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

DEPARTMENT OF AGRICULTURE

Commodity Credit Corporation

7 CFR Part 1487

RIN 0551–AA98

Technical Assistance for Specialty Crops Program

AGENCY: Commodity Credit Corporation and Foreign Agricultural Service, USDA.

ACTION: Final rule.

SUMMARY: This rule revises the Technical Assistance for Specialty Crops (TASC) program regulations to incorporate legislative changes introduced in the Agriculture Improvement Act of 2018 and to incorporate changes that conform the operation of the program to the requirements in the ''Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards'' (Uniform Guidance) and Federal grant-making best practices.

DATES: This rule is effective on December 23, 2019.

FOR FURTHER INFORMATION CONTACT: Curt Alt, (202) 690–4784, *curt.alt@usda.gov.*

SUPPLEMENTARY INFORMATION:

Background

The TASC is authorized by Section 203 of the Agricultural Trade Act of 1978 (7 U.S.C. 5623), as amended. The TASC regulations appear at 7 CFR part 1487.

The Agriculture Improvement Act of 2018 (Pub. L. 115–334), which reauthorized the program for fiscal years 2019–2023, introduced legislative changes to the program that improve the program's flexibility and usefulness to stakeholders, such as making work on potential barriers to trade eligible for funding under the program and eliminating the five-year limit on program funding. In addition, this rule updates the regulations to bring the operation of the program into conformance with the requirements in the Uniform Guidance. Additional changes are desirable to bring the administration of the program into line with the current best practices in Federal grantmaking.

Notice and Comment

This rule is being issued as a final rule without prior notice and opportunity for comment. The Administrative Procedure Act (5 U.S.C. 553) exempts rules ''relating . . . to public property, loans, grants, benefits, or contracts'' from the statutory requirements for prior notice and opportunity for comment and publication of the rule not less than 30 days before its effective date (5 U.S.C. 553(a)(2)). Accordingly, this final rule is effective when published in the **Federal Register**.

Catalog of Federal Domestic Assistance

The program covered by this regulation is listed in the Catalog of Federal Domestic Assistance (CFDA) under the following FAS CFDA number: 10.604, Technical Assistance for Specialty Crops Program.

E-Government Act Compliance

The Foreign Agricultural Service (FAS) is committed to complying with the E-Government Act of 2002 (44 U.S.C. chapter 36), to promote the use of the internet and other information technologies to provide increased opportunities for citizens' access to Government information and services, and for other purposes.

Executive Order 12988

This rule has been reviewed in accordance with Executive Order 12988, ''Civil Justice Reform.'' This rule does not preempt State or local laws, regulations, or policies unless they present an irreconcilable conflict with this rule. This rule will not be retroactive.

Executive Order 12372

Executive Order 12372, ''Intergovernmental Review of Federal Programs,'' requires consultation with officials of State and local governments that would be directly affected by the proposed Federal financial assistance. The objectives of the Executive order are to foster an intergovernmental partnership and a strengthened federalism by relying on State and local processes for the State and local government coordination and review of proposed Federal financial assistance and direct Federal development. This rule will not directly affect State or local governments, and, for this reason, it is excluded from the scope of Executive Order 12372.

Executive Order 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This final rule has been determined to be not significant and was not reviewed by the Office of Management and Budget (OMB) in conformance with Executive Order 12866.

Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs has designated this rule as not a major rule, as defined by 5 U.S.C. 804(2).

Executive Order 13175

This rule has been reviewed for compliance with Executive Order 13175, ''Consultation and Coordination with Indian Tribal Governments.'' Executive Order 13175 requires Federal agencies to consult and coordinate with tribes on a government-to-government basis on policies that have tribal implications, including regulations, legislative comments, proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes or on the distribution of power and responsibilities between the Federal Government and Indian tribes. FAS has assessed the impact of this rule on Indian tribes and determined that this rule does not, to the knowledge of FAS, have tribal implications that require tribal consultation under Executive Order 13175. If a tribe requests

consultation, FAS will work with USDA Office of Tribal Relations to ensure meaningful consultation is provided where changes, additions, and modifications identified herein are not expressly mandated by Congress.

Executive Order 13771

Executive Order 13771 directs agencies to reduce regulation and control regulatory costs and provides that for every new regulation issued, at least two prior regulations be identified for elimination, and that the cost of planned regulations be prudently managed and controlled through a budgeting process. This rule is not an Executive Order 13771 regulatory action because this rule is not significant under Executive Order 12866.

List of Subjects in 7 CFR Part 1487

Agricultural commodities, Exports.

■ For the reasons discussed in the preamble, 7 CFR part 1487 is revised to read as follows:

PART 1487—TECHNICAL ASSISTANCE FOR SPECIALTY CROPS

Sec.

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1487.2 Definitions.
1487.3 Program eligibility.
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Authority: 7 U.S.C. 5623, 5662–5663, as amended.

§ 1487.1 General purpose and scope.

(a) Under the Technical Assistance for Specialty Crops (TASC) program, the Commodity Credit Corporation (CCC), an agency and instrumentality of the United States within the U.S. Department of Agriculture (USDA), provides grant funds to eligible organizations to implement activities that are intended to address existing or potential sanitary, phytosanitary, or technical barriers that prohibit or threaten the export of U.S. specialty crops that are currently available on a commercial basis. The TASC program is intended to benefit the represented industry rather than a specific company or brand.

(b) This part sets forth the general terms, conditions, and policies governing CCC's operation of the TASC program.

(c)(1) The Office of Management and Budget (OMB) issued guidance on Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200. In 2 CFR 400.1, the U.S. Department of Agriculture (USDA) adopted OMB's guidance in subparts A through F of 2 CFR part 200, as supplemented by 2 CFR part 400, as USDA policies and procedures for uniform administrative requirements, cost principles, and audit requirements for Federal awards.

(2) The OMB guidance at 2 CFR part 200, as supplemented by 2 CFR part 400 and this part, applies to the TASC program.

(3) In addition to the provisions of this part, other regulations that are generally applicable to grants and cooperative agreements of USDA, including the applicable regulations set forth in 2 CFR chapters I, II, and IV, also apply to the TASC program, to the extent that these regulations do not directly conflict with the provisions of this part. The provisions of the CCC Charter Act (15 U.S.C. 714 *et seq.*) and any other statutory provisions or regulatory provisions that are generally applicable to CCC also apply to the TASC program.

(d) The TASC program generally operates on a reimbursement basis. The program is administered by the Foreign Agricultural Service (FAS), acting on behalf of CCC.

§ 1487.2 Definitions.

For purposes of this part, the following definitions apply:

Activity means a discrete undertaking within a project to be carried out by a Participant, directly or through a subrecipient or contractor, that is specified in an agreement and is intended to fulfill a specific objective of the agreement.

Agreement means a legally binding grant entered into between CCC and a TASC applicant setting forth the terms and conditions to implement an approved project under the TASC program, including any subsequent amendments to such agreement.

Approval letter means a document by which CCC informs an applicant that its TASC proposal has been approved for funding. This letter may also approve specific activities and contain terms and conditions in addition to the agreement.

Attaché/Counselor means the FAS employee representing United States Department of Agriculture interests in a foreign country.

Eligible organization means any U.S. organization that demonstrates a role or interest in the exports of specialty crops, including, but not limited to: U.S. Government agencies, State government agencies, non-profit trade associations, universities, agricultural cooperatives, and private companies.

Participant means an entity that has entered into a TASC agreement with CCC.

Specialty crop means most cultivated plants produced in the United States, or the products thereof, except wheat, feed grains, oilseeds, cotton, rice, peanuts, sugar, and tobacco.

Unified Export Strategy (UES) system means the online internet system maintained by FAS through which applicants currently may apply to TASC and the other FAS market development programs. The system is currently accessible at *https://apps.fas.usda.gov/ues/webapp/*. FAS may prescribe a different system through which applicants may apply to TASC and will announce such system in the applicable Notice of Funding Opportunity (NOFO).

United States means each of the States, the District of Columbia, Puerto Rico, and the territories and possessions of the United States.

§ 1487.3 Program eligibility.

(a) An eligible organization can submit an application under this part to become a Participant under the TASC Program. FAS will set forth specific eligibility information, including any factors or priorities that will affect the eligibility of an applicant or application for selection, in the full text of the applicable NOFO posted on the U.S. Government website for grant opportunities.

(b) In order to be eligible for funding under the TASC program, activities must address existing or potential sanitary, phytosanitary, or technical barriers to the export of U.S. specialty crops. Examples of expenses that CCC may agree to cover under the TASC program include but are not limited to expenses associated with: Initial pre-clearance programs, export protocol and work plan support, seminars and workshops, study tours, field surveys, development of pest lists, pest and disease research, database development, reasonable logistical and administrative support, and travel and per diem expenses.

(c) Eligible projects may take place in the United States or abroad.

(d) Proposals from research and consulting entities will be considered for funding assistance only with evidence of substantial participation in and financial support to the proposed project by U.S. industry. Such support is most credibly demonstrated through actual monetary contributions to the cost of the project.

(e) Foreign organizations, whether government or private, may participate as third parties in activities carried out by U.S. entities, but are not eligible for funding assistance from the program.

§ 1487.4 Limits on the scope of proposals.

(a) *Funding cap.* Proposals that request more than $500,000 of CCC funding in a given year will not be considered.

(b) *Length of activities.* Awards will generally be granted for a project period not exceeding five calendar years. However, FAS will entertain requests to extend agreements beyond five years when valid justifications are submitted. Participants must submit in writing a valid justification for why an extension is necessary no later than 60 days before the end of the period of performance. Extensions generally will be granted in one-year increments, if warranted. A Participant must wait for written approval from FAS before proceeding with the project.

(c) *Target countries.* Proposals may target barriers in any eligible export market, including single countries or reasonable regional groupings of countries.

(d) *Multiple proposals.* Applicants may submit multiple proposals, but no Participant may have more than five approved projects underway at any given time.

(e) *Program funds only for specific uses.* Participants shall not use program funds to supplement the costs of normal day-to-day operations or to promote their own products or services beyond specific uses approved in a given project.

§ 1487.5 Application process.

(a) *Announcement for TASC program participant.* CCC will periodically announce that it is accepting applications for participation in the TASC program. All relevant information, including application deadlines and proposal content, will be noted in the announcement, and proposals must be submitted in accordance with the terms and conditions, as well as other requirements specified in the announcement and in this part. Currently, applicants are encouraged to submit applications through the UES system, but are not required to use the UES system. CCC may request any additional information it deems necessary from any applicant in order to properly evaluate any proposal

(b) *Universal identifier and System for Award Management (SAM).* In accordance with 2 CFR part 25, each entity that applies to the TASC program and does not qualify for an exemption under 2 CFR 25.110 must:

(1) Be registered in the SAM prior to submitting an application or plan;

(2) Maintain an active SAM registration with current information at all times during which it has an active Federal award or an application or plan under consideration by CCC; and

(3) Provide its DUNS number, or a unique identifier designated as a DUNS replacement, in each application or plan it submits to CCC.

(c) *Reporting subaward and executive compensation information.* In accordance with 2 CFR part 170, each entity that applies to the TASC program and does not qualify for an exception under 2 CFR 170.110(b) must ensure it has the necessary processes and systems in place to comply with the applicable reporting requirements of 2 CFR part 170 should it receive TASC funding.

§ 1487.6 Application review and formation of agreements.

(a) *General.* Proposals received in accordance with the announcement and this part will undergo a multi-phase review by CCC to determine eligibility for the program, the qualifications, quality, and appropriateness of proposed projects, and the reasonableness of proposed project budgets.

(b) *Evaluation criteria.* CCC will review all proposals for eligibility and completeness. CCC will evaluate and score each proposal against the factors described in the NOFO. The purpose of this review is to identify meritorious proposals, recommend an appropriate funding level for each proposal, and submit the proposals and funding recommendations to appropriate officials for decision. CCC may, when appropriate to the subject matter of the proposal, request the assistance of other U.S. Government experts in evaluating the merits of a proposal. Demonstration of substantial U.S. industry participation in or financial or other support of a proposal will be a positive factor in the consideration of proposals. All reviewers will be required to sign a conflict of interest form, and when conflicts of interests are identified the reviewer will be recused from the objective review process.

(c) *Approval decision.* CCC will approve those applications that it determines best satisfy the criteria and factors specified in the announcement and this part. All decisions regarding the disposition of an application are final.

§ 1487.7 Applicant notification.

(a) CCC will notify each applicant in writing of the final decision on its application. CCC will send an agreement and an approval letter to each approved applicant. An applicant that accepts the terms and conditions contained in the agreement and approval letter must so indicate by having the appropriate authorizing official sign the agreement and submit it to CCC. The applicant may not begin to implement approved activities until the applicant's authorizing official and CCC have signed the agreement. The applicant is authorized to begin implementation of the project as of the date specified in the approval letter, unless otherwise indicated.

(b) The approval letter and agreement will outline the activities and budgets that are approved and will specify the terms and conditions applicable to the project, including the levels of TASC funding and cost share requirements.

§ 1487.8 Reimbursements and advances.

(a) *Reimbursement procedures.* (1) Following the implementation of a project for which CCC has agreed to provide funding, a Participant may submit claims for reimbursement of eligible expenses incurred in implementing a TASC project, to the extent that CCC has agreed to pay such expenses. Any changes to approved activities must be approved in writing by CCC before any reimbursable expenses associated with the change can be incurred. A Participant will be reimbursed after CCC reviews the claim and determines that it is complete.

(2) CCC will make all payments to the Participants in U.S. dollars. FAS will initiate payment within 30 days after receipt of the billing, unless the billing is improper.

(3) Participants will be authorized to submit requests for reimbursements or advances at least monthly when electronic fund transfers (EFTs) are not used, and as frequently as desired when electronic transfers are used, in accordance with the provisions of the Electronic Fund Transfer Act (15 U.S.C. 1693–1693r).

(4) Participants may submit claims for reimbursement of the expenses incurred in implementing TASC projects, to the

extent CCC has agreed to pay for such costs, limited initially to 85 percent of the total amount specified in the agreement. The Participant may be reimbursed for the remaining 15 percent of the funds only after the final performance report containing the information required by the agreement is submitted to and approved by FAS.

(5) Final claims for reimbursement must be received no later than 90 calendar days after the completion date of the project or following the expiration or termination date of the agreement, whichever is sooner, and are subject to FAS approval of the Participant's final performance report. Participants are required to use a prescribed system to submit their claims. This system will be clearly stated in the NOFO. Currently the CCC's internet-based UES system is being used to request reimbursement for eligible TASC program expenses.

(6) Participants shall maintain complete records of all program expenditures, identified by TASC agreement number, program year, country or region, activity number, and cost category. Such records shall be accompanied by documentation that supports the expenditure and shall be made available to CCC upon request. CCC may deny a claim for reimbursement if the claim is not supported by acceptable documentation.

(7) In the event that a reimbursement claim is overpaid or is disallowed after payment already has been made, the Participant shall repay CCC within 30 calendar days of such overpayment or disallowance the amount overpaid or disallowed either by submitting a check payable to CCC and referencing the applicable project, or by offsetting its next reimbursement claim. The Participant shall make such payment in U.S. dollars, unless otherwise approved in advance by CCC.

(8) The Participant shall report any actions that may have a bearing on the propriety of any claims for reimbursement in writing to the appropriate Attaché/Counselor and FAS Division Director.

(b) *Advances*—(1) *Policy.* In general, CCC operates the TASC program on a cost reimbursable basis.

(2) *Exception.* Upon request, CCC may make advance payments to a Participant against an approved project budget. Participants may request an advance of up to 85 percent of the funding approved in any given program year. Advances should be limited to the minimum amounts needed and requested as close as is administratively feasible to the actual time of disbursement by the Participant. Reimbursement claims will be used to offset advances. Participants shall deposit and maintain advances in insured, interest-bearing accounts, unless the exceptions in 2 CFR part 200 apply. Interest earned by the Participant on funds advanced by CCC is not program income. Up to $500 of interest earned per year may be retained by the Participant for administrative expenses. Any additional interest earned on Federal advance payments shall be remitted annually to the appropriate entity as required in 2 CFR part 200.

(3) *Refunds due CCC.* A Participant shall fully expend all advances on approved activities within 90 calendar days after the date of disbursement by CCC. By the end of 90 calendar days, the Participant must submit reimbursement claims to offset the advance and submit a check made payable to CCC for any unexpended balance. The Participant shall make such payment in U.S. dollars, unless otherwise approved in advance by CCC.

§ 1487.9 Reporting.

(a) Participants are required to submit regular financial and performance reports in accordance with their agreement. Reporting requirements and formats for both annual financial and performance reports and final financial and performance reports will be specified in the agreement between CCC and the Participant.

(b)(1) In addition to the information required in 2 CFR 200.328(b)(2), a Participant's performance reports must include pertinent information regarding the Participant's progress, measured against established indicators, baselines, and targets, towards achieving the expected results specified in the agreement. This reporting must include, for each performance indicator, a comparison of actual accomplishments with the baseline and the targets established for the period. When actual accomplishments deviate significantly from targeted goals, the Participant must provide an explanation in the report.

(2) A Participant must ensure the accuracy and reliability of the performance data submitted to FAS in performance reports. At any time during the period of performance of the agreement, FAS may review the Participant's performance data to determine whether it is accurate and reliable. The Participant must comply with all requests made by FAS or an entity designated by FAS in relation to such reviews.

(c) All final performance reports will be made available to the public.

(d) If requested by FAS, a Participant must provide to FAS additional information or reports relating to the agreement.

(e) If a Participant requires an extension of a reporting deadline, it must ensure that FAS receives an extension request at least five business days prior to the reporting deadline. FAS may decline to consider a request for an extension that it receives after this time period. FAS will consider requests for reporting deadline extensions on a case by case basis and will make a decision based on the merits of each request. FAS will consider factors such as unforeseen or extenuating circumstances and past performance history when evaluating requests for extensions.

§ 1487.10 Notification of international travel.

The Participant shall notify the Attaché/Counselor in the destination countries in writing in advance of any proposed travel by the Participant or its consultants or other participants. The timing of such notice should be far enough in advance to enable the Attaché/Counselor to schedule appointments, make preparations, or otherwise provide any assistance being requested. Failure to provide advance notification of travel generally will result in disallowance of the expenses related to the travel, unless CCC determines it was impractical to provide such notification.

§ 1487.11 Evaluation.

Project evaluations may be carried out by CCC at its option with or without Participants. CCC may also seek outside expertise to conduct or participate in evaluations.

§ 1487.12 Compliance reviews and notices

(a) *Compliance review process.* (1) USDA staff may conduct compliance reviews of Participant's activities under the TASC program to ensure compliance with this part, applicable Federal laws and regulations, and the terms of the agreements and approval letters. Participants shall cooperate fully with relevant USDA staff conducting compliance reviews and shall comply with all requests from USDA staff to facilitate the conduct of such reviews. Program funds spent inappropriately or on unapproved activities must be returned to CCC.

(2) Any project or activity funded under the program is subject to review or audit at any time during the course of implementation or after the completion of the project.

(3) Upon conclusion of the compliance review, USDA staff will provide a written compliance report to

the Participant. The compliance report will detail any instances where it appears that the Participant is not complying with any of the terms or conditions of the agreement, approval letter, or the applicable laws and regulations. The report will also specify if it appears that CCC may be entitled to recover funds from the Participant and will explain the basis for any recovery of funds from the Participant. If, as a result of a compliance review, CCC determines that further review is needed in order to ensure compliance with the requirements of the TASC program, CCC may require the Participant to contract for an independent audit.

(4) In addition, CCC may notify a Participant in writing at any time if CCC determines that CCC may be entitled to recover funds from the Participant. CCC will explain the basis for any recovery of funds from the Participant in the written notice. The Participant shall, within 30 calendar days of the date of the notice, repay CCC the amount owed either by submitting a check payable to CCC or by offsetting its next reimbursement claim. The Participant shall make such payment in U.S. dollars, unless otherwise approved in advance by CCC. If, however, a Participant notifies CCC within 30 calendar days of the date of the written notice that the Participant intends to file an appeal pursuant to the provisions of this part, the amount owed to CCC by the Participant is not due until the appeal procedures are concluded and CCC has made a final determination as to the amount owed.

(5) The fact that a compliance review has been conducted by USDA staff does not signify that a Participant is in full compliance with its agreement, approval letter, and/or applicable laws and regulations.

(b) *Participant response to compliance report.* (1) A Participant shall, within 60 calendar days of the date of the issuance of a compliance report, submit a written response to CCC. The response may include additional documentation for consideration or a request for reconsideration of any finding along with supporting justification. If the Participant does not wish to contest the compliance report, the response shall include any money owed to CCC, which may be returned by submitting a check payable to CCC or by offsetting a reimbursement claim. The Participant shall make any payments in U.S. dollars, unless otherwise approved in advance by CCC. CCC, at its discretion, may extend the period for response.

(2) After reviewing the response, CCC shall determine whether the Participant owes any funds to CCC and will inform the Participant in writing of the basis for the determination. CCC may initiate action to collect such amount by providing the Participant a written demand for payment of the debt pursuant to the debt settlement policies and procedures in 7 CFR part 1403.

(c) *Participant appeals of CCC determinations.* (1) Within 30 calendar days of the date of the issuance of a determination, the Participant may appeal the determination by making a request in writing that includes the basis for such reconsideration. The Participant may also request a hearing.

(2) If the Participant requests a hearing, CCC will set a date and time for the hearing. The hearing will be an informal proceeding. A transcript will not ordinarily be prepared unless the Participant bears the cost of a transcript; however, CCC may, at its discretion, have a transcript prepared at CCC's expense.

(3) CCC will base its final determination upon information contained in the administrative record. The Participant must exhaust all administrative remedies contained in this section before pursuing judicial review of a determination by CCC.

§ 1487.13 Records retention.

All records related to the project, including records pertaining to subawards, shall be made available upon request to authorized officials of the U.S. Government.

§ 1487.14 Program income.

Program income means gross income earned by the Participant that is directly generated by a supported activity or earned as a result of the Federal award during the period of performance. Any such income generated from an activity, the expenditures for which have been wholly or partially reimbursed with TASC funds, shall be used by the Participant in furtherance of its approved activities in the program period during which the TASC funds are available for obligation by the Participant, or must be returned to CCC. The use of such income shall be governed by this part. Reasonable activity fees or registration fees, if identified as such in a project budget, may be charged for projects approved for program funding. The intent to charge a fee must be part of the original proposal, along with an explanation of how such fees are to be used. Any activity fees charged must be used to offset activity expenses or returned to CCC. Such fees may not be used as profit or counted as cost share.

§ 1487.15 Subrecipients.

(a) A Participant may utilize the services of a subrecipient to implement activities under the agreement if this is provided for in the agreement. The subrecipient may receive CCC-provided funds, program income, or other resources from the Participant for this purpose. The Participant must enter in to a written subaward with the subrecipient and comply with the applicable provisions of 2 CFR 200.331 and/or the Federal Acquisition Regulation (FAR), if applicable. If required by the agreement, the Participant must provide a copy of such subaward to FAS, in the manner set forth in the agreement, prior to the transfer of CCC-provided funds or program income to the subrecipient.

(b) A Participant must include the following requirements in a subaward:

(1) The subrecipient is required to comply with the applicable provisions of this part and 2 CFR parts 200 and 400 and/or the FAR, if applicable. The applicable provisions are those that relate specifically to subrecipients, as well as those relating to non-Federal entities that impose requirements that would be reasonable to pass through to a subrecipient because they directly concern the implementation by the subrecipient of one or more activities under the agreement. If there is a question about whether a particular provision is applicable, FAS will make the determination.

(2) The subrecipient must pay to the Participant the value of CCC-provided funds, interest, or program income that are not used in accordance with the subaward, or that are lost, damaged, or misused as a result of the subrecipient's failure to exercise reasonable care.

(3) In accordance with 2 CFR 200.501(h), subawards must include a description of the applicable compliance requirements and the subrecipient's compliance responsibility. Methods to ensure compliance may include pre-award audits, monitoring during the agreement, and post-award audits.

(c) A Participant must monitor the actions of a subrecipient as necessary to ensure that CCC-provided funds and program income provided to the subrecipient are used for authorized purposes in compliance with applicable U.S. Federal laws and regulations and the subaward and that performance indicator targets are achieved for both activities and results under the agreement.

(d) Participants have full and sole responsibility for the legal sufficiency of all subawards they may enter into with one or more subrecipients in order to

carry out an approved project and shall assume financial liability for any costs or claims resulting from suits, challenges, or other disputes based on subawards entered into by the Participant. Neither CCC nor any other agency of the United States Government nor any official or employee of CCC, FAS, USDA, or the United States Government has any obligation or responsibility with respect to Participant subawards with third parties.

(e) Participants are responsible for ensuring to the greatest extent possible that the terms, conditions, and costs of subawards constitute the most economical and effective use of project funds.

(f) All fees for professional and technical services paid to subrecipients in any part with project funds must be covered by written subawards.

(g) A Participant shall:

(1) Ensure that all expenditures for goods and services in excess of $25 reimbursed by CCC are documented by a purchase order or invoice;

(2) Ensure that no employee, officer, board member, agent, or the employee's, officer's, board member's, or agent's family, partners, or an organization that employs or is about to employ any of the parties indicated herein, participates in the review, selection, award or administration of a subaward in which such entities or their affiliates have a financial or other interest;

(3) Conduct all contracting in an openly competitive manner. Individuals who develop or draft specifications, requirements, statements of work, invitations for bids, or requests for proposals for procurement of any goods or services, and such individuals' families or partners, or an organization that employs or is about to employ any of the aforementioned shall be excluded from competition for such procurement;

(4) Conduct all awarding of grants and agreements in an openly competitive manner, except under the following conditions:

(i) Non-monetary awards of property or services;

(ii) Awards of less than $75,000;

(iii) Awards to fund continuing work already started under a previous award;

(iv) Awards that cannot be delayed due to an emergency or a substantial danger to health or safety;

(v) Awards when it is impracticable to secure competition; or

(vi) Awards to fund unique and innovative unsolicited applications;

(5) Base each solicitation for professional or technical services on a clear and accurate description of and requirements related to the services to be procured;

(6) Perform and document some form of fee, price, or cost analysis, such as a comparison of price quotations to market prices or other price indicia, to determine the reasonableness of the offered fees or prices for procurements in excess of the simplified acquisition threshold defined at 2 CFR 200.88; and

(7) Document the decision-making process.

§ 1487.16 Suspension and termination of agreements.

(a) An agreement or subaward may be suspended or terminated in accordance with 2 CFR 200.338 or 200.339. FAS may suspend or terminate an agreement if it determines that:

(1) One of the bases in 2 CFR 200.338 or 200.339 for termination or suspension by FAS has been satisfied; or

(2) The continuation of the assistance provided under the agreement is no longer necessary or desirable.

(b) If an agreement is terminated, the Participant:

(1) Is responsible for using or returning any CCC-provided funds, interest, or program income that have not been disbursed, as agreed to by FAS; and

(2) Must comply with any closeout and post-closeout procedures specified in the agreement and 2 CFR 200.343 and 200.344.

§ 1487.17 Audit requirements.

(a) Subpart F of 2 CFR part 200 applies to all Participants and subrecipients under this part other than those that are for-profit entities, foreign public entities, or foreign organizations.

(b) A Participant or subrecipient that is a for-profit entity or a subrecipient that is a foreign organization and that expends, during its fiscal year, a total of at least the audit requirement threshold in 2 CFR 200.501 in Federal awards, is required to obtain an audit. Such a Participant or subrecipient has the following two options to satisfy the requirement in this paragraph (b):

(1)(i) A financial audit of the agreement or subaward, in accordance with the Government Auditing Standards issued by the United States Government Accountability Office (GAO), if the Participant or subrecipient expends Federal awards under only one FAS program during such fiscal year; or

(ii) A financial audit of all Federal awards from FAS, in accordance with GAO's Government Auditing Standards, if the Participant or subrecipient expends Federal awards under multiple FAS programs during such fiscal year; or

(2) An audit that meets the requirements contained in subpart F of 2 CFR part 200.

(c) A Participant or subrecipient that is a for-profit entity or a subrecipient that is a foreign organization and that expends, during its fiscal year, a total that is less than the audit requirement threshold in 2 CFR 200.501 in Federal awards, is exempt from requirements under this section for an audit for that year, except as provided in paragraphs (d) and (f) of this section, but it must make records available for review by appropriate officials of Federal agencies.

(d) FAS may require an annual financial audit of an agreement or subaward when the audit requirement threshold in 2 CFR 200.501 is not met. In that case, FAS must provide funds under the agreement for this purpose, and the Participant or subrecipient, as applicable, must arrange for such audit and submit it to FAS.

(e) When a Participant or subrecipient that is a for-profit entity or a subrecipient that is a foreign organization is required to obtain a financial audit under this section, it must provide a copy of the audit to FAS within 60 days after the end of its fiscal year.

(f) FAS, the USDA Office of Inspector General, or GAO may conduct or arrange for additional audits of any Participants or subrecipients, including for-profit entities and foreign organizations. Participants and subrecipients must promptly comply with all requests related to such audits. If FAS conducts or arranges for an additional audit, such as an audit with respect to a particular agreement, FAS will fund the full cost of such an audit, in accordance with 2 CFR 200.503(d).

§ 1487.18 Disclosure of program information.

(a) Documents submitted to CCC by Participants are subject to the provisions of the Freedom of Information Act (FOIA), 5 U.S.C. 552, and 7 CFR part 1, subpart A, including, specifically, 7 CFR 1.11.

(b) Any research conducted by a Participant pursuant to an agreement and/or approval letter shall be subject to the provisions relating to intangible property in 2 CFR part 200.

§ 1487.19 Ethical conduct.

(a) The Participant shall maintain written standards of conduct governing the performance of its employees engaged in the award and administration of contracts.

(b) A Participant shall conduct its business in accordance with the laws and regulations of the country(s) in

which each activity is carried out and in accordance with applicable U.S. Federal, state, and local laws and regulations. A Participant shall conduct its business in the United States in accordance with applicable Federal, state, and local laws and regulations.

(c) Neither a Participant nor its affiliates shall make export sales of U.S. agricultural commodities covered under the terms of an agreement. Neither a Participant nor its affiliates shall charge a fee for facilitating an export sale. A Participant may collect check-off funds and membership fees that are required for membership in the Participant's organization.

(d) The Participant shall not use program activities or project funds to promote private self-interests or conduct private business.

(e) A Participant shall not limit participation in its TASC activities to members of its organization. Participants shall ensure that their TASC-funded programs and activities are open to all otherwise qualified individuals and entities on an equal basis and without regard to any non-merit factors.

(f) A Participant shall select U.S. agricultural industry representatives to participate in activities based on criteria that ensure participation on an equitable basis by a broad cross section of the U.S. industry. If requested by CCC, a Participant shall submit such selection criteria to CCC for approval.

(g) The Participant must report any actions or circumstances that may have a bearing on the propriety of program activities to the appropriate Attaché/Counselor, and the Participant's U.S. office shall report such actions or circumstances in writing to CCC.

(h) The officers, employees, board members, and agents of the Participant shall neither solicit nor accept gratuities, favors, or anything of monetary value from contractors, sub-contractors, or parties to sub-agreements. However, Participants may set standards for situations in which the financial interest is not substantial, or the gift is an unsolicited item of nominal value. The standards of conduct shall provide for disciplinary actions to be applied for violations of such standards by officers, employees, board members, or agents of the Participant.

§ 1487.20 Amendments.

(a) Participants may request to modify approved projects if circumstances change in such a way that they would likely affect the progress and ultimate success of a project. Such modification must be made through a written amendment to the agreement. All requests for project modifications must be made in writing to CCC and must include:

(1) A justification as to why changes to the project as originally designed are needed;

(2) An explanation of the necessary adjustments in approach or strategy; and

(3) A description of necessary changes in the project's time line(s) and/or budget (*e.g.,* shifting of budgetary resources from one-line item to another in order to accommodate the changes).

(b) All requests for project modifications must be reviewed and approved by CCC. Upon approval, CCC will issue an amendment to the agreement, which must be signed by CCC and the Participant.

§ 1487.21 Noncompliance with an agreement.

(a) If a Participant fails to comply with any term in its project agreement, approval letter, or this part, CCC may take one or more of the enforcement actions in 2 CFR part 200 and, if appropriate, initiate a claim against the Participant, following the procedures set forth in this part. CCC may also initiate a claim against a Participant if program income or CCC-provided funds are lost due to an action or omission of the Participant. If any Participant has engaged in fraud with respect to the TASC program, or has otherwise violated program requirements under this part, CCC may:

(1) Hold such Participant liable for any and all losses to CCC resulting from such fraud or violation;

(2) Require a refund of any assistance provided to such Participant plus interest as determined by FAS; and

(3) Collect liquidated damages from such Participant in an amount determined appropriate by FAS.

(b) The provisions of this section shall be without prejudice to any other remedy that is available under any other provision of law.

§ 1487.22 Paperwork reduction requirements.

The paperwork and recordkeeping requirements imposed by this part have been approved by OMB under the Paperwork Reduction Act of 1980. OMB has assigned control number 0551–0038 for this information collection.

Dated: November 27, 2019.

Margo Erny,

Acting Executive Vice President, Commodity Credit Corporation.

In concurrence with:

Dated: November 26, 2019.

Ken Isley,

Administrator, Foreign Agricultural Service.

[FR Doc. 2019–27248 Filed 12–20–19; 8:45 am]

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NUCLEAR REGULATORY COMMISSION

10 CFR Part 50

[NRC–2018–0261; FEMA–2012–0026]

Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants (NUREG–0654/FEMA–REP–1, Rev. 2)

AGENCY: Nuclear Regulatory Commission.

ACTION: Final guidance; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC), concurrently with the Federal Emergency Management Agency (FEMA), is issuing final guidance document entitled, ''Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants; Rev. 2'' (NUREG–0654/FEMA–REP–1, Rev. 2).

DATES: This final guidance document is available on December 23, 2019.

ADDRESSES: Please refer to Docket ID NRC–2018–0261 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2018–0261 or FEMA–2012–0026. Address questions about NRC docket IDs in *Regulations.gov* to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov.* Public comments and supporting materials related to this final guidance document can be found at *https://www.regulations.gov* by searching on Docket ID FEMA–2012–0026. For technical questions, contact the individual 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 Document collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, 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.* NUREG–0654/FEMA–REP–1, Rev. 2, ''Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants,'' Final Report is available in ADAMS under Accession No. ML19347D139.

• *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: Jonathan Fiske, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–287–9228, email: *Jonathan.Fiske@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In November 1980, the NRC and FEMA issued ''Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants; Rev. 1'' (NUREG–0654/FEMA–REP–1, Rev. 1) as a joint interagency guidance document (45 FR 85862; December 30, 1980). NUREG–0654/FEMA–REP–1, Rev. 1 provides guidance on the 16 Planning Standards referenced in the NRC's regulations in § 50.47 of title 10 of the *Code of Federal Regulations* (10 CFR), and in FEMA's regulations at 44 CFR 350.5. Both agencies use these Planning Standards, and the associated Evaluation Criteria contained in NUREG–0654/FEMA–REP–1, Rev. 1, to evaluate the adequacy of emergency plans and preparedness of commercial nuclear power plant owners and operators, and state, local, and tribal government jurisdictions located near commercial nuclear power plant sites.

Since the publication of NUREG–0654/FEMA–REP–1, Rev. 1, there have been substantial changes to NRC and FEMA regulations, guidance, and policies and advances in emergency preparedness planning and technology. As a result, the NRC and FEMA have issued four supplementary documents and one addendum to update and expand upon the guidance in NUREG–0654/FEMA–REP–1, Rev 1. This revision consolidates the four supplementary documents and one addendum, and provides updates and additional guidance reflective of over 35 years of improvements and lessons learned in the radiological emergency preparedness community.

The NRC and FEMA held two public meetings on August 22, 2012, and September 13, 2012, to discuss the scope of the proposed revision to NUREG–0654/FEMA–REP–1, Rev. 1 (77 FR 46766; August 6, 2012). To assist in further defining the scope, the NRC and FEMA solicited public comments on specific issues related to NUREG–0654/FEMA–REP–1, Rev. 1 (77 FR 65700; October 30, 2012). Additionally, stakeholder and public engagement sessions were held during staff development of the revised guidance on October 29–31, 2013 and June 25, 2014.

Following development of the revised guidance, the draft NUREG–0654/FEMA–REP–1, Rev. 2 was posted to the Federal Rulemaking website at *https://www.regulations.gov* for public comment (80 FR 30697; May 29, 2015). The original 90-day comment period was scheduled to conclude on August 27, 2015; however, in response to requests from the public for an extension based on the broad scope of the revision and the extensive review necessary to develop comments, the NRC and FEMA granted a 45-day extension to the original comment period (80 FR 50862; August 21, 2015). The comment period closed on October 13, 2015. In total, the agencies received, reviewed, and considered 609 comments during development of this revision. Of the 609 comments, 64 were accepted (draft guidance was revised exactly as recommended), 154 were agreed to in part, and the remaining 391 were either noted or rejected. In all, 218 comments resulted in revisions to the draft guidance. A detailed report on the comment resolutions, including the agencies' rationales for each comment's disposition, will be available online for review in ADAMS under Accession No. ML19350A378 and at *https://www.regulations.gov/,* under Docket ID NRC–2018–0261, within 30 days after issuance of the final NUREG–0654/FEMA–REP–1, Rev. 2.

II. Congressional Review Act

The NUREG–0654/FEMA–REP–1, Rev. 2 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.

Dated at Rockville, Maryland, this 16th day of December, 2019.

For the Nuclear Regulatory Commission.

Brian E. Holian,

Director, Office of Nuclear Security and Incident Response.

[FR Doc. 2019–27435 Filed 12–20–19; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 72

[NRC–2018–0221, NRC–2019–0030, and NRC–2019–0160]

RIN 3150–AK18, 3150–AK28, and 3150–AK36

List of Approved Spent Fuel Storage Casks: Holtec International HI–STORM 100 Multipurpose Canister Cask System, Certificate of Compliance No. 1014, Amendment Nos. 11, 12, 13, and 14; Corrections

AGENCY: Nuclear Regulatory Commission.

ACTION: Correcting amendments.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) published three direct final rules in the **Federal Register** on December 12, 2018, February 26, 2019, and October 3, 2019, that amended its spent fuel storage regulations by revising the Holtec International HI–STORM 100 Multipurpose Canister Cask System listing within the ''List of approved spent fuel storage casks'' to include Amendment Nos. 11, 12, 13, and 14, respectively, to Certificate of Compliance No. 1014. The technical specifications for Amendment Nos. 11, 12, 13, and 14 contained minor editorial and non-substantive errors. The purpose of this action is to correct these errors.

DATES: This rule is effective on December 23, 2019.

ADDRESSES: For Amendment Nos. 11 and 12, please refer to Docket ID NRC–2018–0221; for Amendment No. 13, please refer to Docket ID NRC–2019–0030; and for Amendment No. 14, please refer to Docket ID NRC–2019–0160 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action using any of the following methods:

• *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket IDs NRC–2018–0221, NRC–2019–0030, or NRC–2019–0160. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

• *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at

https://www.nrc.gov/reading-rm/adams.html. To begin the search, select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in the **SUPPLEMENTARY INFORMATION** 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: Yen-Ju Chen, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–1018; email: *Yen-Ju.Chen@nrc.gov.*

SUPPLEMENTARY INFORMATION: The NRC published three direct final rules in the **Federal Register** on December 12, 2018 (83 FR 63794), February 26, 2019 (84 FR 6055), and October 3, 2019 (84 FR 52747), amending its regulations in part 72 of title 10 of the *Code of Federal Regulations* (10 CFR) by revising the ''List of approved spent fuel storage casks'' to add Amendment Nos. 11 and 12, 13, and 14, respectively, to Certificate of Compliance No. 1014 for the Holtec International HI–STORM 100 Multipurpose Canister Cask System listing. Amendment Nos. 11 and 12 became effective on February 25, 2019; Amendment No. 13 became effective on May 13, 2019; and Amendment No. 14 became effective on December 17, 2019. The technical specifications for these direct final rules contained minor editorial and non-substantive errors. Specifically, Table 3–2 refers to Tables 3–3 and 3–4 for per cell decay heat load limits for the multi-purpose canisters (MPCs) MPC–68/68F/68FF/68M, but Tables 3–3 and 3–4 omitted the MPC–68M.

The NRC previously reviewed and approved the use of model MPC–68M in Amendment No. 8 to Certificate of Compliance No. 1014. In Amendment No. 9, the NRC added Tables 3–3 and 3–4 and, in Table 3–2, added a reference to decay heat loads in Tables 3–3 and 3–4. The reference in Appendix A, Table 3–2, refers to Table 3–3 and 3–4 for the per cell heat load limits for the MPC–68/68F/68FF/68M. However, Tables 3–3 and 3–4 only have rows for MPC–68/68F/68FF and do not specifically include the MPC–68M. Since the decay heat load, whether uniform or regionalized, for all 68 cell MPCs are identical, and the NRC previously reviewed and approved this heat load, it is evident that the omission of MPC–68M in Tables 3–3 and 3–4 was an editorial error. Although this error is editorial and has no impact on the loading of MPCs, it is still appropriate to correct the error. Correcting this error would not change the substantive responsibilities of any person or entity regulated by the NRC. This error has been corrected in Amendment No. 9, Revision 1, and Amendment No. 10 on August 31, 2017 (82 FR 41321).

The NRC is correcting the typographical error in Amendment Nos. 11, 12, 13, and 14 by adding MPC–68M to Appendix A, Tables 3–3 and 3–4. The NRC also is revising Amendment Nos. 11, 12, 13, and 14 to Certificate of Compliance No. 1014 of the Holtec International HI–STORM 100 Multipurpose Canister Cask System listings within 10 CFR 72.214 to note the corrections.

Rulemaking Procedure

Under the Administrative Procedure Act (5 U.S.C. 553(b)), an agency may waive the normal notice and comment requirements if it finds, for good cause, that they are impracticable, unnecessary, or contrary to the public interest. As authorized by 5 U.S.C. 553(b)(3)(B), the NRC finds good cause to waive notice and opportunity for comment on this correction because it will have no substantive impact and is of a minor and administrative nature dealing with a correction to a CFR section. Specifically, this amendment is to correct a minor editorial and non-substantive error. This correction does not require action by any person or entity regulated by the NRC. Also, this final rule does not change the substantive responsibilities of any person or entity regulated by the NRC. Accordingly, for the reasons stated in this document, the NRC finds, pursuant to 5 U.S.C. 553(d)(3), that good cause exists to make this rule effective upon publication.

List of Subjects in 10 CFR Part 72

Administrative practice and procedures, Hazardous waste, Indians, Intergovernmental relations, Nuclear energy, Penalties, Radiation protection, Reporting and recordkeeping requirements, Security measures, Spent fuel, 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; the Nuclear Waste Policy Act of 1982, as amended; and 5 U.S.C. 552 and 553; the NRC is making the following correcting amendment to 10 CFR part 72:

PART 72—LICENSING REQUIREMENTS FOR THE INDEPENDENT STORAGE OF SPENT NUCLEAR FUEL, HIGH-LEVEL RADIOACTIVE WASTE, AND REACTOR-RELATED GREATER THAN CLASS C WASTE

■ 1. The authority citation for part 72 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 51, 53, 57, 62, 63, 65, 69, 81, 161, 182, 183, 184, 186, 187, 189, 223, 234, 274 (42 U.S.C. 2071, 2073, 2077, 2092, 2093, 2095, 2099, 2111, 2201, 2210e, 2232, 2233, 2234, 2236, 2237, 2238, 2273, 2282, 2021); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); National Environmental Policy Act of 1969 (42 U.S.C. 4332); Nuclear Waste Policy Act of 1982, secs. 117(a), 132, 133, 134, 135, 137, 141, 145(g), 148, 218(a) (42 U.S.C. 10137(a), 10152, 10153, 10154, 10155, 10157, 10161, 10165(g), 10168, 10198(a)); 44 U.S.C. 3504 note.

