive services, CHAMPVA will treat those claims as it would the claims for any other beneficiary with OHI.

The general provisions in current § 17.274(b) related to establishing an annual deductible requirement (in addition to beneficiary cost share) would remain substantively the same. We would move the exception to this general requirement in current § 17.274(b) (last sentence) for services obtained through VA facilities to a new § 17.274(b)(1) and also explain that it refers to services and supplies provided through MbM or CITI under the same rationale as expressed above for proposed new § 17.274(a)(1)(i) and (ii), respectively. We would also move the exception to the deductible requirement in current § 17.274(b) (last sentence) for any inpatient services to a new § 17.274(b)(2). Proposed § 17.274(b)(3) would except the listed preventive services in proposed § 17.274(a)(1)(iii)(A)–(G) from the general deductible requirement in current and proposed § 17.274(b), in accordance with the mandate in section 711 of the 2009 NDAA. See Public Law 110–417, section 711(a)(2) (mandating that a beneficiary not be charged for preventive services during a year even if the beneficiary has not paid the amount necessary to cover the beneficiary's deductible for the year. See 32 CFR 199.4(f)(12)). Proposed § 17.274(b)(4) would waive the CHAMPVA beneficiary deductible requirement for hospice services, as is done similarly under TRICARE regulations. See 32 CFR 199.14(g)(9). Lastly, to remain similar to TRICARE, in § 17.274(b)(5), we would add a waiver for other services as determined by the Secretary of Veterans Affairs.

Current § 17.274(c) establishes a calendar year limit on the ''cost-share amount'' incurred by a CHAMPVA beneficiary through the payment of both cost-shares and deductible amounts (See current 38 CFR 17.274(c), indicating that the cap is ''limited to the applied annual deductible(s) and the beneficiary cost-share amount.''). Proposed § 17.274(c) would retain this basic information but would refer instead to a cap on ''out-of-pocket costs'' instead of ''cost-share amounts'' so that it is clear that both cost share and deductible amounts apply to this cap. Current § 17.274(c)(i) establishes an annual cap of cost sharing of $7,500 per CHAMPVA eligible family ''through December 31, 2001'', which is an outdated provision. Current § 17.274(c)(ii) further establishes a current cap of $3000 per CHAMPVA eligible family, which was ''[e]ffective January 1, 2002.'' Under proposed § 17.274(c), we would establish an annual (calendar year) cap on out-of-pocket costs of $3,000 per CHAMPVA eligible family. The annual cap amount would be unchanged from what currently exists but would use the new terminology proposed above for the sake of clarity. We would also remove current § 17.274(c)(i) and (ii).

We do not propose any substantive changes to current § 17.274(d) as this provision is legally adequate, and we are not proposing to revise policies related to it. However, we are adding a subject heading in an effort to mirror the cost share calculation in proposed paragraph (e) to § 17.274.

We propose to add a new paragraph (e) to § 17.274 which would set forth the principles found in current policy manuals that VA uses to establish CHAMPVA beneficiary cost-share amounts. The calculation methodologies that would be described in proposed § 17.274(e) represent current CHAMPVA practice and therefore would not increase or decrease the out-of-pocket costs for CHAMPVA beneficiaries. The methodologies described in proposed § 17.274(e) are also consistent with TRICARE cost-share calculation methodologies for the same or similar types of care, except as indicated below.

In accordance with current practice, and as proposed in § 17.274(e), the CHAMPVA beneficiary's cost-share amount, if applicable, is 25 percent of the CHAMPVA determined allowable amount in excess of the annual calendar year deductible for most CHAMPVA-covered services and supplies. This calculation is similar to that used in TRICARE to determine cost-share amounts for a majority of TRICARE covered services. See 32 CFR 199.4(f)(3)(ii)(C) and (f)(3)(iii). Proposed § 17.274(e)(1) and (2) would establish the services for which the general rule of a 25 percent cost share does not always apply. Proposed paragraph (e)(1) would establish in regulation the current calculation VA uses to determine CHAMPVA beneficiary cost share for inpatient facility services and supplies that are subject to the CHAMPVA Diagnosis Related Group (DRG) payment system. The CHAMPVA DRG system, like that used by TRICARE under 32 CFR 199.14, is based on the Centers for Medicare and Medicaid Services (CMS) prospective payment system for hospital services, as set forth in 42 CFR part 412. For services based on the CHAMPVA DRG system, the CHAMPVA beneficiary cost share would be the lesser of the per diem rate multiplied by the number of inpatient days; or, 25 percent of the hospital's billed amount; or, the base CHAMPVA DRG rate. This calculation is similar to that used in TRICARE regulation. See 32 CFR 199.4(f)(3)(ii)(A) and (f)(8)(ii).

Proposed § 17.274(e)(2) would establish the CHAMPVA beneficiary cost share for covered inpatient facility services and supplies that are subject to the CHAMPVA mental health low volume per diem reimbursement methodology. This methodology covers mental health inpatient services for lower volume hospitals and units (less than 25 mental health discharges per federal fiscal year). For these services, the CHAMPVA beneficiary cost share

would be the lesser of a fixed per diem amount multiplied by the number of inpatient days or 25 percent of the hospital's billed charges. This calculation is similar to that used in TRICARE regulations. See 32 CFR 199.4(f)(3)(ii)(B) and (f)(8)(ii).

Although, as noted above, a majority of the CHAMPVA cost-share methodologies are the same or similar as TRICARE's, we would not adopt a recent TRICARE exception to its general 25 percent cost-share rule for prescription medications. Section 712 of the 2013 NDAA requires the Secretary of DoD, through regulations, to establish specified fixed dollar amounts for cost shares for pharmacy benefits (*e.g.,* generic, formulary, and non-formulary agents or medications). We would not establish similar fixed cost-share amounts because CHAMPVA does not have an established uniform formulary and, therefore, is unable to identify all medications which may be prescribed or approximate their standard retail pricing to determine, with certainty, that a fixed dollar amount would satisfy beneficiaries' cost-share liability. Generally, CHAMPVA coverage of medications depends upon whether medications are approved by the FDA for the indications for which they are prescribed (as explained above in connection with new proposed § 17.272(a)(83)). Additionally, the fixed cost-share amounts required by section 712 of the 2013 NDAA would apply even to medications administered through TRICARE's mail order service; whereas, under proposed § 17.274(a)(1), as revised for clarity, cost-sharing requirements would not apply to services and supplies provided through VA's MbM. As a matter of policy, VA does not wish to apply a cost share for mail order pharmacy supplies provided to CHAMPVA beneficiaries. We believe that this departure from TRICARE is necessary to ensure the most appropriate care for CHAMPVA beneficiaries. Although we would not establish fixed cost-share amounts for medications similar to those set forth in section 712 of the 2013 NDAA, we would revise our regulations to clarify the methodology CHAMPVA uses to determine allowable amounts paid for outpatient medications obtained in the community (explained later in the discussion of proposed § 17.275(f)), upon which the 25 percent CHAMPVA beneficiary cost share is based. We believe these clarifications would provide more transparency related to pharmacy costs and subsequent CHAMPVA beneficiary cost-share amounts for pharmaceutical supplies obtained in the community, which we believe is a reasonable interpretation of the goals of section 712 of the 2013 NDAA in establishing fixed cost-share amounts.

17.275 CHAMPVA Determined Allowable Amount Calculation

We propose to add a new § 17.275 to describe the various payment methodologies used by CHAMPVA to calculate the CHAMPVA determined allowable amount for covered services and supplies. CHAMPVA uses the same or similar payment methodologies to establish allowable reimbursement amounts for providers as TRICARE. See 32 CFR 199.14. As with the cost-share methodologies that would be described in § 17.274(e), proposed § 17.275 represents current practice except as noted below and would not cause changes for CHAMPVA beneficiaries. The reason that § 17.274(e) (regarding cost share) and § 17.275 (regarding CHAMPVA determined allowable amount) would be separated is to clarify for CHAMPVA beneficiaries how much of the CHAMPVA determined allowable amount they are responsible for as a cost share (*e.g.,* 25 percent) and additionally to provide beneficiaries and providers with an idea of how such allowable amounts are calculated.

Proposed § 17.275(a) would establish in regulation the CHAMPVA determined allowable amount for reimbursement of inpatient hospital services based on the CHAMPVA DRG-based payment system. Proposed paragraph (a) would explain that, unless exempt or subject to a methodology in proposed paragraph (b) or (c), hospital services provided in the 50 States, the District of Columbia, and Puerto Rico are subject to the CHAMPVA DRG-based payment system. The CHAMPVA DRG system, similar to that used by TRICARE under 32 CFR 199.14, is also based on the CMS prospective payment system as set forth in 42 CFR part 412. Certain services provided in a DRG reimbursed facility will be reimbursed under the CHAMPVA Cost-to-Charge (CTC) payment method. See, *e.g.,* 32 CFR 199.14(c). However, we will not list these specifically in regulations as the list of services may change more often than regulations can be updated.

Proposed § 17.275(b) would establish in regulation the current CHAMPVA inpatient mental health per diem payment system used to calculate reimbursement for inpatient mental health hospital care in specialty psychiatric hospitals and psychiatric units of general acute hospitals that are exempt from the CHAMPVA DRG-based payment system. The per diem rate would be calculated based on the daily rate times the number of days (length of stay). CHAMPVA's mental health per diem rates are updated each fiscal year for both high volume hospitals (25 or more discharges per fiscal year) and low volume hospitals (less than 25 discharges per fiscal year). The per diem rates used by CHAMPVA are determined by TRICARE per diem rates. See 32 CFR 199.14(a).

Proposed § 17.275(c) would establish in regulation the CHAMPVA CTC payment system that is used to calculate the CHAMPVA determined allowable amount for inpatient services furnished by hospitals or facilities that are exempt from the CHAMPVA DRG-based payment system or the CHAMPVA inpatient mental health per diem payment system. TRICARE establishes an alternate methodology to calculate payments for inpatient services that are exempt from its DRG and inpatient mental health per diem payment systems. See 32 CFR 199.14(a)(4). Proposed § 17.275(c)(1) would establish the CHAMPVA CTC methodology used to calculate costs for hospitals or facilities by multiplying a CTC ratio by billed charges. We would further propose that the billed charges from the applicable hospitals and facilities must be customary and not in excess of rates or fees the hospital or facility charges the general public for similar services in a community. This requirement that the applicable billed charges not be in excess of what is charged of the general public is similar to TRICARE's requirements. See 32 CFR 199.14(a)(4)(i). Proposed § 17.275(c)(2)(i) through (x) would establish the types of hospitals and services subject to the CHAMPVA CTC methodology, similar to TRICARE at 32 CFR 199.14(a)(1)(ii)(D)(1) through (10) and (a)(1)(ii)(E). We would also add in proposed § 17.275(c)(2)(xi) that hospitals and services as determined by the Secretary of Veterans Affairs may be subject to the CHAMPVA CTC methodology.

Proposed § 17.275(d) would establish in regulation the CHAMPVA outpatient prospective payment system (OPPS) used to calculate the allowable amount for outpatient services provided in a hospital subject to Medicare OPPS. This will include the utilization of TRICARE's reimbursement methodology to include specific coding requirements, ambulatory payment classifications (APCs), nationally established APC amounts, and associated adjustments (*e.g.,* discounting for multiple surgery procedures, wage adjustments for variations in labor-related costs across geographical regions, and outlier

calculations). The CHAMPVA OPPS is the same as that utilized by TRICARE under 32 CFR 199.14, which is similar to Medicare's basic OPPS methodology. There are differences between TRICARE's OPPS methodology and Medicare's basic OPPS methodology due to variations in benefit structure and beneficiary population. CHAMPVA is adopting TRICARE's OPPS because the CHAMPVA beneficiary population is more similar to the TRICARE beneficiary population than to the Medicare beneficiary population. See 32 CFR 199.14(a)(6)(ii).

Proposed § 17.275(e) would establish in regulation the reimbursement methodology for services and supplies provided by authorized non-VA providers on an outpatient or inpatient basis where the services are distinct from facility-type charges in proposed § 17.275(a) through (d). Proposed § 17.275(e) would explain that the CHAMPVA determined allowable amount paid to authorized non-VA providers (not hospitals) for services and supplies provided on an outpatient or inpatient basis is the lesser of: The CHAMPVA maximum allowable charge (equivalent to the maximum allowable charge for similar services provided by other than hospitals and skilled nursing facilities under TRICARE, see 32 CFR 199.14(c)); the prevailing amount, which is the amount equal to the maximum reasonable amount allowed providers for a specific procedure in a specific locality; or the billed amount. Certain services that typically may be provided within a hospital setting, but not billed as a facility-type charge under proposed paragraphs (a) through (d), would be included as examples in proposed paragraph (e), namely anesthesia services; laboratory services; and other professional services associated with individual authorized non-VA providers. These examples are not all-inclusive.

Proposed § 17.275(f) would establish in regulation the current payment methodology for outpatient CHAMPVA pharmacy points of service. CHAMPVA negotiates rates with retail pharmacies through its contract with the pharmacy benefit manager. For services and supplies obtained from a retail ''in-network'' pharmacy, proposed § 17.275(f)(1) would establish that VA pays the lesser of the billed amount or the contracted rate. For supplies from a retail ''out-of-network'' pharmacy, proposed § 17.275(f)(2) would establish that VA pays the lesser of the billed amount plus a dispensing fee or the average wholesale price plus a dispensing fee.

Proposed § 17.275(g) would set forth in regulation the current CHAMPVA reimbursement methodology for the provision of services in a Skilled Nursing Facility (SNF). This methodology is based on the CMS prospective payment system for SNFs under 42 CFR part 413, subpart J (Medicare Resource Utilization Group (RUG) rates), which is the same methodology used in TRICARE regulations to calculate SNF payments. See 32 CFR 199.14(b).

Proposed § 17.275(h) would set forth in regulation the current reimbursement methodology for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). Reimbursement of DMEPOS would be based on the same amounts established under the CMS DMEPOS fee schedule under 42 CFR part 414, subpart D, which is the same methodology used in TRICARE regulations to calculate DMEPOS payments. See 32 CFR 199.14(k). The allowed amount would be that which is in effect in the specific geographic location at the time CHAMPVA-covered services and supplies are provided to a CHAMPVA beneficiary.

Proposed § 17.275(i) would establish in regulation the current payment methodology for all ambulance services. CHAMPVA adopts Medicare's Ambulance Fee Schedule (AFS) for ambulance services, which is based on the same methodology used by TRICARE. See TRICARE Reimbursement Manual 6010.61–M, Chapter 1 (''General''), section 14 (''Ambulance Services'') (April 1, 2015). Ambulance services are paid based on the lesser of the Medicare AFS or the billed amount. Payments for ambulance services furnished by a Critical Access Hospital (CAH) are paid on the same basis as the CTC method under paragraph (c) of this section.

Proposed § 17.275(j) would establish in regulation the current reimbursement methodology for hospice care. This methodology uses rates in the CMS hospice per diem rate payment system, which is the same methodology used in TRICARE regulations to calculate hospice payments. See 32 CFR 199.14(g)(9).

Proposed § 17.275(k) would establish in regulation a reimbursement methodology for intermittent or part-time home health services similar to the methodology used in TRICARE, which is based on Medicare's payment methods and rates. See 32 CFR 199.14(h). Under this methodology, a fixed case-mix and wage-adjusted national 60-day episode payment amount will act as payment in full for costs associated with furnishing home health services with exceptions allowing for additional payment to be established. This would be a new limitation in payments for services but is in line with the 60-day episode amount specified in the TRICARE regulation. See 32 CFR 199.14(h).

Proposed § 17.275(l) would establish in regulation the current reimbursement methodology for facility charges associated with procedures performed in a freestanding surgery center, which is the basis of a prospectively determined amount, similar to that used by TRICARE. See 32 CFR 199.14(d). These facility charges would not include physician fees, anesthesiologist fees, or fees of other authorized non-VA providers; such independent professional fees would be submitted separately from facility fees and calculated under the methodology in proposed § 17.275(e). Ambulatory surgery procedures performed in CAHs or in hospital outpatient departments are to be reimbursed in accordance with the provisions of paragraph (c) or (d) respectively of this section.

Proposed § 17.275(m) states that VA shall determine the appropriate reimbursement method or methods to be used in the extension of CHAMPVA benefits for otherwise covered medical services and supplies provided by hospitals or other institutional providers, physicians or other individual professional providers, or other providers outside the United States. The authority to establish these reimbursement methods is similar to that in TRICARE regulation. See 32 CFR 199.14(n).

Proposed § 17.275(n) would establish in regulation the reimbursement methodology for inpatient services provided in a Sole Community Hospital (SCH). TRICARE reimbursement approximates Medicare reimbursement for SCHs. TRICARE reimburses on a two-step process. TRICARE makes an initial payment based upon multiplying the billed amount by the applicable TRICARE percentage, which is the greater of the SCH's most recently available cost-to-charge ratio from the CMS inpatient Provider Specific File or the TRICARE allowed-to-billed ratio. The second step is a year-end adjustment to compare the aggregate allowable cost under the first method to the aggregate amount that would have been allowed for the same care using the DRG method. In the event that the DRG method amount is the greater, the year-end adjustment will be the amount by which it exceeds the aggregate allowable costs. See 32 CFR 199.14(a)(7). Due to certain limitations, CHAMPVA cannot be the same as TRICARE but can be

similar. CHAMPVA would compare the cost-to-charge ratio reimbursement amount versus the DRG reimbursement amount and then pay the higher of the two methods.

17.276 Claim-Filing Deadlines

Proposed § 17.276 is a revision and renumbering of current § 17.275. First, we propose to remove the reference to ''the Center'' and ''[t]he Director, Health Administration Center, or his or her designee'' in § 17.276(a) and (b), as renumbered by this rulemaking. Our intent is to indicate that VA is responsible for administering CHAMPVA and has discretion to assign claims processing responsibility within the Department.

Proposed § 17.276(c) would clarify that claims for services and supplies provided to an individual before the date of the event that qualifies the individual as eligible under § 17.271 are not reimbursable.

We further propose to add new paragraph (d) to proposed § 17.276 to clarify CHAMPVA policy concerning double coverage situations. We would clearly state that CHAMPVA is the last payer to all OHI, with the exceptions noted previously, which would mean that in cases of double coverage, any CHAMPVA benefits would generally not be paid until the claim has first been filed with the OHI and a final payment determination or explanation of benefits has been issued by the other insurer or payer. This is consistent with the purpose of TRICARE's double coverage provisions in 32 CFR 199.8, which address double coverage situations with OHI. Once CHAMPVA, as the last payer, makes its payment to the authorized non-VA provider, the CHAMPVA beneficiary's personal liability for the cost of care is then fully extinguished, as discussed earlier. However, TRICARE has special rules for double coverage situations involving TRICARE beneficiaries who also have Medicare benefits. See 32 CFR 199.8(e)(1). In the case of double coverage based on the availability of both CHAMPVA and Medicare benefits, the provisions of current § 17.271(b) would still apply and be unchanged by this proposed rulemaking. Under current § 17.271(b), VA is the secondary payer to Medicare, as required under 38 U.S.C. 1781(d)(2).

17.277 Appeals

Proposed § 17.277 is a revision and renumbering of current § 17.276. We would make two minor revisions to current § 17.276. First, we would remove references to ''Director, Health Administration Center, or his or her designee'' (an outdated reference within the current Office of Community Care) and replace it with a reference to ''VA.'' This is necessary to ensure that VA is effectively put forth as the general administrator of CHAMPVA. In addition, we would clarify when a beneficiary has OHI, an appeal must first be filed with the OHI, and a determination made, before submitting an appeal to CHAMPVA. We would also like to note that there may be instances where we would not require a beneficiary to appeal with their OHI first, such as when the OHI deems the issue non-appealable. Neither of these revisions are substantive changes. We will also keep the note located in current § 17.276, relocating it to the body of new § 17.277.

We propose to renumber current §§ 17.277–17.278 to §§ 17.278–17.279. Additionally, as with proposed § 17.277, we would remove reference to ''the Center'' in current § 17.277 and in its place insert ''VA.'' This revision would clarify that it is VA, and not HAC independently, that has the authority to pursue medical care cost recovery in accordance with applicable law. We would also remove the reference to third-party liability in proposed § 17.278 because it is unnecessary. VA's specific authority to recover for medical care costs applies to responsible third parties. We would not make any substantive changes to proposed § 17.279.

Effect of Rulemaking

The Code of Federal Regulations, as proposed to be revised by this proposed rulemaking, would represent the exclusive legal authority on this subject. No contrary rules or procedures would be authorized. All VA guidance would be read to conform with this proposed rulemaking if possible or, if not possible, such guidance would be superseded by this rulemaking.

Paperwork Reduction Act

This proposed rule contains no provisions constituting a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521).

Regulatory Flexibility Act

The Secretary hereby certifies that this proposed rule would not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. The new proposed payment methods in this rulemaking will include new reimbursement rates for the Outpatient Prospective Payment System (OPPS), Home Health Prospective Payment System (HH PPS), and Sole Community Hospitals (SCHs) reimbursement methodologies. These revised methodologies would not significantly affect small businesses due to the following reasons: (1) The health care industry, to include Medicare and TRICARE, is currently using these payment methods and most providers are used to these reimbursement rates, if not expecting to receive them; (2) CHAMPVA's beneficiary population is relatively small compared to these other health care payers. Further support and data can also be found in VA's impact analysis as a supporting document at *http://www.regulations.gov,* usually within 48 hours after the rulemaking document is published. Additionally, a copy of this rulemaking and its impact analysis are available on VA's website at *http://www.va.gov/orpm/,* by following the link for ''VA Regulations Published from FY 2004 Through Fiscal Year to Date.'' Therefore, pursuant to 5 U.S.C. 605(b), this amendment would be exempt from the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604.

Executive Orders 12866, 13563 and 13771

Executive Orders 12866 and 13563 direct agencies to assess the 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 effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 12866 (Regulatory Planning and Review) defines a ''significant regulatory action,'' which requires review by the Office of Management and Budget (OMB), as ''any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy

issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.''

The economic, interagency, budgetary, legal, and policy implications of this regulatory action have been examined and OMB has determined the regulatory action to be economically significant, because it will have an annual effect on the economy of $100 million or more. As noted above, VA's impact analysis is available as a supporting document at *http://www.regulations.gov,* usually within 48 hours after the rulemaking document is published. Additionally, a copy of this rulemaking and its impact analysis are available on VA's website at *http://www.va.gov/orpm/,* by following the link for ''VA Regulations Published from FY 2004 Through Fiscal Year to Date.''

This proposed rule is not expected to be subject to the requirements of EO13771 because this proposed rule is expected to result in no more than de minimis costs.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year. This proposed rule would have no such effect on State, local, or tribal governments, or on the private sector.

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance numbers and titles for the programs affected by this document are 64.009, Veterans Medical Care Benefits; 64.010, Veterans Nursing Home Care; and 64.011, Veterans Dental Care; 64.012, Veterans Prescription Service; 64.013, Veterans Prosthetic Appliances; and 64.019, Veterans Rehabilitation Alcohol and Drug Dependence.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Gina S. Farrisee, Deputy Chief of Staff, Department of Veterans Affairs, approved this document on October 2, 2017, for publication.

List of Subjects in 38 CFR Part 17

Administrative practice and procedure, Archives and records, Claims, Dental health, Drug abuse, Health care, Health facilities, Health professions, Health records, Medical devices, Mental health programs, Nursing homes, Veterans.

Dated: January 5, 2018.

Michael Shores,

Director, Office of Regulation Policy & Management, Office of the Secretary, Department of Veterans Affairs.

For the reasons stated in the preamble, The Department of Veterans Affairs (VA) proposes to amend 38 CFR part 17 as follows:

PART 17—MEDICAL

■ 1. The authority citation for part 17 continues to read in part as follows:

Authority: 38 U.S.C. 501, and as noted in specific sections.

* * * * *

■ 2. Revise § 17.270 to read as follows:

§ 17.270 General provisions and definitions.

(a) *Overview of CHAMPVA.* CHAMPVA is the Civilian Health and Medical Program of the Department of Veterans Affairs (VA). Generally, CHAMPVA furnishes medical care in the same or similar manner, and subject to the same or similar limitations, as medical care furnished to certain dependents and survivors of active duty and retired members of the Armed Forces under chapter 55 of title 10, United States Code (CHAMPUS), commonly referred to as the TRICARE Standard plan. Under CHAMPVA, VA shares the cost of medically necessary services and supplies with eligible beneficiaries within the 50 United States, the District of Columbia, the U.S. territories, and abroad. Under CHAMPVA, medical services and supplies may be provided as follows:

(1) By an authorized non-VA provider.

(2) By a VA provider at a VA facility, on a resource-available basis through the CHAMPVA In-house Treatment Initiative (CITI) only to CHAMPVA beneficiaries who are not also eligible for Medicare.

(3) Through VA Medications by Mail (MbM).

(i) Only CHAMPVA beneficiaries who do not have any other type of health insurance that pays for prescriptions, including Medicare Part D, may use MbM.

(ii) Smoking cessation pharmaceutical supplies will only be provided through MbM and only to CHAMPVA beneficiaries that are not also eligible for Medicare.

(b) *Definitions.* The following definitions apply to CHAMPVA (§§ 17.270 through 17.278):

Accepted assignment refers to the action of an authorized non-VA provider who accepts responsibility for the care of a CHAMPVA beneficiary and thereby agrees to accept the CHAMPVA determined allowable amount as full payment for services and supplies rendered to the beneficiary. (The provider's acceptance of the CHAMPVA determined allowable amount extinguishes the beneficiary's payment liability to the provider with the exception of applicable cost shares and deductibles.)

Authorized non-VA provider means an individual or institutional non-VA provider of CHAMPVA-covered medical services and supplies that meets any of the following criteria:

(i) Is licensed or certified by a State to provide the medical services and supplies; or

(ii) Where a State does not offer licensure or certification, is otherwise certified by an appropriate national or professional association that sets standards for the specific medical provider.

Calendar year means January 1 through December 31.

CHAMPVA beneficiary means a person enrolled under § 17.271.

CHAMPVA-covered services and supplies mean those medical services and supplies that are medically necessary and appropriate for the treatment of a condition and that are not specifically excluded under § 17.272(a)(1) through (84).

CHAMPVA determined allowable amount has the meaning set forth in § 17.272(b)(1).

CHAMPVA In-house Treatment Initiative (CITI) means the initiative under 38 U.S.C. 1781(b) under which participating VA medical facilities provide medical services and supplies to CHAMPVA beneficiaries who are not also eligible for Medicare, subject to availability of space and resources.

Child has the definition established in 38 U.S.C. 101.

Claim means a request by an authorized non-VA provider or by a CHAMPVA beneficiary for payment or reimbursement for medical services and supplies provided to a CHAMPVA beneficiary.

Fiscal year means October 1 through September 30.

Medications by Mail (MbM) means the initiative under which VA provides outpatient prescription medications

through the mail to CHAMPVA beneficiaries.

Other health insurance (OHI) means health insurance plans or programs (including Medicare) or third-party coverage that provide coverage to a CHAMPVA beneficiary for expenses incurred for medical services and supplies.

Payer refers to OHI, as defined in this section, that is obligated to pay for CHAMPVA-covered medical services and supplies. In a situation in which, in addition to CHAMPVA, one or more payers is/are responsible to pay for such services and supplies (*i.e.,* a ''double coverage'' situation), there would be a primary payer (*i.e.,* the payer obligated to pay first), secondary payer (*i.e.,* the payer obligated to pay after the primary payer), etc. In double coverage situations, CHAMPVA would be the last payer.

Service-connected has the definition established in 38 U.S.C. 101.

Spouse refers to a person who is married to a veteran and whose marriage is valid as determined under 38 U.S.C. 103(c).

Surviving spouse refers to a person who was married to and is the widow(er) of a veteran as determined under 38 U.S.C. 103(c).

(c) *Discretionary authority.* When it is determined to be in the best interest of VA, VA may waive any requirement in §§ 17.270 through 17.278, except any requirement specifically set forth in 38 U.S.C. 1781, or otherwise imposed by statute. It is VA's intent that such discretionary authority would be used only under very unusual and limited circumstances and not to deny any individual any right, benefit, or privilege provided to him or her by statute or these regulations. Any such waiver shall apply only to the individual circumstance or case involved and will in no way be construed to be precedent-setting.

(Authority: 38 U.S.C. 501, 1781)

■ 3. Amend § 17.271 by:
■ a. Removing the word ''and'' at the end of paragraph (a)(3).
■ b. Redesignating paragraph (a)(4) as paragraph (a)(5).
■ c. Adding a new paragraph (a)(4).
■ d. Revising the authority citation following paragraph (a).

The addition and revision read as follows:

§ 17.271 Eligibility.

(a) * * *

(4) An individual designated as a Primary Family Caregiver, under 38 CFR 71.25(f), who is not entitled to care or services under a health-plan contract (as defined in 38 U.S.C. 1725(f)(2)); and

* * * * *

(Authority: 38 U.S.C. 501, 1720G(a)(7)(A), 1781)

* * * * *

■ 4. Amend § 17.272 by:
■ a. Revising paragraph (a)(2).
■ b. In paragraph (a)(3) introductory text, removing the phrase ''(Medicaid excluded)''.
■ c. Adding paragraphs (a)(3)(iii) and (iv).
■ d. Revising paragraph (a)(21)(ix).
■ e. Removing paragraph (a)(26).
■ f. Redesignating paragraphs (a)(27) through (38) as paragraphs (a)(26) through (37), respectively.
■ g. In newly redesignated paragraph (a)(30), revising the introductory text and paragraphs (a)(30)(v) and (vi) and adding paragraphs (a)(30)(xi) through (xiv).
■ h. Removing paragraph (a)(39).
■ i. Redesignating paragraphs (a)(40) through (56) as paragraphs (a)(38) through (54), respectively.
■ j. In newly redesiganted paragraph (a)(40)(iv), removing ''(a)(42)(iii)(A)'' and adding in its place ''(a)(40)(iii)(A).''
■ k. Removing paragraph (a)(57).
■ l. Redesignating paragraphs (a)(58) through (71) as paragraphs (a)(55) through (68), respectively.
■ m. Revising newly redesignated paragraphs (a)(57) through (59).
■ n. Removing paragraph (a)(72).
■ o. Redesignating paragraphs (a)(73) through (86) as paragraphs (a)(69) through (82), respectively.
■ p. Revising newly redesignated paragraph (a)(76).
■ q. Adding paragraphs (a)(83) and (84).
■ r. Revising paragraph (b).

The revisions and additions read as follows:

§ 17.272 Benefits limitations/exclusions.

(a) * * *

(2) Services and supplies required as a result of an occupational disease or injury for which benefits are payable under workers' compensation or similar protection plan (whether or not such benefits have been applied for or paid) except when such benefits are exhausted and the services and supplies are otherwise not excluded from CHAMPVA coverage.

(3) * * *

(iii) Indian Health Service.

(iv) CHAMPVA supplemental policies.

* * * * *

(21) * * *

(ix) Treatment for stabilization of myofascial pain dysfunction syndrome, also referred to as temporomandibular joint disorder (TMD). Authorization is limited to initial imaging such as radiographs, Computed Tomography, or Magnetic Resonance Imaging; up to four office visits; and the construction of an occlusal splint.

* * * * *

(30) Preventive care (such as employment-requested physical examinations and routine screening procedures). The following exceptions apply, including but not limited to:

* * * * *

(v) Cervical cancer screening.

(vi) Breast cancer screening.

* * * * *

(xi) Colorectal cancer screening.

(xii) Prostate cancer screening.

(xiii) Annual physical examination.

(xiv) Vaccinations/immunizations.

* * * * *

(57) Unless a waiver for extended coverage is granted in advance: Inpatient mental health services in excess of 30 days in any calendar year (or in an admission), in the case of a patient 19 years of age or older; 45 days in any calendar year (or in an admission), in the case of a patient under 19 years of age; or 150 days of residential treatment care in any calendar year (or in an admission).

(58) Outpatient mental health services in excess of 23 visits in a calendar year unless a waiver for extended coverage is granted in advance.

(59) Institutional services for partial hospitalization in excess of 60 treatment days in any calendar year (or in an admission) unless a waiver for extended coverage is granted in advance.

* * * * *

(76) Over-the-counter products except for pharmaceutical smoking cessation supplies that are approved by the U.S. Food and Drug Administration, prescribed, and provided through MbM, and insulin and related diabetic testing supplies and syringes.

* * * * *

(83) Medications not approved by the U.S. Food and Drug Administration (FDA), excluding FDA exceptions to the approval requirement.

(84) Services and supplies related to the treatment of dyslexia.

(b) Costs of services and supplies to the extent such amounts are billed over the CHAMPVA determined allowable amount are specifically excluded from coverage.

(1) The CHAMPVA determined allowable amount is the maximum level of payment by CHAMPVA to an authorized non-VA provider for the provision of CHAMPVA-covered services and supplies to a CHAMPVA

beneficiary. The CHAMPVA determined allowable amount is determined before consideration of cost sharing and the application of deductibles or OHI.

(2) A Medicare-participating hospital must accept the CHAMPVA determined allowable amount for inpatient services provided to a CHAMPVA beneficiary as payment in full. See 42 CFR 489.25.

(3) An authorized non-VA provider who accepts responsibility for the care of a CHAMPVA beneficiary thereby agrees to accept the CHAMPVA determined allowable amount as full payment for services and supplies rendered to the beneficiary (*i.e.,* accepted assignment). The provider's acceptance of the CHAMPVA determined allowable amount extinguishes the beneficiary's payment liability to the provider. Any attempts to collect any additional amount from the CHAMPVA beneficiary may result in the provider being excluded from Federal benefits programs. See 42 CFR 1003.105.

* * * * *

■ 5. Amend § 17.273 by:

■ a. Revising the introductory text and paragraph (d).

■ b. Removing paragraph (e).

■ c. Redesignating paragraph (f) as paragraph (e).

■ d. Adding new paragraph (f).

The revisions and addition read as follows:

§ 17.273 Preauthorization.

Preauthorization or advance approval is required for any of the following, except when the benefit is covered by the CHAMPVA beneficiary's other health insurance (OHI):

* * * * *

(d) Dental care. For limitations on dental care, see § 17.272(a)(21)(i) through (xii).

* * * * *

(f) CHAMPVA will perform a retrospective medical necessity review during the coordination of benefits process if:

(1) It is determined that CHAMPVA is the responsible payer for services and supplies but CHAMPVA preauthorization was not obtained prior to delivery of the services or supplies; and,

(2) The claim for payment is filed within the appropriate one-year period.

* * * * *

■ 6. Amend § 17.274 by:

■ a. Revising paragraphs (a), (b), and (c).

■ b. Adding a heading for paragraph (d).

■ c. Adding paragraph (e).

The revisions and additions read as follows:

§ 17.274 Cost sharing.

(a) *Cost sharing generally.* CHAMPVA is a cost sharing program in which the cost of covered services is shared with the CHAMPVA beneficiary. CHAMPVA pays the CHAMPVA determined allowable amount less the CHAMPVA deductible, if applicable, and less the CHAMPVA beneficiary cost share.

(1) CHAMPVA beneficiary cost-share requirements do not apply to the following:

(i) Supplies provided through VA MbM.

(ii) Any medical services and supplies provided to a CHAMPVA beneficiary through CITI.

(iii) The following services, even if not provided through CITI:

(A) Colorectal cancer screening.

(B) Breast cancer screening.

(C) Cervical cancer screening.

(D) Prostate cancer screening.

(E) Annual physical exams.

(F) Vaccinations/immunizations.

(G) Well child care from birth to age six, as described in § 17.272(a)(30)(i).

(iv) Hospice services.

(v) Or other services as determined by the Secretary of Veterans Affairs.

(2) [Reserved]

(b) *Deductibles.* In addition to the CHAMPVA beneficiary cost share, an annual (calendar year) outpatient deductible requirement ($50 per beneficiary or $100 per family) must be satisfied prior to VA payment of outpatient benefits. The deductible requirement is waived for:

(1) CHAMPVA-covered services and supplies provided through VA MbM or through CITI.

(2) Inpatient services.

(3) Preventive services listed in paragraph (a)(1)(iii) of this section.

(4) Hospice services.

(5) Or other services as determined by the Secretary of Veterans Affairs.

(c) *Cost sharing limitations.* To provide financial protection against the impact of a long-term illness or injury, there is a $3,000 calendar year limit or ''catastrophic cap'' per CHAMPVA eligible family on the CHAMPVA beneficiary's out-of-pocket costs for allowable services and supplies. After a family has paid $3,000 in out-of-pocket costs, to include both cost share and deductible amounts, in a calendar year, CHAMPVA will pay the full allowable amounts for the remaining CHAMPVA-covered services and supplies through the end of that calendar year. Credits to the annual catastrophic cap are limited to the applied annual deductible(s) and the CHAMPVA beneficiary cost-share amount. Costs above the CHAMPVA determined allowable amount, as well as costs associated with non-covered medical services and supplies, are not credited toward the catastrophic cap calculation.

(d) *Non-payment.* * * *

(e) *Cost share calculation.* The CHAMPVA beneficiary's cost-share amount, if not waived under paragraph (a)(1) of this section, is 25 percent of the CHAMPVA determined allowable amount in excess of the annual calendar year deductible (see § 17.275 for procedures related to the calculation of the allowable amount for CHAMPVA-covered services and supplies), except for the following:

(1) For inpatient services subject to the CHAMPVA Diagnosis Related Group (DRG) payment system, the cost share is the lesser of:

(i) The per diem rate multiplied by the number of inpatient days;

(ii) 25 percent of the hospital's billed amount; or

(iii) The base CHAMPVA DRG rate.

(2) For inpatient mental health low volume hospitals and units (less than 25 mental health discharges per federal fiscal year), the cost share is the lesser of:

(i) The fixed per diem rate multiplied by the number of inpatient days; or

(ii) 25 percent of the hospital's billed charges.

* * * * *

§§ 17.275 through 17.278 [Redesignated as §§ 17.276 through 17.279]

■ 7. Redesignate §§ 17.275 through 17.278 as §§ 17.276 through 17.279.

■ 8. Add new § 17.275 to read as follows:

§ 17.275 CHAMPVA determined allowable amount calculation.

CHAMPVA calculates the allowable amount in the following ways, for the following covered services and supplies:

(a) *Inpatient hospital services (non-mental health).* Unless exempt or subject to a methodology under paragraph (b) or (c) of this section, inpatient hospital services provided in the 50 States, the District of Columbia, and Puerto Rico are subject to the CHAMPVA Diagnosis Related Group (DRG)-based reimbursement methodology. Under the CHAMPVA DRG-based payment system, hospitals are paid a predetermined amount per discharge for inpatient hospital services, which will not exceed the billed amount. Certain inpatient services will be reimbursed under the CHAMPVA Cost-to-Charge (CTC) reimbursement methodology.

(b) *Inpatient hospital services (mental health).* The CHAMPVA inpatient mental health per diem reimbursement methodology is used to calculate

reimbursement for inpatient mental health hospital care in specialty psychiatric hospitals and psychiatric units of general acute hospitals that are exempt from the CHAMPVA DRG-based payment system. The per diem rate is calculated by multiplying the daily rate by the number of days (length of stay). The daily rate is updated each fiscal year for both high volume hospitals (25 or more discharges per fiscal year) and low volume hospitals (fewer than 25 discharges per fiscal year).

(c) *Other inpatient hospital services.* (1) The CHAMPVA CTC reimbursement methodology is used to calculate reimbursement for inpatient care furnished by hospitals or facilities that are exempt from either of the methodologies in paragraph (a) or (b) of this section. Such hospitals or facilities will be paid at the CHAMPVA CTC ratio times the billed charges that are customary and not in excess of rates or fees the hospital or facility charges the general public for similar services in a community.

(2) The following hospitals and services are subject to the CHAMPVA CTC payment methodology:

(i) Any hospital that qualifies as a cancer hospital under Medicare standards and has elected to be exempt from the Centers for Medicare and Medicaid Services (CMS) prospective payment system.

(ii) Christian Science sanatoriums.

(iii) Critical Access Hospitals.

(iv) Any hospital outside the 50 States, the District of Columbia, or Puerto Rico.

(v) Hospitals within hospitals.

(vi) Long-term care hospitals.

(vii) Non-Medicare participating hospitals.

(viii) Non-VA Federal Health Care Facilities (*e.g.,* military treatment facilities, Indian Health Service).

(ix) Rehabilitation hospitals.

(x) Hospital or hospital-based services subject to State waiver in any State that has implemented a separate DRG-based payment system or similar payment system in order to control costs.

(xi) Hospitals and services as determined by the Secretary of Veterans Affairs.

(d) *Outpatient hospital services.* The CHAMPVA outpatient prospective payment system (OPPS) is used to calculate the allowable amount for outpatient services provided in hospitals subject to Medicare OPPS. This will include the utilization of TRICARE's reimbursement methodology to include specific coding requirements, ambulatory payment classifications (APCs), nationally established APC amounts, and associated adjustments.

(e) *Outpatient and inpatient non-hospital services.* Payments to individual authorized non-VA providers (not hospitals) for CHAMPVA-covered medical services and supplies provided on an outpatient or inpatient basis, including but not limited to, anesthesia services, laboratory services, and other professional fees associated with individual authorized non-VA providers, are reimbursed based on the lesser of:

(1) The CHAMPVA Maximum Allowable Charge;

(2) The prevailing amount, which is the amount equal to the maximum reasonable amount allowed providers for a specific procedure in a specific locality; or,

(3) The billed amount.

(f) *Pharmacy services and supplies.* The CHAMPVA pharmacy services and supplies payment methodology is based on specific CHAMPVA pharmacy points of service, which dictate the amounts paid by VA. VA pays:

(1) For services and supplies obtained from a retail in-network pharmacy, the lesser of the billed amount or the contracted rate; or

(2) For supplies obtained from a retail out-of-network pharmacy, the lesser of the billed amount plus a dispensing fee or the average wholesale price plus a dispensing fee.

(g) *Skilled Nursing Facility (SNF) care.* The CHAMPVA SNF reimbursement methodology is based on the CMS prospective payment system for SNFs under 42 CFR part 413, subpart J (Medicare Resource Utilization Group (RUG) rates).

(h) *Durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS).* The CHAMPVA DMEPOS reimbursement methodology is based on the same amounts established under the CMS DMEPOS fee schedule under 42 CFR part 414, subpart D. The CHAMPVA determined allowable amount for DMEPOS is the amount in effect in the specific geographic location at the time CHAMPVA-covered medical services and supplies are provided to a CHAMPVA beneficiary.

(i) *Ambulance services.* CHAMPVA adopts Medicare's Ambulance Fee Schedule (AFS) for ambulance services, with the exception of services furnished by a Critical Access Hospital (CAH). Ambulance services are paid based on the lesser of the Medicare AFS or the billed amount. Ambulance services provided by a CAH are paid on the same bases as the CTC method under paragraph (c) of this section.

(j) *Hospice care.* CHAMPVA hospice reimbursement methodology uses Medicare per diem hospice rates.

(k) *Home health care (intermittent or part-time).* CHAMPVA home health care reimbursement methodology, based on Medicare's home health prospective payment system, uses a fixed case-mix and wage-adjusted national 60-day episode payment amount to act as payment in full for costs associated with furnishing home health services with exceptions allowing for additional payment to be established.

(l) *Ambulatory surgery.* The CHAMPVA reimbursement methodology for facility charges associated with procedures performed in a freestanding ambulatory surgery center is based on a prospectively determined amount, similar to that used by TRICARE. These facility charges do not include physician fees, anesthesiologist fees, or fees of other authorized non-VA providers; such independent professional fees must be submitted separately from facility fees and are calculated under the methodology in paragraph (e) of this section.

(m) *CHAMPVA-covered medical services and supplies provided outside the United States.* VA shall determine the appropriate reimbursement method(s) for CHAMPVA-covered medical services and supplies provided by authorized non-VA providers outside the United States.

(n) *Sole Community Hospitals.* The CHAMPVA reimbursement methodology for inpatient services provided in a Sole Community Hospital (SCH) will be the greater of: The allowable amount determined by multiplying the billed charges by the SCH's most recently available cost-to-charge ratio from the CMS Inpatient Provider Specific File or the DRG reimbursement rate.

(Authority: 38 U.S.C. 501, 1781)

■ 9. Amend newly redesignated § 17.276 by:

■ b. Revising paragraphs (a) introductory text and (b).

■ c. Adding paragraphs (c) and (d).

The revisions and additions read as follows:

§ 17.276 Claim-filing deadlines.

(a) Unless an exception is granted under paragraph (b) of this section, claims for medical services and supplies must be filed no later than:

* * * * *

(b) Requests for an exception to the claim filing deadline must be submitted in writing and include a complete explanation of the circumstances resulting in late filing along with all available supporting documentation. Each request for an exception to the

claim filing deadline will be reviewed individually and considered on its own merit. VA may grant exceptions to the requirements in paragraph (a) of this section if it determines that there was good cause for missing the filing deadline. For example, when dual coverage exists, CHAMPVA payment, if any, cannot be determined until after the primary insurance carrier has adjudicated the claim. In such circumstances an exception may be granted provided that the delay on the part of the primary insurance carrier is not attributable to the beneficiary. Delays due to provider billing procedures do not constitute a valid basis for an exception.

(c) Claims for CHAMPVA-covered services and supplies provided before the date of the event that qualifies an individual under § 17.271 are not reimbursable.

(d) CHAMPVA is the last payer to OHI, as that term is defined in § 17.270(b). CHAMPVA benefits will generally not be paid until the claim has been filed with the OHI and the OHI has issued a final payment determination or explanation of benefits. CHAMPVA is secondary payer to Medicare per the terms of § 17.271(b).

* * * * *

■ 10. Revise newly redesignated § 17.277 to read as follows:

§ 17.277 Appeals.

Notice of the initial determination regarding payment of CHAMPVA benefits will be provided to the CHAMPVA beneficiary on a CHAMPVA Explanation of Benefits (EOB) form. The EOB form is generated by the CHAMPVA automated payment processing system. If a CHAMPVA beneficiary or provider disagrees with the determination concerning CHAMPVA-covered services and supplies or calculation of benefits, he or she may request reconsideration. Such requests must be submitted to VA in writing within one year of the date of the initial determination. The request must state why the CHAMPVA claimant believes the decision is in error and must include any new and relevant information not previously considered. Any request for reconsideration that does not identify the reason for dispute will be returned to the claimant without further consideration. After reviewing the claim and any relevant supporting documentation, VA will issue a written determination to the claimant that affirms, reverses, or modifies the previous decision. If the claimant is still dissatisfied, within 90 days of the date of the decision he or she may make a written request for review by VA. After reviewing the claim and any relevant supporting documentation, VA will issue a written determination to the claimant that affirms, reverses, or modifies the previous decision. The decision of VA with respect to benefit coverage and computation of benefits is final. When a CHAMPVA beneficiary has other health insurance (OHI), an appeal must first be filed with the OHI, and a determination made, before submitting the appeal to CHAMPVA with limited exceptions such as if the OHI deems the issue non-appealable. Denial of CHAMPVA benefits based on legal eligibility requirements may be appealed to the Board of Veterans' Appeals in accordance with 38 CFR part 20. Medical determinations are not appealable to the Board. 38 CFR 20.101.

(Authority: 38 U.S.C. 501, 1781)

■ 11. Revise newly redesignated § 17.278 to read as follows:

§ 17.278 Medical care cost recovery.

VA will actively pursue medical care cost recovery in accordance with applicable law.

(Authority: 42 U.S.C. 2651; 38 U.S.C. 501, 1781)

[FR Doc. 2018–00332 Filed 1–16–18; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 54

[WC Docket No. 17–310; FCC 17–164]

Promoting Telehealth in Rural America; Correction

AGENCY: Federal Communications Commission.

ACTION: Notice; correction.

SUMMARY: The Federal Communications Commission (Commission) published a document in the **Federal Register** of January 3, 2018 seeking comment on how to strengthen the Rural Health Care Program and improve access to telehealth in rural America. The document contained an incorrect reply comment date.

FOR FURTHER INFORMATION CONTACT: Radhika Karmarkar, Wireline Competition Bureau, (202) 418–7400 or TTY: (202) 418–0484.

Correction

In the **Federal Register** of January 3, 2018, in FR Doc. 2017–28298, on page 303, in the first column, correct the **DATES** caption to read:

DATES: Comments are due on or before February 2, 2018, and reply comments are due on or before March 5, 2018. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this document, you should advise the contact listed below as soon as possible.

Federal Communications Commission.

Katura Jackson,

Federal Register Liaison Officer.

[FR Doc. 2018–00451 Filed 1–16–18; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 300

[Docket No. 161228999–7867–01]

RIN 0648–BG51

Commerce Trusted Trader Program

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

ACTION: Proposed rule; request for comments.

SUMMARY: The National Marine Fisheries Service is proposing this Commerce Trusted Trader Program (CTTP) as part of an effective seafood traceability process to combat Illegal, Unreported, and Unregulated (IUU) fishing and seafood fraud. The voluntary CTTP supplements the Seafood Import Monitoring Program (SIMP), recently implemented under the Magnuson-Stevens Fishery Conservation and Management Act. Qualified importers who choose to participate in the CTTP would benefit from reduced reporting and recordkeeping requirements, and streamlined entry into U.S. commerce for seafood imports subject to the SIMP.

DATES: Written comments must be received by March 19, 2018.

ADDRESSES: Written comments on this action, identified by NOAA–NMFS–2016–0165, may be submitted by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2016-0165,* click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.
- *Mail:* Melissa Beaudry, Office of International Affairs and Seafood Inspection, NOAA Fisheries, 1315 East-West Highway, Silver Spring, MD 20910.

Instructions: All comments received are a part of the public record and will generally be posted to *http://www.regulations.gov* without change. All personal identifying information (for example, name and address) voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information. NMFS will accept anonymous comments. Enter N/A in the required fields if you wish to remain anonymous. Attachments to electronic comments will be accepted in Microsoft Word, Excel, WordPerfect, or Adobe portable document file (PDF) formats only.

Written comments regarding the burden-hour estimates or other aspects of the collection-of-information requirements contained in this proposed rule may be submitted to the NOAA Fisheries Office of International Affairs and Seafood Inspection (IASI) and by email to: *OIRA_Submission@omb.eop.gov* or fax to (202) 395–7285.

FOR FURTHER INFORMATION CONTACT: Melissa Beaudry, Office of International Affairs and Seafood Inspection, NOAA Fisheries (phone (301) 427–8308, or email *Melissa.Beaudry@noaa.gov*).

SUPPLEMENTARY INFORMATION:

Background

On March 15, 2015, a multi-agency Presidential task force published an Action Plan for combatting IUU fishing and seafood fraud. This Action Plan called for the identification of the seafood species most ''at-risk'' for IUU fishing or subject to significant seafood fraud, and the development of a traceability program to track these ''priority'' species from point of harvest to entry into U.S. commerce, with eventual expansion of the program to all seafood species imported into the United States. A final rule containing measures to address imported fish and fish products as part of this traceability program—called the SIMP)—became effective on January 9, 2017, with a compliance date of January 1, 2018 for most priority species (81 FR 88975; December 9, 2016).

The Action Plan also called for the development of a voluntary Commerce Trusted Trader Program (CTTP) for importers of species that are subject to the SIMP. The CTTP is intended to provide the benefits of reduced reporting and recordkeeping requirements and streamlined entry of applicable species into the United States for importers who are approved as Commerce Trusted Traders (CTTs).

U.S. Customs and Border Protection (CBP) and the U.S. Food and Drug Administration (FDA) are both developing their own voluntary Trusted Trader programs designed to reduce costs to both the government and industry, and streamline processing of imports. While the CTTP shares many features with these programs, it is designed and intended to apply only to the SIMP.

A critical element of the CTTP is the assurance that the entire supply chain for species covered by SIMP, from point of harvest to entry into U.S. commerce, is legal and documented, and that the entry of illegally harvested and misrepresented fishery products into the U.S. market is prevented. The program is intended to increase the security of the supply chain while reducing the burden of compliance for those importers who qualify for CTT status. This proposed rule, if adopted, would establish the qualifying criteria and application procedures for approval as a CTT. It would also establish requirements for a Trusted Trader Compliance Plan, recordkeeping, and third-party audits for CTTP participants. Under the proposed rule, a CTT would be required to establish a secure supply chain (free of IUU fish or fish product and falsely labeled seafood product) and maintain, either directly or through a third party, the records necessary to verify the legality of all seafood products subject to SIMP that he or she enters into U.S. commerce. Compliance with these requirements would replace the SIMP requirement to enter harvest event data into the International Trade Data System (ITDS) at the time of filing an entry, and would provide increased flexibility for complying with SIMP recordkeeping requirements.

The CTT would be expected to produce all traceability documentation associated with an entry filing subject to the SIMP within 14 days upon request by NMFS to support an audit and to make such documentation available for inspection, but would have significantly reduced reporting requirements for imports of SIMP species. With the exception of any records or documents required by other state or Federal programs, such as the Tuna Tracking and Verification Program (TTVP) or FDA's Prior Notice of Imported Food the CTT would only be required to enter their International Fisheries Trade Permit (IFTP) number and species codes into the ITDS at the time of entry filing.

I. Qualifying Criteria and Application for the Commerce Trusted Trader Program

The CTTP, as proposed, is a voluntary program for U.S. importers of record who import, or intend to import, species subject to the SIMP (50 CFR 300.324(a)(2)). This proposed rule provides that certain criteria must be met in order for an importer to be approved as a CTT. In addition to other requirements specified below, an applicant must be a holder of a valid IFTP, which can be obtained via online registration through the NMFS National Permitting System at *https://fisheriespermits.noaa.gov/npspub/pub_cmn_login/index_live.jsp.* IFTP regulations are at 50 CFR 300.322. A single IFTP issued to an importer of record is valid for imports of all seafood species that require an IFTP. Separate permits are not required, for example, if the imported species are covered under more than one NMFS import monitoring program or the importer trades in more than one covered species. Note, however, that for some commodities, permits issued by other agencies may also be required (*e.g.,* U.S. Fish & Wildlife Service permits for products of species listed under the Convention for International Trade in Endangered Species (CITES)).

In addition to being an IFTP holder, the applicant must submit an online application for the CTTP at a website designated by NMFS. Incomplete applications will not be reviewed by NMFS. A complete application must contain the following:

(1) The applicant's IFTP number;

(2) An affirmation that the applicant has no history, during the previous five years, of noncompliance (*i.e.,* violations that resulted in a finding of liability and assessment of a civil monetary penalty or criminal fine) with Federal regulations related to the importation of fish or fish products and is currently in compliance with all licensing, permitting, and reporting requirements applicable to the importation of fish or fish products;

(3) An affirmation that the applicant is in compliance with other state and federal programs, such as the Highly Migratory Species (HMS) International Trade Program, Antarctic Marine Living Resources (AMLR) Import Export Certification, and the TTVP, as applicable, including license and/or registration number(s) applicable to the importation of fish or fish products;

(4) Electronic submission of the applicant's Trusted Trader Compliance Plan (see details below); and

(5) Application fee.

The amount of the fee is calculated, on at least an annual basis, in accordance with the procedures of the NOAA Finance Handbook, available from NMFS, for determining the administrative costs of each special product or service. The fee may not

exceed such costs and is specified on each application form. At present, the fee is expected to be approximately $30.

The NMFS Office of International Affairs and Seafood Inspection (IASI) will review a CTTP application, as well as the applicant's history of compliance with state and federal regulations related to the importation of fish or fish products, in determining whether to approve the application. If the application is complete and the applicant does not have a history of non-compliance with applicable regulations, NMFS will approve the application and will issue a letter to the applicant that will serve as official documentation of CTT status. If the application is incomplete or complete but not approved, NMFS will issue a letter to the applicant explaining the reasons why. If NMFS issues such a letter, the applicant may respond in writing with additional information to address the issues NMFS identified in its letter. After reviewing such information, NMFS will issue a letter to the applicant indicating if CTT status is approved or explaining the reasons why such status continues to not be approved. NMFS' decision is final upon issuance of this letter and is not appealable. NMFS looks forward to receiving comments on the nature and extent of the application and Compliance Plan review.

While the IFTP must be renewed annually (see 50 CFR 300.322(d)), approval under the CTTP remains in effect unless it is revoked (see Section IV below).

For each entry containing species or species groups subject to the SIMP, the CTT or designated entry filer must file electronically, at the time of entry, the CTT's IFTP number and species to be entered, as required under 50 CFR 300.323(a). No further SIMP data needs to be provided. NMFS IASI will notify CBP of the decision to grant CTT status so that CBP will know that the complete SIMP data set is not required. See proposed 50 CFR 300.324(f) for CTT exemptions from SIMP requirements.

II. Trusted Trader Compliance Plan

Under this proposed rule, CTTP applicants must have a written Trusted Trader Compliance Plan (Compliance Plan) showing that they have a secure and controlled supply chain, including, but not limited to, harvest, purchase, landing, shipping, processing, storage, and import entry. Importers, regardless of IFTP status, that do not meet these requirements will not be approved as CTTs.

The Compliance Plan must be designed to meet the objective of the SIMP in preventing the importation of illegally harvested or misrepresented fish and fish products into United States commerce. The Compliance Plan may delegate entry filing, recordkeeping and other responsibilities to other persons, but such roles must be clearly defined in the Compliance Plan, as detailed below. Ultimately, the CTT is responsible for adherence to the Compliance Plan and compliance with all NOAA import requirements, including all applicable requirements of the SIMP and the CTTP, if finalized, and for ensuring the prevention of illegally harvested or misrepresented seafood entering U.S. commerce through the CTT's import activities.

The Compliance Plan must, at a minimum, include the following components:

(1) An Internal Control System (see below for requirements);

(2) Procedures for ensuring that the Compliance Plan and the CTT's adherence to it is audited by a certified third party at least annually (see below for audit requirements);

(3) The applicant's written policy and related supporting materials on preventing the import of illegally harvested and misrepresented seafood, including a description of how the policy is communicated to any affected employees, entry filers, representatives, and suppliers or other parties in the supply chain, and corrective actions to be taken as needed;

(4) An organizational chart that identifies the persons with responsibility for: entry filing; custodianship of recordkeeping documents; developing, administering, and implementing the Compliance Plan and its component measures; and conducting training to ensure effective implementation of the Compliance Plan;

(5) A signature page completed by the applicant and the individual at the highest level of authority in the applicant's organization assuming responsibility for implementing the Compliance Plan; and

(6) Any changes to the Compliance Plan, along with an updated signature page and organizational chart must be included in the mandatory annual audit report required (see below).

Internal Control System Requirements

The Internal Control System, which must be documented in the Compliance Plan described above, must include traceability monitoring procedures for seafood products subject to the SIMP (50 CFR 300.324(a)(2)). The CTT is responsible for ensuring implementation of the Internal Control System, which must include:

(1) Procedures to verify the legal harvest and landing of fish or fish products subject to the SIMP that the CTT enters into U.S. commerce. Verification may rely on flag-state or port-state harvest and landing records. Certification of legal harvest by the flag-state may also be used. In any case, the procedures must be capable of verifying the legal harvest and landing of any fish or fish products imported by the CTT of species that fall under the SIMP by providing the harvest and landing information required by the SIMP regulations at 50 CFR 300.324(b)(1)–(3). A CTT may establish separate procedures for verifying legal harvest and landing from known and trusted fishery sources and for verifying legal harvest and landing from new fishery sources, and may establish separate measures for each fishery source, as appropriate;

(2) Procedures to enable verification of the full chain of custody from point of first landing (or point of aggregation for small-scale fisheries) to entry into U.S. commerce (See 50 CFR 300.324(e)). These procedures should describe the process(es) that will be followed, and documentation that will be used, to verify chain of custody, and measures in place to periodically verify the accuracy of that documentation;

(3) Procedures to ensure that chain of custody documentation will be provided to NMFS, upon request, within 14 days to support an agency audit. Under 50 CFR 300.325(f) of the proposed rule, the Compliance Plan must identify who is responsible for maintaining chain of custody documentation, the point along the supply chain at which the chain of custody documents are stored and how the CTT will ensure access to them when necessary. The documentation must be maintained and made available for inspection as required under § 300.325(i) of the proposed rule. The CTT must be able to access records for no less than two years from the date of entry of the product into U.S. commerce, and records must be made available for inspection, upon request by NOAA to support an agency audit and as necessary for purposes of the annual audit required under § 300.325(j);

(4) Procedures for the CTT (or designee) to perform at least one trace-back annually for each species covered by the SIMP imported by the CTT. A trace-back is a document review of all industry records that follow the product from the point of entry into U.S. commerce backwards through all steps of processing, shipping, and storage to

the point of harvest (or point of first aggregation for small scale fisheries);

(5) Procedures to be taken in response to information that illegally harvested or misrepresented fish or fish products have entered the supply chain (*e.g.,* notice from NOAA's Office of Law Enforcement (OLE) or inclusion of the harvesting vessel in a regional fishery management organization's list of vessels that have engaged in illegal, unreported and unregulated fishing), measures to ensure that such fish or fish products are removed from commerce and further shipments are prevented from entering commerce, and procedures for promptly informing OLE whether such products are inbound to the United States or have entered U.S. commerce;

(6) Procedures to be taken in response to any supplier in the CTT's supply chain for SIMP species being placed on an FDA Import Alert.. Import Alerts inform FDA field staff and the public that the Agency has enough evidence to allow for Detention Without Physical Examination (DWPE) of firms and products that appear to be in violation of FDA laws and regulations. These violations could be related to the product, manufacturer, shipper and/or other information. More information is available online at *https://www.fda.gov/ForIndustry/ImportProgram/ActionsEnforcement/ImportAlerts/ucm516428.htmand*

(7) Procedures to regularly review internal controls and update procedures in response to changes in the fish or fish products that the CTT wants to enter into U.S. commerce, suppliers, or operating conditions or non-conformities identified in an audit.

The CTT must ensure that all information and documentation used for internal controls related to the Compliance Plan and Internal Control System must remain available for U.S. government audit for no less than two years from the date of import entry.

NMFS seeks comment generally on the required elements of the Trusted Trader Compliance Plan, including the Internal Control System. NMFS also invites comment on establishing a species-specific CTTP. As currently drafted, this proposed rule would allow a CTT to import all species subject to SIMP and benefit from reduced reporting requirements at the time of import. As an alternative, an applicant for CTT status could specify in the CTTP Application and Compliance Plan that it has a secure and controlled supply chain for some, but not all, SIMP species and request that CTT status be limited to that subset of SMP species. Under this species-specific alternative, a CTT would be required to comply with all SIMP reporting and recordkeeping requirements for imports of SIMP species not specifically included in its Compliance Plan. NMFS' analysis of the species-specific CTTP, set out in Section 1.3.5 of the regulatory impact review (available from NMFS; see **ADDRESSES**), indicates higher compliance costs for CTTs under the species-specific CTTP. Since the per entry reporting and recordkeeping costs are projected to be greater under SIMP than under CTTP, a CTT who chooses to comply with CTTP requirements for only a subset of the priority species would be assuming the higher fixed costs of CTTP compliance while reducing the economic benefit of that investment that accrues to every import entry of a priority species by a CTT through the reduction of per entry, incremental costs.

Additionally, NMFS estimates that its costs for both ITDS/ACE programming and effective long-term compliance auditing would be higher with a species-specific CTTP. NMFS seeks comment on its assumptions and conclusions related to a species-specific CTTP.

III. Procedures for Annual Third-Party Audit

As noted in Section II, this proposed rule provides that the CTT's Compliance Plan must include procedures for a third-party audit. The CTT is responsible for ensuring that this third-party audit is conducted annually. Paragraphs 300.325(j) and (k) of the proposed rule set forth requirements for the audit and auditor certification.