■ 2. In § 72.214, Certificate of Compliance 1014 is amended to read as follows:

§ 72.214 List of approved spent fuel storage casks.

* * * * *

Certificate Number: 1014.

Initial Certificate Effective Date: May 31, 2000.

Amendment Number 1 Effective Date: July 15, 2002.

Amendment Number 2 Effective Date: June 7, 2005.

Amendment Number 3 Effective Date: May 29, 2007.

Amendment Number 4 Effective Date: January 8, 2008.

Amendment Number 5 Effective Date: July 14, 2008.

Amendment Number 6 Effective Date: August 17, 2009.

Amendment Number 7 Effective Date: December 28, 2009.

Amendment Number 8 Effective Date: May 2, 2012, as corrected on November 16, 2012 (ADAMS Accession No. ML12213A170); superseded by Amendment 8, Revision 1 Effective Date: February 16, 2016.

Amendment Number 8, Revision 1 Effective Date: February 16, 2016.

Amendment Number 9 Effective Date: March 11, 2014, superseded by Amendment Number 9, Revision 1, on March 21, 2016.

Amendment Number 9, Revision 1, Effective Date: March 21, 2016, as corrected (ADAMS Accession No. ML17236A451).

Amendment Number 10 Effective Date: May 31, 2016, as corrected (ADAMS Accession No. ML17236A452).

Amendment Number 11 Effective Date: February 25, 2019, as corrected (ADAMS Accession No. ML19343B024).

Amendment Number 12 Effective Date: February 25, 2019, as corrected on May 30, 2019 (ADAMS Accession No. ML19109A111); further corrected December 23, 2019 (ADAMS Accession No. ML19343A908).

Amendment Number 13 Effective Date: May 13, 2019, as corrected on May 30, 2019 (ADAMS Accession No. ML19109A122); further corrected December 23, 2019 (ADAMS Accession No. ML19343B156).

Amendment Number 14 Effective Date: December 17, 2019, as corrected (ADAMS Accession No. ML19343B287).

Safety Analysis Report (SAR) Submitted by: Holtec International.

SAR Title: Final Safety Analysis Report for the HI–STORM 100 Cask System.

Docket Number: 72–1014.

Certificate Expiration Date: May 31, 2020.

Model Number: HI–STORM 100.

* * * * *

Dated at Rockville, Maryland, this 17th day of December, 2019.

For the Nuclear Regulatory Commission.

Cindy K. Bladey,

Chief, Regulatory Analysis and Rulemaking Support Branch, Division of Rulemaking, Environmental, and Financial Support Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2019–27595 Filed 12–20–19; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF ENERGY

10 CFR Part 955

RIN 1903–AA11

Elemental Mercury Management and Storage Fees

AGENCY: Office of Environmental Management, U.S. Department of Energy.

ACTION: Final rule.

SUMMARY: The Department of Energy publishes a final rule to establish a fee for long-term management and storage of elemental mercury in accordance with the Mercury Export Ban Act.

DATES: This rule is effective January 22, 2020.

FOR FURTHER INFORMATION CONTACT: David Haught, U.S. Department of Energy, Office of Environmental Management, Office of Waste Disposal (EM–4.22), 1000 Independence Avenue SW, Washington, DC 20585, Telephone: (202) 586–5000, Email: *mercury.mgt.fee@em.doe.gov.*

SUPPLEMENTARY INFORMATION:

I. Background
II. Discussion of Fee Basis
III. Response to Comments
IV. Regulatory Review
V. Approval of the Secretary of Energy

I. Background

Section 5(a)(1) of the Mercury Export Ban Act, as amended (MEBA), 42 U.S.C. 6939f(a)(1), provides that the Department of Energy (DOE) shall designate a facility for the purpose of long-term management and storage of elemental mercury generated within the United States.[1] MEBA section 5(b)(1), 42 U.S.C. 6939f(b)(1), further provides that DOE shall assess and collect a fee at the time of delivery for providing such management and storage based on the pro rata cost of long-term management and storage of elemental mercury delivered to the facility. MEBA provides that the fee shall be made publicly available by October 1, 2018. MEBA section 5(b)(1)(B)(i), 42 U.S.C. 6939f(b)(1)(B)(i). The fee may be adjusted annually and shall be set in an amount sufficient to cover costs described in MEBA section 5(b)(2), 42 U.S.C. 6939f(b)(2), subject to certain adjustments. MEBA section 5(b)(1)(B)(ii)–(iv), 42 U.S.C. 6939f(b)(1)(B)(ii)–(iv).

In accordance with MEBA section 5(b), 42 U.S.C. 6939f(b), DOE establishes this fee after consultation with persons who are likely to deliver elemental mercury to a designated facility, and with other interested persons. DOE convened teleconferences from May 2017 through July 2019 and held a meeting on August 1–2, 2018, in Washington, DC, to discuss considerations for the basis of the fee for long-term management and storage of elemental mercury including length of time in storage, the cost of eventual treatment and disposal technology, and different operational scenarios. Participants included representatives of generators producing elemental mercury incidentally from the beneficiation or processing of ore, or related pollution control activities. DOE also consulted with members of the Environmental Technology Council, a private organization whose members include persons likely to deliver elemental mercury to the designated DOE storage facility, on January 23, 2019.

The proposed rule would have established the fee for long-term management and storage of elemental mercury at the designated DOE storage facility as $55,100 per metric ton (MT),[2] plus a receiving charge of $3,250 per shipment. In response to comments received regarding the proposed rule, DOE has adjusted the fee downward to $37,000 per MT. In accordance with MEBA section 5(b)(1)(B)(ii), 42 U.S.C. 6939f(b)(1)(B)(ii), this fee may be adjusted annually according to the factors described in Section II, Discussion of Fee Basis.

II. Discussion of Fee Basis

The fee per metric ton is the sum of (1) the net present value of elementary mercury storage for fifteen years using the 15-year real interest rate from Office of Management and Budget (OMB) Circular A–94; (2) the pro-rated cost of materials required for storage of elemental mercury; (3) the present value of the cost of transporting elemental mercury from the storage facility to a treatment facility in the sixteenth year using the 15-year real interest rate from OMB Circular A–94; and (4) the present value of the cost of treatment and disposal in the sixteenth year using the 15-year real interest rate from OMB Circular A–94. While there is no current regulatory framework to treat and dispose of elemental mercury in the U.S., DOE is assuming a scenario in which there is treatment and disposal capacity for high-concentration elemental mercury waste in the future.

In accordance with 42 U.S.C. 6939f(b)(1)(B), because the designated facility was not operational on January 1, 2019, DOE will adjust the fee adopted in this final rule and assessed for elemental mercury delivered to the designated facility to subtract the cost of the temporary accumulation for those generators accumulating elemental mercury in a facility pursuant to 42 U.S.C. 6939f(g)(2)(B) and (D)(iv) during the period in which the designated facility is not operational. The subtraction will occur after receipt and approval of invoices outlining acceptable costs.

In accordance with 42 U.S.C. 6939f(b)(1)(B)(ii), DOE may adjust the fee annually. As stated in the proposed rule, DOE will adjust the fee by

[1] Elemental mercury stored at the facility will be classified as a hazardous waste under the Resource Conservation and Recovery Act and its implementing regulations. MEBA Section 3 prohibits the sale, distribution or transfer of elemental mercury stored by DOE, and MEBA Sections 5(d)(1) and 5(g)(2)(B) require that the elemental mercury be stored at facilities having permits to manage RCRA hazardous waste (with the exception of waste elemental mercury generated by certain generators, and which is destined for the long-term storage facility as allowed by 42 U.S.C. 6939f(g)(2)(D)). Based on the description of elemental mercury that is destined for and stored at the DOE long-term storage facility, the RCRA hazardous waste code U151 applies (see 40 CFR 261.33).

[2] One metric ton is 2,204.62 lbs.

adjusting the parameters used in calculating the fee. If this adjustment results in a significant adjustment of the fee, DOE will provide an opportunity for public participation. The parameters subject to adjustment are as follows:

- Number of years that elemental mercury will reside in storage at the DOE designated facility.
- Cost to store 1 MT of elemental mercury for the number of years that elemental mercury will reside in storage at the DOE designated facility.
- Pro-rated cost of materials required for storage of elemental mercury.
- Cost of transportation from the elemental mercury storage facility to a treatment facility.
- Cost of treatment of elemental mercury, and disposal of the treated waste form.
- Real interest rate from OMB Circular A–94.

The breakdown of the storage cost per metric ton is given by the following table:

Year	Receipt	Management	Lease	Oversight	State tax	Removal	Total
1	$570.00	$300.84	$300.84	$117.17			$1,288.85
2–15		300.84	300.84	60.17	$120.34		782.18
16					120.34	$9570.00	690.34

The cost of storage from the table above is $12,900. The net present value of this total, using the 15-year real interest rate from OMB Circular A–94 (1.45%), is $11,500. DOE has used 6 hours of labor at $95/hour for receipt of each metric ton of elemental mercury for unloading from transportation vehicles, verifying compliance with waste acceptance criteria, logging receipt and placement in storage. Storage costs are $300.84/MT-year for management, and DOE has allocated $30,234.42 lease costs across an initial contracted inventory of 1,206 MT, resulting in $300.84/MT in lease costs. State taxes are computed at 20% beginning 1 year after incurring the management and lease expense. Oversight expenses are computed at 10% of total annual costs for monitoring of program performance and performing audit functions to assure integrity of the waste acceptance process. Finally, DOE has used 6 hours of labor at $95/hour for removal of elemental mercury from racks, logging shipment and placing on transportation vehicles awaiting shipment to a treatment facility. DOE has allocated the cost of acquiring racks and other required materials for storage across an initial contracted inventory of 1,206 MT, resulting in a per metric ton cost for materials of $200/MT. Adding the cost per metric ton of materials to the net present value of the table above results in a total cost of storage of $11,700/MT.

The present value of the cost of transportation in the sixteenth year using the 15-year real interest rate from OMB Circular A–94 (1.45%) is $800. The current year cost basis is $1,000, assuming approximately 1,800 miles traveled.

The present value of the cost of treatment and disposal of elemental mercury in the sixteenth year using the 15-year real interest rate from OMB Circular A–94 (1.45%) is $24,500.

The resulting fee per metric ton is given by the following table:

Storage cost	$11,700
Transportation cost	800
Treatment and disposal cost	24,500
Total	37,000

III. Response to Comments

DOE published the proposed rule to establish the fee for the management and storage of elemental mercury on October 4, 2019. (84 FR 53066). DOE received comments from interested parties that are available at the following link *https://www.regulations.gov/docket?D=DOE-HQ-2019-0037.* DOE responds to the comments received on the proposal in this section, including changes made to reduce the proposed fee that were made in response to those comments.

Comment: DOE must withdraw the proposed rule.

Response: As discussed in the paragraphs that follow, DOE has addressed the comments received on the proposed rule that form the basis for the commenters' withdrawal request and has revised it accordingly. As a result, DOE declines to withdraw the proposed rule.

Comment: DOE failed to provide information in an accompanying administrative record that would allow sufficient public review of the proposed rule.

Response: As required by the Mercury Export Ban Act, as amended (MEBA), DOE consulted with persons likely to deliver elemental mercury to the designated facility on the fee prior to publication of the proposed rule. Beginning in 2016, DOE contacted the operators of facilities that had made the certification provided for in 42 U.S.C. 6939f(g)(2)(B) to collect information on elemental mercury storage and who was using the storage. This led representatives of the Department to reach out to members of the mining community and to the Nevada Mining Association.

Consultation took the form of meetings and teleconferences, from May 2017 through July 2019, with representatives from Newmont Mining Corporation, Barrick Gold Corporation, Coeur Rochester, Inc., and members of the Environmental Technology Council, some of which had made the certification provided for in 42 U.S.C. 6939f(g)(2)(B) and were storing elemental mercury for clients until the DOE facility opens.[3]

As noted by commenters, DOE engaged in extensive discussions with stakeholders. During these discussions, the basis for the fee calculation (*i.e.,* storage for an unspecified, but limited, time followed by treatment and disposal at another location) was presented. Stakeholders provided information to DOE that was evaluated as part of development of the proposed rule. DOE shared its concerns with some of the scenarios suggested by stakeholders during consultation.

In developing the proposed fee and the fee established in this final rule, with respect to storage costs, DOE used source selection sensitive information in accordance with Federal Acquisition Regulation (FAR) 2.101 and FAR 3.104 and is not approved for release to the public. DOE received information on preliminary pricing for treatment and disposal that it determined was business confidential information. DOE estimated expected pricing for treatment and disposal using publicly available pricing for similar treatment and disposal in accordance with the DOE Cost Estimating Guide (DOE–G–413.3–21) and found a reasonable expected price range of $24,000/MT to $34,600/MT. Since the preliminary pricing fell within

[3] DOE also notes that it held an ex parte meeting with Environmental Technology Council (ETC) members on November 21, 2019. At this meeting, ETC members expressed their concerns with the rulemaking. The ex parte meeting has been included in the record for this rulemaking and is available at *https://www.energy.gov/gc/legal-resources/ex-parte-communications.*

the expected cost range, DOE has adopted $30,900/MT as the cost of treatment and disposal. DOE used information provided during the consultation process as the basis for an estimate for the costs to transport elemental mercury from the storage facility to a future treatment facility. DOE used publicly available information from OMB Circular A–94 as a source for relevant interest rates.

Given the level of consultation and engagement with persons likely to deliver elemental mercury to the facility, as well as, the straightforward fee basis, DOE believes sufficient information was provided to allow the public to meaningfully comment on the proposed rule and to support the fee established in this final rule.

Comment: DOE failed to consider alternatives to the scenario presented in the proposed rule, including scenarios presented during consultation.

Response: During consultation, DOE discussed and considered scenarios suggested by the meeting participants. These discussions included the scenario that ultimately became the basis for the proposed fee.

The scenarios discussed included indefinite storage (including storage at Hawthorne Army Depot (HWAD)), and storage for a relatively short period of time until a regulatory framework for treatment and disposal in the U.S. becomes available, and subsequent treatment and disposal in the United States.

Commenters indicated that storage at HWAD is significantly less expensive than the basis for the proposed rule. On multiple occasions since MEBA was passed DOE discussed the use of HWAD for storage of elemental mercury with the Department of Defense (DoD), including as recently as December 2018 and January 2019. During these discussions DOE and DoD noted that 10 U.S.C. 2692 generally prohibits the storage of non-defense toxic and hazardous materials. The Secretary of Defense may grant exceptions to this prohibition when essential to protect the health and safety of the public from imminent danger if the Secretary otherwise determines the exception is essential, and if the storage or disposal authorized does not compete with private enterprise. However, neither of these conditions can be met because elemental mercury is currently being stored safely at privately owned facilities that made the certification provided for in 42 U.S.C. 6939f(g)(2)(B), and DOE has evaluated reasonable alternative locations for storage of elemental mercury.

Comment: The use of a leased facility is not permitted under MEBA.

Response: The phrase ''facility or facilities of [DOE]'' is not defined in MEBA. DOE operates at both DOE-owned and -leased facilities, and DOE has construed the term ''DOE facility'' to refer to an assortment of ownership and lease relationships. MEBA Section 5(f) authorizes DOE to establish such terms, conditions, and procedures as are necessary to carry out MEBA Section 5. As noted in the *Long-Term Management and Storage of Elemental Mercury Environmental Impact Statement* (EIS) at page 1–3 fn. 2, DOE has interpreted MEBA Section 5 to authorize DOE to designate existing and/or new storage facilities at property owned or leased by DOE.

Comment: DOE has included costs in the fee basis that are not recoverable under MEBA.

Response: MEBA section 5(b)(1)(B)(iii), 42 U.S.C. 6939f(b)(1)(B)(iii), provides that fees shall be set in an amount sufficient to cover costs set forth in MEBA section 5(b)(2), 42 U.S.C. 6939f(b)(2). Such costs are costs to DOE of providing management and storage, including operation and maintenance, security, monitoring, reporting, personnel, administration, inspections, training, fire suppression, closure, and other costs required for compliance with applicable law.

In accordance with MEBA, the costs associated with land acquisition or permitting of the facility under the Solid Waste Disposal Act or other applicable law are not recoverable. The DOE lease agreement for elemental mercury storage only includes a leasehold interest in the portion of the buildings used only; therefore, the lease arrangement does not qualify as land acquisition. DOE has received a cost estimate of necessary permit modifications but has not included them in the fee basis. No building design or construction costs have been incurred and included in the basis for the fee calculation.

In summary, DOE did not include any non-recoverable costs in the basis for the proposed fee. In addition, DOE plans to fulfill its elemental mercury storage mission by hiring a contractor to operate the facility; therefore, DOE believes the inclusion of contractors' profit is a recoverable cost under MEBA.

Comment: DOE failed to consult with persons likely to deliver elemental mercury as required by MEBA. DOE should provide summaries of the meetings and teleconferences.

Response: As required by MEBA, DOE consulted with persons likely to deliver elemental mercury to the designated facility on the fee prior to publication of the proposed rule. This included meetings and teleconferences conducted between May 2017 and July 2019 with persons representing Newmont Mining Corporation, Barrick Gold Corporation, and Coeur Rochester, Inc., and members of the Environmental Technology Council, some of which had made the certification provided for in 42 U.S.C. 6939f(g)(2)(B) and are storing elemental mercury for clients until the DOE facility opens.

During consultation, DOE discussed and considered scenarios suggested by the meeting participants. These discussions included the scenario that ultimately became the basis for the proposed fee.

The scenarios discussed included indefinite storage (including storage at Hawthorne Army Depot (HWAD)), and storage for a relatively short period of time until a regulatory framework for treatment and disposal in the U.S. becomes available, and subsequent treatment and disposal in the United States.

As noted above, DOE evaluated the use of HWAD with DoD. During consultation, DOE kept participants informed of the results of its investigations.

During a meeting in Washington, DC, on January 23, 2019, DOE presented information to members of the Environmental Technology Council (ETC), some of which had made the certification provided for in 42 U.S.C. 6939f(g)(2)(B) and are storing elemental mercury for clients until the DOE facility opens. Additionally, DOE spoke with a representative of ETC on multiple occasions to apprise ETC of the status of preparing the proposed rule and the development of the fee basis.

DOE also has maintained a dialog with appropriate personnel from the Nevada Department of Environmental Protection and the Texas Commission on Environmental Quality during the development of the proposed rule.

DOE believes the level of outreach and consultation that the agency engaged in meets the requirements of MEBA. DOE provided further opportunities for input from interested parties and the public through publication of the proposed rule and solicitation of comments.

Comment: DOE provided insufficient time for the public to comment on the proposed rule and should extend the public comment period.

Response: Given the extensive discussions with stakeholders, the straightforward fee basis, and the fact that the proposed fee was based on a scenario discussed multiple times

during the consultations, DOE did not believe extension of the public comment period was necessary.

Comment: DOE failed to consider less expensive options.

Response: DOE based the proposed fee on information received from a U.S. vendor in response to a solicitation in preparing the proposed rule. In 2017, DOE compared the response to the price for elemental mercury storage by companies engaged in elemental mercury storage that had made certifications in accordance with 42 U.S.C. 6939f(g)(2)(B). Among those companies that responded, the only company that provided specific pricing information indicated $1,200/MT-year was their price for this service. This price information was confirmed by stakeholders that are users of these facilities during consultation. In 2019, DOE also reviewed the responses to a Request for Expressions of Interest received from multiple potential offerors before the solicitation was issued. This led DOE to the conclusion that a reasonable market price for storage of elemental mercury was in a range of approximately $1,000/MT-year to $2,200/MT-year. Since the average annual cost of storage in the scenario used as the basis for the fee is $780/MT, DOE considers this basis to represent a cost-efficient approach.

Several comments were received suggesting that the price for storage should be more on the order of $80/MT-year, some suggesting that this is the cost of storage at HWAD. HWAD storage of elemental mercury is not subject to the Resource Conservation and Recovery Act (RCRA), nor is it required to accept shipments from sources as varied as those expected at the DOE designated facility. DOE is unable to verify the components of the suggested HWAD costs in order to appropriately make a direct comparison to HWAD.

DOE contacted DoD regarding the possibility of using HWAD as the DOE facility for long-term management and storage of elemental mercury and found that, in accordance with 10 U.S.C. 2692, the facility was prohibited from accepting non-defense related hazardous waste. As discussed in response to an earlier comment, to waive the prohibition, two conditions must be met: (1) There must be an imminent danger to public health and safety; and (2) the storage must not compete with private enterprise. Since neither of these conditions could be met, DOE determined that use of HWAD as the DOE facility for long-term management and storage of elemental mercury was not viable.

DOE has not proposed to treat elemental mercury in the United States and dispose of the resulting mercury compound in Canada. DOE notes, however, that treatment of elemental mercury in the United States and subsequent disposal of the resulting mercury compound in Canada is an option for generators of elemental mercury.

Comment: DOE is using an escalation rate for storage costs that is too high.

Response: DOE has revised the fee basis to use discounted funds and has eliminated the escalation rate used in the proposed rule. Consistent with discussions with participants during consultation, OMB Circular A–94 rates are used. The fee basis has been revised using the 15-year real rate from OMB Circular A–94 (1.45%).

Comment: DOE should have used discount rates rather than escalating all costs.

Response: DOE has revised the calculation of the proposed fee to use discounted funds and has eliminated the escalation rate used in the proposed rule. The resulting fee basis has been reduced from $55,100 per MT plus a receiving charge of $3,250 per shipment, to $37,000 per MT.

Comment: DOE failed to provide an explanation for the receiving charge.

Response: The receiving charge is the cost of purchasing required materials, unloading the elemental mercury from the truck, moving it to its storage location, checking compliance with the Waste Acceptance Criteria and logging the shipment.

In response to comments received on the proposed fee, DOE has revised the fee basis to allocate the receiving charge on a per MT basis. As a result, the additional per shipment charge has been deleted.

Comment: DOE failed to provide an explanation for the removal charge.

Response: The removal charge is the cost of removing elemental mercury from storage, loading it onto a truck and logging the shipment. This charge is allocated on a per MT basis.

Comment: DOE failed to provide an explanation for the transportation cost.

Response: As described in the preamble of the proposed rule, the transportation cost is the cost to transport elemental mercury accepted for storage at the DOE facility to an assumed treatment facility after the storage period.

During consultation, DOE learned that generators of elemental mercury in Nevada were paying approximately $1,000 for a shipment of up to 15 MT of elemental mercury from Nevada to Alabama for storage. DOE assumed a similar mileage of approximately 1,800 miles for shipment from the DOE designated storage facility to a future treatment facility. The mileage is based on transportation from Andrews County, TX to Hellertown, PA. DOE considered Hellertown, PA to be a reasonable hypothetical location for treatment of elemental mercury prior to eventual disposal.

The fee has been revised to reflect payment of $1,000 for transportation in year 16 using discounted funds (now, $800/MT).

Comment: DOE failed to provide an explanation for the treatment and disposal cost.

Response: DOE is assuming a treatment and disposal technology similar to that which is currently available for disposal in Canada (*i.e.,* conversion to red mercury sulfide and disposal in a regulated landfill).

DOE has kept apprised of developments in the private sector associated with the development of treatment and disposal technologies and adjusted the fee basis accordingly. As described in the proposed rule, the pricing is based on preliminary pricing from a U.S. vendor and DOE is treating the source as business sensitive. DOE compared the preliminary pricing to treatment and disposal in Canada, making appropriate adjustments using the guidance from the DOE Cost Estimating Guide (DOE–G–413.3–21) for a Class 2 cost estimate and found that the preliminary pricing fell within the range for such an estimate. DOE noted that the technical approach under consideration includes additional encapsulation relative to the currently available disposal in Canada and that no current actions to gain regulatory approval are in progress.

This is included only as a cost basis for an assumed treatment and disposal capability in the U.S. at some future date. It does not imply a commitment on the part of the Environmental Protection Agency (EPA) to promulgate a regulatory framework for treatment and disposal.

Comment: Why did DOE not consider disposal in Canada?

Response: MEBA directs DOE to designate a facility for long-term management and storage of elemental mercury generated within the United States. DOE notes, however, that treatment of elemental mercury in the United States and subsequent disposal of the resulting mercury compound in Canada is an option for generators of elemental mercury.

Comment: The proposed fee is too high.

Response: DOE based the proposed fee on information received from a U.S. vendor in response to a solicitation in preparing the proposed rule. DOE reviewed the response and compared it to market information provided by companies engaged in elemental mercury storage that had made certifications in accordance with 42 U.S.C. 6939f(g)(2)(B). This price information was confirmed by stakeholders that are users of these facilities during consultation. In 2019, DOE also reviewed the responses to a Request for Expressions of Interest received from multiple potential offerors before the solicitation was issued. This led DOE to the conclusion that a reasonable market price for storage of elemental mercury was in a range of $1,000/MT-year to $2,200/MT-year.

The receiving charge is the cost of purchasing required materials, unloading the elemental mercury from the truck, moving it to its storage location, checking compliance with the Waste Acceptance Criteria and logging the shipment.

In response to comments received on the proposed fee, DOE has revised the fee basis to properly allocate the receiving charge on a per MT basis. As a result, the additional per shipment charge has been deleted.

The removal charge is the cost of removing elemental mercury from storage, loading it onto a truck and logging the shipment. This charge is allocated on a per MT basis.

During consultation, DOE learned that generators of elemental mercury in Nevada were paying approximately $1,000 for a shipment of up to 15 MT of elemental mercury from Nevada to Alabama for storage. DOE assumed a similar mileage of approximately 1,800 miles for shipment from the DOE designated storage facility to a future treatment facility. The mileage is based on transportation from Andrews County, TX to Hellertown, PA. DOE considered Hellertown, PA to be a reasonably hypothetical location for treatment of elemental mercury prior to eventual disposal.

The fee has been revised to reflect payment of $1,000 for transportation in year 16 using discounted funds (now, $800/MT). DOE has kept apprised of developments in the private sector associated with the development of treatment and disposal technologies and adjusted the basis accordingly. As described in the proposed rule, the pricing is based on preliminary pricing from a U.S. vendor and DOE is treating the source as business sensitive. DOE compared the preliminary pricing to treatment and disposal in Canada, making appropriate adjustments using the guidance from the DOE Cost Estimating Guide (DOE–G–413.3–21) for a Class 2 cost estimate and found that the preliminary pricing fell within the range for such an estimate. DOE noted that the technical approach under consideration includes additional encapsulation relative to the currently available disposal in Canada and that no current actions to gain regulatory approval are in progress. DOE has also revised the calculation of the proposed fee to use discounted funds. The resulting fee basis has been reduced from $55,100 per MT plus a receiving charge of $3,250 per shipment, to $37,000 per MT. The cost breakdown is given by the following schedule:

Description	Cost
Net present value (NPV) of Total Storage Cost of 15 years of storage @15-year real rate (1.45%)—includes per metric ton materials cost	$11,700
Present value (PV) of Transportation cost ($1,000) in year 15 @15-year real rate (1.45%)	800
PV of Treatment and Disposal cost ($30,900) in year 15 @15-year real rate (1.45%)	24,500
Total Fee/MT (rounded to nearest $)	37,000

Comment: Why is DOE using 15 years of storage as a basis for the fee?

Response: MEBA requires DOE to designate and operate a facility or facilities for the long-term management and storage of elemental mercury per 42 U.S.C. 6939f. Under the Resource Conservation and Recovery Act, EPA is responsible for promulgating regulations for storage, treatment, and disposal of elemental mercury (and other mercury wastes) in the United States. Currently no treatment standard exists or has been proposed that would allow land disposal of high-purity elemental mercury waste, waste mercury compounds, or other high-concentration mercury wastes. Although it is reasonable to assume that this situation may change in the future—as reflected by DOE's estimate of 15 years of storage—it does not imply a commitment on the part of EPA to promulgate a regulatory framework for treatment and disposal. Following consultations with EPA, DOE selected 15 years of storage in recognition of DOE's and EPA's respective roles. DOE believes this amount of time is reasonable given the uncertainty associated with the timing of establishing a regulatory framework for the treatment and disposal of high-purity elemental mercury.

Comment: Will there be any other costs at a future time?

Response: Once the fee has been paid and the elemental mercury has been accepted, there will be no other costs imposed on generators.

Comment: Will DOE take ownership of the elemental mercury received?

Response: MEBA directs DOE to take custody of elemental mercury delivered to the facility for long-term management and storage of elemental mercury and to hold harmless, defend and provide indemnification to persons who deliver elemental mercury to the facility. Once the fee has been paid and the elemental mercury is accepted at the facility, DOE assumes responsibility for its storage and disposition.

Comment: Will there be an opportunity for public participation for future fee increases?

Response: As provided for by MEBA, DOE may adjust the fee annually. If this adjustment results in a significant alteration of the fee, DOE will provide an opportunity for public participation. The parameters that are subject to adjustment, as revised in response to public comments, are as follows:

- Number of years that elemental mercury will reside in storage at the DOE designated facility.
- Cost to store 1 MT of elemental mercury for the number of years that elemental mercury will reside in storage at the DOE designated facility.
- Pro-rated cost of materials required for storage of elemental mercury
- Cost of shipment from the elemental mercury storage facility to a treatment facility.
- Cost of treatment of elemental mercury, and disposal of the treated waste form.
- Real interest rate from OMB Circular A–94.

Comment: Why does elemental mercury delivered to the DOE facility need to be 99.5% pure?

Response: The requirement for 99.5% purity is consistent with the guidance published by DOE in 2009 and has been chosen based on the need to store the elemental mercury for an indefinite period. As noted in the *Long-Term Management and Storage of Elemental Mercury* EIS at page 2–1 fn. 3, the treatment standard for wastes containing high concentrations of mercury (greater than 260 parts per million) is recovery through roasting or retorting, which is performed at various commercial waste recovery facilities. This process yields high-purity elemental mercury (*e.g.,* elemental mercury that is at least 99.5 percent pure by volume) that is generally acceptable for reintroduction back into commerce and is analogous to the materials to be stored in a DOE designated storage facility.

Comment: The Supplement Analysis (SA) notes that Waste Control Specialists (WCS) existing buildings will have to be redesigned, even though no new buildings will have to be built. Again, such costs cannot be included in the fee proposal.

Response: The Supplement Analysis EIS–0423–SA–01 makes no such statement.

The WCS facility is permitted to receive elemental mercury currently and no structural upgrades are anticipated. Consequently, no design or construction costs are included in the fee basis for the proposed fee.

Comment: Will the receiving charge be reduced for shipments under 15 MT?

Response: DOE has revised the fee basis to allocate the receiving charge on a per MT basis. As a result, the additional per shipment charge has been deleted.

Comment: The facility should have been designated/proposed prior to publishing the proposed fee.

Response: DOE acknowledges that the language of MEBA envisions designation of a facility prior to the establishment of the fee. DOE has designated a facility for long-term management and storage of elemental mercury since publication of the proposed rule.

Comment: DOE should consider investing funds in non-U.S. securities for a better return.

Response: MEBA requires DOE to asses and collect the fee, but it does not authorize DOE to retain fee proceeds and invest or otherwise use them. Absent a DOE authority to retain the funds, they will be deposited in the Treasury pursuant to 31 U.S.C. 3302 (Miscellaneous Receipts Act).

Comment: If costs end up lower than the fee basis, will there be a rebate?

Response: DOE will not provide rebates if the actual costs end up lower than the fee basis. Similarly, if costs end up higher than the fee basis, DOE will not invoice generators that have previously delivered elemental mercury to the DOE designated facility for such additional costs.

Comment: Will DOE petition EPA to change the RCRA standard to allow treatment and disposal in U.S.?

Response: This comment is outside the scope of the rulemaking to establish a fee for the long-term management and storage of elemental mercury.

Comment: Mercury collected from recycling should not be subject to fees.

Response: MEBA directs DOE to assess and collect a fee at the time of delivery of elemental mercury to the facility for long-term management and storage of such elemental mercury. MEBA does not include exceptions for elemental mercury collected from recycling.

Comment: Mercury collected from recycling should not be defined as hazardous waste.

Response: This comment is outside the scope of the rulemaking to establish a fee for the long-term management and storage of elemental mercury.

Comment: The proposed fee will substantially reduce recycling.

Response: MEBA directs DOE to conduct a study, in consultation with EPA, on the impact of the long-term management and storage program for elemental mercury on mercury recycling, and include proposals, if necessary, to mitigate any negative impacts. DOE continues to gather empirical information to assess these impacts.

Comment: The proposed fee will promote exportation of elemental mercury.

Response: To export elemental mercury, a person must petition the Administrator of EPA, who may grant an exemption provided that the conditions of 15 U.S.C. 2611 (c)(4)(A)(i)–(vii) are met. To date EPA has not granted any exemptions under this part of the MEBA (for more information, see: *https://www.epa.gov/mercury/questions-and-answers-mercury-export-ban-act-meba-2008*).

DOE has not received any information to suggest the proposed fee will result in a significant increase in such petitions.

Comment: Landfilling of mercury is not condoned.

Response: For purposes of estimating the fee, DOE has assumed a scenario in which elemental mercury is disposed in a regulated landfill following treatment by conversion to red mercury sulfide. This method of treatment of elemental mercury and subsequent disposal of the resulting mercury compound is used safely in Canada.

Although there is no current regulatory framework that allows this practice in the U.S., in order to establish a fee basis, as required by MEBA, DOE considered it reasonable to assume that such a framework may exist in the future.

Comment: What happens after 15 years?

Response: The fee was calculated estimating 15 years of storage followed by treatment and disposal. DOE acknowledges that in the absence of a regulatory framework for such treatment and disposal, elemental mercury in storage at the DOE facility would continue to be stored beyond 15 years.

Comment: What about Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) liability?

Response: MEBA directs DOE to take custody of elemental mercury delivered to the facility for long-term management and storage of elemental mercury and to hold harmless, defend and provide indemnification to persons who deliver elemental mercury to the facility.

Comment: What are the acceptance criteria at the DOE facility for long-term management and storage of elemental mercury?

Response: The Waste Acceptance Criteria (DOE/EM–0007) is available at *https://www.energy.gov/sites/prod/files/2019/12/f69/Waste-Acceptance-Criteria-Final-12-12-2018.pdf.*

Comment: DOE failed to consider the environmental impact of the fee.

Response: The EIS evaluated seven government and commercial sites and the supplemental environmental impact statement (SEIS) evaluated additional alternatives for a facility at and in the vicinity of the Waste Isolation Pilot Plant (WIPP) for long-term management and storage of elemental mercury. The EIS and SEIS noted the relevant statutory provision regarding assessment and collection of a fee. The assessment and collection of the fee is part of the implementation of the proposed action. Elemental mercury that is not delivered to the long-term management and storage site would continue to be managed and stored by the current holder of the elemental mercury. While DOE cannot determine which specific elemental mercury would continue to be managed by the current holder at a given fee basis, such elemental mercury would have impacts similar to those analyzed under the no action alternative in the EIS and SEIS.

Comment: The Council on Environmental Quality (CEQ) regulations require cost-benefit analyses to be appended to or incorporated into an EIS because they are relevant to the choices among environmentally different alternatives.

Response: CEQ National Environmental Policy Act (NEPA) Regulations (40 CFR 1502.23) require that a cost-benefit analysis be incorporated by reference or appended only ''[i]f a cost-benefit analysis relevant to the choice among environmentally different alternatives is being considered for the proposed action.'' As discussed in the Record of Decision, DOE's decision was ''[b]ased on consideration of the analysis in the Final Elemental Mercury Storage EIS, SEIS, and recently prepared SA'' and ''on other programmatic, policy, logistic, and cost considerations.''

Comment: The EIS/SEIS/SA did not discuss potential environmental impacts of treatment and disposal of elemental mercury, or of transportation of elemental mercury for treatment and disposal.

Response: DOE has not proposed to treat and dispose of elemental mercury, or to transport elemental mercury for treatment and disposal. Thus, DOE has not analyzed the potential environmental impacts of such a proposal. Nonetheless, DOE has used treatment, disposal, and related transportation costs to calculate the fee for long-term elemental mercury management and storage. Although commenters have provided feedback regarding the components of a fee calculation based on this scenario, comments have not supported basing the fee on indefinite storage of elemental mercury.

IV. Regulatory Review

A. Review Under Executive Order 12866

This final rule has been determined not to be a ''significant regulatory action'' under Executive Order 12866, ''Regulatory Planning and Review,'' 58 FR 51735 (October 4, 1993), as amended by Executive Order 13258, 67 FR 9385 (February 26, 2002). Accordingly, this action was not subject to review under that Executive Order by the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget.

B. Review Under the National Environmental Policy Act

In accordance with the National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321 *et seq.*), the Council on Environmental Quality regulations and the DOE regulations implementing NEPA, DOE prepared the following documents analyzing the potential environmental impacts of long-term management and storage of elemental mercury: *Long-Term Management and Storage of Elemental Mercury Environmental Impact Statement* (DOE/EIS–0423, January 2011); *Long-Term Management and Storage of Elemental Mercury Supplemental Environmental Impact Statement* (DOE/EIS–0423–S1, September 2013); and *Supplement Analysis of the Final Long-Term Management and Storage of Elemental Mercury Environmental Impact Statement* (DOE/EIS–423–SA–01). The environmental impact statement (and the supplemental environmental impact statement) noted the relevant statutory provision regarding assessment and collection of a fee. The assessment and collection of the fee is part of the implementation of the action.

C. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires preparation of an initial regulatory flexibility analysis for any rule that by law must be proposed for public comment, unless the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. As required by Executive Order 13272, ''Proper Consideration of Small Entities in Agency Rulemaking,'' 67 FR 53461 (August 16, 2002), DOE published procedures and policies on February 19, 2003, to ensure that the potential impacts of its rules on small entities are properly considered during the rulemaking process (68 FR 7990). DOE has made its procedures and policies available on the Office of General Counsel's website: *https://www.energy.gov/sites/prod/files/gcprod/documents/eo13272.pdf.*

DOE has reviewed this rule under the provisions of the Regulatory Flexibility Act and the procedures and policies published on February 19, 2003. For the reasons explained below, DOE has determined that this rule, if adopted, will not have a significant economic impact on a substantial number of small entities.

In 2019, DOE published *Supplement Analysis of the Final Long-Term Management and Storage of Elemental Mercury Environmental Impact Statement* (DOE/EIS–423–SA–01) that updated the expected inventory during the next 40 years to 6,800 MT. DOE expects approximately 35–50 entities to pay the fee established in this final rule. DOE expects that the majority of the fees paid will be paid by less than 10 of these entities. The Nevada Mining Association (NMA) membership includes the generators of elemental mercury that are expected to deliver the majority of elemental mercury to the DOE facility. DOE contacted NMA for information to help determine how many of its membership qualify as small entities under NAICS codes 212221 (Gold ore mining, 1500 employees), 212222 (Silver ore mining, 250 employees), 212230 (Copper, nickel, lead and zinc mining, 750 employees) and 212299 (All other metal ore mining, 750 employees). The information received showed that there are 31 entities that fall below the small business standards versus 2 entities that exceeded the standard. DOE estimates that the largest impact would be to entities engaged in mining that do not qualify as small entities under NAICS codes. This impact will vary based on ore grade and price fluctuations in the precious metals market.

Some entities that have either accepted elemental mercury for storage, in accordance with 42 U.S.C. 6939f(g)(2)(B) or have placed elemental mercury in storage in accordance with 42 U.S.C. 6939f(g)(2)(B) or (D), awaiting the start of operation at the DOE facility will be required to pay the fee for storage at the DOE site. These entities would be classified under the NAICS codes in the previous paragraph or NAICS code 562112 (Hazardous Waste Collection, $41.5M). The largest of these impacts are likely be a one-time expense shortly after the start of operations at the DOE facility. DOE determined, however, that none of these entities are likely to be small entities.

As a result of MEBA, with the exception of elemental mercury that has been placed in storage in accordance with 42 U.S.C. 6939f(g)(2)(B) or (D), generators of elemental mercury can either send elemental mercury that is being discarded to the DOE designated facility for long- term management and storage, or treat the elemental mercury to form a mercury compound and then export the mercury compound for environmentally sound disposal in accordance with 15 U.S.C. 2611(c)(7)(A)–(B) and (D). Export of mercury compounds for environmentally sound disposal in another country may also be subject to that country's obligations under the Basel Convention, if applicable, and that country's applicable domestic laws and regulations. While international sales generally are prohibited by MEBA's export ban, 42 U.S.C. 2611(c)(1), non-Federal generators may also consider

domestic sales of elemental mercury.[4] Although domestic sale of elemental mercury is an option without a negative economic impact, it is likely that the supply would exceed demand and thus that option may not be viable for some non-Federal generators. As stated above, for those non-Federal generators for whom sale is not a viable option, the available options are sending the elemental mercury to the DOE designated facility or environmentally sound disposal of certain mercury compounds in accordance with 15 U.S.C. 2611(c)(7)(D). Treatment and disposal is available at a cost of approximately $26,500 (USD) per metric ton in Canada, for example, and generators can choose this option if it is more cost effective for them.

Because DOE has determined that entities currently storing elemental mercury who will be required to pay the fee established by DOE for storage in the DOE facility are not likely to be small entities, and because those entities not required to pay the fee established by DOE for storage in the DOE facility can choose another disposal option if that option is more cost effective for them, DOE has determined that this rule does not have a significant economic impact on a substantial number of small entities.

DOE's certification and supporting statement of factual basis was provided to the Chief Counsel for Advocacy of the Small Business Administration pursuant to 5 U.S.C. 605(b). The Department did not receive any comments on the certification and has responded to comments regarding the economic impacts of the rule in Section III of this final rule.

D. Review Under the Paperwork Reduction Act

This rulemaking would impose no new information or recordkeeping requirements. Accordingly, OMB clearance is not required under the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501 *et seq.*).

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB Control Number.

E. Review Under the Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires each Federal agency to prepare a written assessment of the effects of any Federal mandate in a proposed or final agency regulation that may result in the expenditure by States, tribal or local governments, in the aggregate, or by the private sector, of $100 million in any one year. The Act also requires Federal agencies to develop an effective process to permit timely input by elected officials of State, tribal, or local governments on a proposed significant intergovernmental mandate, and requires an agency plan for giving notice and opportunity to provide timely input to potentially affected small governments before establishing any requirements that might significantly or uniquely affect small governments. DOE has determined that this rule does not contain any Federal mandates exceeding $100 million in any one year affecting States, tribal, or local governments, or the private sector, and, thus, no assessment or analysis is required under the Unfunded Mandates Reform Act of 1995.

F. Review Under Executive Order 12988

With respect to the review of existing regulations and the promulgation of new regulations, section 3(a) of Executive Order 12988, ''Civil Justice Reform'' 61 FR 4779 (February 7, 1996), imposes on Federal agencies the general duty to adhere to the following requirements: (1) Eliminate drafting errors and ambiguity; (2) write regulations to minimize litigation; (3) provide a clear legal standard for affected conduct rather than a general standard; and (4) promote simplification and burden reduction. With regard to the review required by section 3(a), section 3(b) of Executive Order 12988, specifically requires that Federal agencies make every reasonable effort to ensure that the regulation: (1) Clearly specifies the preemptive effect, if any; (2) clearly specifies any effect on existing Federal law or regulation; (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction; (4) specifies the retroactive effect, if any; (5) adequately defines key terms; and (6) addresses other important issues affecting the clarity and general draftsmanship under guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires executive agencies to review regulations in light of applicable standards in section 3(a) and section 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. DOE has completed the required review and determined that, to the extent permitted by law, this rule meets the relevant standards of Executive Order 12988.

G. Review Under Executive Order 13132

Executive Order 13132, ''Federalism,'' 64 FR 43255 (August 10, 1999) imposes certain requirements on agencies formulating and implementing policies or regulations that preempt State law or that have federalism implications. Agencies are required to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and to carefully assess the necessity for such actions. The Executive order also requires agencies to have an accountable process to ensure meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications. On March 14, 2000, DOE published a statement of policy describing the intergovernmental consultation process it will follow in the development of such regulations. (65 FR 13735). DOE has examined this rule and has determined that it would not preempt State law and would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibility among the various levels of government. No further action is required by Executive Order 13132.

H. Review Under the Treasury and General Government Appropriations Act, 1999

Section 654 of the Treasury and General Government Appropriations Act, 1999 (Pub. L. 105–277) requires Federal agencies to issue a Family Policymaking Assessment for any proposed rule that may affect family well-being. This rule would have no impact on the autonomy or integrity of the family as an institution. Accordingly, DOE has concluded that it is not necessary to prepare a Family Policymaking Assessment.

I. Review Under Executive Order 13211

Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy, Supply, Distribution, or Use,'' 66 FR 28355 (May 22, 2001) requires preparation and submission to OMB of a Statement of Energy Effects for any significant energy action. A ''significant energy action'' is defined as any action by an agency that promulgated or is expected to lead to

[4] MEBA provides that ''no Federal agency shall convey, sell, or distribute . . . any elemental mercury under the control or jurisdiction of the Federal agency.'' 15 U.S.C. 2605(f). MEBA provides an exception for ''a transfer between Federal agencies of elemental mercury under the control or jurisdiction of the Federal agency.'' *Id.* at 15 U.S.C. 2605(f)(2)(A).

promulgation of a final rule, and that: (1)(i) Is a significant regulatory action under Executive Order 12866, or any successor order; and (ii) is likely to have a significant adverse effect on the supply, distribution, or use of energy; or (2) is designated by the Administrator of OIRA as a significant energy action. For any significant energy action, the agency must give a detailed statement of any adverse effects on energy supply, distribution, or use should the proposal be implemented, and of reasonable alternatives to the action and their expected benefits on energy supply, distribution, and use. DOE has determined that this rule would not have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of OIRA has also not determined that this rule is a significant energy action. Thus, the requirement to prepare a Statement of Energy Effects does not apply.

J. Review Under the Treasury and General Government Appropriations Act, 2001

The Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516 note) provides for agencies to review most dissemination of information to the public under guidelines established by each agency pursuant to general guidelines issued by OMB. OMB guidelines were published at 67 FR 8452 (Feb. 22, 2002), and DOE guidelines were published at 67 FR 62446 (Oct. 7, 2002). DOE has reviewed this rule under the OMB and DOE guidelines and has concluded that it is consistent with applicable policies in those guidelines.

K. Review Under Executive Orders 13771

This rule is not subject to the requirements of E.O. 13771 (82 FR 9339, February 3, 2017) because this rule is considered to be a ''transfer rule.''

L. Congressional Notification

As required by 5 U.S.C. 801, DOE will report to Congress on the promulgation of this rule prior to its effective date. The report will state that it has been determined that the rule is a ''major rule'' as defined by 5 U.S.C. 804(2).

V. Approval of the Secretary of Energy

The Secretary of Energy has approved publication of this final rule.

List of Subjects in 10 CFR Part 955

Elemental mercury, Hazardous waste treatment, storage, and disposal, Reporting and recordkeeping requirements.

Signed in Washington, DC, on December 18, 2019.

Paul M. Dabbar,

Under Secretary for Science.

■ For the reasons set forth in the preamble, the Department of Energy adds part 955 to title 10 of the Code of Federal Regulations to read as follows:

PART 955—FEE FOR LONG-TERM MANAGEMENT AND STORAGE OF ELEMENTAL MERCURY UNDER THE MERCURY EXPORT BAN ACT OF 2008, AS AMENDED

Sec.
955.1 Purpose.
955.2 Scope and applicability.
955.3 Definitions.
955.4 Payment of fees.
955.5 Schedule of fees.

Authority: 42 U.S.C. 6939f(b).

§ 955.1 Purpose.

This part establishes a fee for long-term management and storage of elemental mercury in accordance with the Mercury Export Ban Act of 2008, as amended, section 5(b), (42 U.S.C. 6939f(b)).

§ 955.2 Scope and applicability.

This part applies to persons who deliver elemental mercury to the U.S. Department of Energy (DOE) designated facility for long-term management and storage.

§ 955.3 Definitions.

The following definitions are provided for purposes of this part:

DOE means the U.S. Department of Energy.

Elemental mercury means the element with the chemical symbol Hg and atomic number 80 in its liquid form. The form acceptable to DOE is at least 99.5% elemental mercury by volume. DOE will not accept elemental mercury in environmental media or consumer products (fluorescent lamps, batteries, etc.) or elemental mercury in manufactured items (manometers, thermometers, switches, etc.).

Metric ton means 1,000 kilograms (approximately 2,204 lbs.).

§ 955.4 Payment of fees.

Fees are payable upon delivery of elemental mercury to the DOE facility. All fee payments are to be made payable to the U.S. Department of Energy. The payments are to be made in U.S. funds by electronic funds transfer such as ACH (Automated Clearing House) using E.D.I. (Electronic Data Interchange), check, draft, money order, or credit card.

§ 955.5 Schedule of fees.

(a) Persons delivering elemental mercury to the DOE facility for long-term management and storage of elemental mercury shall pay fees in accordance with paragraph (b) of this section.

(b) The fee per metric ton is the sum of:

(1) The net present value of elementary mercury storage for the number of years in storage using the appropriate interest rate from Office of Management and Budget (OMB) Circular A–94;

(2) The pro-rated cost of materials required for storage of elemental mercury;

(3) The present value of the cost of transporting elemental mercury from the storage facility to a treatment facility in the year following the last year of storage using the appropriate interest rate from OMB Circular A–94; and

(4) The present value of the cost of treatment and disposal in the year following the last year of storage using the appropriate interest rate from OMB Circular A–94.

(c) The values in paragraphs (b)(1) through (4) of this section may be updated annually. These values are posted to the DOE Long-Term Management and Storage of Elemental Mercury website (*https://www.energy.gov/em/services/waste-management/waste-and-materials-disposition-information/long-term-management-and*). DOE will publish notice in the **Federal Register** when the values are updated to inform the public of the updates.

[FR Doc. 2019–27672 Filed 12–20–19; 8:45 am]

BILLING CODE 6450–01–P

BUREAU OF CONSUMER FINANCIAL PROTECTION

12 CFR Part 1026

Truth in Lending Act (Regulation Z) Adjustment To Asset-Size Exemption Threshold

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Final rule; official interpretation.

SUMMARY: The Bureau of Consumer Financial Protection (Bureau) is amending the official commentary that interprets the requirements of the Bureau's Regulation Z (Truth in Lending) to reflect a change in the asset-size threshold for certain creditors to qualify for an exemption to the requirement to establish an escrow

account for a higher-priced mortgage loan. This amendment is based on the annual percentage change in the average of the Consumer Price Index for Urban Wage Earners and Clerical Workers (CPI–W). Based on the 1.6 percent increase in the average of the CPI–W for the 12-month period ending in November 2019, the exemption threshold is adjusted to $2.202 billion from $2.167 billion. Therefore, creditors with assets of less than $2.202 billion (including assets of certain affiliates) as of December 31, 2019, are exempt, if other requirements of Regulation Z also are met, from establishing escrow accounts for higher-priced mortgage loans in 2020.

DATES: This rule is effective on January 1, 2020.

FOR FURTHER INFORMATION CONTACT: Rachel Ross, Attorney-Advisor; Kristen Phinnessee, Senior Counsel, Office of Regulations, at (202) 435–7700. If you require this document in an alternative electronic format, please contact *CFPB_Accessibility@cfpb.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 129D of the Truth in Lending Act (TILA) contains a general requirement that an escrow account be established by a creditor to pay for property taxes and insurance premiums for certain first-lien higher-priced mortgage loan transactions. TILA section 129D also generally permits an exemption from the higher-priced mortgage loan escrow requirement for a creditor that meets certain requirements, including any asset-size threshold the Bureau may establish.

In the 2013 Escrows Final Rule,[1] the Bureau established such an asset-size threshold of $2 billion, which would adjust automatically each year, based on the year-to-year change in the average of the CPI–W for each 12-month period ending in November, with rounding to the nearest million dollars.[2] In 2015, the Bureau revised the asset-size threshold for small creditors and how it applies. The Bureau included in the calculation of the asset-size threshold the assets of the creditor's affiliates that regularly extended covered transactions secured by first liens during the applicable period and added a grace period to allow an otherwise eligible creditor that exceeded the asset limit in the preceding calendar year (but not in the calendar year before the preceding year) to continue to operate as a small creditor with respect to transactions with applications received before April 1 of the current calendar year.[3] For 2019, the threshold was $2.167 billion.

During the 12-month period ending in November 2019, the average of the CPI–W increased by 1.6 percent. As a result, the exemption threshold is increased to $2.202 billion for 2020. Thus, if the creditor's assets together with the assets of its affiliates that regularly extended first-lien covered transactions during calendar year 2019 are less than $2.202 billion on December 31, 2019, and it meets the other requirements of § 1026.35(b)(2)(iii), it will be exempt from the escrow-accounts requirement for higher-priced mortgage loans in 2020 and will also be exempt from the escrow-accounts requirement for higher-priced mortgage loans for purposes of any loan consummated in 2021 with applications received before April 1, 2021. The adjustment to the escrows asset-size exemption threshold will also increase the threshold for small-creditor portfolio and balloon-payment qualified mortgages under Regulation Z. The requirements for small-creditor portfolio qualified mortgages at § 1026.43(e)(5)(i)(D) reference the asset threshold in § 1026.35(b)(2)(iii)(C). Likewise, the requirements for balloon-payment qualified mortgages at § 1026.43(f)(1)(vi) reference the asset threshold in § 1026.35(b)(2)(iii)(C). Under § 1026.32(d)(1)(ii)(C), balloon-payment qualified mortgages that satisfy all applicable criteria in § 1026.43(f)(1)(i) through (vi) and (f)(2), including being made by creditors that have (together with certain affiliates) total assets below the threshold in § 1026.35(b)(2)(iii)(C), are also excepted from the prohibition on balloon payments for high-cost mortgages.

II. Procedural Requirements

A. Administrative Procedure Act

Under the Administrative Procedure Act (APA), notice and opportunity for public comment are not required if the Bureau finds that notice and public comment are impracticable, unnecessary, or contrary to the public interest. 5 U.S.C. 553(b)(B). Pursuant to this final rule, comment 35(b)(2)(iii)–1 in Regulation Z (12 CFR part 1026) is amended to update the exemption threshold. The amendment in this final rule is technical and merely applies the formula previously established in Regulation Z for determining any adjustments to the exemption threshold. For these reasons, the Bureau has determined that publishing a notice of proposed rulemaking and providing opportunity for public comment are unnecessary. Therefore, the amendment is adopted in final form.

Section 553(d) of the APA generally requires publication of a final rule not less than 30 days before its effective date, except (1) a substantive rule which grants or recognizes an exemption or relieves a restriction; (2) interpretive rules and statements of policy; or (3) as otherwise provided by the agency for good cause found and published with the rule. 5 U.S.C. 553(d). At a minimum, the Bureau believes the amendments fall under the third exception to section 553(d). The Bureau finds that there is good cause to make the amendments effective on January 1, 2020. The amendment in this final rule is technical and non-discretionary, and it applies the method previously established in the agency's regulations for automatic adjustments to the threshold.

B. Regulatory Flexibility Act

Because no notice of proposed rulemaking is required, the Regulatory Flexibility Act does not require an initial or final regulatory flexibility analysis.[4]

C. Paperwork Reduction Act

The Bureau has determined that this final rule does not impose any new or revise any existing recordkeeping, reporting, or disclosure requirements on covered entities or members of the public that would be collections of information requiring approval by the Office of Management and Budget under the Paperwork Reduction Act.[5]

D. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Bureau will submit a report containing this rule and other required information to the United States Senate, the United States House of Representatives, and the Comptroller General of the United States prior to the rule taking effect. The Office of Information and Regulatory Affairs (OIRA) has designated this rule as not a ''major rule'' as defined by 5 U.S.C. 804(2).

[1] 78 FR 4726 (Jan. 22, 2013).

[2] *See* 12 CFR 1026.35(b)(2)(iii)(C).

[3] *See* 80 FR 59943, 59951 (Oct. 2, 2015). The Bureau also issued an interim final rule in March 2016 to revise certain provisions in Regulation Z to effectuate the Helping Expand Lending Practices in Rural Communities Act's amendments to TILA (Pub. L. 114–94, section 89003, 129 Stat. 1312, 1800–01 (2015)). The rule broadened the cohort of creditors that may be eligible under TILA for the special provisions allowing origination of balloon-payment qualified mortgages and balloon-payment high-cost mortgages, as well as for the escrow exemption. *See* 81 FR 16074 (Mar. 25, 2016).

[4] 5 U.S.C. 603(a), 604(a).

[5] 44 U.S.C. 3501–3521.

List of Subjects in 12 CFR Part 1026

Advertising, Appraisal, Appraiser, Banking, Banks, Consumer protection, Credit, Credit unions, Mortgages, National banks, Reporting and recordkeeping requirements, Savings associations, Truth in lending.

Authority and Issuance

For the reasons set forth above, the Bureau amends Regulation Z, 12 CFR part 1026, as set forth below:

PART 1026—TRUTH IN LENDING (REGULATION Z)

■ 1. The authority citation for part 1026 continues to read as follows:

Authority: 12 U.S.C. 2601, 2603–2605, 2607, 2609, 2617, 3353, 5511, 5512, 5532, 5581; 15 U.S.C. 1601 *et seq.*

■ 2. In supplement I to part 1026, under *Section 1026.35—Requirements for Higher-Priced Mortgage Loans, 35(b)(2) Exemptions, Paragraph 35(b)(2)(iii)* is revised to read as follows:

Supplement I to Part 1026—Official Interpretations

* * * * *

Subpart E—Special Rules for Certain Home Mortgage Transactions

* * * * *

Section 1026.35—Requirements for Higher-Priced Mortgage Loans

* * * * *

35(b)(2) Exemptions

* * * * *

Paragraph 35(b)(2)(iii).

1. *Requirements for exemption.* Under § 1026.35(b)(2)(iii), except as provided in § 1026.35(b)(2)(v), a creditor need not establish an escrow account for taxes and insurance for a higher-priced mortgage loan, provided the following four conditions are satisfied when the higher-priced mortgage loan is consummated:

i. During the preceding calendar year, or during either of the two preceding calendar years if the application for the loan was received before April 1 of the current calendar year, a creditor extended a first-lien covered transaction, as defined in § 1026.43(b)(1), secured by a property located in an area that is either ''rural'' or ''underserved,'' as set forth in § 1026.35(b)(2)(iv).

A. In general, whether the rural-or-underserved test is satisfied depends on the creditor's activity during the preceding calendar year. However, if the application for the loan in question was received before April 1 of the current calendar year, the creditor may instead meet the rural-or-underserved test based on its activity during the next-to-last calendar year. This provides creditors with a grace period if their activity meets the rural-or-underserved test (in § 1026.35(b)(2)(iii)(A)) in one calendar year but fails to meet it in the next calendar year.

B. A creditor meets the rural-or-underserved test for any higher-priced mortgage loan consummated during a calendar year if it extended a first-lien covered transaction in the preceding calendar year secured by a property located in a rural-or-underserved area. If the creditor does not meet the rural-or-underserved test in the preceding calendar year, the creditor meets this condition for a higher-priced mortgage loan consummated during the current calendar year only if the application for the loan was received before April 1 of the current calendar year and the creditor extended a first-lien covered transaction during the next-to-last calendar year that is secured by a property located in a rural or underserved area. The following examples are illustrative:

1. Assume that a creditor extended during 2016 a first-lien covered transaction that is secured by a property located in a rural or underserved area. Because the creditor extended a first-lien covered transaction during 2016 that is secured by a property located in a rural or underserved area, the creditor can meet this condition for exemption for any higher-priced mortgage loan consummated during 2017.

2. Assume that a creditor did not extend during 2016 a first-lien covered transaction secured by a property that is located in a rural or underserved area. Assume further that the same creditor extended during 2015 a first-lien covered transaction that is located in a rural or underserved area. Assume further that the creditor consummates a higher-priced mortgage loan in 2017 for which the application was received in November 2017. Because the creditor did not extend during 2016 a first-lien covered transaction secured by a property that is located in a rural or underserved area, and the application was received on or after April 1, 2017, the creditor does not meet this condition for exemption. However, assume instead that the creditor consummates a higher-priced mortgage loan in 2017 based on an application received in February 2017. The creditor meets this condition for exemption for this loan because the application was received before April 1, 2017, and the creditor extended during 2015 a first-lien covered transaction that is located in a rural or underserved area.

ii. The creditor and its affiliates together extended no more than 2,000 covered transactions, as defined in § 1026.43(b)(1), secured by first liens, that were sold, assigned, or otherwise transferred by the creditor or its affiliates to another person, or that were subject at the time of consummation to a commitment to be acquired by another person, during the preceding calendar year or during either of the two preceding calendar years if the application for the loan was received before April 1 of the current calendar year. For purposes of § 1026.35(b)(2)(iii)(B), a transfer of a first-lien covered transaction to ''another person'' includes a transfer by a creditor to its affiliate.

A. In general, whether this condition is satisfied depends on the creditor's activity during the preceding calendar year. However, if the application for the loan in question is received before April 1 of the current calendar year, the creditor may instead meet this condition based on activity during the next-to-last calendar year. This provides creditors with a grace period if their activity falls at or below the threshold in one calendar year but exceeds it in the next calendar year.

B. For example, assume that in 2015 a creditor and its affiliates together extended 1,500 loans that were sold, assigned, or otherwise transferred by the creditor or its affiliates to another person, or that were subject at the time of consummation to a commitment to be acquired by another person, and 2,500 such loans in 2016. Because the 2016 transaction activity exceeds the threshold but the 2015 transaction activity does not, the creditor satisfies this condition for exemption for a higher-priced mortgage loan consummated during 2017 if the creditor received the application for the loan before April 1, 2017, but does not satisfy this condition for a higher-priced mortgage loan consummated during 2017 if the application for the loan was received on or after April 1, 2017.

C. For purposes of § 1026.35(b)(2)(iii)(B), extensions of first-lien covered transactions, during the applicable time period, by all of a creditor's affiliates, as ''affiliate'' is defined in § 1026.32(b)(5), are counted toward the threshold in this section. Under the Bank Holding Company Act, a company has control over a bank or another company if it directly or indirectly or acting through one or more persons owns, controls, or has power to vote 25 per centum or more of any class of voting securities of the bank or company; it controls in any manner the election of a majority of the directors or trustees of the bank or company; or the Federal Reserve Board determines, after notice and opportunity for hearing, that the company directly or indirectly exercises a controlling influence over the management or policies of the bank or company. 12 U.S.C. 1841(a)(2).

iii. As of the end of the preceding calendar year, or as of the end of either of the two preceding calendar years if the application for the loan was received before April 1 of the current calendar year, the creditor and its affiliates that regularly extended covered transactions secured by first liens, together, had total assets that are less than the applicable annual asset threshold.

A. For purposes of § 1026.35(b)(2)(iii)(C), in addition to the creditor's assets, only the assets of a creditor's ''affiliate'' (as defined by § 1026.32(b)(5)) that regularly extended covered transactions (as defined by § 1026.43(b)(1)) secured by first liens, are counted toward the applicable annual asset threshold. *See* comment 35(b)(2)(iii)–1.ii.C for discussion of definition of ''affiliate.''

B. Only the assets of a creditor's affiliate that regularly extended first-lien covered transactions during the applicable period are included in calculating the creditor's assets. The meaning of ''regularly extended'' is based on the number of times a person extends consumer credit for purposes of the definition of ''creditor'' in § 1026.2(a)(17). Because covered transactions are

''transactions secured by a dwelling,'' consistent with § 1026.2(a)(17)(v), an affiliate regularly extended covered transactions if it extended more than five covered transactions in a calendar year. Also consistent with § 1026.2(a)(17)(v), because a covered transaction may be a high-cost mortgage subject to § 1026.32, an affiliate regularly extends covered transactions if, in any 12-month period, it extends more than one covered transaction that is subject to the requirements of § 1026.32 or one or more such transactions through a mortgage broker. Thus, if a creditor's affiliate regularly extended first-lien covered transactions during the preceding calendar year, the creditor's assets as of the end of the preceding calendar year, for purposes of the asset limit, take into account the assets of that affiliate. If the creditor, together with its affiliates that regularly extended first-lien covered transactions, exceeded the asset limit in the preceding calendar year—to be eligible to operate as a small creditor for transactions with applications received before April 1 of the current calendar year—the assets of the creditor's affiliates that regularly extended covered transactions in the year before the preceding calendar year are included in calculating the creditor's assets.

C. If multiple creditors share ownership of a company that regularly extended first-lien covered transactions, the assets of the company count toward the asset limit for a co-owner creditor if the company is an ''affiliate,'' as defined in § 1026.32(b)(5), of the co-owner creditor. Assuming the company is not an affiliate of the co-owner creditor by virtue of any other aspect of the definition (such as by the company and co-owner creditor being under common control), the company's assets are included toward the asset limit of the co-owner creditor only if the company is controlled by the co-owner creditor, ''as set forth in the Bank Holding Company Act.'' If the co-owner creditor and the company are affiliates (by virtue of any aspect of the definition), the co-owner creditor counts all of the company's assets toward the asset limit, regardless of the co-owner creditor's ownership share. Further, because the co-owner and the company are mutual affiliates the company also would count all of the co-owner's assets towards its own asset limit. *See* comment 35(b)(2)(iii)–1.ii.C for discussion of the definition of ''affiliate.''

D. A creditor satisfies the criterion in § 1026.35(b)(2)(iii)(C) for purposes of any higher-priced mortgage loan consummated during 2016, for example, if the creditor (together with its affiliates that regularly extended first-lien covered transactions) had total assets of less than the applicable asset threshold on December 31, 2015. A creditor that (together with its affiliates that regularly extended first-lien covered transactions) did not meet the applicable asset threshold on December 31, 2015 satisfies this criterion for a higher-priced mortgage loan consummated during 2016 if the application for the loan was received before April 1, 2016 and the creditor (together with its affiliates that regularly extended first-lien covered transactions) had total assets of less than the applicable asset threshold on December 31, 2014.

E. Under § 1026.35(b)(2)(iii)(C), the $2,000,000,000 asset threshold adjusts automatically each year based on the year-to-year change in the average of the Consumer Price Index for Urban Wage Earners and Clerical Workers, not seasonally adjusted, for each 12-month period ending in November, with rounding to the nearest million dollars. The Bureau will publish notice of the asset threshold each year by amending this comment. For calendar year 2020, the asset threshold is $2,202,000,000. A creditor that together with the assets of its affiliates that regularly extended first-lien covered transactions during calendar year 2019 has total assets of less than $2,202,000,000 on December 31, 2019, satisfies this criterion for purposes of any loan consummated in 2020 and for purposes of any loan consummated in 2021 for which the application was received before April 1, 2021. For historical purposes:

1. For calendar year 2013, the asset threshold was $2,000,000,000. Creditors that had total assets of less than $2,000,000,000 on December 31, 2012, satisfied this criterion for purposes of the exemption during 2013.

2. For calendar year 2014, the asset threshold was $2,028,000,000. Creditors that had total assets of less than $2,028,000,000 on December 31, 2013, satisfied this criterion for purposes of the exemption during 2014.

3. For calendar year 2015, the asset threshold was $2,060,000,000. Creditors that had total assets of less than $2,060,000,000 on December 31, 2014, satisfied this criterion for purposes of any loan consummated in 2015 and, if the creditor's assets together with the assets of its affiliates that regularly extended first-lien covered transactions during calendar year 2014 were less than that amount, for purposes of any loan consummated in 2016 for which the application was received before April 1, 2016.

4. For calendar year 2016, the asset threshold was $2,052,000,000. A creditor that together with the assets of its affiliates that regularly extended first-lien covered transactions during calendar year 2015 had total assets of less than $2,052,000,000 on December 31, 2015, satisfied this criterion for purposes of any loan consummated in 2016 and for purposes of any loan consummated in 2017 for which the application was received before April 1, 2017.

5. For calendar year 2017, the asset threshold was $2,069,000,000. A creditor that together with the assets of its affiliates that regularly extended first-lien covered transactions during calendar year 2016 had total assets of less than $2,069,000,000 on December 31, 2016, satisfied this criterion for purposes of any loan consummated in 2017 and for purposes of any loan consummated in 2018 for which the application was received before April 1, 2018.

6. For calendar year 2018, the asset threshold was $2,112,000,000. A creditor that together with the assets of its affiliates that regularly extended first-lien covered transactions during calendar year 2017 had total assets of less than $2,112,000,000 on December 31, 2017, satisfied this criterion for purposes of any loan consummated in 2018 and for purposes of any loan consummated in 2019 for which the application was received before April 1, 2019.

7. For calendar year 2019, the asset threshold was $2,167,000,000. A creditor that together with the assets of its affiliates that regularly extended first-lien covered transactions during calendar year 2018 had total assets of less than $2,167,000,000 on December 31, 2018, satisfied this criterion for purposes of any loan consummated in 2019 and for purposes of any loan consummated in 2020 for which the application was received before April 1, 2020.

iv. The creditor and its affiliates do not maintain an escrow account for any mortgage transaction being serviced by the creditor or its affiliate at the time the transaction is consummated, except as provided in § 1026.35(b)(2)(iii)(D)(*1*) and (*2*). Thus, the exemption applies, provided the other conditions of § 1026.35(b)(2)(iii) are satisfied, even if the creditor previously maintained escrow accounts for mortgage loans, provided it no longer maintains any such accounts except as provided in § 1026.35(b)(2)(iii)(D)(*1*) and (*2*). Once a creditor or its affiliate begins escrowing for loans currently serviced other than those addressed in § 1026.35(b)(2)(iii)(D)(*1*) and (*2*), however, the creditor and its affiliate become ineligible for the exemption in § 1026.35(b)(2)(iii) on higher-priced mortgage loans they make while such escrowing continues. Thus, as long as a creditor (or its affiliate) services and maintains escrow accounts for any mortgage loans, other than as provided in § 1026.35(b)(2)(iii)(D)(*1*) and (*2*), the creditor will not be eligible for the exemption for any higher-priced mortgage loan it may make. For purposes of § 1026.35(b)(2)(iii), a creditor or its affiliate ''maintains'' an escrow account only if it services a mortgage loan for which an escrow account has been established at least through the due date of the second periodic payment under the terms of the legal obligation.

* * * * *

Dated: December 17, 2019.

Thomas Pahl,

Policy Associate Director, Bureau of Consumer Financial Protection.

[FR Doc. 2019–27523 Filed 12–19–19; 8:45 am]

BILLING CODE 4810–AM–P

FEDERAL DEPOSIT INSURANCE CORPORATION

12 CFR Chapter III

RIN 3064–ZA11

Rescission of Statements of Policy

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Rescission of Statements of Policy.

SUMMARY: In an ongoing effort to streamline issuances by the FDIC to the public and to ensure that such issuances are timely, relevant, and effective, the FDIC initiated a comprehensive review

of its Statements of Policy to identify those that were outdated. Additionally, the FDIC, in the 2017 report required by the Economic Growth and Regulatory Paperwork Reduction Act, committed to reviewing published guidance to identify any guidance that should be revised or rescinded because it is out-of-date or otherwise no longer relevant. In furtherance of these initiatives, the FDIC Board of Directors approved a proposal to rescind four FDIC Statements of Policy, which was published in the **Federal Register** on September 30, 2019, with a 30-day comment period. The FDIC did not receive any comments on the proposed rescission of these Statements of Policy and is rescinding them effective December 31, 2019.

DATES: Effective December 31, 2019.

FOR FURTHER INFORMATION CONTACT:

Applicability of the Glass-Steagall Act to the Securities Activities of Subsidiaries of Insured Nonmember Banks:

William R. Baxter, Senior Policy Analyst, (202) 898–8514, *wbaxter@fdic.gov;* Michael B. Phillips, Counsel, (202) 898–3581 *mphillips@fdic.gov.*

Treatment of Collateralized Letters of Credit After Appointment of the FDIC as Conservator or Receiver and *Treatment of Collateralized Put Obligations After Appointment of the FDIC as Conservator or Receiver:*

Thomas P. Bolt, Senior Counsel, (703) 562–2046, *tbolt@fdic.gov;* Philip Mangano, Deputy Director, (571) 858–8279, *pmangano@fdic.gov;* Scott A. Greenup, Associate Director, (571) 858–8207, *sgreenup@fdic.gov;* George H. Williamson, Manager, (571) 858–8199, *gwilliamson@fdic.gov.*

Contracting With Firms That Have Unresolved Audit Issues With FDIC:

Thomas D. Harris, Deputy Director, (703) 562–2203, *tharris@fdic.gov;* Robert J. Brown, Supervisory Counsel, (703) 562–6068, *robertjbrown@fdic.gov.*

SUPPLEMENTARY INFORMATION: After a comprehensive review of FDIC Statements of Policy and following publication of notice [1] and a 30-day comment period which ended on October 30, 2019, during which no comments were received, the FDIC is rescinding the following four Statements of Policy effective December 31, 2019:

Applicability of the Glass-Steagall Act to Securities Activities of Subsidiaries of Insured Nonmember Banks;

Treatment of Collateralized Letters of Credit After Appointment of the FDIC as Conservator or Receiver;

Treatment of Collateralized Put Obligations After Appointment of the FDIC as Conservator or Receiver; and

Contracting with Firms that have Unresolved Audit Issues with the FDIC.

Although these Statements of Policy were not subject to public comment prior to their adoption, the FDIC Board, on a discretionary basis, elected to provide a period for public comment on the proposed rescission of these Policy Statements. The FDIC did not receive any comments regarding the proposed rescissions and therefore is rescinding the Statements of Policy effective December 31, 2019.

Rescission of Statements of Policy

(a) Statement of Policy on Applicability of the Glass-Steagall Act to Securities Activities of Subsidiaries of Insured Nonmember Banks

This 1982 Statement of Policy addresses the applicability of sections 20 and 32 of the Banking Act of 1933 (Glass Steagall Act) to the securities activities of subsidiaries of insured nonmember banks.[2] The Statement of Policy states the opinion of the FDIC Board that the Glass Steagall Act does not prohibit an insured nonmember bank from establishing an affiliate relationship with, or organizing or acquiring, a subsidiary corporation that engages in the business of issuing, underwriting, selling, or distributing stocks, bonds, or other securities. The 1982 Statement of Policy was superseded in its entirety by the enactment of the Gramm-Leach-Bliley Act (GLBA).[3] GLBA allowed commercial banks, investment banks, securities firms, and insurance companies to consolidate and operate as financial conglomerates. Therefore, the information and guidance contained in the 1982 Statement of Policy is out-of-date. For this reason, the FDIC is rescinding the 1982 Statement of Policy effective December 31, 2019.

(b) Statement of Policy on Treatment of Collateralized Letters of Credit After Appointment of the FDIC as Conservator or Receiver

This Statement of Policy was adopted by the FDIC on May 19, 1995, in order to clarify how the FDIC as conservator or receiver of a failed insured depository institution (IDI) would treat certain capital markets financing transactions using collateralized letters of credit (CLOCs) issued by IDIs prior to August 9, 1989, the date on which the Financial Institutions Reform, Recovery, and Enforcement Act of 1989 [4] (FIRREA) was signed into law.[5] The Statement of Policy applies only to CLOCs (i) utilized in capital markets financing transactions originally issued by IDIs prior to August 9, 1989, and any subsequent renewal, replacement or extension of such CLOCs; and (ii) where the security interest in collateral pledged by the IDI was both perfected and legally enforceable under applicable law. The Statement of Policy does not apply to trade letters of credit or letters of credit issued for any other purpose.

The Statement of Policy provides that after its appointment as conservator or receiver of a failed IDI, the FDIC may either (i) continue any CLOCs as enforceable under the terms of the contract during the pendency of the conservatorship or receivership, or (ii) call, redeem or prepay any CLOC by its statutory power to repudiate or disaffirm contracts entered into by the IDI.

Based on market research, the FDIC has concluded, to the best of its knowledge, that it is unlikely that any public or privately issued transactions of the type covered by the Statement of Policy remain outstanding at this time. Therefore, the FDIC is rescinding the Statement of Policy effective December 31, 2019.

(c) Statement of Policy on Treatment of Collateralized Put Obligations After Appointment of the FDIC as Conservator or Receiver

This Statement of Policy was adopted by the FDIC on July 9, 1991, in order to explain how the FDIC as conservator or receiver of a failed IDI would treat certain capital markets financing transactions using collateralized put obligations—also referred to as ''collateralized put options'' (CPOs)—issued by IDIs prior to August 9, 1989, the date on which FIRREA was signed into law.[6] The Statement of Policy applies only to CPOs (i) issued by IDIs in connection with capital markets financing transactions, including the formation of publicly offered unit investment trusts and other sales of an IDI's portfolio securities, prior to August 9, 1989, and any subsequent renewal, replacement or extension of such CPOs; and (ii) collateralized by property owned and pledged by the IDI, and in which the security interest granted is both perfected and legally enforceable.

[1] 84 FR 51467 (Sept. 30, 2019).

[2] 47 FR 38984. (*https://www.govinfo.gov/content/pkg/FR-1982-09-03/pdf/FR-1982-09-03.pdf).*

[3] Public Law 106–102, 113 Stat. 1338, section 101 (1999).

[4] Public Law 101–73, 103 Stat. 103 (1989).

[5] 60 FR 27976. (*https://www.govinfo.gov/content/pkg/FR-1995-05-26/pdf/95-12992.pdf*).

[6] 56 FR 36152. (*https://cdn.loc.gov/service/ll/fedreg/fr056/fr056147/fr056147.pdf*).

The Statement of Policy explains that the FDIC as conservator or receiver has the right to call, redeem or prepay any CPOs by repudiation or disaffirmance of the applicable written contract entered into by the IDI, either directly by cash payment in exchange for release of collateral or by liquidation of the collateral by a trustee or other secured party.

Based on market research, the FDIC has concluded, to the best of its knowledge, that it is unlikely that any public or privately issued transactions of this type remain outstanding at this time. Therefore, the FDIC is rescinding the Statement of Policy effective December 31, 2019.

(d) Statement of Policy on Contracting With Firms That Have Unresolved Audit Issues With FDIC

The *Statement of Policy on Contracting with Firms That Have Unresolved Audit Issues With FDIC* (1997 Statement of Policy) was not approved by the FDIC Board but it is being consolidated in this notice for convenience and completeness.

The 1997 Statement of Policy was adopted to address situations in which the FDIC seeks to contract with firms with which there are unresolved audit issues.[7] The 1997 Statement of Policy established certain rights and procedures for the handling of contracting parties that have unresolved audit issues, as determined by various FDIC auditing agents. After review of the relevant Statement of Policy, the FDIC concluded that the document may give rise to *de facto* exclusions from future FDIC contracting opportunities in a manner that is inconsistent with procedural protections specified in 12 CFR 367.

In determining whether to revise or rescind the Statement of Policy, the FDIC considered a variety of factors, including whether or not the Policy provided the FDIC and its various audit agents with essential or additional protections regarding the repayment of challenged amounts. The FDIC determined that existing remedies are sufficient to allow the FDIC and its agents to pursue such challenged amounts without the need for those measures specified in the Statement of Policy. Therefore, the FDIC is rescinding this Statement of Policy effective December 31, 2019.

(Authority: 12 U.S.C. 1811 *et seq.*)

Dated at Washington, DC, on December 12, 2019.

Federal Deposit Insurance Corporation.

By order of the Board of Directors.

Annmarie H. Boyd,

Assistant Executive Secretary.

[FR Doc. 2019–27225 Filed 12–20–19; 8:45 am]

BILLING CODE 6714–01–P

[7] 62 FR 13382. (*https://www.govinfo.gov/content/pkg/FR-1997-03-20/pdf/97-6995.pdf*).

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2019–0813; Product Identifier 2019–SW–006–AD; Amendment 39–19787; AD 2019–22–08]

RIN 2120–AA64

Airworthiness Directives; Leonardo S.p.A. Helicopters

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

ACTION: Final rule; request for comments.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for Leonardo S.p.A. Model AW169 and AW189 helicopters. This AD requires inspecting certain part-numbered and serial-numbered tail rotor (T/R) actuators, reporting information, and depending on the inspection outcome, marking a part, performing an additional inspection, and removing the T/R actuator from service. This AD also prohibits the installation of affected T/R actuators. This AD is prompted by reports of incorrect installations of the T/R actuator back-end input lever. The actions of this AD are intended to address an unsafe condition on these products.

DATES: This AD becomes effective January 7, 2020.

The Director of the Federal Register approved the incorporation by reference of a certain document listed in this AD as of January 7, 2020.

The FAA must receive comments on this AD by February 21, 2020.

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

- *Federal eRulemaking Docket:* Go to *https://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 *https://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0813; 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 European Aviation Safety Agency (EASA) AD, any service information that is incorporated by reference, the economic evaluation, any comments received, and other information. The street address for Docket Operations is listed above. Comments will be available in the AD docket shortly after receipt.

For Leonardo Helicopters service information identified in this final rule, contact Leonardo S.p.A. Helicopters, Emanuele Bufano, Head of Airworthiness, Viale G.Agusta 520, 21017 C.Costa di Samarate (Va) Italy; telephone +39–0331–225074; fax +39–0331–229046; or at *https://www.leonardocompany.com/en/home.*

For UTC Aerospace Systems service information identified in this final rule, contact Collins Aerospace (previously UTC Aerospace Systems); telephone 1–877–808–7575; fax 1–860–660–0372; email *tech.solutions@hs.utc.com;* or at *https://utcaerospacesystems.com/aftermarket-services/technical-support/.*

You may view the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy, Room 6N–321, Fort Worth, TX 76177. It is also available on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0813.

FOR FURTHER INFORMATION CONTACT: David Hatfield, Aviation Safety Engineer, Safety Management Section, Rotorcraft Standards Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–5110; email *david.hatfield@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

This AD is a final rule that involves requirements affecting flight safety, and the FAA did not provide you with notice and an opportunity to provide your comments prior to it becoming effective. However, the FAA invites you to participate in this rulemaking by submitting written comments, data, or views. The FAA also invites 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. The FAA will file in the docket all comments received, as well as a report summarizing each substantive public contact with FAA personnel concerning this rulemaking during the comment period. The FAA will consider all the comments received and may conduct additional rulemaking based on those comments.

Discussion

EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD No. 2019–0019, dated January 30, 2019 (EASA AD 2019–0019) to correct an unsafe condition for Leonardo S.p.A. (formerly Finmeccanica S.p.A., AgustaWestland S.p.A.) Model AW169 and AW189 helicopters with T/R actuator part number (P/N) 6F6730V00331 and a serial number (S/N) up to 489 inclusive, except those marked with ''SB 67–0007,'' installed. EASA advises of reports of non-conformities of the T/R actuator back-end input lever, indicating incorrect orientation of the lever with its trunnion locking pin.

EASA states this condition could lead to de-bonding and slippage of one of the two redundant lever bearings and possibly affect the functionality of the T/R actuator. A batch of T/R actuators was identified that may be also affected. Accordingly, EASA AD 2019–0019 requires one-time conformity checks of certain T/R actuator input levers, sending information and photos to Leonardo S.p.A., and depending on inspection findings, marking a part, inspecting the bonding of each bearing, and replacing the T/R actuator. EASA AD 2019–0019 also prohibits installation of the affected parts.

FAA's Determination

These helicopters have been approved by EASA and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the European Union, EASA has notified the FAA of the unsafe condition described in its AD. The FAA is issuing this AD after evaluating all information provided by EASA and determining the unsafe condition exists and is likely to exist or develop on other helicopters of these same type designs.

Related Service Information Under 1 CFR Part 51

UTC Aerospace Systems (Collins Aerospace) has issued Service Bulletin 67–0007, Basic Issue, dated January 17, 2019 (SB 67–0007). SB 67–0007 specifies verifying that the width of the bearing circular collar of the input lever is within the allowable limits of 4 ±0.3 mm, and checking the input lever pin head, and the nut and cotter pin of the intermediate bolt for proper installation. Depending on the inspection results, SB 67–0007 specifies replacing the T/R actuator, or marking the input lever and sending its completed registration form and photos of each side of the input lever to Leonardo Helicopters. SB 67–0007 is incorporated by reference in this AD.

SB 67–0007 is attached as Annex A to Leonardo Helicopters Alert Service Bulletin (ASB) No. 169–129, dated January 30, 2019 (ASB 169–129), for Model AW169 helicopters, and Leonardo Helicopters ASB No. 189–220, dated January 30, 2019 (ASB 189–220), for Model AW189 helicopters. ASB 169–129 and ASB 189–220 are not incorporated by reference in this AD.

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

Leonardo Helicopters has issued ASB 169–129 and ASB 189–220. This service information refers to SB 67–0007 for instructions to inspect certain part-numbered and serial-numbered T/R actuator input lever assemblies. Depending on findings, this service information specifies marking the input lever, inspecting the bonding of each bearing, and replacing the T/R actuator on a specified compliance time schedule based on findings. This service information also specifies sending information, photos, and certain T/R actuators to Leonardo Helicopters.

AD Requirements

For Model AW169 and AW189 helicopters with a T/R actuator P/N 6F6730V00331 and an S/N up to 489 inclusive, except those marked with ''SB 67–0007,'' installed, this AD requires inspecting the T/R actuator input lever assembly by determining if the width of the bearing circular collar of the input lever is within allowable limits, and inspecting for proper installation of the pin and of the intermediate bolt's nut and cotter pin. This AD requires reporting certain information and photos to Leonardo S.p.A. Based on the inspection outcome, this AD requires marking ''SB 67–0007'' on the input lever, inspecting each bearing for correct bonding, and removing the T/R actuator from service at different compliance times. This AD also prohibits installation of affected T/R actuators.

Differences Between This AD and the EASA AD

The EASA AD requires returning a removed T/R actuator to Leonardo Helicopters, whereas this AD does not. Depending on the inspection results of the T/R actuator input lever assembly, one of the compliance times to replace the T/R actuator in the EASA AD is 200 hours TIS or 2 months, whichever occurs first. This AD requires removing the T/R actuator from service within 60 hours TIS for the same inspection results instead.