Third-Party Audit Requirements

At least once annually, the CTT must ensure that an audit is conducted by a certified third-party auditor, consistent with the requirements of the rule. The purpose of the audit is to evaluate the adequacy of the CTT's Compliance Plan in meeting the requirements of 50 CFR 300.325(f) and the CTT's adherence to that plan. A third-party audit should include an opening meeting, during which the auditor will discuss audit objectives with the CTT and any personnel supporting the audit.

During each audit, the third party auditor must review the Compliance Plan and relevant documents. The CTT must make all records, written and electronic, that are pertinent to the Compliance Plan and Internal Control System described therein available to the auditor at the time of the audit. The auditor will select a minimum of three import entries containing SIMP species to serve as the subject of the audit. He or she must verify that all processes in the CTT's Compliance Plan are being followed and that the Internal Control Plan effectively meets the requirements of the CTTP. The auditor must also verify that the audited entries can be traced back to legal harvest (or production) and landing and that the species contained in the shipment are truthfully represented. The auditor must conduct interviews as necessary with CTT staff, suppliers, and individuals delegated responsibilities under the Compliance Plan and may conduct other activities as necessary.

A CTT must notify NMFS at least 30 days in advance of each third-party audit. NMFS, at its discretion, may attend a third-party audit as an observer or conduct a side-by-side audit. In a side-by-side audit, NMFS will review the same documentation as the third party auditor at the same time as the third party auditor to evaluate both the shipment(s) and performance of the third party auditor. NMFS may also conduct an independent audit of a CTT at any time.

The auditor must have a closing meeting with the CTT or designee to review observed weaknesses and any non-conformities with the Compliance Plan, and issue a written audit report within 30 calendar days of the audit. In the audit report, the auditor must assess the reliability of the CTT's Compliance Plan and the CTT's adherence to it, provide results of the audit, and identify any non-conformities with the Compliance Plan or its implementation. The audit report must include the auditor's certifying credentials (see below) and attestations that the auditor (*i.e.,* individual auditor(s) and auditing firm): (1) Was not involved in developing the CTT's Compliance Plan, and (2) has no financial relationship with, or substantial interest in, the CTT retaining their services beyond performing the audit and any related follow up.

The CTT is responsible for ensuring that the auditor provides a signed and locked electronic copy of the audit report (in .pdf format) to the CTT and NMFS IASI no later than 30 days following completion of the audit. If the auditor determines that no corrective action is needed, the report is considered the final audit report. If the auditor determines that corrective action is required to address non-conformities with the written Compliance Plan or its implementation, the report is considered an initial audit report. In that case, within 60 days following the audit, the CTT must ensure that a signed and locked electronic copy of the final audit report (in .pdf format) is provided to NMFS

IASI. The final report must include an explanation, along with relevant documentation, of corrective action taken by the CTT and approved by the auditor.

If the CTT fails to provide the audit report to NMFS as required above or take acceptable corrective actions as identified in the report, NMFS may conduct additional audits at its discretion. NMFS may also take additional measures up to and including revocation of CTT status, as deemed appropriate by NMFS. CTT third-party audits may be combined with other Global Food Safety Initiative (GFSI) or chain of custody audits, provided the combined audit is in full compliance with the requirements of the CTTP.

Third-Party Auditor Certification and Other Requirements

Beyond conducting the audit and any related follow up for a CTT, a third-party auditor (*i.e.,* individual auditor(s) and auditing firm) must not have any other financial relationship with, or substantial interest in, the CTT. In addition, an auditor must not have been involved in developing the CTT's Compliance Plan. A third-party auditor should have some familiarity or experience with the seafood trade to ensure accurate and critical review of a CTT's written Compliance Plan and the CTT's adherence to it. The third party auditor must be certified with respect to, and affirm his or her knowledge of current auditing practices and proficiency in conducting process audits, identification of non-conformities and review of corrective actions taken by the CTT. A third-party must be certified by a competent certifying body, as evidenced by one or more of the following:

(1) Current accreditation or certification by the American Institute of Certified Public Accountants (AICPA);

(2) Current accreditation or certification by the Institute of Internal Auditors;

(3) Current accreditation or certification by the American Evaluation Association;

(4) Current accreditation or certification by a chain of custody certifying body;

(5) Current accreditation or certification by Accreditation Services International; or other nationally recognized certifying organizations;

(6) Evidence of current peer-review certification such as Certified Quality Auditor (CQA), Certified Internal Auditor (CIA), Certified Public Accountant (CPA), and Certified HACCP Auditor (CHA);

(7) Successful completion of auditor training recognized by the International Register of Certified Auditors (IRCA) or Registrar Accreditation Board and Quality Society of Australasia (RABQSA), in environmental management standards (EMS); quality management standards (QMS); or Global Food Safety Initiative (GFSI), and registration with IRCA or RABQSA as an EMS or QMS auditor; or

(8) Other training or certification approved in writing by NMFS.

IV. Revocation of CTT Status

While the IFTP must be renewed annually (see 50 CFR 300.322(d)), approval under the CTTP remains in effect unless revoked under this section. If a CTT fails to comply with requirements of the Program as detailed above, NMFS may issue a Notification Letter to the CTT that:

(1) Identifies the alleged failure to comply with Commerce Trusted Trader Program regulations and requirements;

(2) Describes the indications and evidence of the alleged failure;

(3) Sets a Response Date by which the CTT must submit to NMFS a written response to the Notification Letter, including, if applicable, a proposed solution; and

(4) Explains the CTT's options if the CTT believes the Notification Letter is in error.

NMFS will establish a Response Date between 14 and 30 calendar days from the date of the Notification Letter. The CTT's response must be received in writing by NMFS on or before the Response Date. If the CTT fails to respond by the Response Date, CTT status will be revoked. A CTT who has submitted a timely response may meet with NMFS within 21 calendar days of the date of that response to discuss a detailed and agreed-upon procedure for resolving the alleged failure to comply with the Commerce Trusted Trader Program regulations and requirements.

If the CTT disagrees with the Notification Letter and believes that there is no failure to comply with CTTP regulations and requirements, NMFS has incorrectly defined or described the failure, or NMFS is otherwise in error, the CTT may submit a written Objection Letter to NMFS on or before the Response Date. Within 21 calendar days of the date of the Objection Letter, the CTT may meet with NMFS to discuss a resolution or redefinition of the issue. If modifications to any part of the Notification Letter are required, then NMFS will issue a revised Notification Letter to the CTT; however, the Response Date or any other timeline in this process would not restart or be modified unless NMFS decides to do so.

The total process from the date of the Notification Letter to the date of final resolution should not exceed 90 calendar days, and may require a shorter time frame, to be determined by NMFS, depending on the seriousness of the alleged failure. In rare circumstances, NMFS, at its discretion, may extend the time for resolution of the alleged failure. In such a case, NMFS will provide a written notice to the CTT informing him or her of the extension and the basis for the extension. If the failure to comply with CTTP requirements cannot be resolved through this process, NMFS will issue a Revocation Letter to the CTT that:

(1) States that CTT status has been revoked;

(2) Summarizes the failure to comply with CTTP requirements;

(3) Summarizes any proposed procedures, or attempts to produce such procedures pursuant to sub-paragraph (3) of this section, to resolve the failure;

(4) Explains why resolution was not achieved; and

(5) Advises the importer that (1) the importer is no longer exempt from the requirements of the SIMP, and (2) the importer may not reapply for CTT status for a period of one year. NMFS' decision is final upon issuance of the Revocation Letter and is not appealable.

V. Prohibitions

The proposed rule would amend the existing prohibitions section in subpart Q to add five new prohibitions. Specifically, the proposed rule would prohibit: (1) Making a false statement on an application for the CTTP; (2) the falsification of records required to be maintained under 50 CFR 300.324(d) or (e) or 300.325; (3) failure to make records available for inspection, as required under 50 CFR 300.324(d) or (e) or 300.325(i); (4) a CTT from failing to maintain records containing information on the chain of custody and custodian of fish or fish products, provide access to such records to support an agency audit, and make such records available for inspection as required (see 50 CFR 300.325(g)(3) and (i)); and (5) a CTT from failing to implement or follow the Trusted Trade Compliance Plan they are required to have in place as a condition of being granted, and retaining, that status (see 50 CFR 300.325 (f) and (g)).

More information and any updates on the proposed CTTP can be found on our website at *http://www.iuufishing.noaa.gov/.*

Classification

This proposed rule is published under the authority of the Magnuson-Stevens Fishery Conservation and Management Act, 16 U.S.C. 1801 *et seq.* The NMFS Assistant Administrator has determined that this proposed action is consistent with the provisions of this and other applicable laws, subject to further consideration after public comment.

Executive Order 12866

This proposed rule has been determined to be significant for the purposes of Executive Order 12866. NMFS has prepared a regulatory impact review of this action, which is available from NMFS (see **ADDRESSES**). This analysis describes the economic impact this proposed action, if adopted, would have on businesses and consumers. NMFS invites the public to comment on this proposal and the supporting analysis.

The regulatory action being considered is described in the preamble of this proposed rule. For importers subject to the SIMP, this proposed rule would create a voluntary program that includes exemptions from SIMP reporting and recordkeeping requirements. NMFS anticipates that U.S. persons would not have any significant adverse economic effects as a result of this action, because it does not pose any new burdens with regard to existing reporting and recordkeeping requirements. On the contrary, this rule, if adopted, would reduce reporting and recordkeeping requirements under the SIMP for importers who are approved as CTTs, and result in positive economic benefits for them. NMFS seeks comment on whether there could be economic impacts that have not been addressed in this proposed rule, or that could be difficult to anticipate.

Executive Order 13771

This proposed rule is expected to be an E.O. 13771 deregulatory action. As discussed below, this proposed rule would create cost savings of approximately $806,810 industry-wide on an annual basis. Further details on the estimated cost savings of this proposed rule can be found in the regulatory impact review analysis.

Regulatory Flexibility Act

An Initial Regulatory Flexibility Analysis (IRFA) was prepared, as required by section 603 of the Regulatory Flexibility Act (RFA) and is available from NMFS (see **ADDRESSES**). The IRFA describes the economic impact this proposed rule, if adopted, would have on small entities. A description of the action, why it is being considered, and the legal basis for this action are contained at the beginning of this section in the preamble and in the **SUMMARY** section of the preamble. A summary of the analysis follows.

For this proposed rule, NMFS looked at two alternatives: No action and a CTTP, as called for in the March 15, 2015, Presidential task force Action Plan (see Background). By not joining the CTTP, importers will need to fully comply with the SIMP rule and report information pertaining to the harvest of species covered under SIMP via the ITDS prior to entry, and maintain those records as well as records documenting the supply chain from point of harvest to entry into U.S. commerce for a period of no less than two years. For importers who do not apply to become a CTT, there would be no change from current SIMP requirements and thus no economic impacts. In the SIMP final rule, NMFS estimated annual compliance costs of $6,075,000 including permit fees, reporting, recordkeeping, and data storage for 2,000 importers who, combined, filed 215,000 entries through the International Trade Data System (ITDS). There were 216 importers who filed more than 250 entries in 2014 (comprising roughly 72% of all entries). NMFS expects these high volume importers would benefit financially from the CTTP. NMFS seeks public comment on the accuracy of these baseline conditions used in the development of this proposed rule.

In the Final Regulatory Flexibility Analysis for the SIMP rule, NMFS concluded that all persons subject to the program requirements could be classified as small businesses. Likewise, all importers who choose to apply and be approved as CTTs would also be classified as small businesses. CTTs would realize the benefits of reduced reporting and recordkeeping and streamlined entry into U.S. commerce of their fish and fishery products. The increased cost of annual third-party auditing required under the CTTP would be offset by the reduction in reporting costs at time of entry. Consequently, importers with a higher annual volume of entries would accrue greater benefits. In comparing entry reporting cost savings to estimates of the costs to contract with a third-party auditor, NMFS estimates that importers making more than 250 entries per year would benefit from becoming a CTT. Considering the same baseline as that used for the SIMP analysis (entries of priority species seafood products made in 2014), approximately 2000 importers would be required to report harvest event data upon entry. NMFS estimates that 216 of these importers, who each filed more than 250 entries in 2014, would benefit from the reduced reporting burden of becoming a CTT. Assuming all of these importers would elect to become CTTs, cost savings of approximately $806,810 would be realized industry-wide on an annual basis.

National Environmental Policy Act

Under NOAA Administrative Order (NAO 216–6A), the promulgation of regulations that are administrative, financial, legal, technical or procedural in nature are categorically excluded from the requirement to prepare an Environmental Assessment. These proposed regulations to implement a Commerce Trusted Trader Program are procedural and administrative in nature in that they would modify recordkeeping and auditing requirements for ongoing authorized catch and trade activities. Fishing activity and trade in seafood products are not further restricted relative to any existing laws or regulations, either foreign or domestic. Given the procedural and administrative nature of this rulemaking, an Environmental Assessment was not prepared.

Paperwork Reduction Act

This proposed rule contains a collection-of-information requirement subject to review and approval by OMB under the Paperwork Reduction Act (PRA). This requirement has been submitted to OMB for approval. The information collection burden for the requirements proposed under this rule (CTTP application; Compliance Plan development or modification; third-party audit; and traceability documents recordkeeping) are estimated to result in a significant reduction in both time and costs for CTTs relative to the burden associated with compliance with the reporting and recordkeeping requirements of the SIMP.

NMFS estimates that approximately 216 International Fisheries Trade Permit holders would apply for the CTTP, and that they would need approximately 10 minutes to fill out the online application, at an hourly rate of $25, for a total of 36 hours and labor costs of $900. NMFS considers that most of the 216 entities estimated to apply for CTT status will already have some form of internal control plan in place, so the development of a Compliance Plan specific to the CTTP will take no more than 8 hours. If a Compliance Plan needs to be developed from square one, NMFS estimates no more than 24 hours will be required, at an hourly rate of $50. Assuming that this rule would

affect 216 importers, the total one-time burden for application and Compliance Plan development and submission amounts to between 1,764 hours and 5,220 hours, and labor costs of between $87,300 and $260,100.

Because the CTTP removes the requirement of reporting harvest data prior to entry into U.S. commerce, a CTT is expected to realize the cost savings of not entering such data. NMFS has calculated the time and cost of a CTTP entry filing (header record only) to be 12 minutes at $25 per hour, for a cost per entry of $5, versus 36 minutes per SIMP filing (header and all harvest vessel and landing records) and a cost of $15 per filing. Using available data from 2014, the average number of entries for the 216 importers filing 250 or more entries, which is the point at which NMFS believes an entity would likely choose to become a CTT, is 750. This equates to 162,000 entries. The annual burden of contracting with a third-party auditor is estimated to be one hour at the hourly rate of $50, for a total of 216 hours and $10,800 annually. The cost of the actual audit is estimated to be between $1,120 and $3,600, with an average cost of $2,190, for a total of $473,040. These burdens would be offset by the reduced cost benefit of the program, which cuts out 64,800 hours of data entry filing at a cost savings of $1,620,000.

Public comment is sought regarding: whether this proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the assumptions used in calculating the burden estimate; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the collection of information, including through the use of automated collection techniques or other forms of information technology. Send comments on these or any other aspects of the collection of information to the NOAA Fisheries Office of International Affairs and Seafood Inspection at the **ADDRESSES** above, and by email to *OIRA_Submission@omb.eop.gov* or fax to (202) 395–7285.

Notwithstanding any other provision of the law, no person is required to respond to, and no person shall be subject to penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB control number.

List of Subjects in 50 CFR Part 300

Exports, Fisheries, Fishing, Fishing vessels, Illegal, unreported or unregulated fishing, Foreign relations, Imports, International trade permits, Treaties.

Dated: January 11, 2018.

Samuel D. Rauch, III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 300, subpart Q, is proposed to be amended as follows:

PART 300—INTERNATIONAL FISHERIES REGULATIONS

■ 1. The authority citation for 50 CFR part 300 continues to read as follows:

Authority: 16 U.S.C. 951 *et seq.,* 16 U.S.C. 1801 *et seq.,* 16 U.S.C. 5501 *et seq.,* 16 U.S.C. 2431 *et seq.,* 31 U.S.C. 9701 *et seq.*

■ 2. In § 300.321, add, in alphabetical order, a definition for ''Commerce Trusted Trader'', ''Commerce Trusted Trader Program'', ''Internal Control System'', and ''Trusted Trader Compliance Plan'' to read as follows:

§ 300.321 Definitions.

* * * * *

Commerce Trusted Trader (CTT) means an importer of record who holds a valid International Fisheries Trade Permit (see § 300.322) and who has been approved by NMFS under § 300.325.

Commerce Trusted Trader Program (CTTP) means the voluntary program established under § 300.325.

* * * * *

Internal Control System means the written procedures required under § 300.325(g).

* * * * *

Trusted Trader Compliance Plan or *Compliance Plan* means the written plan required under § 300.325(f).

* * * * *

■ 3. In § 300.324, add paragraph (f) to read as follows:

§ 300.324 Seafood Traceability Program.

* * * * *

(f) An importer of record who is approved as a Commerce Trusted Trader (CTT) under § 300.325 shall be exempt from the reporting requirements of § 300.324(b)(1)–(3) and (c) and may delegate the recordkeeping responsibilities under § 300.324(e) to one or more third parties as provided in § 300.325(i). However, a CTT is not exempt from IFTP requirements under § 300.322 or any other applicable requirements and is responsible for compliance with the obligations of § 300.324(e). CTTP application procedures and requirements are set forth at § 300.325.

■ 4. Redesignate § 300.325 as § 300.326 and add a new § 300.325 to read as follows:

§ 300.325 Commerce Trusted Trader Program.

(a) *Establishment.* This section establishes a voluntary Commerce Trusted Trader Program (CTTP) which provides an exemption from the reporting requirements of the Seafood Import Monitoring Program (SIMP) (see § 300.324(f)) and alternative recordkeeping options (see paragraph (i) of this section). Qualifying criteria, application procedures, requirements for Trusted Trader Compliance Plans and recordkeeping, and third-party audit requirements for CTTP participants are set forth in the following sections.

(b) Qualifying Criteria. To be approved as a Commerce Trusted Trader (CTT), an applicant must be a U.S. importer of record who has imported, or who intends to import, products subject to the SIMP and must be a holder of a valid International Fisheries Trade Permit (IFTP) (see § 300.322).

(c) *Application.* The applicant must submit an online application for the CTTP at a website designated by NMFS. Incomplete applications will not be reviewed by NMFS. A complete application must contain the following:

(1) The applicant's IFTP number;

(2) Affirmation that the applicant has no history, during the previous five years, of noncompliance (*i.e.,* violations that resulted in a finding of liability and assessment of a civil monetary fine or criminal penalty) with federal regulations related to the importation of fish and fish products and is currently in compliance with all licensing, permitting, and reporting requirements applicable to the importation of fish and fish products;

(3) Affirmation that the applicant is in compliance with other state and federal programs, as applicable, including license and/or registration number(s) applicable to the importation of fish and fish products;

(4) Electronic submission of the applicant's Trusted Trader Compliance Plan (see paragraph (f) of this section); and

(5) Application fee.

(d) *Fees.* Applicants for the CTTP must electronically pay an application fee assessed by NMFS to recover application review costs. If an application fee is paid with a commercial instrument that is

insufficiently funded, the CTTP application will not be processed.

(e) *Review and Approval of Application.*

(1) The NMFS Office of International Affairs and Seafood Inspection (IASI) will review a CTTP application, as well as the applicant's history of compliance with federal regulations related to the importation of fish and fish products, in determining whether to approve the application.

(2) If NMFS IASI approves the application, it will issue a letter to the applicant that will serve as official documentation of CTT status.

(3) If the application is incomplete or complete but not approved, NMFS will issue a letter to the applicant explaining the reasons why.

(4) If NMFS issues a letter under paragraph (e)(3), the applicant may respond in writing with additional information to address the issues NMFS identified in its letter. After reviewing such information, NMFS will issue a letter to the applicant indicating if CTT status is approved or explaining the reasons why such status continues to not be approved. NMFS' decision is final upon issuance of this letter and is not appealable. The applicant may reapply no earlier than one year from the date of NMFS' final decision.

(5) While the IFTP must be renewed annually (see § 300.322(d)), approval under the CTTP remains in effect unless it is revoked under paragraph (l).

(f) *Trusted Trader Compliance Plan.* In order to be approved as a CTT, the applicant must have a Trusted Trader Compliance Plan (Compliance Plan) that is designed to meet the objective of the SIMP in preventing the importation of illegally harvested or misrepresented fish and fish products into United States commerce. The Compliance Plan may delegate entry filing, recordkeeping and other responsibilities to other persons, but the CTT remains responsible for ensuring adherence to the Compliance Plan and compliance with all NOAA import requirements, including all applicable requirements of the SIMP and the CTTP. The Compliance Plan must, at a minimum, include the following components:

(1) An Internal Control System (see paragraph (g) of this section for requirements);

(2) Procedures for ensuring that the Compliance Plan and the CTT's adherence to it is audited by a certified third party at least annually (see paragraph (j) of this section for audit requirements);

(3) The applicant's written policy and related supporting materials on preventing the import of illegally harvested and misrepresented seafood, including a description of how the policy is communicated to any affected employees, entry filers, representatives, and suppliers or other parties in the supply chain, and corrective actions to be taken as needed;

(4) An organizational chart that identifies the persons with responsibility for: Entry filing; custodianship of recordkeeping documents; developing, administering, and implementing the Compliance Plan and its component measures; and conducting training to ensure effective implementation of the Compliance Plan;

(5) A signature page completed by the applicant and the individual at the highest level of authority in the applicant's organization assuming responsibility for implementing the Compliance Plan. This signature page and the organizational chart must be updated each year at the time of the annual audit in order for a CTT's status to remain current; and

(6) Any changes to the Compliance Plan, along with an updated signature page and organizational chart must be included in the annual audit report required under paragraph (j) of this section.

(g) Internal Control System Requirements. The Internal Control System, which must be documented in the Compliance Plan under paragraph (f) of this section, must include traceability monitoring procedures for seafood products subject to the SIMP (§ 300.324). The CTT is responsible for ensuring implementation of the internal control system, which must include:

(1) Procedures to verify the legal harvest and landing of fish or fish products subject to the SIMP that the CTT enters into U.S. commerce. Such procedures may rely on flag-state and/or port-state harvest and landing records or flag-state certification of legal harvest. A CTT may establish separate verification procedures for each fishery source, as appropriate (*e.g.,* known and trusted vs. new sources);

(2) Procedures to enable verification of the full chain of custody from point of first landing (or point of aggregation for small-scale fisheries) to entry into U.S. commerce (See paragraph (i) of this section). These procedures should describe the process(es) that will be followed, and documentation that will be used, to verify chain of custody, and measures in place to periodically verify the accuracy of that documentation;

(3) Procedures to ensure that chain of custody documentation will be provided to NMFS, upon request, within 14 days to support an agency audit. The Compliance Plan under paragraph (f) of this section must identify who is responsible for maintaining chain of custody documentation, the point along the supply chain at which the chain of custody documents are stored and how the CTT will ensure access to them when necessary. The documentation must be maintained and made available for inspection as required under paragraph (i) of this section;

(4) Procedures for the CTT (or designee) to perform at least one trace-back annually for each species covered by the SIMP that is imported by the CTT. A trace-back is a document review of all records that follow the product from the point of entry into U.S. commerce backwards through the supply chain (*e.g.,* through all steps of processing, shipping, purchase, and storage) to the point of harvest (or point of first aggregation for small scale fisheries);

(5) Procedures to be taken in response to information that illegally harvested or misrepresented fish or fish products have entered the supply chain (*e.g.,* notice from NOAA's Office of Law Enforcement (OLE) or inclusion of the harvesting vessel in a regional fishery management organization's list of vessels that have engaged in illegal, unreported and unregulated fishing), measures to ensure that such fish and fish products are removed from commerce and further shipments are prevented from entering commerce, and procedures for promptly informing OLE whether such products are inbound to the United States or have entered U.S. commerce;

(6) Procedures to be taken in response to a supplier being placed on an FDA Import Alert List. FDA Import Alerts inform FDA field staff and the public that the Agency has enough evidence to allow for Detention Without Physical Examination (DWPE) of products that appear to be in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act) or FDA regulations. These violations could be related to the product, manufacturer, shipper and/or other information. More information is available online at *https://www.fda.gov/ForIndustry/ImportProgram/ActionsEnforcement/ImportAlerts/ucm516428.htm;* and

(7) Procedures to regularly review and update internal control procedures in response to changes in the fish or fish products that the CTT wants to enter into U.S. commerce, suppliers, or operating conditions, or non-conformities identified in an audit.

(h) *Entry filing requirements.* NMFS will alert U. S. Customs and Border Protection when it approves a CTT

under paragraph (e) of this section. For each entry containing species or species groups subject to the SIMP, at the time of entry, the CTT or designated entry filer must file electronically, as required under § 300.323(a), the CTT's IFTP number and species to be entered. No further information needs to be provided. See § 300.324(f) for exemptions from SIMP requirements.

(i) *Recordkeeping requirements.* As specified in § 300.324(e), records containing information on the chain of custody and custodian of fish or fish products (*e.g.,* trans-shipper, processor, storage facility or distributor) must be maintained. However, CTTs have the option of delegating the recordkeeping requirements to one or more third parties. The records must be maintained either by the CTT, or at designated points within the supply chain to which the CTT has unrestricted access, or with any third-party that the CTT designates in its Compliance Plan. Regardless of which option it chooses, the CTT is responsible for ensuring that the required chain of custody documentation for all species and species groups subject to SIMP is maintained for a period of two years from the date of entry of product into U.S. commerce, providing such documentation to NMFS in accordance with paragraph (g)(3) of this section, and making it available for inspection as required under § 300.324(e).

(j) *Third-party Audit Requirements.* At least once annually, the CTT must ensure that an audit is conducted by a certified third-party auditor, consistent with the requirements of this paragraph and paragraph (k) of this section. The purpose of the audit is to evaluate the adequacy of the CTT's Compliance Plan in meeting the requirements of paragraphs (f) and (g) of this section and the CTT's adherence to that plan. The audit must include:

(1) Review of the Compliance Plan and relevant documents; full trace back to point(s) of harvest of at least three shipments of products falling under the SIMP, selected by the third-party auditor; interviews as necessary with CTT staff, suppliers, and individuals delegated responsibilities under the Compliance Plan; and other activities as necessary;

(2) A closing meeting between the auditor and the CTT or designee to review observed weaknesses and any non-conformities with the Compliance Plan; and

(3) Issuance of audit reports.

(i) *Notification and NMFS Audit.* The CTT shall notify NMFS at least 30 days in advance of each third-party audit. NMFS, at its discretion, may attend a third-party audit as an observer or conduct a side-by-side audit. NMFS may conduct an independent audit of a CTT at any time.

(ii) *Audit Reports.* In an audit report, a third-party auditor must assess the reliability of the CTT's Compliance Plan and the CTT's adherence to it, provide results of the audit, and identify any non-conformities with the Compliance Plan or its implementation. The audit report must include the auditor's certifying credentials (see paragraph (k) of this section) and attestations that the auditor (*i.e.,* individual auditor(s) and auditing firm): (1) Was not involved in developing the CTT's Compliance Plan, and (2) has no financial relationship with, or substantial interest in, the CTT retaining their services beyond performing the audit and any related follow up.

(iii) *Follow Up on Audit Reports.* The CTT is responsible for ensuring that the auditor provides a signed and locked electronic copy (in .pdf format) of the audit report to the CTT and IASI no later than 30 days following completion of the audit. If the auditor determines that no corrective action is needed, the report is considered the final audit report. If the auditor determines that corrective action is required to address non-conformities with the Compliance Plan or its implementation, the report is considered an initial audit report. In that case, within 60 days following the audit, the CTT must ensure that a signed and locked electronic copy of the final audit report (in .pdf format) is provided to NMFS IASI. The final report must include an explanation, along with relevant documentation, of corrective action taken by the CTT and approved by the auditor.

(iv) If the CTT fails to provide the audit report as required above or take acceptable corrective actions, NMFS may conduct additional audits at its discretion. NMFS may also take additional measures up to and including revocation of CTT status as deemed appropriate by NMFS.

(k) *Third-Party Auditor Certification and Other Requirements.*

(1) Beyond conducting the audit and any related follow up for a CTT, a third-party auditor (*i.e.,* individual auditor(s) and auditing firm) must not have any other financial relationship with, or substantial interest in, the CTT. In addition, an auditor must not have been involved in developing the CTT's Compliance Plan. A third-party auditor should have some familiarity or experience with the seafood trade to ensure an accurate and critical review of a CTT's Compliance Plan and the CTT's adherence to it. The third party auditor must be certified in and affirm his or her knowledge of current auditing practices and proficiency in conducting process audits, identification of non-conformities and review of corrective actions taken by the CTT.

(2) A third-party auditor must be certified by a competent certifying body, as evidenced by one or more of the following:

(i) Current accreditation or certification by the American Institute of Certified Public Accountants (AICPA);

(ii) Current accreditation or certification by the Institute of Internal Auditors;

(iii) Current accreditation or certification by the American Evaluation Association;

(iv) Current accreditation or certification by a chain of custody certifying body;

(v) Current accreditation or certification by Accreditation Services International, or other nationally recognized certifying organizations;

(vi) Evidence of current peer-review certification such as Certified Quality Auditor (CQA), Certified Internal Auditor (CIA), Certified Public Accountant (CPA), and Certified HACCP Auditor (CHA);

(vii) Successful completion of auditor training recognized by the International Register of Certified Auditors (IRCA) or Registrar Accreditation Board and Quality Society of Australasia (RABQSA), in environmental management standards (EMS); quality management standards (QMS); or Global Food Safety Initiative (GFSI), and registration with IRCA or RABQSA as an EMS or QMS auditor; and

(viii) Other training or certification as approved in writing by NMFS.

(l) *Revocation of CTT status.*

(1) If a CTT fails to comply with requirements under this section, NMFS may issue a Notification Letter to the CTT that:

(i) Identifies the alleged failure to comply with CTTP regulations and requirements;

(ii) Describes the indications and evidence of the alleged failure;

(iii) Sets a Response Date by which the CTT must submit to NMFS a written response to the Notification Letter, including, if applicable, a proposed solution; and

(iv) Explains the CTT's options if the CTT believes the Notification Letter is in error.

(2) NMFS will establish a Response Date between 14 and 30 calendar days from the date of the Notification Letter. The CTT's response must be received in writing by NMFS on or before the

Response Date. If the CTT fails to respond by the Response Date, CTT status will be revoked. At its discretion and for good cause, NMFS may extend the Response Date to a maximum of 60 calendar days from the date of the Notification Letter.

(3) A CTT who has submitted a timely response may meet with NMFS within 21 calendar days of the date of that response to discuss a detailed and agreed-upon procedure for resolving the alleged failure to comply with the CTTP regulations and requirements. The meeting may be in person or via conference call or webcast.

(4) If the CTT disagrees with the Notification Letter and believes that there is no failure to comply with CTTP regulations and requirements, NMFS has incorrectly defined or described the failure, or NMFS is otherwise in error, the CTT may submit a written Objection Letter to NMFS on or before the Response Date. Within 21 calendar days of the date of the Objection Letter, the CTT may meet with NMFS to discuss a resolution or redefinition of the issue. The meeting may be in person, or via conference call or webcast. If modifications to any part of the Notification Letter are required, then NMFS will issue a revised Notification Letter to the CTT; however, the Response Date or any other timeline in this process would not restart or be modified unless NMFS decides to do so, at its discretion.

(5) The total process from the date of the Notification Letter to the date of final resolution should not exceed 90 calendar days, and may require a shorter time frame, to be determined by NMFS, depending on the seriousness of the alleged failure. In rare circumstances, NMFS, at its discretion, may extend the time for resolution of the alleged failure. In such a case, NMFS will provide a written notice to the CTT informing him or her of the extension and the basis for the extension.

(6) If the failure to comply with CTTP requirements cannot be resolved through this process, NMFS will issue a Revocation Letter to the CTT that:

(i) States that CTT status has been revoked;

(ii) Summarizes the failure to comply with CTTP requirements;

(iii) Summarizes any proposed procedures, or attempts to produce such procedures pursuant to sub-paragraph (3) of this paragraph to resolve the failure;

(iv) Explains why resolution was not achieved; and

(v) Advises the importer that:

(A) The importer is no longer exempt from the requirements of the SIMP; and

(B) The importer may not reapply for CTT status for a period of one year.

(7) NMFS' decision is final upon issuance of the Revocation Letter and is not appealable.

■ 5. In newly redesignated § 300.326, add paragraphs (d), (e), (f), (g), and (h) to read as follows:

§ 300.326 Prohibitions.

* * * * *

(d) Make a false statement on an application for the CTTP.

(e) Falsify records required to be maintained under § 300.324(d) or (e) or § 300.325(i).

(f) Fail to make records available for inspection as required under § 300.324(d) or (e) or § 300.325(i).

(g) As a CTT, fail to maintain and provide access to records as required under § 300.325(i) or to produce records as required under § 300.325(g)(3).

(h) As a CTT, fail to implement or follow the procedures in the Trusted Trader Compliance Plan submitted to NMFS in a CTT application or as part of an annual audit report.

[FR Doc. 2018–00653 Filed 1–16–18; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register

Vol. 83, No. 11

Wednesday, January 17, 2018

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Docket No. AMS–LPS–17–0046]

United States Standards for Grades of Pork Carcasses

AGENCY: Agricultural Marketing Service, USDA .

ACTION: Notice; reopening of comment period.

SUMMARY: The U.S. Department of Agriculture's (USDA) Agricultural Marketing Service (AMS) is reopening the comment period on the notice requesting comments on revisions to the United States Standards for Grades of Pork Carcasses (pork standards) published in the **Federal Register** (82 FR 48971) on October 23, 2017. The comment period for this notice closed on December 22, 2017. The revisions are intended to modernize the standards and meet stakeholder demands by segregating the population of commodity pork products into uniform groups (of similar quality, value, etc.) that can facilitate the production and marketing of pork and deliver certain eating expectations for the consumer.

DATES: Comments on the notice published in the **Federal Register** (82 FR 48971) on October 23, 2017, must be received by March 19, 2018.

ADDRESSES: Interested persons are invited to submit comments electronically at *https://www.regulations.gov.* Written comments should be sent to: Pork Carcass Revisions, Standardization Branch, Quality Assessment Division; Livestock, Poultry, and Seed Program, AMS, USDA; 1400 Independence Ave. SW, Room 3932–S, STOP 0258, Washington, DC 20250–0258. Comments may also be emailed to *porkcarcassrevisions@ams.usda.gov.* All comments should reference docket number AMS–LPS–17–0046, the date of submission, the page numbers of this issue, and the October 23, 2017, issue of the **Federal Register**. All comments received will be posted without change, including any personal information provided, and they will be made available for public inspection at the above physical address during regular business hours.

FOR FURTHER INFORMATION CONTACT: Bucky Gwartney, International Marketing Specialist, Standardization Branch, Quality Assessment Division, Livestock, Poultry, and Seed Program, AMS, USDA; 1400 Independence Avenue SW, Room 3932–S, STOP 0258, Washington, DC 20250–0258; phone (202) 720–1424; or via email at *Bucky.Gwartney@ams.usda.gov.*

SUPPLEMENTARY INFORMATION: A notice was published in the **Federal Register** (82 FR 48971) on October 23, 2017, requesting comments on revisions to the pork standards. The 60-day comment period provided in the notice closed on December 22, 2017. Trade organizations submitted comments requesting a 60-day extension to enable industry stakeholders more time to evaluate the proposed changes and to submit comments. Therefore, AMS is reopening the comment period for the notice until March 19, 2018. AMS is reopening the public comment period to ensure that interested persons have sufficient time to review and comment on the notice.

Dated: January 10, 2018.

Bruce Summers,

Acting Administrator, Agricultural Marketing Service.

[FR Doc. 2018–00627 Filed 1–16–18; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2017–0090]

Addition of the Philippines 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 are adding the Philippines to the list of regions that the Animal and Plant Health Inspection Service considers to be affected by highly pathogenic avian influenza (HPAI). This action follows our imposition of HPAI-related restrictions on avian commodities originating from or transiting the Philippines as a result of the confirmation of HPAI in the Philippines.

DATES: The Philippines was added to the list of regions under temporary restrictions on August 16, 2017. The Philippines is added to the list of regions considered to be affected by HPAI as of January 17, 2018.

FOR FURTHER INFORMATION CONTACT: Dr. Ingrid Kotowski, Regionalization Evaluation Services, National Import Export Services, VS, 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 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 contains 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 website 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 August 11, 2017, the veterinary authorities of the Philippines reported to the OIE that

HPAI occurrence in that country was confirmed on August 7, 2017. Subsequent to that report, and after confirming that the HPAI occurred in commercial birds or poultry, APHIS placed restrictions on the importation of poultry, commercial birds, other types of birds (research, performing), ratites, any avian hatching eggs, unprocessed avian products and byproducts, and certain fresh poultry products from the Philippines to mitigate risk of HPAI introduction into the United States. Those restrictions went into effect on August 7, 2017, the reported date of confirmation of the HPAI occurrence in the Philippines. With the publication of this notice, we are adding the Philippines to the list of regions APHIS considers affected with HPAI of any subtype.

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 10th day of January 2018.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2018–00696 Filed 1–16–18; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2017–0106]

Notice of Request for Revision to and Extension of Approval of an Information Collection; Specimen Submission

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 livestock disease surveillance programs.

DATES: We will consider all comments that we receive on or before March 19, 2018.

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

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2017-0106.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2017–0106, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2017-0106* 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) 7997039 before coming.

FOR FURTHER INFORMATION CONTACT: For information regarding livestock disease surveillance programs, contact Ms. Lori Anderson, Chief of Staff, STAS, VS, APHIS, 1920 Dayton Ave., Ames, IA 50010; (515) 337–7405. 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: Specimen Submission.

OMB Control Number: 0579–0090.

Type of Request: Revision to and extension of approval of an information collection.

Abstract: The Animal Health Protection Act (7 U.S.C. 8301 *et seq.*) provides the Secretary of Agriculture broad authority to prohibit or restrict, through orders and regulations, the importation or entry and interstate movement of any animal, article, or means of conveyance if the U.S. Department of Agriculture (USDA) determines that the prohibition or restriction is necessary to prevent the introduction or spread of any pest or disease of livestock within the United States.

Disease prevention is the most effective method for maintaining a healthy animal population and for enhancing the United States' ability to globally compete in the trade of animals and animal products. However, animal disease prevention cannot be accomplished without the existence of an effective disease surveillance program, which is conducted by the USDA's Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS).

The animal disease surveillance program is based on information submitted on the Specimen Submission form and the continuation sheets, as well as equivalent sources. VS forms are critical to VS' mission. They are routinely used whenever specimens (such as blood, milk, tissue, or urine) from any animal (such as cattle, swine, sheep, goats, horses, and poultry) are submitted to the National Veterinary Services Laboratories for disease testing. If the information was not collected or collected less frequently, APHIS would not have the critical information necessary to effectively operate a disease surveillance program and identify the animals and herds from which the specimens were taken, allowing effective disease prevention and eradication.

An additional form that APHIS uses is the Parasite Submission form. This form is used by the Cattle Fever Tick Eradication Program and the National Tick Surveillance Program to identify the individuals submitting tick samples and the animal sources of those samples.

We are asking the Office of Management and Budget (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. APHIS needs this outside input to help accomplish the following:

(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, (such as through the use of appropriate automated, electronic, mechanical, or other technological collection techniques, *e.g.,* permitting electronic submission of responses.)

Estimate of Burden: The public burden for this collection of information is estimated to average 0.31 hours per response.

Respondents: State veterinarians and other State personnel who are qualified and authorized to collect and submit specimens for laboratory analysis, accredited veterinarians, private veterinarians, animal health technicians, herd owners, private laboratories, and research institutions.

Estimated Annual Number of Respondents: 1,773.

Estimated Annual Number of Responses per Respondent: 15.

Estimated Annual Number of Responses: 27,193.

Estimated Total Annual Burden on Respondents: 8,604 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 10th day of January 2018.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2018–00694 Filed 1–16–18; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[S–6–2018]

Foreign-Trade Zone 98—Birmingham, Alabama; Application for Expansion of Subzone 98D; Hyster-Yale Group, Inc. Sulligent, Alabama

An application has been submitted to the Foreign-Trade Zones Board (the Board) by the City of Birmingham, grantee of FTZ 98, requesting an expansion of Subzone 98D on behalf of Hyster-Yale Group, Inc., in Sulligent, Alabama. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a-81u), and the regulations of the FTZ Board (15 CFR part 400). It was formally docketed on January 10, 2018.

The subzone currently consists of one site located at 7711 Highway 278 East in Sulligent, Alabama. The applicant is now requesting authority to include an additional site: *Proposed Site 2* (13 acres)—7668 Highway 278, Sulligent. No additional production authority is being requested at this time. As requested, the entire subzone would be subject to the existing activation limit of FTZ 98.

In accordance with the FTZ Board's regulations, Qahira El-Amin of the FTZ Staff is designated examiner to review the application and make recommendations to the Executive Secretary.

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is February 26, 2018. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to March 13, 2018.

A copy of the application will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 21013, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230–0002, and in the ''Reading Room'' section of the Board's website, which is accessible via *www.trade.gov/ftz.*

For further information, contact Qahira El-Amin at *Qahira.El-Amin@trade.gov* or (202) 482–5928.

Dated: January 11, 2018.

Elizabeth Whiteman,

Acting Executive Secretary.

[FR Doc. 2018–00699 Filed 1–16–18; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[S–01–2018]

Foreign-Trade Zone 18—San Jose, California; Application for Subzone Expansion, Lam Research Corporation, Fremont and Livermore, California

An application has been submitted to the Foreign-Trade Zones (FTZ) Board by the City of San Jose, grantee of FTZ 18, requesting expanded subzone status for the facility of Lam Research Corporation (Lam), located in Tracy, California. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the FTZ Board (15 CFR part 400). It was formally docketed on January 3, 2018.

Subzone 18F consists of the following sites in Fremont and Livermore: *Site 1* (29 acres) 4650 Cushing Parkway, Fremont; *Site 4* (14.82 acres) 1 and 101 Portola Avenue, Livermore; *Site 5* (4.4 acres)—7364 Marathon Drive and 7150 Patterson Pass Road, Unit G, Livermore; *Site 7* (0.91 acres)—6757 Las Positas Road, Livermore; *Site 8* (0.44 acres)—7888 Marathon Drive, Livermore; *Site 9* (1.6 acres)—41707 Christy Street, Fremont; *Site 11* (1.19 acres)—4050 Starboard Drive, Fremont; and, *Site 12* (0.98 acres)—7650 Marathon Drive, Livermore. The applicant is now requesting authority to expand the subzone to include an additional site (3.49 acres) located at 6551 West Schulte Road, Tracy, which would be designated as Site 13. The expanded subzone would be subject to the existing activation limit of FTZ 18.

In accordance with the FTZ Board's regulations, Christopher Kemp of the FTZ Staff is designated examiner to review the application and make recommendations to the Executive Secretary.

Public comment is invited from interested parties. Submissions shall be addressed to the FTZ Board's Executive Secretary at the address below. The closing period for their receipt is February 26, 2018. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to March 13, 2018.

A copy of the application will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 21013, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230–0002, and in the ''Reading Room'' section of the FTZ Board's website, which is accessible via *www.trade.gov/ftz.*

For further information, contact Christopher Kemp at *Christopher.Kemp@trade.gov* or (202) 482–0862.

Dated: January 8, 2018.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2018–00680 Filed 1–16–18; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Environmental Technologies Trade Advisory Committee (ETTAC) Public Meeting

AGENCY: International Trade Administration, DOC.

ACTION: Notice of Federal Advisory Committee meeting.

SUMMARY: This notice sets forth the schedule and proposed agenda of a meeting of the Environmental Technologies Trade Advisory Committee (ETTAC).

DATES: The meeting is scheduled for Tuesday, February 6, 2018 from 8:30 a.m.–3:30 p.m. Eastern Daylight Time (EDT). The deadline for members of the public to register or to submit written comments for dissemination prior to the meeting is 5:00 p.m. EDT on Friday, January 26, 2018. The deadline for members of the public to request auxiliary aids is 5:00 p.m. EDT on Tuesday, January 30, 2018.

ADDRESSES: The meeting will be held in Room 6057–59 at the U.S. Department of Commerce, Herbert Clark Hoover

Building, 1401 Constitution Avenue NW, Washington, DC 20230. The address to register, submit comments, or request auxiliary aids is: Mr. Jeffrey Phillips, Office of Energy & Environmental Industries (OEEI), International Trade Administration, Room 28018, 1401 Constitution Avenue NW, Washington, DC 20230 or email: *jeffrey.phillips@trade.gov.*

FOR FURTHER INFORMATION CONTACT: Mr. Jeffrey Phillips, Office of Energy & Environmental Industries (OEEI), International Trade Administration, Room 28018, 1401 Constitution Avenue NW, Washington, DC 20230 (Phone: 202–482–8342; Fax: 202–482–5665; email: *jeffrey.phillips@trade.gov.*)

SUPPLEMENTARY INFORMATION: The meeting will take place on February 6 from 8:30 a.m. to 3:30 p.m. EDT. The general meeting is open to the public and time will be permitted for public comment from 3:00–3:30 p.m. EDT. Members of the public seeking to attend the meeting are required to register in advance. Those interested in attending must provide notification by Friday, January 26, 2018 at 5:00 p.m. EDT, via the contact information provided above. This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to OEEI at (202) 482–8342 no less than one week prior to the meeting. Requests received after this date will be accepted, but it may not be possible to accommodate them.

Written comments concerning ETTAC affairs are welcome any time before or after the meeting. To be considered during the meeting, written comments must be received by Friday, January 26, 2018 at 5:00 p.m. EDT to ensure transmission to the members before the meeting. Minutes will be available within 30 days of this meeting.

Topic to be considered: During the February 6, 2018 meeting the three ETTAC subcommittees will discuss their top priorities for this charter period, with the goal of generating recommendations for the Secretary of Commerce. Topics under discussion include optimizing the U.S. Government's trade promotion programs, identifying market access barriers, pros and cons of existing trade agreements, and discussing procurement policy, including issues with financing mechanisms, localization requirements and non-tariff barriers. The ETTAC's subcommittees are: Trade Promotion and Export Market Development, Professional Services and Infrastructure Advancement, and Trade Policy and American Competitiveness.

Background: The ETTAC is mandated by Section 2313(c) of the Export Enhancement Act of 1988, as amended, 15 U.S.C. 4728(c), to advise the Environmental Trade Working Group of the Trade Promotion Coordinating Committee, through the Secretary of Commerce, on the development and administration of programs to expand U.S. exports of environmental technologies, goods, services, and products. The ETTAC was originally chartered in May of 1994. It was most recently re-chartered until August 2018.

Dated: January 10, 2018.

Edward A. O'Malley,

Director, Office of Energy and Environmental Industries.

[FR Doc. 2018–00643 Filed 1–16–18; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XF679

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Gulf of Mexico State Management Program Amendment for Recreational Red Snapper

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

ACTION: Notice of intent (NOI) to prepare a draft environmental impact statement (DEIS); request for comments.

SUMMARY: NMFS, Southeast Region, in collaboration with the Gulf of Mexico Fishery Management Council (Council), intends to prepare a DEIS to describe and analyze management alternatives to be included in the State Management Program for Recreational Red Snapper Amendment to the Fishery Management Plan (FMP) for the Reef Fish Resources of the Gulf of Mexico (State Management Program Amendment). The State Management Program Amendment will consider alternatives that would allocate the total recreational red snapper annual catch limit (ACL) for the Gulf of Mexico (Gulf) among the individual Gulf states of Alabama, Florida, Louisiana, Mississippi, and Texas, and designate the components of the recreational sector that would be included under a state's management program (private angling and/or charter vessel/headboat (for-hire) components). These decisions would form the basis for individual state amendments to the FMP to allow each of the Gulf states to establish management measures for the recreational harvest of red snapper in adjacent Gulf Federal waters. State management would enable each state to specify the management measures that best meet the needs of its constituents, thereby addressing regional socio-economic concerns. The purpose of this NOI is to inform the public of upcoming opportunities to provide additional comments on the scope of issues to be addressed in the DEIS, as specified in this notice.

DATES: Written comments on the scope of issues to be addressed in the DEIS must be received by NMFS by February 16, 2018.

ADDRESSES: You may submit comments on the Amendment identified by ''NOAA–NMFS–2017–0122'' by any of the following methods:

- *Electronic submissions:* Submit electronic comments via the Federal e-Rulemaking Portal: *http://www.regulations.gov.* Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2017-0122,* click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments
- *Mail:* Submit written comments to Lauren Waters, Southeast Regional Office, NMFS, 263 13th Avenue South, St. Petersburg, FL 33701.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

FOR FURTHER INFORMATION CONTACT: Lauren Waters, Southeast Regional Office, telephone: (727) 824–5305; or email: *Lauren.Waters@noaa.gov.*

SUPPLEMENTARY INFORMATION: For Gulf red snapper the recreational sector is separated into Federal for-hire (charter vessels and headboats) and private angling components, each managed under their respective recreational quotas and annual catch targets (ACTs). This separation will end after the 2022 fishing year if the Council takes no further action. NMFS annually projects the recreational season length for each component based on the ACTs and the projected average weights of fish and catch rates derived from historical

trends. Despite increases in the total red snapper quota, the recreational season length for the private angler component has become progressively shorter.

Fishermen from different Gulf states have requested more flexibility in recreational red snapper management so that regulations provide greater socio-economic benefits to their particular area. In June 2012, Louisiana requested that the Council develop a recreational red snapper regional management pilot program. As a result of the Louisiana request, the Council initiated development of Amendment 39 to the FMP. Amendment 39 considered several actions that are also currently being considered by the Council, such as the mechanism for implementing regional management, apportioning the recreational annual catch limit (ACL) among the Gulf states, and modifying post-season accountability measures (AMs) consistent with the regional management approach.

In May 2013, NMFS published an NOI to prepare a draft environmental impact statement for Amendment 39 and solicited public comment (78 FR 27956, May 13, 2013). As explained in that NOI, the intent of Amendment 39 was to allow participating states or regions to design management options to better fit their needs. However, red snapper would remain a federally managed species. The Council and NMFS would continue to oversee management of the stock. This includes continuing to comply with the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) and the mandate to ensure the red snapper annual recreational quota is not exceeded and that conservation objectives are achieved. The Council's Scientific and Statistical Committee (SSC) would continue to determine the acceptable biological catch (ABC) for red snapper, and the Council and NMFS would determine the total recreational red snapper quota that could be allocated among regions.

During the development of Amendment 39, the Council received public input on actions and alternatives regarding regional management of recreational red snapper at numerous public hearing meetings and Council meetings held throughout the Gulf states from October 2012 through January 2016, as well as via webinar. Additionally the Council's Reef Fish Advisory Panel reviewed regional management actions and alternatives in September 2015. The Environmental Protection Agency published a Notice of Availability for the DEIS for Amendment 39 in December 2015 (80 FR 79041, December 18, 2015). However, in January 2016, the Council voted to postpone further work on Amendment 39. In April 2017, the Council began discussing regional management concepts again and decided to develop new amendments to provide the management flexibility desired by the Gulf states and their constituents. Similar to Amendment 39, the intent is to allow each participating state to implement management measures to better fit its needs, while achieving the same conservations goals as the Federal management measures in existence at any given time.

The Council is currently considering several FMP amendments that would allow each Gulf state to manage the recreational harvest of red snapper in Federal waters adjacent to their state. The State Management Program Amendment will consider alternatives to apportion the total recreational red snapper ACL for the Gulf among the individual Gulf states and determine which components of the recreational sector would be included under a state's management program (private angling and/or charter vessel/headboat (for-hire) components). Five separate FMP amendments, one for each Gulf state, will consider alternatives to establish the state-specific authority structure, such as delegation or the use of conservation equivalency plans, and state-specific post-season accountability measures for each state that participates in the State Management Program for recreational red snapper (State Amendments).

NMFS, in collaboration with the Council, will develop a DEIS to describe and analyze alternatives to address the management needs described above including the ''no action'' alternative. The State Management Program Amendment DEIS will describe and analyze the apportionment and recreational sector component alternatives as well as describe and analyze the authority structure and accountability measure alternatives included in the five individual State Amendments. Thus, NMFS anticipates that the State Management Program Amendment EIS will include the relevant National Environmental Policy Act (NEPA) analyses for all six FMP amendments. However, NMFS will continue to evaluate this determination as the State Amendments are developed and will provide additional NEPA analysis as appropriate.

In accordance with NOAA's Administrative Order 216–6A, accompanying NEPA Procedures (companion manual), and the Scoping Process, NMFS, in collaboration with the Council, has identified preliminary environmental issues as a means to initiate discussion for scoping purposes only. The public is invited to provide written comments on the preliminary issues, which are identified as actions and alternatives in the State Management Program Amendment draft options paper and action guide. These preliminary issues may not represent the full range of issues that eventually will be evaluated in the DEIS. A copy of the State Management Program Amendment draft options paper and action guide are available at *http://sero.nmfs.noaa.gov/sustainable_fisheries/gulf_fisheries/reef_fish/2017/RSStateManagement/RSStateManage index.html.*

After the DEIS associated with the State Management Program Amendment is completed, it will be filed with the Environmental Protection Agency (EPA). After filing, the EPA will publish a notice of availability (NOA) of the DEIS for public comment in the **Federal Register**. The DEIS will have a 45-day comment period. This procedure is pursuant to regulations issued by the Council on Environmental Quality (CEQ) for implementing the procedural provisions of the NEPA (40 CFR parts 1500–1508) and to NOAA's Administrative Order 216–6A regarding NOAA's compliance with NEPA and the CEQ regulations.

The Council and NMFS will consider public comments received on the DEIS in developing the final environmental impact statement (FEIS), and before the Council votes to submit the State Management Program Amendment to NMFS for Secretarial review, approval, and implementation under the Magnuson-Stevens Act. NMFS will announce in the **Federal Register** the availability of the final amendment and FEIS for public review during the Secretarial review period, and will consider all public comments prior to final agency action to approve, disapprove, or partially approve the final amendment. During Secretarial review, NMFS will also file the FEIS with the EPA and the EPA will publish an NOA for the FEIS in the **Federal Register**.

NMFS will announce, through a notice published in the **Federal Register**, all public comment periods on the final amendment, its proposed implementing regulations, and the availability of its associated FEIS. NMFS will consider all public comments received during the Secretarial review period, whether they are on the final amendment, the proposed regulations, or the FEIS, prior to final agency action.

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

Dated: January 10, 2018.

Emily H. Menashes,

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

[FR Doc. 2018–00666 Filed 1–16–18; 8:45 am]

BILLING CODE 3510–22–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: Alaska American Fisheries Act (AFA) Reports.

OMB Control Number: 0648–0401.

Form Number(s): None.

Type of Request: Regular (extension of a currently approved information collection).

Number of Respondents: 8.

Average Hours per Response: AFA cooperative contract, 8 hours; annual cooperative report, 16 hours; inshore cooperative weekly catch report, 45 minutes; incentive plan agreement (IPA) amendment, 50 hours; incentive plan agreement disapproval appeals, 4 hours; IPA annual report, 80 hours.

Burden Hours: 599.

Needs and Uses: On October 21, 1998, the President signed into law The American Fisheries Act, 16 U.S.C. 1851 (AFA). The AFA authorizes the formation of fishery cooperatives in all sectors of the Bering Sea and Aleutian Islands Management Area (BSAI) pollock fishery, grants antitrust exemptions to cooperatives in the mothership sector, and imposes operational limits on fishery cooperatives in the BSAI pollock fishery. The National Marine Fisheries Service (NMFS) issues a single pollock allocation to each cooperative, and the cooperative may make sub-allocations of pollock to each individual vessel owner in the cooperative.

With respect to the fisheries off Alaska, the AFA Program is a suite of management measures that fall into four general regulatory categories:

- Limit access into the fishing and processing sectors of the BSAI pollock fishery and that allocate pollock to such sectors (50 CFR 679.64).
- Govern the formation and operation of fishery cooperatives in the BSAI pollock fishery, including filing of cooperative contracts (50 CFR 679.61 and 679.62).
- Protection of other fisheries from spillover effects from the AFA (50 CFR 679.64).
- Govern catch measurement and monitoring in the BSAI pollock fishery, including filing of annual reports and completing and submitting inshore catcher vessel pollock cooperative catch reports (50 CFR 679.63).

Affected Public: Business or other for-profit organizations.

Frequency: Annually and on occasion.

Respondent's Obligation: Mandatory.

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 11, 2018.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2018–00691 Filed 1–16–18; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XF951

Whaling Provisions; Aboriginal Subsistence Whaling Quotas

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

ACTION: Notice; notification of quota for bowhead whales.

SUMMARY: NMFS notifies the public of the aboriginal subsistence whaling quota for bowhead whales that it has assigned to the Alaska Eskimo Whaling Commission (AEWC), and of limitations on the use of the quota deriving from regulations of the International Whaling Commission (IWC). For 2018, the quota is 75 bowhead whales struck. This quota and other applicable limitations govern the harvest of bowhead whales by members of the AEWC.

DATES: Applicable January 17, 2018.

ADDRESSES: Office for International Affairs and Seafood Inspection, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910.

FOR FURTHER INFORMATION CONTACT: Carolyn Doherty, (301) 427–8385.

SUPPLEMENTARY INFORMATION: Aboriginal subsistence whaling in the United States is governed by the Whaling Convention Act (WCA) (16 U.S.C. 916 *et seq.*). Under the WCA, IWC regulations shall generally become effective with respect to all persons and vessels subject to the jurisdiction of the United States, within 90 days of notification from the IWC Secretariat of an amendment to the IWC Schedule (16 U.S.C. 916k). Regulations that implement the WCA, found at 50 CFR 230.6, require the Secretary of Commerce (Secretary) to publish, at least annually, aboriginal subsistence whaling quotas and any other limitations on aboriginal subsistence whaling deriving from regulations of the IWC.

At the 64th Annual Meeting of the IWC, the Commission set catch limits for aboriginal subsistence use of bowhead whales from the Bering-Chukchi-Beaufort Seas stock. The bowhead catch limits were based on a joint request by the United States and the Russian Federation, accompanied by documentation concerning the needs of two Native groups: Alaska Eskimos and Chukotka Natives in the Russian Far East.

The IWC set a 6-year block catch limit of 336 bowhead whales landed. For each of the years 2013 through 2018, the number of bowhead whales struck may not exceed 67, except that any unused portion of a strike quota from any prior year may be carried forward. No more than 15 strikes may be added to the strike quota for any one year. At the end of the 2017 harvest, there were 15 unused strikes available for carry-forward, so the combined strike quota set by the IWC for 2018 is 82 (67 + 15).

An arrangement between the United States and the Russian Federation ensures that the total quota of bowhead whales landed and struck in 2018 will not exceed the limits set by the IWC. Under this arrangement, the Russian natives may use no more than seven strikes, and the Alaska Eskimos may use no more than 75 strikes.

Through its cooperative agreement with the AEWC, NOAA has assigned 75 strikes to the Alaska Eskimos. The AEWC will in turn allocate these strikes among the 11 villages whose cultural and subsistence needs have been documented, and will ensure that its hunters use no more than 75 strikes.

Other Limitations

The IWC regulations, as well as the NOAA regulation at 50 CFR 230.4(c), forbid the taking of calves or any whale accompanied by a calf.

NOAA regulations (at 50 CFR 230.4) contain a number of other prohibitions relating to aboriginal subsistence whaling, some of which are summarized here:

- Only licensed whaling captains or crew under the control of those captains may engage in whaling.
- Captains and crew must follow the provisions of the relevant cooperative agreement between NOAA and a Native American whaling organization.
- The aboriginal hunters must have adequate crew, supplies, and equipment to engage in an efficient operation.
- Crew may not receive money for participating in the hunt.
- No person may sell or offer for sale whale products from whales taken in the hunt, except for authentic articles of Native American handicrafts.
- Captains may not continue to whale after the relevant quota is taken, after the season has been closed, or if their licenses have been suspended. They may not engage in whaling in a wasteful manner.

Dated: January 11, 2018.

John Henderschedt,

Director, Office for International Affairs and Seafood Inspection, National Marine Fisheries Service.

[FR Doc. 2018–00677 Filed 1–16–18; 8:45 am]

BILLING CODE 3510–22–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: Greater Atlantic Region Dealer Purchase Reports.

OMB Control Number: 0648–0229.

Form Number(s): None.

Type of Request: Regular (extension of a currently approved information collection).

Number of Respondents: 657.

Average Hours per Response: 4 minutes.

Burden Hours: 2,278.

Needs and Uses: This request is for extension of a currently approved information collection.

Federally permitted dealers, and any individual acting in the capacity of a dealer, must submit to the Regional Administrator or to the official designee a detailed report of all fish purchased or received for a commercial purpose, other than solely for transport on land, by one of the available electronic reporting mechanisms approved by National Marine Fisheries Service (NMFS). The information obtained is used by economists, biologists, and managers in the management of the fisheries. The data collection parameters are consistent with the current requirements for Federal dealers under the authority of the Magnuson-Stevens Fishery Conservation and Management Act.

Affected Public: Business or other for-profit organizations; individuals or households.

Frequency: Weekly.

Respondent's Obligation: Mandatory.

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 11, 2018.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2018–00690 Filed 1–16–18; 8:45 am]

BILLING CODE 3510–22–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: Southeast Region Individual Fishing Quota Programs.

OMB Control Number: 0648–0551.

Form Number(s): None.

Type of Request: Regular (revision and extension of a currently approved information collection).

Number of Respondents: 1,069.

Average Hours per Response: Share Transfer Receipt form, Cost Recovery Fee Submission form, 1 minute; Share Transfer form, IFQ Close Account form, Cost Recovery Fee Submission form, Landing Transaction Correction Request form, Landing Location Submission form, Transfer Allocation form, Cost Recovery Fee payment through *pay.gov,* 3 minutes; Notification of Landing form, 5 minutes; Landing Transaction Report form, 6 minutes; IFQ Online Account Application form, 15 minutes; Wreckfish Quota Share Transfer form, 18 minutes.

Burden Hours: 2,156.

Needs and Uses: This request is for an extension and revision of a currently approved information collection.

The NMFS Southeast Regional Office manages three commercial IFQ and individual transferable quota (ITQ) programs in the Southeast Region under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), 16 U.S.C. 1801 *et seq.* The IFQ programs for red snapper, and grouper and tilefish occur in Federal waters of the Gulf of Mexico, and the ITQ program for wreckfish occurs in Federal waters of the South Atlantic.

This collection of information tracks the transfer and use of IFQ and ITQ shares, and IFQ allocation and landings necessary to operate, administer, and review management of the IFQ and ITQ programs. Regulations for the IFQ and ITQ programs are located at 50 CFR part 622.

The NMFS Southeast Regional Office also proposes to revise parts of the information collection approved under OMB Control Number 0648–0551 to account for updates to burden time and cost estimates, as well as administrative updates to online and paper forms. NMFS intends the revisions would make instructions and data collection requirements clearer and easier to understand, resulting in more accurate and efficient information available for use by fishery managers.

Affected Public: Business or other for-profit organizations; individuals or households.

Frequency: Annually, quarterly and on occasion.

Respondent's Obligation: Mandatory.

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 11, 2018.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2018–00692 Filed 1–16–18; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Telecommunications and Information Administration

Tennessee Broadband Summit Conference

AGENCY: National Telecommunications and Information Administration, U.S. Department of Commerce and Tennessee Department of Economic and Community Development.