Costs of Compliance

The FAA estimates that this AD affects 10 helicopters of U.S. Registry. Labor costs are estimated at $85 per work-hour. Based on these numbers, the FAA estimates the following costs in order to comply with this AD.

Inspecting the T/R actuator input lever assembly takes about 1 work-hour, and reporting information and photos to Leonardo S.p.A. takes about 1 work-hour, for an estimated cost of $170 per helicopter and $1,700 for the U.S. fleet. Marking a part takes a minimal amount of time for a nominal cost. Replacing a T/R actuator takes about 6 work-hours and parts cost about $20,000, for an estimated cost of $20,510 per helicopter.

According to Leonardo Helicopter's service information, some of the costs of this AD may be covered under warranty, thereby reducing the cost impact on affected individuals. The FAA does not control warranty coverage by Leonardo Helicopters. Accordingly, the FAA has included all costs in the cost estimate.

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 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 currently 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 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the

data needed, and completing and reviewing the collection of information. 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, Federal Aviation Administration, 10101 Hillwood Parkway, Fort Worth, TX 76177–1524.

Justification for Immediate Adoption and Determination of the Effective Date

Section 553(b)(3)(B) of the Administrative Procedure Act (APA) (5 U.S.C.) authorizes agencies to dispense with notice and comment procedures for rules when the agency, for ''good cause'' finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under this section, an agency, upon finding good cause, may issue a final rule without seeking comment prior to the rulemaking.

An unsafe condition exists that requires the immediate adoption of this AD without providing an opportunity for public comments prior to adoption. The FAA has found that the risk to the flying public justifies foregoing notice and comment prior to adoption of this rule because the initial inspection requirements must be completed within 30 hours time-in-service. Therefore notice and opportunity for prior public comment are impracticable and contrary to public interest pursuant to 5 U.S.C. 553(b)(3)(B). In addition, for the reason stated above, the FAA finds that good cause exists pursuant to 5 U.S.C. 553(d) for making this amendment 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.

The FAA is 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

The FAA 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, and

2. Will not affect intrastate aviation in Alaska.

The FAA 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.

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):

2019–22–08 Leonardo S.p.A.: Amendment 39–19787; Docket No. FAA–2019–0813; Product Identifier 2019–SW–006–AD.

(a) Applicability

This AD applies to Leonardo S.p.A. Model AW169 and AW189 helicopters, certificated in any category, with a tail rotor (T/R) actuator part number (P/N) 6F6730V00331 with a serial number (S/N) up to 489 inclusive, except those marked with ''SB 67–0007.''

(b) Unsafe Condition

This AD defines the unsafe condition as incorrect installation of the T/R actuator back-end input lever. This condition could result in de-bonding and slippage of one or both of the two redundant lever bearings, a reduction or loss of T/R control, and subsequent loss of control of the helicopter.

(c) Effective Date

This AD becomes effective January 7, 2020.

(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 30 hours time-in-service (TIS), for Model AW169 helicopters, with access panels 470AT and 470BT removed; and for Model AW189 helicopters, with access panels 496A and 495A removed, inspect the T/R actuator input lever assembly by following the Accomplishment Instructions, paragraph 3.B. through 3.C.4., of UTC Aerospace Systems Service Bulletin 67–0007, Basic Issue, dated January 17, 2019 (SB 67–0007).

(i) Report the information requested in the form at the end of SB 67–0007, along with a photo of each side of the installed T/R actuator back-end input lever, by email to: *pse_aw189.mbx.aw@leonardocompany.com.* Refer to Figure 4 and Figure 5 of SB 67–0007 for an example of each photo.

(ii) If the width of the bearing circular collar of the input lever is within the allowable limits of 4 ±0.3 mm, the input lever pin head is not on side ''A'' of the T/R actuator as shown in Figure 2b of SB 67–0007 (the input lever pin head is on side ''B''), and the nut and cotter pin of the intermediate bolt are installed on side ''A'' of the T/R actuator side as shown in Figure 3 of SB 67–0007, before further flight, mark ''SB 67–0007'' on the input lever with permanent ink as shown in Figure 4 of SB 67–0007.

(iii) If the width of the bearing circular collar of the input lever is outside the allowable limits of 4 ±0.3 mm, the input lever pin head is on side ''A'' of the T/R actuator, or the nut and cotter pin of the intermediate bolt are not installed on side ''A'' of the T/R actuator side, before further flight, use Table 1 to paragraph (e)(1)(iii) of this AD for next instruction.

Circular collar width of the input lever is within the allowable limits of 4 +/- 0.3 mm.	The input lever pin head is not on side "A" of the T/R actuator (the input lever pin head is on side "B").	The nut and cotter pin of the intermediate bolt are installed on side "A" of the T/R actuator.	Instruction:
Yes	Yes	No	Proceed to paragraph (e)(1)(v) of this AD
No	No	Yes	Proceed to paragraph (e)(1)(v) of this AD
No	No	No	Proceed to paragraph (e)(1)(v) of this AD
Yes	No	No	Proceed to paragraph (e)(1)(iv) of this AD
Yes	No	Yes	Proceed to paragraph (e)(1)(iv) of this AD
No	Yes	Yes	Proceed to paragraph (e)(1)(iv) of this AD
No	Yes	No	Proceed to paragraph (e)(1)(iv) of this AD

Table 1 to Paragraph (e)(1)(iii)

(iv) Before further flight, inspect for correct bonding (no axial or rotational relative movement compared to the lever) of each bearing by moving the input lever along the pin axial direction.

(A) If there is no axial or rotational relative movement compared to the lever in both bearings, within 10 hours TIS after completing the inspections required by paragraph (e)(1) of this AD, remove from service the T/R actuator.

(B) If there is axial or rotational relative movement compared to the lever in one or both bearings, before further flight, remove from service the T/R actuator.

(v) Within 60 hours TIS after completing the inspections required by paragraph (e)(1) of this AD, remove from service the T/R actuator.

(2) After the effective date of this AD, do not install a T/R actuator P/N 6F6730V00331 with an S/N up to 489 inclusive, except those marked with ''SB 67–0007,'' on any helicopter.

(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 currently 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 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. 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, Federal Aviation Administration, 10101 Hillwood Parkway, Fort Worth, TX 76177–1524.

(h) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Safety Management Section, Rotorcraft Standards Branch, FAA, may approve AMOCs for this AD. Send your proposal to David Hatfield, Aviation Safety Engineer, Safety Management Section, Rotorcraft Standards Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–5110; email *9-ASW-FTW-AMOC-Requests@faa.gov.*

(2) For operations conducted under a 14 CFR part 119 operating certificate or under 14 CFR part 91, subpart K, the FAA suggests 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

(1) Leonardo Helicopters Alert Service Bulletin (ASB) No. 169–129 and Leonardo Helicopters ASB No. 189–220, both dated January 30, 2019, which are not incorporated by reference, contain additional information about the subject of this AD. For service information identified in this AD, contact Leonardo S.p.A. Helicopters, Emanuele Bufano, Head of Airworthiness, Viale G.Agusta 520, 21017 C.Costa di Samarate (Va) Italy; telephone +39–0331–225074; fax +39–0331–229046; or at *https://www.leonardocompany.com/en/home.* 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.

(2) The subject of this AD is addressed in European Aviation Safety Agency (EASA) AD No. 2019–0019, dated January 30, 2019. You may view the EASA AD on the internet at *https://www.regulations.gov* by searching for and locating it in Docket No.FAA–2019–0813.

(j) Subject

Joint Aircraft Service Component (JASC) Code: 6400, Tail Rotor System.

(k) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference 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) UTC Aerospace Systems (Collins Aerospace) Service Bulletin No. 67–0007, Basic Issue, dated January 17, 2019.

Note 1 to paragraph (k)(2)(i): UTC Aerospace Systems (Collins Aerospace) Service Bulletin No. 67–0007, Basic Issue, dated January 17, 2019, is attached as Annex A to Leonardo Helicopters ASB No. 169–129 and Leonardo Helicopters ASB No. 189–220, both dated January 30, 2019, which are not incorporated by reference in this AD.

(ii) [Reserved]

(3) For UTC Aerospace Systems service information identified in this AD, contact Collins Aerospace (previously UTC Aerospace Systems); telephone 1–877–808–7575; fax 1–860–660–0372; email *tech.solutions@hs.utc.com;* or at *https://utcaerospacesystems.com/aftermarket-services/technical-support/.*

(4) You may view this service information at FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy, Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110.

(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, email *fedreg.legal@nara.gov,* or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Fort Worth, Texas, on November 20, 2019.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2019–27633 Filed 12–20–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 31288; Amdt. No. 3884]

Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This rule amends, suspends, or removes Standard Instrument Approach Procedures (SIAPs) and associated Takeoff Minimums and Obstacle Departure Procedures for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are designed to provide for the safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: This rule is effective December 23, 2019. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of December 23, 2019.

ADDRESSES: Availability of matter incorporated by reference in the amendment is as follows:

For Examination

1. U.S. Department of Transportation, Docket Ops-M30, 1200 New Jersey Avenue SE, West Bldg., Ground Floor, Washington, DC 20590–0001;

2. The FAA Air Traffic Organization Service Area in which the affected airport is located;

3. The office of Aeronautical Navigation Products, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or,

4. The National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fedreg.legal@nara.gov* or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Availability

All SIAPs and Takeoff Minimums and ODPs are available online free of charge. Visit the National Flight Data Center online at *nfdc.faa.gov* to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from the FAA Air Traffic Organization Service Area in which the affected airport is located.

FOR FURTHER INFORMATION CONTACT: Thomas J. Nichols, Flight Procedures and Airspace Group, Flight Technologies and Procedures Division, Flight Standards Service, Federal Aviation Administration. Mailing Address: FAA Mike Monroney Aeronautical Center, Flight Procedures and Airspace Group, 6500 South MacArthur Blvd., Registry Bldg. 29, Room 104, Oklahoma City, OK 73169. Telephone: (405) 954–4164.

SUPPLEMENTARY INFORMATION: This rule amends Title 14, Code of Federal Regulations, Part 97 (14 CFR part 97) by amending the referenced SIAPs. The complete regulatory description of each SIAP is listed on the appropriate FAA Form 8260, as modified by the National Flight Data Center (NFDC)/Permanent Notice to Airmen (P–NOTAM), and is incorporated by reference under 5 U.S.C. 552(a), 1 CFR part 51, and 14 CFR 97.20. The large number of SIAPs, their complex nature, and the need for a special format make their verbatim publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, but refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP contained on FAA form documents is unnecessary.

This amendment provides the affected CFR sections, and specifies the SIAPs and Takeoff Minimums and ODPs with their applicable effective dates. This amendment also identifies the airport and its location, the procedure and the amendment number.

Availability and Summary of Material Incorporated by Reference

The material incorporated by reference is publicly available as listed in the **ADDRESSES** section.

The material incorporated by reference describes SIAPs, Takeoff Minimums and ODPs as identified in the amendatory language for part 97 of this final rule.

The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP and Takeoff Minimums and ODP as amended in the transmittal. For safety and timeliness of change considerations, this amendment incorporates only specific changes contained for each SIAP and Takeoff Minimums and ODP as modified by FDC permanent NOTAMs.

The SIAPs and Takeoff Minimums and ODPs, as modified by FDC permanent NOTAM, and contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these changes to SIAPs and Takeoff Minimums and ODPs, the TERPS criteria were applied only to specific conditions existing at the affected airports. All SIAP amendments in this rule have been previously issued by the FAA in a FDC NOTAM as an emergency action of immediate flight safety relating directly to published aeronautical charts.

The circumstances that created the need for these SIAP and Takeoff

Minimums and ODP amendments require making them effective in less than 30 days.

Because of the close and immediate relationship between these SIAPs, Takeoff Minimums and ODPs, and safety in air commerce, I find that notice and public procedure under 5 U.S.C. 553(b) are impracticable and contrary to the public interest and, where applicable, under 5 U.S.C. 553(d), good cause exists for making these SIAPs effective in less than 30 days.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Air traffic control, Airports, Incorporation by reference, Navigation (Air).

Issued in Washington, DC, on December 13, 2019.

Rick Domingo,

Executive Director, Flight Standards Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, Title 14, Code of Federal regulations, Part 97, (14 CFR part 97), is amended by amending Standard Instrument Approach Procedures and Takeoff Minimums and ODPs, effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, MLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, Identified as follows:

** * * Effective Upon Publication*

AIRAC date	State	City	Airport	FDC No.	FDC date	Subject
30–Jan–20	WI	Kenosha	Kenosha Rgnl	9/0071	11/21/19	RNAV (GPS) RWY 25R, Orig-A.
30–Jan–20	WI	Kenosha	Kenosha Rgnl	9/0095	11/21/19	RNAV (GPS) RWY 33, Orig-A.
30–Jan–20	AL	Clayton	Clayton Muni	9/0140	11/20/19	RNAV (GPS) RWY 9, Orig-C.
30–Jan–20	SC	Charleston	Charleston AFB/Intl	9/0142	11/20/19	RNAV (RNP) Z RWY 21, Orig-B.
30–Jan–20	WA	Port Angeles	William R Fairchild Intl.	9/0212	11/20/19	RNAV (GPS) RWY 26, Amdt 1B.
30–Jan–20	CO	Fort Collins/Loveland.	Northern Colorado Rgnl.	9/0217	11/20/19	ILS OR LOC RWY 33, Amdt 6C.
30–Jan–20	CO	Fort Collins/Loveland.	Northern Colorado Rgnl.	9/0218	11/20/19	VOR–A, Amdt 7A.
30–Jan–20	KS	Herington	Herington Rgnl	9/0239	11/21/19	NDB RWY 17, Amdt 2A.
30–Jan–20	KS	Herington	Herington Rgnl	9/0280	11/21/19	NDB RWY 35, Amdt 2A.
30–Jan–20	WI	Solon Springs	Solon Springs Muni	9/0288	11/21/19	RNAV (GPS) RWY 19, Orig-B.
30–Jan–20	OH	Ravenna	Portage County	9/0314	11/20/19	VOR–A, Amdt 6A.
30–Jan–20	NH	Concord	Concord Muni	9/0319	11/20/19	ILS OR LOC RWY 35, Amdt 1C.
30–Jan–20	WA	Pullman/Moscow.	Pullman/Moscow Rgnl.	9/0473	11/20/19	RNAV (GPS) RWY 5, Amdt 3.
30–Jan–20	FL	Miami	Miami Intl	9/0475	11/20/19	RNAV (GPS) RWY 8L, Amdt 2A.
30–Jan–20	FL	Punta Gorda	Punta Gorda	9/0521	12/3/19	ILS OR LOC RWY 4, Orig.
30–Jan–20	FL	Punta Gorda	Punta Gorda	9/0522	12/3/19	RNAV (GPS) RWY 4, Amdt 2.
30–Jan–20	FL	Punta Gorda	Punta Gorda	9/0523	12/3/19	RNAV (GPS) RWY 15, Amdt 1.
30–Jan–20	FL	Punta Gorda	Punta Gorda	9/0529	12/3/19	RNAV (GPS) RWY 22, Amdt 2.
30–Jan–20	OH	Port Clinton	Erie-Ottawa Intl	9/0753	12/3/19	RNAV (GPS) RWY 9, Amdt 1A.
30–Jan–20	MI	Hastings	Hastings	9/0868	12/10/19	RNAV (GPS) RWY 30, Amdt 2.
30–Jan–20	OH	Port Clinton	Erie-Ottawa Intl	9/1073	11/20/19	RNAV (GPS) RWY 27, Amdt 1B.
30–Jan–20	IL	Galesburg	Galesburg Muni	9/1117	11/20/19	ILS OR LOC/DME RWY 3, Amdt 10A.
30–Jan–20	TX	Robstown	Nueces County	9/1118	11/20/19	Takeoff Minimums and Obstacle DP, Amdt 1.
30–Jan–20	AZ	Casa Grande	Casa Grande Muni	9/1564	11/20/19	VOR RWY 5, AMDT 4E.
30–Jan–20	PA	Waynesburg	Greene County	9/1979	11/21/19	RNAV (GPS) RWY 27, Orig-A.
30–Jan–20	IA	Winterset	Winterset Muni	9/2305	11/20/19	RNAV (GPS) RWY 32, Amdt 1.
30–Jan–20	TX	Big Lake	Reagan County	9/2482	12/10/19	RNAV (GPS) RWY 16, Orig.
30–Jan–20	IN	Peru	Peru Muni	9/2483	12/10/19	RNAV (GPS) RWY 1, Orig-B.
30–Jan–20	IN	Peru	Peru Muni	9/2484	12/10/19	VOR RWY 1, Amdt 8D.
30–Jan–20	IN	Peru	Peru Muni	9/2485	12/10/19	RNAV (GPS) RWY 19, Amdt 1A.
30–Jan–20	CA	San Diego/El Cajon.	Gillespie Field	9/3264	11/20/19	RNAV (GPS) RWY 9L, Orig-A.
30–Jan–20	MI	Grand Rapids	Gerald R Ford Intl	9/3347	11/20/19	VOR RWY 17, Orig-E.
30–Jan–20	MA	Vineyard Haven.	Martha's Vineyard	9/3403	11/20/19	RNAV (GPS) RWY 6, Amdt 1A.
30–Jan–20	MA	Vineyard Haven.	Martha's Vineyard	9/3405	11/20/19	RNAV (GPS) RWY 33, Orig-A.
30–Jan–20	AL	Alexander City.	Thomas C Russell Fld.	9/3952	11/20/19	RNAV (GPS) RWY 18, Amdt 2.
30–Jan–20	MD	Frederick	Frederick Muni	9/3957	11/20/19	RNAV (GPS) Y RWY 23, Amdt 1D.
30–Jan–20	MD	Frederick	Frederick Muni	9/3959	11/20/19	RNAV (GPS) Z RWY 23, Orig-F.
30–Jan–20	KS	Phillipsburg	Phillipsburg Muni	9/3963	11/21/19	RNAV (GPS) RWY 13, Amdt 2.

AIRAC date	State	City	Airport	FDC No.	FDC date	Subject
30–Jan–20 ...	KS	Phillipsburg ..	Phillipsburg Muni	9/3964	11/21/19	RNAV (GPS) RWY 31, Amdt 2.
30–Jan–20 ...	GA	Cochran	Cochran	9/3987	11/20/19	VOR/DME RWY 5, Amdt 6A.
30–Jan–20 ...	GA	Cochran	Cochran	9/3988	11/20/19	RNAV (GPS) RWY 11, Amdt 1B.
30–Jan–20 ...	MT	Twin Bridges	Twin Bridges	9/3989	11/20/19	RNAV (GPS) RWY 17, Orig-A.
30–Jan–20 ...	MT	Twin Bridges	Twin Bridges	9/3990	11/20/19	RNAV (GPS) RWY 35, Orig-A.
30–Jan–20 ...	AK	Barrow	Wiley Post-Will Rogers Memorial.	9/4063	11/20/19	VOR RWY 25, Amdt 1.
30–Jan–20 ...	IL	Galesburg	Galesburg Muni	9/4182	11/20/19	VOR RWY 21, Amdt 7B.
30–Jan–20 ...	OH	Dayton	Dayton-Wright Brothers.	9/4743	12/10/19	RNAV (GPS) RWY 2, Orig.
30–Jan–20 ...	OH	Dayton	Dayton-Wright Brothers.	9/4744	12/10/19	RNAV (GPS) RWY 20, Orig-A.
30–Jan–20 ...	WV	Moundsville ..	Marshall County	9/5072	11/20/19	RNAV (GPS) RWY 24, Orig-B.
30–Jan–20 ...	CA	Novato	Gnoss Field	9/5311	11/20/19	GPS RWY 13, Orig.
30–Jan–20 ...	NE	Scottsbluff	Western Nebraska Rgnl/William B Heilig Field.	9/5333	11/20/19	ILS OR LOC/DME RWY 12, Orig-A.
30–Jan–20 ...	NE	Scottsbluff	Western Nebraska Rgnl/William B Heilig Field.	9/5334	11/20/19	RNAV (GPS) RWY 12, Amdt 1.
30–Jan–20 ...	NE	Scottsbluff	Western Nebraska Rgnl/William B Heilig Field.	9/5335	11/20/19	RNAV (GPS) RWY 23, Orig.
30–Jan–20 ...	NE	Scottsbluff	Western Nebraska Rgnl/William B Heilig Field.	9/5336	11/20/19	RNAV (GPS) RWY 30, Amdt 1A.
30–Jan–20 ...	NE	Scottsbluff	Western Nebraska Rgnl/William B Heilig Field.	9/5337	11/20/19	VOR/DME RWY 5, Amdt 5.
30–Jan–20 ...	NE	Scottsbluff	Western Nebraska Rgnl/William B Heilig Field.	9/5339	11/20/19	VOR OR TACAN RWY 23, Amdt 12.
30–Jan–20 ...	ID	Burley	Burley Muni	9/5402	11/20/19	RNAV (GPS) RWY 20, Orig-C.
30–Jan–20 ...	MN	Granite Falls	Granite Falls Muni/ Lenzen-Roe-Fagen Memorial Field.	9/5448	11/20/19	VOR/DME RWY 33, Orig-B.
30–Jan–20 ...	TX	Austin	Austin Executive	9/5479	11/22/19	RNAV (GPS) RWY 13, Orig.
30–Jan–20 ...	KS	Goodland	Renner Fld/Goodland Muni/.	9/5496	11/21/19	ILS OR LOC RWY 30, Amdt 2B.
30–Jan–20 ...	KS	Goodland	Renner Fld/Goodland Muni/.	9/5497	11/21/19	RNAV (GPS) RWY 23, Amdt 1B.
30–Jan–20 ...	KS	Goodland	Renner Fld/Goodland Muni/.	9/5498	11/21/19	RNAV (GPS) RWY 30, Amdt 1B.
30–Jan–20 ...	KS	Goodland	Renner Fld/Goodland Muni/.	9/5499	11/21/19	VOR RWY 30, Amdt 9B.
30–Jan–20 ...	MO	Cuba	Cuba Muni	9/5528	11/20/19	RNAV (GPS) RWY 18, Orig-B.
30–Jan–20 ...	FL	Milton	Peter Prince Field ...	9/5529	11/20/19	RNAV (GPS) RWY 36, Amdt 1B.
30–Jan–20 ...	TX	Taylor	Taylor Muni	9/5949	11/20/19	RNAV (GPS) RWY 17, Orig-A.
30–Jan–20 ...	NY	Oneonta	Oneonta Muni	9/6042	11/20/19	RNAV (GPS) RWY 6, Orig-A.
30–Jan–20 ...	VA	Richmond	Richmond Intl	9/6123	11/20/19	RNAV (RNP) Y RWY 20, Orig-B.
30–Jan–20 ...	VA	Richmond	Richmond Intl	9/6124	11/20/19	RNAV (RNP) Y RWY 34, Orig-C.
30–Jan–20 ...	VA	Richmond	Richmond Intl	9/6125	11/20/19	RNAV (GPS) Z RWY 34, Amdt 1D.
30–Jan–20 ...	VA	Richmond	Richmond Intl	9/6126	11/20/19	VOR RWY 2, Amdt 6A.
30–Jan–20 ...	VA	Richmond	Richmond Intl	9/6127	11/20/19	VOR RWY 16, Amdt 27B.
30–Jan–20 ...	VA	Richmond	Richmond Intl	9/6129	11/20/19	VOR RWY 34, Amdt 23B.
30–Jan–20 ...	CO	Monte Vista ..	Monte Vista Muni	9/6133	11/20/19	VOR/DME–A, Amdt 3.
30–Jan–20 ...	WI	Fond Du Lac	Fond Du Lac County	9/6157	11/20/19	VOR/DME RWY 36, Amdt 6C.
30–Jan–20 ...	VA	Lawrenceville	Lawrenceville/Brunswick Muni.	9/6240	11/20/19	RNAV (GPS)–A, Orig.
30–Jan–20 ...	VA	Lawrenceville	Lawrenceville/Brunswick Muni.	9/6241	11/20/19	Takeoff Minimums and Obstacle DP, Orig.
30–Jan–20 ...	VA	Lawrenceville	Lawrenceville/Brunswick Muni.	9/6242	11/20/19	RNAV (GPS)–B, Orig.
30–Jan–20 ...	OK	Wagoner	Hefner-Easley	9/6887	11/20/19	RNAV (GPS) RWY 18, Amdt 1.
30–Jan–20 ...	NV	Las Vegas	North Las Vegas	9/6985	11/20/19	ILS OR LOC RWY 12L, Orig-C.
30–Jan–20 ...	AK	St Paul Island	St Paul Island	9/7143	11/20/19	ILS OR LOC RWY 36, Amdt 4.
30–Jan–20 ...	AK	St Paul Island	St Paul Island	9/7144	11/20/19	RNAV (GPS) RWY 36, Amdt 1.
30–Jan–20 ...	AK	St Paul Island	St Paul Island	9/7146	11/20/19	LOC/DME BC RWY 18, Amdt 4B.
30–Jan–20 ...	AK	St Paul Island	St Paul Island	9/7152	11/20/19	RNAV (GPS) RWY 18, Amdt 2B.
30–Jan–20 ...	KY	Springfield	Lebanon Springfield-George Hoerter Field.	9/7340	11/25/19	RNAV (GPS) RWY 11, Amdt 1.

AIRAC date	State	City	Airport	FDC No.	FDC date	Subject
30–Jan–20 ...	FL	Panama City	Northwest Florida Beaches Intl.	9/7435	11/20/19	ILS OR LOC RWY 16, ILS RWY 16 (SA CAT I), ILS RWY 16 (SA CAT II), Amdt 3.
30–Jan–20 ...	FL	Merritt Island	Merritt Island	9/7572	11/20/19	RNAV (GPS) RWY 11, Amdt 1C.
30–Jan–20 ...	TX	Kerrville	Kerrville Muni/Louis Schreiner Field.	9/7901	11/26/19	VOR–A, Amdt 3A.
30–Jan–20 ...	ND	Fargo	Hector Intl	9/7935	11/26/19	ILS OR LOC RWY 18, Orig-D.
30–Jan–20 ...	PA	Meadville	Port Meadville	9/8260	11/20/19	RNAV (GPS) RWY 25, Amdt 1E.
30–Jan–20 ...	LA	Lake Charles	Chennault Intl	9/8269	11/20/19	RNAV (GPS) RWY 33, Amdt 1.
30–Jan–20 ...	CO	Telluride	Telluride Rgnl	9/8368	11/20/19	VOR/DME–A, Amdt 1.
30–Jan–20 ...	WY	Rock Springs	Southwest Wyoming Rgnl.	9/8369	11/20/19	VOR/DME RWY 27, Amdt 2A.
30–Jan–20 ...	WY	Rock Springs	Southwest Wyoming Rgnl.	9/8374	11/20/19	VOR RWY 9, Amdt 3A.
30–Jan–20 ...	MI	Grand Haven	Grand Haven Memorial Airpark.	9/8420	11/20/19	RNAV (GPS) RWY 9, Orig.
30–Jan–20 ...	AR	Mena	Mena Intermountain Muni.	9/8444	11/26/19	ILS OR LOC RWY 27, Amdt 1B.
30–Jan–20 ...	AR	Mena	Mena Intermountain Muni.	9/8445	11/26/19	NDB RWY 27, Amdt 1A.
30–Jan–20 ...	MO	Brookfield	North Central Missouri Rgnl.	9/8451	12/10/19	RNAV (GPS) RWY 18, Orig.
30–Jan–20 ...	MO	Brookfield	North Central Missouri Rgnl.	9/8452	12/10/19	RNAV (GPS) RWY 36, Amdt 2A.
30–Jan–20 ...	OR	Baker City	Baker City Muni	9/8453	11/26/19	VOR–A, Amdt 1B.
30–Jan–20 ...	OR	Baker City	Baker City Muni	9/8454	11/26/19	VOR/DME RWY 13, Amdt 11D.
30–Jan–20 ...	CA	Watsonville ...	Watsonville Muni	9/8923	11/20/19	VOR–A, Amdt 1A.
30–Jan–20 ...	CA	Watsonville ...	Watsonville Muni	9/8924	11/20/19	LOC RWY 2, Amdt 4B.
30–Jan–20 ...	FL	Clewiston	Airglades	9/8940	11/20/19	RNAV (GPS) RWY 13, Orig-A.
30–Jan–20 ...	FL	Clewiston	Airglades	9/8968	11/20/19	RNAV (GPS) RWY 31, Orig.
30–Jan–20 ...	ME	Fryeburg	Eastern Slopes Rgnl	9/8981	11/26/19	RNAV (GPS) RWY 32, Amdt 1A.
30–Jan–20 ...	CA	Los Angeles	Whiteman	9/9009	11/26/19	RNAV (GPS) RWY 12, Orig.
30–Jan–20 ...	MN	Duluth	Duluth Intl	9/9022	11/26/19	RADAR–1, Orig.
30–Jan–20 ...	KS	Olathe	New Century Aircenter.	9/9169	11/26/19	RNAV (GPS) RWY 18, Amdt 2.
30–Jan–20 ...	KS	Olathe	New Century Aircenter.	9/9171	11/26/19	RNAV (GPS) RWY 36, Amdt 2.
30–Jan–20 ...	TX	Hondo	South Texas Rgnl At Hondo.	9/9193	11/26/19	NDB RWY 35R, Amdt 5.
30–Jan–20 ...	TX	Hondo	South Texas Rgnl At Hondo.	9/9194	11/26/19	RNAV (GPS) RWY 35R, Orig.
30–Jan–20 ...	FL	Sarasota/Bradenton.	Sarasota/Bradenton Intl.	9/9332	11/27/19	RNAV (GPS) RWY 4, Amdt 2C.
30–Jan–20 ...	FL	Sarasota/Bradenton.	Sarasota/Bradenton Intl.	9/9335	11/27/19	RNAV (GPS) RWY 22, Amdt 2B.
30–Jan–20 ...	FL	Sarasota/Bradenton.	Sarasota/Bradenton Intl.	9/9336	11/27/19	ILS OR LOC RWY 14, Amdt 6B.
30–Jan–20 ...	FL	Sarasota/Bradenton.	Sarasota/Bradenton Intl.	9/9337	11/27/19	ILS OR LOC RWY 32, Amdt 8B.
30–Jan–20 ...	FL	Sarasota/Bradenton.	Sarasota/Bradenton Intl.	9/9338	11/27/19	RNAV (GPS) RWY 14, Amdt 3B.
30–Jan–20 ...	FL	Sarasota/Bradenton.	Sarasota/Bradenton Intl.	9/9339	11/27/19	RNAV (GPS) RWY 32, Amdt 3B.
30–Jan–20 ...	FL	Sarasota/Bradenton.	Sarasota/Bradenton Intl.	9/9341	11/27/19	VOR RWY 14, Amdt 18B.
30–Jan–20 ...	IN	Bedford	Virgil I Grissom Muni	9/9770	11/20/19	VOR/DME RWY 13, Amdt 10B.
30–Jan–20 ...	MD	Baltimore	Baltimore/Washington Intl Thurgood Marshall.	9/9974	11/20/19	RNAV (RNP) Z RWY 33L, Amdt 3.
30–Jan–20 ...	MD	Baltimore	Baltimore/Washington Intl Thurgood Marshall.	9/9975	11/20/19	ILS OR LOC RWY 33L, ILS RWY 33L (SA CAT I & II), Amdt 12.

[FR Doc. 2019–27528 Filed 12–20–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 31287; Amdt. No. 3883]

Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This rule establishes, amends, suspends, or removes Standard Instrument Approach Procedures (SIAPs) and associated Takeoff Minimums and Obstacle Departure Procedures (ODPs) for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: This rule is effective December 23, 2019. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of December 23, 2019.

ADDRESSES: Availability of matters incorporated by reference in the amendment is as follows:

For Examination

1. U.S. Department of Transportation, Docket Ops-M30, 1200 New Jersey Avenue SE, West Bldg., Ground Floor, Washington, DC 20590–0001.

2. The FAA Air Traffic Organization Service Area in which the affected airport is located;

3. The office of Aeronautical Navigation Products, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or,

4. The National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fedreg.legal@nara.gov* or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Availability

All SIAPs and Takeoff Minimums and ODPs are available online free of charge. Visit the National Flight Data Center at *nfdc.faa.gov* to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from the FAA Air Traffic Organization Service Area in which the affected airport is located.

FOR FURTHER INFORMATION CONTACT: Thomas J. Nichols, Flight Procedures and Airspace Group, Flight Technologies and Procedures Division, Flight Standards Service, Federal Aviation Administration. Mailing Address: FAA Mike Monroney Aeronautical Center, Flight Procedures and Airspace Group, 6500 South MacArthur Blvd., Registry Bldg. 29, Room 104, Oklahoma City, OK 73169. Telephone: (405) 954–4164.

SUPPLEMENTARY INFORMATION: This rule amends Title 14 of the Code of Federal Regulations, Part 97 (14 CFR part 97), by establishing, amending, suspending, or removes SIAPS, Takeoff Minimums and/or ODPS. The complete regulatory description of each SIAP and its associated Takeoff Minimums or ODP for an identified airport is listed on FAA form documents which are incorporated by reference in this amendment under 5 U.S.C. 552(a), 1 CFR part 51, and 14 CFR part 97.20. The applicable FAA forms are FAA Forms 8260–3, 8260–4, 8260–5, 8260–15A, and 8260–15B when required by an entry on 8260–15A.

The large number of SIAPs, Takeoff Minimums and ODPs, their complex nature, and the need for a special format make publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, Takeoff Minimums or ODPs, but instead refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP, Takeoff Minimums and ODP listed on FAA form documents is unnecessary. This amendment provides the affected CFR sections and specifies the types of SIAPs, Takeoff Minimums and ODPs with their applicable effective dates. This amendment also identifies the airport and its location, the procedure, and the amendment number.

Availability and Summary of Material Incorporated by Reference

The material incorporated by reference is publicly available as listed in the **ADDRESSES** section.

The material incorporated by reference describes SIAPS, Takeoff Minimums and/or ODPS as identified in the amendatory language for part 97 of this final rule.

The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP, Takeoff Minimums and ODP as Amended in the transmittal. Some SIAP and Takeoff Minimums and textual ODP amendments may have been issued previously by the FAA in a Flight Data Center (FDC) Notice to Airmen (NOTAM) as an emergency action of immediate flight safety relating directly to published aeronautical charts.

The circumstances that created the need for some SIAP and Takeoff Minimums and ODP amendments may require making them effective in less than 30 days. For the remaining SIAPs and Takeoff Minimums and ODPs, an effective date at least 30 days after publication is provided.

Further, the SIAPs and Takeoff Minimums and ODPs contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these SIAPs and Takeoff Minimums and ODPs, the TERPS criteria were applied to the conditions existing or anticipated at the affected airports. Because of the close and immediate relationship between these SIAPs, Takeoff Minimums and ODPs, and safety in air commerce, I find that notice and public procedure under 5 U.S.C. 553(b) are impracticable and contrary to the public interest and, where applicable, under 5 U.S.C. 553(d), good cause exists for making some SIAPs effective in less than 30 days.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Air traffic control, Airports, Incorporation by reference, Navigation (Air).

Issued in Washington, DC, on December 13, 2019.

Rick Domingo,

Executive Director, Flight Standards Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, Title 14, Code of Federal Regulations, Part 97 (14 CFR part 97) is amended by establishing, amending, suspending, or removing Standard Instrument Approach Procedures and/or Takeoff Minimums and Obstacle Departure Procedures effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

Effective 30 January 2020

Klawock, AK, Klawock, RNAV (GPS) RWY 20, Orig
Klawock, AK, Klawock, RNAV (GPS) Y RWY 2, Amdt 1
Riverside, CA, Riverside Muni, RIVERSIDE ONE, Graphic DP
Riverside, CA, Riverside Muni, Takeoff Minimums and Obstacle DP, Amdt 11
Denver, CO, Colorado Air and Space Port, Takeoff Minimums and Obstacle DP, Amdt 3A
Washington, DC, Ronald Reagan Washington National, Takeoff Minimums and Obstacle DP, Amdt 8B
Georgetown, DE, Delaware Coastal, RNAV (GPS) RWY 22, Amdt 2D
Jacksonville, FL, Cecil, ILS OR LOC RWY 36R, Amdt 4
Jacksonville, FL, Cecil, VOR RWY 9R, Amdt 1A, CANCELLED
Jacksonville, FL, Cecil, VOR RWY 27L, Orig
Miami, FL, Miami Intl, LOC RWY 8L, Orig-C
Atlanta, GA, Fulton County Airport—Brown Field, ILS OR LOC RWY 8, Amdt 18
Atlanta, GA, Fulton County Airport—Brown Field, RNAV (GPS) Y RWY 8, Amdt 2
Atlanta, GA, Fulton County Airport—Brown Field, RNAV (RNP) Z RWY 8, Amdt 2
Tifton, GA, Henry Tift Myers, ILS OR LOC RWY 34, Amdt 3
Honolulu, HI, Daniel K Inouye Intl, ILS Y RWY 4R, Amdt 2
Honolulu, HI, Daniel K Inouye Intl, ILS Z RWY 4R, Amdt 2
Mc Call, ID, Mc Call Muni, RNAV (GPS) RWY 34, Amdt 1A
Warsaw, IN, Warsaw Muni, Takeoff Minimums and Obstacle DP, Amdt 3
Washington, KS, Washington County Veteran's Memorial, RNAV (GPS) RWY 35, Amdt 1A
Washington, KS, Washington County Veteran's Memorial, Takeoff Minimums and Obstacle DP, Amdt 1
Pittsfield, MA, Pittsfield Muni, LOC RWY 26, Amdt 10
Pittsfield, MA, Pittsfield Muni, RNAV (GPS) RWY 26, Amdt 2
Grand Rapids, MI, Gerald R Ford Intl, ILS OR LOC RWY 35, ILS RWY 35 (SA CAT I), ILS RWY 35 (SA CAT II), Amdt 2B
Grand Rapids, MI, Gerald R Ford Intl, RNAV (GPS) RWY 8L, Amdt 1B
New Bern, NC, Coastal Carolina Regional, ILS OR LOC RWY 4, Amdt 2
Minot, ND, Minot Intl, RNAV (GPS) RWY 31, Amdt 1C
Toledo, OH, Toledo Express, ILS Z OR LOC Z RWY 25, Amdt 9
Perkasie, PA, Pennridge, Takeoff Minimums and Obstacle DP, Amdt 1
Galveston, TX, Scholes Intl at Galveston, RNAV (GPS) RWY 18, Amdt 2B
Houston, TX, George Bush Intercontinental/Houston, RNAV (GPS) RWY 15R, Amdt 2C
Kerrville, TX, Kerrville Muni/Louis Schreiner Field, RNAV (GPS) RWY 12, Amdt 1B
Kerrville, TX, Kerrville Muni/Louis Schreiner Field, RNAV (GPS) RWY 30, Orig-B
San Angelo, TX, San Angelo Rgnl/Mathis Field, ILS Y OR LOC Y RWY 3, Amdt 22A
Wheatland, WY, Phifer Airfield, SLATR ONE, Graphic DP
Wheatland, WY, Phifer Airfield, Takeoff Minimums and Obstacle DP, Amdt 1

Rescinded: On November 29, 2019 (84 FR 65673), the FAA published an Amendment in Docket No. 31283, Amdt No. 3879, to Part 97 of the Federal Aviation Regulations under sections 97.37. The following entry for Shreveport, LA effective January 30, 2019, is hereby rescinded in its entirety:

Shreveport, LA, Shreveport Downtown, Takeoff Minimums and Obstacle DP, Amdt 4

[FR Doc. 2019–27529 Filed 12–20–19; 8:45 am]

BILLING CODE 4910–13–P

NATIONAL LABOR RELATIONS BOARD

29 CFR Part 102

Rule Exempting an Amended System of Records From Certain Provisions of the Privacy Act

AGENCY: National Labor Relations Board.

ACTION: Final rule; correction.

SUMMARY: On February 24, 2017, the National Labor Relations Board published in the **Federal Register** a comprehensive amendment of its procedural regulations that revised a section in its entirety, but inadvertently failed to include two paragraphs. This document corrects those regulations to include the paragraphs that were inadvertently repealed.

DATES: Effective February 21, 2020.

FOR FURTHER INFORMATION CONTACT: Prem Aburvasamy, Senior Agency Official for Privacy, National Labor Relations Board, 1015 Half Street SE, Washington, DC 20570–0001, (202) 273–3733, *privacy@nlrb.gov.*

SUPPLEMENTARY INFORMATION: On November 21, 2016, the National Labor Relations Board amended one of its systems of records, NLRB–17, Personnel Security Records, in accordance with the Privacy Act of 1974, 5 U.S.C. 552a. Pursuant to subsections (k)(1), (2), (3), (5), (6), and (7) of the Privacy Act, the Board included within Section 102.119, additional paragraphs (o) and (p), exempting portions of the amended system of records (NLRB–17) from subsections (c)(3), (d), (e)(1), (e)(4)(G), (e)(4)(H), (e)(4)(I) and (f) of the Privacy Act. This amendment was published in the **Federal Register** on November 21, 2016. Three months later, on February 24, 2017, the National Labor Relations Board published in the **Federal Register** a comprehensive amendment of its procedural regulations that replaced § 102.119 in its entirety. In the comprehensive amendment, the Board inadvertently failed to include § 102.119, paragraphs (o) and (p). This document corrects the regulations that were published February 24, 2017, to include the paragraphs that were inadvertently repealed.

List of Subjects in 29 CFR Part 102

Privacy, Reporting and Recordkeeping Requirements.

Accordingly, 29 CFR part 102 is corrected by making the following amendments:

PART 102—RULES AND REGULATIONS, SERIES 8

■ 1. The authority citation for part 102 continues to read as follows:

Authority: Sections 1, 6, National Labor Relations Act (29 U.S.C. 151, 156). Section 102.117 also issued under section 552(a)(4)(A) of the Freedom of Information Act, as amended (5 U.S.C. 552(a)(4)(A)), and Section 102.117a also issued under section 552a(j) and (k) of the Privacy Act of 1974 (5 U.S.C. 552a(j) and (k)). Sections 102.143 through 102.155 also issued under section 504(c)(1) of the Equal Access to Justice Act, as amended (5 U.S.C. 504(c)(1)).

Subpart K—Records and Information

■ 2. In § 102.119, paragraphs (o) and (p) are added to read as follows:

§ 102.119 Privacy Act Regulations: notification as to whether a system of records contains records pertaining to requesting individuals; requests for access to records, amendment of requests; fees for document duplication; files and records exempted from certain Privacy Act requirements.

* * * * *

(o) Pursuant to 5 U.S.C. 552a(k)(1), (2), (3), (5), (6), and (7) of the Privacy Act, the system of records maintained by the NLRB containing Personnel Security Records shall be exempted from the provisions of 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G), (H), and (I), and (f) insofar as the system may contain:

(1) Records properly classified pursuant to an Executive Order, within the meaning of section 552(b)(1);

(2) Investigatory material compiled for law enforcement purposes other than material within the scope of 5 U.S.C. 552a(j)(2);

(3) Information maintained in connection with providing protective services to the President of the United States or other individuals pursuant to section 3056 of title 18 of the U.S. Code;

(4) Investigatory material compiled solely for the purpose of determining suitability, eligibility or qualifications for Federal civilian employment and Federal contact or access to classified information;

(5) Testing and examination materials used for a personnel investigation for employment or promotion in the Federal service;

(6) Evaluation materials, compiled during the course of a personnel investigation, that are used solely to determine potential for promotion in the armed services.

(p) The Privacy Act exemptions contained in paragraph (o) of this section are justified for the following reasons:

(1)(i) 5 U.S.C. 552a(c)(3) requires an agency to make the accounting of each disclosure of records available to the individual named in the record at his/her request. These accountings must state the date, nature, and purpose of each disclosure of a record and the name and address of the recipient. 5 U.S.C. 552a(d) requires an agency to permit an individual to gain access to records pertaining to him/her, to request amendment to such records, to request a review of an agency decision not to amend such records, and to contest the information contained in such records.

(ii) Personnel investigations may contain properly classified information which pertains to national defense and foreign policy obtained from another Federal agency. Application of exemption 5 U.S.C. 552a(k)(1) is necessary to preclude an individual's access to and amendment of such classified information under 5 U.S.C. 552a(d).

(iii) Personnel investigations may contain investigatory material compiled for law enforcement purposes other than material within the scope of 5 U.S.C. 552a(j)(2). Application of exemption 5 U.S.C. 552a(k)(2) is necessary to preclude an individual's access to or amendment of such records under 5 U.S.C. 552a(c)(3) and (d).

(iv) Personnel investigations may also contain information obtained from another Federal agency that relates to providing protective services to the President of the United States or other individuals pursuant to 18 U.S.C. 3056. Application of exemption 5 U.S.C. 552a(k)(3) is necessary to preclude an individual's access to and amendment of such records under 5 U.S.C. 552a(d).

(v) Exemption 5 U.S.C. 552a(k)(5) is claimed with respect to the requirements of 5 U.S.C. 552a(c)(3) and (d) because this system contains investigatory material compiled solely for determining suitability, eligibility, and qualifications for Federal employment. To the extent that the disclosure of material would reveal the identity of a source who furnished information to the Government under an express promise that the identity of the source would be held in confidence, or prior to September 27, 1975, under an implied promise that the identity of the source would be held in confidence, the applicability of exemption 5 U.S.C. 552a(k)(5) will be required to honor promises of confidentiality should an individual request access to or amendment of the record, or access to the accounting of disclosures of the record. Similarly, personnel investigations may contain evaluation material used to determine potential for promotion in the armed services. Application of exemption 5 U.S.C. 552a(k)(7) is necessary to the extent that the disclosure of data would compromise the anonymity of a source under an express promise that the identity of the source would be held in confidence, or, prior to September 27, 1975, under an implied promise that the identity of the source would be held in confidence. Both of these exemptions are necessary to safeguard the integrity of background investigations by minimizing the threat of harm to confidential sources, witnesses, and law enforcement personnel. Additionally, these exemptions reduce the risks of improper influencing of sources, the destruction of evidence, and the fabrication of testimony.

(vi) All information in this system that meets the criteria articulated in exemption 5 U.S.C. 552a(k)(6) is exempt from the requirements of 5 U.S.C. 552a(d), relating to access to and amendment of records by an individual. This exemption is claimed because portions of this system relate to testing or examining materials used solely to determine individual qualifications for appointment or promotion to the Federal service. Access to or amendment to this information by an individual would compromise the objectivity and fairness of the testing or examining process.

(2) 5 U.S.C. 552a(e)(1) requires an agency to maintain in its records only such information about an individual as is relevant and necessary to accomplish a purpose of the agency required by statute or by executive order of the President. This requirement could foreclose investigators from acquiring or receiving information the relevance and necessity of which is not readily apparent and could only be ascertained after a complete review and evaluation of all the evidence. This system of records is exempt from this requirement because in the course of personnel background investigations, the accuracy of information obtained or introduced occasionally may be unclear, or the information may not be strictly relevant or necessary to favorably or unfavorably adjudicate a specific investigation at a specific point in time. However, in the interests of protecting the public trust and national security, it is appropriate to retain all information that may aid in establishing patterns in such areas as criminal conduct, alcohol and drug use, financial dishonesty, allegiance, foreign preference or influence, and psychological conditions, that are relevant to future personnel security or suitability determinations.

(3) 5 U.S.C. 552a(e)(4)(G) and (H) require an agency to publish a **Federal Register** notice concerning its procedures for notifying an individual, at his/her request, if the system of records contains a record pertaining to him/her, how to gain access to such a record and how to contest its content. Since this system of records is being exempted from subsection (f) of the Privacy Act, concerning agency rules, and subsection (d) of the Privacy Act, concerning access to records, these requirements are inapplicable to the extent that this system of records will be exempt from subsections (f) and (d) of the Privacy Act. Although the system would be exempt from these requirements, the NLRB has published information concerning its notification, access, and contest procedures because, under certain circumstances, it may be appropriate for a subject to have access to a portion of that individual's records in this system of records.

(4) 5 U.S.C. 552a(e)(4)(I) requires an agency to publish a **Federal Register** notice concerning the categories of sources of records in the system of records. Exemption from this provision is necessary to protect the confidentiality of the sources of information, to protect the privacy and physical safety of confidential sources and witnesses, and to avoid the disclosure of investigative techniques and procedures. Although the system will be exempt from this requirement, the agency has published source information in the accompanying notice in broad generic terms.

(5) 5 U.S.C. 552a(f) requires an agency to promulgate rules which shall establish procedures whereby an individual can be notified in response to a request if any system of records named by the individual contains a record pertaining to that individual. The application of this provision could compromise the progress of an investigation concerning the suitability, eligibility, and fitness for service of applicants for Federal employment and impede a prompt assessment of the appropriate access to the Agency's facilities. Although this system would be exempt from the requirements of subsection (f) of the Privacy Act, the Agency has promulgated rules which establish agency procedures because, under certain circumstances, it could be appropriate for an individual to have access to all or a portion of that individual's records in this system of records.

Dated: December 9, 2019.

Roxanne L. Rothschild,

Executive Secretary.

[FR Doc. 2019–26820 Filed 12–20–19; 8:45 am]

BILLING CODE 7545–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2019–0545]

RIN 1625–AA09

Drawbridge Operation Regulation; Niantic River, Niantic, CT

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is modifying the operating schedule that governs the S156 Bridge across the Niantic River, mile 0.1 at Niantic, CT. The bridge owner, the Connecticut Department of Transportation, submitted a request to allow six hours notice for night time transits during the months of November and April due to infrequent bridge openings. This final rule will approve the request and align the regulations for the S156 Bridge with other Connecticut Department of Transportation Bridges.

DATES: This rule is effective January 22, 2020.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov.* Type USCG–2019–0545 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rulemaking.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Mr. Jeffrey Stieb, First Coast Guard District Bridge Management Specialist; telephone 617–223–8364, email *Jeffrey.D.Stieb@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
CT DOT Connecticut Department of Transportation
DHS Department of Homeland Security
FR Federal Register
OMB Office of Management and Budget
NPRM Notice of Proposed Rulemaking (Advance, Supplemental)
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

On August 20, 2019, the Coast Guard published a notice of proposed rulemaking entitled ''Drawbridge Operation Regulation; Niantic River, Niantic, CT'' in the **Federal Register** (84 FR 43093). In the NPRM, incorrect clearances for the bridge were provided. The correct clearances are provided below in Section III. No comments were received in response to the NPRM and no comments were made concerning the more constrictive clearances in the NPRM.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under the authority of 33 U.S.C. 499. The S156 Bridge at mile 0.1 over the Niantic River at Niantic, Connecticut, has a vertical clearance of 32 feet at mean high water and 34 feet at mean low water. Vertical clearance is unlimited when the draw is open. Horizontal clearance is approximately 100 feet. Waterway users include recreational and small commercial vessels.

The existing regulation, 33 CFR 117.215(b), requires that from December 1 through March 31, from 8 p.m. to 4 a.m., the draw shall open on signal if at least six hours notice is given. CT DOT requested that the start of the winter schedule begin one month sooner and end one month later than presently allowed by the regulation. This rule change will align the winter operation and staffing of the three CT DOT drawbridges located in the same operational area by extending the range of months during which six hours notice is required to include November and April. This rule change will allow for more efficient and economic operation of the bridge while meeting the reasonable needs of navigation.

The bridge logs show that during the last three years only three requests to open occurred between 8 p.m. and 4 a.m. in November and no request to open were received between 8 p.m. and 4 a.m. in April. None of the requests were from commercial vessels. CT DOT and the Coast Guard conducted outreach to stakeholders with no objections received.

IV. Discussion of Comments, Changes and the Final Rule

The Coast Guard provided 60 days for comment and no comments were received. There are no changes in the regulatory text of this rule from the proposed rule in the NPRM.

The final rule provides that from November 1 through April 30, between the hours of 8:00 p.m. and 4:00 a.m., the draw shall open on signal if at least six hours notice is given. It is our opinion that the proposed rule meets the reasonable needs of marine traffic.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive Orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive Orders, and we discuss First Amendment rights of protesters.

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 rule has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, it 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 fact that only three vessel transits would have been affected over the past three years. We believe that this change to the drawbridge operation regulation at 33 CFR 117.215(b) will meet the reasonable needs of navigation.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601–612, as amended, requires federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard received no comment from the Small Business Administration on this rule. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

The bridge will continue to open on signal with six hours notice between the hours of 8 p.m. and 4 a.m. during the months of November and April. Based on the last three years of records, an average of one vessel annually will be affected by the change. While some owners or operators of vessels intending to transit the bridge may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

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

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

C. Collection of Information

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

D. Federalism and Indian Tribal Government

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please call or email 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 rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Environmental Planning COMDTINST 5090.1 (series) which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f). We have made a 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 rule promulgates the operating regulations or procedures for drawbridges. This action is categorically excluded from further review, under paragraph L49, of Chapter 3, Table 3–1 of the U.S. Coast Guard Environmental Planning Implementation Procedures.

Neither a Record of Environmental Consideration nor a Memorandum for the Record are required for this 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.

List of Subjects in 33 CFR Part 117

Bridges.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

■ 1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 33 CFR 1.05–1; and Department of Homeland Security Delegation No. 0170.1.

■ 2. Revise § 117.215(b) to read as follows:

§ 117.215 Niantic River.

* * * * *

(b) The draw of the S156 Bridge, mile 0.1, at Niantic, shall open on signal; except that, from 7 a.m. to 8 a.m., and 4 p.m. to 5 p.m., Monday through Friday, except holidays, the draw shall open only for the passage of commercial vessels. From November 1 through April 30, from 8 p.m. to 4 a.m., the draw shall open on signal if at least six hours notice is given by calling the number posted at the bridge.

Dated: December 4, 2019.

R.W. Warren,

Captain, U.S. Coast Guard, Acting Commander, First Coast Guard District.

[FR Doc. 2019–27272 Filed 12–20–19; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R10–OAR–2018–0810; FRL–10003–25–Region 10]

Air Plan Approval; AK: Infrastructure Requirements for the 2015 Ozone Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: Whenever a new or revised National Ambient Air Quality Standard is promulgated, the Clean Air Act requires states to submit plans for the implementation, maintenance, and enforcement of such standard, commonly referred to as infrastructure requirements. On October 25, 2018, the State of Alaska submitted such a plan for the ozone standard revised on October 1, 2015. In this action, the Environmental Protection Agency (EPA) is approving the Alaska plan as meeting applicable infrastructure requirements.

DATES: This final rule is effective January 22, 2020.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R10–OAR–2018–0810. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information or other information the disclosure of which is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available at *https://www.regulations.gov,* or please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

FOR FURTHER INFORMATION CONTACT: Kristin Hall (15–H13), Air and Radiation Division, EPA Region 10, 1200 Sixth Avenue (Suite 155), Seattle, WA 98101, (206) 553–6357, *hall.kristin@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document wherever ''we,'' ''us,'' or ''our'' is used, it refers to the EPA.

Table of Contents

I. Background
II. Final Action
III. Statutory and Executive Order Review

I. Background

On October 25, 2018, the Alaska Department of Environmental Conservation (ADEC) made a submission addressing the infrastructure requirements of CAA section 110(a)(1) and (2) for the 2015 ozone NAAQS.[1] On October 15, 2019, we proposed to approve Alaska's infrastructure SIP submission (84 FR 55094). The reasons for our proposed approval are included in the proposal and will not be restated here. The public comment period for the proposal closed on November 14, 2019, and we received one supportive comment. The full text of the comment may be found in the docket for this action.

II. Final Action

We are approving the Alaska SIP as meeting the following CAA section 110(a)(2) infrastructure elements for the 2015 ozone NAAQS: (A), (B), (C), (D)(i)(II), (D)(ii), (E), (F), (G), (H), (J), (K), (L), and (M). This action is being taken under section 110 of the CAA.

III. Statutory and Executive Order Review

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves State law as meeting Federal requirements and does not impose additional requirements beyond those imposed by State law. For that reason, this action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because SIP approvals are exempted under Executive Order 12866;
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide the EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

The SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and it will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a

[1] Alaska's October 25, 2018 submission addresses CAA sections 110(a)(1) and (2) infrastructure requirements for the 2015 ozone NAAQS and includes regulatory updates and permitting rule revisions for approval into the SIP. We approved the regulatory updates and permitting rule revisions in a separate rulemaking on August 29, 2019 (84 FR 45419). We are also addressing the interstate transport portion of the infrastructure requirements related to CAA section 110(a)(2)(D)(i)(I) in a separate action proposed on June 5, 2019 (84 FR 26041).

copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by February 21, 2020. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. See section 307(b)(2).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: December 2, 2019.

Chris Hladick,

Regional Administrator, Region 10.

For the reasons set forth in the preamble, 40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart C—Alaska

■ 2. In § 52.70, the table in paragraph (e) is amended by:

■ a. Revising the entry for ''III.II.D. CAA Section 110 Infrastructure Certification Documentation and Supporting Documents''; and

■ b. Adding an entry for ''Infrastructure Requirements—2015 Ozone NAAQS'' at the end of the table.

The revision and addition read as follows:

§ 52.70 Identification of plan.

* * * * *

(e) * * *

EPA-APPROVED ALASKA NONREGULATORY PROVISIONS AND QUASI-REGULATORY MEASURES

Name of SIP provision	Applicable geographic or nonattainment area	State submittal date	EPA approval date	Explanations
*	*	*	*	*
State of Alaska Air Quality Control Plan: Volume III. Appendices				
Section II. State Air Quality Control Program				
*	*	*	*	*
III.II.D. CAA Section 110 Infrastructure Certification Documentation and Supporting Documents.	Statewide	10/25/2018	12/23/2019, [Insert **Federal Register** citation].	
*	*	*	*	*
Infrastructure Requirements—2015 Ozone NAAQS.	Statewide	10/25/2018	12/23/2019, [Insert **Federal Register** citation].	Approves SIP for purposes of CAA section 110(a)(2)(A), (B), (C), (D)(i)(II), (D)(ii), (E), (F), (G), (H), (J), (K), (L), and (M) for the 2015 Ozone NAAQS.

[FR Doc. 2019–27159 Filed 12–20–19; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2019–0358; FRL–10001–86]

Fenpropathrin; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of fenpropathrin in or on fuzzy kiwifruit. This action is in response to EPA's granting of an emergency exemption under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on fuzzy kiwifruit. This regulation establishes a maximum permissible level for residues of fenpropathrin in or on this commodity. The time-limited tolerance expires on December 31, 2022.

DATES: This regulation is effective December 23, 2019. Objections and requests for hearings must be received on or before February 21, 2020 and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2019–0358, is available at *https://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal

holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT:

Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Publishing Office's e-CFR site at *https://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.* To access the OCSPP test guidelines referenced in this document electronically, please go to *https://www.epa.gov/aboutepa/about-office-chemical-safety-and-pollution-prevention-ocspp* and select ''Test Guidelines for Pesticides and Toxic Substances.''

C. How can I file an objection or hearing request?

Under section 408(g) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2019–0358 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before February 21, 2020. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2019–0358, by one of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *https://www.epa.gov/dockets/where-send-comments-epa-dockets.* Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets.*

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with FFDCA sections 408(e) and 408(l)(6) of, 21 U.S.C. 346a(e) and 346a(1)(6), is establishing a time-limited tolerance for residues of fenpropathrin, (alpha-cyano-3-phenoxy-benzyl 2,2,3,3 tetramethylcyclopropanecarboxylate), in or on fuzzy kiwifruit at 5 parts per million (ppm). This time-limited tolerance expires on December 31, 2022.

Section 408(l)(6) of FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under FIFRA section 18. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on FIFRA section 18 related time-limited tolerances to set binding precedents for the application of FFDCA section 408 and the safety standard to other tolerances and exemptions. Section 408(e) of FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, *i.e.,* without having received any petition from an outside party.

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Fenpropathrin on Fuzzy Kiwifruit and FFDCA Tolerances

According to the Alabama Department of Agriculture and Industries (ADAI), in 2017 brown marmorated stink bug (BMSB) damage was observed in a small block of nursery stock plants. This observation alerted the staff at the kiwi nursery to the potential of BMSB for the 2018 crop season. ADAI claimed that in 2018, BMSB severely damaged the kiwifruit crop, making it unmarketable. ADAI estimated losses as high as 50% for 2018 and projected 2019 losses to be over $1.6 million without the use requested under the section 18 emergency exemption. After having reviewed the submission, EPA determined that an emergency condition exists for this State, and that the criteria for approval of an emergency exemption are met.

As part of its evaluation of the emergency exemption application, EPA assessed the potential risks presented by

residues of fenpropathrin in or on fuzzy kiwifruit. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent, non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment as provided in FFDCA section 408(l)(6). Although this time-limited tolerance expires on December 31, 2022, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amount specified in the tolerance remaining in or on fuzzy kiwifruit after that date will not be unlawful, provided the pesticide was applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this time-limited tolerance at the time of that application. EPA will take action to revoke this time-limited tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because this time-limited tolerance is being approved under emergency conditions, EPA has not made any decisions about whether fenpropathrin meets FIFRA's registration requirements for use on fuzzy kiwifruit or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this time-limited tolerance decision serves as a basis for registration of fenpropathrin by a State for special local needs under FIFRA section 24(c), nor does this tolerance by itself serve as the authority for persons in any State other than Alabama to use this pesticide on the applicable crops under FIFRA section 18, absent the issuance of an emergency exemption applicable within that State. For additional information regarding the emergency exemption for fenpropathrin, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. Aggregate Risk Assessment and Determination of Safety

Consistent with the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of, and to make a determination on, aggregate exposure expected as a result of this emergency exemption request and the time-limited tolerance for residues of fenpropathrin on fuzzy kiwifruit at 5 ppm. EPA's assessment of exposures and risks associated with establishing the time-limited tolerance follows.

A. Toxicological Points of Departure/ Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/ safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks.*

A summary of the toxicological endpoints for fenpropathrin used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of November 28, 2012 (77 FR 70904) (FRL–9366–1).

B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to fenpropathrin, EPA considered exposure under the time-limited tolerance established by this action as well as all existing fenpropathrin tolerances in 40 CFR 180.466. EPA assessed dietary exposures from fenpropathrin in food as follows:

i. *Acute exposure.* Acute effects were identified for fenpropathrin. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 2003–2008 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, EPA used tolerance level residues for some commodities and refined the assessment by incorporating distributions of field trial values and Pesticide Data Program (PDP) monitoring data for other commodities. EPA translated data from some commodities to other commodities according to EPA's guidance documents for translating monitoring data and field trial data. EPA also included estimates of percent crop treated in the assessment. For most processed commodities, EPA used the Agency's 2018 default processing factors for those commodities for which they were available. In some cases, EPA used empirical processing factors.

ii. *Chronic exposure.* Based on the available data for fenpropathrin, use of the acute endpoint and dose for risk assessment is protective for repeated dose exposure and risk. Therefore, only an acute dietary assessment was performed, which is considered protective of chronic dietary exposure.

iii. *Cancer.* Based on the data cited in Unit IV.A., EPA has concluded that fenpropathrin does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information.* Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing dietary risk only if:

- *Condition a:* The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.
- *Condition b:* The exposure estimate does not underestimate exposure for any significant subpopulation group.

• *Condition c:* Data are available on pesticide use and food consumption in a particular area, and the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency estimated the PCT for existing uses as follows: Apples, 15%; apricots 2.5%; blueberries, 2.5%; broccoli, 2.5%; Brussels sprouts, 10%; cabbage, 2.5%; cauliflower, 2.5%; cherries, 21%; cotton, 2.5%; cucumbers, 2.5%; grapefruit, 35%; grapes, 10%; nectarines, 9%; oranges, 35%; peaches, 9%; pears, 10%; plums, 2.5%; prune plums, 2.5%; squash, 2.5%; strawberries, 50%; tangerines, 15%; tomatoes, 10%; and watermelons, 2.5%.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6 to 7 years. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%.

The Agency estimated the PCT for new uses as follows: 100% for fuzzy kiwifruit.

The Agency believes that the three conditions discussed in Unit IV.B1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which fenpropathrin may be applied in a particular area.

2. *Dietary exposure from drinking water.* The Agency used water solubility limit at 25 °C in the dietary exposure analysis and risk assessment for fenpropathrin in drinking water. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide.*

The water solubility limit of fenpropathrin at 25 °C is 10.3 parts per billion (ppb). The limit of solubility was directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 10.3 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Fenpropathrin is not registered for any specific use patterns that would result in residential exposure.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at: *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide.*

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

The agency is required to consider the cumulative risks of chemicals sharing a common mechanism of toxicity. The agency has determined that the pyrethroids and pyrethrins share a common mechanism group (see *https://www.regulations.gov;* Docket ID EPA–HQ–OPP–2008–0489–0006). The members of this group share the ability to interact with voltage-gated sodium channels ultimately leading to neurotoxicity. The cumulative risk assessment for the pyrethroids/pyrethrins was published on Nov. 9, 2011 (USEPA, 2011a) and is available at *https://www.regulations.gov;* Docket ID EPA–HQ–OPP–2011–0746. No cumulative risks of concern were identified. This assessment was conservative and appropriate to address use expansions, such as this use on kiwifruit. For information regarding the EPA's efforts to evaluate the risk of exposure to pyrethroids, refer to *https://www.epa.gov/oppsrrd1/reevaluation/pyrethroids-pyrethrins.html.* After all of the chemical-specific interim decisions have been completed for the pyrethroid class of pesticides, an update of the cumulative risk assessment may be performed in association with registration review.

C. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional SF when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* Evidence of increased qualitative or quantitative susceptibility of the offspring was not observed in any of the available animal testing guideline toxicity studies, including the developmental neurotoxicity study (DNT).

3. *Conclusion.* EPA has determined that reliable data show that the safety of infants and children would be adequately protected if the required 10X FQPA SF were reduced to 3X for children less than 6 years old. For the general population, and including children greater than 6 years old, EPA is reducing the FQPA SF to 1X. That decision is based on the following findings:

i. While the database is considered to be complete with respect to the guideline toxicity studies for fenpropathrin, EPA lacks additional data to fully characterize the potential for juvenile sensitivity to neurotoxic effects of pyrethroids. In light of the literature studies indicating a possibility of increased sensitivity in juvenile rats at high doses, EPA identified a need, and requested proposals for, additional non-guideline studies to evaluate the potential for sensitivity in juvenile rats. A group of pyrethroid registrants is currently conducting those studies. Pending the results of those studies, however, the available toxicity studies

for fenpropathrin can be used to characterize toxic effects including potential developmental and reproductive toxicity, immunotoxicity, and neurotoxicity. Acceptable developmental toxicity studies in rats and rabbits, reproduction studies in rats, neurotoxicity studies (acute, subchronic, and developmental) in rats, and immunotoxicity studies in rats are available. In addition, a route-specific dermal toxicity study is available, and the inhalation study has been waived.

ii. After reviewing the extensive body of data and peer-reviewed literature on pyrethroids, the Agency has reached a number of conclusions regarding fetal and juvenile sensitivity for pyrethroids. Based on an evaluation of over 70 guideline toxicity studies for 24 pyrethroids submitted to the Agency, including prenatal developmental toxicity studies in rats and rabbits, and pre- and postnatal multi-generation reproduction toxicity studies and DNTs in rats in support of pyrethroid registrations, there is no evidence that pyrethroids directly impact developing fetuses. None of the studies show any indications of fetal toxicity at doses that do not cause maternal toxicity.

iii. Increased susceptibility was seen in offspring animals in the DNT study with the pyrethroid zeta-cypermethrin (decreased pup body weights) and DNT and reproduction studies with another pyrethroid, beta-cyfluthrin (decreased body weights and tremors). However, the reductions in body weight and the other non-specific effects occur at higher doses than neurotoxicity, the effect of concern for pyrethroids. The available developmental and reproduction guideline studies in rats with zeta-cypermethrin did not show increased sensitivity in the young to neurotoxic effects. Overall, findings of increased sensitivity in juvenile animals in pyrethroid studies are rare. Therefore, the residual concern for the postnatal effects is reduced. High-dose LD50 studies (studies assessing what dose results in lethality to 50% of the tested population) in the scientific literature indicate that pyrethroids can result in increased quantitative sensitivity to juvenile animals. Examination of pharmacokinetic and pharmacodynamic data indicates that the sensitivity observed at high doses is related to pyrethroid age-dependent pharmacokinetics—the activity of enzymes associated with the metabolism of pyrethroids. Furthermore, a rat physiologically-based pharmacokinetic (PBPK) model predicts a 3-fold increase of pyrethroid concentration in juveniles' brains compared to adults at high doses. *In vitro* pharmacodynamic data and *in vivo* data indicate that adult and juvenile rats have similar responses to pyrethroids at low doses and therefore juvenile sensitivity is not expected at relevant environmental exposures. Further, data also show that the rat is a conservative model compared to the human based on species-specific pharmacodynamics of homologous sodium channel isoforms. The Agency has retained a 3X uncertainty factor to protect for exposures of children less than 6 years of age based on increased quantitative susceptibility seen in literature studies on pyrethroid pharmacokinetics (PKs), and the increased quantitative juvenile susceptibility observed in high dose studies in the literature.

iv. There are no residual uncertainties identified in the exposure databases. The Agency used tolerance level residues for some commodities and refined the assessment by incorporating distributions of field trial values and Pesticide Data Program (PDP) monitoring data for other commodities. EPA translated data from some commodities to other commodities according to EPA's guidance documents for translating monitoring data and field trial data. EPA also included estimates of percent crop treated in the assessment. For most processed commodities, EPA used the Agency's 2018 default processing factors for those commodities for which they were available. In some cases, EPA used empirical processing factors.

For this kiwifruit section 18 request, EPA updated the 2016 dietary exposure assessment by including kiwifruit. As residue data are not available for kiwifruit, the Agency translated grape PDP data to kiwifruit. For section 18 requests, the Agency assumes the proposed commodity will be treated to a level of 100% across the country. As a result, 100% crop treated was assumed for kiwifruit. EPA also made refinements to the residue data for dried cranberry, dried mango, and dried papaya. In the 2016 assessment, EPA used tolerance level residues for these commodities. For this section 18 request, EPA translated strawberry PDP data to dried cranberries, avocado field trial data to dried mango, and avocado field trial data to dried papaya. The Agency assumed 100% crop treated for the three dried commodities: Cranberry, mango, and papaya.

EPA made a conservative (protective) assumption in the water concentration used to assess exposure to fenpropathrin in drinking water. These assessments will not underestimate the exposure and risk posed by fenpropathrin.

D. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to fenpropathrin will occupy 99.5% of the aPAD for children 1 to 2 years old, the population group receiving the greatest exposure.

2. *Chronic risk.* A chronic dietary exposure assessment was not conducted because the acute endpoint adequately protects against chronic effects. There are no residential uses for fenpropathrin.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). A short-term adverse effect was identified; however, fenpropathrin is not registered for any use patterns that would result in short-term residential exposure. Because there is no short-term residential exposure and acute dietary exposure has already been assessed under the appropriately protective aPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of short-term risk is necessary, and EPA relies on the acute dietary risk assessment for evaluating short-term risk for fenpropathrin.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term non-dietary, non-occupational exposure plus chronic exposure to food and water (considered to be a background exposure level). Because no intermediate-term adverse effect was identified, fenpropathrin is not expected to pose an intermediate-term risk.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, fenpropathrin is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes

that there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to fenpropathrin residues, including anticipated residues on fuzzy kiwifruit.

V. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology utilizing gas chromatography with electron capture detector (GC/ECD), Residue Method Numbers RM–22–4 (plants) and RM–22A–1 (animals), is available to enforce the tolerance expression.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: *residuemethods@epa.gov.*

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established an MRL for fenpropathrin on fuzzy kiwifruit.

VI. Conclusion

Therefore, a time-limited tolerance is established for residues of fenpropathrin, (alpha-cyano-3-phenoxy-benzyl 2,2,3,3 tetramethylcyclopropanecarboxylate), in or on kiwifruit, fuzzy at 5 ppm. This tolerance expires on December 31, 2022.

VII. Statutory and Executive Order Reviews

This action establishes a tolerance under FFDCA sections 408(e) and 408(l)(6). The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, titled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, titled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), nor is it considered a regulatory action under Executive Order 13771, entitled ''Reducing Regulations and Controlling Regulatory Costs,'' (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.,* nor does it require any special considerations under Executive Order 12898, titled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established in accordance with FFDCA sections 408(e) and 408(l)(6), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the National Government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: December 5, 2019.

Michael Goodis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.466, revise paragraph (b) to read as follows:

§ 180.466 Fenpropathrin; tolerances for residues.

* * * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances specified in Table 2 to this paragraph (b) are established for residues of fenpropathrin, (alpha-cyano-3-phenoxy-benzyl 2,2,3,3 tetramethylcyclopropane carboxylate) in or on the specified agricultural commodities, resulting from use of the pesticide pursuant to FIFRA section 18 emergency exemptions. The tolerance expires on the date specified in Table 2.

TABLE 2 TO PARAGRAPH (b)

Commodity	Parts per million	Expiration date
Kiwifruit, fuzzy ...	5	12/31/2022

* * * * *

[FR Doc. 2019–27379 Filed 12–20–19; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 350

[Docket ID FEMA–2012–0026]

RIN 1660–ZA21

Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants (NUREG–0654/FEMA–REP–1, Rev. 2)

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notification of availability.

SUMMARY: The Federal Emergency Management Agency (FEMA), concurrently with the Nuclear Regulatory Commission (NRC), is issuing final guidance entitled ''Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants'' (NUREG–0654/FEMA–REP–1, Rev. 2). This final guidance document focuses on preparedness for radiological incidents at commercial nuclear power plants that could impact public health and safety.

DATES: This final guidance document was issued in December 2019.

ADDRESSES: This final guidance document is available online at *http://www.regulations.gov* and on FEMA's website at *http://www.fema.gov.* The proposed and final guidance documents, all related **Federal Register** Notices, and all public comments received during the comment period are available at *http://www.regulations.gov* under Docket ID FEMA–2012–0026. You may also view a hard copy of the final guidance document at the Office of Chief Counsel, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472.

FOR FURTHER INFORMATION CONTACT: William Eberst, Policy Supervisor, Policy and Regulations Branch, Technological Hazards Division, National Preparedness Directorate, Resilience, *william.eberst@fema.dhs.gov,* (202) 341–4917.

SUPPLEMENTARY INFORMATION: As part of the domestic licensing of commercial nuclear power plants (NPPs), the Federal Emergency Management Agency (FEMA) and the Nuclear Regulatory Commission (NRC) evaluate emergency preparedness activities at and around these facilities. Emergency preparedness activities for a radiological incident at an NPP are essential for communities that could be affected by an incident at the facility. FEMA's role in the licensing process is to review and evaluate the adequacy of the planning and preparedness activities and capabilities of State, local, and Tribal governments and provide its findings and determinations to the NRC. FEMA performs this activity before the NRC issues a license to operate a NPP and then provides ongoing findings and determinations that planning and preparedness efforts are effective and consistent with regulatory guidelines. The NRC evaluates applicants for NPP site permits, construction permits, and operating licenses. As a part of that evaluation, the NRC reviews the licensees' emergency plans and preparedness efforts. NPP licensees and State, local, and Tribal governments within the emergency planning zones surrounding commercial NPPs must show that plans are in place that provide reasonable assurance that adequate protective measures will be taken to protect public health and safety in the event of an incident at an NPP.

In November 1980, FEMA issued ''Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants (NUREG–0654/FEMA–REP–1, Rev. 1)'' jointly with the Nuclear Regulatory Commission (NRC). (45 FR 85862, Dec. 30, 1980). NUREG–0654/FEMA–REP–1, Rev. 1 provides guidance on the 16 Planning Standards referenced in FEMA's regulations at 44 CFR 350.5 and the NRC's regulations at 10 CFR 50.47. Both agencies use these Planning Standards, and associated Evaluation Criteria contained in NUREG–0654/FEMA–REP–1, Rev. 1, to evaluate the adequacy of emergency plans and preparedness of NPP owners and operators, and the State, local, and Tribal government jurisdictions in which NPPs are sited.

Since the publication of NUREG–0654/FEMA–REP–1, Rev. 1 in 1980, four supplementary documents and one addendum (66 FR 22270, May 3, 2001) have been issued that update and modify specific planning and procedural elements. Since publication of these documents, there have been changes to FEMA and NRC regulations, guidance, policies and advances in technology. NUREG–0654/FEMA–REP–1, Rev. 2 consolidates the four supplementary documents and one addendum, clarifies the relationship of radiological emergency planning and preparedness to the larger National Preparedness System and its components, and provides updates and additional guidance reflective of over 30 years of improvements and lessons learned in the radiological emergency preparedness community.

To begin this revision process, FEMA held two public meetings on August 22, 2012 and September 13, 2012 to discuss the scope of the proposed revision to NUREG–0654/FEMA–REP–1, Rev. 1 (77 FR 46766, Aug. 6, 2012). Based on feedback from the two public meetings, FEMA solicited comments from stakeholders and interested members of the public on the scope of future revisions to NUREG–0654/FEMA–REP–1, Rev. 1 (77 FR 65700, Oct. 30, 2012). A series of stakeholder engagement sessions were held on October 29–31, 2013 and June 25, 2014. Summaries of the stakeholder engagement sessions are posted to the Federal eRulemaking Portal at *http://www.regulations.gov* under Document ID: FEMA–2012–0026–0055 and FEMA–2012–0026–0053, respectively.

The NUREG–0654/FEMA–REP–1, Rev. 2 draft was posted to the Federal eRulemaking Portal for public comment (80 FR 30697, May 29, 2015). The original comment period was scheduled to conclude on August 27, 2015, however, several commenters requested an extension beyond the original 90-day comment period. Commenters cited the voluminous material put forth by the agencies for comment and that the proposed guidance document covered many policy matters that required a time consuming review by licensees and their offsite counterparts. FEMA and the NRC determined that it was in the interest of all parties to extend the comment period to October 13, 2015 (80 FR 50862, Aug. 21, 2015). Most of the changes made to the proposed guidance document are clarifying, non-substantive changes that reflect current practice.

FEMA and the NRC are issuing the final guidance document: ''Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants'' (NUREG–0654/FEMA–REP–1, Rev. 2). The final guidance document included adjudication of 631 comments from 32 commenters. FEMA and the NRC prepared a comment/response matrix entitled ''Adjudication Report for NUREG–0654/FEMA–REP–1, Rev. 2 Public Comments Sorted by Document Order December 2019'' that may be viewed at *www.regulations.gov* under Docket ID FEMA–2012–0026. The substantive changes in the final guidance document align with the national preparedness doctrine, as directed by the President in directives and supported by the National Preparedness System (NPS).

Additionally, this final guidance document incorporates the Radiological Emergency Preparedness Program guidance into the NPS, thus ensuring that it is risk- and threat-informed and appropriate for the whole community.

The contents of this final guidance document do not have the force and effect of law and are not meant to bind the public in any way. This final guidance document is intended only to provide clarity to the public regarding existing requirements under the law or agency policies.

Implementation: The timeframe for transition to the final guidance document, ''Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants'' (NUREG–0654/FEMA–REP–1, Rev. 2), will vary amongst State, local, and Tribal governments and will be tied to their individual exercise cycle. FEMA intends to work with each jurisdiction to determine the best timeframe for transition, taking both the level of effort and where each is within their exercise cycle into account.

Authority: NRC Authorization Acts of 1980 (Pub. L. 96–295) and 1982–1983 (Pub. L. 97–415); Robert T. Stafford Disaster Relief and Emergency Assistance Act, as amended, Titles II and VI, Sections 201 and 611, 42 U.S.C. 5131 and 5196; Homeland Security Act of 2002, as amended, Title VI, Chapter 1, Subchapter V, Sections 503 and 504, 6 U.S.C. 313 and 314; Security and Accountability for Every Port Act of 2006, Title V, Section 612, 6 U.S.C. 314a; Department of Veterans Affairs and Housing and Urban Development, and Independent Agencies Appropriations for 1999, 42 U.S.C. 5196e; Post-Katrina Emergency Management Reform Act of 2006, Title VI, Sections 602, 642, 643, and 644, 6 U.S.C. 701, 742, 743, and 744; Reorganization Plan No. 3 of 1978; E.O. 12241, as amended; E.O. 12127, as amended. E.O. 12148, as amended; E.O. 12657, as amended; FEMA's regulations in title 44, chapter I, parts 350–354 of the CFR.

Dated: November 27, 2019.

Pete Gaynor,

Acting Administrator, Federal Emergency Management Agency.

[FR Doc. 2019–27384 Filed 12–20–19; 8:45 am]

BILLING CODE 9111–46–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 180831813–9170–02; RTID 0648–XY058]

Fisheries of the Exclusive Economic Zone Off Alaska; Inseason Adjustment to the 2020 Gulf of Alaska Pollock and Pacific Cod Total Allowable Catch Amounts

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

ACTION: Temporary rule; inseason adjustment; request for comments.

SUMMARY: NMFS is adjusting the 2020 total allowable catch (TAC) amounts for the Gulf of Alaska (GOA) pollock and Pacific cod fishery. This action is necessary because NMFS has determined these TACs are incorrectly specified, and will ensure the GOA pollock and Pacific cod TACs are the appropriate amount based on the best available scientific information for pollock and Pacific cod in the GOA. This action is consistent with the goals and objectives of the Fishery Management Plan for Groundfish of the Gulf of Alaska.

DATES: Effective 0001 hours, Alaska local time (A.l.t.), January 1, 2020, until the effective date of the final 2020 and 2021 harvest specifications for GOA groundfish, unless otherwise modified or superseded through publication of a notification in the **Federal Register**.

Comments must be received at the following address no later than 4:30 p.m., A.l.t., January 7, 2020.

ADDRESSES: Submit your comments, identified by NOAA–NMFS–2018–0103 by any of the following methods:

- *Federal e-Rulemaking Portal:* Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2018–0103,* click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.
- *Mail:* Submit written comments to Glenn Merrill, Assistant Regional Administrator, Sustainable Fisheries Division, Alaska Region NMFS, Attn: Records. Mail comments to P.O. Box 21668, Juneau, AK 99802–1668.

Instructions: NMFS may not consider comments if they are sent by any other method, to any other address or individual, or received after the comment period ends. All comments received are a part of the public record, and NMFS will post the comments for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address), 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: Obren Davis, 907–586–7228.

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

The final 2019 and 2020 harvest specifications for groundfish in the GOA (84 FR 9416, March 14, 2019) set the 2020 pollock TAC at 114,943 metric tons (mt) in the GOA. In December 2019, the North Pacific Fishery Management Council (Council) recommended a 2020 pollock TAC of 115,930 mt for the GOA, which is more than the 114,943 mt established by the final 2019 and 2020 harvest specifications for groundfish in the GOA. The Council's recommended 2020 TAC, and the area and seasonal apportionments, is based on the Stock Assessment and Fishery Evaluation report (SAFE), dated November 2019.

The final 2019 and 2020 harvest specifications for groundfish in the GOA (84 FR 9416, March 14, 2019) set the 2020 Pacific cod TAC at 15,709 metric tons (mt) in the GOA. In December 2019, the North Pacific Fishery Management Council (Council) recommended a 2020 Pacific cod TAC of 6,431 mt for the GOA, which is less than the 15,709 mt established by the final 2019 and 2020 harvest specifications for groundfish in the GOA. The Council's recommended 2020 TAC, and the area and seasonal apportionments, is based on the Stock Assessment and Fishery Evaluation report (SAFE), dated November 2019.

Steller sea lions occur in the same location as the pollock and Pacific cod fisheries and are listed as endangered under the Endangered Species Act (ESA). Pollock and Pacific cod are principal prey species for Steller sea lions in the GOA. The seasonal apportionment of pollock and Pacific

cod harvests are necessary to ensure the groundfish fisheries are not likely to cause jeopardy of extinction or adverse modification of critical habitat for Steller sea lions. The regulations at § 679.20(a)(5)(iv) specify how the pollock TAC will be apportioned and the regulations at § 679.20(a)(6)(ii) and (a)(12)(i) specify how the Pacific cod TAC will be apportioned.

In accordance with § 679.25(a)(1)(iii), (a)(2)(i)(B), and (a)(2)(iv) the Administrator, Alaska Region, NMFS (Regional Administrator), has determined that, based on the best available scientific information for this fishery, the current GOA pollock and Pacific cod TACs are incorrectly specified. Consequently, pursuant to § 679.25(a)(1)(iii), the Regional Administrator is adjusting the 2020 GOA pollock TAC to 115,930 mt and the 2020 Pacific cod TAC to 6,431 mt. Therefore, Tables 4 and 6 of the final 2019 and 2020 harvest specifications for groundfish in the GOA (84 FR 9416, March 14, 2019) are revised consistent with this adjustment.

Pursuant to § 679.20(a)(5)(iv), Table 4 of the final 2019 and 2020 harvest specifications for groundfish in the GOA (84 FR 9416, March 14, 2019) is revised for the 2020 TACs of pollock in the Central and Western Regulatory Area of the GOA.

TABLE 4—FINAL 2020 DISTRIBUTION OF POLLOCK IN THE WESTERN AND CENTRAL REGULATORY AREAS OF THE GOA; SEASONAL BIOMASS DISTRIBUTION, AREA APPORTIONMENTS; AND SEASONAL ALLOWANCES OF ANNUAL TAC

Season [1]	Shumagin (area 610)		Chirikof (area 620)		Kodiak (area 630)		Total [2]
A (Jan 20–Mar 10)	517	2.06%	18,757	74.86%	5,783	23.08%	25,057
B (Mar 10–May 31)	517	2.06%	22,222	88.68%	2,318	9.25%	25,057
C (Aug 25–Oct 1)	9,070	36.20%	6,739	26.89%	9,248	36.91%	25,057
D (Oct 1–Nov 1)	9,070	36.20%	6,739	26.89%	9,248	36.91%	25,057
Annual Total	19,175		54,456		26,597		100,228

[1] As established by § 679.23(d)(2)(i) through (iv), the A, B, C, and D season allowances are available from January 20 to March 10, March 10 to May 31, August 25 to October 1, and October 1 to November 1, respectively. The amounts of pollock for processing by the inshore and offshore components are not shown in this table.

[2] The WYK and SEO District pollock TACs are not allocated by season and are not included in the total pollock TACs shown in this table.

Note: Seasonal apportionments may not total precisely due to rounding. Values are rounded to the nearest metric ton and percentages are rounded to the nearest 0.01.