ACTION: Notice of open meeting.

SUMMARY: The National Telecommunications and Information Administration's BroadbandUSA Program, in partnership with the Tennessee Department of Economic and Community Development, will host a Broadband Summit about ''Creating Partnerships to Ensure Access for All'' on March 20, 2018. Speakers and attendees from Tennessee, federal agencies, and across the country will come together to explore ways to increase broadband deployment and improve broadband adoption to advance their overarching business, social, economic, and community goals. This Summit will highlight the initiatives and outreach driven through the newly enacted Tennessee Broadband Accessibility Act, which promotes broadband deployment thorough grants to providers, tax credits, deregulation, and education.

DATES: The Broadband Summit will be held on March 20, 2018, from 8:00 a.m. to 5:00 p.m., Central Time.

ADDRESSES: The meeting will be held in Nashville, Tennessee at the William Snodgrass Tennessee Tower, 312 Rosa L Parks Avenue, Tennessee Room, 3rd Floor, Nashville, TN 37243.

FOR FURTHER INFORMATION CONTACT: Janice Wilkins, National Telecommunications and Information Administration (NTIA), U.S. Department of Commerce, Room 4678, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–5791; email: *jwilkins@ntia.doc.gov.* Please direct media inquiries to NTIA's Office of Public Affairs, (202) 482–7002; email: *press@ntia.doc.gov.*

SUPPLEMENTARY INFORMATION: The NTIA's BroadbandUSA program promotes innovation and economic growth by supporting efforts to expand broadband access and meaningful use across America. The Tennessee Department of Economic and Community Development (TNECD) is responsible for implementing the Tennessee Broadband Accessibility Act (TBAA), which facilitates broadband access to all Tennesseans while promoting practices that increase deployment and encourage adoption. The ''Creating Partnerships to Ensure Access for All'' Broadband Summit will facilitate the sharing of best practices for public-private partnerships to improve broadband deployment, enhance digital skills, and stimulate innovation and economic development.

The Summit is open to the public. Pre-registration is requested, and space is limited. NTIA asks registrants to provide their first and last names and email addresses for both registration purposes and to receive any updates on the workshop. Registration information, meeting updates, changes in the agenda, if any, and relevant documents will be available on NTIA's website at *https://www2.ntia.doc.gov/tennessee-broadband-summit-03202018.*

The public meeting is physically accessible to people with disabilities. Individuals requiring accommodations, such as language interpretation or other ancillary aids, should notify Janice Wilkins at the contact information listed above at least five (5) business days before the meeting so that accommodations can be made.

Dated: January 11, 2018.

Kathy D. Smith,

Chief Counsel, National Telecommunications and Information Administration.

[FR Doc. 2018–00689 Filed 1–16–18; 8:45 am]

BILLING CODE 3510–60–P

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Application Package for the AmeriCorps Alumni Outcome Survey

AGENCY: Corporation for National and Community Service (CNCS).

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, CNCS is proposing to renew an information collection.

DATES: Written comments must be submitted to the individual and office listed in the **ADDRESSES** section by March 19, 2018.

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 Adrienne DiTommaso, 250 E Street SW, Washington, DC, 20525.

(2) By hand delivery or by courier to the CNCS mailroom 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 *www.regulations.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.

Comments submitted in response to this notice may be made available to the public through *regulations.gov.* For this reason, please do not include in your comments information of a confidential nature, such as sensitive personal information or proprietary information. If you send an email comment, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. Please note that responses to this public comment request containing any routine notice about the confidentiality of the communication will be treated as public comment that may be made available to the public notwithstanding the inclusion of the routine notice.

FOR FURTHER INFORMATION CONTACT: Adrienne DiTommaso, 202–606–3611, or by email at *aditommaso@cns.gov.*

SUPPLEMENTARY INFORMATION:

Title of Collection: AmeriCorps Alumni Outcome Survey.

OMB Control Number: #3045–0170.

Type of Review: Renewal.

Respondents/Affected Public: AmeriCorps Members.

Total Estimated Number of Annual Respondents: 3000.

Total Estimated Annual Frequency: One time.

Total Estimated Average Response Time per Response: 25 Minutes.

Total Estimated Number of Annual Burden Hours: 1,250 Hours.

Total Burden Cost (capital/startup): None.

Total Burden Cost (operating/maintenance): None.

Abstract

CNCS seeks to renew the current information request with revisions to the survey administered in 2015 (OMB

#3045–0170). Information will be collected from a nationally representative sample of AmeriCorps alumni who served in AmeriCorps NCCC, AmeriCorps VISTA, and AmeriCorps State and National programs and completed their most recent term of service 2, 5, or 10 years ago.

Information will be collected from AmeriCorps Alumni through an online survey that will be administered by a contractor on behalf of CNCS. The purpose of the survey is to better understand the long-term civic participation and career pathways of AmeriCorps alumni, the acquisition of hard and soft career skills obtained through national service, and the utilization of the Education Award and its effect on future post-secondary outcomes and career choices. These data may also be matched to administrative data collected by the US Census for the Longitudinal Employment and Household Data Set and by the National Student Clearinghouse in order to assess both employment and education outcomes within the national population. In addition, the agency is interested in exploring how member outcomes vary by life stage and by different types of service experiences. This survey is also an opportunity to determine the value of data collected from alumni who are at different stages following their service year for informing policy and program decisions. CNCS also seeks to continue using the current clearance until the revised survey is approved by OMB. The current clearance is due to expire on 4/30/18.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information. All written comments will be available for public inspection on *regulations.gov.*

Dated: January 9, 2018.

Mary Morris Hyde,

Director, Office of Research and Evaluation.

[FR Doc. 2018–00682 Filed 1–16–18; 8:45 am]

BILLING CODE 6050–28–P

DEPARTMENT OF DEFENSE

Department of the Army

Surplus Properties; Notice

AGENCY: Department of the Army, DoD.

ACTION: Notice.

SUMMARY: This amended notice provides information regarding the properties that have been determined surplus to the requirements of the United States in accordance with the Defense Base Closure and Realignment Act of 1990, Public Law 101–510, as amended, and following screening with Federal agencies and Department of Defense components. This Notice amends the Notice published in the **Federal Register** on June 25, 1996.

DATES: Applicable January 17, 2018.

FOR FURTHER INFORMATION CONTACT: Headquarters, Department of the Army, Assistant Chief of Staff for Installation Management, Base Realignment and Closure (BRAC) Division, Attn: DAIM–ODB, 600 Army Pentagon, Washington DC 20310–0600, (703) 545–2487, *usarmy.pentagon.hqda-acsim.mbx.braco-webmaster@mail.mil.* For information regarding the specific property subject to this notice, a point of contact is provided below.

SUPPLEMENTARY INFORMATION: Under the provisions of Codifying Title 40, United States Code—Public Buildings, Property, and Works Act of 2002 (Pub. L. 107–217, 40 U.S.C. 101, *et seq.,* as amended), section 2905(b) of the Defense Base Closure and Realignment Act of 1990 (Pub. L. 101–510; 10 U.S.C. 2687 note), and other public benefit conveyance authorities, this surplus property may be available for conveyance to State and local governments and other eligible entities for public benefit purposes. The Jo-Carroll Depot Local Redevelopment Authority has been recognized by Department of Defense as the Local Redevelopment Authority (LRA) for this surplus property. Notices of interest from representatives of the homeless, and other interested parties located in the vicinity of the listed surplus property should be submitted to the Jo-Carroll Depot Local Redevelopment Authority. The LRA's Point of Contact is Ms. Mara Roche, Executive Director, Jo-Carroll Depot Local Redevelopment Authority. The LRA is located at 18901 B Street, Savanna, Illinois 61074, telephone (815) 599–1818. Notices of interest from representatives of the homeless shall include the information required by 32 CFR 176.20(c)(2)(ii). The Jo-Carroll Depot Local Redevelopment Authority will assist interested parties in evaluating the surplus property for the intended use. The deadline for notices of interest shall be 90 days from the date the LRA publishes a corresponding notice in a newspaper of general circulation in the vicinity of the surplus property.

Surplus Property List

Addition

Savanna, Illinois

Savanna Army Depot, Illinois, a portion of, comprising approximately 132.2 acres. Additional information for this surplus property can be found at *http://www.hqda.pentagon.mil/acsimweb/brac/sites.html?state=IL?brac=1995?site=IL_SavannaAD_1995*

The Army's Point of Contact for this surplus property is Mr. George Triggs, Realty Specialist, Louisville District, U.S. Army Corps of Engineers, telephone (502) 315–7014, email: *George.S.Triggs@usace.army.mil.*

Authority: This action is authorized by the Defense Base Closure and Realignment Act of 1990 (Pub. L. 101–510; 10 U.S.C. 2687 note).

Dated: January 5, 2018.

Paul D. Cramer,

Deputy Assistant Secretary of the Army (Installations, Housing & Partnerships).

[FR Doc. 2018–00668 Filed 1–16–18; 8:45 am]

BILLING CODE 5001–03–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 17–50]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense.

ACTION: Arms sales notice.

SUMMARY: The Department of Defense is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT: Pamela Young, (703) 697–9107, *pamela.a.young14.civ@mail.mil* or Kathy Valadez, (703) 697–9217, *kathy.a.valadez.civ@mail.mil;* DSCA/DSA–RAN.

SUPPLEMENTARY INFORMATION: This 36(b)(1) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 17–50 with attached Policy Justification and Sensitivity of Technology.

Dated: January 11, 2018.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–P

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

JAN 05 2018

The Honorable Paul D. Ryan
Speaker of the House
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 17-50, concerning the Air Force's proposed Letter(s) of Offer and Acceptance to the Government of the Oman for defense articles and services estimated to cost $62 million. After this letter is delivered to your office, we plan to issue a news release to notify the public of this proposed sale.

Sincerely,

Charles W. Hooper
Lieutenant General, USA
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Sensitivity of Technology
4. Regional Balance (Classified document provided under separate cover)

BILLING CODE 5001–06–C

Transmittal No. 17–50

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser:* Government of Oman

(ii) *Total Estimated Value:*

Major Defense Equipment *	$ 0 million
Other	$62 million
Total	$62 million

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:* The Government of Oman has requested a possible sale of items and services to support an incremental Operational Flight Profile (OFP) software upgrade for F–16 subsystems, as well as Identification Friend or Foe (IFF) and secure communications equipment for Mode 5 operations, on twenty-three (23) F–16 aircraft.

Major Defense Equipment (MDE): None

Non-MDE includes:

Non-MDE items and services consist of twenty-nine (29) KIV–78 cryptographic/timing modules (twenty-three (23) installed and six (6) spares); twenty-nine (29) KY–100M cryptographic radio encryptors (twenty-three (23) installed and six (6) spares); twenty-nine (29) AN/APX–126 Combined Interrogator Transponders (twenty-three (23) installed and six (6) spares); Classified and Unclassified Computer Program Identification Numbers (CPINS) upgrades; OFP upgrades for IFF Mode 5 capable systems; Joint Mission Planning (JMPS) upgrade; Sniper Advanced Targeting Pod software, service support, support equipment, spares, and training; systems support and test equipment; spare and repair parts; publications and technical documentation; training and training equipment; U.S. Government and contractor engineering; logistics and technical support services; and other related elements of logistics and program support.

(iv) *Military Department:* Air Force (MU–D–QAR)

(v) *Prior Related Cases, if any:* None

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* See Attached Annex

(viii) *Date Report Delivered to Congress:* January 5, 2018

*As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Oman—F–16 Operational Flight Profile and Identification Friend or Foe Mode 5 Upgrade

The Government of Oman has requested a possible sale of items and services to support an incremental Operational Flight Profile (OFP) software upgrade for F–16 subsystems, as well as Identification Friend or Foe (IFF) and secure communications equipment for Mode 5 operations on twenty-three (23) F–16 aircraft. Non-MDE items and services consist of twenty-nine (29) KIV–78 cryptographic/timing modules (twenty-three (23) installed and six (6) spares); twenty-nine (29) KY–100M cryptographic radio encryptors (twenty-three (23) installed and six (6) spares); twenty-nine (29) AN/APX–126 Combined Interrogator Transponders (twenty-three (23) installed and six (6) spares); Classified and Unclassified Computer Program Identification Numbers (CPINS) upgrades; OFP upgrades for IFF Mode 5 capable systems, Joint Mission Planning (JMPS) upgrade; Sniper Advanced Targeting Pod software, service support, support equipment, spares, and training; systems support and test equipment; spare and repair parts; publications and technical documentation; training and training equipment; U.S. Government and contractor engineering; logistics and technical support services; and other related elements of logistics and program support. The estimated cost is $62 million.

This proposed sale will support the foreign policy and national security objectives of the United States by helping to improve the security of a friendly country which has been, and continues to be, an important force for political stability and economic progress in the Middle East.

The proposed sale allows the U.S. military to support the Royal Air Force of Oman, further strengthen the U.S.-Omani military-to-military relationship, and ensure continued interoperability of forces and opportunities for bilateral training and exercises with Oman's military forces.

This proposed sale of items and services will enable Oman's twenty-three (23) F–16s currently using Mode 4 IFF to become interoperable on Mode 4/5. Mode 5 IFF allows U.S. and partner airborne and surface armed forces to conduct complimentary air operations. Incremental OFP software upgrades required to support Mode 5 will provide additional incremental improvement for other associated F–16 subsystems. Oman will have no difficulty in absorbing these upgrades into its F–16 fleet.

This proposed sale of equipment and support will not alter the basic military balance in the region.

The prime contractor will be Lockheed Martin of Fort Worth, Texas. There are no known offset agreements proposed in conjunction with this potential sale.

The proposed sale will not require the long-term assignment of any additional U.S. Government or contractor representatives to Oman.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 17–50

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act

Annex

Item No. vii

(vii) *Sensitivity of Technology:*

1. This proposed sale of items and services to upgrade Oman's F–16 aircraft will involve the release of sensitive technology related to the Identification Friend or Foe (IFF) and secure communications equipment.

2. The AN/APX–126 Combined Interrogator Transponder is an IFF dual Mode 4 and 5 capable system. It is UNCLASSIFIED unless/until Mode 4 and/or Mode 5 operational evaluator parameters are loaded into the equipment, which are classified up to SECRET. Classified elements of the IFF system include software object code, operating characteristics, parameters, and technical data. Mode 4 and Mode 5 anti-jam performance specifications/data, software source code, algorithms, and tempest plans or reports will not be offered, released, discussed, or demonstrated.

3. KIV–78 is a crypto appliqué for Mode 5 IFF. The hardware is UNCLASSIFIED unless loaded with Mode 4 and/or Mode 5 classified elements, which are classified up to SECRET.

4. KY–100M is a cryptographic encryptor for voice radios to provide secure communication capabilities. The hardware is UNCLASSIFIED unless loaded with cryptograph keys, which are classified up to SECRET.

5. Joint Mission Planning System (JMPS) is a multi-platform, PC-based mission planning system. JMPS hardware is UNCLASSIFIED, but the software is classified up to SECRET.

6. If a technologically advanced adversary were to obtain knowledge of the specific hardware and software elements, the information could be used

to develop countermeasures that might reduce weapon system effectiveness or be used in the development of a system with similar or advanced capabilities.

7. A determination has been made that Oman can provide substantially the same degree of protection for the sensitive technology being released as the U.S. Government. This sale is necessary in furtherance of the U.S. foreign policy and national security objectives outlined in the policy justification.

8. All defense articles and services listed in this transmittal are authorized for release and export to the Government of Oman.

[FR Doc. 2018–00667 Filed 1–16–18; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 17–63]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense.

ACTION: Arms sales notice.

SUMMARY: The Department of Defense is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT: Pamela Young, (703) 697–9107, *pamela.a.young14.civ@mail.mil* or Kathy Valadez, (703) 697–9217, *kathy.a.valadez.civ@mail.mil;* DSCA/DSA–RAN.

SUPPLEMENTARY INFORMATION: This 36(b)(1) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 17–63 with attached Policy Justification and Sensitivity of Technology.

Dated: January 11, 2018.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–P

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

JAN 0 5 2018

The Honorable Paul D. Ryan
Speaker of the House
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 17-63, concerning the Navy's proposed Letter(s) of Offer and Acceptance to the Government of Mexico for defense articles and services estimated to cost 598.4 million. After this letter is delivered to your office, we plan to issue a news release to notify the public of this proposed sale.

Sincerely,

Charles W. Hooper
Lieutenant General, USA
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Sensitivity of Technology

BILLING CODE 5001–06–C

Transmittal No. 17–63

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser:* The Government of Mexico

(ii) *Total Estimated Value:*

Major Defense Equipment * ..	$55.0 million
Other	$43.4 million
Total	$98.4 million

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:*

Major Defense Equipment (MDE):

Six (6) RGM–84L Harpoon Block II Surface Launched Missiles

Twenty-three (23) Block II Rolling Airframe Missile (RAM) Tactical Missiles

Six (6) MK 54 Mod 0 Lightweight Torpedoes

Non-MDE includes:

Also included are eight (8) MK 825 Mod 0 RAM Guided Missile Round Packs (GMRP) tri-pack shipping and storage containers; RAM Block 2 MK 44 Mod 4 Guided Missile Round Pack (GMRP); two (2) MK 32 Surface Vessel Torpedo Tubes (SVTT) triple tube launchers; two hundred and fifty (250) rounds of AA98 25 mm high explosive and semi-armor piercing ammunition; seven hundred and fifty (750) rounds A976 25mm target practice and tracer ammunition; four hundred and eighty (480) rounds of BA22 57mm high explosive programmable fuze ammunition; nine hundred and sixty (960) rounds of BA23 57mm practice ammunition; containers; spare and repair parts; support and test equipment; publications and technical documentation; personnel training and training equipment; U.S. Government and contractor representatives' technical assistance; engineering and logistics support services; installation services; associated electronics and hardware to control the launch of torpedoes; and other related elements of logistics and program support.

(iv) *Military Department:* Navy

(v) *Prior Related Cases, if any:* None

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* See Attached Annex

(viii) *Date Report Delivered to Congress:* January 5, 2018

*As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Government of Mexico—Harpoon Block II Missiles, RAM Missiles and MK 54 Torpedoes

The Government of Mexico has requested to buy six (6) RGM–84L Harpoon Block II surface launched missiles, twenty-three (23) Block II Rolling Airframe Missile (RAM) tactical missiles and six (6) MK 54 Mod 0 lightweight torpedoes. Also included are eight (8) MK 825 Mod 0 RAM Guided Missile Round Packs (GMRP) tri-pack shipping and storage containers; RAM Block 2 MK 44 Mod 4 Guided Missile Round Pack (GMRP); two (2) MK 32 Surface Vessel Torpedo Tubes (SVTT) triple tube launchers; two hundred and fifty (250) rounds of AA98 25 mm high explosive and semi-armor piercing ammunition; seven hundred and fifty (750) rounds A976 25mm target practice and tracer ammunition; four hundred and eighty (480) rounds of BA22 57mm high explosive programmable fuze ammunition; nine hundred and sixty (960) rounds of BA23 57mm practice ammunition; containers; spare and repair parts; support and test equipment; publications and technical documentation; personnel training and training equipment; U.S. Government and contractor representatives' technical assistance; engineering and logistics support services; installation services; associated electronics and hardware to control the launch of torpedoes; and other related elements of logistics and program support. The estimated cost is $98.4 million.

This proposed sale will support the foreign policy and national security of the United States by helping to improve the security of a strategic partner. Mexico has been a strong partner in combating organized crime and drug trafficking organizations. The sale of these ship-based systems to Mexico will significantly increase and strengthen its maritime capabilities. Mexico intends to use these defense articles and services to modernize its armed forces and expand its existing naval and maritime support of national security requirements and in its efforts to combat criminal organizations.

Mexico intends to use the weapon systems on its Mexican Navy Sigma 10514 Class ship. The systems will provide enhanced capabilities in effective defense of critical sea lanes. The proposed sale of these systems and support will increase the Mexican Navy's maritime partnership potential and align its capabilities with existing regional navies. Mexico has not purchased these systems previously. Mexico will have no difficulty absorbing this equipment into its armed forces.

The proposed sale of this equipment will not alter the basic military balance in the region.

The equipment will be provided from U.S. stocks. There are no known offset agreements proposed in connection with this potential sale.

Implementation of this proposed sale will require annual trips to Mexico involving U.S. Government personnel and contractor representatives for technical reviews, support, and oversight for approximately two years.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 17–63

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act

Annex

Item No. vii

(vii) *Sensitivity of Technology:*

1. The MK 32 SVTT system is UNCLASSIFIED, but the system has one classified firmware card that controls launches. The system is currently in service in the U.S. Navy and in various other foreign nations that utilize shipboard launched torpedoes. The firmware card is essential to the ability of the system to successfully launch torpedoes when directed by the shipboard command and control system.

2. The RGM–84L Harpoon Surface Launched Block II missile system, to include publications, documentation, operations, supply, maintenance, and training to be conveyed with this proposed sale have the highest classification level of CONFIDENTIAL. The Harpoon Block II missile is a non-nuclear tactical weapon system currently in service in the U.S. Navy and in 29 other foreign nations. It provides a day, night, and adverse weather, standoff surface-to-surface capability and is an effective Anti-Surface Warfare missile. The RGM–84L incorporates components, software, and technical design information that are considered SENSITIVE.

3. The following components being conveyed by the proposed sale are considered sensitive and are classified CONFIDENTIAL:

a. The Radar Seeker
b. The GPS/INS System
c. Operational Flight Program Software
d. Missile operational characteristics and performance data

These elements are essential for the Harpoon Block II missile to selectively engage hostile targets under a wide range of operational, tactical and environmental conditions. The version being sold to Mexico is not the Coastal Target Suppression land attack missile version.

4. MK 54 All-Up-Round Lightweight (Warshot) torpedoes and associated support equipment, training, test equipment, and technical support; Recoverable Exercise Torpedoes (REXTORPs); and Exercise Torpedoes (EXTORPs) are associated with this sale. The MK 54 Lightweight Torpedo (LWT) can be launched from surface ships, helicopters, and fixed wing aircraft. The MK 54 LWT is an upgrade to the MK 46 Torpedo. The MK 54 LWT contains new sonar, guidance and control systems with modern technology. The new guidance and control system uses a mixture of commercial-off-the-shelf and custom-built electronics. The warhead, fuel tank, and propulsion system from the MK 46 torpedo are re-used in the MK 54 configuration with minor modifications. The MK 54 is highly

effective against modern diesel and nuclear submarines. It has advanced logic that allows it to detect and prosecute threat submarines operating in challenging littoral environments. It is also effective in the presence of advanced countermeasures that may be deployed by threat submarines. The assembled MK 54 torpedo and several of its individual components are classified CONFIDENTIAL. The MK 54 operational software is classified as SECRET as is any hardware upon which the software has been installed. Mexico has not requested nor will it be provided the source code for the MK 54 operational software. The MK 54 has a feature referred to as ''Memory Scuttle'' that erases the operational software at the conclusion of any exercise firing so that the software will not be compromised if the torpedo is not recovered after the exercise firing. Possession of MK 54 Torpedoes and associated equipment should not lead to any vulnerability disclosures.

5. If a technologically advanced adversary were to obtain knowledge of the specific hardware and software elements, the information could be used to develop countermeasures or equivalent systems which might reduce weapon system effectiveness or be used in the development of a system with similar or advanced capabilities.

6. A determination has been made that the Government of Mexico can provide substantially the same degree of protection for the sensitive technology being released as the U.S. Government. This proposed sale is necessary to the furtherance of the U.S. foreign policy and national security objectives outlined in the Policy Justification.

7. All defense articles and services listed in this transmittal are authorized for release and export to the Government of Mexico.

[FR Doc. 2018–00670 Filed 1–16–18; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 17–0C]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense.

ACTION: Arms sales notice.

SUMMARY: The Department of Defense is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT: Pamela Young, (703) 697–9107, *pamela.a.young14.civ@mail.mil* or Kathy Valadez, (703) 697–9217, *kathy.a.valadez.civ@mail.mil;* DSCA/DSA–RAN.

SUPPLEMENTARY INFORMATION: This 36(b)(5)(C) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 17–0C with attached Policy Justification.

Dated: January 11, 2018.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–P

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

JAN 0 5 2018

The Honorable Paul D. Ryan
Speaker of the House
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(5)(C) of the Arms Export Control Act (AECA), as amended, we are forwarding Transmittal No. 17-0C. This notification relates to enhancements or upgrades from the level of sensitivity of technology or capability described in Section 36(b)(1) AECA certification 16-30 of August 18, 2016.

Sincerely,

Charles W. Hooper
Lieutenant General, USA
Director

Enclosure:
1. Transmittal

BILLING CODE 5001–06–C

Transmittal No. 17–0C

Report of Enhancement or Upgrade of Sensitivity of Technology or Capability (Sec. 36(b)(5)(c), AECA)

(i) *Purchaser:* NATO Support and Procurement Agency (NSPA) as lead-nation for Belgium, Czech Republic, Denmark, Greece, Netherlands, Norway, Portugal, and Spain

(ii) *Sec. 36(b)(1), AECA Transmittal No.:* 16–30

Date: 18 August 2016

Military Department: Air Force

(iii) *Description:* On August 18, 2016, Congress was notified by Congressional certification transmittal number 16–30, of the possible sale under Section 36(b)(1) of the Arms Export Control Act of Five hundred (500) Joint Direct Attack Munition (JDAM) Guidance Kits, KMU–556 F/B Forty (40) JDAM Guidance Kits, KMU–557 F/B, one thousand five hundred (1,500) JDAM Guidance Kits, KMU–572 F/B, one thousand (1,000) MAU 210 E/B

Computer Control Groups for 1,000-lb Enhanced Paveway IIs, three hundred (300) MAU 210 E/B Computer Control Groups for GBU–49s, one thousand twenty-five (1,025) MAU 169 L/B Computer Control Groups for GBU–12s, one thousand three hundred fifty (1,350) Joint Programmable Fuzes, FMU–152 A/B, sixty (60) Bomb Fin Assembly and Airfoil Group 650–MXU K/B for GBU–12s, one thousand twenty-five (1,025) Bomb Fin Assembly and Airfoil Group, MXU–650 K/B AFG for GBU–12s. Non-MDE: Detector Sensing Unit (DSU)–38A/B Laser sensors, DSU–330/B proximity sensors, Wireless Paveway Avionics Kit (WIPAK) interfaces for Enhanced Paveway II bombs, FMU–139C/B electronic bomb fuzes, repair and return services, transportation, engineering services, and other support services. The estimated total cost was $231 million. Major Defense Equipment (MDE) constituted $151 million of this total.

The original notification listed ''kit'' components to build one thousand (1,000) GBU–48 (1,000-lb) Enhanced Paveway IIs (EPII) (MDE items), three hundred (300) GBU–49 (500-lb) EPIIs (MDE items), and one thousand and twenty-five (1,025) GBU–12 (500-lb) Paveway II (PWII) (MDE items). Each ''kit'' includes a Computer Control Group (CCG) and Air Foil Group (AFG) to convert a general purpose bomb into EPII or PWII.

This transmittal reports the replacement of one thousand (1,000) MAU–210 E/B (MDE items) with one thousand (1,000) MAU–210 F/B (MDE items) for the GBU–48 1,000-lb EPII and three hundred (300) MAU–210 E/B (MDE items) with three hundred (300) MAU–210 F/B (MDE items) for the GBU–49 500-lb EPII, to reflect the change from Lot 3A to Lot 5 for the moving target variant CCGs being procured to build EPIIs.

This transmittal also supplements the description of the AFGs kit components to include one thousand (1,000) MXU–667 H/B AFGs for the GBU–48 and three hundred (300) MXU–650 K/B AFGs for the GBU–49.

This transmittal also increases the number of FMU–152 A/B fuzes (MDE items) from one thousand three hundred and fifty (1,350) to four thousand three hundred and sixty five (4,365) to match the total number of JDAM and Paveway Kits. The numbers reflect their substitution for FMU–139 C/B fuzes (non-MDE) previously notified.

The upgrade of the MAUs from Lot 3A to Lot 5, enumerating the MDE status of the tail groups, and increasing the number of fuzes will result in a net increase in the MDE cost of $49 million. The total case value will increase to $280 million.

(iv) *Significance:* This notification reports the replacement of the EPII MAU–210E/B with the EPII MAU–210F/B, the further clarification of AFGs for EPIIs, and upgrades the fuze type from FMU–139 C/B to FMU–152 A/B for this sale. Upgrading these MDE items results in an increase in capability over what was originally notified. The MAU–210F/B adds 3–D proportional navigation, improved accuracy for high speed (>70 mph) and maneuvering targets, wider laser field of view, and an improved Inertial Measurement Unit (IMU). This transmittal provides information about the airfoil groups required to match the total number of EPIIs notified on Transmittal 15–33. The sensitivity of technology statement contained in the original transmittal applies to the FMU–152 A/B reported here.

(v) *Justification:* The proposed sale improves NATO members' capability to meet current and future ground threats with precision. They will use the enhanced capacity as a deterrent to regional threats, and to increase interoperability within contingency operations. Many of the purchasing nations already have precision-guided munitions in their inventories and will have no difficulty absorbing these additional munitions. The proposed sale of this equipment and support will not alter the basic military balance in the region.

Implementation of this proposed sale will not require the assignment of any additional U.S. Government or contractor representatives to NATO. There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

(vi) *Date Report Delivered to Congress:* January 5, 2018

[FR Doc. 2018–00681 Filed 1–16–18; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID DOD–2018–OS–0001]

Proposed Collection; Comment Request

AGENCY: Office of the Secretary of Defense, DoD.

ACTION: 60-Day information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Defense Security Service (DSS) announces the proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: 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; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by March 19, 2018.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Department of Defense, Office of the Deputy Chief Management Officer, Directorate for Oversight and Compliance, Regulatory and Advisory Committee Division, 4800 Mark Center Drive, Mailbox #24, Suite 08D09B, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

Any associated form(s) for this collection may be located within this same electronic docket and downloaded for review/testing. Follow the instructions at *http://www.regulations.gov* for submitting comments. Please submit comments on any given form identified by docket number, form number, and title.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to: Defense Security Service, ATTN: Mr. Troy Littles, Chief of Staff, 27130 Telegraph Road, Quantico, VA 22134.

SUPPLEMENTARY INFORMATION:

Title and OMB Number: Personnel Security Investigation Projection for Industry Census Survey; OMB Number 0704–0417.

Needs and Uses: Executive order (E.O.) 12829, ''National Industrial Security Program (NISP),'' stipulates that the Secretary of Defense shall serve as the Executive Agent for inspecting and monitoring the contractors, licensees, and grantees who require or will require access to classified information; and for determining the eligibility for access to classified information of contractors, licensees, and grantees and their respective employees. The Under Secretary of Defense for Intelligence assigned Defense Security Service (DSS) the responsibility for central operational management of NISP personnel security investigation (PSI) workload projections, and for monitoring of NISP PSI funding and investigations. The execution of the collection instrument is an essential element of DSS' ability to plan, program and budget for the PSI needs of NISP personnel security investigations.

Affected Public: Cleared business or other for profit; not-for-profit institutions under Department of Defense Security Cognizance approved for storage of classified materials.

Annual Burden Hours: 5,210.50.

Number of Respondents: 10,421.

Responses per Respondent: 1.

Average Burden per Response: 30 minutes.

Frequency: Annually.

In this annual collection of information, DSS asks the Facility Security Officers of cleared contractor entities to provide for each of three upcoming fiscal years (*e.g.,* 2018, 2019, 2020): projections of the numbers and types of personnel security investigations (PSIs) required; a description of methodology used for the projections; and estimates of the numbers and types of cleared contractor's PSI projections that are separately attributable to DoD contracts and the contracts of non-DoD agencies. The data will be incorporated into DSS budget submissions and used to track against actual PSI submissions. PSI projections are collected electronically via a PSI module within the National Industrial Security System (NISS) which displays OMB approval number 0704–0417.

Dated: January 11, 2018.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2018–00702 Filed 1–16–18; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2017–ICCD–0138]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Fast Response Survey System (FRSS) 109: Teachers' Use of Technology for School and Homework Assignments—Preliminary Activities

AGENCY: National Center for Education Statistics (NCES), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing a reinstatement of a previously approved information collection.

DATES: Interested persons are invited to submit comments on or before February 16, 2018.

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–0138. 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 216–34, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Kashka Kubzdela, 202–245–7377.

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: Fast Response Survey System (FRSS) 109: Teachers' Use of Technology for School and Homework Assignments—Preliminary Activities.

OMB Control Number: 1850–0857.

Type of Review: A reinstatement of a previously approved information collection.

Respondents/Affected Public: Individuals or Households.

Total Estimated Number of Annual Responses: 3,100.

Total Estimated Number of Annual Burden Hours: 2,161.

Abstract: The National Center for Education Statistics (NCES) requests OMB approval to conduct teacher list collection and district recruitment for the Fast Response Survey System (FRSS) 109 survey on teachers' use of technology for school and homework assignments in public schools. NCES is conducting this FRSS survey as part of the IES response to the request in the Every Student Succeeds Act of 2015 (ESSA, 20 U.S.C. 6301 *et seq.*) to provide information about the educational impact of access to digital learning resources (DLRs) outside of the classroom. The expanding use of technology affects the lives of students both inside and outside the classroom. For this reason, the role of technology in education is an increasingly important area of research. While access to technology can provide valuable learning opportunities to students, technology by itself does not guarantee successful outcomes. Schools and teachers play an important role in successfully integrating technology into teaching and learning. Findings from the FRSS 109 study will provide insight on the types and availability of DLRs outside of the classroom, and will contribute to IES legislatively mandated report on the educational impact of access to DLRs outside the classroom.

To provide the needed data, FRSS 109 will collect nationally representative data from public school teachers about their use of DLRs for teaching, and how their knowledge and beliefs about their students' access to DLRs outside the classroom affect the assignments they give. The survey will focus on information that can best be provided by teachers from their perspective and direct interaction with students. FRSS 109 will provide national statistics on: (1) Teachers' knowledge and beliefs about students' access to technology for doing school assignments outside of school; (2) Barriers and challenges teachers believe their students face in using technology for class assignments outside of school; and (3) Computers that the district or school may make available to students for use outside of class time. This request is for FRSS 109 preliminary activities, including securing research approval from special contact school districts beginning in April 2018 and obtaining teacher lists from sampled schools beginning in August 2018.

Dated: January 10, 2018.

Kate Mullan,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2018–00638 Filed 1–16–18; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No. ED–2018–ICCD–0005]

Agency Information Collection Activities; Comment Request; Impact Study of Federally-Funded Magnet Schools

AGENCY: Institute of Education Sciences (IES), 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 19, 2018.

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–2018–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 216–32, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Lauren Angelo, 202–245–7474.

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: Impact Study of Federally-Funded Magnet Schools.

OMB Control Number: 1850—NEW.

Type of Review: A new information collection.

Respondents/Affected Public: Individuals or Households.

Total Estimated Number of Annual Responses: 179.

Total Estimated Number of Annual Burden Hours: 265.

Abstract: This Office of Management and Budget (OMB) package requests clearance for data collection activities to support a rigorous Impact Study of Federally-Funded Magnet Schools. The Institute of Education Sciences (IES) at the U.S. Department of Education (ED) has contracted with Mathematica Policy Research and its subcontractor, Social Policy Research Associates (SPR), to conduct this evaluation (ED–IES–17–C–0066). The evaluation includes an initial feasibility assessment, to determine whether an impact study can be conducted appropriately. First, the study team will interview fiscal year (FY) 2016 and 2017 Magnet Schools Assistance Program (MSAP) grantee districts and schools to gather detailed information on student recruitment and admissions policies and practices, paying particular attention to the use of randomized lotteries for student admissions. The feasibility phase will result in a brief describing how MSAP-funded schools recruit and select students for admission, a topic of interest to the program office. Second, if a sufficient number of students are being admitted to these schools through lotteries, the impact study will collect survey data from principals and district administrative records on admissions lotteries and student progress. The study would use these data to estimate the impacts of magnet schools on student achievement and diversity and to describe whether particular features of magnet schools are associated with greater success.

Dated: January 11, 2018.

Stephanie Valentine,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2018–00655 Filed 1–16–18; 8:45 am]

BILLING CODE 4000–01–P

ELECTION ASSISTANCE COMMISSION

Proposed Information Collection—2018 Election Administration and Voting Survey; Comment Request

AGENCY: U.S. Election Assistance Commission (EAC).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the EAC announces an information collection and seeks public comment on the provisions thereof. The EAC intends to submit this proposed information collection (2018 Election Administration and Voting Survey) to the Director of the Office of Management and Budget for approval. The 2018 Election Administration and Voting Survey (Survey) asks election officials questions concerning voting and election administration. These questions request information concerning ballots cast; voter registration; overseas and military

voting; Election Day activities; voting technology; and other important issues. The EAC issues the survey to meet its obligations under the Help America Vote Act to serve as national clearinghouse and resource for the compilation of information with respect to the administration of Federal elections; to fulfill both the EAC's and the Department of Defense Federal Voting Assistance Programs' (FVAP) quantitative State data collection requirements under the Uniformed and Overseas Citizens Absentee Voting Act (UOCAVA); and meet its National Voter Registration Act (NVRA) mandate to collect information from states concerning the impact of that statute on the administration of Federal Elections.

DATES: Written comments must be submitted on or before 5:00 p.m. EST on February 16, 2018.

ADDRESSES: Comments on the proposed information collection should be submitted electronically to *electiondaysurvey@eac.gov.* Written comments on the proposed information collection can also be sent to the U.S. Election Assistance Commission, 1335 East-West Highway, Suite 4300, Silver Spring, MD 20910, Attn: Election Administration and Voting Survey.

Obtaining a Copy of the Survey: To obtain a free copy of the survey: (1) Email Sean Greene at the U.S. Election Assistance Commission at *sgreene@eac.gov;* or (2) write to the EAC (including your address and phone number) at U.S. Election Assistance Commission, 1335 East-West Highway, Suite 4300, Silver Spring, MD 20910, Attn: Election Administration and Voting Survey.

FOR FURTHER INFORMATION CONTACT: Mr. Sean Greene at 301–563–3919, or email *sgreene@eac.gov,* U.S. Election Assistance Commission, 1335 East-West Highway, Suite 4300, Silver Spring, MD 20910.

SUPPLEMENTARY INFORMATION:

Comments: Public comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

Needs and Uses

The EAC issues the survey to meet its obligations under the Help America Vote Act (HAVA) to serve as national clearinghouse and resource for the compilation of information with respect to the administration of Federal elections; to fulfill both the EAC and FVAP's data collection requirements under the UOCAVA; and meet its NVRA mandate to collect information from states concerning the impact of that statute on the administration of Federal Elections. HAVA requires the EAC to serve as a national clearinghouse and resource for the compilation of information and review of procedures with respect to the administration of Federal Elections. This includes the obligation to study and report on election activities, practices, policies, and procedures, such as methods of voter registration, methods of conducting provisional voting, poll worker recruitment and training, and such other matters as the Commission determines are appropriate. In addition, under the NVRA, the EAC is responsible for collecting information and reporting, biennially, to the United States Congress on the impact of that statute. The information the States are required to submit to the EAC for purposes of the NVRA report are found under Title 11 of the Code of Federal Regulations.

States that respond to questions in this survey concerning voter registration related matters will meet their NVRA reporting requirements under 52 U.S.C. 20508 and EAC regulations. Finally, the UOCAVA mandates that the FVAP work with the EAC and State Chief Election officials to develop standards for reporting UOCAVA voting information (52 U.S.C. 20302) and that the FVAP will store the reported data and present the findings within the congressionally-mandated report to the President and Congress. Additionally, UOCAVA requires that ''not later than 90 days after the date of each regularly scheduled general election for Federal office, each State and unit of local government which administered the election shall (through the State, in the case of a unit of local government) submit a report to the EAC on the combined number of absentee ballots transmitted to absent uniformed services voters and overseas voters for the election and the combined number of such ballots which were returned by such voters and cast in the election, and shall make such a report available to the general public.'' States that complete and timely submit the UOCAVA section of the survey to the EAC will fulfill their UOCAVA reporting requirement under 52 U.S.C. 20302. In order to fulfill the above requirements, the EAC is seeking information relating to the period from the Federal general election day 2016 +1 through the November 2018 Federal general election. The EAC will provide the data regarding UOCAVA voting to FVAP after data collection is completed. This data sharing reduces burden on local election offices because FVAP does not have to conduct its own data collection to meet its reporting requirements.

Title and OMB Number: 2018 Election Administration and Voting Survey; OMB Number Pending.

Summary of the Collection of Information: The survey requests information on a state- and county-level (or township-, independent city-, borough-level, where applicable) concerning the following categories:

Voter Registration Applications (From the Period of Federal General Election Day +1, 2016 Through Federal General Election Day, 2018)

(a) Total number of registered voters;

(b) Number of active and inactive registered voters;

(c) Number of persons who registered to vote on Election Day—only applicable to States with Election Day registration;

(d) Number of voter registration applications received from all sources;

(e) Number of voter registration applications that were duplicates, invalid or rejected, new, changes of name, address, party, and not categorized;

(f) Total number of removal/confirmation notices mailed to voters and the reason for removal;

(g) total number of voters removed from the registration list or moved to the inactive registration list.

Uniformed and Overseas Citizens Absentee Voting Act (UOCAVA)

(a) Total number and type of registered and eligible UOCAVA voters;

(b) Total number of Federal Post Card Applications (FPCAs) received by type of voter;

(c) Total number of FPCAs rejected by type of voter;

(d) Total number of FPCAs rejected after the absentee ballot request deadline;

(e) Total number of UOCAVA absentee ballots transmitted by type of UOCAVA voter and mode of transmission;

(f) Total number of transmitted UOCAVA ballots returned by type of UOCAVA voter and mode of transmission;

(g) Total number of transmitted UOCAVA ballots counted by type of UOCAVA voter and mode of return;

(h) Total number of transmitted UOCAVA ballots rejected by type of UOCAVA voter and reason for rejection;

(i) Total number of FWABs received by type of voter;

(j) Total number of FWABs rejected by type of voter; and

(k) Total number of FWABs rejected by reason for rejection.

Domestic Civilian By-Mail Voting

(a) Total number of by-mail ballots transmitted to voters;

(b) Total number of ballots returned by voters;

(c) Total number of ballots counted; and

(d) Total number of ballots rejected, by reason for rejection.

Polling Places and Poll Workers

(a) Total number of precincts in the state/jurisdiction;

(b) Number of polling places available for early and Election Day voting in the November 2018 Federal general election;

(c) Number of poll workers used during early voting and during Election Day voting;

(d) The age of poll workers who worked in the election; and

(e) Extent to which jurisdictions had enough poll workers available for the general election.

Provisional Voting

(a) Number of provisional ballots cast, counted, and rejected; and

(b) Reasons for provisional ballot rejection.

Total Votes Cast and Election Technologies

(a) Total number of votes cast in the election;

(b) Use of electronic and printed poll books during the 2018 Federal general election; and

(c) Type and number of voting equipment used for the 2018 Federal general election for precinct, absentee, early vote site, accessible to disabled voters, provisional voting.

Statutory/Policy Overview (2018 Federal General Election)

(a) Who answers the questions in each section of the EAVS;

(b) Description of the state's voter registration database system;

(c) Description of the types of electronic data connections the state has with various other government entities;

(d) Information on whether the state has online voter registration, automatic voter registration, and same day voter registration;

(e) Type of absentee voting and early voting regime the state has;

(f) Information on whether the state has vote centers;

(g) If the state accepts provisional ballots from voters registered in a different precinct;

(h) The type of election audit regime the state has;

(i) The type of voter identification regime the state has; and

(j) The voting eligibility requirements for individuals who have been convicted of a felony.

Affected Public (Respondents): State or local governments, the District of Columbia, Commonwealth of Puerto Rico, Guam, American Samoa, and the United States Virgin Islands.

Affected Public: State or local government.

Number of Respondents: 55.

Responses per Respondent: 1.

Estimated Burden per Response: 150 hours per collection, 75 hours annualized.

Estimated Total Annual Burden Hours: 8,250 hours per collection, 4,125 hours annualized.

Frequency: Biennially.

Bryan Whitener,

Director of National Clearinghouse on Elections, U.S. Election Assistance Commission.

[FR Doc. 2018–00697 Filed 1–16–18; 8:45 am]

BILLING CODE 4810–71–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Sunshine Act Meeting Notice

The following notice of meeting is published pursuant to section 3(a) of the government in the Sunshine Act (Pub. L. 94–409), 5 U.S.C. 552b:

AGENCY HOLDING MEETING: Federal Energy Regulatory Commission.

DATE AND TIME: January 18, 2018, 10:00 a.m.

PLACE: Room 2C, 888 First Street NE, Washington, DC 20426.

STATUS: Open.

MATTERS TO BE CONSIDERED: Agenda, * NOTE—Items listed on the agenda may be deleted without further notice.

CONTACT PERSON FOR MORE INFORMATION: Kimberly D. Bose, Secretary, Telephone (202) 502–8400. For a recorded message listing items struck from or added to the meeting, call (202) 502–8627.

This is a list of matters to be considered by the Commission. It does not include a listing of all documents relevant to the items on the agenda. All public documents, however, may be viewed on line at the Commission's website at *http://ferc.capitolconnection.org/* sing the eLibrary link, or may be examined in the Commission's Public Reference Room.

1039TH—MEETING

[Regular meeting January 18, 2018; 10:00 a.m.]

Item No.	Docket No.	Company
	ADMINISTRATIVE	
A–1	AD18–1–000	Agency Administrative Matters.
A–2	AD18–2–000	Customer Matters, Reliability, Security and Market Operations.
	ELECTRIC	
E–1	ER18–1–000, ER18–1–001	California Independent System Operator Corporation.
E–2	RM17–13–000	Supply Chain Risk Management Reliability Standards.
E–3	RM17–12–000	Emergency Preparedness and Operations Reliability Standards.
E–4	ER16–2217–005	Logan Generating Company, L.P.
	ER17–2515–001	Chambers Cogeneration, Limited Partnership.
E–5	ER17–603–000	Bear Swamp Power Company LLC.

1039TH—MEETING—Continued

[Regular meeting January 18, 2018; 10:00 a.m.]

Item No.	Docket No.	Company
E–6	ER17–1459–000, ER06–615–000, ER02–1656–027, ER02–1656–029, ER02–1656–030, ER02–1656–031.	California Independent System Operator Corporation.
E–7	ER17–2113–000	Midcontinent Independent System Operator, Inc.
E–8	ER16–2493–002	South Carolina Electric & Gas Company.
E–9	ER16–1169–001	Ameren Illinois Company.
E–10	ER16–1251–003	Entergy Louisiana, LLC.
	ER13–1508–004	Entergy Louisiana, LLC, Entergy Texas, Inc. and Entergy New Orleans, Inc.
E–11	ER17–2495–000	Southwest Power Pool, Inc.
E–12	ER17–2579–000	Entergy Arkansas, Inc.
	ER15–1436–000	Entergy Gulf States Louisiana, L.L.C.
	ER15–1453–000	Entergy Louisiana, LLC.
	ER16–1528–000	Entergy Mississippi, Inc.
	(consolidated)	Entergy New Orleans, Inc.
		Entergy Texas, Inc.
	ER17–827–000	Midcontinent Independent System Operator, Inc.
E–13	TX17–1–000	Wheatridge Wind Energy, LLC.
E–14	EL16–89–000, EL17–40–000, ER06–554–000, ER17–512–000, ER17–512–001, ER17–512–002, ER17–512–003.	Virginia Electric and Power Company.
E–15	Omitted.	
E–16	Omitted.	
E–17	EL16–100–000, ER14–1193–003	West Deptford Energy, LLC.
E–18	ER14–874–001, EL18–25–000	Calpine Bethlehem, LLC.
	ER14–875–001, ER17–2566–000	Calpine Mid-Atlantic Generation, LLC.
	ER12–954–003	Calpine Mid Merit, LLC.
	ER14–873–001, ER15–2495–001	Calpine New Jersey Generation, LLC.
	ER15–2735–003	Garrison Energy Center LLC.
	ER10–2214–003	Zion Energy LLC.
E–19	ER17–1236–000, ER17–1236–001	PJM Interconnection, L.L.C.
E–20	ER17–419–000, ER17–419–003	PJM Interconnection, L.L.C.
E–21	ER16–2401–000, EL16–96–000	PJM Interconnection, L.L.C.
E–22	ER15–623–010, EL15–29–006	PJM Interconnection, L.L.C.
	EL15–41–002	Essential Power Rock Springs, LLC, Essential Power OPP, LLC and Lakewood Co-generation, L.P. v. PJM Interconnection, L.L.C.
E–23	EC17–49–001	GridLiance West Transco LLC.
E–24	EL16–64–001	Belmont Municipal Light Department, Braintree Electric Light Department, Concord Municipal Light Plant, Georgetown Municipal Light Department, Groveland Electric Light Department, Hingham Municipal Lighting Plant, Littleton Electric Light & Water Department, Middleborough Gas & Electric Department, Middleton Electric Light Department, Reading Municipal Light Department, Rowley Municipal Lighting Plant, Taunton Municipal Lighting Plant, and Wellesley Municipal Light Plant v. Central Maine Power Company, Emera Maine (formerly known as Bangor Hydro- Electric Company), Eversource Energy Service Company and its operating company affiliates: The Connecticut Light and Power Company, Western Massachusetts Electric Company, Public Service Company of New Hampshire, and NSTAR Electric Company, New England Power Company, New Hampshire Transmission LLC, The United Illuminating Company, Fitchburg Gas and Electric Light Company and Vermont Transco, LLC.
E–25	EL16–107–001	Southern Maryland Electric Cooperative, Inc. and Choptank Electric Cooperative, Inc.
E–26	EL15–47–002	NextEra Desert Center Blythe, LLC v. California Independent System Operator Corporation.
GAS		
G–1	OR17–11–000	Wood River Pipe Lines LLC.
G–2	IS17–498–000, IS17–498–001, IS17–499–000, IS17–499–001, IS17–506–000, IS17–506–001.	Leveret Pipeline Company LLC.
	IS17–500–000, IS17–500–001, IS17–501–000, IS17–501–001.	Mid-America Pipeline Company, LLC.
G–3	RP17–944–000	Equitrans, L.P.
HYDRO		
H–1	P–2485–076	FirstLight Hydro Generating Company.
H–2	P–12569–015	Public Utility District No. 1 of Okanogan County, Washington.
CERTIFICATES		
C–1	CP17–58–000	Transcontinental Gas Pipe Line Company, LLC.

1039TH—MEETING—Continued

[Regular meeting January 18, 2018; 10:00 a.m.]

Item No.	Docket No.	Company
C–2	CP13–520–000	EQT Gathering LLC.

Dated: January 11, 2018.

Kimberly D. Bose,

Secretary.

A free webcast of this event is available through *http://ferc.capitolconnection.org/.* Anyone with internet access who desires to view this event can do so by navigating to *www.ferc.gov's* Calendar of Events and locating this event in the Calendar. The event will contain a link to its webcast. The Capitol Connection provides technical support for the free webcasts. It also offers access to this event via television in the DC area and via phone bridge for a fee. If you have any questions, visit *http://ferc.capitolconnection.org/* or contact Danelle Springer or David Reininger at 703–993–3100.

Immediately following the conclusion of the Commission Meeting, a press briefing will be held in the Commission Meeting Room. Members of the public may view this briefing in the designated overflow room. This statement is intended to notify the public that the press briefings that follow Commission meetings may now be viewed remotely at Commission headquarters, but will not be telecast through the Capitol Connection service.

[FR Doc. 2018–00740 Filed 1–12–18; 11:15 am]

BILLING CODE 6717–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice to All Interested Parties of Intent To Terminate the Receivership of 10172, Evergreen Bank, Seattle, Washington

Notice is hereby given that the Federal Deposit Insurance Corporation (FDIC or Receiver) as Receiver for Evergreen Bank, Seattle, Washington, intends to terminate its receivership for said institution. The FDIC was appointed Receiver of Evergreen Bank on January 22, 2010. The liquidation of the receivership assets has been completed. To the extent permitted by available funds and in accordance with law, the Receiver will be making a final dividend payment to proven creditors.

Based upon the foregoing, the Receiver has determined that the continued existence of the receivership will serve no useful purpose. Consequently, notice is given that the receivership shall be terminated, to be effective no sooner than thirty days after the date of this notice. If any person wishes to comment concerning the termination of the receivership, such comment must be made in writing and sent within thirty days of the date of this notice to: Federal Deposit Insurance Corporation, Division of Resolutions and Receiverships, Attention: Receivership Oversight Department 34.6, 1601 Bryan Street, Dallas, TX 75201.

No comments concerning the termination of this receivership will be considered which are not sent within this time frame.

Dated at Washington, DC, on January 10, 2018.

Federal Deposit Insurance Corporation.

Valerie J. Best,

Assistant Executive Secretary.

[FR Doc. 2018–00639 Filed 1–16–18; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice to All Interested Parties of Intent To Terminate the Receivership of 10080, Bank of Wyoming, Thermopolis, Wyoming

Notice is hereby given that the Federal Deposit Insurance Corporation (FDIC or Receiver) as Receiver for Bank of Wyoming, Thermopolis, Wyoming, intends to terminate its receivership for said institution. The FDIC was appointed Receiver of Bank of Wyoming on July 10, 2009. The liquidation of the receivership assets has been completed. To the extent permitted by available funds and in accordance with law, the Receiver will be making a final dividend payment to proven creditors.

Based upon the foregoing, the Receiver has determined that the continued existence of the receivership will serve no useful purpose. Consequently, notice is given that the receivership shall be terminated, to be effective no sooner than thirty days after the date of this notice. If any person wishes to comment concerning the termination of the receivership, such comment must be made in writing and sent within thirty days of the date of this notice to: Federal Deposit Insurance Corporation, Division of Resolutions and Receiverships, Attention: Receivership Oversight Department 34.6, 1601 Bryan Street, Dallas, TX 75201.

No comments concerning the termination of this receivership will be considered which are not sent within this time frame.

Dated at Washington, DC, on January 10, 2018.

Federal Deposit Insurance Corporation.

Valerie J. Best,

Assistant Executive Secretary.

[FR Doc. 2018–00641 Filed 1–16–18; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice to All Interested Parties of Intent To Terminate the Receivership of 10344, Citizens Bank of Effingham, Springfield, Georgia

Notice is hereby given that the Federal Deposit Insurance Corporation (FDIC or Receiver) as Receiver for Citizens Bank of Effingham, Springfield, Georgia, intends to terminate its receivership for said institution. The FDIC was appointed Receiver of Citizens Bank of Effingham on February 18, 2011. The liquidation of the receivership assets has been completed. To the extent permitted by available funds and in accordance with law, the receiver will be making a final dividend payment to proven creditors.

Based upon the foregoing, the receiver has determined that the continued existence of the receivership will serve no useful purpose. Consequently, notice is given that the receivership shall be terminated, to be effective no sooner than thirty days after the date of this notice. If any person wishes to comment concerning the termination of the receivership, such comment must be made in writing and sent within thirty days of the date of this notice to: Federal Deposit Insurance Corporation, Division of Resolutions and Receiverships, Attention: Receivership Oversight Department 34.6, 1601 Bryan Street, Dallas, TX 75201.

No comments concerning the termination of this receivership will be considered which are not sent within this time frame.

Dated at Washington, DC, on January 10, 2018.

Valerie J. Best,

Assistant Executive Secretary,

Federal Deposit Insurance Corporation.

[FR Doc. 2018–00640 Filed 1–16–18; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL MARITIME COMMISSION

[Petition No. P4–16]

Petition of the Coalition for Fair Port Practices for Rulemaking; Final Notice of Public Hearing Schedule

The Commission will hold public hearings on January 16 and 17, 2018, to receive oral testimony concerning the Petition of the Coalition for Fair Port Practices for Rulemaking. Below is the final order of presentation. Each panelist may make a five minute presentation, which will be followed by questions from the Commissioners.

The hearings will be held in the Commission's Main Hearing Room, 800 North Capitol Street NW, Washington, DC 20573 and are open to the public. Please arrive with sufficient time to clear through the building security process. The hearing will be live streamed and the URL will be posted to the Commission's website prior to the hearing: *https://www.fmc.gov/p4_16hearings.aspx.*

Written comments and statements for the record relative to the issues being addressed at the hearing from persons who are unable to testify in person should be submitted to *secretary@fmc.gov* as a PDF file by January 26, 2018. Copies of all written submissions will be posted to the Commission's website, *https://www.fmc.gov/p4-16/,* and will be available in the Commission's Office of the Secretary.

Day 1: Tuesday, January 16, 2018

Panel 1: Coalition Panel—10:00 a.m.

- Karyn Booth, Esq., Partner, Thompson Hine, LLP
- Nick DiMichael, Esq., Senior Counsel, Thompson Hine, LLP
- Ms. Laura Crowe, Senior Director, Global Logistics, Walmart Stores
- Mr. Don Pisano, President, American Coffee Corporation
- Mr. Fred Johring, President, Golden State Express
- Mr. Robert Leef, Senior Vice President, East Region, ContainerPort Group, Inc., representing the Association of Bi-State Motor Carriers
- Mr. Alex Cherin, Executive Director, Englander, Knabe & Allen, representing the California Trucking Association Intermodal Conference

Panel 2: Shipper Panel—11:15 a.m.

- Peter Friedmann, Esq., Executive Director, AgTC Agriculture Transportation Coalition
- Steven Hughes, President/CEO of HCS International, representing the Auto Care Association
- Mr. Sam J. Sorbello, President, Atlantic Coast Freezers, representing the Meat Import Council of America
- Mr. Tim Avanzato, Lanca Sales, Inc.
- Mr. Frans A. de Jong, President, R1 International (Americas) Inc.

Panel 3: Intermediary Panel—2:00 p.m.

- Mr. Richard J. Roche, Vice President of International Transportation, Mohawk Global Logistics, and NVOCC Sub-Committee Chairman at NCBFAA
- Mr. Charles Riley, Chairman, Board of Governors, New York New Jersey Foreign Freight Forwarders and Brokers Association, Inc. (NYNJFFF&BA), and Vice President, Steer Company
- Ms. Jeanette Gioia, Vice President Exports, New York New Jersey Foreign Freight Forwarders and Brokers Association, Inc. (NYNJFFF&BA), and President, Serra International, Inc.
- Cameron W. Roberts, Esq., representing Roberts & Kehagiaras LLP and the Foreign Trade Association
- Mr. Joseph T. Quinn, President, Sefco Export Management Company, Inc.
- Mr. Bryan Vickers, Pace LLP, representing the International Association of Movers

Day 2: Wednesday, January 17, 2018

Panel 1: Drayage Panel—10:00 a.m.

- Mr. Thomas J. Adamski, representing the New Jersey Motor Truck Association
- Mr. William J. Shea, CEO, Direct ChassisLink, Inc.

Panel 2: Ocean Carrier Panel—11:15 a.m.

- Mr. Richard J. Craig, President and CEO, Mitsui O.S.K. Lines (America), Inc.
- Mr. Paolo Magnani, Executive Vice President for Quality Control and Marketing, Mediterranean Shipping Company USA
- Mr. Howard Finkel, Executive Vice President, COSCO Shipping Lines (North America), Inc.
- John Butler, Esq., President and CEO, World Shipping Council

Panel 3: Ports and Terminals Panel—2:00 p.m.

- Mr. Edward DeNike, President, SSA Containers
- Mr. John E. Crowley, Jr., Executive Director, National Association of Waterfront Employers
- Mr. John Atkins, President, GCT Bayone LP

By the Commission.

Rachel E. Dickon,

Assistant Secretary.

[FR Doc. 2018–00624 Filed 1–16–18; 8:45 am]

BILLING CODE 6731–AA–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[CDC–2018–0005, Docket Number NIOSH–303]

Law Enforcement Officer Motor Vehicle Crash and Struck-By Fatality Investigations; Notice of Public Meeting; Request for Comments

AGENCY: National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of public meeting and solicitation for public comment.

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) is seeking stakeholder input on *NIOSH's Law Enforcement Officer Motor Vehicle Crash and Struck-by Fatality Investigations—a pilot program.*

Table of Contents

- Dates:
- Addresses:
- For Further Information Contact:
- Supplementary Information:
- Background
- References

DATES: A public meeting will be held on Tuesday, February 27, 2018, from 9:00 a.m. to 3:00 p.m. Eastern Time, or until the last public presenter has spoken, whichever occurs first. Please note that public comments may end before the time. Members of the public who wish to provide oral comments should plan to attend the meeting at the start time listed. As an alternative, electronic or written comments must be received by April 17, 2018.

ADDRESSES: The public meeting will be held at the Office of Justice Programs (OJP), 810 7th Street NW, Washington, DC 20531. Attendees will be escorted to the room from the security checkpoint.

Written Comments: You may submit written comments by either of the two methods below.

- *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* National Institute for Occupational Safety and Health, NIOSH Docket Office, 1090 Tusculum Avenue, MS C–34, Cincinnati, Ohio 45226–1998.

All comments received in response to this notice must be identified by CDC–2017–0118 and Docket Number NIOSH–303. All relevant comments received, including any personal information, will be posted without change to *www.regulations.gov.* To access the docket, read background documents or read comments, go to *www.regulations.gov* and enter CDC–2017–0118 in the search field and click ''Search.'' All information received in response to this notice will be available for public examination and copying at the NIOSH Docket Office, 1150 Tusculum Avenue, Room 155, Cincinnati, Ohio 45226–1998.

FOR FURTHER INFORMATION CONTACT: Paul Moore, NIOSH, Division of Safety Research, 1095 Willowdale Road, Morgantown, West Virginia 26505, telephone (304) 285–6016, facsimile (304) 285–5774 (not toll free numbers), email *PMoore@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Registration: Notification of intent to attend the meeting, either for participation or to make presentations, must be made by email to Paul Moore, email *PMoore@cdc.gov,* telephone (304) 285–6016, facsimile (304) 285–5774 or John Myers, email *JMyers@cdc.gov,* telephone (304) 285–6005, facsimile (304) 285–5774 no later than February 12, 2018, for U.S. citizens, and no later than February 5, 2018, for non-U.S. citizens, to allow sufficient time for mandatory facility security clearance procedures to be completed. Priority for attendance will be given to those providing oral comments. All requests to present should include the name, address, telephone number, relevant business affiliation of the presenter, and a brief summary of the presentation. After reviewing the requests for presentation, NIOSH will notify each presenter of the approximate time that their presentation is scheduled to begin. If a participant is not available when their presentation is scheduled to begin, the remaining participants will be heard in order. Presenters who missed their assigned time slot will be permitted to present later in the meeting if time permits.

Status: The meeting is open to the public, limited only by the space available. The meeting space accommodates approximately 150 people. There is no registration fee to attend this public meeting. However, those wishing to attend must sign up by the dates noted in the **SUPPLEMENTARY INFORMATION** section with the contact persons in this notice.

Security Considerations: Due to mandatory security clearance procedures at the location of the meeting, in-person attendees who are U.S. citizens must sign up with either of the contact persons identified in this notice by February 12, 2018, and present a valid government-issued picture identification to security personnel upon entering the building and go through an airport-type security check. No weapons will be allowed inside of the building.

To attend in person, a non-U.S. citizen must sign up with either of the contact persons identified in this notice by February 5, 2018. They will also need to provide passport information and photo identification to security personnel upon entering the building and go through an airport-type security check. No weapons will be allowed inside of the building.

To allow sufficient time for mandatory facility security clearance procedures to be completed, non-U.S. Citizens must provide the following information by email to Paul Moore, email *PMoore@cdc.gov,* telephone (304) 285–6016 or John Myers, email *JMyers@cdc.gov,* telephone (304) 285–6005, by February 5, 2018: Name; gender; date of birth; place of birth (city, province, state, country); citizenship; passport number; date of passport issue; date of passport expiration; type of visa; U.S. naturalization number (if a naturalized citizen); U.S. naturalization date (if a naturalized citizen); visitor's organization; organization address; organization telephone number; and visitor's position/title within the organization. Priority for attendance will be given to those providing oral comments. This information will be transmitted to the CDC Security Office and the Office of Justice Programs Security Office for approval. Non-U.S citizens will be notified once approval has been obtained. If approval is not received, non-U.S. citizens will not be able to attend the meeting.

Background

In the United States, there are approximately 765,000 state and local law enforcement officers (LEOs) working in stressful and dangerous conditions. LEOs are at increased risk for both fatal and non-fatal injuries, especially those occurring from motor-vehicle incidents. According to data from the National Law Enforcement Officer Memorial Fund (NLEOMF, 2016), 135 officers were killed in the line of duty in 2016; 47% were from intentional acts of violence (n = 64), 39% were motor-vehicle related (n = 53), and 13% were due to other causes.

Motor-vehicle related fatalities have been the leading cause of LEO line-of-duty-deaths in 15 of the last 20 years. As of November 14, 2017, the number of LEO line-of-duty-motor vehicle-related fatalities was 41. Between 2010 and 2014, 58% of fatal motor vehicle crashes were single vehicle crashes. [NLEOMF, 2016]

While the number of LEO motor vehicle-related fatalities remain high, efforts towards the collection of data on the circumstances and characteristics surrounding motor-vehicle related events for prevention purposes are limited. Detailed information on the causes and risk factors for LEO motor-vehicle related fatalities can provide stakeholders, researchers, and the law enforcement community with information to develop evidence-based prevention programs and policies to reduce crashes and injures.

Project Description

Under the Law Enforcement Officer Motor Vehicle Crash and Struck-by Fatality Investigations project, NIOSH staff have conducted field investigations of LEO line-of-duty-deaths due to motor vehicle crashes and being struck-by moving vehicles. This pilot project, implemented in partnership with the National Institute of Justice through an Interagency Agreement, sought to identify motor vehicle related fatality risks for LEOs and develop industry-wide recommendations. The project aimed to:

1. Learn about the motor vehicle-related risks LEOs are exposed to by studying the circumstances surrounding motor vehicle crash and struck-by fatalities,
2. Explore the feasibility of using NIOSH Fatality Assessment and Control Evaluation investigation techniques to identify contributing factors for these fatal incidents, and;
3. Disseminate NIOSH developed injury prevention recommendations to stakeholders, researchers, and the law enforcement community.

Methods and Approach

The project evaluated whether the NIOSH Fatality Assessment and Control Evaluation (FACE) methodology could appropriately collect information on the circumstances and contributing factors related to motor-vehicle fatalities among

LEOs. The FACE method follows the public health approach that the etiology of injury is multifaceted and injury is preventable. FACE collects data about the circumstances and contributors to fatal occupational injuries through on-site field investigations. This type of detailed data is not generally available from injury surveillance databases. As NIOSH does not have regulatory responsibility or enforcement authority, agency participation in a FACE investigation is voluntary. The FACE method has been used to successfully investigate fatalities involving fire fighters through the NIOSH Fire Fighter Fatality Investigation and Prevention Program. However, the ability to conduct these types of investigations among one occupation does not guarantee success in another. This may be especially true for law enforcement agencies that conduct vehicle crash reconstructions as part of their normal responsibilities. Crash reconstructions generally focus on environmental conditions and technical information such as vehicle dynamics. However, the FACE methodology evaluates all circumstances surrounding an incident, including decedent information, training programs, operating procedures, social aspects of the job, equipment design, and the work environment to identify contributing factors that can lead to the development of prevention recommendations.

Investigation results are publicly reported through a narrative report that describes the incident, identifies contributing factors, and provides recommendations aimed at preventing similar incidents. The NIOSH reports do not determine fault or assign blame. The reports also do not identify the victim or other agency members. Reports are publicly available on the NIOSH website: NIOSH Law Enforcement Officer Motor Vehicle Safety.

Case Criteria and Selection

In this pilot project, a limited number of law enforcement motor-vehicle deaths were investigated using the FACE Model. For the purpose of this pilot study, the following definitions were used to identify law enforcement motor-vehicle fatalities:

- *Law Enforcement Officer:* An individual involved in crime control or reduction and who is directly employed on a full-time basis by a university or college, tribal, local, county, state, or federal law enforcement agency of the United States or its territories, with or without compensation, who is duly sworn and has full arrest powers.
- *Law Enforcement Motor Vehicle:* A motor vehicle, excluding motorcycles, that is owned by any university or college, tribal, local, county, State, or Federal police agency. Personal vehicles not owned by the agency but used by officers or agents (*e.g.,* undercover) do not fall into this category.
- *Motor vehicle crash:* A crash that occurred while operating a law enforcement motor vehicle engaged in pursuit, patrol, emergency response, or commute between duty stations.
- *Struck-by:* A LEO struck-by a motor vehicle while operating on foot or in a parked vehicle at a roadside emergency, traffic stop or roadblock, or while assisting motorists.

Several sources were used to identify LEO fatalities that met the case selection criteria including internet searches, newspaper clippings, the National Law Enforcement Officers Memorial Fund (NLEOMF), and the Officer Down Memorial Page (ODMP). Assistance from NIJ was also obtained to identify potential cases.

Results to Date

From September 2013 through December 2017, through this pilot project, NIOSH identified 18 LEO line-of-duty motor-vehicle crash fatalities to pursue as potential fatality investigations. Contact information for each deceased LEO's agency was obtained from the NLEOMF. NIOSH attempted to contact the agencies through phone calls and or emails. Of the 18 agencies, 5 agreed to participate in the program. Investigations for 3 of these cases have been completed and the reports have been published on the NIOSH Law Enforcement Officer Motor Vehicle Safety website: NIOSH Law Enforcement Officer Motor Vehicle Safety. Two investigations are still ongoing, but should be completed and published on the NIOSH web page in early 2018.

Completed investigations include:

Sergeant Struck by a Motor Vehicle on Interstate Highway—New Mexico

Trooper struck by vehicle while investigating crash on interstate highway—Oklahoma

Officer Struck By a Motorhome While Establishing Temporary Traffic Control on Interstate—Tennessee

The NIOSH pilot program has identified unique opportunities and challenges for investigating LEO motor vehicle deaths. Unique opportunities include: The availability of vehicle dash camera recordings to help determine how the event occurred; police crash reconstruction reports outlining the vehicle dynamics, and the availability of in-vehicle telematics to better understand the speed at impact at the time of the event. Challenges identified included the delay in initiating investigations because of ongoing litigation surrounding the officer's death, and in certain events, the lack of witnesses involving single vehicle LEO crashes. We have also observed some reluctance on the part of law enforcement agencies to participate in a NIOSH investigation stating concerns for exposing the fallen officer's family members and department colleagues to emotional distress.

Areas for Input

Specific areas where NIOSH desires input include:

1. Is the approach NIOSH used to investigate these deaths appropriate for the law enforcement community?

2. Does the approach have the potential to prevent LEO injury and death from motor-vehicle incidents?

3. How can the approach be improved to better focus on the law enforcement community's need for prevention of motor-vehicle related fatalities?

4. How can NIOSH better gain law enforcement agency cooperation and participation for conducting these investigations?

5. What is the best way to disseminate NIOSH fatality reports to law enforcement agencies, officers, and leaders?

References

NLEOMF [2016]. 124 law enforcement fatalities nationwide in 2015. Washington, DC: National Law Enforcement Memorial Fund.

NLEOMF [2016] Deadly Calls and Fatal Encounters, Analysis of U. S. law enforcement line of duty death when officers responded to dispatched calls for service and conducted enforcement (2101–2016), Washington, DC: National Law Enforcement Officers Memorial Fund.

Frank Hearl,

Chief of Staff, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. 2018–00649 Filed 1–16–18; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket Number CDC–2018–0007, NIOSH–307]

Draft—National Occupational Research Agenda for Agriculture, Forestry and Fishing

AGENCY: National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Request for comment.

SUMMARY: The National Institute for Occupational Safety and Health of the Centers for Disease Control and Prevention announces the availability of a draft NORA Agenda entitled *National Occupational Research Agenda for Agriculture, Forestry and Fishing* for public comment. To view the notice and related materials, visit *https://www.regulations.gov* and enter CDC–2018–0007 in the search field and click ''Search.''

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DATES: Electronic or written comments must be received by March 19, 2018.

ADDRESSES: You may submit comments, identified by CDC–2018–0007 and docket number NIOSH–307, by any of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* National Institute for Occupational Safety and Health, NIOSH Docket Office, 1090 Tusculum Avenue, MS C–34, Cincinnati, Ohio 45226–1998.

Instructions: All submissions received in response to this notice must include the agency name and docket number [CDC–2018–0007; NIOSH–307]. All relevant comments received will be posted without change to *https://www.regulations.gov,* including any personal information provided. For access to the docket to read background documents or comments received, go to *https://www.regulations.gov.* All information received in response to this notice will also be available for public examination and copying at the NIOSH Docket Office, 1150 Tusculum Avenue, Room 155, Cincinnati, OH 45226–1998.

FOR FURTHER INFORMATION CONTACT: Emily Novicki (*NORACoordinator@cdc.gov*), National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Mailstop E–20, 1600 Clifton Road NE, Atlanta, GA 30329, phone (404) 498–2581 (not a toll free number).

SUPPLEMENTARY INFORMATION: The National Occupational Research Agenda (NORA) is a partnership program created to stimulate innovative research and improved workplace practices. The national agenda is developed and implemented through the NORA sector and cross-sector councils. Each council develops and maintains an agenda for its sector or cross-sector.

Background: The National Occupational Research Agenda for Agriculture, Forestry and Fishing is intended to identify the research, information, and actions most urgently needed to prevent occupational illnesses and injuries in the Agriculture, Forestry and Fishing sector. The National Occupational Research Agenda for Agriculture, Forestry and Fishing provides a vehicle for stakeholders to describe the most relevant issues, gaps, and safety and health needs for the sector. Each NORA research agenda is meant to guide or promote high priority research efforts on a national level, conducted by various entities, including: Government, higher education, and the private sector.

The first National Occupational Research Agenda for Agriculture, Forestry and Fishing was published in 2008 for the second decade of NORA (2006–2016). This draft is an updated agenda for the third decade of NORA (2016–2026). The revised agenda was developed considering new information about injuries and illnesses, the state of the science, and the probability that new information and approaches will make a difference. As the steward of the NORA process, NIOSH invites comments on the draft *National Occupational Research Agenda for Agriculture, Forestry and Fishing.* Comments expressing support or with specific recommendations to improve the Agenda are requested. A copy of the draft Agenda is available at *https://www.regulations.gov* (see Docket Number CDC–2018–0007).

Frank Hearl,

Chief of Staff, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. 2018–00647 Filed 1–16–18; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS–10494]

Agency Information Collection Activities: Proposed Collection; 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 (the 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 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates 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 must be received by March 19, 2018.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number ____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

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' website 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: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10494 Exchange Functions: Standards for Navigators and Non-Navigator Assistance Personnel—CAC

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. 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 requires federal agencies to publish a 60-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.

Information Collection

1. *Type of Information Collection Request:* Revision of a previously approved collection; *Title of Information Collection:* Exchange Functions: Standards for Navigators and Non-Navigator Assistance Personnel—CAC; *Use:* Section 1321(a)(1) of the Affordable Care Act directs and authorizes the Secretary to issue regulations setting standards for meeting the requirements under title I of the Affordable Care Act, with respect to, among other things, the establishment and operation of Exchanges. Pursuant to this authority, regulations establishing the certified application counselor program have been finalized at 45 CFR 155.225. In accordance with 155.225(d)(1) and (7), certified application counselors in all Exchanges are required to be initially certified and recertified on at least an annual basis and successfully complete Exchange-required training. *Form Number:* CMS–10494 (OMB control number: 0938–1205); *Frequency:* On Occasion; *Affected Public:* State, Local, or Tribal Governments, Private Sector (not-for-profit institutions); individuals or households; *Number of Respondents:* 30,000; *Total Annual Responses:* 30,000; *Total Annual Hours:* 7,500. For policy questions regarding this collection contact Deborah Bryant at 301–492–5213.

Dated: January 10, 2018.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2018–00632 Filed 1–16–18; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–E–1235]

Determination of Regulatory Review Period for Purposes of Patent Extension; AVYCAZ

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for AVYCAZ and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (in the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by March 19, 2018. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by July 16, 2018. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before March 19, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of March 19, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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–E–1235 for ''Determination of

Regulatory Review Period for Purposes of Patent Extension; AVYCAZ.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff 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 *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. 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 § 10.20 (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: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product AVYCAZ (ceftazidime pentahydrate and avibactam sodium). AVYCAZ is indicated for treatment of patients 18 years or older with the following infections caused by designated susceptible microorganisms:

• Complicated intra-abdominal infections used in combination with metronidazole and

• Complicated urinary tract infections, including pyelonephritis.

Subsequent to this approval, the USPTO received a patent term restoration application for AVYCAZ (U.S. Patent No. 7,112,592) from Forest Laboratories Holdings Ltd., and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated July 12, 2016, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of AVYCAZ represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for AVYCAZ is 2,579 days. Of this time, 2,333 days occurred during the testing phase of the regulatory review period, while 246 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i)) became effective:* February 5, 2008. FDA has verified the applicant's claim that February 5, 2008, is the date the investigational new drug application (IND) became effective.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* June 25, 2014. FDA has verified the applicant's claim that the new drug application (NDA) for AVYCAZ (NDA 206494) was initially submitted on June 25, 2014.

3. *The date the application was approved:* February 25, 2015. FDA has verified the applicant's claim that NDA 206494 was approved on February 25, 2015.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,411 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: Must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.)

Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: January 11, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–00678 Filed 1–16–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–7012]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Use of Public Human Genetic Variant Databases To Support Clinical Validity for Genetic and Genomic-Based In Vitro Diagnostics

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 16, 2018.

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—NEW and title ''Use of Public Human Genetic Variant Databases to Support Clinical Validity for Genetic and Genomic-Based In Vitro Diagnostics.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *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.

Use of Public Human Genetic Variant Databases To Support Clinical Validity for Genetic and Genomic-Based In Vitro Diagnostics—OMB Control Number 0910—NEW

This information collection supports the above captioned Agency guidance document. In the **Federal Register** of July 8, 2016 (81 FR 44611), FDA announced the availability of a draft guidance for industry entitled ''Use of Public Human Genetic Variant Databases To Support Clinical Validity for Next Generation Sequencing (NGS)-Based In Vitro Diagnostics,'' and included an analysis of the associated information collection.

The draft guidance described FDA's considerations in determining whether a genetic variant database is a source of valid scientific evidence that could support the clinical validity of an NGS-based test. This draft guidance further outlines the process by which administrators [1] of genetic variant databases could voluntarily apply to FDA for recognition, and how FDA would review such applications and periodically reevaluate recognized databases. The draft guidance also recommends that, at the time of recognition, the database administrator make information regarding policies, procedures, and conflicts of interest publicly available and accessible on the genetic variant database's website.

Based on our experience and the nature of the information, we estimate that it will take an average of 80 hours to complete and submit an application for recognition. We estimate that maintenance of recognition activities will take approximately one-fourth of that time (20 hours) annually. We estimate that it will take approximately 1 hour to post the information on the website.

Respondents are administrators of genetic databases. Our estimate of five respondents per year is based on the current number of databases that may meet FDA recommendations for recognition and seek such recognition.

FDA received 36 comments on the draft guidance, none of which pertained to the information collection burden estimate.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Application for recognition of genetic database	5	1	5	80	400

[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	Number of recordkeepers	Number of records per record-keeper	Total annual records	Average burden per recordkeeping	Total hours
Maintenance of recognition activities	5	1	5	20	100

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

[1] FDA acknowledges that many databases may not use the term ''administrator'' or may have a committee of individuals that oversee the database. Therefore, for the purpose of this guidance, a genetic variant database administrator is the entity or entities that oversee database operations.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Public disclosure of policies, procedures, and conflicts of interest	5	1	5	1	5

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The draft guidance also refers to previously approved collections of information. These collections of information are subject to review by the OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in the guidance document ''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff'' have been approved under OMB control number 0910–0756. The collections of information regarding premarket submissions have been approved as follows: The collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120 and the collections of information in 21 CFR part 814, subparts A through E, have been approved under OMB control number 0910–0231.

Dated: January 11, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–00685 Filed 1–16–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–E–2227]

Determination of Regulatory Review Period for Purposes of Patent Extension; SYNERGY EVEROLIMUS–ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for SYNERGY EVEROLIMUS–ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that medical device.

DATES: Anyone with knowledge that any of the dates as published (in the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by March 19, 2018. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by July 16, 2018. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before March 19, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of March 19, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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–E–2227 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; SYNERGY EVEROLIMUS–ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff 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 *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. 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 § 10.20 (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: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA has approved for marketing the medical device SYNERGY EVEROLIMUS–ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM (SYNERGY). SYNERGY is indicated for improving luminal diameter in patients with symptomatic heart disease, stable angina, unstable angina, non-ST elevation myocardial infarction or documented silent ischemia due to atherosclerotic lesions in native coronary arteries ≥2.25 millimeters (mm) to ≤4.0 mm in length. Subsequent to this approval, the USPTO received a patent term restoration application for SYNERGY (U.S. Patent No. 8,348,992) from Boston Scientific Scimed, Inc., and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated October 14, 2016, FDA advised the USPTO that this medical device had undergone a regulatory review period and that the approval of SYNERGY represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for SYNERGY is 1,206 days. Of this time, 950 days occurred during the testing phase of the regulatory review period, while 256 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360j(g)) involving this device became effective:* June 15, 2012.

FDA has verified the applicant's claim that the date the investigational device exemption (IDE) required under section 520(g) of the FD&C Act for human tests to begin became effective was June 15, 2012.

2. *The date an application was initially submitted with respect to the device under section 515 of the FD&C Act (21 U.S.C. 360e):* January 20, 2015. The applicant claims January 15, 2015, as the date the premarket approval application (PMA) for SYNERGY (PMA P150003) was initially submitted. However, FDA records indicate that PMA P150003 was submitted on January 20, 2015.

3. *The date the application was approved:* October 2, 2015. FDA has verified the applicant's claim that PMA P150003 was approved on October 2, 2015.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 629 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: January 11, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–00679 Filed 1–16–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–E–1265]

Determination of Regulatory Review Period for Purposes of Patent Extension; DAKLINZA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for DAKLINZA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (in the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by March 19, 2018. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by July 16, 2018. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before March 19, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of March 19, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, 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–E–1265 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; DAKLINZA.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff 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 *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. 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 § 10.20 (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: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the

actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product DAKLINZA (daclatasvir dihydrochloride). DAKLINZA is indicated for use with sofosbuvir for the treatment of chronic HCV genotype 3 infection. Subsequent to this approval, the USPTO received a patent term restoration application for DAKLINZA (U.S. Patent No. 8,329,159) from Bristol-Myers Squibb Company, and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated July 12, 2016, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of DAKLINZA represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for DAKLINZA is 2,808 days. Of this time, 2,327 days occurred during the testing phase of the regulatory review period, while 481 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i)) became effective:* November 17, 2007. The applicant claims November 16, 2007, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was November 17, 2007, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* March 31, 2014. FDA has verified the applicant's claim that the new drug application (NDA) for DAKLINZA (NDA 206843) was initially submitted on March 31, 2014.

3. *The date the application was approved:* July 24, 2015. FDA has verified the applicant's claim that NDA 206843 was approved on July 24, 2015.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 467 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: Must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: January 11, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–00675 Filed 1–16–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–0002]

Delcor Asset Corp. et al.; Withdrawal of Approval of 22 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 22 abbreviated new drug applications (ANDAs) from multiple applicants. The holders of the applications notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of February 16, 2018.

FOR FURTHER INFORMATION CONTACT: Trang Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1671, Silver Spring, MD 20993–0002, 240–402–7945, *Trang.Tran@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The holders of the applications listed in table 1 have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

TABLE 1—ANDAS FOR WHICH FDA IS WITHDRAWING APPROVAL

Application No.	Drug	Applicant
ANDA 060577	Mycostatin (nystatin) Vaginal Tablets, 100,000 units	Delcor Asset Corp., 411 South State St., Suite E–100, Newtown, PA 18940.
ANDA 063302	Cefamandole Nafate for Injection	ACS Dobfar SpA, c/o Interchem Corp., 120 Route 17 North, Paramus, NJ 07653.
ANDA 070462	Diazepam Tablets USP, 2 milligrams (mg)	Virtus Pharmaceuticals, 12 Penns Trail, Newtown, PA 18940.
ANDA 070463	Diazepam Tablets USP, 5 mg	Do.
ANDA 070998	Potassium Chloride Extended-Release Tablets, 8 milliequivalents (mEq).	Future Pak, Ltd., 28115 Lakeview Dr., Wixom, MI 48393.
ANDA 070999	Potassium Chloride Extended-Release Tablets, 10 mEq	Do.

TABLE 1—ANDAS FOR WHICH FDA IS WITHDRAWING APPROVAL—Continued

Application No.	Drug	Applicant
ANDA 075375	Diltiazem Hydrochloride (HCl) Injection, 5 mg/milliliter (mL)	Mylan Laboratories, Ltd., c/o Mylan Pharmaceuticals, Inc., 781 Chestnut Ridge Rd., P.O. Box 4310, Morgantown, WV 26504.
ANDA 076911	Clorazepate Dipotassium Tablets USP, 3.75 mg, 7.5 mg, and 15 mg.	Sun Pharmaceutical Industries, Ltd., c/o Sun Pharmaceutical Industries, Inc., 2 Independence Way, Princeton, NJ 08540.
ANDA 077102	Calcitriol Injection, 0.001 mg/mL	Sagent Pharmaceuticals, Inc., 1901 N. Roselle Rd., Suite 450, Schaumburg, IL 60195.
ANDA 084656	Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/30 mg.	Roxane Laboratories, Inc., 1809 Wilson Rd., Columbus, OH 43228.
ANDA 087977	Diphenhydramine HCl Capsules, 25 mg	LNK International, Inc., 145 Ricefield Ln., Hauppauge, NY 11788.
ANDA 088676	Methylprednisolone Sodium Succinate for Injection USP, Equivalent to 40 mg base/vial.	LyphoMed, Division of Fujisawa USA, Inc., 2045 North Cornell Ave., Melrose Park, IL 60160.
ANDA 089080	Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/30 mg.	Purepac Pharmaceutical Co., 200 Elmora Ave., Elizabeth, NJ 07207.
ANDA 089183	Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/15 mg.	Superpharm Corp., 1769 Fifth Ave., Bayshore, NY 11706.
ANDA 089253	Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/30 mg.	Do.
ANDA 089219	Procainamide HCl Capsules USP, 250 mg, 375 mg, and 500 mg.	IDT Australia, Ltd., c/o Facet Life Sciences, Inc., 6122 Stone Wolfe Dr., Glen Carbon, IL 62034.
ANDA 089254	Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/60 mg.	Do.
ANDA 089369	Procainamide HCl Extended-Release Tablets USP, 250 mg, 500 mg, and 750 mg.	Do.
ANDA 089481	Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/15 mg.	American Therapeutics, Inc., 75 Carlough Rd., Bohemia, NY 11716.
ANDA 089482	Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/30 mg.	Do.
ANDA 089483	Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/60 mg.	Do.
ANDA 206711	Olanzapine Tablets USP, 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg, and 20 mg.	Ajanta Pharma, Ltd., c/o Ajanta Pharma USA, Inc., One Grande Commons, 440 U.S. Highway 22 East, Suite 150, Bridgewater, NJ 08807.

Therefore, approval of the applications listed in table 1, and all amendments and supplements thereto, is hereby withdrawn as of February 16, 2018. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in table 1 that are in inventory on the date that this notice becomes effective (see the **DATES** section) may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: January 11, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–00695 Filed 1–16–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0155]

Agency Information Collection Activities; Proposed Collection; Comment Request; Veterinary Feed Directive

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. 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 of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of our veterinary feed directive (VFD) regulation.

DATES: Submit either electronic or written comments on the collection of information by March 19, 2018.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before March 19, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of March 19, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, 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–2010–N–0155 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Veterinary Feed Directive.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff office 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 *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. 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: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Veterinary Feed Directive—21 CFR 558.6

OMB Control Number 0910–0363—Extension

Section 504 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 354) establishes a regulatory category for certain new animal drugs called VFD drugs. Our VFD regulation is set forth at § 558.6 (21 CFR 558.6). VFD drugs are new animal drugs intended for use in or on animal feed which are limited to use under the professional supervision of a licensed veterinarian in the course of the veterinarian's professional practice (§ 558.3 (21 CFR 558.3(b)(6))). An animal feed containing a VFD drug or a combination VFD drug may be fed to animals only by or upon a lawful VFD issued by a licensed veterinarian (§ 558.6(a)(1)).

Veterinarians issue three copies of the VFD: one for their own records, one for their client, and one to the client's VFD feed distributor (§§ 558.6(a)(4) and 558.6(b)(8)–(9)). The VFD includes information about the number and species of animals to receive feed containing one or more of the VFD drugs (§ 558.6(b)(3)), along with other information required under § 558.6. All distributors of medicated feed containing VFD drugs must notify us of their intent to distribute such feed and must maintain records of the receipt and distribution of all medicated feeds containing VFD drugs.

The VFD regulation ensures the protection of public health while enabling animal producers to obtain and use needed drugs as efficiently and cost-effectively as possible. The VFD regulation is tailored to the unique circumstances relating to the distribution and use of animal feeds containing a VFD drug.

We will use the information collected to assess compliance with the VFD regulation. The required recordkeeping and third party disclosures provide assurance that the medicated feeds will be safe and effective for their labeled conditions of use and that edible

products from treated animals will be free of unsafe drug residues.

We estimate the burden of this collection of information as follows. We base our estimates on our analysis of the information collection provisions of the final rule entitled ''Veterinary Feed Directive,'' published in the **Federal Register** of June 3, 2015 (80 FR 31708 at 31728) (the June 3, 2015, final rule).

A. Reporting Requirements

Description of Respondents: VFD Feed Distributors, VFD Drug Sponsors.

A distributor of animal feed containing a VFD drug must notify us prior to the first time it distributes the VFD feed (§ 558.6(c)(5)). This notification is required one time per distributor and must include the information set forth in § 558.6(c)(5). In addition, a distributor must notify us within 30 days of any change in ownership, business name, or business address (§ 558.6(c)(6)). Additional reporting burdens for current VFD drug sponsors are approved under OMB control numbers 0910–0032 (New Animal Drug Applications) and 0910–0669 (Abbreviated New Animal Drug Applications).

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section, activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
558.6(c)(5); requires a distributor to notify us prior to the first time it distributes a VFD feed.	300	1	300	.125 (7 minutes)	37.5
558.6(c)(6); requires a distributor to notify us within 30 days of any change in ownership, business name, or business address.	20	1	20	.125 (7 minutes)	2.5
Total					40

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

B. Recordkeeping Requirements

Description of Respondents: VFD Feed Distributors, Food Animal Veterinarians, and Clients (Food Animal Producers).

As stated previously, veterinarians issue three copies of the VFD: One for their own records, one for their client, and one to the client's VFD feed distributor. All involved parties (the veterinarian, the distributor, and the client) must retain a copy of the VFD for 2 years (§ 558.6(a)(4)). In addition, VFD feed distributors must also keep receipt and distribution records of VFD feeds they manufacture and make them available for inspection by us for 2 years (§ 558.6(c)(3)).

If a distributor manufactures the VFD feed, the distributor must also keep VFD manufacturing records for 1 year in accordance with 21 CFR part 225 and such records must be made available for inspection and copying by FDA upon request (§ 558.6(c)(4)). These record requirements are currently approved under OMB control number 0910–0152, ''Current Good Manufacturing Practice Regulations for Medicated Feed.'' Distributors may distribute VFD to another distributor only if the originating distributor first obtains a written acknowledgement letter. Such letters, like VFDs, are also subject to a 2-year record retention requirement (§ 558.6(c)(8)).

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section, activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
558.6(a)(4); required recordkeeping by veterinarians and producers.	13,050	114.9	1,500,000	.0167 (1 minute)	25,050
558.6(a)(4), (c)(3)–(4), and (c)(8); required recordkeeping by distributors.	1,376	545.1	750,000	.0167 (1 minute)	12,525
Total					37,575

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

C. Third-Party Disclosure Requirements

Description of Respondents: VFD Drug Sponsors, Food Animal Veterinarians, VFD Feed Distributors, and Clients.

Our regulation requires that veterinarians include the information specified at § 558.6(b)(3) through (5) on the VFD. Additional requirements relating to the VFD are specified at § 558.6(b)(7) through (9). A distributor may only distribute a VFD feed to another distributor for further distribution if the originating distributor (consignor) first obtains a written acknowledgement letter from the receiving distributor (consignee) before the feed is shipped (§ 558.6(c)(8)).

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR section, activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
558.6(b)(3)–(5) and (b)(7)-(9); required disclosures when a veterinarian issues a VFD.	3,050	246	750,000	.125 (7 minutes)	93,750
558.6(c)(8); required disclosure (acknowledgement letter) from one distributor to another.	1,000	5	5,000	.125 (7 minutes)	625
Total					94,375

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The VFD regulation also contains several labeling provisions that are exempt from OMB review and approval under the PRA because they are a ''public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)) and therefore do not constitute a ''collection of information'' under the PRA (44 U.S.C. 3501, *et seq.*). All labeling and advertising for VFD drugs, combination VFD drugs, and feeds containing VFD drugs or combination VFD drugs must prominently and conspicuously display the following cautionary statement: ''Caution: Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian'' (§ 558.6(a)(6)). In addition, the veterinarian must ensure that the following statement is included on the VFD (§ 558.6(b)(3)(xiii)): ''Use of feed containing this veterinary feed directive (VFD) drug in a manner other than as directed on the labeling (extralabel use) is not permitted.''

The veterinarian may restrict VFD authorization to only include the VFD drug(s) cited on the VFD or such authorization may be expanded to allow the use of the cited VFD drug(s) along with one or more over-the-counter animal drugs in an approved, conditionally approved, or indexed combination VFD drug (§ 558.6(b)(6)). The veterinarian must affirm his or her intent regarding combination VFD drugs by including one of the following statements on the VFD:

1. ''This VFD only authorizes the use of the VFD drug(s) cited in this order and is not intended to authorize the use of such drug(s) in combination with any other animal drugs'' (§ 558.6(b)(6)(i)).

2. ''This VFD authorizes the use of the VFD drug(s) cited in this order in the following FDA-approved, conditionally approved, or indexed combination(s) in medicated feed that contains the VFD drug(s) as a component.'' (List specific approved, conditionally approved, or indexed combination medicated feeds following this statement. § 558.6(b)(6)(ii).)

3. ''This VFD authorizes the use of the VFD drug(s) cited in this order in any FDA-approved, conditionally approved, or indexed combination(s) in medicated feed that contains the VFD drug(s) as a component'' (§ 558.6(b)(6)(iii)).

These labeling statements are not subject to review by OMB because, as stated previously, they are a ''public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)) and therefore do not constitute a ''collection of information'' under the PRA (44 U.S.C. 3501, *et seq.*). Our estimate of the annual burden for this information collection has not changed since the last OMB approval, which was associated with the June 3, 2015, final rule. However, the one-time burdens that we included in our analysis of the June 3, 2015, final rule (80 FR 31708 at 31729 to 31732) are not included in our current estimate.

Dated: January 11, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–00676 Filed 1–16–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–E–3619]

Determination of Regulatory Review Period for Purposes of Patent Extension; AXUMIN

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for AXUMIN and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (in the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by March 19, 2018. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by July 16, 2018. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before March 19, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of March 19, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://*

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 *https://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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, 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–E–3619 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; AXUMIN.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff 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 *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. 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 § 10.20 (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: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product AXUMIN (fluciclovine F-18). AXUMIN is indicated for positron emission tomography imaging in men with suspected prostate cancer recurrence based on elevated blood prostate specific antigen levels following prior treatment. Subsequent to this approval, the USPTO received a patent term restoration application for AXUMIN (U.S. Patent No. 5,808,146) from Emory University, and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated December 1, 2016, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of AXUMIN represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for AXUMIN is 4,006 days. Of this time, 3,763 days occurred during the testing phase of the regulatory review period, while 243 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* June 10, 2005. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on June 10, 2005

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* September 28, 2015. FDA has verified the applicant's claim that the new drug application (NDA) for AXUMIN (NDA 208054) was initially submitted on September 28, 2015.

3. *The date the application was approved:* May 27, 2016. FDA has verified the applicant's claim that NDA 208054 was approved on May 27, 2016.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 5 years of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: January 11, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–00684 Filed 1–16–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R1–ES–2017–N135; FF01EWFW00–FXES111601M000]

Marine Mammal Protection Act; Stock Assessment Report for the Northern Sea Otter in Washington

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comments.

SUMMARY: In accordance with the Marine Mammal Protection Act of 1972, as amended, and its implementing regulations, we, the U.S. Fish and Wildlife Service, have developed a draft revised marine mammal stock assessment report for the northern sea otter stock in the State of Washington. We now make the draft stock assessment report available for public review and comment.

DATES: We will consider comments that are received or postmarked on or before April 17, 2018.

ADDRESSES: If you wish to review the draft revised stock assessment report for the northern sea otter stock in Washington, you may obtain a copy from our website at *http://www.fws.gov/wafwo.* Alternatively, you may contact the Washington Fish and Wildlife Office, 510 Desmond Dr., Suite 102, Lacey, WA 98503 (telephone: 360–753–9440). If you wish to comment on the stock assessment report, you may submit your comments in writing by any one of the following methods:

- *U.S. mail:* State Supervisor, at the above address;
- *Hand delivery:* Washington Fish and Wildlife Office at the above address;
- *Fax:* 360–753–9565; or
- *Email: fw1_waseaottersar@fws.gov.*

FOR FURTHER INFORMATION CONTACT: Deanna Lynch, at the above street address, by telephone (360–753–9545), or by email (*deanna_lynch@fws.gov*). Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION: We announce the availability for review and comment of a draft revised marine mammal stock assessment report (SAR) for the northern sea otter (*Enhydra lutris kenyoni*) stock in the State of Washington.

Background

Under the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 *et seq.*), and its implementing regulations in the Code of Federal Regulations (CFR) at 50 CFR part 18, the U.S. Fish and Wildlife Service (Service) regulates the taking; import; and, under certain conditions, possession; transportation; purchasing; selling; and offering for sale, purchase, or export, of marine mammals. One of the goals of the MMPA is to ensure that stocks of marine mammals occurring in waters under U.S. jurisdiction do not experience a level of human-caused mortality and serious injury that is likely to cause the stock to be reduced below its *optimum sustainable population* (OSP) level. OSP is defined under the MMPA as ''the number of animals which will result in the maximum productivity of the population or the species, keeping in mind the carrying capacity of the habitat and the health of the ecosystem of which they form a constituent element'' (16 U.S.C. 1362(9)).

To help accomplish the goal of maintaining marine mammal stocks at their OSPs, section 117 of the MMPA requires the Service and the National Marine Fisheries Service (NMFS) to prepare a SAR for each marine mammal stock that occurs in waters under U.S. jurisdiction. A SAR must be based on the best scientific information available; therefore, we prepare it in consultation with established regional scientific review groups established under 117(d) of the MMPA. Each SAR must include:

1. A description of the stock and its geographic range;
2. A minimum population estimate, current and maximum net productivity rate, and current population trend;
3. An estimate of the annual human-caused mortality and serious injury by source and, for a strategic stock, other factors that may be causing a decline or impeding recovery of the stock;
4. A description of commercial fishery interactions;
5. A categorization of the status of the stock; and
6. An estimate of the *potential biological removal* (PBR) level.

The MMPA defines the PBR as ''the maximum number of animals, not including natural mortalities, that may be removed from a marine mammal stock while allowing that stock to reach or maintain its [OSP]'' (16 U.S.C. 1362(20)). The PBR is the product of the minimum population estimate of the stock (N_{min}); one-half the maximum theoretical or estimated net productivity rate of the stock at a small population size (R_{max}); and a recovery factor (F_r) of between 0.1 and 1.0, which is intended to compensate for uncertainty and unknown estimation errors. This can be written as:

$$PBR = (N_{min})(\tfrac{1}{2} \text{ of the } R_{max})(F_r)$$

Section 117 of the MMPA also requires the Service and NMFS to review the SARs (a) at least annually for stocks that are specified as strategic stocks, (b) at least annually for stocks for which significant new information is available, and (c) at least once every 3 years for all other stocks. If our review of the status of a stock indicates that it has changed or may be more accurately determined, then the SAR must be revised accordingly.

A *strategic stock* is defined in the MMPA as a marine mammal stock ''(A) for which the level of direct human-caused mortality exceeds the [PBR] level; (B) which, based on the best available scientific information, is

declining and is likely to be listed as a threatened species under the Endangered Species Act of 1973, [as amended] (16 U.S.C. 1531 *et seq.*) [the ''ESA''], within the foreseeable future; or (C) which is listed as a threatened species or endangered species under the [ESA], or is designated as depleted under [the MMPA]'' 16 U.S.C. 1362(19).

Stock Assessment Report History for the Northern Sea Otter in Washington

The Washington sea otter SAR was last revised in August 2008. The Washington sea otter is not a strategic stock, thus the Service is required to review the stock assessment at least once every 3 years. The Service reviewed the Washington sea otter SAR in 2011 and concluded that a revision was not warranted because the status of the stock had not changed, nor could it be more accurately determined. However, upon review in 2016, the Service determined that revision was warranted because of changes in population estimates and distribution.

Summary of Draft Revised Stock Assessment Report for the Northern Sea Otter in the State of Washington

The following table summarizes some of the information contained in the draft revised SAR for northern sea otters in Washington State, which includes the stock's N_{min}, R_{max}, F_r, PBR, annual estimated human-caused mortality and serious injury, and status. After consideration of any public comments we receive, the Service will revise and finalize the SAR, as appropriate. We will publish a notice of availability and summary of the final SAR, including responses to submitted comments.

SUMMARY—DRAFT STOCK ASSESSMENT REPORT FOR THE NORTHERN SEA OTTER IN WASHINGTON STATE

Stock	N_{min}	R_{max}	F_r	PBR	Annual estimated human-caused mortality and serious injury	Stock status
Northern Sea Otter (Washington State).	1,806	0.20	0.1	18	Figures by specific source, where known, are provided in the SAR.	Non-Strategic.

Public Availability of Comments

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

References

In accordance with the MMPA, we include in this notice a list of the information sources and public reports upon which we based the SAR:

Bigg, M.A. and I.B. MacAskie. 1978. Sea otters re-established in British Columbia. J. Mammalogy 59 (4):874–876.

Department Fisheries and Oceans, Canada (DFO). 2015. Trends in the abundance and distribution of sea otters (*Enhydra lutris*) in British Columbia updated with 2013 survey results. DFO Can. Sci. Advis. Sec. Sci. Advis. Rep. 2015/043.

DeMaster, D.P., C. Marzin, and R.J. Jameson. 1996. Estimating the historical abundance of sea otters in California. Endangered Species Update 13(12):79–81.

Estes, J.A. 1990. Growth and equilibrium in sea otter populations. J. Anim. Ecol. 59:358–401.

Hatfield, B.B., J.A. Ames, J.A. Estes, M.T. Tinker, A.B. Johnson, M.M Staelder, and M.D. Harris. 2011. Sea otter mortality in fish and shellfish traps: estimated potential impacts and exploring possible solutions. Endangered Species Research 13:219–229.

Hatfield, B.B. and J.A. Estes. 2000. Preliminary results of an evaluation of the potential threat to sea otters posed by the nearshore finfish trap fishery. Unpublished, 6 pp. + appendices.

Jameson, R.J., K.W. Kenyon, A.M. Johnson, and H.M. Wight. 1982. History and status of translocated sea otter populations in North America. Wildl. Soc. Bull. 10:100–107.

Jameson, R.J., K.W. Kenyon, S.Jeffries and G.R. VanBlaricom. 1986. Status of a translocated sea otter and its habitat in Washington. Murrelet 67:84–87.

Jameson, R.J. 1996. Status reports: West Coast translocation projects, Oregon and Washington. The Otter Raft No. 55, Page 8.

Jameson, R.J., and S. Jeffries. 1999. Results of the 1999 Survey of the Washington Sea Otter

Population. Unpublished Report. 5 pp.

Jeffries, S., D. Lynch, and S. Thomas. 2016. Results of the 2016 Survey of the Reintroduced Sea Otter Population in Washington State. Unpublished Report. 9 pp. Copies may be obtained from the Washington Department of Fish and Wildlife or U.S. Fish and Wildlife Service's Washington Fish and Wildlife Office.

Laidre, K., R.J. Jameson, S.J. Jeffries, and E. Gurarie. 2011. Updated estimates of carrying capacity for sea otters in Washington state. Unpublished final contract report, December 31, 2011, 12 pp. + appendix.

Lance, M.M., S.A. Richardson, and H. Allen. 2004. State of Washington sea otter recovery plan. WDFW, Olympia WA. 91 pp.

Riedman, M.L., and J.A. Estes. 1990. The sea otter (*Enhydra lutris*): behavior, ecology, and natural history. U.S. Fish and Wildlife Service, Washington, DC, Biological Report 90(14). 126 pp.

Scheffer, V.B. 1940. The sea otter on the Washington coast. Pacific Northwest Quarterly, 3:370–388.

Taylor, B.L., M. Scott, J. Heyning, and J. Barlow. 2003. Suggested guidelines for recovery factors for endangered marine mammals. NOAA Technical Memorandum NOAA–TM–NMFS–SWFSC–354, September 2003. 6 pp.

Wilson, D.E., M.A. Bogan, R.L. Brownell, Jr., A.M. Burdin, and M.K. Maminov. 1991. Geographic variation in sea otters, *Enhydra lutris.* J. Mammal. 72(1):22–36.

Authority

The authority for this action is the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*).

Dated: November 30, 2017.

James W. Kurth,

Deputy Director, U.S. Fish and Wildlife Service, Exercising the Authority of the Director, U.S. Fish and Wildlife Service.

[FR Doc. 2018–00672 Filed 1–16–18; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[189A2100DD/AAKC001030/ A0A501010.999900 253G]

Indian Gaming; Approval of an Amendment to a Tribal-State Class III Gaming Compact in the State of Washington

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: The Puyallup Tribe of the Puyallup Reservation negotiated the Fifth Amendment to the Tribal-State Compact for Class III Gaming between the Puyallup Indian Tribe and the State of Washington governing Class III

gaming; this notice announces approval of the amended Compact.

DATES: This compact takes effect on January 17, 2018.

FOR FURTHER INFORMATION CONTACT: Ms. Paula L. Hart, Director, Office of Indian Gaming, Office of the Assistant Secretary—Indian Affairs, Washington, DC 20240, (202) 219–4066.

SUPPLEMENTARY INFORMATION: Section 11 of the Indian Gaming Regulatory Act (IGRA) requires the Secretary of the Interior to publish in the **Federal Register** notice of approved Tribal-State compacts that are for the purpose of engaging in Class III gaming activities on Indian lands. *See* Public Law 100–497, 25 U.S.C. 2701 *et seq.* All Tribal-State Class III compacts, including amendments, are subject to review and approval by the Secretary under 25 CFR 293.4. The Fifth Amendment to the Tribal-State Compact for Class III Gaming between the Puyallup Indian Tribe and the State of Washington amends the previous compact. The Amendment adds to and revises the definition section; modifies Appendix X2 to increase the Tribe's allocation of player terminals; changes the calculation of State regulatory costs; clarifies the timing for payment to Problem Gambling and Smoking Cessation and Prevention Programs; and prohibits the acceptance of Electronic Benefit Cards. The Fifth Amendment to the Tribal-State Compact for Class III Gaming between the Puyallup Indian Tribe and the State of Washington is approved. *See* 25 U.S.C. 2710(d)(8)(A).

Dated: December 22, 2017.

John Tahsuda,

Principal Deputy Assistant Secretary—Indian Affairs, Exercising the Authority of the Assistant Secretary—Indian Affairs.

[FR Doc. 2018–00637 Filed 1–16–18; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Office of the Secretary

[18XD4523WU, DWUCM0000.000000, DS62400000, DX62432; OMB Control Number 1084–0034]

Agency Information Collection Activities; Documenting, Managing and Preserving Department of the Interior Museum Collections Housed in Non-Federal Repositories

AGENCY: Office of Acquisition and Property Management, Interior.

ACTION: Notice of information collection; request for public comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the Office of Acquisition and Property Management, Office of the Secretary, Department of the Interior are proposing to renew an information collection.

DATES: Interested persons are invited to submit comments on or before March 19, 2018.

ADDRESSES: Send written comments on this information collection request (ICR) by mail to Elizabeth Varner, Office of Acquisition and Property Management, U.S. Department of the Interior, 1849 C Street NW, MS 4262–MIB, Washington, DC 20240; fax (202) 513–7634; or by email to *Elizabeth_Varner@ios.doi.gov.* Please reference OMB Control Number 1084–0034 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Elizabeth Varner by email at *Elizabeth_Varner@ios.doi.gov,* or by telephone at (202) 513–7564.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995, we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are soliciting comments on the proposed ICR that is described below. We are especially interested in public comment addressing the following issues: (1) Is the collection necessary to the proper functions of the Office of Acquisition and Property Management; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Office of Acquisition and Property Management enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Office of Acquisition and Property Management minimize the burden of this collection on the respondents, including through the use of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: The Department of the Interior (DOI) owns and manages over 204 million artifacts, scientific specimens, and documents in trust for the American public. This diverse collection consists of archaeological artifacts, archives, art, biological specimens, ethnographic objects, geological specimens, historic objects, and paleontological specimens that are held by ten of DOI's bureaus and offices. The majority of DOI's collections are housed in bureau facilities; however, over ten percent (more than 25 million objects and 19,000 cubic feet of objects) are housed by at least 882 non-Federal repositories, the majority of which are museums associated with, or departments of, U.S. colleges and universities. Most are scientific collections from the disciplines of archaeology, biology, geology, and paleontology and include associated archival records.

DOI museum collections, regardless of where they are housed, must be managed according to preservation, documentation, educational, and other requirements in the public interest. These requirements are mandated by a number of Federal laws, notably: Archaeological Resources Protection Act of 1979, as amended (16 U.S.C. 470aa–mm); Paleontological Resources Preservation Act of 2009 (16 U.S.C. 470aaa–4); Migratory Bird Treaty Act of 1918 (16 U.S.C. 703–712); Marine Mammal Protection Act of 1972 (16 U.S.C. 1361–1407); Endangered Species Act of 1973, as amended (16 U.S.C. 1531–1543); Lacy Act of 1900 (16 U.S.C. 3371–3378; 18 U.S.C. 43–44); Native American Graves Protection and Repatriation Act of 1990 (25 U.S.C. 3001–3013); Federal Property and Administrative Services Act of 1949, as amended (40 U.S.C. 524); National Park Service Organic Act of 1916 (54 U.S.C. 100101); Management of Museum Properties Act of 1955, as amended (54 U.S.C. 102501–102504); National Historic Preservation Act of 1966, as amended (54 U.S.C. 300101 *et seq.*); Historic Sites Act of 1935 (54 U.S.C. 320101–320104, 320106); and Monuments, Ruins, Sites, and Objects of Antiquity (Act for the Preservation of American Antiquities of 1906 (''Antiquities Act'')) (54 U.S.C. 320301–320303). Pertinent regulations are Curation of Federally-Owned and Administered Archaeological Collections (36 CFR part 79); Federal Management Regulation, Subchapter B:

Personal Property (41 CFR part 102); Protection of Archaeological Resources (43 CFR part 7); and Native American Graves Protection and Repatriation Act Regulations (43 CFR part 10). Pertinent policies are the Department of the Interior Departmental Manual, Part 410: Personal Property Management and Part 411: Identifying and Managing Museum Property (411 DM), and DOI Museum Property Directives that implement 411 DM.

The Departmental Manual chapter, 411 DM, which implements the Federal laws and regulations noted above, requires the following information be collected, used, and retained by all bureaus that hold ownership of museum collections: Facility Checklist for Spaces Housing DOI Museum Property; catalog records; accession records; and inventories of museum collections. These requirements apply to all DOI museum collections regardless of each collection's location (DOI facility or non-DOI facility) or the personnel that accomplished the work (DOI staff, contractors, partners, cooperators, agencies, institutions, or similar organizations associated with DOI).

Title of Collection: Documenting, Managing and Preserving Department of the Interior Museum Collections Housed in Non-Federal Repositories.

OMB Control Number: 1084–0034.

Form Number: None.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: Museums; academic, cultural, and research institutions; and, state or local agencies and institutions.

Total Estimated Number of Annual Respondents: 900.

Total Estimated Number of Annual Responses: 900.

Estimated Completion Time per Response: 2 hours, 20 minutes.

Total Estimated Number of Annual Burden Hours: 2,100.

Respondent's Obligation: Voluntary.

Frequency of Collection: Maximum of once per year per collection instrument, and likely less frequently.

Total Estimated Annual Non Hour Burden Cost: None.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Tammy Bagley,

Acting Director, Office of Acquisition and Property Management.

[FR Doc. 2018–00669 Filed 1–16–18; 8:45 am]

BILLING CODE 4334–63–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–D–COS–POL–24502; PPWODIREP0; PPMPSPD1Y.YM0000]

National Park System Advisory Board; Charter Renewal

AGENCY: National Park Service, Interior.

ACTION: Charter renewal.

SUMMARY: The Secretary of the Interior intends to renew the National Park System Advisory Board, in accordance with section 14(b) of the Federal Advisory Committee Act. This action is necessary and in the public interest in connection with the performance of statutory duties imposed upon the Department of the Interior and the National Park Service.

FOR FURTHER INFORMATION CONTACT: Shirley Sears, Office of Policy, National Park Service, 202–354–3955.

SUPPLEMENTARY INFORMATION: The Board is authorized by 54 U.S.C. 102303 (part of the 1935 Historic Sites, Buildings and Antiquities Act) and has been in existence almost continuously since 1935. Pursuant to 54 U.S.C. 102303, the legislative authorization for the Board expired January 1, 2010. However, due to the importance of the issues on which the Board advises, the Secretary of the Interior exercised the authority contained in 54 U.S.C. 100906 to re-establish and continue the Board as a discretionary committee from January 1, 2010, until such time as it may be legislatively reauthorized. If the Board is reauthorized legislatively within 2 years of the date of the renewal charter, the Board will revert to a legislative Board.

The advice and recommendations provided by the Board and its subcommittees fulfill an important need within the Department of the Interior and the National Park Service, and it is necessary to re-establish the Board to ensure its work is not disrupted. The Board's 12 members will be balanced to represent a cross-section of disciplines and expertise relevant to the National Park Service mission. The renewal of the Board comports with the requirements of the Federal Advisory Committee Act, as amended.

Certification: I hereby certify that the renewal of the National Park System Advisory Board is necessary and in the public interest in connection with the performance of duties imposed on the Department of the Interior by the National Park Service Organic Act (54 U.S.C. 100101(a) *et seq.*), and other statutes relating to the administration of the National Park Service.

Dated: January 4, 2018.

Ryan K. Zinke,

Secretary of the Interior.

[FR Doc. 2018–00633 Filed 1–16–18; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF JUSTICE

Foreign Claims Settlement Commission

[F.C.S.C. Meeting and Hearing Notice No. 1–18]

Sunshine Act Meeting

The Foreign Claims Settlement Commission, pursuant to its regulations (45 CFR part 503.25) and the Government in the Sunshine Act (5 U.S.C. 552b), hereby gives notice in regard to the scheduling of open meetings as follows:

Thursday, January 25, 2018: 10:00 a.m.—Issuance of Proposed Decisions in claims against Iraq.

Status: Open.

All meetings are held at the Foreign Claims Settlement Commission, 600 E Street NW, Washington, DC. Requests for information, or advance notices of intention to observe an open meeting, may be directed to: Patricia M. Hall, Foreign Claims Settlement Commission, 600 E Street NW, Suite 6002, Washington, DC 20579. Telephone: (202) 616–6975.

Brian M. Simkin,

Chief Counsel.

[FR Doc. 2018–00787 Filed 1–12–18; 4:15 pm]

BILLING CODE 4410–BA–P

DEPARTMENT OF JUSTICE

U.S. Marshals Service

[OMB Number XXXX—New]

Agency Information Collection Activities; Proposed eCollection eComments Requested; New Collection; Form CSO–005, Preliminary Background Check Form

AGENCY: U.S. Marshals Service, Department of Justice.

ACTION: Notice.

SUMMARY: The Department of Justice, U.S. Marshals Service (USMS), is submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: The Department of Justice encourages public comment and will accept input until March 19, 2018.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Nicole Timmons either by mail at CG–3, 10th Floor, Washington, DC 20530–0001, by email at *Nicole.Timmons@usdoj.gov*, or by telephone at 202–236–2646.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the USMS, 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;
—Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; 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.

Overview of This Information Collection

1. *Type of Information Collection:* New Collection.

2. *The Title of the Form/Collection:* Preliminary Background Check Form.

3. The agency form number, if any, and the applicable component of the Department sponsoring the collection: CSO–005. The applicable component within the Department of Justice is the USMS.

4. Affected public who will be asked or required to respond, as well as a brief abstract: Primary respondents—Court Security Officers/Special Security Officer (CSO/SSO) Applicants. The CSO–005 Preliminary Background Check Form is used to collect applicant information for CSO/SSO positions. The applicant information provided to USMS from the Vendor gives information about which District and Facility the applicant will be working, the applicant's personal information, prior employment verification, employment performance and current financial status. The information allows the selecting official to hire applicants with a strong history of employment performance and financial responsibility. The questions on this form have been developed from the OPM, MSPB and DOJ ''Best Practice'' guidelines for reference checking.

5. An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond: An estimated 750 respondents will utilize the form, and it will take each respondent approximately 60 minutes to complete the form.

6. An estimate of the total public burden (in hours) associated with the collection: The estimated annual public burden associated with this collection is 750 hours, which is equal to 750 (total # of annual responses) * 60 minutes.

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E.405A, Washington, DC 20530.

Dated: January 11, 2018.

Jake Bishop-Green,

Acting Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2018–00654 Filed 1–16–18; 8:45 am]

BILLING CODE 4410–04–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2011–0181]

Coke Oven Emissions Standard; Extension of the Office of Management and Budget's (OMB) Approval of Information Collection (Paperwork) Requirements

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Request for public comments.

SUMMARY: OSHA solicits public comments concerning its proposal to extend OMB approval of the information collection requirements specified by the Coke Oven Emissions Standard.

DATES: Comments must be submitted (postmarked, sent, or received) by March 19, 2018.

ADDRESSES:

Electronically: You may submit comments and attachments electronically at *http://www.regulations.gov,* which is the Federal eRulemaking Portal. Follow the instructions online for submitting comments.

Facsimile: If your comments, including attachments, are not longer than 10 pages, you may fax them to the OSHA Docket Office at (202) 693–1648.

Mail, hand delivery, express mail, messenger, or courier service: When using this method, you must submit a copy of your comments and attachments to the OSHA Docket Office, Docket No. OSHA–2011–0181, Occupational Safety and Health Administration, U.S. Department of Labor, Room N–3653, 200 Constitution Avenue NW, Washington, DC 20210. Deliveries (hand, express mail, messenger, and courier service) are accepted during the Department of Labor's and Docket Office's normal business hours, 10:00 a.m. to 3:00 p.m., e.t.

Instructions: All submissions must include the Agency name and OSHA docket number (OSHA–2011–0181) for the Information Collection Request (ICR). All comments, including any personal information you provide, are placed in the public docket without change, and may be made available online at *http://www.regulations.gov.* For further information on submitting comments, see the ''Public Participation'' heading in the section of this notice titled **SUPPLEMENTARY INFORMATION.**

Docket: To read or download comments or other material in the docket, go to *http://www.regulations.gov* or the OSHA Docket Office at the address above. All documents in the docket (including this **Federal Register** notice) are listed in the *http://www.regulations.gov* index; however, some information (*e.g.,* copyrighted material) is not publicly available to read or download through the website. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. You may also contact Theda Kenney at the phone number below to obtain a copy of the ICR.

FOR FURTHER INFORMATION CONTACT: Charles McCormick or Theda Kenney, Directorate of Standards and Guidance, OSHA, U.S. Department of Labor, telephone (202) 693–2222 or email: *https://www.regulations.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Department of Labor, as part of its continuing effort to reduce paperwork

and respondent (*i.e.,* employer) burden, conducts a preclearance consultation program to provide the public with an opportunity to comment on proposed and continuing information collection requirements in accord with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)). This program ensures that information is in the desired format, reporting burden (time and costs) is minimal, collection instruments are clearly understood, and OSHA's estimate of the information collection burden is accurate. The Occupational Safety and Health Act of 1970 (the OSH Act) (29 U.S.C. 651 *et seq.*) authorizes information collection by employers as necessary or appropriate for enforcement of the OSH Act or for developing information regarding the causes and prevention of occupational injuries, illnesses, and accidents (29 U.S.C. 657). The OSH Act also requires that OSHA obtain such information with minimum burden upon employers, especially those operating small businesses, and to reduce to the maximum extent feasible unnecessary duplication of effort in obtaining information (29 U.S.C. 657).

The information collection requirements in the Coke Oven Emissions Standard provide protection for workers from the adverse health effects associated with exposure to coke oven emissions. In this regard, the Coke Oven Emissions Standard requires employers to monitor workers' exposure to coke oven emissions, monitor worker health, and provide workers with information about their exposures and the health effects of exposure to coke oven emissions.

II. Special Issues for Comment

OSHA has a particular interest in comments on the following issues:

- Whether the proposed information collection requirements are necessary for the proper performance of the Agency's functions to protect workers, including whether the information is useful;
- The accuracy of OSHA's estimate of the burden (time and costs) of the information collection requirements, including the validity of the methodology and assumptions used;
- The quality, utility, and clarity of the information collected; and
- Ways to minimize the burden on employers who must comply; for example, by using automated or other technological information collection and transmission techniques.

III. Proposed Actions

The Agency is requesting a slight adjustment decrease of 148 burden hours (from 51,792 hours to 51,644). The adjustment decrease is due to an increase in the total number of workers identified in (NAICS 331111). The Agency will summarize the comments submitted in response to this notice and will include this summary in the request to OMB.

Type of Review: Extension of a currently approved collection.

Title: Coke Oven Emissions Standard (29 CFR 1910.1029).

OMB Control Number: 1218–0128.

Affected Public: Business or other for-profits.

Number of Respondents: 3,984.

Number of Responses: 40,939.

Frequency of Responses: On occasion.

Average Time per Response: Various.

Estimated Total Burden Hours: 51,644.

Estimated Cost (Operation and Maintenance): $969,307.

IV. Public Participation—Submission of Comments on This Notice and Internet Access to Comments and Submissions

You may submit comments in response to this document as follows: (1) Electronically at *http://www.regulations.gov,* which is the Federal eRulemaking Portal; (2) by facsimile; or (3) by hard copy. All comments, attachments, and other material must identify the Agency name and the OSHA docket number for the ICR (Docket No. OSHA–2011–0181. You may supplement electronic submissions by uploading document files electronically. If you wish to mail additional materials in reference to an electronic or a facsimile submission, you must submit them to the OSHA Docket Office (see the section of this notice titled **ADDRESSES**). The additional materials must clearly identify your electronic comments by your name, date, and the docket number so that the Agency can attach them to your comments.

Because of security procedures, the use of regular mail may cause a significant delay in the receipt of comments. For information about security procedures concerning the delivery of materials by hand, express delivery, messenger, or courier service, please contact the OSHA Docket Office at (202) 693–2350, (TTY (877) 889–5627).

Comments and submissions are posted without change at *http://www.regulations.gov.* Therefore, OSHA cautions commenters about submitting personal information such as social security numbers and dates of birth. Although all submissions are listed in the *http://www.regulations.gov* index, some information (*e.g.,* copyrighted material) is not publicly available to read or download through this website. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. Information on using the *http://www.regulations.gov* website to submit comments and access the docket is available at the website's ''User Tips'' link. Contact the OSHA Docket Office for information about materials not available from the website, and for assistance in using the internet to locate docket submissions.

V. Authority and Signature

Loren Sweatt, Deputy Assistant Secretary of Labor for Occupational Safety and Health, directed the preparation of this notice. The authority for this notice is the Paperwork Reduction Act of 1995 (44 U.S.C. 3506 *et seq.*) and Secretary of Labor's Order No. 1–2012 (77 FR 3912).

Signed at Washington, DC, on January 10, 2018.

Loren Sweatt,

Deputy Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2018–00704 Filed 1–16–18; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2011–0063]

Slings; Extension of the Office of Management and Budget's (OMB) Approval of Information Collection (Paperwork) Requirements

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Request for public comments.

SUMMARY: OSHA solicits public comments concerning its proposal to extend OMB approval of the information collection requirements contained in the Slings Standard. The collection of information (paperwork) provisions of the Standard specify affixing identification tags or markings to slings, developing and maintaining inspection records, and retaining proof-testing certificates.

DATES: Comments must be submitted (postmarked, sent, or received) by March 19, 2018.

ADDRESSES:

Electronically: You may submit comments and attachments electronically at *http://www.regulations.gov,* which is the Federal eRulemaking Portal. Follow the

instructions online for submitting comments.

Facsimile: If your comments, including attachments, are not longer than 10 pages, you may fax them to the OSHA Docket Office at (202) 693–1648.

Mail, hand delivery, express mail, messenger, or courier service: When using this method, you must submit a copy of your comments and attachments to the OSHA Docket Office, Docket No. OSHA–2011–0063, Occupational Safety and Health Administration, U.S. Department of Labor, Room N–3653, 200 Constitution Avenue NW, Washington, DC 20210. Deliveries (hand, express mail, messenger, and courier service) are accepted during the Department of Labor's and Docket Office's normal business hours, 10:00 a.m. to 3:00 p.m., E.T.

Instructions: All submissions must include the Agency name and the OSHA docket office number (OSHA–2011–0063) for the Information Collection Request (ICR). All comments, including any personal information you provide, are placed in the public docket without change, and may be made available online at *http://www.regulations.gov.* For further information on submitting comments, see the ''Public Participation'' heading in the section of this notice titled **SUPPLEMENTARY INFORMATION**.

Docket: To read or download comments or other material in the docket, go to *http://www.regulations.gov* or the OSHA Docket Office at the address above. All documents in the docket (including this **Federal Register** notice) are listed in the *http://www.regulations.gov* index; however, some information (*e.g.,* copyrighted material) is not publicly available to read or download from the website. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. You may also contact Theda Kenney at the address below to obtain a copy of the ICR.

FOR FURTHER INFORMATION CONTACT: Charles McCormick or Theda Kenney, Directorate of Standards and Guidance, OSHA, U.S. Department of Labor, telephone (202) 693–2222.