Pursuant to § 679.20(a)(6)(ii) and (a)(12)(i), Table 6 of the final 2019 and 2020 harvest specifications for groundfish in the GOA (84 FR 9416, March 14, 2019) is revised for the 2020 TACs of Pacific cod in the GOA.

TABLE 6—FINAL 2020 SEASONAL APPORTIONMENTS AND ALLOCATION OF PACIFIC COD TOTAL ALLOWABLE CATCH (TAC) AMOUNTS IN THE GOA; ALLOCATIONS IN THE WESTERN GOA AND CENTRAL GOA SECTORS, AND THE EASTERN GOA INSHORE AND OFFSHORE PROCESSING COMPONENTS

Regulatory area and sector	Annual allocation (mt)	A Season		B Season	
		Sector percentage of annual non-jig TAC	Seasonal allowances (mt)	Sector percentage of annual non-jig TAC	Seasonal allowances (mt)
Western GOA:					
Jig (2.5% of TAC)	52	N/A	31	N/A	21
Hook-and-line CV	28	0.70	14	0.70	14
Hook-and-line C/P	401	10.90	221	8.90	180
Trawl CV	777	27.70	561	10.70	217
Trawl C/P	49	0.90	18	1.50	30
All Pot CV and Pot C/P	769	19.80	401	18.20	368
Total	2,076	60.00	1,246	40.00	830
Central GOA:					
Jig (1.0% of TAC)	38	N/A	23	N/A	15
Hook-and-line <50 CV	550	9.32	351	5.29	199
Hook-and-line ≥50 CV	253	5.61	211	1.10	41
Hook-and-line C/P	192	4.11	155	1.00	38
Trawl CV [1]	1,567	21.14	796	20.45	771
Trawl C/P	158	2.00	75	2.19	83
All Pot CV and Pot C/P	1,048	17.83	672	9.97	376
Total	3,806	60.00	2,284	40.00	1,522
Eastern GOA:		Inshore (90% of Annual TAC)		Offshore (10% of Annual TAC)	
	549		494		55

[1] Trawl catcher vessels participating in Rockfish Program cooperatives receive 3.81 percent, or 145 mt, of the annual Central GOA TAC (see Table 28c to 50 CFR part 679), which is deducted from the Trawl CV B season allowance (see Table 12. Final 2020 Apportionments of Rockfish Secondary Species in the Central GOA and Table 28c to 50 CFR part 679).

Note: Values are rounded to the nearest metric ton.

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would allow for harvests that exceed the appropriate allocation for pollock and Pacific cod based on the best scientific information available. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of December 9, 2019, and additional time for prior public comment would result in conservation concerns for the ESA-listed Steller sea lions.

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

Under § 679.25(c)(2), interested persons are invited to submit written comments on this action to the above address until January 7, 2020.

This action is required by §§ 679.20 and 679.25 and is exempt from review under Executive Order 12866.

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

Dated: December 17, 2019.

Jennifer M. Wallace,

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

[FR Doc. 2019–27539 Filed 12–20–19; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 180831813–9170–02; RTID 0648–XY057]

Fisheries of the Exclusive Economic Zone Off Alaska; Pacific Cod in the Gulf of Alaska

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting directed fishing for Pacific cod in the Gulf of Alaska (GOA). This action is necessary because a biological assessment of stock condition for Pacific cod in the GOA projects that the spawning biomass will be below 20 percent of the projected unfished spawning biomass during 2020.

DATES: Effective 0001 hours, Alaska local time (A.l.t.), January 1, 2020, through 2400 hours, A.l.t., December 31, 2020.

FOR FURTHER INFORMATION CONTACT: Mary Furuness, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the GOA exclusive economic zone according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679. Regulations governing sideboard protections for GOA groundfish fisheries appear at subpart B of 50 CFR part 680.

The most recent biological assessment available of the stock condition for Pacific cod in the GOA has determined that the spawning biomass will be below 20 percent of the projected unfished spawning biomass during 2020 *(https://www.fisheries.noaa.gov/alaska/population-assessments/north-pacific-groundfish-stock-assessment-and-fishery-evaluation).*

In accordance with § 679.20(d)(4), the Administrator, Alaska Region, NMFS (Regional Administrator) has determined that a biological assessment of stock condition for Pacific cod in the GOA projects that the spawning biomass will be below 20 percent of the projected unfished spawning biomass during 2020. Consequently, NMFS is prohibiting directed fishing for Pacific cod in the GOA. While this closure is effective the maximum retainable amounts at § 679.20(e) and (f) apply at any time during a trip.

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the directed fishing closure of Pacific cod in the GOA. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of December 6, 2019.

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

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

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

Dated: December 17, 2019.

Jennifer M. Wallace,

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

[FR Doc. 2019–27567 Filed 12–20–19; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 84, No. 246
Monday, December 23, 2019

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.

FEDERAL LABOR RELATIONS AUTHORITY

5 CFR Part 2424

Negotiability Proceedings

AGENCY: Federal Labor Relations Authority.

ACTION: Proposed rule with request for comments.

SUMMARY: The Federal Labor Relations Authority (FLRA) intends to revise the regulations governing negotiability appeals to better ''expedite proceedings,'' consistent with Congress's direction, and with the FLRA's goal in its strategic plan to ''ensure quality, timely . . . decision-making processes.'' The proposed rule is designed to streamline the adjudication process for negotiability appeals, resulting in more timely decisions for the parties.

DATES: Written comments must be received on or before January 22, 2020.

ADDRESSES: You may send comments, which must include the caption ''Negotiability Proceedings,'' by one of the following methods:

- *Email: FedRegComments@flra.gov.* Include ''Negotiability Proceedings'' in the subject line of the message.
- *Mail or Hand Delivery:* Emily Sloop, Chief, Case Intake and Publication, Federal Labor Relations Authority, Docket Room, Suite 200, 1400 K Street NW, Washington, DC 20424–0001.

Instructions: Please do not email comments if you have mailed or hand delivered the same comments.

FOR FURTHER INFORMATION CONTACT: Rebecca Osborne, Deputy Solicitor, at *rosborne@flra.gov* or at: (202) 218–7986.

SUPPLEMENTARY INFORMATION:

Background

The Federal Service Labor-Management Relations Statute (the Statute) authorizes the FLRA to adjudicate a number of matters related to federal sector labor-management relations, including negotiability appeals. Specifically, the Statute provides that ''if an agency involved in collective bargaining with an exclusive representative alleges that the duty to bargain in good faith does not extend to any matter, the exclusive representative may appeal the allegation to the Authority in accordance with the provisions of this subsection.'' 5 U.S.C. 7117(c)(1). The Statute provides further that ''[t]he Authority shall expedite proceedings under this subsection to the extent practicable and shall issue . . . a written decision on the allegation and specific reasons therefor at the earliest practicable date.'' 5 U.S.C. 7117(c)(6). The proposed changes are intended to allow the Authority to expedite negotiability appeal proceedings to allow for a written decision at the earliest practicable date.

Analysis of the Regulations

Section 2424.2 Definitions

Section 2424.2 clarifies the definition of a ''bargaining obligation dispute'' and provides an additional example of such a dispute. The section also changes the definition of Alternative Dispute Resolution to reflect the current practice. The section adds several examples of a ''negotiability dispute'' to provide a more complete, but not necessarily exhaustive, list. The section proposes removing the definition of ''severance'' because it is unclear whether providing for severance of a proposal or provision adds value to the adjudicatory process. Other changes to the regulations will allow for FLRA consideration of particular matters when those matters are submitted as distinct proposals or provisions. However, as discussed in connection with section 2424.22, the Authority is also considering a second option that would limit the opportunities for severance, rather than eliminating it completely.

Section 2424.10 is amended to change the heading to ''Alternative Dispute Resolution'' and is clarified to explain that the use of alternative dispute resolution is at the discretion of the FLRA.

Section 2424.11 is amended so paragraph (a) requires an exclusive representative to put in writing its request that an agency provide a written allegation concerning the duty to bargain. Paragraph (b) is amended to obligate an agency to respond within ten (10) days to an exclusive representative's written request for a written allegation concerning the duty to bargain. The section clarifies that if an exclusive representative chooses to file a petition based on an unrequested written allegation concerning the duty to bargain, then the petition must be filed within fifteen (15) days after the date of service of the unrequested written allegation.

Section 2424.21 is amended to state that if an agency fails to respond to a written request for a written allegation within ten (10) days of the request, then the exclusive representative may file a petition within the next sixty (60) days. If the agency serves a written allegation on the exclusive representative more than ten (10) days after receiving a written request for such allegation, and a petition has not yet been filed, then the petition must be filed within fifteen (15) days of the service of that allegation. If the exclusive representative files a petition after the expiration of the ten (10) day period, and the agency subsequently serves a written allegation on the exclusive representative, then the FLRA will consider the appeal based upon the petition filed prior to the allegation but may allow the exclusive representative to amend the petition. However, the exclusive representative may not file an additional petition. The FLRA is seeking to prevent negotiability disputes from lingering unresolved for a potentially unlimited period of time, to avoid the inefficiencies of adjudicating stale disputes, and to reduce the potential surprise of a negotiability petition being filed long after a written request for an allegation of nonnegotiability was served. The FLRA seeks comments on whether the proposed language would meet those objectives, and the FLRA welcomes comments with alternative proposals to meet those objectives.

Section 2424.22 adds a new paragraph to allow for division of matters into proposals or provisions. Although the FLRA is proposing the revised subsection wording in this notice, the FLRA is also considering another possible option. It requests comments on the advantages and disadvantages of both options:

Option 1. Eliminating severance altogether and replacing it with the proposed wording in this notice.

Option 2. Allowing only one point in the filing process at which an exclusive representative may request severance. Under this option, the FLRA seeks comments on: (a) When during the filing process this opportunity to request severance should occur; and (b) the advantages and disadvantages of automatically granting all timely severance requests in order to reduce the burden of litigating and resolving these requests. If the FLRA were to automatically grant all timely requests, then: (1) The exclusive representative would bear the burden of requesting severance in a manner that allowed each severed portion to stand alone, and the burden of explaining the meaning and operation of each portion; (2) even if the exclusive representative failed to meet those burdens, the FLRA would automatically grant severance as requested; and (3) where the exclusive representative failed to meet those burdens, after automatically granting severance, the FLRA would find the severed portions outside the duty to bargain, based on the failure to provide an adequate record.

Section 2424.22 also requires greater specificity in what must be included in a petition and requires the submission of relevant documents. The section is also amended to require that an exclusive representative respond in a petition to any specific arguments that are set forth in an agency's written allegation concerning the duty to bargain or an agency head's disapproval of an agreement.

Section 2424.23 is amended to clarify that the decision to hold a post-petition conference is at the discretion of the FLRA and that, regardless of whether one does occur, the parties must observe all filing deadlines. The FLRA seeks comments on the most appropriate juncture, within the stages of pleading, for the post-petition conference to occur, in cases where a conference is held. The section is also amended to clarify that the FLRA may take other appropriate action, in the exercise of its discretion, to aid in decision making, regardless of whether a post-petition conference occurs.

Section 2424.24 clarifies the content of the agency's statement of position, requires greater specificity about certain matters within the statement of position, and requires the submission of relevant documents.

Section 2424.25 clarifies what is to be included in the exclusive representative's response and removes surplus language. This section is amended to limit the content of the response to matters raised for the first time in the agency's statement of position. Because changes to section 2424.22 would require the exclusive representative to address, in its petition, specific arguments in an agency's written allegation concerning the duty to bargain or an agency head's disapproval of an agreement, the exclusive representative could not wait until filing its response under section 2424.25 to address those matters. Any facts or arguments that should be included in the petition in accordance with the changes to section 2424.22, but are not included in the petition, would be barred from consideration in the exclusive representative's response under section 2424.25.

Section 2424.26 is amended to shorten the time period for the agency's submission of a reply to the exclusive representative's response to ten (10) days and specifies the content to be included. The section also reorganizes the content requirements.

Section 2424.27 removes the time period for filing additional submissions authorized in the discretion of the FLRA. When authorizing additional submissions, the FLRA will establish the deadline for their submission.

Section 2424.30, in paragraph (a), clarifies when the deadline begins to run for refiling a petition that was previously dismissed without prejudice by the FLRA in the case of a related grievance that was administratively resolved. The FLRA requests comments on whether the proposed clarification accurately captures all of the scenarios under which a grievance mentioned in this subsection could be administratively resolved. Subsection (b) of the section clarifies the process by which the FLRA will resolve matters under various factual scenarios.

Section 2424.31 is amended to include a new heading that more accurately reflects its contents, and to make other minor wording changes.

Section 2424.32 is amended to highlight that the parties' failures to explain their positions thoroughly could lead to an adverse ruling, and that assessing the consequences of such a failure (*e.g.,* waiver, concession) is within the discretion of the FLRA.

Section 2424.40 is amended to make conforming changes to reflect the proposed removal of severance. The section also proposes altering the content of an FLRA order where it finds a duty to bargain by deleting the reference to a ''request'' to bargain concerning the proposal. The FLRA seeks comments on whether the ''request'' wording serves a useful purpose. The wording may imply that the burden is on an exclusive representative to re-start negotiations following a negotiability decision, and that the agency is not obligated to take any action until the exclusive representative requests that the agency do so.

Section 2424.41 proposes altering the description of noncompliance with an FLRA order by deleting wording that is already present in section 2424.40. As with the proposed change to section 2424.40, the FLRA seeks comments on whether this wording serves a useful purpose or whether it is duplicative of the wording in 2424.40. In addition, this section proposes adding a deadline of thirty (30) days for an exclusive representative to report the failure to comply with an order, following the expiration of the 60-day period under 5 U.S.C. 7123(a).

Section 2424.50 is amended to explain the criteria in the section are illustrative and there may be other, or more appropriate, examples of an agency rule or regulation for which there is a compelling need. The FLRA solicits specific examples of an agency rule or regulation for which there is a compelling need and appropriate illustrative criteria that would establish a compelling need for the rule or regulation.

Executive Order 12866

The FLRA is an independent regulatory agency, and as such, is not subject to the requirements of E.O. 12866.

Executive Order 13132

The FLRA is an independent regulatory agency, and as such, is not subject to the requirements of E.O. 13132.

Regulatory Flexibility Act Certification

Pursuant to section 605(b) of the Regulatory Flexibility Act, 5 U.S.C. 605(b), the Chairman of the FLRA has determined that this rule, as amended, will not have a significant impact on a substantial number of small entities, because this rule applies only to federal agencies, federal employees, and labor organizations representing those employees.

Executive Order 13771, Reducing Regulation and Controlling Regulatory Costs

This proposed rule is not expected to be subject to the requirements of E.O. 13771 (82 FR 9339, Feb. 3, 2017) because this proposed rule is expected to be related to agency organization, management, or personnel.

Executive Order 13132, Federalism

This regulation will not have substantial direct effects on the States, on the relationship between the National Government and the States, or on distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132, this proposed rule does not have sufficient federalism implications to warrant preparation of a Federalism assessment.

Executive Order 12988, Civil Justice Reform

This regulation meets the applicable standard set forth in section 3(a) and (b)(2) of Executive Order 12988.

Unfunded Mandates Reform Act of 1995

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

Small Business Regulatory Enforcement Fairness Act of 1996

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

Paperwork Reduction Act of 1995

The amended regulations contain no additional information collection or record-keeping requirements under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501, *et seq.*

List of Subjects in 5 CFR Part 2424

Negotiability Proceedings.

Federal Labor Relations Authority.

Rebecca Osborne,

Federal Register Liaison.

Accordingly, for the reasons stated in the preamble, FLRA proposes to amend 5 CFR part 2424 as follows:

PART 2424—[AMENDED]

■ 1. The authority citation for part 2424 continues to read as follows:

Authority: 5 U.S.C. 7134.

■ 2. Revise Section 2424.1 to read as follows:

§ 2424.1 Applicability of this part.

This part applies to all petitions for review filed on or after [DATE 30 DAYS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE **FEDERAL REGISTER**].

■ 3. Amend § 2424.2 by:

■ a. Revising paragraphs (a), (b), (c)(2) and (c)(3);

■ b. Adding paragraphs (c)(4) through (8); and

■ c. Revising paragraphs (e) and (f);

■ d. Removing paragraph (h);

■ e. Redesignating paragraph (i) as (h); and

■ f. Revising newly redesignated paragraph (h).

The revisions and additions to read as follows:

§ 2424.2 Definitions.

* * * * *

(a) *Bargaining obligation dispute* means a disagreement between an exclusive representative and an agency concerning whether, in the specific circumstances involved in a particular case, the parties are obligated by law to bargain over a proposal that otherwise may be negotiable. Examples of bargaining obligation disputes include disagreements between an exclusive representative and an agency concerning agency claims that:

(1) A proposal concerns a matter that is covered by a collective bargaining agreement;

(2) Bargaining is not required because there has not been a change in bargaining unit employees' conditions of employment; and

(3) The exclusive representative is attempting to bargain at the wrong level of the agency.

(b) *Alternative Dispute Resolution* refers to the Federal Labor Relations Authority's efforts to assist parties in reaching agreements to resolve disputes.

(c) * * *

(2) Directly affects bargaining-unit employees' conditions of employment;

(3) Enforces an ''applicable law,'' within the meaning of 5 U.S.C. 7106(a)(2);

(4) Concerns a matter negotiable at the election of the agency under 5 U.S.C. 7106(b)(1);

(5) Constitutes a ''procedure'' or ''appropriate arrangement'' within the meaning of 5 U.S.C. 7106(b)(2) and (3), respectively;

(6) Is consistent with an Executive Order;

(7) Is consistent with a Government-wide rule or regulation; and

(8) Is negotiable notwithstanding agency rules or regulations because:

(i) The proposal or provision is consistent with agency rules or regulations for which a compelling need exists under 5 U.S.C. 7117(a)(2);

(ii) The agency rules or regulations violate applicable law, rule, regulation, or appropriate authority outside the agency;

(iii) The agency rules or regulations were not issued by the agency or by any primary national subdivision of the agency;

(iv) The exclusive representative represents an appropriate unit including not less than a majority of the employees in the rule- or regulation-issuing agency or primary national subdivision; or

(v) No compelling need exists for the rules or regulations to bar negotiations.

* * * * *

(e) *Proposal* means any matter offered for bargaining that has not been agreed to by the parties. If a petition for review concerns more than one proposal, then the term ''proposal'' includes each proposal concerned.

(f) *Provision* means any matter that has been disapproved by the agency head on review pursuant to 5 U.S.C. 7114(c). If a petition for review concerns more than one provision, then the term ''provision'' includes each provision concerned.

* * * * *

(h) *Written allegation concerning the duty to bargain* means an agency allegation that the duty to bargain in good faith does not extend to a proposal.

■ 4. Revise § 2424.10 to read as follows:

§ 2424.10 Alternative Dispute Resolution.

Where an exclusive representative and an agency are unable to resolve disputes that arise under this part, they may request that the Office of Case Intake and Publication refer them to alternative dispute resolution. As resources permit, and in the discretion of the Authority, the FLRA may attempt to assist the parties to resolve these disputes. Parties seeking information or assistance under this part may call or write the Office of Case Intake and Publication at (202) 218–7740, 1400 K Street NW, Washington, DC 20424–0001.

■ 5. Revise § 2424.11 to read as follows:

§ 2424.11 Requesting and providing written allegations concerning the duty to bargain.

(a) *General.* An exclusive representative may file a petition for

review after receiving a written allegation concerning the duty to bargain from the agency. An exclusive representative also may file a petition for review if it requests in writing that the agency provide it with a written allegation concerning the duty to bargain and the agency does not respond to the request within ten (10) days.

(b) *Agency allegation in response to request.* The agency has an obligation to respond within ten (10) days to a written request by the exclusive representative for a written allegation concerning the duty to bargain. The agency's allegation in response to the exclusive representative's request response must be in writing and must be served in accord with § 2424.2(g).

(c) *Unrequested agency allegation.* If an agency provides an exclusive representative with an unrequested written allegation concerning the duty to bargain, then the exclusive representative may either file a petition for review under this part, or continue to bargain and subsequently request in writing a written allegation concerning the duty to bargain, if necessary. If the exclusive representative chooses to file a petition for review based on an unrequested written allegation concerning the duty to bargain, then the time limit in § 2424.21(a)(1) applies.

■ 6. Amend § 2424.21 by revising paragraph (b) amending paragraph (b) introductory text and paragraph (b)(1) to read as follows:

§ 2424.21 Time limits for filing a petition for review.

* * * * *

(b) If the agency has not served a written allegation on the exclusive representative within ten (10) days after the agency's principal bargaining representative has received a written request for such allegation, as provided in § 2424.11(a), then:

(1) The petition may be filed within sixty (60) days after the expiration of the ten (10) day period, subject to the following:

(i) If the agency serves a written allegation on the exclusive representative more than ten (10) days after receiving a written request for such allegation, and the exclusive representative *has not* previously filed a petition under this paragraph, then the petition must be filed within fifteen (15) days after the date of service of that allegation on the exclusive representative;

(ii) If the agency serves a written allegation on the exclusive representative more than ten (10) days after receiving a written request for such allegation, and the exclusive representative *has* previously filed a petition under this paragraph, then the Authority will consider the appeal filed on the date of the previous petition. The exclusive representative may not file an additional petition, but the Authority may allow amendments to the previous petition based on the written allegation.

* * * * *

■ 7. Revise § 2424.22 to read as follows:

§ 2424.22 Exclusive representative's petition for review; purpose; divisions; content; service.

(a) *Purpose.* The purpose of a petition for review is to initiate a negotiability proceeding and provide the agency with notice that the exclusive representative requests a decision from the Authority that a proposal or provision is within the duty to bargain or not contrary to law, respectively.

(b) *Divisions.* The petition will be resolved according to how the exclusive representative divides matters into proposals or provisions. If the exclusive representative seeks a negotiability determination on particular matters standing alone, then the exclusive representative must submit those matters as distinct proposals or provisions.

(c) *Content.* You must file a petition for review on a form that the Authority has provided for that purpose, or in a substantially similar format. You meet this requirement if you file your petition electronically through use of the eFiling system on the FLRA's website at *www.flra.gov.* That website also provides copies of petition forms. You must date the petition, unless you file it electronically through use of the FLRA's eFiling system. And, regardless of how you file the petition, you must ensure that it includes the following:

(1) The exact wording and explanation of the meaning of the proposal or provision, including an explanation of special terms or phrases, technical language, or other words that are not in common usage, as well as how the proposal or provision is intended to work;

(2) Specific citation to any law, rule, regulation, section of a collective bargaining agreement, or other authority on which you rely in your argument or that you reference in the proposal or provision, and a copy of any such material that the Authority cannot easily access (which you may upload as attachments if you file the petition electronically through use of the FLRA's eFiling system);

(3) An explanation of how the cited law, rule, regulation, section of a collective bargaining agreement, or other authority relates to your argument, proposal, or provision;

(4) A statement as to whether the proposal or provision is also involved in an unfair labor practice charge under part 2423 of this subchapter, a grievance pursuant to the parties' negotiated grievance procedure, or an impasse procedure under part 2470 of this subchapter, and whether any other petition for review has been filed concerning a proposal or provision arising from the same bargaining or the same agency head review; and

(5) Documents relevant to the statement, including a copy of any related unfair labor practice charge, grievance, request for impasse assistance, or other petition for review.

(d) *Response.* Where the agency's written allegation concerning the duty to bargain, or the agency head's disapproval, relies on a specific law, rule, regulation, section of a collective bargaining agreement, or other authority to support the agency's bargaining-obligation or negotiability claims, the exclusive representative must respond to those specific claims in the petition for review.

(e) *Service.* The petition for review, including all attachments, must be served in accord with § 2424.2(g).

■ 8. Amend § 2424.23 by:

■ a. Revising paragraphs (a), (b)(4), and (c); and

■ b. Adding paragraphs (d) and (e).

The additions and revisions to read as follows:

§ 2424.23 Post-petition conferences; conduct and record.

(a) *Scheduling a post-petition conference.* The FLRA may, in its discretion, schedule a post-petition conference to be conducted by an FLRA representative by telephone, in person, or through other means. Unless the Authority or an FLRA representative directs otherwise, parties must observe all time limits in this part, regardless of whether a post-petition conference is conducted or may be conducted.

(b) * * *

(4) Status of any proposal or provision that is also involved in an unfair labor practice charge under part 2423 of this subchapter, in a grievance under the parties' negotiated grievance procedure, or an impasse procedure under part 2470 of this subchapter.

* * * * *

(c) *Discretionary extension of time limits.* The FLRA representative may, on determining that it will effectuate the purposes of the Federal Service Labor—Management Relations Statute, 5 U.S.C. 7101 *et seq.,* and this part, extend the time limits for filing the agency's

statement of position and any subsequent filings.

(d) *Record of the conference.* After the post-petition conference has been completed, the representative of the FLRA will prepare and serve on the parties a written statement that includes whether the parties agree on the meaning of the disputed proposal or provision, the resolution of any disputed factual issues, and any other appropriate matters.

(e) *Hearings.* Instead of, or in addition to, conducting a post-petition conference, the Authority may exercise its discretion under § 2424.31 to hold a hearing or take other appropriate action to aid in decision making.

■ 9. Amend § 2424.24 by:
■ a. Revising the heading of the section;
■ b. Revising paragraphs (a) and (b);
■ c. Revising the introductory text of paragraph (c)(2);
■ d. Revising paragraphs (c)(3) and (c)(4);
■ e. Removing paragraph (d); and
■ f. Redesignating paragraph (e) as paragraph (d).

§ 2424.24 Agency's statement of position; purpose; time limits; content; service.

(a) *Purpose.* The purpose of the agency's statement of position is to inform the Authority and the exclusive representative why a proposal or provision is not within the duty to bargain or contrary to law, respectively, and whether the agency disagrees with any facts or arguments made by the exclusive representative in the petition.

(b) *Time limit for filing.* The agency must file its statement of position within thirty (30) days after the date the head of the agency receives a copy of the petition for review.

(c) * * *

(2) Set forth in full your position on any matters relevant to the petition that you want the Authority to consider in reaching its decision, including: A statement of the arguments and authorities supporting any bargaining obligation or negotiability claims; any disagreement with claims that the exclusive representative made in the petition for review; specific citation to, and explanation of the relevance of, any law, rule, regulation, section of a collective bargaining agreement, or other authority on which you rely; and a copy of any such material that the Authority may not easily access (which you may upload as attachments if you file your statement of position electronically through use of the FLRA's eFiling system). Your statement of position must also include the following:

* * * * *

(3) Status of any proposal or provision that is also involved in an unfair labor practice charge under part 2423 of this subchapter, a grievance pursuant to the parties' negotiated grievance procedure, or an impasse procedure under part 2470 of this subchapter, and whether any other petition for review has been filed concerning a proposal or provision arising from the same bargaining or the same agency head review; and

(4) If they have not already been provided with the petition, documents relevant to the updates, including a copy of any related unfair labor practice charge, grievance, request for impasse assistance, or other petition for review.

(d) *Service.* A copy of the agency's statement of position, including all attachments, must be served in accord with § 2424.2(g).

■ 10. Revise § 2424.25 to read as follows:

§ 2424.25 Response of the exclusive representative; purpose; time limits; content; service.

(a) *Purpose.* The purpose of the exclusive representative's response is to inform the Authority and the agency why, despite the agency's arguments in its statement of position, the proposal or provision is within the duty to bargain or not contrary to law, respectively, and whether the union disagrees with any facts or arguments made for the first time in the agency's statement of position.

(b) *Time limit for filing.* Within fifteen (15) days after the date the exclusive representative receives a copy of an agency's statement of position, the exclusive representative must file a response.

(c) *Content.* You must file your response on a form that the Authority has provided for that purpose, or in a substantially similar format. You meet this requirement if you file your response electronically through use of the eFiling system on the FLRA's website at *www.flra.gov.* That website also provides copies of response forms. You must limit your response to the matters that the agency raised in its statement of position. You must date your response, unless you file it electronically through use of the FLRA's eFiling system. And, regardless of how you file your response, you must ensure that it identifies any disagreement with the agency's bargaining-obligation or negotiability claims. You must: State the arguments and authorities supporting your opposition to any agency argument; include specific citation to, and explanation of the relevance of, any law, rule, regulation, section of a collective bargaining agreement, or other authority on which you rely; and provide a copy of any such material that the Authority may not easily access (which you may upload as attachments if you file your response electronically through use of the FLRA's eFiling system). You are not required to repeat arguments that you made in your petition for review. If not included in the petition for review, then you must state the arguments and authorities supporting your position on all of the relevant bargaining-obligation and negotiability matters identified in § 2424.2(a) and (c), respectively.

(d) *Service.* A copy of the response of the exclusive representative, including all attachments, must be served in accord with § 2424.2(g).

■ 11. Revise § 2424.26 to read as follows:

§ 2424.26 Agency's reply; purpose; time limits; content; service.

(a) *Purpose.* The purpose of the agency's reply is to inform the Authority and the exclusive representative whether and why it disagrees with any facts or arguments made for the first time in the exclusive representative's response.

(b) *Time limit for filing.* Within ten (10) days after the date the agency receives a copy of the exclusive representative's response to the agency's statement of position, the agency may file a reply.

(c) *Content.* You must file your reply on a form that the Authority has provided for that purpose, or in a substantially similar format. You meet this requirement if you file your reply electronically through use of the eFiling system on the FLRA's website at *www.flra.gov.* That website also provides copies of reply forms. You must limit your reply to matters that the exclusive representative raised for the first time in its response. You must date your reply, unless you file it electronically through use of the FLRA's eFiling system. And, regardless of how you file your reply, you must ensure that it identifies any disagreement with the exclusive representative's assertions in its response, including your disagreements with assertions about the bargaining-obligation and negotiability matters identified in § 2424.2(a) and (c). You must: State the arguments and authorities supporting your position; include specific citation to, and explanation of the relevance of, any law, rule, regulation, section of a collective bargaining agreement, or other authority on which you rely; and provide a copy of any such material that the Authority may not easily access (which you may upload as attachments if you file your

reply electronically through use of the FLRA's eFiling system). You are not required to repeat arguments that you made in your statement of position.

(d) *Service.* A copy of the agency's reply, including all attachments, must be served in accord with § 2424.2(g).

■ 12. Revise § 2424.27 to read as follows:

§ 2424.27 Additional submissions to the Authority.

The Authority will not consider any submission filed by any party other than those authorized under this part, provided however that the Authority may, in its discretion, grant permission to file an additional submission based on a written request showing extraordinary circumstances by any party. All documents filed under this section must be served in accord with § 2424.2(g).

■ 13. Revise § 2424.30 to read as follows:

§ 2424.30 Procedure through which the petition for review will be resolved.

(a) *Exclusive representative has filed related unfair labor practice charge or grievance alleging an unfair labor practice.* Except for proposals or provisions that are the subject of an agency's compelling need claim under 5 U.S.C. 7117(a)(2), the Authority will dismiss a petition for review when an exclusive representative files an unfair labor practice charge pursuant to part 2423 of this subchapter or a grievance alleging an unfair labor practice under the parties' negotiated grievance procedure, and the charge or grievance concerns issues directly related to the petition for review filed pursuant to this part. The dismissal will be without prejudice to the right of the exclusive representative to refile the petition for review after the unfair labor practice charge or grievance has been resolved administratively, including resolution pursuant to an arbitration award that has become final and binding. No later than thirty (30) days after the date on which the unfair labor practice charge or grievance is resolved administratively, the exclusive representative may refile the petition for review, and the Authority will determine whether resolution of the petition is still required. For purposes of this subsection, a grievance is resolved administratively when:

(1) The exclusive representative withdraws the grievance;

(2) The parties mutually resolve the grievance;

(3) An arbitrator has issued an award resolving the grievance, and the 30-day period under 5 U.S.C. 7122(b) has passed without an exception being filed; or

(4) An arbitrator has issued an award resolving the grievance, a party has filed an exception to that award, and the Authority has issued a decision resolving that exception.

(b) *Exclusive representative has not filed related unfair labor practice charge or grievance alleging an unfair labor practice.* The petition will be processed as follows:

(1) *No bargaining obligation dispute exists.* The Authority will resolve the petition for review under the procedures of this part.

(2) *A bargaining obligation dispute exists.* The exclusive representative may file an unfair labor practice charge pursuant to part 2423 of this subchapter or a grievance under the parties' negotiated grievance procedure concerning the bargaining obligation dispute, and, where the exclusive representative pursues either of these courses, the Authority will proceed in accord with paragraph (a) of this section. If the exclusive representative does not file an unfair labor practice charge or grievance concerning the bargaining obligation dispute, then the Authority will proceed to resolve all disputes necessary for disposition of the petition unless, in its discretion, the Authority determines that resolving all disputes is not appropriate because, for example, resolution of the bargaining obligation dispute under this part would unduly delay resolution of the negotiability dispute, or the procedures in another, available administrative forum are better suited to resolve the bargaining obligation dispute.

■ 14. Amend § 2424.31 by revising the introductory text and paragraph (c) to read as follows:

§ 2424.31 Hearings and other appropriate action.

When necessary to resolve disputed issues of material fact in a negotiability or bargaining obligation dispute, or when it would otherwise aid in decision making, the Authority, or its designated representative, may, in its discretion:

* * * * *

(c) Refer the matter to a hearing pursuant to 5 U.S.C. 7117(b)(3) or (c)(5); or

* * * * *

■ 15. Revise § 2424.32 to read as follows:

§ 2424.32 Parties' responsibilities; failure to raise, support, or respond to arguments; failure to participate in conferences or respond to Authority orders.

(a) *Responsibilities of the exclusive representative.* The exclusive representative has the burden of explaining the meaning, operation, and effects of the proposal or provision; and raising and supporting arguments that the proposal or provision is within the duty to bargain, within the duty to bargain at the agency's election, or not contrary to law, respectively.

(b) *Responsibilities of the agency.* The agency has the burden of explaining the meaning, operation, and effects of the proposal or provision, if the agency disagrees with the exclusive representative's explanations; and raising and supporting arguments that the proposal or provision is outside the duty to bargain or contrary to law, respectively.

(c) *Responsibilities to sufficiently explain.* Each party has the burden to give sufficiently detailed explanations to enable the Authority to understand the party's position regarding the meaning, operation, and effects of a proposal or provision. A party's failure to provide such explanations may affect the Authority's decision in a manner that is adverse to the party.

(d) *Failure to raise, support, and respond to arguments.* (1) Failure to raise and support an argument may, in the Authority's discretion, be deemed a waiver of such argument. Absent good cause:

(i) Arguments that could have been but were not raised by an exclusive representative in the petition for review, or made in its response to the agency's statement of position, may not be made in this or any other proceeding; and

(ii) Arguments that could have been but were not raised by an agency in the statement of position, or made in its reply to the exclusive representative's response, may not be raised in this or any other proceeding.

(2) Failure to respond to an argument or assertion raised by the other party may, in the Authority's discretion, be treated as conceding such argument or assertion.

(e) *Failure to participate in conferences; failure to respond to Authority orders.* Where a party fails to participate in a post-petition conference pursuant to § 2424.23, a direction or proceeding under § 2424.31, or otherwise fails to provide timely or responsive information pursuant to an Authority order, including an Authority procedural order directing the correction of technical deficiencies in filing, the Authority may, in addition to those actions set forth in paragraph (d) of this section, take any other action that, in the Authority's discretion, it deems appropriate, including dismissal of the petition for review (with or without prejudice to the exclusive

representative's refiling of the petition for review), and granting the petition for review and directing bargaining and/or rescission of an agency head disapproval under 5 U.S.C. 7114(c) (with or without conditions).

■ 16. Amend § 2424.40 by revising paragraphs (b) and (c) to read as follows:

§ 2424.40 Authority decision and order.

* * * * *

(b) *Cases involving proposals.* If the Authority finds that the duty to bargain extends to the proposal, then the Authority will order the agency to bargain concerning the proposal. If the Authority finds that the duty to bargain does not extend to the proposal, then the Authority will dismiss the petition for review. If the Authority finds that the proposal is bargainable only at the election of the agency, then the Authority will so state. If the Authority resolves a negotiability dispute by finding that a proposal is within the duty to bargain, but there are unresolved bargaining obligation dispute claims, then the Authority will order the agency to bargain in the event its bargaining obligation claims are resolved in a manner that requires bargaining.

(c) *Cases involving provisions.* If the Authority finds that a provision is not contrary to law, rule, or regulation, or is bargainable at the election of the agency, then the Authority will direct the agency to rescind its disapproval of such provision in whole or in part as appropriate. If the Authority finds that a provision is contrary to law, rule, or regulation, the Authority will dismiss the petition for review as to that provision.

■ 17. Revise § 2424.41 to read as follows:

§ 2424.41 Compliance.

The exclusive representative may report to the appropriate Regional Director an agency's failure to comply with an order issued in accordance with § 2424.40. The exclusive representative must report such failure within thirty (30) days following expiration of the 60–day period under 5 U.S.C. 7123(a), which begins on the date of issuance of the Authority order. If, on referral from the Regional Director, the Authority finds such a failure to comply with its order, the Authority will take whatever action it deems necessary to secure compliance with its order, including enforcement under 5 U.S.C. 7123(b).

■ 18. Amend § 2424.50 by revising the introductory text to read as follows:

§ 2424.50 Illustrative criteria.

A compelling need exists for an agency rule or regulation concerning any condition of employment when the rule or regulation was issued by the agency or any primary national subdivision of the agency, and the agency demonstrates that either the rule or regulation meets one or more of the following illustrative criteria, or the Authority determines that other circumstances establish a compelling need for the rule or regulation:

* * * * *

Approved: December 12, 2019.

Colleen Duffy Kiko,

Chairman, Federal Labor Relations Authority.

[FR Doc. 2019–27193 Filed 12–20–19; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

15 CFR Part 7

[Docket No. 191217–0118]

RIN 0605–AA51

Securing the Information and Communications Technology and Services Supply Chain

AGENCY: U.S. Department of Commerce.

ACTION: Proposed rule; extension of comment period.

SUMMARY: On November 27, 2019, the U.S. Department of Commerce (the Department) published a proposed rule to implement regulations pursuant to the Executive order of of May 15, 2019, entitled ''Securing the Information and Communications Technology and Services Supply Chain,'' that would govern the process and procedures that the Secretary of Commerce (Secretary) will use to identify, assess, and address certain information and communications technology and services transactions that pose an undue risk to critical infrastructure or the digital economy in the United States, or an unacceptable risk to U.S. national security or the safety of United States persons. The Department opened a public comment period through December 27, 2019. Through this document, the Department is extending the period for public comment until January 10, 2020.

DATES: The comment period for the proposed rule published on November 27, 2019 (84 FR 65316), is extended. Comments and information regarding this proposed rule must be received by close of business on January 10, 2020.

ADDRESSES: You may submit comments on the proposed rule by any of the following methods:

- *By the Federal eRulemaking Portal: http://www.regulations.gov* at docket number DOC–2019–0005.
- *By email directly to: ICTsupplychain@doc.gov.* Include ''RIN 0605–AA51'' in the subject line.
- *By mail or hand delivery to:* Henry Young, U.S. Department of Commerce, ATTN: RIN 0605–AA51, 1401 Constitution Avenue NW, Washington, DC 20230.
- *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. For those seeking to submit confidential business information (CBI), please submit such information by email or mail or hand delivery as instructed above. Each CBI submission must also contain a summary of the CBI in sufficient detail to permit a reasonable understanding of the substance of the information for public consumption. Such summary information will be posted on *regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Henry Young, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: 202–482–0224. For media inquiries: Rebecca Glover, Director, Office of Public Affairs, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4883.

SUPPLEMENTARY INFORMATION:

Background

On November 27, 2019, the Department published a proposed rule to implement regulations pursuant to Executive Order 13873, ''Securing the Information and Communications Technology and Services Supply Chain'' (84 FR 22689) that would govern the process and procedures that the Secretary of Commerce (Secretary) will use to identify, assess, and address certain information and communications technology and services transactions that pose an undue risk to critical infrastructure or the digital economy in the United States, or an unacceptable risk to U.S. national security or the safety of United States persons. The document requested comments on or before December 27, 2019. Through this document, the Department is extending the period for public comment until January 10, 2020, to give interested members of the public additional time to submit comments. All other information and instructions to commenters provided in the original document remain unchanged.

Previously submitted comments do not need to be resubmitted.

Authority: 50 U.S.C. 1701 *et seq.;* 50 U.S.C. 1601 *et seq.;* and section 301 of Title 3, United States Code.

Wilbur L. Ross,

Secretary of Commerce.

[FR Doc. 2019–27596 Filed 12–19–19; 8:45 am]

BILLING CODE 3510–20–P

COMMODITY FUTURES TRADING COMMISSION

17 CFR Part 50

RIN 3038–AE92

Exemption From the Swap Clearing Requirement for Certain Affiliated Entities—Alternative Compliance Frameworks for Anti-Evasionary Measures

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Commodity Futures Trading Commission (Commission or CFTC) is proposing revisions to the Commission regulation that exempts certain affiliated entities within a corporate group from the swap clearing requirement under the applicable provision of the Commodity Exchange Act (CEA or Act). The revisions concern the anti-evasionary condition that swaps subject to the clearing requirement entered into with unaffiliated counterparties either be cleared or be eligible for an exception to or exemption from the clearing requirement. Specifically, the revisions would make permanent certain temporary alternative compliance frameworks intended to make this anti-evasionary condition workable for international corporate groups in the absence of foreign clearing regimes determined to be comparable to U.S. requirements.

DATES: Comments must be received on or before February 21, 2020.

ADDRESSES: You may submit comments, identified by RIN 3038–AE92, by any of the following methods:

- *CFTC Comments Portal: http://comments.cftc.gov.* Select the ''Submit Comments'' link for this rulemaking and follow the instructions on the Public Comment Form.
- *Mail:* Send to Christopher Kirkpatrick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581.
- *Hand Delivery/Courier:* Follow the same instructions as for Mail, above.

Please submit your comments using only one of these methods. Submissions through the CFTC Comments Portal are encouraged.

All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to *https://comments.cftc.gov.* You should submit only information that you wish to make available publicly. If you wish the Commission to consider information that you believe is exempt from disclosure under the Freedom of Information Act (FOIA), a petition for confidential treatment of the exempt information may be submitted according to the procedures established in § 145.9 of the Commission's regulations.[1]

The Commission reserves the right, but shall have no obligation, to review, pre-screen, filter, redact, refuse or remove any or all of your submission from *https://www.cftc.gov* that it may deem to be inappropriate for publication, such as obscene language. All submissions that have been redacted or removed that contain comments on the merits of the rulemaking will be retained in the public comment file and will be considered as required under the Administrative Procedure Act and other applicable laws, and may be accessible under the FOIA.

FOR FURTHER INFORMATION CONTACT: Sarah E. Josephson, Deputy Director, Division of Clearing and Risk, at 202–418–5684 or *sjosephson@cftc.gov;* Melissa A. D'Arcy, Special Counsel, Division of Clearing and Risk, at 202–418–5086 or *mdarcy@cftc.gov;* or Stephen A. Kane, Office of the Chief Economist, at 202–418–5911 or *skane@cftc.gov,* in each case at the Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581.