SUPPLEMENTARY INFORMATION:

I. Background

The Department of Labor, as part of its continuing effort to reduce paperwork and respondent (*i.e.,* employer) burden, conducts a preclearance consultation program to provide the public with an opportunity to comment on proposed and continuing information collection requirements in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)). This program ensures that information is in the desired format, reporting burden (time and costs) is minimal, collection instruments are clearly understood, and OSHA's estimate of the information collection burden is accurate. The Occupational Safety and Health Act of 1970 (the OSH Act) (29 U.S.C. 651 *et seq.*) authorizes information collection by employers as necessary or appropriate for enforcement of the OSH Act or for developing information regarding the causes and prevention of occupational injuries, illnesses, and accidents (29 U.S.C. 657). The OSH Act also requires that OSHA obtain such information with minimum burden upon employers, especially those operating small businesses, and to reduce to the maximum extent feasible unnecessary duplication of efforts in obtaining information (29 U.S.C. 657).

The Slings Standard (29 CFR 1910.184) specifies several paperwork requirements, depending on the type of sling (paragraph (e) of the Standard covers alloy steel chain slings; paragraph (f) covers wire rope slings; paragraph (g) covers metal mesh slings; paragraph (h) covers natural and synthetic fiber-rope slings; and paragraph (i) covers synthetic web slings).

The purpose of each of these requirements is to prevent workers from using defective or deteriorated slings, thereby reducing their risk of death or serious injury caused by sling failure during material handling. The information on the identification tags, markings, and coding's assist the employer in determining whether the sling can be used for lifting. The sling inspections enable early detection of faulty slings. The inspection and repair records provide employers with the date of the last inspection and the type of repairs made. This information provides assurance about the condition of the slings. These records also provide the most efficient means for an OSHA compliance officer to determine that an employer is complying with the Standard. Proof-testing certificates give employers, workers, and OSHA compliance officers assurance that the slings are safe to use.

II. Special Issues for Comment

OSHA has a particular interest in comments on the following issues:

- Whether the proposed information collection requirements are necessary for the proper performance of the Agency's functions, including whether the information is useful;
- The accuracy of OSHA's estimate of the burden (time and costs) of the information collection requirements, including the validity of the methodology and assumptions used;
- The quality, utility, and clarity of the information collected; and
- Ways to minimize the burden on employers who must comply; for example, by using automated or other technological information collection and transmission techniques.

III. Proposed Actions

OSHA is requesting that OMB extend its approval of the information collection requirements contained in the Slings Standard. The Agency is requesting an increase in its current burden hours from 23,614 to 26,673, a total increase of 3,059 hours. This adjustment increase results from increasing the number of slings (from 1,350,000 to 1,525,000).

Type of Review: Extension of a currently approved collection.

Title: Slings (29 CFR 1910.184).

OMB Control Number: 1218–0223.

Affected Public: Business or other for-profits.

Number of Respondents: 2,245,14.

Frequency of Response: On occasion.

Total Responses: 314,913.

Average Time per Responses: Various.

Estimated Total Burden Hours: 26,673.

Estimated Cost (Operation and Maintenance): $0.

IV. Public Participation—Submission of Comments on This Notice and Internet Access to Comments and Submissions

You may submit comments in response to this document as follows: (1) Electronically at *http://www.regulations.gov,* which is the Federal eRulemaking Portal; (2) by facsimile (fax); or (3) by hard copy. All comments, attachments, and other material must identify the Agency name and the OSHA docket number for the ICR (Docket No. OSHA–2011–0063). You may supplement electronic submissions by uploading document files electronically. If you wish to mail additional materials in reference to an electronic or facsimile submission, you must submit them to the OSHA Docket Office (see the section of this notice titled (**ADDRESSES**). The additional materials must clearly identify your electronic comments by your name, date, and the docket number so the Agency can attach them to your comments.

Because of security procedures, the use of regular mail may cause a significant delay in the receipt of comments. For information about

security procedures concerning the delivery of materials by hand, express delivery, messenger, or courier service, please contact the OSHA Docket Office at (202) 693–2350, (TTY (877) 889–5627).

Comments and submissions are posted without change at *http://www.regulations.gov.* Therefore, OSHA cautions commenters about submitting personal information such as social security numbers and dates of birth. Although all submissions are listed in the *http://www.regulations.gov* index, some information (*e.g.,* copyrighted material) is not publicly available to read or download from this website. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. Information on using the *http://www.regulations.gov* website to submit comments and access the docket is available at the website's ''User Tips'' link. Contact the OSHA Docket Office for information about materials not available from the website, and for assistance in using the internet to locate docket submissions.

V. Authority and Signature

Loren Sweatt, Deputy Assistant Secretary of Labor for Occupational Safety and Health, directed the preparation of this notice. The authority for this notice is the Paperwork Reduction Act of 1995 (44 U.S.C. 3506 *et seq.*) and Secretary of Labor's Order No. 1–2012 (77 FR 3912).

Signed at Washington, DC, on January 10, 2018.

Loren Sweatt,

Deputy Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2018–00705 Filed 1–16–18; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2011–0187]

Electrical Standards for Construction and General Industry; Extension of the Office of Management and Budget's (OMB) Approval of the Information Collection (Paperwork) Requirements

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Request for public comments.

SUMMARY: OSHA solicits public comments concerning its request for an extension of the information collection requirements contained in the Electrical Standards for Construction and for General Industry. The Standards address safety procedures for installation and maintenance of electric utilization equipment that prevent death and serious injuries among construction and general industry workers in the workplace caused by electrical hazards.

DATES: Comments must be submitted (postmarked, sent, or received) by March 19, 2018.

ADDRESSES:

Electronically: You may submit comments and attachments electronically at *https://www.regulations.gov,* which is the Federal eRulemaking Portal. Follow the instructions online for submitting comments.

Facsimile: If your comments, including attachments, are not longer than 10 pages, you may fax them to the OSHA Docket Office at (202) 693–1648.

Mail, hand delivery, express mail, messenger, or courier service: When using this method, you must submit a copy of your comments and attachments to the OSHA Docket Office, Docket No. OSHA–2011–0187, U.S. Department of Labor, Occupational Safety and Health Administration, Room N3653, 200 Constitution Avenue NW, Washington, DC 20210. Deliveries (hand, express mail, messenger, and courier service) are accepted during the Docket Office's normal business hours, 10:00 a.m. to 3:00 p.m., ET.

Instructions: All submissions must include the Agency name and OSHA docket number (OSHA–2011–0187) for the Information Collection Request (ICR). All comments, including any personal information you provide, are placed in the public docket without change, and may be made available online at *https://www.regulations.gov.* For further information on submitting comments, see the ''Public Participation'' heading in the section of this notice titled **SUPPLEMENTARY INFORMATION**.

Docket: To read or download comments or other material in the docket, go to *https://www.regulations.gov* or the OSHA Docket Office at the address above. All documents in the docket (including this **Federal Register** notice) are listed in the *https://www.regulations.gov* index; however, some information (*e.g.,* copyrighted material) is not publicly available to read or download through the website. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. You may also contact Theda Kenney at the address below to obtain a copy of the ICR.

FOR FURTHER INFORMATION, CONTACT: Theda Kenney or Charles McCormick, Directorate of Standards and Guidance, OSHA, U.S. Department of Labor, Washington, DC; telephone (202) 693–2222 or email: *https://www.regulations.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Department of Labor, as part of its continuing effort to reduce paperwork and respondent (*i.e.,* employer) burden, conducts a preclearance consultation program to provide the public with an opportunity to comment on proposed and continuing information collection requirements in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3506(c)(2)(A)).

This program ensures that information is in the desired format, reporting burden (time and costs) is minimal, collection instruments are clearly understood, and OSHA's estimate of the information collection burden is accurate. The Occupational Safety and Health Act of 1970 (the OSH Act) (29 U.S.C. 651 *et seq.*) authorizes information collection by employers as necessary or appropriate for enforcement of the Act or for developing information regarding the causes and prevention of occupational injuries, illnesses, and accidents (29 U.S.C. 657). The OSH Act also requires that OSHA obtain such information with minimum burden upon employers, especially those operating small businesses, and to reduce to the maximum extent feasible unnecessary duplication of efforts in obtaining information (29 U.S.C. 657).

The information collection requirements specified by the Electrical Standards for Construction and for General Industry alert workers to the presence and types of electrical hazards in the workplace, thereby preventing serious injury and death by electrocution. The information collection requirements in these Standards involve the following: the employer using electrical equipment that is marked with the manufacturer's name, trademark, or other descriptive markings that identify the producer of the equipment, and marking the equipment with the voltage, current, wattage, or other ratings necessary; requiring each disconnecting means for motors and appliances to be marked legibly to indicate its purpose, unless located and arranged so the purpose is evident; requiring the entrances to rooms and other guarded locations containing exposed live parts to be marked with conspicuous warning signs forbidding unqualified persons from

entering; and, for construction employers only, establishing and implementing the assured equipment grounding conductor program instead of using ground-fault circuit interrupters.

II. Special Issues for Comment

OSHA has a particular interest in comments on the following issues:

- Whether the proposed information collection requirements are necessary for the proper performance of the Agency's functions, including whether the information is useful;
- The accuracy of OSHA's estimate of the burden (time and cost) of the information collection requirements, including the validity of the methodology, and assumptions used;
- The quality, utility, and clarity of the information collected; and
- Ways to minimize the burden on employers who must comply. For example, by using automated or other technological information collection and transmission techniques.

III. Proposed Actions

OSHA is proposing a decrease adjustment to the existing burden hours from 220,789 hours to 194,976 hours for the Electrical Standards for Construction and for General Industry, a total decrease of 25,813. The cost of the labels is $4.25, which increased from $3.75, a difference of 50 cents. The cost of caution and warning signs remains $10.95. The total cost over a five-year period to the employer is $25,476,949 (or $5,095,390 per year). The Agency will summarize any comments submitted in response to this notice, and will include this summary in the request to OMB to extend the approval of the information collection requirements contained in these Standards.

Type of Review: Extension of a currently approved collection.

Title: Electrical Standards for Construction (29 CFR part 1926, subpart K) and for General Industry (29 CFR part 1910, subpart S).

OMB Number: 1218–0130.

Affected Public: Business or other for-profits; Not-for-profit institutions; Federal Government; State, local, or tribal governments.

Number of Respondents: 915,681.

Frequency of Response: Occasionally.

Total Responses: 2,841,370.

Average Time per Response: Various.

Estimated Total Burden Hours: 194,976.

Estimated Cost (Operation and Maintenance): $5,095,390.

IV. Public Participation—Submission of Comments on This Notice and Internet Access to Comments and Submissions

You may submit comments in response to this document as follows: (1) Electronically at *https://www.regulations.gov,* which is the Federal eRulemaking Portal; (2) by facsimile (fax); or (3) by hard copy. All comments, attachments, and other materials must identify the Agency name and the OSHA docket number for the ICR (Docket No. OSHA–2011–0187). You may supplement electronic submissions by uploading document files electronically. If you wish to mail additional materials in reference to an electronic or facsimile submission, you must submit them to the OSHA Docket Office (see the section of this notice titled **ADDRESSES**). The additional materials must clearly identify your electronic comments by your name, date, and the docket number so the Agency can attach them to your comments.

Because of security procedures, the use of regular mail may cause a significant delay in the receipt of comments. For information about security procedures concerning the delivery of materials by hand, express delivery, messenger, or courier service, please contact the OSHA Docket Office at (202) 693–2350, (TTY (877) 889–5627).

Comments and submissions are posted without change at *https://www.regulations.gov.* Therefore, OSHA cautions commenters about submitting personal information such as social security numbers and date of birth. Although all submissions are listed in the *https://www.regulations.gov* index, some information (*e.g.,* copyrighted material) is not publicly available to read or download through this website. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. Information on using the *https://www.regulations.gov* website to submit comments and access the docket is available at the website's ''User Tips'' link. Contact the OSHA Docket Office for information about materials not available through the website, and for assistance in using the internet to locate docket submissions.

V. Authority and Signature

Loren Sweatt, Deputy Assistant Secretary of Labor for Occupational Safety and Health, directed the preparation of this notice. The authority for this notice is the Paperwork Reduction Act of 1995 (44 U.S.C. 3506 *et seq.*) and Secretary of Labor's Order No. 1–2012 (77 FR 3912).

Signed at Washington, DC, on January 10, 2018.

Loren Sweatt,

Deputy Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2018–00703 Filed 1–16–18; 8:45 am]

BILLING CODE 4510–26–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (18–001)]

Notice of Intent To Grant Partially Exclusive Term License

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of Intent to Grant Partially Exclusive Term License—CORRECTION.

SUMMARY: This is an amended version of NASA's earlier **Federal Register** Notice which was published on January 3, 2018, Document 2017–28388, and Notice Number 17–091. There was an error in the third line in which ''Take Out This Space'' was added after ''Notice of Intent to Grant Partially Exclusive Term License'' and needed to be deleted.

NASA hereby gives notice of its intent to grant a partially-exclusive term license in the United States to practice the invention described and claimed in U.S. Patent 6,760,487 entitled, ''Estimated Spectrum Adaptive Postfilter And The Iterative Prepost Filtering Algorithms'', and in U.S. Patent 9,414,072 entitled ''Improved Performance of the JPEG Estimated Spectrum Adaptive Postfilter (JPEG–ESAP) for Low Bit Rates'' to Human Health Organization (''H2O''), having its principal place of business in Studio City, CA.

DATES: The prospective partially-exclusive term license may be granted unless NASA receives written objections, including evidence and argument no later than February 1, 2018, that establish that the grant of the license would not be consistent with the requirements regarding the licensing of federally owned inventions as set forth in the Bayh-Dole Act and implementing regulations. Competing applications completed and received by NASA no later than February 1, 2018 will also be treated as objections to the grant of the contemplated partially exclusive license. Objections submitted in response to this notice will not be made available to the public for inspection and, to the extent permitted by law, will

not be released under the Freedom of Information Act.

ADDRESSES: Objections relating to the prospective license may be submitted to Patent Counsel, Bryan A. Geurts, Goddard Space Flight Center, 8800 Greenbelt Road M/S 140.1, Greenbelt MD 20771. Phone (301) 286–7351. Facsimile (301) 286–9502.

FOR FURTHER INFORMATION CONTACT: Enidia Santiago-Arce, Innovative Partnerships Program Office, Goddard Space Flight Center, 8800 Greenbelt Road M/S 504, Greenbelt, MD 20771. Phone (301) 286–5810.

SUPPLEMENTARY INFORMATION: This notice of intent to grant a partially-exclusive term patent license is issued in accordance with 35 U.S.C. 209(e) and 37 CFR 404.7(a)(1)(i). The patent rights in these inventions have been assigned to the United States of America as represented by the Administrator of the National Aeronautics and Space Administration. The prospective partially exclusive license will comply with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Information about other NASA inventions available for licensing can be found online at *http://technology.nasa.gov.*

Mark P. Dvorscak,

Agency Counsel for Intellectual Property.

[FR Doc. 2018–00661 Filed 1–16–18; 8:45 am]

BILLING CODE 7510–13–P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meetings

TIME AND DATE: 2:00 p.m. on Thursday, January 18, 2018.

PLACE: Closed Commission Hearing Room 10800.

STATUS: This meeting will be closed to the public.

MATTERS TO BE CONSIDERED: Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the closed meeting. Certain staff members who have an interest in the matters also may be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(3), (5), (6), (7), (8), 9(B) and (10) and 17 CFR 200.402(a)(3), (a)(5), (a)(6), (a)(7), (a)(8), (a)(9)(ii) and (a)(10), permit consideration of the scheduled matters at the closed meeting.

Commissioner Stein, as duty officer, voted to consider the items listed for the closed meeting in closed session.

The subject matters of the closed meeting will be:

Institution and settlement of injunctive actions;

Institution and settlement of administrative proceedings; and

Other matters relating to enforcement proceedings.

At times, changes in Commission priorities require alterations in the scheduling of meeting items.

CONTACT PERSON FOR MORE INFORMATION: For further information and to ascertain what, if any, matters have been added, deleted or postponed; please contact Brent J. Fields from the Office of the Secretary at (202) 551–5400.

Dated: January 11, 2018.

Brent J. Fields,

Secretary.

[FR Doc. 2018–00739 Filed 1–12–18; 11:15 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Securities Act of 1933 Release No. 33–10453/January 10, 2018; Securities Exchange Act of 1934 Release No. 34–82483/January 10, 2018]

Order Approving Public Company Accounting Oversight Board Budget and Annual Accounting Support Fee for Calendar Year 2018

The Sarbanes-Oxley Act of 2002, as amended (the ''Sarbanes-Oxley Act''),[1] established the Public Company Accounting Oversight Board (''PCAOB'') to oversee the audits of companies that are subject to the securities laws, and related matters, in order to protect the interests of investors and further the public interest in the preparation of informative, accurate and independent audit reports. Section 982 of the Dodd-Frank Wall Street Reform and Consumer Protection Act (the ''Dodd-Frank Act'') [2] amended the Sarbanes-Oxley Act to provide the PCAOB with explicit authority to oversee auditors of broker-dealers registered with the Commission. The PCAOB is to accomplish these goals through registration of public accounting firms and standard setting, inspection, and disciplinary programs. The PCAOB is subject to the comprehensive oversight of the Securities and Exchange Commission (the ''Commission'').

Section 109 of the Sarbanes-Oxley Act provides that the PCAOB shall establish a reasonable annual accounting support fee, as may be necessary or appropriate to establish and maintain the PCAOB. Under Section 109(f) of the Sarbanes-Oxley Act, the aggregate annual accounting support fee shall not exceed the PCAOB's aggregate ''recoverable budget expenses,'' which may include operating, capital and accrued items. The PCAOB's annual budget and accounting support fee are subject to approval by the Commission. In addition, the PCAOB must allocate the annual accounting support fee among issuers and among brokers and dealers.

Section 109(b) of the Sarbanes-Oxley Act directs the PCAOB to establish a budget for each fiscal year in accordance with the PCAOB's internal procedures, subject to approval by the Commission. Rule 190 of Regulation P governs the Commission's review and approval of PCAOB budgets and annual accounting support fees.[3] This budget rule provides, among other things, a timetable for the preparation and submission of the PCAOB budget and for Commission actions related to each budget, a description of the information that should be included in each budget submission, limits on the PCAOB's ability to incur expenses and obligations except as provided in the approved budget, procedures relating to supplemental budget requests, requirements for the PCAOB to furnish on a quarterly basis certain budget-related information, and a list of definitions that apply to the rule and to general discussions of PCAOB budget matters.

In accordance with the budget rule, in March 2017 the PCAOB provided the Commission with a narrative description of its program issues and outlook for the 2018 budget year. In response, the Commission provided the PCAOB with economic assumptions and general budgetary guidance for the 2018 budget year. The PCAOB subsequently delivered a preliminary budget and budget justification to the Commission. Staff from the Commission's Office of the Chief Accountant and Office of Financial Management dedicated a substantial amount of time to the review and analysis of the PCAOB's programs, projects, and budget estimates; reviewed the PCAOB's estimates of 2017 actual spending; and attended several meetings with management and staff of the PCAOB to further develop their understanding of the PCAOB's budget and operations. During the course of this review, Commission staff relied upon representations and supporting documentation from the PCAOB. Based

[1] 15 U.S.C. 7201 *et seq.*

[2] Public Law 111–203, 124 Stat. 1376 (2010).

[3] 17 CFR 202.190.

on this review, the Commission issued a ''pass back'' letter to the PCAOB on October 25, 2017. On November 16, 2017, the PCAOB adopted its 2018 budget during an open meeting, and subsequently submitted that budget to the Commission for approval.

After considering the above, the Commission did not identify any proposed disbursements in the 2018 budget adopted by the PCAOB that are not properly recoverable through the annual accounting support fee, and the Commission believes that the aggregate proposed 2018 annual accounting support fee does not exceed the PCAOB's aggregate recoverable budget expenses for 2018.

The Commission also acknowledges the PCAOB's updated strategic plan and encourages the PCAOB to continue keeping the Commission and its staff apprised of significant new developments. The Commission looks forward to providing its views to the PCAOB as future updates are made to the plan. In addition, the PCAOB should submit its 2017 annual report to the Commission by April 2, 2018.

The Commission directs the Board during 2018 to continue to provide periodic updates to the Commission relating to the monitoring of estimated cost savings and efficiencies gained through certain initiatives implemented in recent years. The Board shall continue its review of its compensation and travel policies and report to the Commission the results of this review.

In May 2017, the PCAOB formed the Office of Economic and Risk Analysis (''ERA'') by integrating the staff of the Center for Economic Analysis (''CEA'') that conducted economic analysis and research with staff from the Office of Research and Analysis (''ORA'') that conducted risk assessment and data analysis. The Commission directs the PCAOB during 2018 to provide quarterly updates to the Commission on ERA's activities and progress towards its stated goals, including the work to integrate staff from the former CEA and ORA.

The Commission directs the Board during 2018 to continue to provide in its quarterly reports to the Commission detailed information about the state of the PCAOB's information technology (''IT'') program, including planned, estimated, and actual costs for IT projects, and the level of involvement of consultants. These reports also should continue to include: (a) A discussion of the Board's assessment of the IT program; and (b) the quarterly IT report that is prepared by PCAOB staff and submitted to the Board.

The Commission also directs the Board during 2018 to continue to include in its quarterly reports to the Commission information about the PCAOB's inspections program. Such information is to include: (a) Statistics relative to the numbers and types of firms budgeted and expected to be inspected in 2018, including by location and by year the inspections are required to be conducted in accordance with the Sarbanes-Oxley Act and PCAOB rules; (b) information about the timing of the issuance of inspections reports for domestic and non-U.S. inspections; and (c) updates on the PCAOB's efforts to establish cooperative arrangements with respective non-U.S. authorities for inspections required in those countries.

The Commission understands that the Office of Management and Budget (''OMB'') has determined the 2018 budget of the PCAOB to be sequestrable under the Budget Control Act of 2011.[4] For 2017, the PCAOB sequestered $17 million. That amount will become available in 2018. For 2018, the sequestration amount will be 6.6% or $17.2 million. Accordingly, the PCAOB should submit a revised spending plan for 2018 reflecting a $0.2 million reduction to budgeted expenditures as a result of the increase in sequestration amount from 2017 to 2018.

The Commission has determined that the PCAOB's 2018 budget and annual accounting support fee are consistent with Section 109 of the Sarbanes-Oxley Act. Accordingly,

It is ordered, pursuant to Section 109 of the Sarbanes-Oxley Act, that the PCAOB budget and annual accounting support fee for calendar year 2018 are approved.

By the Commission.

Brent J. Fields,

Secretary.

[FR Doc. 2018–00642 Filed 1–16–18; 8:45 am]

BILLING CODE 8011–01–P

[4] *See* ''OMB Report to the Congress on the Joint Committee Reductions for Fiscal Year 2018'', Appendix page 16 of 16 *available at https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/sequestration_reports/2018_jc_sequestration_report_may2017_potus.pdf.*

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meetings

TIME AND DATE: Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Public Law 94–409, that the Commission will co-host the SEC–NYU Dialogue on Securities Markets—Shareholder Engagement on Friday, January 19, 2018, beginning at 9:10 a.m. (ET).

PLACE: The meeting will be held at the New York University's Salomon Center for the Study of Financial Institutions, 44 W. 4th Street, New York, NY 10112.

STATUS: This meeting will begin at 9:10 a.m. (ET) and will be open to the public. Attendees can pre-register for in-person attendance or webcast. The meeting will be webcast live by NYU and later archived on the Commission's website at *www.sec.gov.*

MATTERS TO BE CONSIDERED: The event is scheduled to include welcome remarks by SEC Chairman Jay Clayton, concluding remarks by SEC Commissioner Kara Stein, and panel discussions that Commissioners may attend. The panel discussions will address, among other matters, the increasing ownership of public companies by large institutional investors, the influence of activist investors, the role of proxy advisory services, and other changes in the way investors and public companies engage with each other.

This Sunshine Act notice is being issued because a majority of the Commission may attend the meeting.

CONTACT PERSON FOR MORE INFORMATION: For further information and to ascertain what, if any, matters have been added, deleted or postponed; please contact Brent J. Fields from the Office of the Secretary at (202) 551–5400.

Dated: January 11, 2018.

Brent J. Fields,

Secretary.

[FR Doc. 2018–00738 Filed 1–12–18; 11:15 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–82479; File No. SR–NASDAQ–2018–002]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Add a New Rule 6200 To Codify Participant Risk Settings in the Exchange's Trading System (as Set Forth in a Proposed IM–6200–1) and To Authorize the Exchange To Share Those Settings With the Clearing Member That Clears Transactions on Behalf of the Participant

January 10, 2018.

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, 2018, The Nasdaq Stock Market LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by 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 add a new Rule 6200 to codify Participant risk settings in the Exchange's trading system (as set forth in a proposed IM–6200–1) and to authorize the Exchange to share such risk settings with the clearing member that clears transactions on behalf of the Participant.

The text of the proposed rule change is set forth below. Proposed new language is *italicized;* deleted text is in brackets.

* * * * *

The Nasdaq Stock Market Rules

* * * * *

Equity Rules

* * * * *

[6200. Reserved.]

6200. Exchange Sharing of Participant Risk Settings

The Exchange may share any Participant risk settings in the trading system specified in IM–6200–1 with the clearing member that clears transactions on behalf of the Participant. For purposes of this Rule, the term ''Participant'' has the meaning set forth in Rule 4701(c).

IM–6200–1. Risk Settings

The Exchange offers certain risk settings applicable to a Participant's activities on the Exchange. The risk settings currently offered by the Exchange are:

(a) Share Size Control—When enabled by a Participant, this optional control will allow a Participant to limit the number of shares that the Participant may associate with an order placed on the Exchange;

(b) ISO Control—When enabled by a Participant, this optional control will prevent a Participant from entering an ISO order onto the Exchange;

(c) Cancel-on-Disconnect Control—When enabled by a Participant, this optional control will allow a Participant, when it experiences a disruption in its connection to the Exchange, to immediately cancel all pending Exchange orders except for those designated for the Opening or Closing Crosses and Good-Till-Canceled orders (RASH & FIX only);

(d) The Nasdaq Kill Switch—This control is described in Rule 6130;

(e) Limit Order Protection—This control is described in Rule 4757(c);

(f) Price Collar Check—This control will automatically restrict a routed order from executing at a price that differs from the NBBO (at the time of order entry) by more than five percent or $0.25, whichever difference is greater. The system will proceed to route an order unless and until it crosses the greater of these two price collars, and if it does so, then the system will block further routings of the order that fall outside of the collars. For example, if the NBBO is $99 x $100 at the time of entry of a buy order, then the system will route the order at prices at or below $105, but will stop doing so if the offer price rises above $105 (five percent of the NBO).

(g) Maximum Order Volume Check—This control will automatically reject an order for routing away that exceeds a maximum volume of shares. As applied to equity orders, the default maximum order volume is set at 25,000 shares, but the Participant may request that the Exchange set a higher default based on historic volume.

(h) Cumulative Order Volume Check—This control will automatically block an attempt by a Participant using a particular MPID to route orders away to buy or sell equity securities that, cumulatively, exceed 9.5 million shares during a five second time period; and

(i) Duplication Control—This control will automatically reject an order that a Participant submits to the Exchange to the extent that it is duplicative of another order that the Participant submitted to the Exchange during the prior five seconds.

* * * * *

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 adopt proposed IM–6200–1, which codifies a comprehensive list of Participant risk settings in the Exchange's trading system. The Exchange also proposes to adopt new Rule 6200 to authorize the Exchange to share these risk settings with the clearing member that clears transactions on behalf of the Participant. For purposes of Rule 6200, the term ''Participant'' has the meaning set forth in Rule 4701(c).[3]

Participants are required to be members of the Exchange. Rule 4618 states that ''all transactions through the facilities of the Nasdaq Market Center shall be cleared and settled through a registered clearing agency using a continuous net settlement system.'' It further provides that this requirement may be satisfied by ''direct participation, use of direct clearing services, by entry into a correspondent clearing arrangement with another member that clears trades through such a clearing agency. . . .'' Further, pursuant to Rule 4627, every clearing member acting on a Participant's behalf that constitutes a side of a system trade is responsible for honoring such trades of that Participant.

All Participants that are not clearing members require a clearing member's consent to clear transactions on their behalf in order to conduct business on the Exchange. Each Participant that transacts through a clearing member on the Exchange must have an arrangement between the Participant and the clearing member. The Exchange is provided notice of which clearing members have relationships with which Participants. The clearing member that guarantees the Participant's transactions on the Exchange has a financial interest in understanding the risk tolerance of the Participant. The proposal would provide the Exchange with authority to directly provide clearing members with information that may otherwise be available to such clearing members by virtue of their relationship with the respective Participants.[4]

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] A ''Participant'' is an entity that fulfills the obligations contained in Rule 4611 regarding participation in the System, and includes Nasdaq ECNs, Nasdaq Market Makers, and Order Entry Firms.

[4] The Exchange notes that its proposal would cover Sponsored Participants, as set forth in Rule

Proposed IM–6200–1 would codify a list of risk settings that are currently offered by the Exchange and would be covered by proposed Rule 6200. This list is comprehensive with respect to the risk settings that the Exchange presently offers. Certain of these risk settings are mandatory for Participants, meaning that the Exchange either imposes specific risk tolerances that are uniform for all Participants or it sets default risk tolerances, but it affords flexibility to Participants to select their own risk tolerance levels. In certain instances, the Exchange does not require Participants to utilize risk settings, but instead makes them available for use at the option of Participants. The risk settings set forth in proposed IM–6200–1 comprise the following:

- *Share Size Control*—When enabled by a Participant, this optional control will allow a Participant to limit the number of shares that the Participant may associate with an order placed on the Exchange;
- *ISO Control*—When enabled by a Participant, this optional control will prevent a Participant from entering an ISO order onto the Exchange;
- *Cancel-on-Disconnect Control*—When enabled by a Participant, this optional control will allow a Participant, when it experiences a disruption in its connection to the Exchange, to immediately cancel all pending Exchange orders except for those designated for the Opening or Closing Crosses, and Good-Till-Canceled orders (RASH & FIX only);
- *The Nasdaq Kill Switch*—This control is described in Rule 6130;
- *Limit Order Protection*—This control is described in Rule 4757(c);
- *Price Collar Check*—This control will automatically restrict a routed order from executing at a price that differs from the NBBO (at the time of order entry) by more than five percent or $0.25, whichever difference is greater. The system will proceed to route an order unless and until it crosses the greater of these two price collars, and if it does so, then the system will block further routings of the order that fall outside of the collars. For example, if the NBBO is $99 × $100 at the time of entry of a buy order, then the system will route the order at prices at or below $105, but will stop doing so if the offer price rises above $105 (five percent of the NBO).
- *Maximum Order Volume Check*—This control will automatically reject an order for routing away that exceeds a maximum volume of shares. As applied to equity orders, the default maximum order volume is set at 25,000 shares, but the Participant may request that the Exchange set a higher default based on historic volume.
- *Cumulative Order Volume Check*—This control will automatically block an attempt by a Participant using a particular MPID to route orders away to buy or sell equity securities that, cumulatively, exceed 9.5 million shares during a five second time period; and
- *Duplication Control*—This control will automatically reject an order that a Participant submits to the Exchange to the extent that it is duplicative of another order that the Participant submitted to the Exchange during the prior five seconds.

As set forth above, the proposal to authorize the Exchange to share any of the Participant's risk settings with the clearing member that clears transactions on behalf of the Participant would be limited to the risk settings specified in proposed IM–6200–1. The Exchange notes that use by a Participant of the risk settings offered by the Exchange is optional for share size, ISO, kill switch, and cancel-on disconnect controls, and is required in other instances.[5] By using the optional risk settings, following this proposed Rule change a Participant therefore also opts-in to the Exchange sharing its risk settings with its clearing member. The Exchange notes that any Participant that does not wish to share its mandatory risk settings with its clearing member could avoid sharing such settings by becoming a clearing member.

To the extent that a clearing member might reasonably require a Participant to provide access to its risk settings as a prerequisite to continuing to clear trades on the Participant's behalf, the Exchange's proposal to share those risk settings directly reduces the administrative burden on Participants and ensures that clearing members are receiving information that is up-to-date and conforms to the settings active in the Exchange's trading system. Further, the Exchange believes that the proposal will help such clearing members to better monitor and manage the potential risks that they assume when clearing for Participants of the Exchange.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[6] in general, and furthers the objectives of Section 6(b)(5) of the Act,[7] in particular, in that it is designed 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.

The proposed rule change will allow the Exchange to directly provide a Participant's risk settings to the clearing member that clears trades on behalf of the Participant. A clearing member guarantees transactions executed on Nasdaq for members with whom it has entered into a clearing arrangement, and therefore bears the risk associated with those transactions. The Exchange therefore believes that it is appropriate for the clearing member to have knowledge of what risk settings the Participant may utilize within the Exchange's trading system. The proposal will permit clearing members who have a financial interest in the risk settings of Participants with whom the Participants have entered into clearing arrangements to better monitor and manage the potential risks assumed by clearing members, thereby providing clearing members with greater control and flexibility over setting their own risk tolerance and exposure and aiding clearing members in complying with the Act. To the extent a clearing member might reasonably require a Participant to provide access to its risk settings as a prerequisite to continuing to clear trades on the Participant's behalf, the Exchange's proposal to share those risk settings directly reduces the administrative burden on Participants and ensures that clearing members are receiving information that is up-to-date and conforms to the settings active in the Exchange's trading system. Moreover, the proposal will foster cooperation and coordination with persons engaged in facilitating transactions in securities and more generally, will protect investors and the public interest, by reducing administrative burdens on both clearing members and other Participants and by allowing clearing members to better monitor their risk exposure.

The Exchange further believes that codifying the risk settings described above in proposed IM–6200–1 is consistent with the Act. These settings

4615, meaning that the proposal would authorize the Exchange to share the risk settings of Sponsored Participants with clearing members that clear trades on their behalf.

[5] As noted above, for the Maximum Order Volume Check, the Exchange sets a default order volume but Participants have flexibility to adjust this level.

[6] 15 U.S.C. 78f(b).

[7] 15 U.S.C. 78f(b)(5).

assist Participants in managing and controlling the risks associated with their access to and activity on the Exchange, both for the benefit of Participants and investors. The Exchange's risk settings, moreover, are consistent with risk settings employed by other exchanges, such as Cboe BYX. Although the Exchange presently offers these risk settings, codifying them will provide additional transparency to Participants regarding the risk settings offered by the Exchange. It will also foster cooperation and coordination with persons engaged in facilitating transactions in securities and more generally, will protect investors and the public interest, by providing additional transparency regarding risk settings offered by the Exchange.

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, as amended. The proposed rule change is not designed to address any competitive issues and does not pose an undue burden on non-clearing members because, unlike clearing members, non-clearing members do not guarantee the execution of a Participant's transactions on the Exchange. Moreover, the proposal to share risk settings with clearing members will not burden competition among clearing members because it will apply to all clearing members equally and regardless of size. The Exchange notes that this proposal will not affect competition among Participants because the proposal provides for sharing of all of Participants' risk settings set forth in IM–6200–1. Any Participant that does not wish to share its risk settings with its clearing member could avoid sharing such settings by becoming a clearing member. Lastly, the proposal to codify the Exchange's risk settings will not burden competition among Participants because the risk settings are already available to or required of Participants and will continue to be available or required of all Participants going forward.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act [8] and Rule 19b–4(f)(6) thereunder.[9]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

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–2018–002 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–2018–002. 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 website (*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 website 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. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2018–002 and should be submitted on or before February 7, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[10]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–00634 Filed 1–16–18; 8:45 am]

BILLING CODE 8011–01–P

[8] 15 U.S.C. 78s(b)(3)(A).

[9] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and the text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[10] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–82481; File No. SR–NASDAQ–2017–133]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Eliminate Transitional Rules That Have Expired Related to Compensation Committee Listing Standards

January 10, 2018.

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 December 27, 2017, The Nasdaq Stock Market LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission (''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

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

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 eliminate transitional rules that have expired related to compensation committee listing standards.

The text of the proposed rule change is available on the Exchange's website 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

Nasdaq proposes to delete the introductory language to Rule 5605(d), Rule 5605(d)(6), Rule 5605A and IM–5605A–6, and part of Rule 5615 to remove transitional rules that are no longer applicable to any companies and references to those transitional rules. These transitional rules were adopted in 2013 in connection with changes to the compensation committee requirements.[3] Those changes to the compensation committee requirements were fully phased in on October 31, 2014 and the transitional rules no longer apply to any listed company.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[4] in general, and furthers the objectives of Section 6(b)(5) of the Act,[5] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest. Nasdaq believes that it is in the public interest to eliminate the obsolete compensation committee requirements because the rules that replaced these provisions have been found to protect investors and the public interest[6] and because eliminating these provisions, which were fully phased out in October 2014, will improve the readability of Nasdaq's rules.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. Nasdaq does not believe the proposed rule change, which merely eliminates obsolete provisions and does not make any substantive change to Nasdaq's rules, will impose any burden, nor have any impact, on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act[7] and subparagraph (f)(6) of Rule 19b–4 thereunder.[8]

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–2017–133 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–2017–133. 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 website (*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 website 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. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2017–133, and should be submitted on or before February 7, 2018.

[3] Securities Exchange Act Release No. 68640 (January 11, 2013), 78 FR 4554 (January 22, 2013) (approving SR–NASDAQ–2012–109).

[4] 15 U.S.C. 78f(b).

[5] 15 U.S.C. 78f(b)(5).

[6] *See* Securities Exchange Act Release No. 68640, *supra.*

[7] 15 U.S.C. 78s(b)(3)(A)(iii).

[8] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[9]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–00636 Filed 1–16–18; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 32967; File No. 812–14714]

The Guardian Insurance & Annuity Company, Inc., et al.

January 10, 2018.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice.

Notice of application for an order approving the substitution of certain securities pursuant to section 26(c) of the Investment Company Act of 1940, as amended (the ''Act'').

APPLICANTS: The Guardian Insurance & Annuity Company, Inc., (''Guardian''), The Guardian Separate Account Q, and The Guardian Separate Account R (each, a ''Separate Account'' and together, the ''Separate Accounts''). Guardian and the Separate Accounts are referred to as the ''Applicants.''

SUMMARY OF APPLICATION: Applicants seek an order pursuant to section 26(c) of the Act, approving the substitution of shares issued by certain investment portfolios of registered investment companies (the ''Existing Portfolios'') for shares of certain investment portfolios of Guardian Variable Products Trust (the ''Replacement Portfolios''), held by the Separate Accounts to support certain variable annuity contracts (the ''Contracts''). Guardian Variable Products Trust is referred to as the ''Trust.''

FILING DATE: The application was filed on November 3, 2016 and was amended on April 10, 2017 and September 18, 2017. Applicants have agreed to file an amendment during the notice period, the substance of which is reflected in this notice.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Secretary of the Commission and serving the Applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on February 6, 2018 and should be accompanied by proof of service on the Applicants in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090. Applicants: Richard T. Potter, Senior Vice President, Counsel and Assistant Corporate Secretary, The Guardian Insurance & Annuity Company, Inc., 7 Hanover Square, New York, New York 10004.

FOR FURTHER INFORMATION CONTACT: Laura J. Riegel, Senior Counsel, at (202) 551–6873, or Robert H. Shapiro, Branch Chief at (202) 551–6821 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's website by searching for the file number, or for an Applicant using the Company name box, at *http://www.sec.gov.search/search.htm*, or by calling (202) 551–8090.

Applicants' Representations

1. Guardian is a Delaware stock life insurance company licensed to conduct insurance business in the District of Columbia and all fifty states of the United States. Guardian is wholly-owned by The Guardian Life Insurance Company of America (''Guardian Life''), a mutual life insurance company.

2. Each Separate Account meets the definition of ''separate account,'' as defined in section 2(a)(37) of the Act and rule 0–1(e) thereunder. The Separate Accounts are registered under the Act as unit investment trusts. The assets of the Separate Accounts support the Contracts and interests in the Separate Accounts offered through such Contracts. Guardian is the legal owner of the assets in the Separate Accounts. The Separate Accounts are segmented into subaccounts, and each subaccount invests in an underlying registered open-end management investment company or series thereof.

3. The Contracts are each registered under the Securities Act of 1933, as amended (the ''1933 Act'') on Form N–4. Each Contract has particular fees, charges, and investment options, as described in the Contracts' respective prospectuses.

4. The Contracts are individual flexible or single premium deferred variable annuity contracts. As set forth in the prospectuses for the Contracts, each Contract provides that Guardian reserves the right to substitute shares of the funds in which the Separate Accounts invest for shares of any funds already held or to be held in the future by the Separate Accounts.[1]

5. Guardian, on behalf of itself and the Separate Accounts, proposes to exercise its contractual right to substitute shares of the Existing Portfolios for shares of the Replacement Portfolios (''Substitutions''), as shown in the table below:

Substitution No.	Existing portfolio	Replacement portfolio
1	Variable Portfolio Loomis Sayles Growth Fund (Class 2)	Guardian Large Cap Disciplined Growth VIP Fund.
2	Fidelity VIP Contrafund Portfolio (Service Class 2)	Guardian Large Cap Disciplined Growth VIP Fund.
3	Fidelity VIP Growth Portfolio (Service Class 2)	Guardian Large Cap Disciplined Growth VIP Fund.
4	Alger Capital Appreciation Portfolio (Class S)	Guardian Large Cap Fundamental Growth VIP Fund.
5	BlackRock Capital Appreciation V.I. Fund (Class III)	Guardian Large Cap Fundamental Growth VIP Fund.
6	Columbia Variable Portfolio Large Cap Growth Fund (Class 2).	Guardian Large Cap Fundamental Growth VIP Fund.
7	Invesco V.I. American Franchise Fund (Series II)	Guardian Large Cap Fundamental Growth VIP Fund.
8	MFS® Growth Series (Service Class)	Guardian Large Cap Fundamental Growth VIP Fund.

[9] 17 CFR 200.30–3(a)(12).

[1] Certain Contracts make or made available guaranteed living benefit riders (each, a ''Living Benefit Rider'' and collectively, the ''Living Benefit Riders''). The terms of certain Living Benefit Riders include investment restrictions that limit the available investment options to identified allocation models consisting of a specified selection of investment options. A Contract owner with a Living Benefit Rider that has investment restrictions may transfer Contract value by reallocating all of his Contract value to a different allocation model under the rider or, depending on the terms of the rider, by reallocating his Contract value within the parameters of the allocation model.

Substitution No.	Existing portfolio	Replacement portfolio
9	Oppenheimer Capital Appreciation Fund/VA (Service Shares)	Guardian Large Cap Fundamental Growth VIP Fund.
10	T. Rowe Price Blue Chip Growth Portfolio (Class II)	Guardian Large Cap Fundamental Growth VIP Fund.
11	Invesco V.I. Core Equity Fund (Series II)	Guardian Diversified Research VIP Fund.
12	MFS® Core Equity Portfolio (Service Class)	Guardian Diversified Research VIP Fund.
13	MFS® Investors Trust Series (Service Class)	Guardian Diversified Research VIP Fund.
14	Pioneer Fund VCT Portfolio (Class II)	Guardian Diversified Research VIP Fund.
15	MFS® Value Series (Service Class)	Guardian Large Cap Disciplined Value VIP Fund.
16	Pioneer Equity Income VCT Portfolio (Class II)	Guardian Large Cap Disciplined Value VIP Fund.
17	AB Value Portfolio (Class B)	Guardian Growth & Income VIP Fund.
18	Invesco V.I. Comstock Fund (Series II)	Guardian Growth & Income VIP Fund.
19	Invesco V.I. Growth and Income Fund (Series II)	Guardian Growth & Income VIP Fund.
20	Invesco V.I. International Growth Fund (Series II)	Guardian International Growth VIP Fund.
21	Oppenheimer International Growth Fund/VA (Service Shares).	Guardian International Growth VIP Fund.
22	Wells Fargo VT International Equity Fund (Class 2)	Guardian International Value VIP Fund.
23	Ivy VIP Mid Cap Growth	Guardian Mid Cap Traditional Growth VIP Fund.
24	American Century VP Mid Cap Value Fund (Class II)	Guardian Mid Cap Relative Value VIP Fund.
25	Invesco V.I. American Value Fund (Series II)	Guardian Mid Cap Relative Value VIP Fund.
26	Invesco V.I. Mid Cap Core Equity Fund (Series II)	Guardian Mid Cap Relative Value VIP Fund.
27	MFS® Total Return Bond Series (Service Class)	Guardian Core Plus Fixed Income VIP Fund.
28	PIMCO Total Return Portfolio (Advisor Class)	Guardian Core Plus Fixed Income VIP Fund.

6. The Replacement Portfolios are series of the Trust, a Delaware statutory trust registered as an open-end management investment company under the Act (File No. 811–23148) and whose shares are registered under the 1933 Act (File No. 333–210205). The Replacement Portfolios are currently available only as investment allocation options under variable insurance contracts issued by Guardian.

7. Park Avenue Institutional Advisers LLC (''Park Avenue''), an indirect wholly-owned subsidiary of Guardian Life, serves as the investment adviser of each Replacement Portfolio. Park Avenue is a Delaware limited liability company that is registered as an investment adviser under the Investment Advisers Act of 1940. Each Replacement Portfolio is sub-advised by a registered investment adviser that is unaffiliated with Applicants, the Trust, or Park Avenue.

8. Applicants state that the proposed Substitutions are part of a strategic business goal of Guardian to improve the administrative efficiency and cost-effectiveness of the Contracts, as well as to make the Contracts more attractive to Contract owners. Applicants note that the proposed Substitutions are intended to improve portfolio manager selection [2] and simplify fund lineups while reducing costs and maintaining a menu of investment options that would offer a similar diversity of investment options after the proposed Substitutions as is currently available under the Contracts. Applicants believe that the Replacement Portfolios have investment objectives, principal investment strategies, and principal risks, as described in their prospectuses, which are substantially similar to the corresponding Existing Portfolios, making those Replacement Portfolios appropriate candidates as substitutes. Information for each Existing Portfolio and Replacement Portfolio, including investment objectives, principal investment strategies, principal risks, and comparative performance history, can be found in the application.

9. Applicants state that for all the proposed Substitutions, the net annual operating expenses of the Replacement Portfolio will not exceed, on an annualized basis, the annual net operating expenses of any corresponding Existing Portfolio for the last fiscal year preceding the date of the application (the ''Expense Cap''). Applicants will cause Park Avenue, as the investment adviser of each Replacement Portfolio, to enter into a written contract with the Replacement Portfolio under which the net annual operating expenses of the Replacement Portfolio will not exceed the Expense Cap. The Expense Cap for each proposed Substitution will remain in place for a period of two years following the implementation of the proposed Substitution (the ''Substitution Date''), except that for those proposed Substitutions for which the sum of the current management fee and rule 12b–1 fees of the Replacement Portfolio is greater than that of the corresponding Existing Portfolio, the Expense Cap for that proposed Substitution will extend for the life of the affected Contracts following the Substitution Date. The Expense Cap applicable to Substitution No. 10 will also extend for the life of the affected Contracts following the Substitution Date. Any amounts waived or reimbursed by Park Avenue pursuant to any Expense Cap will not be subject to Park Avenue's recoupment rights.

10. Applicants represent that as of the Substitution Date, the Separate Accounts will redeem shares of the Existing Portfolios for cash. Redemption requests and purchase orders will be placed simultaneously so that Contract values will remain fully invested at all times.

11. Each Substitution will be effected at the relative net asset values of the respective shares of the Replacement Portfolios in conformity with section 22(c) of the Act and rule 22c–1 thereunder without the imposition of any transfer or similar charges by Applicants. The Substitutions will be effected without change in the amount

[2] The Trust and Park Avenue may rely on an order from the Commission that permits Park Avenue, subject to certain conditions, including approval of the Trust's board of directors but without the approval of shareholders, to select certain wholly-owned and non-affiliated investment sub-advisers to manage all or a portion of the assets of each portfolio of the Trust pursuant to an investment sub-advisory agreement with Park Avenue, and to materially amend sub-advisory agreements with Park Avenue. *See* Guardian Variable Products Trust and Park Avenue Institutional Advisers LLC, Investment Company Act Release Nos. 32420 (Jan. 9, 2017) (notice) and 32468 (Feb. 6, 2017) (the ''Manager of Managers Order''). After the Substitution Date (defined below), Park Avenue will not change a Replacement Portfolio's sub-adviser, add a new sub-adviser, or otherwise rely on the Manager of Managers Order or any replacement order from the Commission with respect to any Replacement Portfolio without first obtaining shareholder approval of the change in sub-adviser, the new sub-adviser, or the Replacement Portfolio's ability to rely on the Manager of Managers Order or any replacement order from the Commission, at a shareholder meeting, the record date for which will be after the proposed Substitution has been effected.

or value of any Contracts held by affected Contract owners.[3]

12. Contract owners will not incur any fees or charges as a result of the proposed Substitutions. The obligations of Applicants and the rights of the affected Contract owners, under the Contracts of affected Contract owners will not be altered in any way. Guardian and/or its affiliates (other than the Trust) will pay all expenses and transaction costs of the Substitutions, including legal and accounting expenses, any applicable brokerage expenses and other fees and expenses. No fees or charges will be assessed to the affected Contract owners to effect the Substitutions. The proposed Substitutions will not cause the Contract fees and charges currently being paid by Contract owners to be greater after the proposed Substitution than before the proposed Substitution. In addition, the Substitutions will in no way alter the tax treatment of affected Contract owners in connection with their Contracts, and no tax liability will arise for Contract owners as a result of the Substitutions.

13. From the date of the Pre-Substitution Notice (defined below) through 30 days following the Substitution Date, subject to the terms of certain Living Benefit Riders, Contract owners may make at least one transfer of Contract value from the subaccount investing in an Existing Portfolio (before the Substitution) or the Replacement Portfolio (after the Substitution) to any other available subaccount under the Contract without charge and without imposing any transfer limitations. Further, on the Substitution Date, Contract values attributable to investments in each Existing Portfolio will be transferred to the corresponding Replacement Portfolio without charge and without being subject to any transfer limitations. Moreover, except with respect to market timing policies and procedures and the terms of the Living Benefit Riders, Guardian will not exercise any rights reserved under the Contracts to impose restrictions on transfers between the subaccounts under the Contracts for a period beginning at least 30 days, including limitations on the future number of transfers, before the Substitution Date through at least 30 days following the Substitution Date.

14. At least 30 days prior to the Substitution Date, Contract owners will be notified via prospectus supplements that Applicants received or expect to receive Commission approval of the applicable proposed Substitutions and of the anticipated Substitution Date (the ''Pre-Substitution Notice''). Pre-Substitution Notices sent to Contract owners will be filed with the Commission pursuant to rule 497 under the 1933 Act. The Pre-Substitution Notice will advise Contract owners that from the date of the Pre-Substitution Notice through the date 30 days after the Substitutions, subject to the terms of certain Living Benefit Riders, Contract owners may make at least one transfer of Contract value from the subaccounts investing in the Existing Portfolios (before the Substitutions) or the Replacement Portfolios (after the Substitutions) to any other available subaccount without charge and without imposing any transfer limitations. Among other information, the Pre-Substitution Notice will inform affected Contract owners that, except with respect to market timing policies and procedures and limitations imposed by Living Benefit Riders, Guardian will not exercise any rights reserved under the Contracts to impose additional restrictions on transfers out of a Replacement Portfolio subaccount from the date of the Pre-Substitution Notice, including limitations on the future number of transfers, until at least 30 days after the Substitution Date. Additionally, all affected Contract owners will be sent prospectuses of the applicable Replacement Portfolios at least 30 days before the Substitution Date.

15. In addition to the Supplements distributed to the Contract owners, within five business days after the Substitution Date, Contract owners whose assets are allocated to a Replacement Portfolio as part of the proposed Substitutions will be sent a written notice (each, a ''Confirmation'') informing them that the Substitutions were carried out as previously notified. The Confirmation also will restate the information set forth in the Pre-Substitution Notice. The Confirmation will also reflect the values of the Contract owner's positions in the Existing Portfolio before the Substitution and the Replacement Portfolio after the Substitution.

Legal Analysis

1. Applicants request that the Commission issue an order pursuant to section 26(c) of the Act approving the proposed Substitutions. Section 26(c) prohibits any depositor or trustee of a unit investment trust that invests exclusively in the securities of a single issuer from substituting the securities of another issuer without the approval of the Commission. Section 26(c) provides that such approval shall be granted by order from the Commission if the evidence establishes that the substitution is consistent with the protection of investors and the purposes of the Act.

2. Applicants submit that the Substitutions meet the standards set forth in section 26(c) and that, if implemented, the Substitutions would not raise any of the concerns that Congress intended to address when the Act was amended to include this provision. Applicants state that each Substitution protects the Contract owners who have Contract value allocated to an Existing Portfolio by providing Replacement Portfolios with substantially similar investment objectives, strategies, and risks, and providing Contract owners with investment options that have net annual operating expenses that will not exceed the Expense Cap.

3. Guardian has reserved the right under the Contracts to substitute shares of another underlying fund for one of the current funds offered as an investment option under the Contracts. The Contracts and the Contracts' prospectuses disclose this right.

4. Applicants submit that the ultimate effect of the proposed Substitutions will be to streamline and simplify the investment line-ups that are available to Contract owners while reducing expenses and continuing to provide Contract owners with a wide array of investment options. Applicants state that the proposed Substitutions will not reduce in any manner the nature or quality of the available investment options and the proposed Substitutions also will permit Guardian to present information to its Contract owners in a simpler and more concise manner. Applicants also state it is anticipated that after the proposed Substitutions, Contract owners will be provided with disclosure documents that contain a simpler presentation of the available investment options under the Contracts. Applicants also assert that the proposed Substitutions are not of the type that section 26 was designed to prevent because they will not result in costly forced redemption, nor will they affect

[3] Applicants state that, because the Substitutions will occur at relative net asset value, and the fees and charges under the Contracts will not change as a result of the Substitutions, the benefits offered by the guarantees under the Contracts will be the same immediately before and after the Substitutions. Applicants also state that what effect the Substitutions may have on the value of the benefits offered by the Contract guarantees would depend, among other things, on the relative future performance of the Existing Portfolios and Replacement Portfolios, which Applicants cannot predict. Nevertheless, Applicants note that at the time of the Substitutions, the Contracts will offer a comparable variety of investment options with as broad a range of risk/return characteristics.

other aspects of the Contracts. In addition, the proposed Substitutions will not adversely affect any features or riders under the Contracts. Accordingly, no Contract owner will involuntarily lose his or her features or riders as a result of any proposed Substitution. Moreover, Applicants will offer Contract owners the opportunity to transfer amounts out of the affected subaccounts without any cost or other penalty (other than those necessary to implement policies and procedures designed to detect and deter disruptive transfers and other ''market timing'' activities and administer the terms of the Living Benefit Riders) that may otherwise have been imposed for a period beginning on the date of the Pre-Substitution Notice (which supplement will be delivered to the Contract owners at least 30 days before the Substitution Date) and ending no earlier than 30 days after the Substitution Date. The proposed Substitutions are also unlike the type of substitution that section 26(c) was designed to prevent in that the Substitutions have no impact on other aspects of the Contracts.

5. The proposed transactions will take place at relative net asset value in conformity with the requirements of section 22(c) of the Act and rule 22c–1 thereunder without the imposition of any transfer or similar charges by the Applicants. The Substitutions will be effected without change in the amount or value of any Contract held by the affected Contract owners. The Substitutions will in no way alter the tax treatment of affected Contract owners in connection with their Contracts, and no tax liability will arise for Contract owners as a result of the Substitutions. The fees and charges under the Contracts will not increase because of the Substitutions.

Applicants' Conditions

Applicants agree that any order granting the requested relief will be subject to the following conditions:

1. The Substitutions will not be effected unless Guardian determines that: (i) The Contracts allow the substitution of shares of registered open-end investment companies in the manner contemplated by the application; (ii) the Substitutions can be consummated as described in the application under applicable insurance laws; and (iii) any regulatory requirements in each jurisdiction where the Contracts are qualified for sale have been complied with to the extent necessary to complete the Substitutions.

2. After the Substitution Date, Park Avenue will not change a Replacement Portfolio's sub-adviser, add a new sub-adviser, or otherwise rely on the Manager of Managers Order or any replacement order from the Commission with respect to any Replacement Portfolio without first obtaining shareholder approval of the change in sub-adviser, the new sub-adviser, or the Replacement Portfolio's ability to rely on the Manager of Managers Order, or any replacement order from the Commission, at a shareholder meeting, the record date for which shall be after the proposed Substitution has been effected.

3. Guardian or an affiliate thereof (other than the Trust) will pay all expenses and transaction costs of the Substitutions, including legal and accounting expenses, any applicable brokerage expenses and other fees and expenses. No fees or charges will be assessed to the affected Contract owners to effect the Substitutions. The proposed Substitutions will not cause the Contract fees and charges currently being paid by Contract owners to be greater after the proposed Substitution than before the proposed Substitution.

4. The Substitutions will be effected at the relative net asset values of the respective shares of the Replacement Portfolios in conformity with section 22(c) of the Act and rule 22c–1 thereunder without the imposition of any transfer or similar charges by the Applicants. The Substitutions will be effected without change in the amount or value of any Contracts held by affected Contract owners.

5. The Substitutions will in no way alter the tax treatment of affected Contract owners in connection with their Contracts, and no tax liability will arise for Contract owners as a result of the Substitutions.

6. The obligations of the Applicants and the rights of the affected Contract owners, under the Contracts of affected Contract owners will not be altered in any way.

7. Affected Contract owners will be permitted to transfer Contract value from the subaccount investing in the Existing Portfolio (before the Substitution Date) or the Replacement Portfolio (after the Substitution Date) to any other available investment option under the Contract without charge for a period beginning at least 30 days before the Substitution Date through at least 30 days following the Substitution Date. Contract owners with Living Benefit Riders, as applicable, may transfer Contract value from the subaccounts investing in the Existing Portfolios (before the Substitutions) or the Replacement Portfolios (after the Substitutions) to any other available investment option available under their respective riders without charge and without imposing any transfer limitations. Except as described in any market timing/short-term trading provisions of the relevant prospectus, the Applicants will not exercise any rights reserved under the Contracts to impose restrictions on transfers between the subaccounts under the Contracts, transfers, including limitations on the future number of transfers, for a period beginning at least 30 days before the Substitution Date through at least 30 days following the Substitution Date.

8. All affected Contract owners will be notified via the Pre-Substitution Notice, at least 30 days before the Substitution Date, about: (i) The intended Substitution of Existing Portfolios with the Replacement Portfolios; (ii) the intended Substitution Date; and (iii) information with respect to transfers as set forth in Condition 7 above. In addition, the Applicants will also deliver to affected Contract owners, at least 30 days before the Substitution Date, a prospectus for each applicable Replacement Portfolio.

9. The Applicants will deliver to each affected Contract owner within five business days of the Substitution Date a written confirmation which will include: (i) A confirmation that the Substitutions were carried out as previously notified; (ii) a restatement of the information set forth in the Pre-Substitution Notice; and (iii) values of the Contract owner's positions in the Existing Portfolio before the Substitution and the Replacement Portfolio after the Substitution.

10. Guardian will cause Park Avenue, as the investment adviser of each Replacement Portfolio, to enter into a written contract with the Replacement Portfolio whereby the net annual operating expenses of the Replacement Portfolio will not exceed the Expense Cap. The Expense Cap for each proposed Substitution will remain in place for a period of two years following the Substitution Date. For those proposed Substitutions for which the sum of the current management fee and rule 12b–1 fees of the Replacement Portfolio is greater than that of the corresponding Existing Portfolio, the Expense Cap for that proposed Substitution will extend for the life of the affected Contracts following the Substitution Date. The Expense Cap applicable to Substitution No. 10 will also extend for the life of the affected Contracts following the Substitution Date.

For the Commission, by the Division of Investment Management, under delegated authority.

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–00626 Filed 1–16–18; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–82482; File No. SR–BatsBZX–2017–30]

Self-Regulatory Organizations; Bats BZX Exchange, Inc.; Notice of Withdrawal of a Proposed Rule Change To Permit the Listing and Trading of Managed Portfolio Shares and To List and Trade Shares of the Following Under Proposed Rule 14.11(k): ClearBridge Appreciation ETF, ClearBridge Large Cap ETF, ClearBridge MidCap Growth ETF, ClearBridge Select ETF, and ClearBridge All Cap Value ETF

January 10, 2018.

On June 1, 2017, Bats BZX Exchange, 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: (1) Adopt Rule 14.11(k) (Managed Portfolio Shares); and (2) list and trade shares of the ClearBridge Appreciation ETF, ClearBridge Large Cap ETF, ClearBridge MidCap Growth ETF, ClearBridge Select ETF, and ClearBridge All Cap Value ETF under proposed Rule 14.11(k). The proposed rule change was published for comment in the **Federal Register** on June 19, 2017.[3] On July 28, 2017, 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] The Commission received four comment letters on the proposed rule change.[6] On September 13, 2017, the Commission instituted proceedings under Section 19(b)(2)(B) of the Act [7] to determine whether to approve or disapprove the proposed rule change.[8] The Commission subsequently received one comment letter on the proposed rule change.[9] On December 12, 2017, the Commission designated a longer period for action on the proposed rule change.[10]

On January 10, 2018, the Exchange withdrew the proposed rule change (SR–BatsBZX–2017–30).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–00645 Filed 1–16–18; 8:45 am]

BILLING CODE 8011–01–P

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 80911 (June 13, 2017), 82 FR 27925.

[4] 15 U.S.C. 78s(b)(2).

[5] *See* Securities Exchange Act Release No. 81247, 82 FR 36031 (August 2, 2017). The Commission designated September 17, 2017 as the date by which the Commission shall approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change.

[6] *See* Letter from Gary L. Gastineau, President, ETF Consultants.com, Inc., to Brent J. Fields, Secretary, Commission, dated July 7, 2017; Letter from Todd J. Broms, Chief Executive Officer, Broms & Company LLC, to Brent J. Fields, Secretary, Commission, dated July 10, 2017; Letter from James J. Angel, Associate Professor of Finance, Georgetown University, McDonough School of Business, to the Commission, dated July 10, 2017; and Letter from Terence W. Norman, Founder, Blue Tractor Group, LLC, to Brent J. Fields, Secretary, Commission, dated August 1, 2017. The comment letters are available on the Commission's website at: *https://www.sec.gov/comments/sr-batsbzx-2017-30/batsbzx201730.htm.*

[7] 15 U.S.C. 78s(b)(2)(B).

[8] *See* Securities Exchange Act Release No. 81599, 82 FR 43621 (September 18, 2017).

[9] *See* Letter from Terence W. Norman, Founder, Blue Tractor Group, LLC, to Brent J. Fields, Secretary, Commission, dated December 5, 2017. The comment letter is available on the Commission's website at: *https://www.sec.gov/comments/sr-batsbzx-2017-30/batsbzx201730.htm.*

[10] *See* Securities Exchange Act Release No. 82301, 82 FR 60073 (December 18, 2017). The Commission designated February 14, 2018 as the date by which the Commission must either approve or disapprove the proposed rule change.

[11] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–82480; File No. SR–FINRA–2018–001]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Extend the Expiration Date of FINRA Rule 0180 (Application of Rules to Security-Based Swaps)

January 10, 2018.

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 4, 2018, Financial Industry Regulatory Authority, Inc. (''FINRA'') 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 FINRA. FINRA has designated the proposed rule change as constituting a ''non-controversial'' rule change under paragraph (f)(6) of Rule 19b–4 under the Act,[3] which renders the proposal effective upon receipt of this filing by the Commission. 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

FINRA is proposing to extend the expiration date of FINRA Rule 0180 (Application of Rules to Security-Based Swaps) to February 12, 2019. FINRA Rule 0180 temporarily limits, with certain exceptions, the application of FINRA rules with respect to security-based swaps.