SUPPLEMENTARY INFORMATION:

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I. Background

A. Overview of Existing Practice

This proposed rulemaking addresses the compliance requirements for market participants electing not to clear inter-affiliate swaps under Commission regulation 50.52. This regulation permits counterparties to elect not to clear swaps between certain affiliated entities, subject to a set of conditions.[2] These conditions include a general requirement that each eligible affiliate counterparty clear swaps executed with unaffiliated counterparties, if the swaps are covered by the Commission's clearing requirement.[3]

As adopted in 2013, the regulation also included two alternative compliance frameworks (Alternative Compliance Frameworks) that allowed counterparties to pay and collect variation margin in place of swap clearing for certain outward-facing swaps.[4] The Alternative Compliance Frameworks were adopted for a limited time period and expired on March 11, 2014.[5] Since that time, market participants have requested that Commission staff provide relief equivalent to the Alternative Compliance Frameworks through no-action letters. The Division of Clearing and Risk (DCR) first provided no-action relief in 2014. DCR issued CFTC Letter No. 14–25 in response to a request from the International Swaps and Derivatives Association (ISDA) to provide relief equivalent to the expiring Alternative Compliance Frameworks set forth in Commission regulation 50.52.[6] DCR subsequently extended the no-action relief provided under CFTC Letter No. 14–25 and later expanded the relief in a series of five additional no-action letters.[7]

[1] 17 CFR 145.9. Commission regulations referred to herein are found at 17 CFR chapter I.

[2] Clearing Exemption for Swaps Between Certain Affiliated Entities, 78 FR 21750 (Apr. 11, 2013).

[3] Commission regulation 50.52(b)(4)(i).

[4] Commission regulation 50.52(b)(4)(ii) through (iii) (discussed in the **Federal Register** release adopting Commission regulation 50.52, the Clearing Exemption for Swaps Between Certain Affiliated Entities, 78 FR 21750, 21763–21766 (Apr. 11, 2013)).

[5] 78 FR 21763—21765.

[6] CFTC Letter No. 14–25 (Mar. 6, 2014).

[7] CFTC Letter Nos. 14–135 (Nov. 7, 2014), 15–63 (Nov. 17, 2015), 16–81 (Nov. 28, 2016), 16–84 (Dec. 15, 2016), and 17–66 (Dec. 14, 2017), all available at *https://www.cftc.gov/LawRegulation/CFTCStaffLetters/index.htm.* CFTC Letter No. 17–66 expanded relief to parties transacting in Australia, Canada, Hong Kong, Mexico, or Switzerland and extended the relief to the earlier of (i) December 31, 2020 at 11:59 p.m. (Eastern Time); or (ii) the

In response to a 2017 request for information[8] seeking suggestions from the public for simplifying the Commission's regulations and practices, removing unnecessary burdens, and reducing costs, commenters asked the Commission to codify the Alternative Compliance Frameworks.[9] Among the comment letters received by the Commission were six comments discussing the Commission's inter-affiliate exemption, and four of those commenters specifically requested that the Commission extend the availability of, or codify, CFTC Letter No. 16–81.

The Commission preliminarily believes that adopting rules to permit affiliated entities to comply with revised Alternative Compliance Frameworks on a permanent basis (in line with the relief granted in CFTC Letter No. 17–66 and prior letters) will provide legal certainty to swap market participants and increase the flexibility offered to counterparties electing not to clear inter-affiliate swaps, while keeping compliance costs and burdens on market participants low. As a result, the Commission is proposing to adopt regulatory revisions to (i) reinstate the Alternative Compliance Frameworks as a permanent option for certain swaps between affiliated entities in line with the existing no-action relief under CFTC Letter No. 17–66, and (ii) make other minor changes to Commission regulation 50.52. In this proposal, the Commission is not considering any changes with regard to the trade execution requirement because those are the subject of another ongoing rulemaking.[10]

B. Swap Clearing Requirement

Under section 2(h)(1)(A) of the CEA, if the Commission requires a swap to be cleared, then it is unlawful to enter into that swap unless the swap is submitted for clearing to a derivatives clearing organization (DCO) that is registered under the CEA or a DCO that the Commission has exempted from registration under section 5b(h) of the CEA. In 2012, the Commission issued its first clearing requirement determination, pertaining to four classes of interest rate swaps and two classes of credit default swaps.[11] In 2016, the Commission expanded the classes of interest rate swaps subject to the clearing requirement to cover fixed-to-floating interest rate swaps denominated in nine additional currencies, as well as certain additional basis swaps, forward rate agreements, and overnight index swaps.[12] The regulations implementing the clearing requirement are in subpart A to part 50 of the Commission's regulations. Subpart C to part 50 provides for an exception to, as well as two exemptions from, the clearing requirement.

C. Commission Regulation 50.52

One of the exemptions from the clearing requirement, in Commission regulation 50.52, provides an exemption for swaps between certain affiliated entities, subject to specific requirements and conditions (Inter-Affiliate Exemption).[13] Two affiliated entities are eligible to elect the Inter-Affiliate Exemption for a swap if each of the counterparties meets the definition of ''eligible affiliate counterparty'' set forth in Commission regulation 50.52(a). The terms of the exempted swap must comply with a documentation requirement and be subject to a centralized risk management program.[14] The election of the Inter-Affiliate Exemption, as well as how the requirements of the exemption are met, must be reported to a Commission-registered swap data repository (SDR).[15] Finally, as discussed above, the Inter-Affiliate Exemption generally requires each eligible affiliate counterparty to clear swaps executed with unaffiliated counterparties (*i.e.,* outward-facing swaps), if the swaps are covered by the Commission's clearing requirement and do not otherwise qualify for an exception to or exemption from the clearing requirement.[16]

The Commission continues to believe that it is necessary to impose risk-mitigating conditions on inter-affiliate swaps. As the Commission stated in the **Federal Register** adopting release issuing the Inter-Affiliate Exemption, entities that are affiliated with each other are separate legal entities notwithstanding their affiliation.[17] As separate legal entities, affiliates generally are not legally responsible for each other's contractual obligations. This legal reality becomes readily apparent when one or more affiliate(s) become insolvent.[18] Affiliates, as separate legal entities, are managed in bankruptcy as separate estates and the trustee for each debtor estate has a duty to the creditors of the affiliate, not the corporate family, the parent of the affiliates, or the corporate family's creditors.[19]

effective date of amendments to Commission regulation 50.52.

[8] *See* 82 FR 21494 (May 6, 2017) and 82 FR 23765 (May 24, 2017).

[9] *See* the Financial Services Roundtable's comments dated Sept. 30, 2017, available at *https://comments.cftc.gov/PublicComments/ViewComment.aspx?id=61430* (requesting that the Commission exempt inter-affiliate swaps transactions from the scope of all swaps regulations or, as an alternative, codify the no-action relief provided under CFTC Letter No. 16–81). *See* the Institute of International Bankers' comments dated September 29, 2017, available at: *https://comments.cftc.gov/PublicComments/ViewComment.aspx?id=61384* (requesting that the Commission codify the no-action relief granted under CFTC Letter Nos. 16–81 and 16–84, as well as provide that market participants can presume that the five percent test (discussed in more detail below) does not apply to swaps with affiliates located in jurisdictions that have adopted a clearing requirement). *See* the Securities Industry and Financial Markets Association's comments dated September 29, 2017, available at *https://comments.cftc.gov/PublicComments/ViewComment.aspx?id=61360* (requesting that the Commission eliminate the outward-facing swap condition to the inter-affiliate exemption or, as an alternative, codify the no-action relief granted under CFTC Letter No. 16–81, and eliminate the five percent test). *See* the International Swaps and Derivatives Association, Inc.'s comments dated September 29, 2017, available at *https://comments.cftc.gov/PublicComments/ViewComment.aspx?id=61352* (requesting that the Commission grant relief that is not time-limited that is similar to the no-action relief provided under CFTC Letter Nos. 16–81 and 16–84). *See also* the Commodity Markets Council's comments dated September 29, 2017, available at *https://comments.cftc.gov/PublicComments/ViewComment.aspx?id=61348* (requesting that the Commission establish a permanent exemption for all inter-affiliate swaps from the clearing requirement). *See also* Credit Suisse Holdings USA's comments dated September 29, 2017, available at *https://comments.cftc.gov/PublicComments/ViewComment.aspx?id=61424* (requesting that the Commission exempt all inter-affiliate swaps from the clearing requirement, so long as the transactions are: Reported to a swap data repository; centrally risk-managed; and subject to the exchange of variation margin).

[10] The Commission previously proposed an exemption from the trade execution requirement under section 2(h)(8) of the CEA for swap transactions to which the exceptions or exemptions to the clearing requirement that are specified under part 50 apply. The Commission continues to evaluate this proposal as part of its larger evaluation of the regulatory framework for swap execution facilities. *See* Swap Execution Facilities and Trade Execution Requirement, 83 FR 61946 (Nov. 30, 2018).

[11] Clearing Requirement Determination Under Section 2(h) of the CEA, 77 FR 74284 (Dec. 13, 2012).

[12] Clearing Requirement Determination Under Section 2(h) of the CEA for Interest Rate Swaps, 81 FR 71202 (Oct. 14, 2016).

[13] Clearing Exemption for Swaps Between Certain Affiliated Entities, 78 FR 21750 (Apr. 11, 2013).

[14] Commission regulation 50.52(b)(2) through (3).

[15] Commission regulation 50.52(c) through (d).

[16] Commission regulation 50.52(b)(4)(i) (the ''Outward-Facing Swaps Condition'').

[17] Clearing Exemption for Swaps Between Certain Affiliated Entities, 78 FR 21752–21753.

[18] Note, for example, that while Rule 1015 of the Federal Rules of Bankruptcy Procedure (FRBP) permits a court to consolidate bankruptcy cases between a debtor and affiliates, FRBP Rule 2009 provides that, among other things, if the court orders a joint administration of two or more estates under FRBP Rule 1015, the trustee shall keep separate accounts of the property and distribution of each estate. *See* Federal Rules of Bankruptcy Procedure (2011).

[19] *See In re L & S Indus., Inc.,* 122 B.R. 987, 993–994 (Bankr. N.D. Ill. 1991), *aff'd* 133 B.R. 119, *aff'd* 989 F.2d 929 (7th Cir. 1993) (''A trustee in

Continued

D. Outward-Facing Swaps Condition

The Outward-Facing Swaps Condition requires that an eligible affiliate counterparty relying on the Inter-Affiliate Exemption clear any swap covered by the Commission's clearing requirement (*i.e.,* an interest rate or credit default swap identified in Commission regulation 50.4) that is entered into with an unaffiliated counterparty, unless the swap qualifies for an exception or exemption from the clearing requirement under part 50.[20] This provision applies to any eligible affiliate counterparty electing the Inter-Affiliate Exemption, including an eligible affiliate counterparty located outside of the United States.

The Outward-Facing Swaps Condition is intended to prevent swap market participants from using the Inter-Affiliate Exemption to evade the clearing requirement or to transfer risk to U.S. firms by entering into uncleared swaps with non-U.S. affiliates in jurisdictions that do not have mandatory clearing regimes comparable to the Commission's clearing requirement regime.[21] Such evasion could be accomplished if the non-U.S. affiliate enters into a swap with an unaffiliated party also located outside of the U.S. and that swap is related on a back-to-back or matched book basis with the swap executed with the affiliated party located in the U.S.[22] In the adopting release to the Inter-Affiliate Exemption, the Commission noted that section 2(h)(4)(A) of the CEA requires the Commission to prescribe rules to prevent evasion of the clearing requirement.[23]

E. Alternative Compliance Frameworks

1. Background

When the Commission adopted the Inter-Affiliate Exemption, it provided two Alternative Compliance Frameworks with which eligible affiliate counterparties located outside of the United States could comply, until March 11, 2014, instead of complying with the Outward-Facing Swaps Condition.[24] These Alternative Compliance Frameworks were not in the original rule proposal, but the Commission added them to the final rule in order to address concerns raised by commenters about the need to align the Commission's Inter-Affiliate Exemption with clearing regimes in other jurisdictions.[25] In the proposal, the Commission did not identify specific jurisdictions for specially-tailored outward-facing swaps requirements.[26] Rather, the Commission proposed a set of conditions that would have required non-U.S. affiliate counterparties to clear almost all outward-facing swaps.[27] Recognizing the concerns expressed by commenters,[28] the Commission adopted a final rule that gave non-U.S. affiliates more flexibility in complying with the outward-facing swap requirements. At the time the Commission adopted its final rule, the Commission expected other jurisdictions to adopt their own clearing requirements soon thereafter and determined that an alternative compliance framework was needed for only twelve months after required clearing began in the United States.[29] The Outward-Facing Swaps Condition under Commission regulation 50.52 was an attempt to balance flexibility for non-U.S. affiliates with the need to protect against evasion of the Commission's clearing requirement.

Under existing Commission regulation 50.52(b)(4)(ii)(A), which expired on March 11, 2014, if one of the eligible affiliate counterparties to a swap is located in the European Union, Japan, or Singapore, either of the following satisfies the Outward-Facing Swaps Condition:

(1) Each eligible affiliate counterparty, or a third party that directly or indirectly holds a majority interest in both eligible affiliate counterparties, pays and collects full variation margin daily on all swaps entered into between the eligible affiliate counterparty located in the European Union, Japan, or Singapore and an unaffiliated counterparty; or

(2) Each eligible affiliate counterparty, or a third party that directly or indirectly holds a majority interest in both eligible affiliate counterparties, pays and collects full variation margin daily on all of the eligible affiliate counterparties' swaps with other eligible affiliate counterparties.[30]

Under existing Commission regulation 50.52(b)(4)(ii)(B), which expired on March 11, 2014, an eligible affiliate counterparty located in the European Union, Japan, or Singapore is not required to comply with either the Outward-Facing Swaps Condition or the variation margin provisions of Commission regulation 50.52(b)(4)(ii)(A), provided that the one counterparty that directly or indirectly holds a majority ownership interest in the other counterparty or the third party

bankruptcy represents the interests of the debtor's estate and its creditors, not interests of the debtor's principals, other than their interests as creditors of estate.''); *In re New Concept Housing, Inc.,* 951 F.2d 932, 938 (8th Cir. 1991) (quoting *In re L & S Indus., Inc.*). While the concept of ''substantive consolidation'' of affiliates in a business enterprise when they all enter into bankruptcy is sometimes used by a bankruptcy court, substantive consolidation is generally considered an extraordinary remedy to be used in limited circumstances. *See Substantive Consolidation—A Post-Modern Trend,* 14 Am. Bankr. Inst. L. Rev. 527 (Winter 2006).

[20] Commission regulation 50.52(b)(4)(i). The Outward-Facing Swaps condition also permits an eligible affiliate counterparty to clear a swap pursuant to a non-U.S. clearing requirement that the Commission has determined to be ''comparable, and comprehensive but not necessarily identical, to the clearing requirement of section 2(h) of the [CEA]'' and to part 50, or to comply with an exception to or an exemption from a non-U.S. clearing requirement that the Commission has determined to be comparable to an exception or exemption under section 2(h)(7) of the CEA and part 50. The Commission has made no such comparability determination.

[21] Clearing Exemption for Swaps Between Certain Affiliated Entities, 78 FR 21760–21762.

[22] *Id.* at 21760.

[23] Clearing Exemption for Swaps Between Certain Affiliated Entities, 78 FR 21761. The Commission also notes that Commission regulation 1.6 makes it unlawful to conduct activities outside the United States, including entering into agreements, contracts, and transactions and structuring entities, to willfully evade or attempt to evade any provision of Title VII of the Dodd-Frank Wall Street Reform and Consumer Protection Act, including the swap clearing requirement under section 2(h)(1) of the CEA. Any such evasionary conduct will be subject to the relevant provisions of Title VII. In determining whether a transaction or entity structure is designed to evade, the Commission considers the extent to which there is a legitimate business purpose for such structure. 77 FR 48208, 48301 (Aug. 13, 2012).

[24] Commission regulation 50.52(b)(4)(ii) through (iii) (discussed in the **Federal Register** release adopting Commission regulation 50.52, the Clearing Exemption for Swaps Between Certain Affiliated Entities, 78 FR 21763–21766).

[25] *See* Clearing Exemption for Swaps Between Certain Affiliated Entities, 78 FR 21764.

[26] *See* Clearing Exemption for Swaps Between Certain Affiliated Entities, 77 FR 50423 (Aug. 21, 2012) (proposing regulation 39.6(g)(2)(v)) hereinafter, the ''Affiliated Entities Proposal'').

[27] The Commission's proposed inter-affiliate exemption would have required all inter-affiliate swaps with non-U.S. persons to satisfy one of three conditions: (i) The non-U.S. person affiliate is domiciled in a jurisdiction with a comparable and comprehensive regulatory regime for swap clearing, (ii) the non-U.S. person affiliate is otherwise required to clear swaps with third parties in compliance with U.S. law, or (iii) the non-U.S. person does not enter into swaps with third parties. *See* Affiliated Entities Proposal, 77 FR 50431 (discussing proposed regulation 39.6(g)(2)(v)).

[28] ''Notwithstanding the progress of other jurisdictions to implement their clearing regimes, as discussed above, the Commission is mindful of commenters' concerns that the compliance timeframe for the clearing requirement in the U.S. is likely to precede the adoption and/or implementation of the clearing regimes of most other jurisdictions.'' Clearing Exemption for Swaps Between Certain Affiliated Entities, 78 FR 21764.

[29] ''The Commission believes that a transition period of 12 months after required clearing began in the U.S. is appropriate given its understanding of the progress being made on mandatory clearing in the specified foreign jurisdictions.'' Clearing Exemption for Swaps Between Certain Affiliated Entities, 78 FR at 21764.

[30] Commission regulation 50.52(b)(4)(ii)(A).

that directly or indirectly holds a majority ownership interest in both counterparties is not a ''financial entity'' under section 2(h)(7)(C)(i) of the CEA and neither eligible affiliate counterparty is affiliated with an entity that is a swap dealer or major swap participant, as defined in Commission regulation 1.3.

In both of these provisions, the Commission determined that eligible affiliate counterparties located in the European Union, Japan, or Singapore were entitled to special flexibility because it had reason to believe that those jurisdictions would be moving forward with their own clearing requirements quickly.[31] Japan implemented a clearing regime and adopted a clearing requirement for certain products that was effective as of November 1, 2012, before the final Inter-Affiliate Exemption rule was published.[32] The European Union's over-the-counter derivatives reform legislation, including a requirement to adopt a clearing obligation, entered into force on August 16, 2012.[33] Later that year, on December 19, 2012, the European Commission adopted regulatory technical standards relating to the clearing obligation.[34] However, the European Securities and Markets Authority's first clearing obligation did not become effective until June 21, 2016. Finally, although Singapore was expected to make steady progress on its clearing requirement, it experienced some delays. The Singapore Parliament passed legislation adopting an over-the-counter derivatives regulatory regime in 2012,[35] and the clearing mandate for certain interest rate swaps became effective on October 1, 2018.[36]

Today, the Commission recognizes that some non-U.S. jurisdictions are still in the process of adopting their domestic clearing regimes, some non-U.S. jurisdictions may never implement clearing for swaps, and a number of non-U.S. regimes vary significantly in terms of product and participant scope from the Commission's clearing requirement. Given this reality, and the fact that relief equivalent to the Alternative Compliance Frameworks has been provided through a series of CFTC staff letters for over six years, the Commission is proposing amendments that would codify the relief provided in the CFTC staff letters, make the Alternative Compliance Frameworks a permanent option for certain swaps between affiliated entities, and make other minor changes to Commission regulation 50.52.

2. CFTC Staff Letters Providing Relief Equivalent to the Alternative Compliance Frameworks

CFTC staff examined and evaluated the swap market's continued reliance on the Alternative Compliance Frameworks each year following the Inter-Affiliate Exemption's adoption.[37] In March 2014, CFTC staff noted that the clearing mandates in the European Union and Singapore were not yet effective, and there was no comparability determination for Japan. CFTC staff issued CFTC Letter No. 14–25 providing relief equivalent to the Alternative Compliance Frameworks to December 31, 2014.[38] Later that year, CFTC staff extended the relief again until December 31, 2015.[39] CFTC staff continued to extend the availability of relief equivalent to the Alternative Compliance Frameworks annually and ultimately issued relief through December 31, 2020.[40]

It also was thought that the Alternative Compliance Frameworks would be needed only until the Commission issued comparability determinations with respect to the Commission's clearing requirement for non-U.S. jurisdictions. However, to date, the CFTC has not issued any comparability determinations.[41] Without a comparability determination, eligible affiliated entities could not elect to comply with their domestic clearing regime instead of the CFTC's requirements for the Outward-Facing Swaps Condition as provided for under Commission regulations 50.52(b)(4)(i)(B) and (D). As a result of this and other difficulties, market participants have continued to seek relief from CFTC staff relating to both of the Alternative Compliance Frameworks.[42]

Aside from providing relief equivalent to the Alternative Compliance Frameworks, CFTC staff also issued relief to market participants that are transacting in swaps subject to the Commission's clearing requirement with eligible affiliates in jurisdictions other than the three identified under regulation 50.52 (the European Union, Japan, and Singapore). As explained above, in issuing Commission regulation 50.52(b)(4)(ii), the Commission limited the provision to swaps with counterparties located in those three jurisdictions because, at that time, they had established legal authority to adopt, and were in the process of implementing, clearing regimes.[43] Once additional jurisdictions started to adopt clearing mandates, the Commission monitored their progress and adopted

[31] The European Union, Japan, and Singapore were included in Commission regulation 50.52(b)(4)(ii) because they were seen as having taken ''significant steps towards further implementation'' of a clearing regime. Clearing Exemption for Swaps Between Certain Affiliated Entities, 78 FR 21763.

[32] Clearing Exemption for Swaps Between Certain Affiliated Entities, 78 FR 21763–21764.

[33] Regulation (EU) No 648/2012 of the European Parliament and of the Council of 4 July 2012 on OTC derivatives, central counterparties and trade repositories.

[34] Commission Delegated Regulation (EU) No 149/2013 of 19 December 2012 supplementing Regulation (EU) No 648/2012 with regard to regulatory technical standards on indirect clearing arrangements, the clearing obligation, the public register, access to a trading venue, non-financial counterparties, and risk mitigation techniques for OTC derivatives contracts not cleared by a central counterparty.

[35] Clearing Exemption for Swaps Between Certain Affiliated Entities, 78 FR 21763.

[36] *See* the Securities and Futures (Clearing of Derivatives Contracts) Regulations 2018, May 2, 2018, *available at https://sso.agc.gov.sg/SL-Supp/S264-2018. See also* the Monetary Authority of Singapore's press release, May 2, 2018, *available at http://www.mas.gov.sg/News-and-Publications/Media-Releases/2018/MAS-Requires-OTC-Derivatives-to-be-Centrally-Cleared-to-Mitigate-Systemic-Risk.aspx.*

[37] *See* CFTC Letter Nos. 14–25 (Mar. 6, 2014), 14–135 (Nov. 7, 2014), 15–63 (Nov. 17, 2015), 16–81 (Nov. 28, 2016), 16–84 (Dec. 15, 2016), and 17–66 (Dec. 14, 2017).

[38] CFTC Letter No. 14–25 (Mar. 6, 2014). The letter noted that ''extending the alternative compliance frameworks until December 31, 2014 may promote the adoption of comparable and comprehensive clearing requirements. [DCR] also believes that such extensions will allow for a more orderly transition as jurisdictions establish and implement clearing requirements and the Commission issues comparability determinations with regard to those requirements.'' CFTC Letter No. 14–25 (Mar. 6, 2014), at 4.

[39] CFTC Letter No. 14–135 (Nov. 7, 2014).

[40] *See* CFTC Letter Nos. 15–63 (Nov. 17, 2015), 16–81 (Nov. 28, 2016), and 17–66 (Dec. 14, 2017). Pursuant to CFTC Letter No. 17–66, DCR will not recommend that the Commission commence an enforcement action against an entity that uses Commission regulation 50.52(b)(4)(ii) or (iii) to meet the requirements of the Outward-Facing Swaps Condition until the earlier of (i) 11:59 p.m. (Eastern Time), December 31, 2020, or (ii) the effective date of amendments to Commission regulation 50.52.

[41] The CFTC continues to monitor and communicate with regulators in other jurisdictions as they consider and adopt clearing regimes. *See* discussion of non-U.S. jurisdictions' clearing regimes in the Commission's 2016 final rule adopting the expanded interest rate swap clearing requirement. Clearing Requirement Determination Under Section 2(h) of the CEA for Interest Rate Swaps, 81 FR 71202, 71203–71205 (Oct. 14, 2016). However, each jurisdiction's clearing mandate is unique and tailored to its derivatives markets and its market participants. For example, in many non-U.S. jurisdictions, the scope of entities subject to a clearing mandate and the swaps covered by a clearing mandate varies significantly from the Commission's clearing requirement.

[42] Letter from the International Swaps and Derivatives Association, Inc. (ISDA) to the Commission ''Request for Commission Action—Part 50,'' dated Nov. 14, 2017 (2017 ISDA Letter), (requesting that the Commission make permanent the relief provided in CFTC Letter Nos. 16–81 and 16–84, among other things).

[43] Clearing Exemption for Swaps Between Certain Affiliated Entities, 78 FR 21764.

an expanded clearing requirement covering additional interest rate swaps that had been, or were expected to be, required to be cleared in other jurisdictions.[44] In the Commission's 2016 clearing requirement determination, the Commission expanded the clearing requirement to cover certain fixed-to-floating interest rate swaps denominated in the Australian dollar, Canadian dollar, Hong Kong dollar, Mexican peso, Norwegian krone, Polish zloty, Singapore dollar, Swedish krona, and Swiss franc, as well as specified other interest rate swaps.[45]

Approximately one month after the Commission adopted the expanded interest rate swap clearing requirement, market participants requested that the Commission broaden the list of jurisdictions included in the Alternative Compliance Framework under Commission regulation 50.52(b)(4)(ii).[46] In response to ISDA's request, DCR issued CFTC Letter No. 16–84 to provide relief to eligible affiliate counterparties located in Australia and Mexico on the condition that they comply with the Inter-Affiliate Exemption using the Alternative Compliance Frameworks described in Commission regulation 50.52(b)(4)(ii).[47] DCR granted the relief with respect to only Australia and Mexico because the Commission's clearing requirement followed a phase-in compliance schedule and products denominated in Australian dollars and Mexican pesos were the first to be subject to the Commission's expanded clearing requirement.[48]

More recently, ISDA requested that the Commission codify the relief provided under CFTC Letter Nos. 16–81 and 16–84, because market participants continue to rely on the relief equivalent to Alternative Compliance Frameworks under Commission regulation 50.52(b)(4)(ii) and (iii).[49] In addition, ISDA requested that the Commission make the Alternative Compliance Frameworks available in five additional jurisdictions (for a total of eight) instead of limiting relief to the three jurisdictions included in Commission regulation 50.52.[50] The 2017 ISDA Letter requested that both of the Alternative Compliance Frameworks cover the home jurisdictions of the currencies included in the Commission's 2016 expanded clearing requirement determination (Australia, Canada, Hong Kong, Mexico, and Switzerland) because market participants would be increasing their swaps activity in those jurisdictions. For example, U.S. market participants and their affiliated entities would be expected to increase the number and percentage of their swaps in Mexico once the Commission adopted a clearing requirement for the Mexican peso, and a greater percentage of such affiliate's swaps subject to the clearing requirement would be conducted in Mexico as well. As non-U.S. currencies were added to the Commission's clearing requirement, market participants were expected to conduct more inter-affiliate swaps in those currencies and, most importantly, with affiliates located in the home jurisdiction of those currencies.[51]

In CFTC Letter No. 17–66, DCR extended further the availability of relief equivalent to Commission regulation 50.52(b)(4)(ii) to include eligible affiliate counterparties located in Australia, Canada, Hong Kong, Mexico, and Switzerland, so that those counterparties could use the relief equivalent to the Alternative Compliance Framework under Commission regulation 50.52(b)(4)(ii) as well.[52] Once counterparties were permitted to rely on the Alternative Compliance Framework in Commission regulation 50.52(b)(4)(ii), they could use that Alternative Compliance Framework to satisfy the Outward-Facing Swaps Condition, instead of trying to stay within the limits of the five percent test under Commission regulation 50.52(b)(4)(iii).[53] CFTC Letter No. 17–66 permits eligible affiliates in any of the eight jurisdictions to comply with the Outward-Facing Swaps Condition using relief equivalent to Commission regulation 50.52(b)(4)(ii) until the letter expires on December 31, 2020.

3. Five Percent Limitation for Affiliated Counterparties in Certain Jurisdictions

Under existing Commission regulation 50.52(b)(4)(iii), which expired on March 11, 2014, an eligible affiliate counterparty located in the U.S. could comply with certain variation margin provisions in lieu of clearing, with respect to a swap executed opposite an eligible affiliate counterparty located in a non-U.S. jurisdiction other than the European Union, Japan, or Singapore, so long as a five percent test was met. According to this test, the aggregate notional value of swaps included in a class of swaps identified by Commission regulation 50.4 (classes of swaps covered by the Commission's clearing requirement) executed between an eligible affiliate counterparty located in the U.S. and an eligible affiliate counterparty located in a non-U.S. jurisdiction other than the European Union, Japan, or Singapore may not exceed five percent of the aggregate notional value of all swaps included in a class of swaps identified by Commission regulation 50.4 that are executed by the U.S. eligible affiliate counterparty. If the five percent threshold was exceeded, the Alternative Compliance Framework was unavailable, under existing Commission regulation 50.52(b)(4)(iii), in connection with swaps with eligible affiliate counterparties located in a non-U.S. jurisdiction other than the European Union, Japan, or Singapore.

Eligible affiliates in the jurisdictions discussed above have been granted relief through CFTC staff letters with respect to the Alternative Compliance Framework under Commission regulation 50.52(b)(4)(ii), but CFTC staff has not issued no-action relief to remove those jurisdictions from the category of ''other jurisdictions'' contemplated by Commission regulation 50.52(b)(4)(iii). In light of the Commission's intent to clarify the application of its rules while maintaining protections against evasion of the clearing requirement, the Commission is proposing to exclude a number of non-U.S. jurisdictions from

[44] Clearing Requirement Determination under Section 2(h) of the CEA for Interest Rate Swaps, 81 FR 71202 (Oct. 14, 2016).

[45] *Id.*

[46] Letter from ISDA to the Commission dated Nov. 16, 2016, (requesting that certain provisions of the inter-affiliate exemption be available for swaps executed between U.S. swap market participants and their affiliated counterparties located in Australia, Canada, Hong Kong, Mexico, Singapore, and Switzerland).

[47] CFTC Letter No. 16–84 (Dec. 15, 2016). Regulators in Australia and Mexico adopted clearing requirements that became effective in their home countries in April 2016.

[48] CFTC Letter No. 16–84 (Dec. 15, 2016). The first compliance date, December 13, 2016, applied to Australian dollar-denominated fixed-to-floating interest rate swap and basis swaps, as well as Mexican peso-denominated fixed-to-floating interest rate swaps.

[49] 2017 ISDA Letter.

[50] *Id.*

[51] *See also* CFTC Letter No. 16–84 (Dec. 15, 2016), at 4 (discussing the effect of the Commission's 2016 expanded interest rate swap clearing determination on entities relying on relief equivalent to the Alternative Compliance Framework under Commission regulation 50.52(b)(4)(iii)).

[52] CFTC Letter No. 17–66 (Dec. 14, 2017). All of the Commission's 2016 expanded interest rate swap clearing requirements have now become effective. The last compliance date for Singapore dollar-denominated fixed-to-floating interest rate swaps and Swiss franc-denominated fixed-to-floating interest rate swaps was on October 15, 2018.

[53] The Commission notes that at this point in time all jurisdictions that are being considered for inclusion in the text of regulation 50.52(b)(4)(ii) have established domestic clearing requirement regimes. Non-U.S. clearing requirements are in force for all of the eight jurisdictions included in proposed amendments to regulation 50.52(b)(4)(ii).

the category of ''other'' by listing them in the text of proposed regulation 50.52(b)(4)(iii), as discussed below.

II. Proposed Amended Regulation 50.52

The Commission proposes to revise the provisions of the expired Alternative Compliance Frameworks under Commission regulation 50.52(b)(4)(ii) through (iii). The proposed revisions would reinstate modified Alternative Compliance Frameworks in a manner substantially similar to the previously adopted provisions. The proposed frameworks will streamline the provision and simplify the manner by which market participants comply with the Outward-Facing Swaps Condition. The proposed regulations are designed to be consistent with the staff no-action relief that has been available since 2014.

The Commission believes that the revised regulations also would continue to prevent swap market participants from using inter-affiliate swaps to evade the clearing requirement or to transfer risk back to U.S. firms by entering into uncleared swaps in non-U.S. jurisdictions. In this proposal, the Commission maintains the Outward-Facing Swaps Condition and is suggesting small revisions to the Alternative Compliance Frameworks.

The Commission is not seeking to weaken the protections against evasion of the clearing requirement. For example, as proposed, there would be no change to the requirement that any swaps that are exempted from the clearing requirement under the Inter-Affiliate Exemption must be subject to a centralized risk management program.[54] All swaps exempted from the clearing requirement pursuant to the Inter-Affiliate Exemption will continue to be subject to the reporting requirements outlined in Commission regulation 50.52(c) through (d) and part 45 of the Commission's regulations. The Commission relies on these reporting requirements to monitor the number of entities electing the Inter-Affiliate Exemption, as well as the number of inter-affiliate swaps for which the exemption is claimed. Data on the election of the Inter-Affiliate Exemption is discussed in more detail below [55] and is presented as support for the Commission's view that this proposal to reinstate the Alternative Compliance Frameworks will not increase opportunities for affiliated entities to evade the clearing requirement.

A. Proposed Revised Alternative Compliance Frameworks

1. Variation Margin for Swaps With Affiliated Counterparties—In General

This proposal to revise the Alternative Compliance Frameworks would permit all non-U.S. eligible affiliate counterparties to comply with one of the Alternative Compliance Frameworks by paying and collecting full variation margin daily on all swaps with other eligible affiliate counterparties. The relevant provisions are in proposed revised regulation 50.52(b)(4). Paragraph (ii) of this proposed section applies if at least one of the eligible affiliate counterparties is located in Australia, Canada, the European Union, Hong Kong, Japan, Mexico, Singapore, Switzerland, or the United Kingdom, while paragraph (iii) of this proposed section addresses swaps entered into by eligible affiliate counterparties in the remaining jurisdictions.

The Commission preliminarily believes that the variation margin requirement included in both of the revised Alternative Compliance Frameworks, under proposed revised regulation 50.52(b)(4)(ii) and (iii), will mitigate the impact of any potential evasion of the Commission's clearing requirement. Although paying and collecting variation margin daily does not mitigate counterparty credit risk to the same extent that central clearing does, the Commission believes, as stated in the 2013 adopting release for the Inter-Affiliate Exemption, that variation margin is an essential risk management tool.[56] Variation margin requirements may prevent risk-taking that exceeds a party's financial capacity and acts as a limitation on the accumulation of losses when there is a counterparty default or failure to make payments. The process of paying and collecting variation margin accomplishes this by requiring swap counterparties to mark open positions to their current market value each day and to transfer funds between them to reflect any change in value since the previous time the positions were marked to market. This process prevents uncollateralized exposures from accumulating over time, which prevents the accumulation of additional counterparty credit risk on a position, and thereby reduces the size of exposure at default should one occur.

Accordingly, the Commission proposes to reinstate and revise the provision permitting all non-U.S. counterparties to pay and collect full variation margin daily on all of the eligible affiliate counterparties' swaps with other eligible affiliate counterparties.

Request for Comment. The Commission requests comment on the provisions for the collection of variation margin on swaps with affiliated counterparties. The proposed alternative compliance frameworks may produce a permanent residual class of swaps that are not cleared but instead result in the exchange of variation margin between eligible affiliate counterparties. Are there any additional risks to the counterparties or the market that have not been considered in this proposal, or any systemic risk implications for the United States, from the existence of such a class of swaps? If so, please describe such risks.

Are there other alternatives to the provisions for the collection of variation margin that the Commission should consider?

2. Variation Margin for Swaps With Affiliated Counterparties Under Commission Regulation 50.52(b)(4)(ii)

Commission regulation 50.52(b)(4)(ii), as reinstated and revised, would permit each eligible affiliate counterparty, or a third party that directly or indirectly holds a majority interest in both eligible affiliate counterparties, to pay and collect full variation margin daily on all of the eligible affiliate counterparties' swaps with other eligible affiliate counterparties, if at least one of the eligible affiliate counterparties is located in Australia, Canada, the European Union, Hong Kong, Japan, Mexico, Singapore, Switzerland, or the United Kingdom.[57] This approach is similar to current Commission regulation 50.52(b)(4)(ii)(A)(*2*), but with an expanded list of jurisdictions.

However, the Commission is not proposing to reinstate the provision to permit eligible affiliate counterparties to pay and collect variation margin on all swaps entered into between the eligible affiliate counterparty located outside of the U.S. and an unaffiliated counterparty (current Commission regulation 50.52(b)(4)(ii)(A)(*1*)). The Commission understands that eligible affiliate counterparties electing to comply with the Alternative Compliance Framework as permitted by

[54] Commission regulation 50.52(b)(3).

[55] *See* discussion regarding SDR data on the number of counterparties electing the Inter-Affiliate Exemption below.

[56] Clearing Exemption for Swaps Between Certain Affiliated Entities, 78 FR 21765 (citing the Affiliated Entities Proposal, 77 FR at 50429).

[57] The Commission is proposing to expand the list of jurisdictions under Commission regulation 50.52(b)(4)(ii) to include the United Kingdom as a separate jurisdiction from the European Union, in order to codify the no-action relief issued in preparation for the United Kingdom's withdrawal from the European Union, commonly referred to as ''Brexit.'' CFTC Letter No. 19–09 (April 5, 2019), *available at https://www.cftc.gov/csl/19-09/download.*

a staff no-action letter currently choose to pay and collect variation margin on swaps with affiliated counterparties rather than with unaffiliated counterparties. Therefore, in order to offer a simplified and streamlined Alterative Compliance Framework, the Commission proposes to reinstate only the provision upon which the Commission preliminarily believes eligible affiliate counterparties have been relying as a matter of market practice.

Request for Comment. The Commission requests comment as to whether any eligible affiliate counterparty has paid and collected variation margin on swaps with unaffiliated counterparties only under the relief equivalent to current Commission regulation 50.52(b)(4)(ii)(A)(*1*). If an eligible affiliate counterparty has complied with this provision, then the Commission requests comment as to why that provision was preferable to paying and collecting variation margin on all swaps with other eligible affiliate counterparties under the relief equivalent to current Commission regulation 50.52(b)(4)(ii)(A)(*2*). To what extent is compliance with the Outward-Facing Swaps Condition via the Alternative Compliance Frameworks consistent or inconsistent with margin requirements in non-U.S. jurisdictions?

3. Permanent Availability of the Alternative Compliance Framework Under Commission Regulation 50.52(b)(4)(ii)

Unlike Commission regulation 50.52(b)(4)(ii)(A), which expired on March 11, 2014, proposed revised regulation 50.52(b)(4)(ii) would be reinstated without an expiration date. The proposed regulation also would be expanded to include non-U.S. eligible affiliate counterparties located in Australia, Canada, Hong Kong, Mexico, Switzerland, or the United Kingdom, as well as eligible affiliate counterparties located in the European Union, Japan, or Singapore.

Market participants began relying on the Alternative Compliance Frameworks under Commission regulation 50.52(b)(4)(ii)(A) in 2013. The Commission is unaware of any compliance problems during the year-long period the regulation was in effect or under the DCR no-action letters that have provided relief equivalent to the expired Alternative Compliance Frameworks. This includes the period of time during which counterparties from the expanded list of countries have been eligible to use an Alternative Compliance Framework. Accordingly, the Commission preliminarily believes that codifying the current practice sufficiently addresses the risk transfer concerns that the Outward-Facing Swaps Condition was intended to resolve and would be responsive to the clear request from market participants for the staff no-action letters to be codified.[58]

Request for Comment. The Commission requests comment regarding the proposal to make the Alternative Compliance Frameworks a permanent option for non-U.S. eligible affiliate counterparties to comply with the Outward-Facing Swaps Condition of the Inter-Affiliate Exemption. Does codifying the current practice sufficiently address the risk transfer concerns that the Outward-Facing Swaps Condition was intended to resolve?

4. Proposing Not To Reinstate Commission Regulation 50.52(b)(4)(ii)(B)

The proposed reinstated and revised Alternative Compliance Frameworks would not include a provision similar to Commission regulation 50.52(b)(4)(ii)(B). Expired Commission regulation 50.52(b)(4)(ii)(B) permitted an eligible affiliate counterparty located in the European Union, Japan, or Singapore to elect the Inter-Affiliate Exemption without clearing an outward-facing swap or complying with the variation margin requirements currently set forth in subparagraph (b)(4)(ii)(A), provided that the majority owner of the affiliate counterparties, is not a ''financial entity'' under section 2(h)(7)(C)(i) of the CEA and neither eligible affiliate counterparty is affiliated with an entity that is a swap dealer or major swap participant, as defined in Commission regulation 1.3.

Based on a review of swap data, the Commission preliminarily believes that the Inter-Affiliate Exemption has been elected only by financial entities or entities affiliated with a swap dealer. The absence of other entity types electing the Inter-Affiliate Exemption may be due to the existence of the exception to the clearing requirement for non-financial end-users (End-User Exception under Commission regulation 50.50) and the exemption from the clearing requirement for certain cooperative entities (Cooperative Exemption under Commission regulation 50.51). Thus, in order to codify simplified Alternative Compliance Frameworks, the Commission proposes not to reinstate the provision under Commission regulation 50.52(b)(4)(ii)(B).

Request for Comment. The Commission requests comment as to whether an entity has relied on, or intends to rely on, the relief equivalent to the expired Alternative Compliance Framework in Commission regulation 50.52(b)(4)(ii)(B).

5. Proposing To Reinstate and Revise Commission Regulation 50.52(b)(4)(iii)

While proposed revised regulation 50.52(b)(4)(ii) would be available to six additional jurisdictions, the Commission recognizes that eligible affiliate counterparties may be located in other non-U.S. jurisdictions and proposes to reinstate a modified Alternative Compliance Framework under Commission regulation 50.52(b)(4)(iii) to address swaps entered into by eligible affiliate counterparties in the remaining jurisdictions that have not been identified under proposed revised regulation 50.52(b)(4)(ii).

As described above, expired Commission regulation 50.52(b)(4)(iii) permitted an eligible affiliate counterparty located in a non-U.S. jurisdiction (other than the European Union, Japan, or Singapore) to comply with variation margin requirements analogous to those available in Commission regulation 50.52(b)(4)(ii) for uncleared swaps subject to Commission regulation 50.4, provided that the U.S. counterparty's swaps with affiliates in all jurisdictions other than the European Union, Japan, and Singapore did not exceed five percent of the aggregate notional value of all of the U.S. counterparty's swaps subject to Commission regulation 50.4. The provisions of Commission regulation 50.52(b)(4)(iii) (including the ''five percent test'') are intended to apply to the ''other jurisdictions.'' Because the Commission is proposing to expand the jurisdictions eligible for the Alternative Compliance Framework under Commission regulation 50.52(b)(4)(ii), it is proposing to amend the jurisdictions identified as ''other jurisdictions'' in a corresponding manner.