The text of the proposed rule change is available on FINRA's website at *http://www.finra.org,* at the principal office of FINRA 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, FINRA 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. FINRA 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

On July 1, 2011, the SEC issued an Order granting temporary exemptive relief (the ''Temporary Exemptions'') from compliance with certain provisions of the Exchange Act in connection with the revision, pursuant to Title VII of the Dodd-Frank Wall Street Reform and Consumer Protection Act (the ''Dodd-Frank Act''),[4] of the Exchange Act definition of ''security'' to encompass security-based swaps.[5]

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 17 CFR 240.19b–4(f)(6).

[4] Public Law 111–203, 124 Stat. 1376 (2010).

[5] *See* Securities Exchange Act Release No. 64795 (July 1, 2011), 76 FR 39927 (July 7, 2011) (Order Granting Temporary Exemptions Under the Securities Exchange Act of 1934 in Connection With the Pending Revision of the Definition of ''Security'' To Encompass Security-Based Swaps,

Consistent with the Commission's action, on July 8, 2011, FINRA filed for immediate effectiveness FINRA Rule 0180,[6] which, with certain exceptions, is intended to temporarily limit the application of FINRA rules[7] with respect to security-based swaps, thereby helping to avoid undue market disruptions resulting from the change to the definition of ''security'' under the Act.[8]

The Commission, noting the need to avoid a potential unnecessary disruption to the security-based swap market in the absence of an extension of the Temporary Exemptions, and the need for additional time to consider the potential impact of the revision of the Exchange Act definition of ''security'' in light of ongoing Commission rulemaking efforts under Title VII of the Dodd-Frank Act, issued an Order which extended and refined the applicable expiration dates for the previously granted Temporary Exemptions.[9] The Commission previously noted that extending the Temporary Exemptions would facilitate a coordinated consideration of these issues with the relief provided pursuant to FINRA Rule 0180.[10] In establishing Rule 0180, and in extending the rule's expiration date, FINRA noted its intent, pending the implementation of any SEC rules and guidance that would provide greater regulatory clarity in relation to security-based swap activities, to align the expiration date of FINRA Rule 0180 with the termination of relevant provisions of the Temporary Exemptions.[11]

The Commission's rulemaking and development of guidance in relation to security-based swap activities is ongoing. As such, FINRA believes it is appropriate and in the public interest, in light of the Commission's goals as set forth in the Exemptive Release, the 2014 Extension Release and the 2017 Extension Release, to extend FINRA Rule 0180 for a limited period, to February 12, 2019, so as to avoid undue market disruptions resulting from the change to the definition of ''security'' under the Act.[12]

FINRA has filed the proposed rule change for immediate effectiveness. FINRA is proposing that the implementation date of the proposed rule change will be February 12, 2018.

2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act,[13] which requires, among other things, that FINRA rules must be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest. FINRA believes that the proposed rule change would further the purposes of the Act because, consistent with the goals set forth by the Commission in the Exemptive Release, the 2014 Extension Release and the 2017 Extension Release, the proposed rule change will help to avoid undue market disruption that could result if FINRA Rule 0180 expires before the implementation of any SEC rules and guidance that would provide greater regulatory clarity in relation to security-based swap activities.

B. Self-Regulatory Organization's Statement on Burden on Competition

FINRA does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. FINRA believes that the proposed rule change would prevent undue market disruption that would otherwise result if security-based swaps were, by virtue of the expansion of the Act's definition of ''security'' to encompass security-based swaps, subject to the application of all FINRA rules before the implementation of any SEC rules and guidance that would provide greater regulatory clarity in relation to security-based swap activities. FINRA believes that, by extending the expiration of FINRA Rule 0180, the proposed rule change will serve to promote regulatory clarity and consistency, thereby reducing burdens on the marketplace and facilitating investor protection.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public

and Request for Comment) (the ''Exemptive Release''). The term ''security-based swap'' is defined in Section 761 of the Dodd-Frank Act. *See also* Securities Exchange Act Release No. 67453 (July 18, 2012), 77 FR 48207 (August 13, 2012) (Further Definition of ''Swap,'' ''Security-Based Swap,'' and ''Security-Based Swap Agreement''; Mixed Swaps; Security-Based Swap Agreement Recordkeeping).

[6] *See* Securities Exchange Act Release No. 64884 (July 14, 2011), 76 FR 42755 (July 19, 2011) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change; File No. SR–FINRA–2011–033) (''FINRA Rule 0180 Notice of Filing''). *See also* Securities Exchange Act Release No. 79752 (January 6, 2017), 82 FR 3824 (January 12, 2017) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change; File No. SR–FINRA–2017–001) (extending the expiration date of FINRA Rule 0180 to February 12, 2018).

[7] The current FINRA rulebook consists of: (1) FINRA Rules; (2) NASD Rules; and (3) rules incorporated from NYSE (''Incorporated NYSE Rules''). While the NASD Rules generally apply to all FINRA members, the Incorporated NYSE Rules apply only to those members of FINRA that are also members of the NYSE. The FINRA Rules apply to all FINRA members, unless such rules have a more limited application by their terms. For more information about the rulebook consolidation process, *see Information Notice,* March 12, 2008 (Rulebook Consolidation Process).

[8] In its Exemptive Release, the Commission noted that the relief is targeted and does not include, for instance, relief from the Act's antifraud and anti-manipulation provisions. FINRA has noted that FINRA Rule 0180 is similarly targeted. For instance, paragraph (a) of FINRA Rule 0180 provides that FINRA rules shall not apply to members' activities and positions with respect to security-based swaps, except for FINRA Rules 2010 (Standards of Commercial Honor and Principles of Trade), 2020 (Use of Manipulative, Deceptive or Other Fraudulent Devices), 3310 (Anti-Money Laundering Compliance Program) and 4240 (Margin Requirements for Credit Default Swaps). *See also* paragraphs (b) and (c) of FINRA Rule 0180 (addressing the applicability of additional rules) and FINRA Rule 0180 Notice of Filing.

[9] *See* Securities Exchange Act Release No. 71485 (February 5, 2014), 79 FR 7731 (February 10, 2014) (Order Extending Temporary Exemptions Under the Securities Exchange Act of 1934 in Connection With the Revision of the Definition of ''Security'' to Encompass Security-Based Swaps, and Request for Comment) (''2014 Extension Release'') stating that, for those expiring Temporary Exemptions ''that are not directly linked to pending security-based swap rulemakings, the Commission is extending the expiration date until the earlier of such time as the Commission issues an order or rule determining whether any continuing exemptive relief is appropriate for security-based swap activities with respect to any of these Exchange Act provisions or until three years following the effective date of this Order.'' The 2014 Extension Release further stated that for each expiring Temporary Exemption ''that is related to pending security-based swap rulemakings, the Commission is extending the expiration date until the compliance date for the related security-based swap-specific rulemaking.'' On January 18, 2017, the Commission further extended the Temporary Exemptions that are not directly linked to a security-based swap rulemaking, which otherwise would have expired on February 5, 2017, three years from the effective date of the 2014 Extension Release. *See* Securities Exchange Act Release No. 79833 (January 18, 2017), 82 FR 8467 (January 25, 2017) (Order Extending Certain Temporary Exemptions Under the Securities Exchange Act of 1934 in Connection With the Revision of the Definition of ''Security'' to Encompass Security-Based Swaps and Request for Comment) (''2017 Extension Release'').

[10] *See* Securities Exchange Act Release No. 68864 (February 7, 2013), 78 FR 10218 (February 13, 2013) (Order Extending Temporary Exemptions Under the Securities Exchange Act of 1934 in Connection With the Revision of the Definition of ''Security'' to Encompass Security-Based Swaps, and Request for Comment).

[11] *See* note 6 *supra.*

[12] FINRA may amend the expiration date of FINRA Rule 0180 based on any related Commission action.

[13] 15 U.S.C. 78*o*–3(b)(6).

interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act [14] and Rule 19b–4(f)(6) thereunder.[15]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. 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–FINRA–2018–001 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–FINRA–2018–001. 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 website (*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 website 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 such filing also will be available for inspection and copying at the principal office of FINRA. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–FINRA–2018–001 and should be submitted on or before February 7, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Eduardo Aleman,

Assistant Secretary.

[FR Doc. 2018–00635 Filed 1–16–18; 8:45 am]

BILLING CODE 8011–01–P

[14] 15 U.S.C. 78s(b)(3)(A).

[15] 17 CFR 240.19b–4(f)(6).

[16] 17 CFR 200.30–3(a)(12).

DEPARTMENT OF STATE

[Public Notice 10268]

Notice of Change of Ownership of Permit Holder of Presidential Permit for Express Pipeline Facilities on the Border of the United States and Canada

AGENCY: Department of State.

ACTION: Notice.

SUMMARY: Notice is hereby given of a change in ownership of Express Pipeline LLC (''Express US''), which owns, operates, and maintains pipeline facilities (''Express Pipeline'') authorized under a Presidential permit issued on July 9, 2015 (80 FR 45695).

SUPPLEMENTARY INFORMATION: On May 25, 2017, the Department published a **Federal Register** Notice providing notice of its receipt of a notification from the current permit holder regarding this change in ownership (82 FR 24200). Consistent with the procedures set forth in Public Notice 10111 (82 FR 42410, Sept. 7, 2017), the Department has reviewed that notification and has determined that the change in ownership does not affect the prior national interest determination that resulted in issuance of the Presidential permit issued to Express US on July 9, 2015. That permit, therefore, remains valid, subject to its terms and conditions. Additional information concerning the Express Pipeline is available at *https://www.state.gov/e/enr/applicant/.*

FOR FURTHER INFORMATION CONTACT: Marcus Lee, Presidential Permit Coordinator, Energy Resources Bureau, Office of Policy Analysis and Public Diplomacy, United States Department of State, 2201 C St. NW, Suite 4422, Washington, DC 20520. Tel: 202–485–1522.

Richard W. Westerdale II,

Senior Advisor, Bureau of Energy Resources, Department of State.

[FR Doc. 2018–00648 Filed 1–16–18; 8:45 am]

BILLING CODE 4710–AE–P

DEPARTMENT OF STATE

[Public Notice 10269]

Notice of Determinations; Culturally Significant Objects Imported for Exhibition Determinations: ''Adrian Piper: A Synthesis of Intuitions 1965–2016'' Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that certain objects to be included in the exhibition ''Adrian Piper: A Synthesis of Intuitions 1965–2016,'' imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at The Museum of Modern Art, New York, New York, from on or about March 31, 2018, until on or about July 22, 2018, at the Hammer Museum, Los Angeles, California, from on or about September 30, 2018, until on or about January 6, 2019, and at possible additional exhibitions or venues yet to be determined, is in the national interest.

FOR FURTHER INFORMATION CONTACT: Elliot Chiu in the Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, SA–5, Suite 5H03, Washington, DC 20522–0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), E.O. 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28,

2000 (and, as appropriate, Delegation of Authority No. 257–1 of December 11, 2015). I have ordered that Public Notice of these determinations be published in the **Federal Register.**

Alyson Grunder,

Deputy Assistant Secretary for Policy, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2018–00644 Filed 1–16–18; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice 10271]

Biennial Review Under the United States-Singapore Memorandum of Intent on Environmental Cooperation

ACTION: Notice of a biennial review under the United States-Singapore Memorandum of Intent on Environmental Cooperation, and request for comments.

SUMMARY: The U.S. Department of State is providing notice that the United States and Singapore intend to hold a biennial review under the Memorandum of Intent between the United States of America and the Republic of Singapore on Cooperation in Environmental Matters (MOI) on January 19, 2018. The purpose of the meeting is to review the results of environmental cooperation under the MOI guided by the 2016–2017 Plan of Action (POA). The United States and Singapore also expect to approve a new 2018–2019 POA.

The meeting's public session will be held on January 19, 2018, at 5:00 p.m., at the Ministry of the Environment and Water Resources, 40 Scotts Road, #24–00, Level 23, Environment Building, Singapore 228231, Tel: (65) 6731 9000. The U.S. Department of State invites interested organizations and members of the public to attend the public session, and to submit in advance written comments or suggestions regarding implementation of the POA, and any issues that should be discussed at the meeting. If you would like to attend the public session, please notify Tiffany Prather at the email address listed below under the heading **ADDRESSES**. Please include your full name and any organization or group you represent. In preparing comments, submitters are encouraged to refer to:

- 2016–2017 POA, *https://www.state.gov/e/oes/eqt/trade/singapore/246192.htm*

Other useful documents are available at: *https://www.state.gov/e/oes/eqt/trade/singapore/index.htm.*

DATES: The public session for the Biennial Review under the MOI will be held on January 19, 2018, at 5:00 p.m., at the Ministry of the Environment and Water Resources, 40 Scotts Road, #24–00, Level 23, Environment Building, Singapore 228231, Tel: (65) 6731 9000. Written comments and suggestions should be submitted no later than noon on January 18, 2018 to facilitate consideration.

ADDRESSES: Written comments and suggestions should be submitted to: Tiffany Prather, Office of Environmental Quality and Transboundary Issues, U.S. Department of State, by electronic mail at *PratherTA@state.gov* with the subject line ''United States-Singapore Biennial Review.''

FOR FURTHER INFORMATION CONTACT: Tiffany Prather, Telephone (202) 647–4548 or email *PratherTA@state.gov.*

SUPPLEMENTARY INFORMATION: The MOI was signed on June 13, 2003. Section 3 of the MOI calls for biennial meetings to review the status of environmental cooperation and update the POA, as appropriate.

Robert Wing,

Acting Director, Office of Environmental Quality and Transboundary Issues, Department of State.

[FR Doc. 2018–00700 Filed 1–16–18; 8:45 am]

BILLING CODE 4710–09–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

[Docket Number: DOT–OST–2017–0179]

Agency Request for Renewal of a Previously Approved Information Collection: Office of Small and Disadvantaged Business Utilization (OSDBU) Mentor Protégé Program

ACTION: Notice and request for comments.

SUMMARY: The Department of Transportation (DOT) invites public comments about our intention to request the Office of Management and Budget (OMB) approval for an information collection. The collection involves two reports in which DOT will use the data to measure program achievement to determine whether the intention of the program to assist small businesses getting the developmental tools required to compete and perform in DOT and federal procurement programs is achieved. In addition, DOT is seeking comments on form OST F 5020.1 (2–12), which we have updated with two additional questions about number of employees and amount of federal contracts.

DATES: Written comments should be submitted by on or before March 19, 2018.

ADDRESSES: You may submit comments, identified by Docket No. DOT–OST–2017–0179, through one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 1 (202) 493–2251.
- *Mail or Hand Delivery:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

FOR FURTHER INFORMATION CONTACT: Leonardo San Román, Mentor Protégé Program, U.S. Department of Transportation, Office of Small and Disadvantaged Business Utilization, 1200 New Jersey Avenue SE, Washington, DC 20590, (202) 366–1930.

SUPPLEMENTARY INFORMATION:

Title: U.S. DOT Mentor Protégé program.

OMB Control Number: 2105–0570

Forms: Mentor Protégé program annual report; and Mentor Protégé program evaluation form.

Type of Review: Renewal.

Affected Public: Prime contractors and small businesses participating in DOT's Mentor Protégé Program.

Respondents: Approximately 25.

Frequency: One-time.

Estimated Average Burden per Response: 1 hour.

Estimated Total Annual Burden Hours: 25 hours.

The U.S. Department of Transportation (DOT) administers a Mentor-Protégé program that encourages agreements between large and small business prime contractors and eligible small business protégés.

A small business concern includes small disadvantaged businesses, 8(a) firms, women owned businesses, HUBZone small businesses, veteran-owned-businesses and service disabled veteran-owned small businesses. The program is also designed to improve the performance of DOT contractors and subcontractors, foster the establishment of long-term business relationships between small businesses and prime contractors, and increase the overall number of small businesses that receive DOT contract and subcontract awards.

Purpose

Mentor Protégé program participants must submit an annual report to

document the developmental assistance and achievements. All responses to this collection of information are required to support the type of development assistance provided to the protégé from the mentor, per their Mentor-Protégé agreement. Also, program participants must submit a Mentor Protégé program evaluation form at the end of the agreement. Program participants will provide feedback and recommendations to DOT on program satisfaction. This form is a single consolidated document that is easy to read and understand for all program participants, including small businesses.

In accordance with Public Law 95–507, an amendment to the Small Business Act and the Small Business Investment Act of 1953, OSDBU is responsible for the implementation and execution of the U. S. Department of Transportation (DOT) activities on behalf of small businesses, in accordance with Section 8, 15 and 31 of the Small Business Act (SBA), as amended. The Office of Small and Disadvantaged Business Utilization also administers the provisions of Title 49, of the United States Code, Section 332, the Minority Resource Center (MRC) which includes the design and carry out programs to encourage, promote, and assist minority entrepreneurs and businesses in getting contracts, subcontracts, and projects related to those business opportunities.

The Department of Transportation (DOT) administers a Mentor Protégé Program to assist small business concerns enhance their capacity to compete for federal contracts. This program designed to motivate and encourage large business and prime contractor firms to provide mutually beneficial developmental assistance to small businesses.

DOT's Mentor-Protégé Program enhances the capability of minority and small business owners to compete more successfully for federal procurement opportunities. The program encourages private-sector relationships and expands DOT's efforts to identify and respond to the developmental needs of small and minority owned businesses.

The term small business includes small disadvantaged businesses, women owned businesses, HUBZone small businesses, veteran-owned-businesses and service disabled veteran-owned small businesses. The program is also designed to improve the performance of DOT contractors and subcontractors, foster the establishment of long-term business relationships between small businesses and prime contractors, and increase the overall number of small businesses that receive DOT contract and subcontract awards.

General Policy

1. Eligible business prime contractors (not under a suspension or debarment action and not in the Excluded Parties List System (ELPS) database) approved as mentor firms may enter into agreements with eligible protégés. Mentors provide appropriate developmental assistance to enhance the capabilities of protégés to perform as contractors and/or subcontractors.

2. Eligible small business prime contractors (not under a suspension or debarment action and not in the ELPS database) capable of providing developmental assistance may act as mentors.

3. Protégés may participate in the program in pursuit of a prime contract or as subcontractors under the mentor's prime contract with the Department of Transportation.

4. Mentors and Protégés are solely responsible for finding their counterpart. Therefore, we strongly encourage firms to explore existing business relationships to establish a Mentor-Protégé relationship.

5. Mentor-Protégé agreements should be for up to 36 months.

6. NON-AFFILIATION—a protégé will not be considered an affiliate of a mentor solely on the basis that the protégé has or will receive developmental assistance from the mentor under this program. For more information concerning size standards and affiliation, refer to FAR 19.101.

Incentives for Mentors

There are no costs involved for a firm to participate in DOT's Mentor-Protégé Program. DOT does not provide direct reimbursement to the mentors.

Measurement of Program Success

The overall success of the Mentor-Protégé Program will be measured by the extent to which it results in:

a. An increase in the quality of the technical capabilities of the protégé firms.

b. An increase in the number, dollar value and percentage of contracts or subcontracts awarded to protégés since the date of entry into the program.

c. An increase in the number of full time employees since the date of entry into the program.

Annual reports should be submitted by the mentor and protégé firms to the OSDBU on program progress. Only one report per agreement will be submitted for review. The OSDBU will evaluate these reports by considering the following:

1. Detailed actions taken by the mentor, to increase the participation of protégé as seller to the Federal Government;

2. Detailed actions taken by the mentor, to develop the technical capabilities of a protégé as defined in the agreement;

3. The degree to which the protégé has met the developmental objectives in the agreement;

4. The degree to which the mentor firm's participation in the Mentor-Protégé Program resulted in the protégé receiving contract(s) and subcontract(s) from private firms, DOT or any other federal agency.

5. In addition to the annual report, mentor and protégé firms should submit an evaluation to the OSDBU after the mutually agreed upon program period, or the voluntary withdrawal by either party from the program, whichever comes first.

Mentor Firms

Eligibility. The mentor can be a business that has graduated from the 8(a) Business Development program, a firm in the transitional stage of the program, or a small or large business. In addition, the mentor must be able to show that it is currently eligible for Federal contracting opportunities, is not under a suspension or debarment action, and is not in the ELPS database. Mentors may have multiple protégés. Mentors participating in Mentor-Protégé programs from other Federal agencies should keep a record system to prepare separate reports of mentoring activities for each agency's program.

Protégé Firms

(1) Eligibility. A protégé should be:

(a) A Small Business (SB), HUBZone, Small Disadvantaged Business (SDB), Women Owned Small Business, Veteran Owned Small Business, or Service Disabled Veteran Owned Small Business

(b) Able to show that it is currently eligible for Federal contracting opportunities, is not under a suspension or debarment action, and is not in the Excluded Parties List System (ELPS) database.

(2) Protégés may have multiple mentors. Protégés participating in mentor-protégé programs in addition to the DOT program should maintain a system for preparing separate reports of mentoring activity for each agency's program.

Selection of Mentor or Protégé Firms

Mentor and protégé firms are responsible for selecting their counterpart. The mentor is encouraged

to select from a broad base of Small Businesses including SB, SDB, WOSB, VOSB, SDVOSB, and HUBZone firms whose core competencies support the Department of Transportation's missions.

Mentor-Protege Agreement Process

Firms interested in becoming a mentor firm should submit copy of a signed mentor-protégé application for each mentor-protégé relationship DOT OSDBU for approval. This will provide OSDBU the opportunity to evaluate the nature and extent of technical and managerial support, and traditional subcontracting support involved in the mentor-protégé relationship, enabling OSDBU to provide advice and assistance to the parties.

The Mentor Protégé agreement should contain:

(1) Name, address, phone, and email of mentor and protégé firm(s) and a point of contact within both firms who will oversee the agreement;

(2) A description of the type of developmental program that will be provided by the mentor firm to the protégé firm, including a schedule for providing assistance, and criteria for evaluation of the protégé's developmental success;

(3) Program participation term not to exceed 36 months;

(4) A clause or statement of the protégé's intent and agreement to report its progress to the OSDBU annually for two (2) years after exiting the program;

(5) Other terms and conditions, as appropriate;

(6) Procedures for the mentor's voluntary withdrawal from the program including notification of the protégé firm and the OSDBU. The Mentor should provide at least 30 days' written notice to OSDBU before withdrawing from the program.

(7) OSDBU will review a Mentor Protégé agreement no later than 30 days after receipt.

(8) Following OSDBU review, the mentor may implement the developmental assistance program.

OSDBU Review of Mentor-Protégé Agreement

(1) The agreement defines the relationship between the mentor and protégé firms only. The agreement itself does not create any privity of contract between the mentor or protégé and DOT.

(2) OSDBU will review the information to ensure the mentor and protégé are both eligible for the program and provide appropriate advice and assistance to the firms concerning the agreement and its implementation.

(3) OSDBU will notify the parties if changes in the agreement are advisable in order to make the agreement meet the objectives of the mentor-protégé program. The mentor and protégé should incorporate OSDBU recommendations before implementing the agreement.

(4) Upon completion of the review, the mentor may implement the developmental assistance program.

Developmental Assistance

The forms of developmental assistance a mentor can provide to a protégé include:

- Management, financial and/or technical assistance
- Overall business management/planning
- Cooperation on joint venture projects
- Rent-free use of facilities and/or equipment
- Temporary assignment of personnel to protégé for the purpose of training
- Any other types of mutually beneficial assistance

Internal Controls

1. The OSDBU will oversee the program to achieve program objectives.

2. OSDBU will review and evaluate mentor-protégé agreements for practicality, and accuracy of provided information.

3. OSDBU can perform site visits where Mentor-Protégé activity is performed.

4. OSDBU will review annual reports to measure protégé progress against the established developmental assistance included in the approved agreement.

5. If OSDBU determines that the objectives of the agreement are not met, OSDBU may conclude the existing Mentor-Protégé agreements if it determines that such actions are in the best interest of the agency. The OSDBU will communicate this decision in writing, and will be sent to the mentor and protégé after approval by the Director, OSDBU or representative.

For additional information related to the Mentor Protégé program, visit OSDBU's website at *www.transportation.gov/osdbu.*

Issued in Washington, DC, on January 9, 2018.

Willis Morris,

Director, Office of Small and Disadvantaged Business Utilization.

BILLING CODE 4910–9X–P

U.S. Department of Transportation
Mentor Protégé Program Evaluation

OMB Control Number: 2105-0570
xpiration Date: 02/28/2018

Public Burden Statement

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2105-0570. Public reporting for this collection of information is estimated to be approximately 30 minutes per response, including the time for reviewing instructions, gathering the data needed, and completing and reviewing the collection of information. All responses to this collection of information are mandatory. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Information Collection Clearance Officer, U.S. Department of Transportation, Office of the Secretary, Office of Small and Disadvantaged Business Utilization (OSDBU) Room W56-444, 1200 New Jersey Ave, SE, Washington, D.C. 20590.

PART A – MENTOR INFORMATION

1. Business Name	**2. Business Mailing Address (Do not include P.O Box)**
3. Business Physical Address	**4. Phone Number:**
5. Point of Contact:	**6. Email address:**

PART B – PROTEGE INFORMATION

7. Protégé Name	**8. Business Mailing Address (Do not include P.O. Box)**
9. Business Physical Address	**10. Phone Number:**
11. Point of Contact	**12. Email Address:**

PART C: PERIOD OF PERFORMANCE

13. Agreement Period of Performance

Start Date: **End Date:**

PART D – INSTRUCTIONS

Please complete this form at the end of the Mentor-Protégé agreement and submit to the Director of the U.S. Department of Transportation, Office of the Secretary, Office of Small and Disadvantaged Business Utilization by fax at (202) 366-7228 or email at mentorprotege@dot.gov . Please base your ratings on the criteria listed below:

5 - Exceptional	**4 – Very Good**	**3 – Satisfactory**	**2 - Fair**	**1 - Unsatisfactory**
Consistently exceeds in achieving goals and objectives far above the established standards	Generally exceeds the established performance standards	Meets the established performance standards	Meets some, but not all, of the established performance standards	Generally fails to meet the established performance standards

U.S. Department of Transportation
Mentor Protégé Program Evaluation
Program Participant Evaluation

OMB Control Number: 2105-0570
Expiration Date: 02/28/2018

PART E – EVALUATION

14. Evaluation

a. Performance Elements:	1	2	3	4	5	N/A	Comments
Procurement Program Knowledge: Mentor staff knowledge of the federal procurement process met protégé's expectations.	☐	☐	☐	☐	☐	☐	
Developmental Work: Development assistance provided to the Protégé was adequate, as agreed upon in the Mentor-Protégé agreement.	☐	☐	☐	☐	☐	☐	
Competences: The protégé's staff knowledge of DOT and federal procurement process increased from the time the firm entered the Mentor-Protégé agreement.	☐	☐	☐	☐	☐	☐	
Business Acumen: Protégé staff acquired techniques to improve contract performance increasing protégé's ability to compete and perform on DOT and/or federal contracts.	☐	☐	☐	☐	☐	☐	
Subcontracting programs: Protégé staff demonstrates understanding and knowledge of DOT subcontracting programs.	☐	☐	☐	☐	☐	☐	
Mentor/Protégé selection: The process to select the mentor or the protégé is adequate.	☐	☐	☐	☐	☐	☐	
Agency Role: DOT participation in the program is adequate.	☐	☐	☐	☐	☐	☐	
Overall Performance: Mentor Protégé program provides the ability to enhance small business participation in DOT Procurement programs.	☐	☐	☐	☐	☐	☐	

b. Was the developmental assistance provided to the protégé useful to enhance its core capabilities?

c. How would you improve DOT's Mentor-Protégé program?

d. What other factors, relevant to the developmental assistance, would you like to comment upon?

e. Has the protégé been able to compete in federal procurement opportunities since the Mentor-Protégé agreement was signed?

f. Other Comments:

g. Would the mentor or the protégé be willing to participate in the program again in the future? ☐ Yes ☐ No

PART F – REVIEWER'S SIGNATURE
15. Reviewer's Signature:
Signature: _____ Date: _____
Print Name: _____ Title: _____

General Instructions

Purpose of Form

Use form Mentor Protégé Program Evaluation form, OMB Control Number 21xx-0570, to evaluate the performance of businesses that have entered and finished into a Mentor Protégé agreement in DOT's Mentor-Protégé program.

How do I Obtain More Information?

You can contact the U.S. Department of Transportation, Office of the Secretary, Office of Small and Disadvantaged Business Utilization for further information:

Email. mentorprotege@dot.gov .

Voice. 1-800-532-1169 or 202-366-1930. A long-distance charge to callers located outside of the local calling area will apply when calling the 202-366-1930 number.

For direct assistance, please contact the Field Office that serves your state. A complete list of field offices, the states that each region serves, and their contact information is located at https://www.transportation.gov/osdbu/SBTRCs.

How to submit the evaluation

You can submit the Mentor Protégé program evaluation to the Director of the U.S. Department of Transportation, Office of the Secretary, Office of Small and Disadvantaged Utilization by email or by fax. Use only one method per evaluation. Evaluations must be **received** within thirty (30) days from the Mentor-Protégé agreement end date.

Email. Scan your signed evaluation to a pdf document and email to mentorprotege@dot.gov.

Fax. Fax your signed evaluation to (202) 366-7228.

Specific Instructions

Print or type all entries on the Mentor Protégé Program evaluation, OMB Control Number 2105-0570. The evaluation form is an electronically fillable form. We strongly suggest evaluators utilize the electronically fillable form to complete the evaluation entries. Follow the instructions for each line to expedite processing and to avoid unnecessary requests for additional information.

Line 1. Mentor Name. Enter the business name of the mentor.
Line 2. Business Mailing Address. Enter the mailing address of the mentor's primary physical location. Do not enter a P.O. Box here.

Line 3. Business Physical Address Enter the physical address of the mentor's primary physical location.
Line 4. Phone Number: Enter the mentor's primary phone number.

Line 5. Mentor Point of Contact. Enter the name of the mentor's primary point of contact for the Mentor-Protégé program.
Line 6. Email Address. Enter the email address of the mentor's primary point of contact.
Line 7. Protégé Name. Enter the business name of the protégé.
Line 8. Business Mailing Address. Enter the mailing address of the protégé's primary physical location. Do not enter a P.O. Box here.
Line 9 Business Physical Address Enter the physical address of the protégé's primary physical location.
Line 10. Phone Number: Enter the mentor's primary phone number.
Line 11. Protégé Point of Contact. Enter the name of the mentor's primary point of contact for the Mentor-Protégé program.
Line 12. Email Address. Enter the email address of the mentor's primary point of contact.
Line 13. Period of Performance. Enter the period of Performance for the report.
Line 14a. Performance Elements. Rate the program performance and enter comments for each performance element. Rate each element on the following scale:

5 - Exceptional Consistently exceeds in achieving goals and objectives far above the established standards	**N/A** Not applicable. Performance element does not apply to the type of developmental assistance
3 – Satisfactory Meets the established performance standards	**4 – Very Good** Generally exceeds the established performance standards
1 - Unsatisfactory Generally fails to meet the established performance standards	**2 - Fair** Meets some, but not all, of the established performance standards

Line 14b. Was the developmental assistance provided to the protégé useful to enhance its core capabilities? Given the specific developmental assistance provided to Protégé, describe the intern's strengths as a potential professional.
Line 14c. How would you improve DOT's Mentor-Protégé program? Describe how you would enhance DOT's Mentor Protégé program.

Line 14d. What other factors, relevant to the developmental assistance, would you like to comment upon? Describe additional performance factors, if any, that the evaluator would like to comment upon.
Line 14e. Has the protégé been able to compete in federal procurement opportunities since the Mentor-Protégé agreement was signed? Describe whether the protégé has been able to compete on federal procurement opportunities.
Line 14f. Other Comments. Enter other general comments related to the Mentor Protégé program, if any.
Line 14g. Would the mentor or the protégé be willing to participate in the program again in the future? Check "Yes" or "No" to indicate the companies' willingness to participate on the Mentor Protégé program in the future.
Line 15. Reviewer's Signature. Sign and date the application. This section is for official use only.

U.S. Department of Transportation
Mentor Protégé Program
Participant Annual Report

OMB Control Number: 2105-0570
Expiration Date: 02/28/2018
Form 0ST OST F 5020.1 (2-12)

Public Burden Statement

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2105-0570. Public reporting for this collection of information is estimated to be approximately 30 minutes per response, including the time for reviewing instructions, gathering the data needed, and completing and reviewing the collection of information. All responses to this collection of information are mandatory. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Information Collection Clearance Officer, U.S. Department of Transportation, Office of the Chief Information Officer, 1200 New Jersey Avenue, S.E. Rm. W56-312 . Washington, D.C. 20590.

PART D: DEVELOPMENTAL ASSISTANCE

	14 Developmental Task	15 Performed By
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		

16. Business Capabilities Enhanced

17. Certifications

18. Technology Transferred

19. Number of Employees (Protégé)

Beginning of Reporting Period	End of Reporting Period

20. Amount of Federal Contracts Received During The Reporting Period (Protégé)

Prime	Subcontractor

21. Mentor Signature:

Print Name: _____

Title: _____

22. Protégé Signature:

Print Name: _____

Title: _____

Signature: _____ Date: _____	Signature: _____ Date: _____
23. Reviewer's Signature: Signature: _____ Date: _____ Print Name: _____ Title: _____	

General Instructions

Purpose of Form

Use the Mentor Protégé Annual Report form, OMB Control Number 2105-0570, to evaluate the performance of businesses that have entered and finished into a Mentor Protégé agreement in DOT's Mentor-Protégé program.

How do I Obtain More Information?

You can contact the U.S. Department of Transportation, Office of the Secretary, Office of Small and Disadvantaged Business Utilization for further information:

Email. mentorprotege@dot.gov .

Voice. 1-800-532-1169 or 202-366-1930. A long-distance charge to callers located outside of the local calling area will apply when calling the 202-366-1930 number.

For direct assistance, please contact the OSDBU Field Office that serves your state. A complete list of Field Offices, the states that each region serves, and their contact information is located at https://www.transportation.gov/osdbu/SBTRCs

How to submit the Annual Report

You can submit the Mentor Protégé Annual Report to the Director of the U.S. Department of Transportation, Office of the Secretary, Office of Small and Disadvantaged Utilization by email or by fax. Use only one method per submission. Reports must be **received** within thirty (30) days from the Mentor-Protégé agreement end of year and thirty (30) days from the Mentor Protégé end date.

Email. Scan your signed annual report to a pdf document and email to mentorprotege@dot.gov.

Fax. Fax your signed report to (202) 366-7228.

Specific Instructions

Print or type all entries on the Mentor-Protégé Annual Report, OMB Control Number 2105-0570. The report is an electronically fillable form. We strongly suggest evaluators utilize the electronically fillable form to complete the report. Follow the instructions for each line to expedite processing and to avoid unnecessary requests for additional information.

Line 1. Mentor Name. Enter the business name of the mentor.
Line 2. Business Mailing Address. Enter the mailing address of the mentor's primary physical location. Do not enter a P.O. Box here.
Line 3. Business Physical Address Enter the physical address of the mentor's primary physical location.

Line 4. Phone Number: Enter the mentor's primary phone number.

Line 5. Mentor Point of Contact. Enter the name of the mentor's primary point of contact for the Mentor-Protégé program.
Line 6. Email Address. Enter the email address of the mentor's primary point of contact.
Line 7. Protégé Name. Enter the business name of the protégé.
Line 8. Business Mailing Address. Enter the mailing address of the protégé's primary physical location. Do not enter a P.O. Box here.
Line 9 Business Physical Address Enter the physical address of the protégé's primary physical location.
Line 10. Phone Number: Enter the mentor's primary phone number.
Line 11. Protégé Point of Contact. Enter the name of the mentor's primary point of contact for the Mentor-Protégé program.
Line 12. Email Address. Enter the email address of the mentor's primary point of contact.
Line 13. Period of Performance. Enter the period of Performance for the report.
Line 14. **Developmental Tasks.** Provide clear information on the developmental activities performed throughout the period of performance.

Line 15. **Performed by.** State whether the mentor or the protégé performed the type of activity.
Line 16.Business Capabilities Enhanced. Describe how business capabilities of the protégé were enhanced through the period of performance of the subject agreement.
Line 17. Certifications. Describe the type of certifications received by the protégé through the period of performance of the subject agreement.
Line 18. Technology Transferred. Include in this section if any type of technology was transferred from the mentor to the protégé through the period of performance of the subject agreement.
Line 19. Number of employees (protégé). Enter the number of full time employees of the protégé at the beginning and the end of the reporting period.
Line 20. Amount of federal contracts received during the reporting period (protégé) The protégé must enter the dollar value of all the federal contracts received during the reporting period as a prime contractor or subcontractor.
Line 21. Mentor Signature. Enter name of the person responsible to submit this report from the mentor, include title, signature and date.
Line 22. Protégé Signature. Enter name of the person responsible to submit this report from the mentor, include title, signature and date.
Line 23. Reviewer. For official use only, do not enter any information in this box.

[FR Doc. 2018–00673 Filed 1–16–18; 8:45 am]
BILLING CODE 4910–9X–C

DEPARTMENT OF THE TREASURY

Proposed Collection; Comment Request

AGENCY: Departmental Offices; Department of the Treasury.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork burdens, invites the general public and other Federal agencies to comment on the revision of an information collection that is to be proposed for approval by the Office of Management and Budget. The Office of International Affairs of the Department of the Treasury is soliciting comments concerning Treasury International Capital Form SLT, Aggregate Holdings of Long-Term Securities by U.S. and Foreign Residents.

DATES: Written comments should be received on or before March 19, 2018 to be assured of consideration.

ADDRESSES: Direct all written comments to Dwight Wolkow, International Portfolio Investment Data Systems, Department of the Treasury, Room 5422, 1500 Pennsylvania Avenue NW, Washington, DC 20220. In view of possible delays in mail delivery, please also notify Mr. Wolkow by email (*comments2TIC@treasury.gov*), FAX (202–622–2009) or telephone (202–622–1276).

FOR FURTHER INFORMATION CONTACT: Copies of the proposed forms and instructions are available on the Treasury's TIC Forms web page, *https://www.treasury.gov/resource-center/data-chart-center/tic/Pages/forms-slt.aspx.* Requests for additional information should be directed to Mr. Wolkow.

SUPPLEMENTARY INFORMATION: *Title:* Treasury International Capital Form SLT, Aggregate Holdings of Long-Term Securities by U.S. and Foreign Residents.

OMB Control Number: 1505–0235.

Abstract: Form SLT is part of the Treasury International Capital (TIC) reporting system, which is required by law (22 U.S.C. 286f; 22 U.S.C. 3103; E.O. 10033; 31 CFR 128), and is designed to collect timely information on international portfolio capital movements. Form SLT is a monthly report on cross-border portfolio investment in long-term marketable securities by U.S. and foreign residents. This information is used by the U.S. Government in the formulation of international financial and monetary policies and for the preparation of the U.S. balance of payments accounts and the U.S. international investment position.

Current Actions: No changes in the form are being proposed at this time. The proposed changes in the instructions are:

(1) The section II.A ''Who Must Report,'' the section II.F ''What Must Be Reported,'' and the section II.G.1 ''How to Report'' of the instructions are updated to list out separately ''certain private funds'', which are a subgroup of the class of financial entities defined by the Securities and Exchange Commission as private funds on Form PF: ''any issuer that would be an investment company as defined in

section 3 of the Investment Company Act of 1940 but for section 3(c)(1) or 3(c)(7) of . . . [that] Act.'' In cooperation with the Bureau of Economic Analysis (BEA), effective for TIC reports beginning as of January 1, 2017 and afterwards, reporters of investments in private funds that meet the definition of direct investment (that is, ownership by one person of 10 percent or more of the voting interest of a business enterprise) but display characteristics of portfolio investment (specifically, investors who do not intend to control or influence the management of an operating company) are required to report through the Treasury International Capital (TIC) reporting system, where other related portfolio investments are already being reported, and not to report on BEA's direct investment surveys. Specifically, cross-border investments by or into private funds are included in TIC reports regardless of ownership share if they meet BOTH of the following criteria: (i) The private fund does not own, directly or indirectly through another business enterprise, an ''operating company''—*i.e.,* a business enterprise that is not a private fund or a holding company—in which the U.S. or foreign parent owns at least 10 percent of the voting interest, and (ii) If the private fund is owned indirectly (through one or more other business enterprises), there are no ''operating companies'' between the U.S. or foreign parent and the indirectly-owned private fund. Direct investment in operating companies, including investment by and through private funds, will continue to be reported to BEA. Guidance on the decision to report investments in certain private funds or between entities of certain private funds in the TIC system or in BEA surveys can be found at: *https://www.bea.gov/privatefunds;* use the tools labeled ''U.S. Investments in Foreign Private Funds'' and ''Foreign Investments in U.S. Private Funds.'' This change aligns the U.S. direct investment and portfolio investment data more closely with the intent of the investment with respect to management control. In addition, it reduces the burden for respondents, many of whom previously reported both to the TIC reporting system and to BEA's direct investment reporting system. This change in reporting was effective January 1, 2017; this update will formalize the reporting requirements. Note: This change applies also to these other TIC forms if the reporting requirements of the form are met: BC, BL–1, BL–2, BQ–1, BQ–2, BQ–3, D, S, SHC(A) and SHL(A).

(2) The section II.A ''Who Must Report'' of the instructions is updated to list out separately ''principal trading firms'' and ''fund administrators.''

(3) The section II.A ''Who Must Report'' and section II.B ''Consolidation Rules'' of the instructions are updated to list out separately Intermediate Holding Companies (IHCs), as defined by Regulation YY, 12 CFR 252, and to clarify that IHCs should follow the same consolidation rules that are applicable to Bank Holding Companies (BHCs), Financial Holding Companies (FHCs), and Savings and Loan Holding Companies. Regulation YY was effective by January 1, 2015, and IHCs are filing TIC reports; this update will formalize their reporting requirements.

(4) The section II.F.2 ''What Must Be Reported'' of the instructions is updated to clarify that, regarding securities involved in security lending agreements and repurchase/resale (reverse repurchase) agreements, sales of the underlying security collateral to other parties and the purchases of such securities from other parties, undertaken in order to return the security collateral to the lenders, must be reported.

(5) The section IV.C.1 columns 1 & 2 ''Column by Column Instructions'' of the instructions is updated to clarify that the stripped securities ''teddy bears'' (TBRs), ''tigers'' (TIGRs), ''cats'' (CATS) and ''cougars'' (COUGRs) should also be classified as U.S. Treasury securities.

(6) The section II.F.2 ''What Must Be Reported'' clarifies that long-term Treasury securities are

Bonds, Notes, TIPS, FRNs and Savings Bonds.

(7) Some other clarifications and format changes may be made to improve the instructions.

Type of Review: Revision of a currently approved collection.

Affected Public: Business or other for-profit organizations. Form SLT (1505–0235).

Estimated Number of Respondents: 408.

Estimated Average Time per Respondent: Average 8.8 hours per respondent per filing. The estimated average burden per respondent varies widely, from about 17 hours per filing for a U.S.-resident custodian filing Part A and Part B to about 6.5 hours for a U.S.-resident issuer or U.S.-resident end-investor filing Part B.

Estimated Total Annual Burden Hours: 42,912 hours, based on 12 reporting periods per year.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval. All comments will become a matter of public record. The public is invited to submit written comments concerning: (a) Whether Form SLT is necessary for the proper performance of the functions of the Office, including whether the information will have practical uses; (b) the accuracy of the above estimate of the burdens; (c) ways to enhance the quality, usefulness and clarity of the information to be collected; (d) ways to minimize the reporting and/or record keeping burdens on respondents, including the use of information technologies to automate the collection of the data; and (e) estimates of capital or start-up costs of operation, maintenance and purchase of services to provide information.

Dwight Wolkow,

Administrator, International Portfolio Investment Data Reporting Systems.

[FR Doc. 2018–00674 Filed 1–16–18; 8:45 am]

BILLING CODE 4810–25–P

DEPARTMENT OF VETERANS AFFAIRS

Health Services Research and Development Service, Scientific Merit Review Board; Notice of Meetings

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act the Health Services Research and Development Service Scientific Merit Review Board will conduct in-person and teleconference meetings of its eleven Health Services Research (HSR) subcommittees on the dates below from 8:00 a.m. to approximately 4:30 p.m. (unless otherwise listed) at the FHI 360, 1825 Connecticut Ave. NW, Washington, DC 20009 (unless otherwise listed):

- HSR 0—Community Care on March 13, 2018;
- HSR 1—Health Care and Clinical Management on March 13–14, 2018;
- HSR 2—Behavioral, Social, and Cultural Determinants of Health and Care on March 13–14, 2018;
- HSR 3—Healthcare Informatics on March 16, 2018;
- HSR 4—Mental and Behavioral Health on March 15–16, 2018;
- HSR 5—Health Care System Organization and Delivery on March 15–16, 2018;
- HSR 6—Post-acute and Long-term Care on March 14, 2018;
- MRA 0—Mentored Research on March 16, 2018;
- HSR 8—Implementation Research Project on March 13, 2018;

• HS8 A—Randomized Program Evaluations on March 13, 2018; and

• HSR 9—Learning Health Initiative on March 15, 2018.

The purpose of the Board is to review health services research and development applications involving: The measurement and evaluation of health care services; the testing of new methods of health care delivery and management; and mentored research. Applications are reviewed for scientific and technical merit, mission relevance, and the protection of human and animal subjects. Recommendations regarding funding are submitted to the Chief Research and Development Officer.

Each subcommittee meeting of the Board will be open to the public the first day for approximately one half-hour from 8:00 a.m. to 8:30 a.m. at the start of the meeting on March 13 (HSR 0, 1, 2, 8, and HS8A), March 14 (HSR 1, 2, 6), March 15 (HSR 4, 5, 9), and March 16 (HSR 3, 4, 5, and MRA 0) to cover administrative matters and to discuss the general status of the program. Members of the public who wish to attend the open portion of the subcommittee meetings may dial 1 (800) 767–1750, participant code 10443#.

The remaining portion of each subcommittee meeting will be closed for the discussion, examination, reference to, and oral review of the intramural research proposals and critiques. During the closed portion of each subcommittee meeting, discussion and recommendations will include qualifications of the personnel conducting the studies (the disclosure of which would constitute a clearly unwarranted invasion of personal privacy), as well as research information (the premature disclosure of which would likely compromise significantly the implementation of proposed agency action regarding such research projects). As provided by subsection 10(d) of Public Law 92–463, as amended by Public Law 94–409, closing the meeting is in accordance with 5 U.S.C. 552b(c)(6) and (9)(B).

No oral or written comments will be accepted from the public for either portion of the meetings. Those who plan to participate during the open portion of a subcommittee meeting should contact Ms. Liza Catucci, Administrative Officer, Department of Veterans Affairs, Health Services Research and Development Service (10P9H), 810 Vermont Avenue NW, Washington, DC 20420, or by email at *Liza.Catucci@va.gov*. For further information, please call Ms. Catucci at (202) 443–5797.

Dated: January 11, 2018.

LaTonya L. Small,

Federal Advisory Committee Management Officer.

[FR Doc. 2018–00650 Filed 1–16–18; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0712]

Agency Information Collection Activity: Survey of Healthcare Experiences of Patients (SHEP)

AGENCY: Veterans Health Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the Veterans Health Administration, Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden and it includes the actual data collection instrument.

DATES: Comments must be submitted on or before February 16, 2018.

ADDRESSES: Submit written comments on the collection of information through *www.Regulations.gov*, or to Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: VA Desk Officer; 725 17th St. NW, Washington, DC 20503 or sent through electronic mail to *oira_submission@omb.eop.gov.* Please refer to ''OMB Control No. 2900–0712'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Cynthia Harvey-Pryor, Office of Quality, Privacy and Risk (OQPR), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420, (202) 461–5870 or email *cynthia.harvey-pryor@va.gov*. Please refer to ''OMB Control No. 2900–0712'' in any correspondence.

SUPPLEMENTARY INFORMATION:

Authority: E.O. 12862—Setting Customer Service Standards.

Title: Survey of Healthcare Experiences of Patients (SHEP).

SHEP Inpatient Long Form: 10–1465–1
SHEP Inpatient Short Form: 10–1465–2
Ambulatory Care Long Form: 10–1465–3
Ambulatory Care Short Form: 10–1465–4
Clinician and Group CAHPS 3.0 Patient Centered Medical Home Short Form: 10–1465–5
Clinician and Group CAHPS 3.0 Patient Centered Medical Home Long Form: 10–1465–6
Home Healthcare CAHPS Long Form: 10–1465–7
In-Center Hemodialysis CAHPS Long Form: 10–1465–8
Clinician & Group CAHPS 3.0: 10–1465–9
SHEP Community Care survey: 10–1465–10

OMB Control Number: 2900–0712.

Type of Review: Reinstatement of a currently approved collection.

Abstract: The Survey of Health Experience of Patients (SHEP) has been developed to measure patient satisfaction in the Veterans Health Administration, and has been in use in its present form since 2008. The mission of the Veterans Health Administration (VHA) is to provide high quality medical care to eligible veterans. Executive Order 12862, dated September 11, 1993, calls for the establishment and implementation of customer service standards, and for agencies to ''survey customers to determine the kind and quality of services they want and their level of satisfaction with current services''. Further emphasized by the Executive Order 13571, on ''Streamlining Service Delivery and Improving Customer Service,'' issued on April 27, 2011, VA must work continuously to ensure that their programs are effective and meet their customers' needs. To this end, VA is always seeking new and innovative ways to ensure the highest levels of customer satisfaction.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published at 82 FR 50488 on October 31, 2017, pages 50488.

Affected Public: Individuals or Households.

Estimated Annual Burden:

10–1465–1—160 hours.
10–1465–2—18,000 hours.
10–1465–3—160 hours.
10–1465–4—120 hours.
10–1465–5—48,000 hours.
10–1465–6—8,000 hours.
10–1465–7—80 hours.
10–1465–8—120 hours.
10–1465–9—30,000 hours.
10–1465–10—72,000 hours.

Estimated Average Burden per Respondent:

10–1465–1—20 minutes.
10–1465–2—15 minutes.
10–1465–3—20 minutes.
10–1465–4—15 minutes.
10–1465–5—10 minutes.
10–1465–6—20 minutes.
10–1465–7—10 minutes.
10–1465–8—15 minutes.
10–1465–9—15 minutes.
10–1465–10—15 minutes.

Frequency of Response: Annually.

Estimated Number of Respondents:

10–1465–1—480.
10–1465–2—72,000.
10–1465–3—480.
10–1465–4—480.
10–1465–5—288,000.
10–1465–6—24,000.
10–1465–7—480.
10–1465–8—480.
10–1465–9—120,000.
10–1465–10—288,000.

By direction of the Secretary.

Cynthia Harvey-Pryor,

Department Clearance Officer, Office of Quality, Privacy and Risk, Department of Veterans Affairs.

[FR Doc. 2018–00651 Filed 1–16–18; 8:45 am]

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Part II

Department of Agriculture

Agricultural Marketing Service

7 CFR Part 205

National Organic Program; Amendments to the National List of Allowed and Prohibited Substances (Crops, Livestock and Handling); Proposed Rule

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 205

[Document Number AMS–NOP–14–0079; NOP–14–05]

RIN 0581–AD60

National Organic Program; Amendments to the National List of Allowed and Prohibited Substances (Crops, Livestock and Handling)

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule would amend the National List of Allowed and Prohibited Substances (National List) provisions of the U.S. Department of Agriculture's (USDA's) organic regulations to implement recommendations submitted to the Secretary of Agriculture (Secretary) by the National Organic Standards Board (NOSB). This rule proposes to change the use restrictions for seventeen substances allowed for organic production or handling on the National List: Micronutrients; chlorhexidine; parasiticides; fenbendazole; moxidectin; xylazine; lidocaine; procaine; methionine; excipients; alginic acid; flavors; carnauba wax; chlorine; cellulose; colors; and, glycerin. This rule also proposes to add sixteen new substances on the National List to be allowed in organic production or handling: Hypochlorous acid; magnesium oxide; squid byproducts; activated charcoal; calcium borogluconate; calcium propionate; injectable vitamins, minerals, and electrolytes; kaolin pectin; mineral oil; propylene glycol; acidified sodium chlorite; zinc sulfate; potassium lactate; and, sodium lactate. In addition, this proposed rule would list the botanical pesticide, rotenone, as a prohibited substance in organic crop production. Finally, this proposed rule would remove ivermectin as an allowed parasiticide for use in organic livestock production.

DATES: Comments must be received by March 19, 2018.

ADDRESSES: Interested persons may comment on the proposed rule using the following procedures:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Robert Pooler, Standards Division, National Organic Program, USDA–AMS–NOP, 1400 Independence Ave. SW, Room 2642–S., Ag Stop 0268, Washington, DC 20250–0268. Telephone: (202) 720–3252.

Instructions: All submissions received must include the docket number AMS–NOP–14–0079; NOP–14–05, and/or Regulatory Information Number (RIN) 0581–AD60 for this rulemaking. When submitting a comment, clearly indicate the proposed rule topic and section number to which your comment refers. In addition, comments should clearly indicate whether you support or oppose the action being proposed and the reason(s) for your position. Your comments can also include information on alternative management practices, where applicable, that support alternatives to the proposed amendments. You should also offer any recommended language change(s) that would be appropriate to your position. Please include relevant information and data to support your position, such as scientific, environmental, manufacturing, industry, or impact information, or similar sources. Only relevant material supporting your position should be submitted. All comments received will be posted without change to *http://www.regulations.gov.*

Document: For access to read background documents or comments received, go to *http://www.regulations.gov.* Comments submitted in response to this proposed rule will also be available for viewing in person at USDA–AMS, National Organic Program, Room 2642-South Building, 1400 Independence Ave. SW, Washington, DC, from 9 a.m. to 12 noon and from 1 p.m. to 4 p.m., Monday through Friday (except official Federal holidays). Persons wanting to visit the USDA South Building to view comments received in response to this proposed rule are requested to make an appointment in advance by calling (202) 720–3252.

FOR FURTHER INFORMATION CONTACT: Robert Pooler, Standards Division, National Organic Program. Telephone: (202) 720–3252.

SUPPLEMENTARY INFORMATION:

I. Background

On December 21, 2000, the Secretary published the National List of Allowed and Prohibited Substances in §§ 205.600 through 205.607 of the USDA organic regulations (7 CFR 205.1–205.690). This National List identifies the synthetic substances that may be used and the nonsynthetic (natural) substances that may not be used in organic production. The National List also identifies synthetic, nonsynthetic nonagricultural, and nonorganic agricultural substances that may be used in organic handling. The Organic Foods Production Act of 1990, as amended (7 U.S.C. 6501–522) (OFPA), and § 205.105 of the USDA organic regulations specifically prohibit the use of any synthetic substance in organic production and handling unless the synthetic substance is on the National List. Section 205.105 also requires that any nonorganic agricultural and any nonsynthetic nonagricultural substance used in organic handling be on the National List. Under the authority of OFPA, the National List can be amended by the Secretary based on recommendations presented by the NOSB. Since the final rule establishing the National Organic Program (NOP) became effective on October 21, 2002, AMS has published multiple rules amending the National List.

This proposed rule would amend the National List to implement 29 NOSB recommendations on 35 amendments to the National List that were submitted to the Secretary on November 17, 2000, September 19, 2002, May 6, 2009, November 5, 2009, October 28, 2010, December 2, 2011, March 20, 2012, October 16, 2012, May 2, 2014, April 30, 2015, October 29, 2015, April 26, 2016, and November 18, 2016.

Table 1 summarizes the NOSB recommendations on adding substances to the National List or amending currently listed substances that are included in this proposed rule.

TABLE 1—SUBSTANCES BEING ADDED TO THE NATIONAL LIST OR CURRENT LISTINGS BEING AMENDED

Substance	National List section	Proposed rule action
Hypochlorous acid	205.601	Add to National List.
Magnesium oxide	205.601	Add to National List.
Micronutrients	205.601(a)	Amend listing.
Squid byproducts	205.601	Add to National List.
Rotenone	205.602	Add to National List.
Activated charcoal	205.603(a)	Add to National List.

TABLE 1—SUBSTANCES BEING ADDED TO THE NATIONAL LIST OR CURRENT LISTINGS BEING AMENDED—Continued

Substance	National List section	Proposed rule action
Calcium borogluconate	205.603(a)	Add to National List.
Calcium propionate	205.603(a)	Add to National List.
Chlorhexidine	205.603(a)	Amend listing.
Hypochlorous acid	205.603(a)	Add to National List.
Kaolin pectin	205.603(a)	Add to National List.
Mineral oil	205.603(a)	Add to National List.
Nutritive supplements—Injectable vitamins, minerals, & electrolytes	205.603(a)	Add to National List.
Parasiticides	205.603(a)	Amend listing.
Fenbendazole	205.603(a)	Amend listing.
Ivermectin	205.603(a)	Remove from National List.
Moxidectin	205.603(a)	Amend listing.
Propylene glycol	205.603(a)	Add to National List.
Sodium chlorite, acidified	205.603(a & b)	Add to National List.
Xylazine	205.603(a)	Amend listing.
Zinc sulfate	205.603(a)	Add to National List.
Lidocaine	205.603(b)	Amend listing.
Procaine	205.603(b)	Amend listing.
Methionine	205.603(d)	Amend listing.
Excipients	205.603(f)	Amend listing.
Alginic acid	205.605(a)	Reclassify listing.
Flavors	205.605(a)	Amend listing.
Carnauba wax	205.605(a)	Reclassify listing.
Cellulose	205.605(b)	Amend listing.
Chlorine	205.605(b)	Amend listing.
Hypochlorous acid	205.605(b)	Add to National List.
Potassium lactate	205.605(b)	Add to National List.
Sodium lactate	205.605(b)	Add to National List.
Glycerin	205.605(a) & 205.606	Reclassify listing.
Colors	205.606	Amend listing.

Each substance included in Table 1 is addressed in the Overview of Proposed Amendments. Substances recommended by the NOSB between November 2000 and April 2015 are described in more detail because less petition and technical information is available in NOP's petitioned substance database.[1] Less technical and petition information is provided within the overview for substances recommended by the NOSB after its three public meetings between October, 2015, and November, 2016, because such information is available in NOP's petitioned substance database.

II. Overview of Proposed Amendments

The following provides an overview of the proposed amendments to designated sections of the National List regulations:

§ 205.601 Synthetic Substances Allowed for Use in Organic Crop Production

This proposed rule would add three new substances, and amend one substance currently on the National List in § 205.601, Synthetic substances allowed for use in organic crop production.

Hypochlorous Acid

The proposed rule would amend the National List to add hypochlorous acid as a chlorine material for use as a disinfectant and sanitizer in §§ 205.601, 205.603, and 205.605. Table 2 illustrates the proposed listing.

TABLE 2—PROPOSED RULE ACTION FOR HYPOCHLOROUS ACID

Current rule: N/A.
Proposed rule action: §§ 205.601(a), 205.603(a), 205.605(b), Hypochlorous acid—generated from electrolyzed water.

On May 29, 2015, AMS received a petition to add hypochlorous acid to the National List in §§ 205.601 and 205.605, for use as an antimicrobial/sanitizer on equipment and raw agricultural products in organic crop production and handling.[2] In water, chlorine materials such as calcium and sodium hypochlorite are in equilibrium with related chlorine species, including hypochlorous acid (HOCl) and hypochlorite (ClO^-). These related chlorine species are formed in the generation of electrolyzed water. Chlorine materials (calcium hypochlorite, chlorine dioxide and sodium hypochlorite) are included on the National List in §§ 205.601, 205.603 and 205.605.

On September 11, 2015, AMS published NOP Policy Memorandum PM 15–4, Electrolyzed Water.[3] This memo revised a prior NOP determination about the status of electrolyzed water by stating that hypochlorous acid, generated by electrolyzed water, is an allowable type of chlorine material. The petition review process continued after that memo was issued in order to codify the allowance for hypochlorous acid on the National List.

[1] NOP petitioned substance database, A–Z: *https://www.ams.usda.gov/rules-regulations/organic/national-list/petitioned.*

[2] The hypochlorous acid petition is available in the NOP Petitioned Substances Database: *https://www.ams.usda.gov/rules-regulations/organic/national-list/petitioned.*

[3] The policy memo is published in the NOP Handbook: *http://www.ams.usda.gov/sites/default/files/NOP-PM-15-4-ElectrolyzedWater.pdf.*

At its April 25–27, 2016, public meeting, the NOSB considered the petition to add hypochlorous acid to the National List for uses in organic production and organic handling and received public comment on these allowances. During its review, the NOSB also considered a technical evaluation report on hypochlorous acid [4] that described its manufacture, industry uses, regulation, and chemical properties.

In consideration of the petition, technical report, and public comments, the NOSB determined that the use of hypochlorous acid generated from electrolyzed water as a disinfectant and sanitizer satisfies OFPA evaluation criteria for National List substances and recommended adding hypochlorous acid to the existing listings for chlorine materials in § 205.601(a) as an algicide, disinfectant, and sanitizer, including irrigation cleaning systems in organic crop production; § 205.603(a) for use as a disinfectant, sanitizer, and medical treatment in organic livestock production; and § 205.605(b) as a disinfectant and sanitizer in organic handling. The NOSB included the annotation ''generated from electrolyzed water'' to clarify that the source of hypochlorous acid allowed for use in organic production or handling must be production from electrolyzed water.

AMS has reviewed and proposes to address this NOSB recommendation through this proposed rule. Consistent with the NOSB recommendation, this proposed rule would amend the listings for Chlorine materials in § 205.601(a)(2), § 205.603(a), and § 205.605(b) to add hypochlorous acid—generated from electrolyzed water.

Magnesium Oxide

This proposed rule would add magnesium oxide to § 205.601(j) as an allowed substance to control the viscosity of a clay suspension agent for humates. In consideration of the petition, technical report, and public comments, the NOSB determined that this use of magnesium oxide satisfies the OFPA evaluation criteria for National List substances. Table 3 illustrates the proposed listing.

TABLE 3—PROPOSED RULE ACTION FOR MAGNESIUM OXIDE

Current rule: N/A.
Proposed rule action: § 205.601(j) Magnesium oxide—for use only to control the viscosity of a clay suspension agent for humates.

Applications

Magnesium oxide (CAS Number 1309–48–4) is a white, free flowing, odorless powder. The technical report for magnesium hydroxide [5] states that magnesium oxide is considered to be a relatively benign substance with a wide range of applications. There are several manufacturing processes used to produce magnesium oxide. The petition [6] to add magnesium oxide to the National List describes an efficient and inexpensive process for producing magnesium oxide by combining sea water or salt brine with dolomitic limestone to precipitate magnesium hydroxide, which is then dehydrated by heating to form magnesium oxide. Since magnesium oxide is physically and chemically stable at high temperatures, it is widely used for agricultural and nonagricultural applications. For food use, magnesium oxide is listed in 21 CFR part 184—Direct Food Additives Affirmed as Generally Recognized As Safe (GRAS), in § 184.1431, for the following uses: anticaking and free-flow agent, firming agent, lubricant and release agent, nutrient supplement, and a pH control agent.

Timeline

On January 3, 2013, AMS received a petition to add magnesium oxide to the National List in § 205.601. The petition states that the substance is ''intended to be used in combination with other organic inputs applied as a liquid foliar on a wide variety of different agricultural, vegetable, fruit and horticultural crops.'' According to the petition, small quantities of magnesium oxide would be used during the processing of attapulgite clay to control its viscosity when the clay is used as a suspension agent for finely ground humates. As stated in the petition, the rate of magnesium oxide use per the manufacturer's recommended rate would be 0.074 percent of the diluted humate product applied, or approximately 0.0007–0.0014 pounds of magnesium oxide per acre, which is a very low application rate.

At its May 2, 2014, public meeting, the NOSB considered the petition to add magnesium oxide to the National List in § 205.601. At this meeting, the NOSB considered magnesium oxide against the evaluation criteria stipulated in OFPA § 2119(m). After review of the petition, technical report, and public comments, the NOSB determined that magnesium oxide satisfies the evaluation criteria and recommended magnesium oxide as a soil amendment for use in organic crop production.

AMS has reviewed and proposes to address this NOSB recommendation through this proposed rule. Consistent with the NOSB recommendation, this proposed rule would amend § 205.601(j) by adding: Magnesium oxide—for use only to control the viscosity of a clay suspension agent for humates.

Micronutrients

This proposed rule would amend the current listing on micronutrients in § 205.601(j) as an allowed plant or soil amendment material for use in organic crop production. This proposed rule would change the listing for micronutrients to remove soil testing as the required method for demonstrating a soil micronutrient deficiency. Table 4 illustrates the proposed listing.

TABLE 4—PROPOSED RULE ACTION FOR MICRONUTRIENTS

Current rule: § 205.601(j) Micronutrients—not to be used as a defoliant, herbicide, or desiccant. Those made from nitrates or chlorides are not allowed. Soil deficiency must be documented by testing.
Proposed rule action: § 205.601(j) Micronutrients—not to be used as a defoliant, herbicide, or desiccant. Those made from nitrates or chlorides are not allowed. Micronutrient deficiency must be documented by soil or tissue testing, advice from certified crop advisors or professional agronomists, agricultural extension information, or other methods approved by the certifying agent.

[4] Hypochlorous acid technical report: *https://www.ams.usda.gov/sites/default/files/media/Hypochlorous%20Acid%20TR%2008%2013%2015.pdf.*

[5] 2007 magnesium hydroxide technical report, see: *https://www.ams.usda.gov/rules-regulations/organic/national-list/petitioned.*

[6] Petition for magnesium oxide, see: *https://www.ams.usda.gov/rules-regulations/organic/national-list/petitioned.*

In April 2015, the NOSB initiated a change to the existing listing for micronutrients in § 205.601(j) based on public comments [7] received during the NOSB 2017 sunset review for micronutrients. The USDA organic regulations permit micronutrients to be used as a soil amendment only when soil deficiency is documented by testing. Commenters suggested that alternative methods to document micronutrient deficiency, including, but not limited to, tissue testing, the incorporation of professional opinions and regional knowledge from agronomists, crop advisors, extension agents and publications, should be permitted in lieu of testing.

During a public meeting on October 26–29, 2015, the NOSB considered an amendment to the micronutrients listing to remove the requirement for testing as the only method for documenting a soil micronutrient deficiency. In consideration of public comments, the NOSB determined that requiring soil testing for micronutrients was outdated and that other means of assessing micronutrient deficiencies in soil are acceptable.[8]

AMS has reviewed and proposes to address this NOSB recommendation through this proposed rule. Consistent with the NOSB recommendation, this proposed rule would amend § 205.601(j) Micronutrients, by removing soil testing as the only way to document a deficiency and stating that a deficiency must be documented.

Squid Byproducts

This proposed rule would add squid byproducts to § 205.601(j) as an allowed substance for use in organic crop production. Table 5 illustrates the proposed listing.

TABLE 5—PROPOSED RULE ACTION FOR SQUID BYPRODUCTS

Current rule: N/A.
Proposed rule action: § 205.601(j) squid byproducts—from food waste processing only. Can be pH adjusted with sulfuric, citric or phosphoric acid. The amount of acid used shall not exceed the minimum needed to lower the pH to 3.5.

In April 2015, AMS received a petition to add ''squid and squid byproducts'' to the National List under the listing for liquid fish products allowed as plant or soil amendments in organic crop production, § 205.601(j)(7). Squid byproducts are used as starting ingredients in the production of enzymatically produced hydrolysates which are used as foliar sprays and soil amendments for propagating crops such as cranberries, cherries and apples. Squid byproduct hydrolysates are similar in composition to fish emulsions and can be used as a fertilizer that provides organic matter to the soil.

At the April 25–27, 2016 NOSB meeting, the Board reviewed the petition, public comments, and information in a technical report on squid and squid byproducts. The NOSB explained that squid byproducts are stabilized with acid to lower the pH, and that this practice is consistent with the existing listing for liquid fish products that are stabilized with synthetic sulfuric, citric, or phosphoric acid. The NOSB also stated that only squid byproducts from the food waste processing stream are acceptable; fertilizer from whole squid would not be acceptable.

Based on the petition, technical report, and public comments, the NOSB determined that squid byproducts meet the OFPA evaluation criteria for National List substances. AMS has reviewed and proposes to address this NOSB recommendation through this proposed rule. Consistent with the NOSB recommendation, this proposed rule would add amend § 205.601(j)(7) of the National List to list squid byproducts as an allowed plant or soil amendment that can be pH adjusted with sulfuric, citric, or phosphoric acid. The amount of acid used shall not exceed the minimum needed to lower the pH to 3.5. AMS also accepts the source parameters specified by the NOSB, *i.e.,* only squid byproducts from food waste processing are permitted.

§ 205.602 Nonsynthetic Substances Prohibited for Use in Organic Crop Production

This proposed rule would add rotenone to paragraph (j) of § 205.602 and prohibit its use in organic crop production. Nonsynthetic substances are allowed in organic crop production except for those specifically listed as prohibited in § 205.602.

Rotenone

This proposed rule would add rotenone to § 205.602 and prohibit its use in organic crop production, as recommended by the NOSB in 2012. Table 6 illustrates the proposed changes to this section.

TABLE 6—PROPOSED RULE ACTION FOR ROTENONE

Current rule: N/A.
Proposed rule action: § 205.602(f) Rotenone (CAS # 83–79–4).

Applications

Rotenone (CAS Number 83–79–4) is a substance that is extracted from various plant species such as Hoary pea (*Tephrosia* spp.) or Jicama vine (*Pachyrhizus erosus*) and similar tropical and subtropical plants. Rotenone preparations made from plants are also known as barbasco, derris, and cube root. Naturally occurring rotenone is used as a pesticide, insecticide, and as a piscicide (fish toxin). Pesticide formulations containing rotenone are nonsynthetic (natural) when prepared without synthetic extractions. Nonsynthetic substances are allowed in organic crop production except for those specifically listed as prohibited in § 205.602.

Timeline

The U.S. Environmental Protection Agency (EPA) cancelled the registration of rotenone for use on food commodities within the U.S. on March 23, 2011. Aligning with EPA's regulation of rotenone, AMS is adding rotenone to the list of prohibited nonsynthetic materials in § 205.602, and organic producers both within and outside of the U.S.

[7] The public comments to the NOSB pertaining to the 2017 sunset review are posted here: *https://www.ams.usda.gov/event/spring-nosb-meeting-2015-ca,* and *https://www.ams.usda.gov/event/nosb-meeting-2015-vt.*

[8] *https://www.ams.usda.gov/rules-regulations/organic/nosb/recommendations/fall2015.*

would be prohibited from using rotenone on crops grown in accordance with USDA organic regulations.

The NOSB considered rotenone and other botanical pesticides at its meeting on October 14, 1994, and determined that rotenone should not be prohibited. The USDA agreed and did not prohibit rotenone or other botanical pesticides to control plant diseases, but did require producers to use management practices to prevent crop pests, weeds, and diseases before using botanical pesticides, as specified in the USDA organic regulations at § 205.206.

In August 2012, the NOSB revisited the allowance for rotenone in organic production. After reviewing technical documents and considering public comment, the NOSB recommended to prohibit rotenone, citing adverse environmental and health impacts, lack of essentiality, and incompatibility with organic principles. AMS has reviewed and proposes to address this NOSB recommendation through this proposed rule. Therefore, this proposed rule would amend § 205.602 of the National List by adding rotenone as a prohibited nonsynthetic substance in organic crop production.

§ 205.603 Synthetic Substances Allowed for Use in Organic Livestock Production

The proposed rule would add the following substances to the National List in paragraph § 205.603(a) for use in organic livestock production: Activated charcoal, calcium borogluconate, calcium propionate, hypochlorous acid, kaolin pectin, mineral oil, nutritive supplements—injectable vitamins, trace minerals and electrolytes, propylene glycol, acidified sodium chlorite, and zinc sulfate. The proposed rule would also add acidified sodium chlorite to § 205.603(b). This proposed rule would also amend the allowances for the following substances currently allowed in organic livestock production: Chlorhexidine, parasiticides, fenbendazole, moxidectin, and xylazine, § 205.603(a); lidocaine and procaine, § 205.603(b); methionine, § 205.603(d); and excipients, § 205.603(f). In addition, this proposed rule would remove ivermectin, § 205.603(a).

Activated Charcoal

This proposed rule would add activated charcoal to § 205.603(a) for use in organic livestock production. In consideration of the petition and public comments from livestock producers and animal health experts, the NOSB determined that activated charcoal should be allowed for use in organic livestock production. Synthetic forms of activated charcoal would continue to be prohibited. Table 7 illustrates the proposed listing.

TABLE 7—PROPOSED RULE ACTION FOR ACTIVATED CHARCOAL

Current rule: N/A.
Proposed rule action: § 205.603(a) Activated charcoal—must be from vegetative sources.

Applications

Activated charcoal is manufactured from a physical activation process using high temperature and hot gases on raw materials such as coconut shells, various hardwoods, or bone. It can also be derived from coal or petroleum. The resulting product is a carbon based substance with small pore size and large surface area for adsorption or chemical reaction.

While this basic process provides sufficient activation capability, the use of a strong acid or strong base, such as phosphoric acid or potassium hydroxide, enhances the activation process and adsorption properties. Chemical activation with a strong chemical acid or base is the preferred activated charcoal manufacturing process since lower temperatures and less time are needed to create the final product. Activated charcoal is distinguished from elemental carbon by the removal of non-carbon impurities and oxidation of the carbon surface.

Activated charcoal is considered to be an adsorbent. Administered orally, activated charcoal chemically interacts with toxins in the intestines and prevents systemic absorption of the toxin into the blood. These bound toxins pass through the intestine to be excreted in the animal's manure. Under 21 CFR 310.545(a)(8), activated charcoal is approved as an ingredient in digestive aid drug products for humans.

Timeline

This proposed rule would implement a 2002 NOSB recommendation to add activated charcoal (CAS # 7440–44–0) with the annotation ''must be from vegetative sources'' to § 205.603(a) of the National List.[9] The NOSB recommended that activated charcoal be added to § 205.603(a) as a medical treatment in organic livestock production.

The petition to add activated charcoal to the National List states that this material is a high-priority livestock medication and is commonly used as a therapeutic treatment on an as-needed basis with mammalian livestock, particularly in cases of suspected ingestion of toxic plants and control of diarrhea caused by moldy silage. This information was also supported in public comments to the NOSB from organic livestock producers and veterinarians. The petition also states that there are no comparable nonsynthetic substances that provide a comparable therapeutic benefit nor practices to prevent the occasional ingestion of toxins that warrant treatment.

The NOSB recommendation to add activated charcoal specifies that only vegetative sources of this material would be permitted. The NOSB determined that activated charcoal derived from bone charcoal or lampblack (a by-product from incomplete burning of oil, tar, natural gas, or fat) is not consistent with organic farming and handing, as described in the OFPA substance evaluation criteria. The NOSB also noted that activated charcoal, when used as a toxin binder, is safe, effective, and difficult to overdose.

AMS has reviewed and proposed to address the NOSB recommendation through this proposed rule. Therefore, AMS is proposing to add activated charcoal to the National List at § 205.603(a) with the following annotation: must be from vegetative sources. Only activated charcoal from vegetative sources would be permitted.

Calcium Borogluconate

This proposed rule would add calcium borogluconate to § 205.603(a) of the National List for use in organic livestock production. Specifically, calcium borogluconate would be allowed only for the treatment of milk fever. Table 8 illustrates the proposed listing.

[9] Recommendation for activated charcoal in livestock processing, see *https://www.ams.usda.gov/sites/default/files/media/Activated%20Charcoal%20Committee%20Rec.pdf.*

TABLE 8—PROPOSED RULE ACTION FOR CALCIUM BOROGLUCONATE

Current rule: N/A.
Proposed rule action: § 205.603(a), Calcium Borogluconate—for treatment of milk fever only.

Applications

Calcium borogluconate, a D-gluconic acid, cyclic 4,5-ester with boric acid, is a stable, nonhazardous white powder derived from the reaction of five parts calcium gluconate to one part boric acid in an aqueous solution. Calcium borogluconate has been used for treatment of hypocalcemia (milk fever or parturient paresis) in cattle, sheep, and goats. Hypocalcemia, or milk fever, is a disease—observed mostly in high producing dairy cows—that can be induced by low blood calcium levels occurring just before birth or in early lactation just after birth, when demand for calcium for milk production exceeds the animal's ability to mobilize calcium reserves. Low blood calcium levels can inhibit muscle function causing general weakness, loss of appetite, and eventually heart failure. The condition is more frequent in high producing dairy cows that are five or more years old in age. Mature animals may have reduced ability to mobilize calcium from bone. Certain breeds, such as Jersey cattle, may be more susceptible to milk fever.

When used to treat milk fever, calcium borogluconate is administered intravenously, intramuscularly, or subcutaneously, and has no established required withdrawal time. The calcium borogluconate technical report [10] developed for the NOSB states that calcium borogluconate is recognized as an electrolyte in the European Union. The NOSB has determined that the use of calcium borogluconate in organic livestock production for the treatment of this condition meets the requirements of the OFPA substance evaluation criteria for organic production.

Timeline

This proposed rule would implement a November 2000 NOSB recommendation to add calcium borogluconate (CAS # 5743–34–0) to § 205.603 of the National List. At its public meeting the NOSB determined that calcium borogluconate should be added to § 205.603(a) as a medical treatment in organic livestock production for treatment of milk fever. Comments indicated that organic livestock producers use calcium borogluconate as directed by veterinarians. During the meeting, the NOSB discussed that calcium borogluconate would be used rarely, and only in emergency situations.

In formulating its recommendation, the NOSB determined that calcium borogluconate should be allowed for use in organic ruminants when production practices fail to prevent milk fever. AMS has reviewed and proposes to address the NOSB recommendations through this proposed rule. Therefore, AMS is proposing to add calcium borogluconate to § 205.603(a) with the following annotation: for treatment of milk fever only.

Calcium Propionate

This proposed rule would add calcium propionate to the National List at § 205.603(a) for use in organic livestock production. Specifically, this substance would be allowed only as a treatment for milk fever. Table 9 provides the proposed listing.

TABLE 9—PROPOSED RULE ACTION FOR CALCIUM PROPRIONATE

Current rule: N/A.
Proposed rule action: § 205.603(a), Calcium Propionate—for treatment of milk fever only.

Applications

Calcium propionate, also known as calcium propanoate, is a white crystalline water soluble powder manufactured from combining calcium hydroxide and propionic acid. Calcium propionate is a direct food additive affirmed as generally recognized as safe (GRAS) (21 CFR 184.1221) for human food and is primarily used as a preservative in bakery products. It is also allowed as a preservative for hay and silage in nonorganic livestock production agriculture (21 CFR 582.3221).

In 2002, AMS received a petition [11] to add calcium propionate to the National List for use in organic livestock production as a treatment for milk fever and as a mold inhibitor in dry formulated herbal remedies. According to the petition, calcium propionate can be administered to prevent milk fever or when milk fever symptoms first appear.

Timeline

This proposed rule would implement a September 2002 NOSB recommendation to add calcium propionate (CAS # 4075–81–4) to § 205.603 of the National List. At this meeting, the NOSB recommended that calcium propionate be allowed only for the treatment of milk fever. The NOSB recognized that calcium propionate would not be used routinely, but only as an emergency treatment for milk fever. Public comments informed that organic livestock producers use this substance as directed by veterinarians.

During its 2003 public meeting, the NOSB also considered allowing calcium propionate to also be used as a mold inhibitor for aloe pellets, but the NOSB did not include this use in its final recommendation. The technical report on calcium propionate indicates the substance has been used as a feed preservative in nonorganic hay crops. During deliberation, the NOSB crops subcommittee did not propose to allow the use of calcium propionate as a feed preservative, or propose allowing the general use of calcium propionate as a feed additive. As a result, the final NOSB recommendation included the use of calcium propionate for use in organic livestock for the treatment of milk fever only.

The NOSB also determined that the limited use of calcium propionate in organic livestock production in this manner meets the OFPA substance evaluation criteria for organic production. In formulating its recommendation, the NOSB determined that calcium propionate can be used in organic livestock production when

[10] Technical report for calcium borogluconate, see *https://www.ams.usda.gov/sites/default/files/media/Calcium%20Borogluconate%20TR.pdf.*

[11] Petition for calcium propionate, see *https://www.ams.usda.gov/sites/default/files/media/Calcium%20Propionate%20Petition.pdf.*

organic practices fail to prevent milk fever. AMS has reviewed and proposes to address the NOSB recommendation through this proposed rule. Therefore, AMS is proposing to add calcium propionate to § 205.603(a) with the following annotation: for treatment of milk fever only.

Chlorhexidine

This proposed rule would amend the allowance for chlorhexidine in § 205.603(a). The amendment—as recommended by the NOSB and public comment—will improve organic livestock producers' ability to establish and maintain preventive livestock health care practices. Table 10 illustrates the changes between the current rule and the proposed rule.

TABLE 10—PROPOSED RULE ACTION FOR CHLORHEXIDINE

Current rule: § 205.603(a)(6) Chlorhexidine—Allowed for surgical procedures conducted by a veterinarian. Allowed for use as a teat dip when alternative germicidal agents and/or physical barriers have lost their effectiveness.
Proposed rule action: § 205.603(a) Chlorhexidine—for medical procedures conducted under the supervision of a licensed veterinarian. Allowed for use as a teat dip when alternative germicidal agents and/or physical barriers have lost their effectiveness.

Applications

Chlorhexidine is a white to pale yellow, odorless powder. It is only slightly soluble in water and in most organic solvents. Chlorhexidine is manufactured by a two-step process beginning with sodium dicyanamide reacting with hexamethylene diamine to form hexamethylene-biscyanoguanidine (HMBCG). Subsequently, HMBCG is reacted with p-chloroaniline to yield the chlorhexidine base used in applications. In animals, chlorhexidine is used as a topical disinfectant, for wound healing, and for managing skin infection in dogs. Chlorhexidine is also used as a germicidal compound in teat dips for dairy production and as an umbilical cord treatment, udder and eye wash, and surgical scrub and sterilization material. Chlorhexidine's bactericidal effect is due to its binding with the bacterial cell wall or, when chlorhexidine concentrations are higher, inducing bacterial cell membrane disruption.

Timeline

This proposed rule would implement a 2009 NOSB recommendation to amend the allowance for chlorhexidine as listed in § 205.603(a) of the National List. Chlorhexidine is allowed for use in two applications: (1) For surgical procedures in organic livestock as performed by a licensed veterinarian, and (2) as a teat dip when alternative germicidal agents and/or physical barriers have lost their effectiveness.[12] At the 2009 meeting, the NOSB determined that the annotation should reflect the use of chlorhexidine by livestock producers and veterinarians for antiseptic purposes and for hygienic cleansing of wounds encountered during livestock production. The NOSB determined that the current annotation is overly restrictive and that the general use of chlorhexidine for antiseptic purposes and for hygienic cleansing of wounds is compatible with organic standards. This proposed change to broaden the allowance from surgical to medical procedures would improve organic livestock producers' ability to establish and maintain preventive livestock health care practices. The use of chlorhexidine may also minimize pain and stress. Such use could preclude the need to use antibiotics, which are prohibited for use in organic livestock production. This proposed rule to amend the chlorhexidine annotation would not alter the existing restriction on using chlorhexidine as a teat dip when alternative germicidal agents and/or physical barriers have lost their effectiveness.

In October 1999, the NOSB originally recommended chlorhexidine for addition to the National List for medical procedures conducted under the supervision of a licensed veterinarian. Chlorhexidine was added to the National List that was published in the final rule establishing the NOP (The allowance for chlorhexidine has been renewed via the sunset process in 2007 (October 21, 2007 (72 FR 58469)) and 2012 (June 21, 2012 (77 FR 33290)).

The 2009 NOSB chlorhexidine recommendation[13] would allow broader use of chlorhexidine for treating injuries and allow use before and after medical procedures to prevent bacterial infections and potentially avoid the need for antibiotics. The NOSB has determined that the use of chlorhexidine in organic livestock production in this manner meets the evaluation criteria for National List substances. In formulating its recommendation, the NOSB concluded that chlorhexidine is an important substance for treating livestock to cleanse infected areas that need medical attention. AMS has reviewed and proposes to address the NOSB recommendation through this proposed rule. Therefore, AMS is proposing to amend the listing for chlorhexidine in § 205.603(a) to: Chlorhexidine—for medical procedures conducted under the supervision of a licensed veterinarian. Allowed for use as a teat dip when alternative germicidal agents and/or physical barriers have lost their effectiveness.

Hypochlorous Acid

See discussion above under § 205.601 Synthetic substances allowed for use in organic crop production.

Kaolin Pectin

This proposed rule would add kaolin pectin to § 205.603(a) of the National List for use as an adsorbent, antidiarrheal, and gut protectant in organic livestock production. Table 11 provides the proposed listing.

TABLE 11—PROPOSED RULE ACTION FOR KAOLIN PECTIN

Current rule: N/A.
Proposed rule action: § 205.603(a), Kaolin Pectin, for use as an adsorbent, antidiarrheal, and gut protectant.

[12] 2009 NOSB Recommendation to amend chlorhexidine, see *https://www.ams.usda.gov/sites/default/files/media/NOP%20Final%20Rec%20Chlorhexidine.pdf.*

[13] NOSB Final recommendation on chlorhexidine, see: *https://www.ams.usda.gov/sites/default/files/media/NOP%20Final%20Rec%20Chlorhexidine.pdf.*

Applications

Kaolin pectin is a combination of kaolin clay and pectin. Kaolin clay is geologically formed and can be either a white, light yellow, light gray, or light brown powder composed of silica, alumina, and water. Kaolin is listed under 21 CFR 186.1256 as an indirect food substance affirmed as GRAS for human food and is used mostly as a gelling or thickening agent or stabilizer. Pectin is present in plant cell walls and consists of a polymer of galacturonic acid often disrupted by short branches of neutral sugars. Pectin is produced commercially as a white to light brown powder, produced mostly from hot dilute acid extraction of fruit juice production byproducts. Pectin is used in foods as an emulsifier or as a stabilizer and is listed as GRAS under 21 CFR 184.1588 for human food. Pectin molecules vary in the degree of methoxylation, either high (above 50 percent) or low (less than 50 percent) where the degree of methoxylation determines the gelling properties of the pectin.

Timeline

This proposed rule would implement a September 2002 NOSB recommendation to add kaolin pectin to § 205.603 of the National List for use as an adsorbent, antidiarrheal, and gut protectant in organic livestock production. The NOSB indicated that kaolin pectin should not be used routinely as a preventive practice but only when organic practices fail to treat gastrointestinal irritants or diarrhea. The NOSB determined that synthetic forms of pectin were compatible with organic livestock production and could be used in formulations to produce kaolin pectin.

The NOSB has determined that the use of kaolin pectin in organic livestock production in this manner meets the requirements of the OFPA material evaluation criteria for organic production. AMS has reviewed and proposes to address the NOSB recommendation through this proposed rule. Therefore, AMS is proposing to add kaolin pectin to section § 205.603(a) with the following annotation: For use as an adsorbent, antidiarrheal, and gut protectant.

Mineral Oil

This proposed rule would add mineral oil to the National List for use in organic livestock production for relief of intestinal impaction. The NOSB recommended that this substance be included in paragraph (a) of § 205.603 as a medical treatment in livestock production. Table 12 provides the proposed listing.

TABLE 12—PROPOSED RULE ACTION FOR MINERAL OIL

Current rule: N/A.
Proposed rule action: § 205.603(a) Mineral oil, for relief of intestinal impaction, prohibited for use as a dust suppressant.

Applications

Mineral oil, also known as white oil, liquid paraffin, pariffinum liquidum, and liquid petroleum, is colorless, insoluble in water, and odorless. It is a complex mixture of straight and branched chain aromatic hydrocarbons, such as paraffinic, and naphthenic oils, and is derived mostly from petroleum distillate.

Applications for mineral oil include use as a lubricant (both mechanical and biological), in veterinary treatments, cosmetic products, pharmaceutical preparation (processing aids, intestinal lubricants), food preparation (release agents, binders, defoamers, protective coatings), and as an ingredient in animal feed products.

Mineral oil is permitted as described at 21 CFR 172.878 for direct addition to food for human consumption. When administered orally, mineral oil absorption from the intestine is limited.[14] Mineral oil is currently on the National List and is allowed in organic production for topical use and as a lubricant (§ 205.603(b)(6)). This proposed action does not affect this current allowance.

Timeline

This proposed rule would implement a September 2002 NOSB recommendation to add mineral oil to section § 205.603 of the National List for use in organic livestock production. During the September 2002 meeting, the NOSB considered allowing mineral oil to be used as a medical treatment for bloat (rumen-reticulum overdistention) and as a medical treatment of omasal impaction.[15] The NOSB indicated that ruminal bloat or omasal impaction would occur infrequently. The 2002 NOSB recommendation intended to allow mineral oil as an internal treatment for impaction.

The NOSB has determined that the use of mineral oil in organic livestock production for the proposed use meets the requirements of the OFPA material evaluation criteria for organic production. AMS has reviewed and proposes to address the NOSB recommendation through this proposed rule. Therefore, AMS is proposing to add mineral oil to § 205.603(a) with the following annotation: For treatment of intestinal impaction, prohibited for use as a dust suppressant.

Nutritive Supplements—Injectable Vitamins, Minerals, and Electrolytes

This proposed rule would also add injectable vitamins, minerals, and electrolytes to § 205.603(a) of the National List for use in organic livestock production. Currently, these substances are allowed to be provided only orally as feed additives (vitamins and minerals per § 205.603(d)) or medical treatments (electrolytes without antibiotics per § 205.603(a)). Table 13 illustrates the proposed listings.

TABLE 13—PROPOSED RULE ACTION FOR NUTRITIVE SUPPLEMENTS—INJECTABLE MINERALS, VITAMINS, AND ELECTROLYTES

Current rule: N/A.
Proposed rule action: § 205.603(a) Nutritive supplements—Injectable minerals, vitamins, and electrolytes—formulated injectable supplements of trace minerals per 205.603(d)(2), vitamins per 205.603(d)(3), and electrolytes per 205.603(a)(8), with excipients per 205.603(f), in accordance with FDA and restricted to use by or on the order of a licensed veterinarian.

[14] Mineral Oil technical report: *https://www.ams.usda.gov/rules-regulations/organic/national-list/petitioned.*

[15] The NOSB also considered allowing mineral oil as a dust suppressant in livestock feed, but deferred consideration of this use to a subsequent meeting and did not include this use in its final 2002 recommendation.

Application

Vitamins and trace minerals were added to the National List as feed additives, and electrolytes were added to the National List as a medical treatment when the NOP final rule became effective on October 21, 2002.[16] Organic livestock producers are required to provide livestock with a total feed ration, including pasture and forage, that is sufficient to meet the nutritional requirements of the animal. To provide a total feed ration, livestock producers may use nonsynthetic feed additives, and synthetic feed additives included on the National List in § 205.603. As currently allowed under the regulations, vitamins, trace minerals, and electrolytes may be consumed only as part of the total feed ration. On occasion animals go off feed when their appetites are suppressed. If suppressed for an extended period, feeding a total ration with the required nutrients may not provide adequate amounts of vitamins, minerals, or electrolytes to alleviate any existing nutrient deficiencies. During its deliberation on their recommendation at the 2009 meeting, the NOSB received comments indicating that in livestock production it is common practice to provide off feed (low appetite) animals with injectable nutrients to help restore animal health. The NOSB concurred with this practice and argued in its justification that injectable formulations of vitamins and minerals (including electrolytes) can deliver increased amounts of these nutrients and can be used to quickly alleviate symptoms and reverse declines in livestock health resulting from nutrient deficiency.

This proposed rule would implement a 2009 NOSB recommendation to add formulated (*i.e.,* multiple ingredient products) injectable vitamins, trace minerals, and electrolytes, with or without excipients, to the National List under § 205.603(a).[17] The NOSB determined that an allowance for injectable vitamins, trace minerals, and electrolytes was necessary to rapidly deliver higher amounts of vitamins and minerals to targeted tissues in situations where an animal has higher vitamin and mineral demands. The NOSB also determined that use of these products would be occasional and as-needed. AMS is requesting comments on whether including electrolytes in the proposed listing for injectable vitamins and minerals is needed since electrolytes are currently listed as an allowed medical treatment in § 205.603(a)(8). AMS would interpret the proposed listing to mean that an operation would be allowed to use these substances individually or in combination.

Timeline

Both vitamins and trace minerals were included in § 205.603(d) in the USDA organic regulations (65 FR 13512, December 21, 2000), which became effective on October 21, 2002. Since this original listing, both vitamins and trace minerals were renewed under the 2007 and 2012 sunset review processes as recommended by the NOSB. These recommendations were accepted by the Secretary and processed through final rulemaking effective October 21, 2007 (72 FR 58469) and June 21, 2012 (77 FR 33290).

Electrolytes were included in § 205.603(a) in the original National List in the final rule (65 FR 13512, December 21, 2000), which became effective on October 21, 2002. Since this original listing, electrolytes have been renewed under the 2007 and 2012 sunset review process as recommended by the NOSB. These recommendations were accepted by the Secretary and processed through final rulemaking effective October 21, 2007 (72 FR 58469) and June 21, 2012 (77 FR 33290).

At its May 6, 2009, meeting, the NOSB issued a recommendation to the Secretary to add injectable vitamins, trace minerals and electrolytes to the National. In formulating this recommendation, the NOSB determined that allowing injectable forms of these substances would provide organic livestock producers with the use of injectable vitamins, trace minerals, and electrolytes as nutritive supplements, on an as-needed basis.

This proposed rule would require that injectable vitamins, minerals or electrolytes only be administered or ordered by a licensed veterinarian. Livestock producers would need to keep records that document the need for any use of these materials. Further, producers and certifying agents would need to review the specific formulations intended for use on organic livestock to ensure they comply with the USDA organic regulations.

The NOSB stated in its recommendation that this allowance would provide organic producers with more opportunity to enhance the overall welfare of certified organic livestock. AMS has reviewed and proposes to address this NOSB recommendation through this proposed rule. AMS is proposing to add injectable vitamins, minerals and electrolytes to § 205.603(a) of the National List with the following annotation: formulated injectable supplements of trace minerals per 205.603(d)(2), vitamins per 205.603(d)(3), and electrolytes per 205.603(a)(8), with excipients per 205.603(f), in accordance with FDA and restricted to use by or on the order of a licensed veterinarian.

Parasiticides, Fenbendazole, and Moxidectin

This proposed rule would amend the National List to revise the listing for parasiticides (§ 205.603(a)(17)) and the listings for fenbandazole (§ 205.603(a)(17)(i)) and moxidectin (§ 205.603(a)(17)(iii)). This rule also proposes to amend the livestock health care practice standard in § 205.238(b) to allow the use of parasiticides in organic fiber-bearing animals. Table 14 illustrates the proposed listings.

TABLE 14—PROPOSED RULE ACTION FOR PARASITICIDES

Current rule: § 205.603(a)(17) Parasiticides—Prohibited in slaughter stock, allowed in emergency treatment for dairy and breeder stock when organic system plan-approved preventive management does not prevent infestation. Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for 90 days following treatment. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period for breeding stock.
§ 205.603(a)(17)(i) Fenbendazole (CAS #43210–67–9)—only for use by or on the lawful written order of a licensed veterinarian.
§ 205.603(a)(17)(iii) Moxidectin (CAS #113507–06–5)—for control of internal parasites only.

[16] This final rule established the National Organic Program. It became effective on October 21, 2002. Sunset reviews for the listings for vitamins, minerals, and electrolytes were completed in 2007 (72 FR 58469, October 21, 2007) and 2012 (77 FR 33290, June 21, 2012).

[17] NOSB Recommendation on injectable vitamins and minerals, see *https://www.ams.usda.gov/sites/default/files/media/Injectable%20Vitamins%20and%20Minerals%20Formal%20Rec.pdf.*

TABLE 14—PROPOSED RULE ACTION FOR PARASITICIDES—Continued

Proposed rule action: § 205.603(a)(23) Parasiticides—Prohibited in slaughter stock, allowed in emergency treatment for dairy and breeder stock when organic system plan-approved preventive management does not prevent infestation. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period for breeding stock. Allowed for fiber-bearing animals when used a minimum of 90 days prior to harvesting of fleece or wool that is to be sold, labeled, or represented as organic.
§ 205.603(a)(23)(i) Fenbendazole (CAS #43210–67–9) Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for: 2 days following treatment of cattle; 36 days following treatment of goats, sheep and other dairy species.
§ 205.603(a)(17)(ii). Moxidectin (CAS #113507–06–5) Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for: 2 days following treatment of cattle; 36 days following treatment of goats, sheep and other dairy species.

The USDA organic regulations specify conditions under which parasiticides may be used in organic livestock production (§ 205.238(b)) and identify which parasiticides are allowed (§ 205.603(a)(17)). These conditions include: (1) Emergency treatment for dairy and breeder stock only when preventive measures have failed; (2) a 90-day withdrawal period before milk or milk products from treated animals can be sold as organic; and (3) a prohibition on use in breeder stock during the last third of gestation or during lactation if progeny will be sold as organic. Organic livestock producers are required to use preventive practices as described in § 205.238 before using any parasiticide included on the National List. However, animals in need of medical attention cannot be left untreated in order to retain organic status (§ 205.238(c)(7)).

In April 2016, the NOSB considered amendments to the use restrictions for parasiticides allowed in organic production based on updated information. The NOSB recommended: (1) Removing the 90-day withholding time for milk and milk products and specifying withholding times in the listings for specific parasiticides; and (2) permitting fiber-bearing organic animals to be treated with allowed parasiticides, provided there is a 90-day interval from treatment to harvest of fleece or wool to be sold as organic.[18] The NOSB recommended that the provision for the use of parasiticides in the livestock health care practice standard, § 205.238(b)(2), also be amended to reflect these changes.

The NOSB determined that these modifications would benefit sick animals in emergency situations without impacting the organic integrity of the products. Public comment received by the NOSB requested that the USDA organic regulations allow for animal skin and fleece treated with parasiticides to be sold as organic. The NOSB determined that parasiticide use in fiber-bearing animals should be allowed in organic production if necessary.

In April 2016, the NOSB also considered modifications to the use restrictions for two allowed parasiticides, fenbendazole, and moxidectin. The USDA organic regulations permit the use of fenbendazole only when there is a written order of a licensed veterinarian. The NOSB recommended removing the requirement for the written order of a licensed veterinarian and reducing the 90-day withdrawal period for milk or milk products that will be sold as organic to 2 days for cattle and 36 days for goats, sheep and other dairy species.

The USDA organic regulations permit the use of moxidectin only to control internal parasites and require a 90-day withdrawal period for milk and milk products after use. The NOSB recommended removing that restriction and reducing the 90-day withdrawal time for milk or milk products that will be sold as organic to 2 days for cattle and 36 days for goats, sheep and other dairy species.

In addition, the NOSB recommended allowing the use of parasiticides in organic fiber-bearing animals.

At its April 25–27, 2016 meeting, the NOSB received public comment on the proposals to amend the allowances for parasiticides generally in addition to the allowances for fenbendazole and moxidectin. Based on updated technical reports on parasiticides and public comments, the NOSB recommended the above amendments to the use parameters for parasiticides in organic livestock production.[19]

AMS has reviewed and proposes to address these NOSB recommendations on parasiticides as a category, fenbendazole, and moxidectin through this proposed rule. Consistent with the NOSB recommendations, this proposed rule would amend § 205.238(b) and § 205.603(a)(17) as follows:

- § 205.238(b)(2) will be amended by replacing the 90-day withholding time for milk and milk products with a cross-reference to withholding times specified in § 205.603. In addition, the term ''stock'' will be replaced with ''animal.''
- § 205.238(b) will be amended to add an allowance for parasiticide use in fiber-bearing animals.
- The 90-day withholding time described in § 205.603(a)(17) for milk and milk products following treatment with allowed parasiticides will be deleted.
- The listing for parasiticides in § 205.603(a)(17) will be amended to allow for use in fiber bearing animals with a 90-day withdrawal time from treatment to harvest of wool or fleece.
- The annotation for fenbendazole in § 205.603(a)(17)(i) will be amended to delete the requirement for use by or on the lawful written order of a licensed veterinarian, and modified withholding times for milk and milk products will be added.
- The annotation for moxidectin in § 205.603(a)(17)(iii) will be amended to delete the requirement for use by or on the lawful written order of a licensed veterinarian, and modified withholding times for milk and milk products will be added.

Ivermectin

This proposed rule would remove ivermectin from § 205.603(a) as an allowed parasiticide for use in organic livestock production. Table 15 illustrates the proposed listing.

[18] The April 2016 NOSB recommendation is available here: *https://www.ams.usda.gov/sites/default/files/media/LS%20Parasiticides%20NOP.pdf.*

[19] The 2015 technical evaluation report on parasiticides is available here: *https://www.ams.usda.gov/sites/default/files/media/Para%20Technical%20Evaluation%20Report%20%282015%29.pdf.*

TABLE 15—PROPOSED RULE ACTION FOR IVERMECTIN

Current rule: § 205.603(a)(17) (ii) Ivermectin (CAS #70288–86–7).
Proposed rule action: Remove § 205.603(a)(17) (ii) Ivermectin (CAS #70288–86–7).

Ivermectin has been on the National List since October 21, 2002. On June 26, 2016, AMS received a petition to remove ivermectin [20] from the National List. The petition explained that ivermectin does not meet the OFPA criteria for the National List because: (1) The availability of two other synthetic parasiticides which are allowed in organic production as emergency treatment when preventive measures have failed; (2) environmental toxicity, more specifically, that ivermectin residues adversely affect soil organisms and dung beetles that support healthy pastures and rangelands. Further, the petition stated that the NOSB received new information during the 2017 sunset review of ivermectin indicating that this substance is not always effective.

At its November 16–18, 2016, meeting in St. Louis, Missouri, the NOSB reviewed the petition information, parasiticide technical report, and public comments. The NOSB recommended removing ivermectin from § 205.603(a) of the National List.

AMS has reviewed and proposes to address this NOSB recommendation through this proposed rule. The removal of ivermectin would leave organic livestock producers with two parasiticides for emergency treatment, fenbendazole and moxidectin. Based on public comments during the NOSB deliberations on parasiticides, AMS understands that there is support among organic livestock producers to remove ivermectin if AMS concurrently removes the requirement for a veterinarian's order to administer fenbendazole. As discussed above, this action proposes to remove that requirement and to reduce the withdrawal times following the use of fenbendazole or moxidectin. Consistent with the NOSB recommendation, this proposed rule would amend § 205.603(a)(17) by removing Ivermectin (CAS #70288–86–7).

Propylene Glycol

This proposed rule would add propylene glycol to § 205.603(a) of the National List for use in organic livestock production. The NOSB originally recommended that this substance be included in paragraph (a) of § 205.603 as a medical treatment in livestock production. Table 16 provides the proposed listing.

TABLE 16—PROPOSED RULE ACTION FOR PROPYLENE GLYCOL

Current rule: N/A.
Proposed rule action: § 205.603(a). Propylene Glycol—only for treatment of ketosis in ruminants.

Applications

Propylene glycol is a viscous, colorless, nearly odorless, substance with a slightly sweet taste, and when mixed with water, it lowers the freezing point of water. Propylene glycol is chemically categorized as a diol (a compound containing two hydroxyl groups) and is miscible with many solvents, including water. It is stable substance under most conditions of use and storage, and it decomposes in water and soil within seven days.

Propylene glycol is noncorrosive, and has a low volatility and low toxicity level, although toxicity varies with animal species as cats show more toxic susceptibility to propylene glycol compared to other animals.

Propylene glycol can be manufactured from a variety of sources and procedures. Food-grade propylene glycol is produced from propylene oxide using either a non-catalytic high temperature process or a lower temperature catalytic process. Propylene glycol can also be manufactured from heating glycerol (biodiesel byproduct) with sodium hydroxide and distillation.

Propylene glycol is considered to be GRAS and is a direct food substance for human food listed at 21 CFR 184.1666. As a food additive, it is used as a humectant (moisture retention), solvent, and preservative. Propylene glycol is also used as a solvent in many pharmaceuticals in oral, topical, or injectable formulations, including those where the active ingredient is insoluble in water.

When present in surface water, propylene glycol can exert a high level of biochemical oxygen demand during degradation. This high demand could adversely affect aquatic species by consuming oxygen needed by aquatic organisms. Similarly, when microbial organisms decompose propylene glycol in surface water, significant amounts of dissolved oxygen are consumed. Low dissolved oxygen levels in surface water may reduce the amount of suitable aquatic habitat.

Timeline

This proposed rule would implement a September 2002 NOSB recommendation to add propylene glycol (CAS # 57–55–6) to section 205.603(a) of the National List. At this public meeting the NOSB determined that propylene glycol should be added to § 205.603(a) as a medical treatment in organic livestock production. Propylene glycol was petitioned to the NOSB for addition onto the National List as a medical treatment for ketosis (elevated blood ketones) in ruminants. Primary ketosis (or acetonaemia) of dairy cows is a metabolic disorder. Ketosis or pregnancy toxaemia has been observed in beef cows near parturition. The NOSB recommended restricting the use of propylene glycol to treatment of acute ketosis in ruminants.

During early lactation, the energy intake from feed may be insufficient to meet the energy output in milk, causing the animal to go into negative energy balance. To satisfy the nutrient requirements of milk production, dairy cows may draw on two sources of nutrients, food intake and body reserves. When in negative energy balance, the cow will metabolize fat reserves for energy, producing ketones. When ketone production exceeds ketone use by muscle and other animal tissue, ketosis can occur. Ketosis is an important clinical and sub-clinical disease, as several metabolic disorders

[20] Access to Ivermentin petition: *https://www.ams.usda.gov/rules-regulations/organic/national-list/petitioned.*

and diseases that are common in the periparturient (near calving) and early lactation periods have been linked to ketosis, including milk fever, retained foetal membranes, and displaced abomasums.

The NOSB has determined that the proposed use of propylene glycol in organic livestock production fulfills the OFPA material evaluation criteria. AMS has reviewed and proposes to address the NOSB recommendation through this proposed rule. Therefore, AMS is proposing to add propylene glycol to § 205.603(a).

Sodium Chlorite, Acidified

This proposed rule would add two listings for acidified sodium chlorite for use as a teat dip in organic livestock (dairy) production (§ 205.603(a) and § 205.603(b)). In 2015, the NOSB recommended an allowance for this substance as a pre- and post-milking teat dip treatment and cited supportive public comments from livestock producers and a lower environmental impact than other substances allowed for this use. Table 17 illustrates the proposed changes to this section.

TABLE 17—PROPOSED RULE ACTION FOR ACIDIFIED SODIUM CHLORITE

Current rule: N/A.
Proposed rule action: § 205.603(a) and § 205.603(b) Sodium Chlorite, Acidified—allowed for use on organic livestock as a teat dip treatment.

Applications

Acidified sodium chlorite is produced from mixing an aqueous solution of sodium chlorite with a food grade acid, such as citric acid. Acidified sodium chlorite can also be produced by mixing any FDA GRAS acid with an aqueous solution of sodium chlorite. The FDA has approved acidified sodium chlorite solutions as antimicrobial agents with proscribed sodium chlorite concentrations and pH values for several food product applications.

Acidified sodium chloride is commonly used during livestock production as a standard practice for teat dips in order to prevent mastitis in dairy livestock. Mastitis is the inflammation of udder tissue resulting from bacterial infection. Teat dips are substances used in dairy livestock to control mastitis and reduce contamination of mastitis causing bacteria.

Mastitis can be controlled by practices such as ensuring adequate nutrition, practicing good hygiene pre- and post-milking, and culling chronically mastitis-infected cows. Livestock producers can also use mastitis prevention practices to decrease the incidence of transmission, such as ensuring that cows have clean, dry bedding and carrying out routine sanitation of milking machines between milkings. A mastitis prevention program usually includes applying a pre-milking and a post-milking teat dip. After milking, the teat canal may remain open for several minutes. A post-milking dip is used as a disinfectant and a barrier between the open teat and the bacteria in the air.

Timeline

This proposed rule would implement an April 2015 NOSB recommendation to add acidified sodium chlorite to sections 205.603(a) and (b) of the National List [21] for use as a pre- and post-milking teat dip treatment. The NOSB received a petition [22] in April 2012 to add acidified sodium chlorite to section 205.603(a) and (b) for use as a teat dip in organic livestock production. At its April 2014 meeting, the NOSB tabled a recommendation not to approve acidified sodium chlorite for use as a teat dip because several substances on the National List were already approved as teat dips. One factor in delaying a recommendation was a lack of public comments from organic livestock producers supporting a need for acidified sodium chlorite for this use.

During the April 2015 public meeting, the NOSB reviewed the 2013 technical report [23] on acidified sodium chlorite that included an assessment on the effectiveness of acidified sodium chlorite as a teat dip indicating that it may be as effective as iodine solution teat dips. The NOSB considered information indicating that alternative practices to teat dipping or udder washing did not prevent mastitis, and may actually increase udder infection. The NOSB also received comments from livestock producers supporting the use of acidified sodium chlorite as a teat dip in organic livestock production. Further, the NOSB determined that acidified sodium chlorite has comparatively lower environmental impacts than other teat dip substances that are currently on the National List. In its recommendation, the NOSB stated that preventive health care is an essential component of organic production and that clean animals and clean milking parlors are paramount for dairy livestock production. Therefore, the NOSB determined that acidified sodium chlorite for pre- and post-milking teat dipping is an important tool in preventing mastitis.

In summary, based on alignment with OFPA evaluation criteria for National List substances, supportive comments from livestock producers on the need for acidified sodium chlorite, and information regarding low environmental impacts, the NOSB recommended allowing acidified sodium chlorite for use as a teat dip. AMS has reviewed and proposes to address the NOSB recommendation through this proposed rule. Therefore, AMS is proposing to add acidified sodium chlorite to sections 205.603(a) and (b) of the National List with the following annotation: Allowed for use on organic livestock as a pre and post teat dip treatment.

Xylazine

This proposed rule would amend the current listing for xylazine in § 205.603(a) by removing the limitation on use of this substances to ''*The existence of an emergency.*'' Xylazine is used by veterinarians as a means for sedation of animals in both emergency and non-emergency procedures. Therefore, the NOSB recommended omitting the emergency condition restriction because it is overly restrictive for a substance that meets all OFPA evaluation criteria for National List substances. This proposed rule would not affect the provisions for the use of xylazine in the USDA organic regulations that require the written order of a licensed veterinarian and withdrawal periods for slaughter stock

[21] Acidified sodium chlorite was originally recommended for addition onto the National List as a microbial control substance for organic handing at the NOSB's May 2009 meeting. On March 15, 2012, acidified sodium chlorite was added onto the National List in § 205.605(b) when final rule 77 FR 8089, published on February 14, 2012, became effective.

[22] Petition for acidified sodium chlorite, see *https://www.ams.usda.gov/sites/default/files/media/S%20Chlorite%20Acidified.pdf.*

[23] Technical report on acidified sodium chlorite, see *https://www.ams.usda.gov/sites/default/files/media/S%20Chlorite%20A2%20report.pdf.*

and dairy animals. Table 18 illustrates the proposed changes to this section.

TABLE 18—PROPOSED RULE ACTION FOR XYLAZINE

Current rule: § 205.603(a)(23) Xylazine—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR part 205, the NOP requires: (i) Use by or on the lawful written order of a licensed veterinarian; (ii) The existence of an emergency; and (iii) A meat withdrawal period of at least 8 days after administering to livestock intended for slaughter; and a milk discard period of at least 4 days after administering to dairy animals.
Proposed rule action: § 205.603(a) Xylazine—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR part 205, the NOP requires: (i) Use by or on the lawful written order of a licensed veterinarian; (ii) A meat withdrawal period of at least 8 days after administering to livestock intended for slaughter; and a milk discard period of at least 4 days after administering to dairy animals.

Applications

Xylazine is synthesized by reacting 2,6-dimethylphenylisothiocyanate with 3-amino-1-propanol in a polar solvent (ether) to form a thiourea. Concentrated hydrochloric acid is added after the solvent is removed. Water is added to the cooled mixture which is then filtered, and the filtrate is made basic to form a precipitate that is recrystallized as xylazine.

Xylazine is used as a sedative, analgesic, and muscle relaxant in veterinary medicine. As a medical treatment, it can be administered intravenously, intramuscularly, subcutaneously, or orally, usually as a water based injectable solution. Xylazine can also be found as a white crystalline powder. Xylazine sedative properties are due to its depressiant mode of action on nervous system synaptic receptors. Sedation of animals is necessary for both planned medical procedures and emergency procedures to prevent the pain and suffering of animals as well as injury to the veterinarians performing the procedures.

Timeline

This proposed rule would implement a November 2009 NOSB recommendation to amend the allowance for xylazine as listed in § 205.603(a) of the National List.[24] At this meeting, the NOSB determined that the restriction limiting xylazine only to emergency use should be lifted to allow use for sedation of animals when necessary to perform non-emergency health care procedures in organic livestock. The NOSB determined that the proposed change in the xylazine annotation would allow organic livestock producers to improve their ability to establish and maintain preventive livestock health care practices since there are no alternatives to xylazine on the National List or nonsynthetic substances that provide sedative properties.

The NOSB recommended adding xylazine to the National List in September 2002. Xylazine was petitioned for use as a sedative and analgesic during short surgical procedures. Xylazine was added to the National List in 2007, with the use conditions stated in Table 6.[25] The allowance for xylazine was renewed via sunset review in 2012 (77 FR 33290, June 6, 2012).

During its initial xylazine deliberation, the NOSB considered limiting xylazine use to ''once in a lifetime'' applications. The NOSB's decision to recommend an allowance upon ''the existence of an emergency'' was the result of a compromise between two objectives, avoiding significant interference with a veterinarian's judgment and preventing routine use of xylazine. The NOSB described an emergency as an unplanned event requiring immediate medical attention. During its 2009 deliberation, the NOSB received information indicating that xylazine is used more frequently as a sedative for non-emergencies and less often for actual emergencies.

The NOSB has determined that the use of xylazine in organic livestock production for non-emergency medical procedures meets the requirements of the OFPA evaluation criteria for National List substances. AMS has reviewed and proposes to address the NOSB recommendation through this proposed rule. Therefore, AMS is proposing to amend the current listing of xylazine in § 205.603 with the following annotation: Federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR part 205, the NOP requires: (i) Use by or on the lawful written order of a licensed veterinarian; and (ii) A meat withdrawal period of at least 8 days after administering to livestock intended for slaughter; and a milk discard period of at least four days after administering to dairy animals.

Zinc Sulfate

This proposed rule would add zinc sulfate to the National List for use in organic livestock production. Table 19 illustrates the changes between the current rule and the proposed rule.

TABLE 19—PROPOSED RULE ACTION FOR ZINC SULFATE

Current rule: N/A.
Proposed rule action: § 205.603(a). Zinc Sulfate—for use in hoof and foot treatments only.

[24] 2009 NOSB Final Recommendation on xylazine, see *https://www.ams.usda.gov/sites/default/files/media/NOP%20Final%20Rec%20;Xylazine%20Technical%20Correction.pdf.*

[25] 2002 Technical Advisory Report on xylazine, see *https://www.ams.usda.gov/sites/default/files/media/Xylazine%20TR.pdf.*

Applications

Zinc sulfate is a white, odorless powder that is soluble in water and alcohol (nonhydrates). The hydrates of zinc sulfate are the primary forms used for commercial applications. Agricultural applications of zinc sulfate include as a zinc supplement in animal feeds since zinc is an essential element in several biological processes. It is also used in fertilizers and agricultural sprays (mold or bacterial inhibitors).

Zinc sulfate is manufactured from mined zinc ore that is crushed and ground. The ground ore is heated to produce a zinc ash that is subsequently mixed with sulfuric acid. The zinc dissolves in the sulfuric acid to yield a zinc sulfate solution that is further processed to yield a zinc sulfate powder.

The 2015 zinc sulfate technical report [26] developed for the NOSB states that zinc sulfate can stimulate an immune response to microbes that may cause foot rot to develop. The technical report also indicates that elevated zinc levels are toxic to some bacteria. Research cited in the technical report indicates that zinc sulfate, used alone or in combination with excipients, is effective in controlling foot rot. Zinc sulfate is not currently FDA approved as a treatment for controlling foot rot or digital dermatitis as described in the zinc sulfate petition submitted to the NOSB.[27]

Zinc sulfate is allowed as a GRAS food additive for human food under FDA regulation 21 CFR 182.8997. Under the USDA organic regulations, zinc sulfate is on the National List as a synthetic trace mineral in organic livestock feed under § 205.603(d)(2).

As proposed, zinc sulfate would be used in a footbath for control of foot rot in livestock, primarily dairy cattle, sheep and goats. Foot rot, as the name indicates, is a disease that rots away the foot of the animal, specifically the area between the two toes of the affected animal. Foot rot is an infection of anaerobic bacteria that are common in the environments where cattle, sheep, and goats live. Temperature and moisture are factors in the transmission and invasion of these bacteria. More foot rot infections are likely with above average rainfall, elevated temperatures, and lush pasture growth. Infection may occur directly from the soil to the animals, usually though a lesion in the skin. If left untreated, foot rot can cause lameness in sheep, goats, and cattle and an infected animal can infect a whole herd.

Once foot rot is detected, the animal is usually isolated from the herd and treated with antibiotics, or antibacterial treatments such as iodine or zinc sulfate. Foot-bathing solutions with ethanol, copper sulfate, formalin, or zinc sulfate are used when a large number of animals requires treatment. Ethanol, copper sulfate, and iodine are on the National List in § 205.603, each with varying degrees of efficacy (therapeutic effect).

Timeline

This proposed rule would implement an April 2015 NOSB recommendation to add zinc sulfate (CAS # 7733–02–0) to § 205.603 of the National List. At its public meeting, the NOSB determined that zinc sulfate should be allowed as a medical treatment (§ 205.603(a)) and as a topical treatment, local parasiticide, or local anesthetic (§ 205.603(b)) in organic livestock production, specifically for use in hoof and foot treatments only. As proposed, zinc sulfate would be used in a footbath for control of foot rot in livestock, primarily dairy cattle, sheep and goats.

In its recommendation, the NOSB indicated that copper sulfate and zinc sulfate are the two most accepted foot rot treatments, with similar efficacy. The NOSB considered that there are alternatives to zinc sulfate for foot rot treatment, but noted concerns about the efficacy of other materials and that some are not permitted for use in organic livestock. The NOSB determined that zinc sulfate provides organic livestock producers with an additional tool to treat foot disease, aids the welfare of the animals, and is preferable to the use of copper sulfate because of the buildup of potentially toxic persistent copper in the soil. The NOSB also noted that zinc has the potential to accumulate in soils, but persistence depends on several factors, and excess zinc can be reduced in soil by planting crops such as sunflower or canola.

At its April 2015 public meeting, the NOSB voted to expand the allowed use of zinc sulfate as a treatment for foot disease in livestock for the purpose of ensuring the welfare of animals. The NOSB determined that the availability of zinc sulfate as a foot treatment would reduce the use of copper sulfate for treatment of foot disease, which may contribute to lower copper build up in soils. The NOSB considers zinc sulfate to be a more benign substance when compared to copper sulfate. The NOSB has determined that the use of zinc sulfate in organic livestock production as a foot treatment meets the requirements of the OFPA material evaluation criteria for organic production. In formulating its recommendation, the NOSB determined that use of zinc sulfate in organic livestock production promotes animal welfare and is preferable to the use of copper sulfate.

AMS has reviewed and proposes to address the NOSB recommendation through this proposed rule. Therefore, AMS is proposing to add zinc sulfate to § 205.603(a) with the following annotation: for use in hoof and foot treatments only.

Lidocaine and Procaine

This proposed rule would amend the current listing of lidocaine in § 205.603(b), Synthetic substances allowed for use in organic livestock production. Table 20 illustrates the proposed listing.

TABLE 20—PROPOSED RULE ACTION FOR LIDOCAINE AND PROCAINE

Current rule:
§ 205.603(b)(4) Lidocaine—as a local anesthetic. Use requires a withdrawal period of 90 days after administering to livestock intended for slaughter and 7 days after administering to dairy animals.
§ 205.603(b)(7) Procaine—as a local anesthetic. Use requires a withdrawal period of 90 days after administering to livestock intended for slaughter and 7 days after administering to dairy animals.
Proposed rule action:
§ 205.603(b)(4) Lidocaine—as a local anesthetic. Use requires a withdrawal period of 8 days after administering to livestock intended for slaughter and 6 days after administering to dairy animals.
§ 205.603(b)(7) Procaine—as a local anesthetic. Use requires a withdrawal period of 8 days after administering to livestock intended for slaughter and 6 days after administering to dairy animals.

[26] *https://www.ams.;usda.gov/rules-regulations/organic/national-list/petitioned.*

[27] *https://www.ams.usda.gov/rules-regulations/organic/national-list/petitioned.*

This proposed rule would amend the allowances for lidocaine and procaine in § 205.603(b).

Lidocaine [28] and procaine [29] have been on the National List since October, 2002, as local anesthetics to reduce pain after de-budding horns or minor livestock surgery.[30] The allowance requires withholding periods for livestock treated with either substance: 90 days for livestock intended for slaughter and 7 days for dairy animals.

Based on new information and public comments received during the 2015 sunset review, the NOSB determined that the withholding times should be reduced. The NOSB explained that lengthy withholding times could result in animals not being timely treated, or not treated at all. The NOSB also noted that in 2007 it agreed that withholding times should be double the U.S. Food and Drug Administration (FDA) withholding times.[31] For lidocaine, FDA recommended withdrawal intervals for cattle are 1 day for meat and 24 hours for milk following an epidural administration, or 4 days for meat and 72 hours for milk following subcutaneous administration. FDA provides information on procaine only as it relates to procaine with an antibiotic as part of delivery and thus it would not be used in organic production. The NOSB determined that withholding periods following the use of lidocaine or procaine should be revised from 90 days to 8 days for slaughter stock and from 7 days to 6 days for dairy animals.

During a public meeting on October 26–29, 2015, the NOSB reviewed public comments on the proposal to amend lidocaine and procaine on the National List.[32] Based on new information received in technical reports and public comments, the NOSB determined that reducing the withdrawal times for lidocaine and procaine supports animal health and is consistent with prior NOSB decisions regarding withdrawal times.

AMS has reviewed and proposes to address the NOSB recommendation on lidocaine and procaine through this proposed rule. Consistent with the NOSB recommendation, AMS proposes to amend section 205.603(b) of the National List to reduce the withholding periods for lidocaine and procaine from 90 days to 8 days for slaughter stock and from 7 days to 6 days for milk.

Methionine

This proposed rule would amend the allowance for methionine in § 205.603(d) by requiring that maximum methionine levels in feed be calculated as averages over the lifespan of the birds rather than a constant percentage of the feed. The NOSB considered reports of methionine deficiency in some organic poultry flocks. Alternatives to synthetic methionine have yet to be developed for commercial use. In consideration of public comments, NOSB input, and technical reports, AMS proposes to continue to allow methionine in restricted amounts. The proposed amendment to the methionine annotation includes limits on the amount that may be used over the life of the flock, as well as breed-specific limits. Table 21 illustrates the changes proposed change for this substance.

TABLE 21—PROPOSED RULE ACTION FOR METHIONINE

Current rule: § 205.603(d)(1) DL-Methionine, DL-Methionine—hydroxy analog, and DL-Methionine—hydroxy analog calcium (CAS Numbers 59–51–8, 583–91–5, 4857–44–7, and 922–50–9)—for use only in organic poultry production at the following maximum levels of synthetic methionine per ton of feed: Laying and broiler chickens—2 pounds; turkeys and all other poultry—3 pounds.
Proposed rule action: § 205.603(d) DL-Methionine, DL-Methionine—hydroxy analog, and DL-Methionine—hydroxy analog calcium (CAS Numbers 59–51–8, 583–91–5, 4857–44–7, and 922–50–9)—for use only in organic poultry production at the following pounds of synthetic 100 percent methionine per ton of feed in the diet, averaged over the life of the flock: Laying chickens—2 pounds; Broiler chickens—2.5 pounds; Turkeys and all other poultry—3 pounds.

Applications

Methionine is a sulfur containing amino acid that is a white solid or white crystalline powder, or may be in liquid form when produced as a hydroxyl analog. The 2011 methionine technical report developed for the NOSB states that methionine is soluble in water, methanol, alkali solutions, and mineral acids. Methionine is stable under normal temperature and pressure but is susceptible to strong oxidizing agents. Methionine can be produced or extracted from nonsynthetic sources or manufactured through a synthetic process. Nonsynthetic methionine is produced from microbial fermentation and extraction or by hydrolyzing protein. Amino acids can also be produced by bacterial fermentation. However, the technical report prepared for the NOSB in 2011 states that methionine yields from bacterial fermentation are low and not cost effective. According to a 2011 petition submitted to AMS, the most economical chemical method involves combining reagents acrolein, methyl mercaptan, hydrogen cyanide, and ammonia carbonate to yield an intermediary substance that is saponified with potassium carbonate, which results in high yields of methionine.

Methionine can be provided either as part of an intact protein or as an amino acid that is added to a poultry diet. As a single ingredient animal feed supplement, it is regulated by the Food and Drug Administration (21 CFR 582.5475). In the 2011 technical report, methionine is described as the first limiting amino acid for the synthesis of protein in poultry. It is considered to be an essential amino acid for poultry production because it is required for cell tissue growth and metabolism, but it cannot be synthesized by poultry and must be supplied in the diet.

To meet requirements for cell growth and function, poultry must obtain adequate methionine from agricultural feed ingredients or receive methionine to the ration through supplementation (addition). In the 2011 NOSB methionine technical report, poultry rations composed of corn and soybean meal may not provide adequate non-synthetic methionine to prevent deficiency symptoms.

To compensate for low methionine content in corn–soybean meal diets, poultry producers may use various production practices to meet methionine requirements. Such production practices include increasing intake of the existing diet (ration); increasing the protein content of a ration by either increasing soybean meal content or by adding other protein feed ingredients that contain higher

[28] *https://www.ams.usda.gov/rules-regulations/organic/national-list/l.*

[29] *https://www.ams.usda.gov/rules-regulations/organic/national-list/p.*

[30] *https://www.ams.usda.gov/sites/default/files/media/LS%20Lidocaine_Procaine%20NOP.pdf.*

[31] *https://www.ams.usda.gov/sites/default/files/media/LS%20Lidocaine_Procaine%20NOP.pdf.*

[32] *https://www.ams.usda.gov/rules-regulations/organic/nosb/recommendations/fall2015.*

concentrations of methionine; or by adding synthetic methionine to the ration. Each of these practices presents challenges in ensuring that sufficient methionine is available to meet requirements for the various stages of poultry production.

Young birds, especially those less than three weeks in age, may be physically unable to ingest the additional ration needed to meet minimum methionine levels required at that production stage. These few weeks can represent a significant portion of the production cycle where bird growth may be restricted, resulting in lower production or even increased bird death. When implemented, this practice may not provide adequate methionine to the birds during the early phase of the production cycle. For example, young broilers physically that are unable to increase feed intake for the initial three weeks out of seven weeks of production may not obtain adequate methionine during their production cycle and will have less growth. This practice may also result in reduced feed efficiency and an increase in feed costs. Conversely, increasing feed intake to meet methionine needs could also result in overfeeding of other nutrients and lead to subsequent livestock health problems.

An alternative to increasing feed intake is to increase the protein content of the diet by adding more soybean meal to the corn–soybean meal ration. Since animals consume feed to meet their energy requirements, adding additional protein may be more effective in meeting poultry methionine requirements when compared to only increasing feed intake. However, increasing protein content in a feed may result in excessive amino acids—the amino acids remaining after methionine is no longer available for protein synthesis—to be used in energy metabolism. When used as an energy source, amino acids are deaminated and the resulting nitrogen is excreted as uric acid. Continued feeding of a higher protein, low methionine ration may result in excessive nitrogen being excreted as uric acid and, subsequently, higher ammonia levels within the bird house.

Increasing methionine content in the diet can be achieved through the use of alternative protein feed sources that can be added to the standard soybean–corn poultry diet. Protein feed sources known to have a high methionine content include blood meal, meat meal, fish meal, crab meal, and corn gluten meal. Organic producers, however, have limited options to use these because of: (1) A lack of commercially available nonsynthetic or organic sources of methionine, such as organic corn gluten meal, and (2) the prohibition on feeding slaughter by-products derived from mammalian or avian sources (§ 205.237(b)(5)), which prohibits feeding blood meal or meat meal to organic poultry. Further, the use of fish meal and crab meal in poultry diets may be limited by the potential for off flavors in the poultry products, especially eggs. For this and other reasons, organic producers have petitioned the NOSB to allow the use synthetic sources of methionine for supplementation.

The NOSB has acknowledged that certain production practices support the need for synthetic methionine supplementation, but stated that methionine obtained from outdoor access or pasturing alone may not be adequate to offset the need for methionine supplementation. The NOSB also considered that the breed of bird can affect methionine needs.

Timeline

This proposed rule would implement an April 2015 NOSB recommendation to amend the allowance for methionine as listed in § 205.603(d)(1) of the National List.[33] At this meeting, the NOSB determined that the annotation should be amended to allow organic poultry producers to adjust the concentration of synthetic methionine in poultry feed rations to meet the nutritional requirements of the birds at different life stages, while simultaneously limiting the total amount of synthetic methionine used in a poultry ration that is fed during the lifetime of the flock. Table 21 shows the comparison of the current and proposed allowances for synthetic methionine. At this meeting the NOSB considered information that the current restriction on methionine could result in methionine deficiency in poultry flocks. In its recommendation, the NOSB noted that a methionine deficiency may suppress immune system development and cause poor feathering, feather pecking, cannibalism, and increased bird death.

The NOSB also received comments from poultry producers indicating that the use of synthetic methionine is necessary because alternatives to synthetic methionine are not commercially available or are prohibited by § 205.237(b)(5), which states that the producer of an organic operation must not feed mammalian or poultry slaughter by-products to organic mammalian livestock or poultry.

In 2001, the NOSB recommended adding methionine to the National List as a feed supplement for use in organic poultry production. Methionine was added to § 205.603 of the National List on October 31, 2003, with the annotation ''for use in organic poultry production until October 21, 2005 (68 FR 61987).'' When the NOSB approved its 2001 recommendation to allow methionine, an expiration date was inserted into the annotation to indicate that synthetic methionine would be phased out when non-synthetic alternatives to synthetic methionine were developed and were commercially available. Based on multiple NOSB recommendations, AMS has amended section 205.603 of the National List to allow methionine as a synthetic substance for use in organic poultry production several times. A full description of the NOSB recommendations and rulemaking related to synthetic methionine for organic poultry through 2012 is available in a Final Rule, September 19, 2012 (77 FR 57985).

Between 2010 and 2012, AMS completed two rules that revised the allowance for synthetic methionine by specifying maximum levels as recommended by the NOSB.[34] The NOSB conveyed that the intent of this recommendation was to balance various interests including: (1) Providing for the basic maintenance requirements of organic poultry; (2) satisfying consumer preference to reduce the use of synthetic methionine in organic poultry production; and (3) motivating the organic poultry industry to continue the pursuit of commercially sufficient sources of allowable natural sources of methionine. The two-part April 2010 NOSB recommendation specified:

- Allow synthetic methionine in organic poultry production until October 1, 2012, at the following maximum levels per ton of feed: Laying chickens—4 pounds; broiler chickens—5 pounds; and turkey and all other poultry—6 pounds. This recommendation was implemented through a final rule published on March 14, 2011 (76 FR 13501).
- After October 1, 2012, reduce the maximum levels of synthetic methionine allowed in organic poultry feed to: laying and broiler chickens—2 pounds; turkeys and all other poultry—3 pounds. This recommendation was implemented through a final rule

[33] *https://www.ams.usda.gov/sites/default/files/media/LS%20MET%20Final%20Rec.pdf.*

[34] A detailed discussion of this part of the NOSB recommendation is available in the proposed rule that was published in the **Federal Register** on February 6, 2012 (77 FR 5717).

published on September 19, 2012 (77 FR 57985).

In 2011, a group of organic poultry producers resubmitted a petition to revise the maximum rates of synthetic methionine as averages per ton of feed over the life of the bird, rather than as a maximum quantity (pounds) per ton of feed.

At the April 2015 meeting, the NOSB considered how the current restriction on methionine, a constant maximum per ton of feed, was impacting organic poultry and described this in its recommendation. The recommendation explained that organic poultry producers have been feeding additional levels of protein to provide sufficient methionine because the maximum allowance is inadequate for certain growth stages. The excess amino acids from the protein are excreted in urine, which causes ammonia levels to rise indoors during winter. The elevated ammonia levels may cause blisters on birds' feet. The recommendation noted reports from producers of increased feather pecking, which is a symptom of a methionine deficiency. Feather pecking may lead to cannibalism, agitation, nervousness, and other harmful behaviors.

The NOSB reasoned that providing flexibility for producers to adjust methionine supplementation based on the nutritional needs of the birds at specific stages of production could have positive impacts on animal welfare. In effect, the NOSB predicted that overall methionine rates could be lower as supplementation levels would be matched with an average rate and not added at a maximum rate. Further, the NOSB explained that maintaining limitations on the use of synthetic methionine would preserve the incentive to develop viable nonsynthetic alternatives.

Therefore, AMS is proposing to amend the current listing of methionine in § 205.603 with the following annotation: DL- Methionine, DL-Methionine—hydroxy analog, and DL-Methionine—hydroxy analog calcium (CAS Numbers 59–51–8, 583–91–5, 4857–44–7, and 922–50–9)—for use only in organic poultry production at the following pounds of synthetic 100 percent methionine per ton of feed in the diet, averaged over the life of the flock: Laying chickens—2 pounds; Broiler chickens—2.5 pounds; Turkeys and all other poultry—3 pounds.

Excipients

This proposed rule would further clarify the allowance for excipients in animal drugs to treat organic livestock by adding a provision that the excipient must be approved by the USDA Animal and Plant Health Inspection Service (APHIS) for use in veterinary biologics. The proposed amendment, based on a 2009 NOSB recommendation, would minimize the variation in certifying agents' interpretation of excipients and ensure consistent enforcement. Table 22 illustrates the changes between the current and proposed rule.

TABLE 22—PROPOSED RULE ACTION FOR EXCIPIENTS

Current rule: § 205.603(f) Excipients—only for use in the manufacture of drugs used to treat organic livestock when the excipient is: Identified by the FDA as Generally Recognized As Safe; Approved by the FDA as a food additive; or Included in the FDA review and approval of a New Animal Drug Application or New Drug Application.

Proposed rule action: § 205.603(f) Excipients—only for use in the manufacture of drugs and biologics used to treat organic livestock when the excipient is:

(1) Identified by the FDA as Generally Recognized As Safe;
(2) Approved by the FDA as a food additive;
(3) Included in the FDA review and approval of a New Animal Drug Application or New Drug Application; or
(4) Approved by APHIS for use in veterinary biologics.

Applications

Under the USDA organic regulations, excipients are defined at § 205.2 as ''any ingredients that are intentionally added to livestock medications but do not exert therapeutic or diagnostic effects at the intended dosage, although they may act to improve product delivery (*e.g.,* enhancing absorption or controlling release of the drug substance). Examples of such ingredients include fillers, extenders, diluents, wetting agents, solvents, emulsifiers, preservatives, flavors, absorption enhancers, sustained-release matrices, and coloring agents.''

Most animal medications are regulated under the Federal Food Drug and Cosmetic Act, as implemented by FDA. Biologics (*e.g.,* vaccines, bacterins, antisera, diagnostic kits and other products of biological origin) are regulated by APHIS under the Virus-Serum-Toxin Act (21 U.S.C. 151–159).

Timeline

This proposed rule would implement a recommendation approved by the NOSB at its November 5, 2009 meeting to amend the allowance for excipients as listed in § 205.603(f) of the National List.[35] At its November 2009 meeting, the NOSB determined that the annotation required amending to clarify the use of excipients in formulated livestock products and to minimize variation in certifying agent interpretation of excipient use.

The allowance for excipients was added to the National List on December 12, 2007 (72 FR 70479). The NOSB renewed excipients under the 2012 Sunset review process (77 FR 33290, June 6, 2012). This listing specified criteria for excipients for use in organic livestock production. These criteria pertained to the regulatory status of the substances under FDA authority, but the existing listing for excipients does not include an allowance for excipients approved by APHIS for use in veterinary biologics.

[35] NOSB Technical Report on excipients, see *https://www.ams.usda.gov/sites/default/files/media/NOP%20Final%20Rec%20Excipients%20Technical%20Correction.pdf.*

Based on the consideration of National List petitions to allow the use of certain active ingredients in animal drugs, the NOSB observed that verifying the compliance status of excipients in therapeutic and diagnostic products and other formulated livestock products is burdensome and unclear for organic farmers and certifying agents. For example, federal regulations do not require excipients used in therapeutic and diagnostic products to appear on product ingredient labels. In addition, the identity of excipients may not be disclosed when product formulations are held as confidential business information.

Therefore, AMS is proposing to amend the current listing of excipients in § 205.603 with the following annotation: Only for use in the manufacture of drugs and biologics used to treat organic livestock when the excipient is: (1) Identified by the FDA as Generally Recognized As Safe; (2) Approved by the FDA as a food additive; (3) Included in the FDA review and approval of a New Animal Drug

Application or New Drug Application; or (4) Approved by APHIS for use in veterinary biologics.

§ 205.605 Nonagricultural (Nonorganic) Substances Allowed as Ingredients in or on Processed Products Labeled as ''Organic'' or ''Made With Organic (Specified Ingredients or Food Group(s))''

The proposed rule would add the following substances to the National List in paragraph § 205.605 for use in organic handling: Hypochlorous acid, potassium lactate, and sodium lactate. This proposed rule would also amend the allowances for the following substances currently allowed in organic handling: Alginic acid, flavors, carnauba wax (§ 205.605(a)), and cellulose and chlorine (§ 205.605(b)). In addition, this proposed rule removes glycerin from § 205.605(b) and adds it to § 205.606 as an agricultural product.

Alginic Acid

The proposed rule would amend the National List to reclassify alginic acid from a non-synthetic substance included in § 205.605(a) to a synthetic substance listed included in § 205.605(b), for use in organic handling. Table 23 illustrates the proposed listing.

TABLE 23—PROPOSED RULE ACTION FOR ALGINIC ACID

Current rule: § 205.605(a) *Nonsynthetics allowed:* Acids (Alginic; Citric—produced by microbial fermentation of carbohydrate substances; and Lactic).
Proposed rule action: Remove alginic acid from § 205.605(a) and reinsert alginic acid under § 205.605(b) *synthetics allowed.*

Alginic acid is allowed as a nonorganic ingredient in or on processed products labeled as ''organic'' or ''made with organic (specified ingredients or food group(s)).'' During the 2017 sunset review, the NOSB considered new information in an updated technical report [36] on alginic acid. This technical report described how alginic acid is extracted from brown seaweed using alkali treatment and acid precipitation. To isolate alginic acid from its salt forms, several pH adjustments are made during the extraction.

Based upon guidance document NOP 5033, Classification of Materials,[37] and the definition of ''synthetic' in § 205.2 of the USDA organic regulations, the NOSB determined that alginic acid should be reclassified as synthetic because of the pH adjustments used to extract alginic acid. In conjunction with a recommendation to renew alginic acid for the 2017 sunset review, the NOSB also forwarded a separate recommendation to reclassify alginic acid as a synthetic substance on the National List.[38]

At its October 26–29, 2015, public meeting, the NOSB received public comment and reviewed information in an updated technical report. In order to be consistent with NOP 5033, the NOSB recommended reclassifying alginic acid from a non-synthetic substance under § 205.605(a) to a synthetic substance under § 205.605(b). AMS has reviewed and proposes to address this NOSB recommendation through this proposed rule. Consistent with the NOSB recommendation, this proposed rule would amend § 205.605 by removing alginic acid from § 205.605(a) and inserting alginic acid in § 205.605(b).

Flavors

The proposed rule would amend the National List to revise the annotation of flavors in § 205.605(a), nonsynthetic, nonagricultural substances allowed in organic handling. Table 24 illustrates the proposed listing.

TABLE 24—PROPOSED RULE ACTION FOR FLAVORS

Current rule: § 205.605(a) Flavors, nonsynthetic sources only and must not be produced using synthetic solvents and carrier systems or any artificial preservative.
Proposed rule action: § 205.605(a) Flavors, non-synthetic flavors may be used when organic flavors are not commercially available. All flavors must be derived from organic or nonsynthetic sources only, and must not be produced using synthetic solvents and carrier systems or any artificial preservative.

On November 6, 2014, AMS received a petition to change the allowance for nonorganic flavors to require the use of organic flavors when they are commercially available.[39] [40] Flavors are allowed in organic products if they are derived from nonsynthetic sources and are not produced using synthetic solvents and carrier systems or any artificial preservative (§ 205.605(a)). Flavors have been on the National List since October 2002. The allowance for flavors is a broad category that includes many substances derived from different methods.

At its October 26–29, 2015, public meeting, the NOSB received public comment on the proposal to require organic flavors when commercially available. During its petition review the NOSB determined that organic flavors have become more available, but acknowledged the continued need for nonorganic forms in organic handling because of limited organic availability across the category. Due to the number of distinctly different natural flavors and the pace of new product development in flavors, the NOSB determined it would be impractical to list individual flavors on the National List to indicate which are commercially available in organic form. Based on the petition and public comments, the NOSB recommended revising the allowance for flavors to require the use

[36] Petitioned substance database: *https://www.ams.usda.gov/rules-regulations/organic/national-list/petitioned.* See alginic acid, under the ''A'' sublink.

[37] NOP 5033, Classification of Materials: *https://www.ams.usda.gov/sites/default/files/media/Program%20Handbk_TOC.pdf.*

[38] The NOSB recommendation to reclassify alginic acid is available here: *https://www.ams.usda.gov/sites/default/files/media/HS%20Reclassification%20Alginic%20Acid_final%20rec.pdf.*

[39] The petition for flavors is available here: *https://www.ams.usda.gov/sites/default/files/media/Flavors%20nonsynthetic%201%20Petition.pdf.*

[40] The USDA organic regulations define ''commercial availability'' as: ''The ability to obtain a production input in an appropriate form, quality, or quantity to fulfill an essential function in a system of organic production or handling, as determined the certifying agent in the course of reviewing the organic plan.'' (§ 205.2 Terms Defined).

of organic flavors when commercially available.

The NOSB recommended retaining the existing requirements that all flavors must be derived from organic or nonsynthetic sources only, and must not be produced using synthetic solvents and carrier systems, or any artificial preservative. In addition, the NOSB recommended a revision to convey that the listing for flavors applies to products in the ''organic'' and ''made with organic (specified ingredients or food group(s))'' categories.

AMS has reviewed and proposes to address this NOSB recommendation through this proposed rule. Consistent with the NOSB recommendation, this proposed rule would amend § 205.605(a) by revising the listing of flavors to read: Flavors, non-synthetic flavors may be used when organic flavors are not commercially available. All flavors must be derived from organic or non-synthetic sources only, and must not be produced using synthetic solvents and carrier systems, or any artificial preservative.

Carnauba Wax

This proposed rule would reclassify carnauba wax from a nonagricultural substance on § 205.605(a), to an agricultural substance on § 205.606, that may be used in organic handling when organic carnauba wax is not commercially available. Table 25 illustrates the proposed listing.

TABLE 25—PROPOSED RULE ACTION FOR CARNAUBA WAX

Current rule: § 205.605(a), Waxes—nonsynthetic (Carnauba wax; and Wood resin).
Proposed rule action: Remove carnauba wax from § 205.605(a) and insert carnauba wax under § 205.606.

Carnauba wax is allowed as a nonsynthetic substance for use in organic handling. Carnauba wax has been on the National List since October 2002. During the 2017 sunset review, the NOSB reviewed an updated technical report [41] on carnauba wax. This report described how carnauba wax is extracted from the leaves and buds of palm trees. Based upon NOP 5033,[42] the NOSB determined that carnauba wax meets the definition of an agricultural product in § 205.2 of the USDA organic regulations.[43] While the NOSB recommended renewing carnauba wax as part of the 2017 sunset review, it also forwarded a separate recommendation to reclassify carnauba wax as an agricultural substance.[44]

At its October 26–29, 2015, public meeting, the NOSB reviewed public comment and reviewed information in an updated technical report. To be consistent with NOP 5033, the NOSB recommended reclassifying carnauba wax as an agricultural substance under § 205.606.

AMS has reviewed and proposes to address this NOSB recommendation through this proposed rule. Consistent with the NOSB recommendation, this proposed rule would amend § 205.605 by removing carnauba wax from § 205.605(a) and inserting carnauba wax in § 205.606.

Cellulose

This proposed rule would amend the current allowance for the use of cellulose in organic processing in section 205.605 of the National List. The revision specifies the type of cellulose allowed for certain uses. Table 26 illustrates the changes between the current rule and the proposed rule.

TABLE 26—PROPOSED RULE ACTION FOR CELLULOSE

Current rule: § 205.605(b) Cellulose—for use in regenerative casings, as an anti-caking agent (non-chlorine bleached) and filtering aid.
Proposed rule action: § 205.605(b) Cellulose—for use in regenerative casings, powdered cellulose as an anti-caking agent (non-chlorine bleached) and filtering aid. Microcrystalline cellulose is prohibited.

Applications

Cellulose is a major component of plant cell walls and is one of the most abundant compounds in nature. It can be derived from several sources and is available in many forms that provide different functional properties in food products. In addition to the petitioned uses as a processing aid for juice filtration, anti-caking agent, or peelable meat casings, cellulose is also used as a fat substitute, bulking agent, texturizer, emulsifier, and an extender. In 2001, the NOSB considered a petition for the use of three forms of cellulose, powdered cellulose, regenerative casing cellulose, and microcrystalline cellulose.

Powdered cellulose is a purified white, odorless polysaccharide consisting of a linear polymer of D-glucose units joined together by glycosidic linkages. When forming, cellulose molecules develop as long chain fibrous bundles with crystalline and amorphous regions. Cellulose is isolated from several biological sources, but most commercial cellulose is derived from cotton linters and wood pulp. Mechanical and chemical extraction procedures are used to isolate the cellulose. Varying these manufacturing procedures can result in a range of cellulose products differing in molecular weight and fiber length, which yields a range of food or drug processing properties.

The NOSB considered two cellulose derivatives in 2001, microcrystalline cellulose and regenerative casing cellulose. Microcrystalline cellulose, also known as nanocrystalline cellulose, is manufactured from the acid hydrolysis of powdered cellulose. This process reduces the degree of molecular polymerization (number of glucose units that make up the polymer molecule) where the amorphous region of the cellulose molecule is extracted, leaving the shorted fiber crystalline region. Altering cellulose to its microcrystalline form provides different ingredient and processing aid uses in addition to the uses provided by powdered cellulose. Comments submitted by organic food processors during the 2013 sunset review stated that they do not use microcrystalline cellulose and they were

[41] 2014 carnauba technical report: *https://www.ams.usda.gov/rules-regulations/organic/national-list/petitioned*. Under ''C.''

[42] NOP 5033, Classification of Materials: *https://www.ams.usda.gov/sites/default/files/media/Program%20Handbk_TOC.pdf.*

[43] The USDA organic regulations define ''agricultural product'' as: ''Any agricultural commodity or product, whether raw or processed, including any commodity or product derived from livestock, that is marketing in the United States for human or livestock consumption.''

[44] The NOSB recommendation for the reclassification of carnauba wax is available here: *https://www.ams.usda.gov/sites/default/files/media/HS%20Reclassification%20Carnauba_final%20rec.pdf.*

not aware of any organic food processor using microcrystalline cellulose.

Powdered cellulose is also used to manufacture regenerative casing cellulose where the cellulose fibers are dissolved into smaller polymers, regenerated into tubular forms, and used as a casing to pack skinless meat products such as hot dogs and sausage. The regenerative casing cellulose is then removed from the packed meat product since this form of cellulose is considered to be inedible.

Timeline

Cellulose was added to § 205.605(b) of the National List in November 2003 (68 FR 62215) for limited uses: In regenerative casings, as an anti-caking agent (non-chlorine bleached) and filtering aid. For the 2013 sunset review, the NOSB provided two recommendations in May 2012.[45] AMS addressed one recommendation by renewing the current listing for cellulose in a final rule (78 FR 61154, October 3, 2013). This renewal action established October 3, 2018, as the next sunset date for cellulose. For the second 2013 sunset recommendation issued in May 2012, the NOSB recommended revising the cellulose listing to specify that only powdered cellulose is allowed as an anticaking agent and filtering aid, and specifically prohibiting the use of microcrystalline cellulose. This proposed rule addresses the latter recommendation.

During the 2013 sunset review, the NOSB reviewed its 2001 cellulose recommendation, Technical Advisory Panel reports on this substance from 2001 and 2016, NOSB records from the 2008 cellulose sunset review, other technical documents, and received public comments prior to and during the May 2012 NOSB meeting. Some of the public comments requested that the NOSB specifically prohibit microcrystalline cellulose for use in organic handling, asserting that this was the intent of the NOSB's 2001 cellulose recommendation. However, other comments stated that the 2001 cellulose recommendation did not clearly convey the intent to prohibit microcrystalline cellulose as an ingredient or processing aid in organic handling. During the 2013 sunset review, the NOSB determined that the intent of the current annotation was to allow only powdered cellulose and regenerative casing cellulose. In formulating its recommendation, the NOSB received information indicating that certifying agents were already implementing a prohibition of microcrystalline cellulose, so that a specific prohibition in the annotation was not needed. In preparation of this proposed rule, AMS learned that microcrystalline cellulose is also marketed in powdered form. Consequently, AMS revised the NOSB's recommended annotation for cellulose to specifically prohibit microcrystalline cellulose. The revised annotation is consistent with the NOSB recommendation to allow powdered cellulose as defined by the NOSB. Therefore, we have proposed adding language to prohibit the use of microcrystalline cellulose to avoid ambiguity about its status. AMS specifically seeks comments on the need for this additional language concerning microcrystalline cellulose.

Consistent with the NOSB recommendation, this action would clarify the allowed forms of cellulose and corresponding uses. In effect, it would prohibit other forms of cellulose, such as microcrystalline cellulose, that might be used for the same functions as powdered cellulose. Therefore, AMS is proposing to amend the current listing of cellulose in § 205.605 with the following annotation: For use in regenerative casings, powdered cellulose as an anti-caking agent (non-chlorine bleached) and filtering aid. Microcrystalline cellulose is prohibited.

Chlorine

This proposed rule would implement a December 2011 NOSB recommendation[46] to amend the current allowance for chlorine in organic processing. The proposed change would be consistent with the NOP guidance, ''The Use of Chlorine Materials in Organic Production and Handling,'' NOP 5026, which clarifies the use of chlorine materials in organic production and handling. Table 27 illustrates the changes between the current rule and the proposed rule.

TABLE 27—PROPOSED RULE ACTION FOR CHLORINE MATERIALS IN § 205.605

Current rule: § 205.605(b) Chlorine materials—for disinfecting and sanitizing food contact surfaces, *Except,* That, residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (Calcium hypochlorite; Chlorine dioxide; and Sodium hypochlorite).
Proposed rule action: § 205.605(b) Chlorine materials—for disinfecting and sanitizing food contact surfaces, equipment and facilities may be used up to maximum labeled rates. Chlorine materials in water used in direct crop or food contact are permitted at levels approved by the FDA or EPA for such purpose, provided the use is followed by a rinse with potable water at or below the maximum residual disinfectant limit for the chlorine material under the Safe Drinking Water Act. Chlorine in water used as an ingredient in organic food handling must not exceed the maximum residual disinfectant limit for the chlorine material under the Safe Drinking Water Act.'' (Calcium hypochlorite; Chlorine dioxide; and Sodium hypochlorite).

Applications

Chlorine is a highly reactive element that rarely exists in free form in the environment. It readily combines with many other elements, including metals, from which metal salts, or chlorides are formed. The most common chloride is sodium chloride (table salt). This substance and other chloride ions are essential for cellular metabolism of all known species of life. Chlorine can be extracted from chlorides through oxidation induced by electrolysis. In free form, chlorine's high oxidizing property is utilized in bleaching and disinfectant chlorine compound products. These products are the most utilized equipment and food contact sanitizers in food processing and handling.

Timeline

Chlorine materials were added to the National List that was published in the final rule establishing the National Organic Program (65 FR 13512, December 21, 2000). The chlorine materials listings were renewed through the 2007 (72 FR 58469) and 2012 sunset reviews (77 FR 33290).

When the NOSB initially considered chlorine materials in November 1995, the annotation included in the resulting recommendation acknowledged that levels of chlorine permitted in municipal drinking water were acceptable for organic production and handling. The 1995 recommendation stated that chlorine materials should be

[45] *https://www.ams.usda.gov/sites/default/files/media/Cellulose%20Rec.pdf.*

[46] NOSB Final Recommendation on Chlorine, see: *https://www.ams.usda.gov/sites/default/files/media/NOP%20Handling%20Final%20Rec%20Chlorine%20Materials%20Annotation.pdf.*

allowed for use in organic crop production, organic food processing, and organic livestock production with the following annotation: ''Allowed for disinfecting and sanitizing food contact surfaces. Residual chlorine levels for wash water in direct crop or food contact and in flush water from cleaning irrigation systems that is applied to crops or fields cannot exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.'' In 2010, the NOP issued guidance on the use of chlorine materials in organic production and handling in order to provide clarity on chlorine materials.

At its December 2011 public meeting, the NOSB recommended modifying the chlorine materials annotation listed in § 205.605(b) to improve consistency between the USDA organic regulations and the NOP guidance, ''The Use of Chlorine Materials in Organic Production and Handling,'' NOP 5026. The proposed amendment would clarify what levels of chlorine are permitted for use in water in direct contact with food versus in water used as an ingredient in food. This aligns with the NOP guidance on this subject, provides clarity on the allowed uses of chlorine, and reflects current industry practice. Therefore, AMS is proposing to amend the current listing of chlorine materials in § 205.605(b) with the following annotation:

For disinfecting and sanitizing food contact surfaces, equipment and facilities may be used up to maximum labeled rates. Chlorine materials in water used in direct crop or food contact are permitted at levels approved by the FDA or EPA for such purpose, provided the use is followed by a rinse with potable water at or below the maximum residual disinfectant limit for the chlorine material under the Safe Drinking Water Act. Chlorine in water used as an ingredient in organic food handling must not exceed the maximum residual disinfectant limit for the chlorine material under the Safe Drinking Water Act.'' (Calcium hypochlorite; Chlorine dioxide; and Sodium hypochlorite).

Hypochlorous Acid

See discussion above under § 205.601, Synthetic substances allowed for use in organic crop production.

Potassium Lactate and Sodium Lactate

This proposed rule would add potassium lactate and sodium lactate to § 205.605(b) as an allowed synthetic substance for use in organic handling. Table 28 illustrates the proposed listing.

TABLE 28—PROPOSED RULE ACTION FOR POTASSIUM LACTATE AND SODIUM LACTATE

Current rule: N/A.
Proposed rule action:
§ 205.605(b) potassium lactate, for use as an antimicrobial agent and pH regulator only.
§ 205.605(b) sodium lactate, for use as an antimicrobial agent and pH regulator only.

Potassium lactate and sodium lactate were originally petitioned [47] for addition to the National List on January 5, 2005, for use in organic handling as antimicrobial ingredients. On January 27, 2005, the NOP notified the petitioner that their petition was not necessary because the precursors, lactic acid and potassium hydroxide or sodium hydroxide, which are used to manufacture potassium lactate or sodium lactate, were on the National List. This decision caused confusion in the industry on the use of potassium lactate and sodium lactate, as well as other lactate salts.

To resolve this confusion, the NOP issued a memorandum to the NOSB on June 25, 2014, requesting that the NOSB review the petition to add potassium lactate and sodium lactate to the National List in § 205.605(b).[48]

At its April 25—27, 2016, public meeting, the NOSB received public comment and reviewed the petition and technical report.[49] During this review, the NOSB determined that uses for potassium lactate and sodium lactate had expanded from the original petitioned use as an antimicrobial. As a result, the NOSB determined that adding potassium lactate and sodium lactate to the National List would need the annotation, ''for use as an antimicrobial agent and pH regulator only'' to maintain use applications in organic handling. Based on the petition, technical report, and public comments, the NOSB determined that potassium lactate and sodium lactate, as petitioned, meet the OFPA criteria for National List substances.

AMS has reviewed and proposes to address this NOSB recommendation through this proposed rule. Consistent with the NOSB recommendation, this proposed rule would amend § 205.605(b) by adding potassium lactate and sodium lactate with the same restrictive annotation: for use as an antimicrobial agent and pH regulator only.

Glycerin

This proposed rule would remove glycerin from section 205.605(b) and amend section 205.606 to include this substance with annotation. In effect, for organic processing activities, this proposed action would change the classification of glycerin under the USDA organic regulations from an allowed synthetic to an agricultural product which must be in organic form unless an organic version is not commercially available. Table 29 illustrates the changes between the current rule and the proposed rule.

TABLE 29—PROPOSED RULE ACTION FOR GLYCERIN

Current rule: Remove from § 205.605(b). Glycerin—produced by the hydrolysis of fats and oils.
Proposed rule action: Add to § 205.606. Glycerin—produced from agricultural source materials and processed using biological or mechanical/physical methods as described under § 205.270(a).

[47] Potassium lactate and sodium lactate petition: *https://www.ams.usda.gov/rules-regulations/organic/national-list/s.*

[48] The June 25, 2014 memorandum is available at: *https://www.ams.usda.gov/sites/default/files/media;/S%20Lactate%20national%20list%20petitions_0.pdf.*

[49] Potassium lactate/Sodium lactate technical report: *https://www.ams.usda.gov/sites/default/files/media/Lactic%20Acid%20and%20Lactates%20TR%2002-17-15%20Final.pdf.*

Applications

Glycerin, whether made by fermentation of carbohydrate substrates or by hydrolysis of fats and oils, is listed as GRAS by the FDA and has a long history of safe use in a wide variety of food, cosmetic, and medical applications, including but not limited to use as a solvent, emollient, bodying agent, plasticizer, pharmaceutical agent, and sweetening agent in a wide range of processed food and cosmetic products. Glycerin is metabolized as a carbohydrate in the body.

Commercial glycerin can be produced in several ways: Common methods include hydrogenolysis of carbohydrates or by synthesis from propylene; as a waste byproduct of biodiesel production; and by saponification of natural fats and oils. Glycerin produced from saponification was recommended by the NOSB in 1995 for inclusion on the National List with the annotation ''produced by hydrolysis of fats and oils.'' It is currently included on the National List as a synthetic nonagricultural substance at § 205.605(b) and also for livestock use as a teat dip at § 205.603(a)(12).

Saponification of natural fats and oils is a process of hydrolyzing agricultural product fat or oil with water (steam) under pressure (or chemically with sodium carbonate, sodium hydroxide, or potassium hydroxide) to produce synthetic glycerin and fatty acids. The steam process is described in the 1995 Technical Advisory Panel Report on glycerin. The alkali process is the traditional process used to saponify fats and oils. The three sources of alkali used in this process, identified above, are included in the National List.

According to a 2013 Technical Report,[50] glycerin can be produced organically by microbial fermentation using only mechanical and biological processes and without the use of allowed synthetics listed in section 205.605(b). Those are acceptable methods for processing organically produced products as provided in section 205.270(a). Glycerin produced organically by fermentation is an agricultural product as defined in § 205.2 since it is a processed product produced from an agricultural commodity, *e.g.* cornstarch. In addition, certified organic glycerin can be produced by hydrolysis of organic fats and oils using either steam splitting or traditional saponification with a catalytic amount of an alkali (sodium carbonate, sodium hydroxide, or potassium hydroxide) on the National List.

The NOSB determined that glycerin produced by hydrolysis of fats and oils using a chemical process is considered to yield synthetic glycerin, which may be used only when certified organic glycerin is not commercially available. In summary, glycerin produced through saponification of fats and oils using steam, and glycerin produced by microbial fermentation of carbohydrate substances, would be agricultural products that may be certified organic. The technical report for glycerin indicates that there are currently 21 USDA certified organic operations supplying glycerin.[51]

Timeline

This proposed rule would amend paragraph (b) of § 205.605 of the National List regulations by removing the exemption for the following substance: Glycerin—produced by the hydrolysis of fats and oils. This proposed rule would also amend § 205.606 of the National List regulations by adding Glycerin—produced from agricultural source materials and processed using biological or mechanical/physical methods as described under § 205.270(a), and would require organic glycerin to be used unless not commercially available. Glycerin was included in § 205.605(b) of the National List as originally published on December 21, 2000 (FR 65 80548), as an allowed synthetic ingredient in or on processed products labeled as ''organic'' or ''made with organic (specified ingredients or food group(s)).''

In December 2012, a petition was submitted to the NOSB for the removal of glycerin from § 205.605(b). The petition stated that certified organic glycerin had become available and could replace nonorganic glycerin. Specifically, the petition cited that certified organic glycerin is currently available, but there is no ''commercial availability'' requirement to incentivize processors to use it or certifiers to require it. The petition described how the process of microbial fermentation used to produce organic glycerin is consistent with USDA organic regulation requirements because it relies on mechanical and biological processes as required in § 205.270(a) without the use of allowed synthetics, and stated that the removal of glycerin from § 205.605(b) will encourage organic agricultural production.

Based upon NOP guidance, ''Classification of Materials Draft Guidance,'' NOP 5033[52] published in the **Federal Register** on April 2, 2013 (78 FR 19637), the NOSB determined that some forms of glycerin could be listed as an agricultural product at § 205.606 rather than a nonagricultural product as currently listed at § 205.605. The NOSB determined that agricultural forms of glycerin would include glycerin produced by microbial fermentation of carbohydrate substances as well as glycerin produced from hydrolysis of fats and oils using mechanical/physical methods, as long as the original source material was agricultural.

The petition to remove glycerin from § 205.605(b) was first considered at the 2014 Spring NOSB meeting. At its spring 2015 meeting, the NOSB evaluated glycerin against the evaluation criteria of 7 U.S.C. 6517 and 6518 of the OFPA and NOP criteria on commercial availability, received public comment, and concluded that agricultural forms of glycerin are consistent with the OFPA evaluation criteria. The NOSB determined that the manufacturing processes used to produce glycerin differentiate how the types of glycerin are classified, *e.g.,* as synthetic or agricultural, and that because of the concerns regarding the commercial availability of organically produced glycerin in appropriate quality and quantity, agricultural glycerin should be listed at § 205.606.

This proposed rule would prohibit the use of nonorganic synthetic glycerin and allow the use of nonorganic agricultural glycerin—produced from agricultural source materials and processed using biological or mechanical/physical methods as described under § 205.270(a)—when an organic version is not commercially available.

Consistent with this NOSB recommendation, AMS proposes to: (1) Remove the exemption for synthetic Glycerin—produced by the hydrolysis of fats and oils in paragraph (b) of § 206.605 and (2) amend § 205.606 of the USDA organic regulations to allow the use of agricultural forms of glycerin as a nonorganically produced agricultural substance allowed as an ingredient in or on processed products labeled as ''organic'' as follows: Glycerin—produced from agricultural source materials and processed using biological or mechanical/physical

[50] Petition to remove glycerin from § 205.605 to add to § 205.606 and the Glycerin Technical Report, see *https://www.ams.usda.gov/sites/default/files/media/Glycerin%20Petition%20to%20remove%20TR%202013.pdf.*

[51] The April 2015 NOSB recommendation for Glycerin is available at the following link: *https://www.ams.usda.gov/sites/default/files/media/HS%20Glycerin%20Final%20Rec.pdf.*

[52] NOP 5033 Classification of Materials Draft Guidance, see *https://www.ams.usda.gov/sites/default/files/media/NOP-5033.pdf.*

methods as described under § 205.270(a).

§ 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic."

This proposed rule would amend the allowance for colors currently allowed in organic handling by replacing color Chemical Abstract Services (CAS) numbers with the binomial name of the agricultural source of the color.

Colors Derived From Agricultural Products

This proposed rule would amend USDA organic regulations to replace Chemical Abstract Services (CAS) numbers included in the annotation of each color listed under National List § 205.606(c) with the binomial name of the agricultural source of the color. The NOSB requested that AMS conduct a review on the accuracy of these CAS numbers and propose any necessary changes.[53] During its 2012 sunset review, the NOSB received comments stating that the CAS numbers within annotations for several colors were incorrect. After completing its 2012 sunset review, the NOSB recommended retaining the current color listings without change until either CAS numbers could be verified or until corrections to the USDA organic regulations could be added. Subsequently, the final rule (77 FR 33290) on the 2012 sunset review retained CAS numbers in the annotations for each color derived from agricultural product.

Colors—nonsynthetic sources only, was included in § 205.605(a), in the original National List incorporated into the USDA organic final rule (65 FR 80548) published on December 21, 2000, and became effective on October 21, 2002. Based upon comments received during the 2007 sunset review process, the NOSB recommended not to renew this category of substances in National List § 205.605(a). Comments on listing of colors in § 205.605(a) that were provided during the 2007 sunset review informed the NOSB that the listing of colors in § 205.605(a) never received a formal NOSB recommendation to be added to the National List. Since OFPA states that the National List shall be based upon recommendations developed by the NOSB, it was determined that colors, as listed in § 205.605(a), were erroneously included in the final rule. Several comments also requested the NOSB to recommend the removal of colors from the National List in § 205.605(a), and to have nonsynthetic colors be evaluated by the NOSB through the National List petition process. Additional comments indicated that the broad category of ''nonsynthetic colors'' as listed in § 205.605(a) hindered certifying agents in determining and verifying nonsynthetic colors and that this ambiguity could give rise to the use of inappropriate substances in organically handled products.

During the 2007 sunset review, the NOSB deliberated on the fact that colors, as listed under § 205.605(a), had been allowed for use by organic handlers for more than five years. Some commenters expressed concern that removing colors from § 205.605(a) would cause disruption in the manufacture of organic products in the organic handling sector. While considering these comments the NOSB determined that, since there was no formal recommendation from the NOSB to allow nonsynthetic colors as a broad category for use in organic handling, the listing of colors in § 205.605(a) could not continue.

At the completion of the 2007 sunset review, the NOSB voted not to renew the listing of colors on § 205.605(a). Prior to this decision, the NOSB decided that there is a need to provide the organic industry with the opportunity to petition to add nonsynthetic colors to the National List before finalizing its vote. In April 2006 the NOSB announced it would defer its vote not to renew the colors from nonsynthetic sources listing in § 205.605(a) and proposed that organic handling operations using nonsynthetic colors in organic handling submit petitions to add specific nonsynthetic colors to the National List. Prior to its March 2007 NOSB meeting, the NOSB received several National List petitions to add individual nonsynthetic colors to the National List. At the March 2007 meeting, the NOSB voted to add 19 nonsynthetic colors to National List § 205.606. These nonsynthetic colors, with CAS numbers listed in their annotations, were added to the National List in June 2007 (72 FR 35137).

In May 2013 (78 FR 31815), the listing of annatto extract color in § 205.606 was removed from the National List as recommended by NOSB after considering a petition to remove this color from the National List. The petition to remove annatto extract color was submitted by the same petitioner that submitted the 2007 petition to add annatto extract color to the National List. This petitioner indicated that annatto extract color is no longer needed on the National List in § 205.606 since certified organic annatto extract is available in adequate quantities and in the forms needed to meet demand for organic annatto extract color.

Each color listed under § 205.606(c) includes CAS numbers cited in the annotation. Some listed colors have several CAS numbers within the annotation. The listed CAS numbers actually apply to the pigments contained in the color extract. CAS numbers are unique numerical identifiers assigned by CAS to every known chemical substance. Such numbers are not assigned to chemical compounds or formulations. As requested by the NOSB, AMS reviewed the CAS numbers contained in the color annotations in § 205.606(c). The AMS review determined that CAS numbers are not assigned to the fruit and vegetable raw materials used to make colors. Consequently, CAS numbers may not be appropriate for use when classifying agricultural colors as the use of CAS numbers would not indicate an agricultural source. The AMS review also determined that the petitions to add nonsynthetic colors to the National List may have cited incorrect CAS numbers or applied multiple CAS numbers to the same material. Some of the written comments received during the 2012 sunset review provided more than one CAS number for the same substance. Other comments stated that CAS numbers are not appropriate for nonorganic agricultural substances listed in § 205.606 and some operations may consider a substance represented by a certain CAS number obtained from any source to be compliant with the USDA organic regulations. Some comments received during the 2012 sunset review suggested that binomial nomenclature (genus and species classifications) is more appropriate for identifying nonorganic agricultural products listed in § 205.606. For colors that are derived from agricultural product, use of binomial name may better define these color extracts. Since CAS numbers may not be appropriate for use with agricultural products, and there is variation in what CAS numbers should be applied to some of the color extracts, AMS agrees with the comments that use of binomial nomenclature may provide better clarification on source of colors that are listed in § 205.606.

This rule proposes to make a amendments to the color listings in § 205.606(c) by removing the CAS numbers assigned to the color extracts and substituting in the binomial name

[53] On October 28, 2010, the NOSB requested the review of CAS numbers in its recommendation on amending the National List to prohibit the use of synthetic solvents and carrier systems or any artificial preservatives in manufacturing colors derived from agricultural product.

of the agricultural source that was identified in the color petitions submitted to the NOSB. AMS has inserted this information into Table 30 below describing each binomial name for each color derived from agricultural product listed in § 205.606(c).

TABLE 30—COLORS WITH CAS NUMBERS CHANGED TO BINOMIAL NAMES

Current 205.606 listing: Color—agricultural source/CAS Nos.	Proposed 205.606 listing: Color—agricultural source/Binomial nomenclature
Beet juice extract color (pigment CAS #7659–95–2)	Beet juice extract color, derived from sugarbeet (*Beta vulgaris).*
Beta-carotene extract color—derived from carrots and algae (pigment CAS #1393–63–1).	Beta-carotene extract color derived from carrots (*Daucus carota),* or algae (*Dunaliella salina).*
Black currant juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).	Black currant juice color, derived from *Ribes nigrum.*
Black/purple carrot juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).	Black/purple carrot juice color, derived from *Apiaceae daucus carota.*
Blueberry juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).	Blueberry juice color, derived from *Vaccinium cyanococcus.*
Carrot juice color (pigment CAS #1393–63–1)	Carrot juice color, derived from *Daucus carota.*
Cherry juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).	Cherry juice color, derived from *Prunus avium.*
Chokeberry—Aronia juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).	Chokeberry—Aronia juice color, derived from *Aronia prunifolia.*
Elderberry juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).	Elderberry juice color, derived from *Sambucus nigra.*
Grape juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).	Grape juice color, derived from *Vitis vinifera.*
Grape skin extract color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).	Grape skin extract color, derived from *Vitis vinifera.*
Paprika color—dried, and oil extracted (CAS #68917–78–2)	Paprika color—dried powder and vegetable oil extract, derived from *Capsicum annuum.*
Pumpkin juice color (pigment CAS #127–40–2)	Pumpkin juice color, derived from *Cucurbita pepo.*
Purple potato juice (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).	Purple potato juice color, derived from *Solanum andigenum.*
Red cabbage extract color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).	Red cabbage extract color, derived from *Brassica oleracea.*
Red radish extract color (pigment CAS #'s 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3),.	Red radish extract color, derived from *Raphanus sativus.*
Saffron extract color (pigment CAS #1393–63–1)	Saffron extract color, derived from *Crocus sativus.*
Turmeric extract color (CAS #458–37–7)	Turmeric extract color, derived from *Curcuma longa.*

The use of binomial nomenclature in § 205.606 will clarify which agricultural sources may be used to derive the color extract. Varieties or subspecies of the same agricultural product may be used as sources for a particular color extract. Agricultural sources with the same genus but not the same species will not be eligible for use as a source for a color listed in § 205.606(c). For agricultural products, the application of binomial nomenclature for colors derived from agricultural product is appropriate when classifying colors since it better indicates the agricultural source of the color. Therefore, AMS is proposing to amend the current listing of colors in § 205.606 by inserting the binomial nomenclature of the color described in Table 30 into each respective annotation.

III. Related Documents

Thirteen notices were published regarding the meetings of the NOSB and deliberations on recommendations and substances petitioned for amending the National List. Substances and recommendations included in this proposed rule were announced for NOSB deliberation in the following **Federal Register** notices: 65 FR 64657, October 30, 2000; 67 FR 54784, August 26, 2002; 74 FR 11904, March 20, 2009; 74 FR 46411, September 9, 2009; 75 FR 57194, September 20, 2010; 76 FR 62336, October 7, 2011; 77 FR 21067, April 9, 2012; 77 FR 2679, August 30, 2012; 79 FR 13272, March 10, 2014; 80 FR 12975, March 12, 2015; 80 FR 53759, September 8, 2015; 81 FR 14079, March 16. 2016; and 81 FR 50460, August 1, 2016.

IV. Statutory and Regulatory Authority

The OFPA, as amended (7 U.S.C. 6501 *et seq.*), authorizes the Secretary to make amendments to the National List based on recommendations developed by the NOSB. Sections 6518(k) and 6518(n) of the OFPA authorize the NOSB to develop recommendations to amend the National List for submission to the Secretary and establish a petition process by which persons may petition the NOSB for the purpose of having substances evaluated for inclusion on or deletion from the National List. The National List petition process is implemented under § 205.607 of the NOP regulations. The current petition process (81 FR 12680, March 10, 2016) can be accessed through the NOP Program Handbook on the NOP website at *https://www.ams.usda.gov/rules-regulations/organic/handbook.*

A. Executive Orders 12866 and 13771, and Regulatory Flexibility Act

This proposed rule is not expected to be an E.O. 13771 regulatory action because this proposed rule is not significant under E.O. 12866. *See* OMB's Memorandum titled ''Interim Guidance Implementing Section 2 of the Executive Order of January 30, 2017 titled 'Reducing Regulation and Controlling Regulatory Costs' '' (February 2, 2017).

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612) requires agencies to consider the economic impact of each rule on small entities and evaluate alternatives that would accomplish the objectives of the rule without unduly burdening small entities or erecting barriers that would restrict their ability to compete in the market. The purpose is to fit regulatory actions to the scale of businesses subject to the action. Section 605 of the RFA allows an agency to

certify a rule, in lieu of preparing an analysis, if the rulemaking is not expected to have a significant economic impact on a substantial number of small entities.

Pursuant to the requirements set forth in the RFA, AMS performed an economic impact analysis on small entities in the final rule published in the **Federal Register** on December 21, 2000 (65 FR 80548). AMS has also considered the economic impact of this action on small entities. The impact on entities affected by this rule would not be significant. The effect of this rule, if implemented as final, would be to allow the use of additional substances in organic crop or livestock production and organic handling. This action would increase regulatory flexibility and would give small entities more tools to use in day-to-day operations. AMS concludes that the economic impact of this addition, if any, would be minimal and beneficial to small agricultural service firms. Accordingly, USDA certifies that this rule will not have a significant economic impact on a substantial number of small entities.

Small agricultural service firms, which include producers, handlers, and accredited certifying agents, have been defined by the Small Business Administration (SBA) (13 CFR 121.201) as those having annual receipts of less than $7,000,000 and small agricultural producers are defined as those having annual receipts of less than $750,000.

According to USDA, National Agricultural Statistics Service, certified organic acreage exceeded 5.0 million acres in 2016.[54] According to NOP's Organic Integrity Database, there are 25,239 certified organic operations in the U.S.[55] AMS believes that most of these entities would be considered small entities under the criteria established by the SBA. U.S. sales of organic food products and non-food products have grown from $1 billion in 1990 to more than $47 billion in 2016.[56] In addition, the USDA has 83 accredited certifying agents who provide certification services to producers and handlers. A complete list of names and addresses of accredited certifying agents may be found on the AMS NOP website, at *https://www.ams.usda.gov/services/organic-certification/certifying-agents.* AMS believes that most of these accredited certifying agents would be considered small entities under the criteria established by the SBA. A complete list of NOP certified operations may be found on the AMS NOP website, at *https://apps.ams.usda.gov/integrity/.*

B. Executive Order 12988

Executive Order 12988 instructs each executive agency to adhere to certain requirements in the development of new and revised regulations in order to avoid unduly burdening the court system. This proposed rule is not intended to have a retroactive effect.

States and local jurisdictions are preempted under the OFPA from creating programs of accreditation for private persons or State officials who want to become certifying agents of organic farms or handling operations. A governing State official would have to apply to USDA to be accredited as a certifying agent, as described in section 6514(b) of the OFPA. States are also preempted under sections 6503 through 6507 of the OFPA from creating certification programs to certify organic farms or handling operations unless the State programs have been submitted to, and approved by, the Secretary as meeting the requirements of the OFPA.

Pursuant to section 6507(b)(2) of the OFPA, a State organic certification program may contain additional requirements for the production and handling of organically produced agricultural products that are produced in the State and for the certification of organic farm and handling operations located within the State under certain circumstances. Such additional requirements must (a) further the purposes of the OFPA, (b) not be inconsistent with the OFPA, (c) not be discriminatory toward agricultural commodities organically produced in other States, and (d) not be effective until approved by the Secretary.

Pursuant to section 6519(c)(6) of the OFPA, this proposed rule would not alter the authority of the Secretary under the Federal Meat Inspection Act (21 U.S.C. 601–624), the Poultry Products Inspection Act (21 U.S.C. 451–471), or the Egg Products Inspection Act (21 U.S.C. 1031–1056), concerning meat, poultry, and egg products, nor any of the authorities of the Secretary of Health and Human Services under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 *et seq.*), nor the authority of the Administrator of EPA under the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136 *et seq.*).

C. Paperwork Reduction Act

No additional collection or recordkeeping requirements are imposed on the public by this proposed rule. Accordingly, OMB clearance is not required by the Paperwork Reduction Act of 1995, 44 U.S.C. 3501, Chapter 35.

D. Executive Order 13175

This proposed rule has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. The review reveals that this regulation will not have substantial and direct effects on Tribal governments and will not have significant Tribal implications.

E. General Notice of Public Rulemaking

This proposed rule reflects 29 recommendations submitted by the NOSB to the Secretary to amend the annotation for 17 substances currently on the National List, add 17 substances to the National List, and remove one substance from the National List. A 60-day period for interested persons to comment on this rule is provided and is deemed appropriate.

List of Subjects in 7 CFR Part 205

Administrative practice and procedure, Agriculture, Animals, Archives and records, Imports, Labeling, Organically produced products, Plants, Reporting and recordkeeping requirements, Seals and insignia, Soil conservation.

For the reasons set forth in the preamble, 7 CFR part 205, subpart G is proposed to be amended as follows:

PART 205—NATIONAL ORGANIC PROGRAM

■ 1. The authority citation for 7 CFR part 205 continues to read as follows:

Authority: 7 U.S.C. 6501—6522.

■ 2. Amend § 205.238 by revising paragraph (b)(2) and adding paragraph (b)(3) to read as follows:

§ 205.238 Livestock health care practice standard.

* * * * *

(b) * * *

(2) Dairy animals, as allowed under § 205.603.

(3) Fiber bearing animals, as allowed under § 205.603.

■ 3. Amend § 205.601 as follows:

■ a. Redesignate paragraph (a)(2)(iii) as (a)(2)(iv) and add new paragraph (a)(2)(iii),

■ b. Redesignate paragraphs (j)(5) through (j)(8) as (j)(6) through (j)(9), redesignate paragraph (j)(10) as (j)(11),

[54] U.S. Department of Agriculture, National Agricultural Statistics Service. September 2017. Certified Organic Survey, 2016 Summary. *http://usda01.library.cornell.edu/usda/current/OrganicProduction/OrganicProduction-10-04-2012.pdf.*

[55] Organic Integrity Database: *https://organic.ams.usda.gov/Integrity/.* Accessed on October 13, 2017.

[56] Organic Trade Association, 2017 Organic Industry Survey.

add new paragraphs (j)(5) and (j)(10), and revise newly redesignated paragraph (j)(7).

The additions and revisions to read as follows:

§ 205.601 Synthetic substances allowed for use in organic crop production.

* * * * *

(a) * * *

(2)(iii) Hypochlorous acid—generated from electrolyzed water.

* * * * *

(j) * * *

(5) Magnesium oxide (CAS #1309–48–4)—for use only to control the viscosity of a clay suspension agent for humates.

* * * * *

(7) Micronutrients—not to be used as a defoliant, herbicide, or desiccant. Those made from nitrates or chlorides are not allowed. Micronutrient deficiency must be documented by soil or tissue testing, advice from certified crop advisors or professional agronomists, agricultural extension information, or other methods approved by the certifying agent.

* * * * *

(10) Squid byproducts—from food waste processing only. Can be pH adjusted with sulfuric, citric, or phosphoric acid. The amount of acid used shall not exceed the minimum needed to lower the pH to 3.5.

* * * * *

■ 4. Amend § 205.602 by redesignating paragraphs (f) through (i) as (g) through (j), and add new paragraph (f) to read as follows:

§ 205.602 Nonsynthetic substances prohibited for use in organic crop production.

* * * * *

(f) Rotenone (CAS #83–79–4).

* * * * *

■ 5. Amend § 205.603 by revising paragraphs (a)(6) through (a)(31), paragraphs (b)(4) and (b)(7), redesignating paragraph (b)(8) as (b)(9) adding new paragraph (b)(8); and revising paragraphs (d)(1) and (f) to read as follows:

§ 205.603 Synthetic substances allowed for use in organic livestock production.

* * * * *

(a) * * *

(6) Activated charcoal (CAS #7440–44–0)—must be from vegetative sources.

(7) Calcium borogluconate (CAS #5743–34–0)—for treatment of milk fever only.

(8) Calcium propionate (CAS #4075–81–4)—for treatment of milk fever only.

(9) Chlorhexidine (CAS #55–56–1)—for medical procedures conducted under the supervision of a licensed veterinarian. Allowed for use as a teat dip when alternative germicidal agents and/or physical barriers have lost their effectiveness.

(10) Chlorine materials—disinfecting and sanitizing facilities and equipment. Residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.

(i) Calcium hypochlorite.

(ii) Chlorine dioxide.

(iii) Hypochlorous acid—generated from electrolyzed water.

(iv) Sodium hypochlorite

(11) Electrolytes—without antibiotics.

(12) Flunixin (CAS #38677–85–9)—in accordance with approved labeling; except that for use under 7 CFR part 205, the NOP requires a withdrawal period of at least two-times that required by the FDA.

(13) Glucose.

(14) Glycerin—Allowed as a livestock teat dip, must be produced through the hydrolysis of fats or oils.

(15) Hydrogen peroxide.

(16) Iodine.

(17) Kaolin pectin—for use as an adsorbent, antidiarrheal, and gut protectant.

(18) Magnesium hydroxide (CAS #1309–42–8)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR part 205, the NOP requires use by or on the lawful written order of a licensed veterinarian.

(19) Magnesium sulfate.

(20) Mineral oil—for treatment of intestinal compaction, prohibited for use as a dust suppressant.

(21) Nutritive supplements—injectable supplements of trace minerals per § 205.603(d)(2), vitamins per § 205.603(d)(3), and electrolytes per § 205.603(a)(11), with excipients per § 205.603(f), in accordance with FDA and restricted to use by or on the order of a licensed veterinarian.

(22) Oxytocin—use in postparturition therapeutic applications.

(23) Parasiticides— Prohibited in slaughter stock, allowed in emergency treatment for dairy and breeder stock when organic system plan-approved preventive management does not prevent infestation. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period for breeding stock. Allowed for fiber bearing animals when used a minimum of 90 days prior to harvesting of fleece or wool that is to be sold, labeled, or represented as organic.

(i) Fenbendazole (CAS #43210–67–9)—milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for: 2 days following treatment of cattle; 36 days following treatment of goats, sheep, and other dairy species.

(ii) Moxidectin (CAS #113507–06–5)—milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for: 2 days following treatment of cattle; 36 days following treatment of goats, sheep, and other dairy species.

(24) Peroxyacetic/peracetic acid (CAS #79–21–0)—for sanitizing facility and processing equipment.

(25) Phosphoric acid—allowed as an equipment cleaner, *Provided,* That, no direct contact with organically managed livestock or land occurs.

(26) Poloxalene (CAS #9003–11–6)—for use under 7 CFR part 205, the NOP requires that poloxalene only be used for the emergency treatment of bloat.

(27) Propylene glycol (CAS #57–55–6)—for treatment of ketosis in ruminants only.

(28) Sodium chlorite, acidified, allowed for use on organic livestock as a teat dip treatment only.

(29) Tolazoline (CAS #59–98–3)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR part 205, the NOP requires:

(i) Use by or on the lawful written order of a licensed veterinarian;

(ii) Use only to reverse the effects of sedation and analgesia caused by Xylazine; and,

(iii) A meat withdrawal period of at least 8 days after administering to livestock intended for slaughter; and a milk discard period of at least 4 days after administering to dairy animals.

(30) Xylazine (CAS #7361–61–7)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR part 205, the NOP requires:

(i) Use by or on the lawful written order of a licensed veterinarian; and,

(ii) A meat withdrawal period of at least 8 days after administering to livestock intended for slaughter; and a milk discard period of at least 4 days after administering to dairy animals.

(31) Zinc sulfate—for use in hoof and foot treatments only.

(b) * * *

* * * * *

(4) Lidocaine—as a local anesthetic. Use requires a withdrawal period of 8 days after administering to livestock intended for slaughter and 6 days after administering to dairy animals.

* * * * *

(7) Procaine—as a local anesthetic. Use requires a withdrawal period of 8 days after administering to livestock intended for slaughter and 6 days after administering to dairy animals.

(8) Sodium chlorite, acidified—allowed for use on organic livestock as teat dip treatment only.

* * * * *

(d) * * *

(1) DL-Methionine, DL-Methionine—hydroxy analog, and DL-Methionine—hydroxy analog calcium (CAS #'s 59–51–8, 583–91–5, 4857–44–7, and 922–50–9)—for use only in organic poultry production at the following pounds of synthetic 100 percent methionine per ton of feed in the diet, averaged over the life of the flock: laying chickens—2 pounds; broiler chickens—2.5 pounds; turkeys and all other poultry—3 pounds.

* * * * *

(f) Excipients, only for use in the manufacture of drugs and biologics used to treat organic livestock when the excipient is:

(1) Identified by the FDA as Generally Recognized As Safe;

(2) Approved by the FDA as a food additive;

(3) Included in the FDA review and approval of a New Animal Drug Application or New Drug Application; or

(4) Approved by APHIS for use in veterinary biologics.

* * * * *

■ 6. Amend § 205.605 as follows:

■ a. In paragraph (a), revise the entry for ''Acids,'' revise the entries for ''Flavors,'' and ''Waxes;''

■ b. In paragraph (b) add in alphabetical order an entry for ''alginic acid'', revise the entries for ''cellulose'' and ''chlorine materials'' and remove the entry for ''Glycerin—produced by hydrolysis of fats and oils.''

The revisions and addition to read as follows:

§ 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as ''organic'' or ''made with organic (specified ingredients or food group(s)).''

* * * * *

(a) * * *

Acids (Citric—produced by microbial fermentation of carbohydrate substances; Lactic).

* * * * *

Flavors, non-synthetic flavors may be used when organic flavors are not commercially available. All flavors must be derived from organic or nonsynthetic sources only, and must not be produced using synthetic solvents and carrier systems or any artificial preservative.

* * * * *

Waxes—nonsynthetic (Wood resin).

* * * * *

(b) * * *

Alginic acid (CAS #9005–32–7)

* * * * *

Cellulose (CAS #9004–34–6)—for use in regenerative casings, powdered cellulose as an anti-caking agent (non-chlorine bleached) and filtering aid. Microcrystalline cellulose is prohibited.

Chlorine materials—disinfecting and sanitizing food contact surfaces, equipment and facilities may be used up to maximum labeled rates. Chlorine materials in water used in direct crop or food contact are permitted at levels approved by the FDA or EPA for such purpose, provided the use is followed by a rinse with potable water at or below the maximum residual disinfectant limit for the chlorine material under the Safe Drinking Water Act. Chlorine in water used as an ingredient in organic food handling must not exceed the maximum residual disinfectant limit for the chlorine material under the Safe Drinking Water Act.

(1) Calcium hypochlorite.

(2) Chlorine dioxide.

(3) Hypochlorous acid—generated from electrolyzed water.

(4) Sodium hypochlorite.

* * * * *

■ 7. Amend § 205.606 by

■ a. Redesignating paragraphs (g) through (t) as paragraphs (i) through (v);

■ b. Redesignating paragraphs (a) through (f) as paragraphs (b) through (g);

■ c. Adding new paragraphs (a) and (h and revising newly redesignated paragraphs (d)(1) through (d)(18).

The additions and revisions to read as follows:

§ 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as ''organic.''

* * * * *

(a) Carnauba wax

* * * * *

(d) * * *

(1) Beet juice extract color, derived from sugarbeet (*Beta vulgaris).*

(2) Beta-carotene extract color derived from carrots (*Daucus carota*), or algae (*Dunaliella salina*).

(3) Black currant juice color, derived from *Ribes nigrum.*

(4) Black/purple carrot juice color, derived from *Apiaceae daucus carota.*

(5) Blueberry juice color, derived from *Vaccinium cyanococcus.*

(6) Carrot juice color, derived from *Daucus carota.*

(7) Cherry juice color, derived from *Prunus avium.*

(8) Chokeberry—Aronia juice color, derived from *Aronia prunifolia.*

(9) Elderberry juice color, derived from *Sambucus nigra.*

(10) Grape juice color, derived from *Vitis vinifera.*

(11) Grape skin extract color, derived from *Vitis vinifera.*

(12) Paprika color—dried powder and vegetable oil extract, derived from *Capsicum annuum.*

(13) Pumpkin juice color, derived from *Cucurbita pepo.*

(14) Purple potato juice color, derived from *Solanum andigenum.*

(15) Red cabbage extract color, derived from *Brassica oleracea.*

(16) Red radish extract color, derived from Raphanus sativus.

(17) Saffron extract color, derived from *Crocus sativus.*

(18) Turmeric extract color, derived from Curcuma longa.

* * * * *

(h) Glycerin (CAS #56–81–5)—produced from agricultural source materials and processed using biological or mechanical/physical methods as described under § 205.270(a).

* * * * *

Dated: December 26, 2017.

Bruce Summers,

Acting Administrator, Agricultural Marketing Service.

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