The five percent test establishes a relative limit on the amount of uncleared swaps activity—activity that would otherwise be subject to the Commission's clearing requirement—that any one U.S. eligible affiliate counterparty may conduct with its affiliated counterparties in certain ''other jurisdictions.'' In other words, the U.S. affiliate cannot enter into swaps that total (in aggregate) more than five percent of all of its swaps that are

[58] As noted above, the Commission received four comment letters in 2017 requesting that the Commission extend the availability of, or codify, CFTC Letter No. 16–81.

subject to the Commission's clearing requirement, with affiliates in the ''other jurisdictions.'' The five percent test has the practical effect of limiting the relative notional amount of uncleared swaps activity that affiliates conduct in jurisdictions that are not identified in Commission regulation 50.52(b)(4)(ii). The Commission continues to believe that limiting the relative notional amount of uncleared swaps executed in jurisdictions that have not established or implemented clearing regimes, along with conditioning relief on the use of variation margin, protects the eligible affiliate counterparty located in the United States from exposure to the risks associated with material swaps exposure in jurisdictions that do not have their own domestic clearing regime. There also exists the possibility that parties may alter their swaps trading in response to the proposed expansion of the number of jurisdictions excluded from the five percent limitation. To the extent that it now applies to fewer countries, a market participant's five percent exposure may be comprised of swaps with counterparties in less sophisticated swaps markets. The Commission invites comment on the market incentives and likely outcomes of its proposal.

The five percent test was adopted by the Commission as a time-limited measure to facilitate compliance with the Outward-Facing Swaps Condition. Before the provisions of the Alternative Compliance Frameworks expired in March 2014, DCR issued no-action letters designed to lengthen the transition period and to permit entities to continue complying with the terms in Commission regulation 50.52(b)(4)(iii). The Commission recognized that there may be affiliated counterparties located outside of the United States, the European Union, Japan, or Singapore, that would be engaging in inter-affiliate swaps and would need an alternative compliance mechanism until the unlisted jurisdictions implemented a clearing regime.

Now, six years after the Commission implemented its first clearing requirement, affiliated entities still face difficulties clearing outward-facing swaps locally, particularly in jurisdictions that have not adopted domestic clearing regimes. For this reason, the Commission is proposing to reinstate the Alternative Compliance Framework included under Commission regulation 50.52(b)(4)(iii), and to redefine the jurisdictions that will be eligible. The Commission is proposing to amend regulation 50.52(b)(4)(iii) to identify jurisdictions other than Australia, Canada, the European Union, Hong Kong, Japan, Mexico, Singapore, Switzerland, the United Kingdom, or the United States as the ''other jurisdictions.'' The Commission preliminarily believes that the jurisdictions included in revised regulation 50.52(b)(4)(ii) have all established domestic clearing regimes and requirements that will help to protect against evasion of the Commission's clearing requirement. The list of jurisdictions excluded from ''other'' is the same as the list of jurisdictions eligible for the Alternative Compliance Framework under 50.52(b)(4)(ii), and then it also adds the United States.

Request for Comment. The Commission requests comment as to whether an entity has relied on, or intends to rely on, the relief equivalent to the expired Alternative Compliance Framework provided in Commission regulation 50.52(b)(4)(iii)(B). Additionally, the Commission requests comment as to whether the five percent test outlined in Commission regulation 50.52(b)(4)(iii) should be reinstated and updated as proposed, or whether the Commission should delete the expired provision and eliminate the five percent test.

6. Proposing Not To Reinstate Commission Regulation 50.52(b)(4)(iii)(A)

As the Commission has noted above, it is not aware of any eligible affiliate counterparties that have chosen to comply with the relief equivalent to the expired Alternative Compliance Frameworks using the option to pay and collect variation margin on swaps with all unaffiliated counterparties. The Commission understands that, just as eligible affiliate counterparties elect to comply with the Alternative Compliance Framework under the terms of Commission regulation 50.52(b)(4)(ii)(A)(*2*), any eligible affiliate counterparties complying with Commission regulation 50.52(b)(4)(iii) choose to pay and collect variation margin on swaps with all other eligible affiliate counterparties as contemplated by Commission regulation 50.52(b)(4)(iii)(B). Thus, in order to reinstate a simplified Alternative Compliance Framework and because the Commission preliminarily believes that the relief equivalent to Commission regulation 50.52(b)(4)(iii)(A) has not been relied upon by market participants, the Commission proposes not to reinstate the provision under Commission regulation 50.52(b)(4)(iii)(A).

Request for Comment. The Commission requests comment as to whether a market participant has relied on, or intends to rely on, the relief equivalent to the expired Alternative Compliance Framework provided in Commission regulation 50.52(b)(4)(iii)(A).

7. Additional Revisions to Commission Regulation 50.52

As part of its proposal to reinstate the Alternative Compliance Framework provisions of Commission regulation 50.52(b)(4)(iii), and to make them available to eligible affiliate counterparties located in certain non-U.S. jurisdictions, the Commission is proposing to add a definition of ''United States'' to revised regulation 50.52(a)(2) identical to the one in Commission regulation 23.160(a) (cross-border application of the uncleared margin regulations). This provision defines the United States to mean ''the United States of America, its territories and possessions, any State of the United States, and the District of Columbia.'' The new definition of United States is referenced in proposed revised regulation 50.52(b)(4)(iii).

The Commission preliminarily believes that the proposed revisions to regulation 50.52(b)(4) provide an exemption from the Commission's clearing requirement, in a manner that is demonstrated to be workable, while imposing conditions necessary to ensure that inter-affiliate swaps exempted from required clearing meet certain risk-mitigating conditions. In addition, the Commission preliminarily believes that the proposed revisions would provide more flexibility to eligible affiliate counterparties electing the Inter-Affiliate Exemption and would increase legal certainty for the reasons stated above.

Request for Comment. The Commission requests comment on the proposal to include a definition for the term ''United States'' as it is used in the revised and reinstated regulation 50.52. More broadly, the Commission requests comment as to whether the proposed modified Outward-Facing Swaps Condition and reinstated Alternative Compliance Frameworks will prevent market participants from using the Inter-Affiliate Exemption to evade the Commission's clearing requirement or transfer risk to U.S. firms by entering into uncleared swaps with non-U.S. affiliates.

B. Commission's Section 4(c) Authority

The Commission issued the Inter-Affiliate Exemption pursuant to section 4(c)(1) of the CEA, which grants the Commission the authority to exempt any transaction or class of transactions,

including swaps, from certain provisions of the CEA, including the Commission's clearing requirement, in order to ''promote responsible economic or financial innovation and fair competition.'' Section 4(c)(2) of the CEA further provides that the Commission may not grant exemptive relief unless it determines that: (1) The exemption is appropriate for the transaction and consistent with the public interest; (2) the exemption is consistent with the purposes of the CEA; (3) the transaction will be entered into solely between ''appropriate persons''; and (4) the exemption will not have a material adverse effect on the ability of the Commission or any contract market to discharge its regulatory or self-regulatory responsibilities under the CEA. In enacting section 4(c), Congress noted that the purpose of the provision is to give the Commission a means of providing certainty and stability to existing and emerging markets so that financial innovation and market development can proceed in an effective and competitive manner.[59]

The Commission preliminarily believes that the exemption, as modified in this proposal, is consistent with the public interest and with the purposes of the CEA. As the Commission noted in the adopting release to the Inter-Affiliate Exemption, inter-affiliate swaps provide an important risk management role within corporate groups.[60] These swaps may be beneficial to the entity as a whole. The proposed revisions to the Outward-Facing Swaps Condition and the Alternative Compliance Frameworks would facilitate use of the Inter-Affiliate Exemption by permitting the variation margin provisions under proposed Commission regulation 50.52(b)(4)(ii) and (iii) to be used in connection with swaps with eligible affiliate counterparties located in any non-U.S. jurisdiction, not only those located in the European Union, Japan, or Singapore. Pursuant to no-action relief issued by DCR, as discussed above, these provisions have been in use since 2013.

Based on the Commission's review of data reported to the Depository Trust & Clearing Corporation's (DTCC's) swap data repository, DTCC Data Repository (U.S.) LLC (DDR), the Alternative Compliance Framework provisions under Commission regulation 50.52(b)(4)(ii) appear to be working because the Commission has identified approximately 50 entities located in Australia, Canada, the European Union, Hong Kong, Japan, Mexico, Singapore, Switzerland, or the United Kingdom that elected the Inter-Affiliate Exemption between January 1, 2018 to December 31, 2018.[61] The Commission preliminarily believes that these entities chose to, or could have, complied with the Alternative Compliance Framework under Commission regulation 50.52(b)(4)(ii) because of the jurisdiction in which they are organized. Based on the same data set from January 1, 2018 to December 31, 2018, the Commission identified 12 entities located in jurisdictions other than Australia, Canada, the European Union, Hong Kong, Japan, Mexico, Singapore, Switzerland, the United Kingdom, or the United States that elected the Inter-Affiliate Exemption and chose to, or could have, complied with the Alternative Compliance Framework under Commission regulation 50.52(b)(4)(iii). During the same time period, the data showed that approximately 70 U.S. entities elected the Inter-Affiliate Exemption.

The Commission preliminarily believes that reinstating the Alternative Compliance Frameworks as permanent provisions, and extending the availability of the first framework under Commission regulation 50.52(b)(4)(ii) to eligible affiliate counterparties located in Australia, Canada, the European Union, Hong Kong, Japan, Mexico, Singapore, Switzerland, and the United Kingdom while correspondingly narrowing the availability of the second framework under Commission regulation 50.52(b)(4)(iii), would be appropriate for inter-affiliate swap transactions, would promote responsible financial innovation and fair competition, and would be consistent with the public interest.

In this regard, the Commission considered whether the availability of the proposed Alternative Compliance Frameworks might result in fewer affiliated counterparties clearing their outward-facing swaps and the significance of any such reduction in terms of the use of inter-affiliate swaps as a risk management tool. Generally speaking, it is difficult to estimate whether the proposed rule will reduce central clearing of outward-facing swaps. Among other factors, the application of mandatory clearing and the availability of central clearing for particular types of swaps vary by jurisdiction. Also, market participants' response to the proposed rule may depend on which of their swaps are eligible for the Inter-Affiliate Exemption. Despite this uncertainty, the Commission believes that there may be a significant number of affiliated counterparties that will continue to engage in uncleared swaps activity as permitted under the proposed Alternative Compliance Frameworks.[62]

As noted above, swap dealers electing the exemption use inter-affiliate swaps as an important risk management tool within corporate groups and these affiliated groups are subject to a range of regulatory and other controls as part of their swap activities in the United States and in other jurisdictions. In sum, in considering whether the proposed exemption would promote responsible financial innovation and fair competition and would be consistent with the public interest, the Commission took the factors discussed above into account—*i.e.,* the value of inter-affiliate swaps as a risk management tool, the extent to which the Alternative Compliance Frameworks would foster this use of inter-affiliate swaps, and the potential for more elections not to clear outward-facing swaps.

The Commission believes that the proposed revisions to the Outward-Facing Swaps Condition and Alternative Compliance Frameworks would be available only to ''appropriate persons.'' Section 4(c)(3) of the CEA includes within the term ''appropriate person'' a number of specified categories of persons, including such other persons that the Commission determines to be appropriate in light of their financial or other qualifications, or the applicability of appropriate regulatory protections. In the 2013 Inter-Affiliate Exemption final rulemaking, the Commission found that eligible contract participants (ECPs) are appropriate persons within the scope of

[59] House Conf. Report No. 102–978, 1992 U.S.C.C.A.N. 3179, 3213.

[60] Clearing Exemption for Swaps Between Certain Affiliated Entities, 78 FR 21754 (citing to commenters and the proposal in support of the conclusion that ''inter-affiliate transactions provide an important risk management role within corporate groups'' and that ''swaps entered into between corporate affiliates, if properly risk-managed, may be beneficial to the entity as a whole.'').

[61] The Commission notes that although current Commission regulation 50.52 does not permit entities to comply with either of the Alternative Compliance Frameworks because they have expired, the relief provided by DCR no-action letters means that market participants have continued to use and report swaps activity in compliance with the Alternative Compliance Frameworks.

[62] Based on a review of DDR data reflecting past use of the Inter-affiliate Exemption, the Commission estimates that up to 70 eligible affiliate counterparties located outside of the United States may elect to comply with one of the reinstated Alternative Compliance Frameworks thereby choosing not to clear their outward-facing swaps and rather to pay and collect variation margin on all swaps with other eligible affiliated counterparties instead. These 70 entities include affiliates of swap dealers that are active in multiple jurisdictions.

section 4(c)(3)(K) of the CEA.[63] The Commission noted that the elements of the ECP definition (as set forth in section 1a(18)(A) of the CEA and Commission regulation 1.3(m)) generally are more restrictive than the comparable elements of the enumerated ''appropriate person'' definition. Given that only ECPs are permitted to enter into uncleared swaps, there is no risk that a non-ECP or a person who does not satisfy the requirements for an ''appropriate person'' could enter into an uncleared swap using the Inter-Affiliate Exemption. Therefore, for purposes of this proposal, the Commission reaffirms its finding that the class of persons eligible to rely on the Inter-Affiliate Exemption will be limited to ''appropriate persons'' within the scope of section 4(c)(3) of the CEA.

Finally, the Commission preliminarily finds that the proposed revised Inter-Affiliate Exemption will not have a material effect on the ability of the Commission to discharge its regulatory responsibilities. This exemption continues to be limited in scope and, as described further below, the Commission will continue to have access to information regarding the inter-affiliate swaps subject to this exemption because they will be reported to an SDR pursuant to the conditions of the exemption. In addition to the reporting conditions in the rule, the Commission retains its special call, anti-fraud, and anti-evasion authorities, which will enable it to adequately discharge its regulatory responsibilities under the CEA.

For the reasons described in this proposal, the Commission preliminarily believes it would be appropriate and consistent with the public interest to amend the Outward-Facing Swaps Condition and Alternative Compliance Frameworks as proposed.

Request for Comment. The Commission requests comment as to whether the proposed revisions to the Outward-Facing Swaps Condition and Alternative Compliance Frameworks would be an appropriate exercise of the Commission's authority under section 4(c) of the CEA. The Commission also requests comment as to whether the proposed revisions to the Outward-Facing Swaps Condition and Alternative Compliance Frameworks would be in the public interest.

III. Related Matters

A. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) requires agencies to consider whether the rules they propose will have a significant economic impact on a substantial number of small entities and, if so, provide a regulatory flexibility analysis respecting the impact.[64] The proposed revisions to the Inter-Affiliate Exemption contained in this proposed rulemaking will not affect any small entities, as the RFA uses that term. Pursuant to section 2(e) of the CEA, only ECPs may enter into swaps, unless the swap is listed on a DCM. The Commission has previously determined that ECPs are not small entities for purposes of the RFA.[65] The proposed revisions to the Inter-Affiliate Exemption would only affect ECPs because all persons that are not ECPs are required to execute their swaps on a DCM, and all contracts executed on a DCM must be cleared by a DCO, as required by statute and regulation, not by operation of any clearing requirement determination. Therefore, the Chairman, on behalf of the Commission, hereby certifies pursuant to 5 U.S.C. 605(b) that this proposed rulemaking will not have a significant economic impact on a substantial number of small entities.

B. Paperwork Reduction Act

The Paperwork Reduction Act (PRA)[66] imposes certain requirements on federal agencies, including the Commission, in connection with conducting or sponsoring any collection of information as defined by the PRA. This proposed rulemaking will not require a new collection of information from any persons or entities. The Commission is not proposing to amend the reporting requirements of Commission regulations 50.52(c) and (d), for which the Office of Management and Budget has assigned control number 3038–0104.

C. Cost-Benefit Considerations

1. Statutory and Regulatory Background

Section 15(a) of the CEA requires the Commission to consider the costs and benefits of its actions before promulgating a regulation under the CEA or issuing certain orders. Section 15(a) further specifies that the costs and benefits shall be evaluated in light of the following five broad areas of market and public concern: (1) Protection of market participants and the public; (2) efficiency, competitiveness and financial integrity; (3) price discovery; (4) sound risk management practices; and (5) other public interest considerations (collectively referred to herein as the Section 15(a) Factors.) Accordingly, the Commission considers the costs and benefits associated with the proposed amendments to the Inter-Affiliate Exemption in light of the Section 15(a) Factors.

In the sections that follow, the Commission considers: (1) The costs and benefits of reinstating modified Alternative Compliance Frameworks to the Inter-Affiliate Exemption as described in this proposed rule; (2) the alternatives contemplated by the Commission and their costs and benefits; and (3) the impact on the Section 15(a) Factors of reinstating the availability of modified Alternative Compliance Frameworks to the Inter-Affiliate Exemption.

The regulatory baseline for this rulemaking is the current swap clearing requirement and the inter-affiliate exemption codified in Commission regulation 50.52. The Alternative Compliance Frameworks included in Commission regulations 50.52(b)(4)(ii) and (iii) expired as of March 11, 2014. As a practical matter, market participants have continued to use the Alternative Compliance Frameworks because DCR issued a series of no-action letters stating that it would not recommend that the Commission commence an enforcement action against entities using the Alternative Compliance Frameworks. As such, to the extent that market participants have relied upon relevant Commission staff action, the actual costs and benefits of this proposal, as realized in the market, may not be as significant.

However, because the current Alternative Compliance Frameworks have expired, the Commission's regulatory baseline for the costs and benefits consideration is the requirement that all market participants must comply with the Outward-Facing Swaps Condition pursuant to Commission regulation 50.52(b)(4)(i), by either clearing the swap or complying with an exception to or exemption from the clearing requirement. The Commission will assess the costs and benefits of reinstating modified Alternative Compliance Frameworks as if they are not available currently.

Although the Alternative Compliance Frameworks were unavailable according to the text of Commission regulation 50.52, during the 2018 calendar year the Commission was able to monitor the number of entities complying with the Outward-Facing Swaps Condition through the Alterative Compliance Frameworks, as permitted by DCR no-action letters.

The Commission notes that the consideration of costs and benefits

[63] Clearing Exemption for Swaps Between Certain Affiliated Entities, 78 FR 21754.

[64] 5 U.S.C. 601 *et seq.*

[65] 66 FR 20740, 20743 (Apr. 25, 2001).

[66] 44 U.S.C. 3507(d).

below is based on the understanding that the markets function internationally, with many transactions involving U.S. firms taking place across international boundaries; with some Commission registrants being organized outside of the United States; with leading industry members typically conducting operations both within and outside the United States; and with industry members commonly following substantially similar business practices wherever located. Where the Commission does not specifically refer to matters of location, the below discussion of costs and benefits refers to the effects of the proposed rule on all activity subject to the proposed and amended regulations, whether by virtue of the activity's physical location in the United States or by virtue of the activity's connection with or effect on U.S. commerce under section 2(i) of the CEA.[67] In particular, the Commission notes that a significant number of entities affected by this proposed rulemaking are located outside of the United States.

2. Considerations of the Costs and Benefits of the Commission's Action

a. Costs

By reinstating modified Alternative Compliance Frameworks to the Outward-Facing Swaps Condition in the Inter-Affiliate Exemption, the proposed rule would permit affiliated entities to elect not to clear swaps with unaffiliated entities that would otherwise be subject to the Commission's clearing requirement. Under current Commission regulation 50.52, all eligible affiliate counterparties must either clear swaps subject to the clearing requirement or qualify for an exception to or exemption from the clearing requirement. This proposal would allow eligible affiliate counterparties to be exposed to greater measures of counterparty credit risk under the Alternative Compliance Frameworks than if they cleared these swaps. Clearing, along with the Commission's requirements related to swap clearing, mitigates counterparty credit risk in the following ways: (1) An FCM guarantees the performance of a customer and in so doing, takes steps to monitor and mitigate the risk of a counterparty default; (2) a clearinghouse collects sufficient initial margin to cover potential future exposures and regularly collects and pays variation margin to cover current exposures; (3) a clearinghouse has rules, and enforcement mechanisms to ensure the rules are followed, to mark a swap to market and to require that margin be posted in a timely fashion; (4) a clearinghouse facilitates netting within portfolios of swaps and among counterparties; and (5) a clearinghouse holds collateral in a guaranty fund in order to mutualize the remaining tail risk not covered by initial margin contributions among clearing members.[68] These risk mitigating factors may be attenuated as parties elect to use the Alternative Compliance Frameworks.

Furthermore, there may be an increased risk of contagion and systemic risk to the financial system that results from permitting additional market participants to use the Alternative Clearing Frameworks to avoid clearing certain swaps subject to the clearing requirement. Swap clearing mitigates risk on a transaction level, as outlined above, and it also provides protection against risk transfer throughout the financial system. As discussed further below, this cost is minimized to the extent that variation margin is an effective risk management tool for swap market participants to prevent the accumulation of uncollateralized risk.

As proposed, reinstating the modified Alternative Compliance Frameworks would permit eligible affiliates that would otherwise be required to clear an outward-facing swap, to instead pay and collect full variation margin daily on all swaps between eligible affiliate counterparties, provided that all other conditions of the Alternative Compliance Frameworks are satisfied. This may result in decreased clearing activity and decreased liquidity in non-U.S. markets and at clearinghouses where eligible affiliate counterparties previously might have cleared such outward-facing swaps, but will now be able to maintain such risk internally through a series of inter-affiliate swaps and variation margining.

Finally, the availability of the modified Alternative Compliance Frameworks may increase the costs to any third party creditor to an entity using an Alternative Compliance Framework instead of clearing its outward-facing swaps. While the variation margin requirement included in this proposal mitigates the buildup of credit risk within a corporate group that uses a centralized risk management structure, it is still possible that using variation margin instead of clearing outward-facing swaps could produce additional counterparty risk to external creditors and/or third parties. In addition, as discussed above, expanding the number of jurisdictions excluded from the five percent limitation may cause market participants to alter their swaps trading behavior. To the extent that it now applies to fewer countries, a market participant's five percent exposure may be comprised of swaps with counterparties located in less sophisticated swaps markets. Such swaps may pose higher risks and overall costs could increase.

Request for Comment. The Commission requests comment, including any available quantitative data and analysis, on the expected costs resulting from the proposed revisions to the Outward-Facing Swaps Condition and Alternative Compliance Frameworks in the Inter-Affiliate Exemption.

b. Benefits

Because the Commission's current regulation does not permit eligible affiliate counterparties to use the Alternative Compliance Frameworks, this proposal is expected to provide a benefit to eligible affiliate counterparties seeking additional flexibility in their inter-affiliate swap risk management. To the extent that complying with the variation margin provisions of the modified Alternative Compliance Frameworks is less expensive than clearing an outward-facing swap, market participants would be able to avail themselves of these cost savings. For example, entities that choose to comply with the Alternative Compliance Frameworks as proposed would not need to pay the costs of posting incremental initial margin to either FCMs or clearinghouses, or paying any additional clearing fees. All of these savings would provide a benefit to eligible affiliate counterparties that choose to comply with the Alternative Compliance Frameworks rather than to clear a swap.

Entities within a corporate group may benefit from better risk transfers between affiliates. Current Commission regulation 50.52 provides little flexibility to market participants and requires them to either clear the outward-facing swap or comply with an exception to or exemption from the clearing requirement. Certain corporate entities might be incentivized by the new availability of the Alternative Compliance Frameworks to increase their inter-affiliate swap activity in order to increase the benefits of centralized risk management because they can use the Alternative Compliance Frameworks rather than clearing outward-facing swaps.

[67] 7 U.S.C. 2(i).

[68] *See* Clearing Requirement Determination Under Section 2(h) of the CEA for Interest Rate Swaps, 81 FR 71230.

There are additional benefits this proposal may provide to affiliates by improving and increasing options for the transfer of risk between affiliated entities. Entities most often elect to transact and clear inter-affiliate swaps in the most liquid market (reducing costs). The Commission notes that affiliated entities may choose in which jurisdiction to clear outward-facing swaps under current Commission regulation 50.52. The modified Alternative Compliance Frameworks may increase the number of options that affiliate entities have to comply with the Outward-Facing Swaps Condition, and thus, may increase the number of entities electing the Inter-Affiliate Exemption or even increase the number of inter-affiliate swaps that are entered into to transfer risk between entities. This represents an additional benefit to entities that would be induced to elect the Inter-Affiliate Exemption because of changes to the Alternative Compliance Frameworks that otherwise would not have engaged in any (or would have engaged in less) centralized risk management or risk transfers.

As stated above, the Commission estimates that approximately 50 entities in Australia, Canada, the European Union, Hong Kong, Japan, Mexico, Singapore, Switzerland, or the United Kingdom have used or potentially would use the modified Alternative Compliance Framework under Commission regulation 50.52(b)(4)(ii), if adopted pursuant to this proposal. Furthermore, the Commission estimates that as many as 12 entities might elect to use the modified Alternative Compliance Framework under Commission regulation 50.52(b)(4)(iii).[69] Besides the difficulty in determining who might use the Alternative Compliance Framework, the estimation of the benefit to each entity is further complicated by the differing costs and capital structures related to each entity. Further, the Commission realizes that there may be more entities in the future that would elect to pay and collect variation margin rather than clear outward-facing swaps if they are electing the Inter-Affiliate Exemption.

Request for Comment. The Commission requests comment on which entities might elect to use the Alternative Compliance Framework. The Commission also requests comment on the benefits that would likely result from the proposed revisions to the Outward-Facing Swaps Condition and Alternative Compliance Frameworks in the Inter-Affiliate Exemption, and, if any, the expected magnitude of such benefits.

3. Costs and Benefits of the Proposed Rule as Compared to Alternatives

The Commission considered two alternatives to this proposal to adopt modified Alternative Compliance Frameworks.[70] First, the Commission considered adopting new Alternative Compliance Frameworks that include expiration dates, after which point in time non-U.S. eligible affiliate counterparties would be required to clear any outward-facing swaps, or otherwise satisfy the Outward-Facing Swaps Condition. When the Commission adopted the Inter-Affiliate Exemption in 2013 it included an expiration date, March 11, 2014, for the alternative compliance framework because the Commission believed that a one year transition period after the adoption of the Commission's clearing requirement in March 2013 was appropriate. The Commission preliminarily believes that time-limited Alternative Compliance Frameworks would provide little additional benefit to market participants while potentially distorting long-range planning. In general, a regulatory time limit can be useful in focusing attention, but it can also cause distortions as market participants make plans based on an arbitrary date rather than their business needs. The Commission preliminarily believes that adopting modified Alternative Compliance Frameworks without expiration dates would increase planning flexibility for swap market participants, which could be especially beneficial as additional jurisdictions adopt, implement, and change their mandatory clearing regimes in ways that the Commission cannot predict at this time. In view of this uncertainty and the uncertainty regarding clearing requirement comparability determinations described above, the Commission preliminarily does not see the value in setting a new expiration date for the regulation. The Commission notes that it generally retains the authority to modify its regulations as changing conditions warrant.

Second, the Commission considered the alternative of not amending the current Alternative Compliance Frameworks regulations that have expired. Without modified Alternative Compliance Frameworks that permit eligible affiliate counterparties to pay and collect variation margin on certain inter-affiliate swaps, market participants would have to determine whether any alternatives to clearing outward-facing swaps are available. The availability of these alternatives to clearing, if any, would vary in across jurisdictions and may depend on the terms of the transaction in question. Therefore, the Commission cannot predict whether eliminating the Alternative Compliance Frameworks is a viable option. In addition, the potential lack of alternatives to clearing could lead eligible affiliate counterparties to reduce their use of inter-affiliate swaps for risk management purposes, which would not be a positive result because inter-affiliate swaps are an important component of centralized risk management. Finally, eliminating the Alternative Compliance Frameworks could cause market distortions if it leads market participants to conduct their swap-related activities based on the availability of regulatory exemptions rather than their business needs.

Request for Comment. The Commission requests comment on the costs and benefits of reinstating modified Alternative Compliance Frameworks compared to the costs and benefits of (i) adopting modified Alternative Compliance Frameworks that include expiration dates, and (ii) making no amendments to the current Outward-Facing Swaps Condition to the Inter-Affiliate Exemption. The Commission requests quantitative data and analysis where possible.

4. Section 15(a) Factors

a. Protection of Market Participants and the Public

In revising the Outward-Facing Swaps Condition and Alternative Compliance Frameworks, the Commission considered various ways to appropriately protect affiliated entities, third parties in the swaps market, and the public. The Commission seeks to

[69] The Commission would expect use of the Alternative Compliance Framework available under proposed revised regulation 50.52(b)(4)(iii) to increase in additional jurisdictions over time as swaps markets develop. The current estimate of up to 12 entities complying with the Alternative Compliance Framework under proposed revised regulation 50.52(b)(4)(iii) in unlisted jurisdictions may be a low estimate.

[70] The Commission acknowledges that the legal framework for establishing a substituted compliance regime could have been an additional component of this proposal. This proposal would have taken into account existing regulation 50.52(b)(4)(i)(B), which provides for compliance with a foreign jurisdiction's clearing mandate that is comparable, and comprehensive, but not necessarily identical to the Commission clearing requirement as a means of satisfying the conditions of the regulation. However, the Commission believes that it is impractical at this time to set up a substituted compliance regime for required clearing that would serve as a meaningful alternative given that the swaps and types of market participants covered by foreign mandatory clearing regimes vary significantly from Part 50 of the Commission's regulations. Accordingly, the Commission is not proposing or considering this alternative at this time.

ensure that the proposal prevents swap market participants from evading the Commission's clearing requirement and/or transferring excessive risk to an affiliated U.S. entity through the use of uncleared inter-affiliate swaps. The Commission proposes to permit eligible affiliate counterparties to elect not to clear an outward-facing swap subject to the clearing requirement, but only if eligible affiliates pay and collect daily variation margin on swaps.

The Commission also considered the potential effects on the public of providing this alternative to clearing outward-facing swaps subject to the clearing requirement. In particular, the Commission considered the extent to which the proposed Alternative Compliance Frameworks might result in fewer affiliated counterparties clearing their outward-facing swaps. One difficulty in estimating the effect of the proposal is the fact that the application of mandatory clearing and the availability of central clearing for particular types of swaps vary by jurisdiction. Also, many market participants enter into swaps and other financial instruments in multiple jurisdictions, which may give them the ability to adjust their financial and risk management activity in response to regulatory requirements.

In the face of this uncertainty, the Commission believes that, even if the change in clearing activity and business for clearinghouses is uncertain, there may be a significant number of affiliated counterparties that will continue to engage in swaps activity permitted under the proposed Alternative Compliance Frameworks.[71] The Commission understands that the swap dealers conduct their swaps activities using affiliates in various jurisdictions. Swap dealers engage in inter-affiliate swaps in order to distribute risk among their affiliates. Thus, inter-affiliate swaps are an important part of prudent risk management and a significant number of swap dealers and other market participants engage in inter-affiliate swaps. This inter-affiliate swaps activity is subject to a range of regulatory and other controls.

In considering how the proposed rule would affect the protection of market participants and the public, the Commission took into account the value of inter-affiliate swaps as a risk management tool and the extent to which the Alternative Compliance Frameworks would foster this use of inter-affiliate swaps. The Commission also considered potential increases in systemic risk if affiliates elect not to clear outward-facing swaps and use the Alternative Compliance Frameworks instead. In view of these factors, the Commission preliminarily believes that the potential increases in systemic risk will be mitigated by the controls on the use of inter-affiliate swaps, their inherent risk management features, and the conditions set out in the proposed Alternative Compliance Frameworks.

The proposed revisions also would create certain costs that would be borne by entities electing the Inter-Affiliate Exemption. Under the proposed revisions, entities that choose to comply with an Alternative Compliance Framework would now be required to pay and collect variation margin on their inter-affiliate swaps, which could be a significant cost for those entities. However, the proposed revisions also provide that an entity may continue to choose to clear an outward-facing swap with an unaffiliated counterparty instead of paying and collecting variation margin on all swaps with other eligible affiliate counterparties. Therefore, affected entities are free to choose which of these alternatives is best for them.

b. Efficiency, Competitiveness, and Financial Integrity of Swap Markets

The Commission preliminarily believes that the proposed revisions to the Inter-Affiliate Exemption may have some, but not a significant, impact on the efficiency or competiveness of swaps markets. As noted above, inter-affiliate swaps are an important risk management tool for affiliated corporate groups. To the extent that swap dealers may participate more extensively in swap markets in non-U.S. jurisdictions because they can use inter-affiliate swaps to manage risk efficiently, the proposed amendments to the Inter-Affiliate Exemption may increase the efficiency, competitiveness, and financial integrity of swap markets by increasing the range of swaps that are available to market participants. The Commission also preliminarily believes that the revised Outward-Facing Swaps Condition and adoption of modified Alternative Compliance Frameworks should discourage misuse of the Inter-Affiliate Exemption. For example, the Commission recognizes that internal calculations and swaps portfolio management is required to comply with the five percent test under Commission regulation 50.52(b)(4)(iii). If the Commission had proposed to reinstate the Alternative Compliance Frameworks, without adjusting the list of non-U.S. jurisdictions in which an affiliated counterparty may be located for purposes of Commission regulation 50.52(b)(4)(ii), entities may have failed to appropriately calculate the permissible limits under the five percent test under Commission regulation 50.52(b)(4)(iii). Aligning the scope of jurisdictions included in the Alternative Compliance Frameworks with the jurisdictions for which the domestic currency is subject to the Commission's clearing requirement may help to make these calculations and compliance with the provisions easier. This should promote the financial integrity of swap markets and financial markets as a whole.

c. Price Discovery

Under Commission regulation 43.2, a ''publicly reportable swap transaction,'' means, among other things, any executed swap that is an arms'-length transaction between two parties that results in a corresponding change in the market risk position between the two parties.[72] The Commission does not consider non-arms'-length swaps as swaps that contribute to price discovery in the markets, as they are not publically reported, generally.[73] Given that inter-affiliate swaps as defined in this proposed rulemaking are usually not arms'-length transactions, the Commission preliminarily believes that the proposed revisions to the Inter-Affiliate Exemption would not have a significant effect on price discovery.[74] However, if the availability of the Alternative Compliance Frameworks reduces the use of outward-facing swaps, which may or may not be publicly reported depending on the jurisdiction, there could be a negative

[71] Based on a review of DDR data reflecting past use of the Inter-affiliate Exemption, the Commission estimates that up to 70 eligible affiliate counterparties located outside of the United States may elect to comply with one of the reinstated Alternative Compliance Frameworks thereby choosing not to clear their outward-facing swaps and rather to pay and collect variation margin on all swaps with other eligible affiliated counterparties instead. These 70 entities include affiliates of swap dealers that are active in multiple jurisdictions.

[72] 17 CFR 43.2. *See also* Real-Time Public Reporting of Swap Transaction Data, 77 FR 1182 (Jan. 9, 2012).

[73] Transactions that fall outside the definition of ''publicly reportable swap transaction''—that is, transactions that are not arms-length—''do not serve the price discovery objective of CEA section 2(a)(13)(B).'' Real-Time Public Reporting of Swap Transaction Data, 77 FR at 1195. *See also id.* at 1187 (discussing ''Swaps Between Affiliates and Portfolio Compression Exercises'') and Clearing Exemption for Swaps Between Certain Affiliated Entities, 78 FR at 21780.

[74] The definition of ''publicly reportable swap transaction'' identifies two examples of transactions that fall outside the definition, including internal swaps between one-hundred percent owned subsidiaries of the same parent entity. 17 CFR 43.2 (adopted by Real-Time Public Reporting of Swap Transaction Data, 77 FR at 1244). The Commission notes that the list of examples is not exhaustive.

impact on price discovery when outward-facing swaps would otherwise be publically reported.

d. Sound Risk Management Practices

The conditions of the Inter-Affiliate Exemption do not eliminate the possibility that risk may impact an entity, its affiliates, and counterparties of those affiliates.[75] Without clearing a swap to mitigate the transmission of risk among affiliates, the risk that any one affiliate takes on through its swap transactions, and any contagion that may result through that risk, increases. This makes the risk mitigation requirements for outward-facing swaps more important as risk can be transferred more easily between affiliates.

Exempting certain inter-affiliate swaps from the clearing requirement creates additional counterparty exposure for affiliates.[76] DCOs have many tools to mitigate risks. This increased counterparty credit risk among affiliates may increase the likelihood that a default of one affiliate could cause significant losses in other affiliated entities. If the default causes other affiliated entities to default, third parties that have entered into uncleared swaps or other agreements with those entities also could be affected.

In 2013, when the Commission finalized the Inter-Affiliate Exemption, it assessed the risks of inter-affiliate swaps and stated that the partial internalization of costs among affiliated entities, combined with the documentation, risk management, reporting, and treatment of outward-facing swaps requirements for electing the exception, would mitigate some of the risks associated with uncleared inter-affiliate swaps.[77] However, the Commission indicated that these mitigants are not a perfect substitute for the protections that would otherwise be provided by clearing, or by a requirement to use more of the risk management tools that a clearinghouse uses to mitigate counterparty credit risk (*i.e.,* both initial and variation margin, FCMs monitoring credit risk of customers, clearing member contributions to default funds, etc.).[78]

e. Other Public Interest Considerations

The Commission has identified no other public interest considerations.

D. General Request for Comment

The Commission invites information regarding whether and the extent to which specific foreign requirement(s) may affect the costs and benefits of the proposal, including information identifying the relevant foreign requirement(s) and any monetary or other quantitative estimates of the potential magnitude of those costs and benefits. The Commission also requests comment on other aspects of the costs and benefits relating to the proposed revisions to the Outward-Facing Swaps Condition and Alternative Compliance Frameworks. The Commission requests that commenters provide any data or other information that would be useful in estimating the quantifiable costs and benefits of this proposed rulemaking.

E. Antitrust Considerations

Section 15(b) of the Act requires the Commission to take into consideration the public interest to be protected by the antitrust laws and endeavor to take the least anticompetitive means of achieving the purposes of the Act, in issuing any order or adopting any Commission rule or regulation (including any exemption under section 4(c) or 4c(b)), or in requiring or approving any bylaw, rule, or regulation of a contract market or registered futures association established pursuant to section 17 of the Act.[79] The Commission believes that the public interest to be protected by the antitrust laws is generally to protect competition. The Commission requests comment on whether the proposal implicates any other specific public interest to be protected by the antitrust laws.

The Commission has considered the proposal to determine whether it is anticompetitive and has preliminarily identified no anticompetitive effects. The Commission requests comment on whether the proposal is anticompetitive and, if it is, what the anticompetitive effects are.

Because the Commission has preliminarily determined that the proposal is not anticompetitive and has no anticompetitive effects, the Commission has not identified any less anticompetitive means of achieving the purposes of the Act. The Commission requests comment on whether there are less anticompetitive means of achieving the relevant purposes of the Act that would otherwise be served by adopting the proposal.

List of Subjects in 17 CFR Part 50

Business and industry, Clearing, Swaps.

For the reasons stated in the preamble, the Commodity Futures Trading Commission proposes to amend 17 CFR part 50 as set forth below:

PART 50—CLEARING REQUIREMENT AND RELATED RULES

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

Authority: 7 U.S.C. 2(h), 6(c), and 7a–1 as amended by Pub. L. 111–203, 124 Stat. 1376.

■ 2. Amend § 50.52 as follows:
■ a. Revise paragraphs (a)(2)(i) and (ii);
■ b. Add paragraph (a)(2)(iii); and
■ c. Revise paragraph (b)(4).

The revisions and addition read as follows:

§ 50.52 Exemption for swaps between affiliates.

(a) * * *

(2) * * *

(i) A counterparty or third party directly or indirectly holds a majority ownership interest if it directly or indirectly holds a majority of the equity securities of an entity, or the right to receive upon dissolution, or the contribution of, a majority of the capital of a partnership;

(ii) The term ''eligible affiliate counterparty'' means an entity that meets the requirements of this paragraph; and

(iii) The term ''United States'' means the United States of America, its territories and possessions, any State of the United States, and the District of Columbia.

(b) * * *

(4)(i) Subject to paragraphs (b)(4)(ii) and (iii) of this section, each eligible affiliate counterparty that enters into a swap, which is included in a class of swaps identified in § 50.4, with an unaffiliated counterparty shall:

(A) Comply with the requirements for clearing the swap in section 2(h) of the Act and this part;

(B) Comply with the requirements for clearing the swap under a foreign jurisdiction's clearing mandate that is comparable, and comprehensive but not necessarily identical, to the clearing requirement of section 2(h) of the Act and this part, as determined by the Commission;

(C) Comply with an exception or exemption under section 2(h)(7) of the Act or this part;

(D) Comply with an exception or exemption under a foreign jurisdiction's clearing mandate, provided that:

(*1*) The foreign jurisdiction's clearing mandate is comparable, and

[75] The Commission notes that even in the absence of required clearing or margin requirements for swaps between certain affiliated entities, such entities may choose to use initial and variation margin to manage risks that could otherwise be transferred from one affiliate to another. Similarly, third parties that have entered into swaps with affiliates also may include variation margin requirements in their swap agreements.

[76] Clearing Exemption for Swaps Between Certain Affiliated Entities, 78 FR 21780–21781.

[77] *Id.*

[78] *Id.* at 21778.

[79] 7 U.S.C. 19(b).

comprehensive but not necessarily identical, to the clearing requirement of section 2(h) of the Act and this part, as determined by the Commission; and

(*2*) The foreign jurisdiction's exception or exemption is comparable to an exception or exemption under section 2(h)(7) of the Act or this part, as determined by the Commission; or

(E) Clear such swap through a registered derivatives clearing organization or a clearing organization that is subject to supervision by appropriate government authorities in the home country of the clearing organization and has been assessed to be in compliance with the Principles for Financial Market Infrastructures.

(ii) If one of the eligible affiliate counterparties is located in Australia, Canada, the European Union, Hong Kong, Japan, Mexico, Singapore, Switzerland, or the United Kingdom and each eligible affiliate counterparty, or a third party that directly or indirectly holds a majority interest in both eligible affiliate counterparties, pays and collects full variation margin daily on all of the eligible affiliate counterparties' swaps with other eligible affiliate counterparties, the requirements of paragraph (b)(4)(i) of this section shall be satisfied.

(iii) If an eligible affiliate counterparty located in the United States enters into swaps, which are included in a class of swaps identified in § 50.4, with eligible affiliate counterparties located in jurisdictions other than Australia, Canada, the European Union, Hong Kong, Japan, Mexico, Singapore, Switzerland, the United Kingdom, or the United States, and the aggregate notional value of such swaps, which are included in a class of swaps identified in § 50.4, does not exceed five percent of the aggregate notional value of all swaps, which are included in a class of swaps identified in § 50.4, in each instance the notional value as measured in U.S. dollar equivalents and calculated for each calendar quarter, entered into by the eligible affiliate counterparty located in the United States, then the requirements of paragraph (b)(4)(i) of this section shall be satisfied when each eligible affiliate counterparty, or a third party that directly or indirectly holds a majority interest in both eligible affiliate counterparties, pays and collects full variation margin daily on all of the eligible affiliate counterparties' swaps with other eligible affiliate counterparties.

* * * * *

Issued in Washington, DC, on December 12, 2019, by the Commission.

Christopher Kirkpatrick,

Secretary of the Commission.

NOTE: The following appendices will not appear in the Code of Federal Regulations.

Appendices to Exemption From the Swap Clearing Requirement for Certain Affiliated Entities—Alternative Compliance Frameworks for Anti-Evasionary Measures—Commission Voting Summary and Commissioner's Statement

Appendix 1—Commission Voting Summary

On this matter, Chairman Tarbert and Commissioners Quintenz, Behnam, Stump, and Berkovitz voted in the affirmative. No Commissioner voted in the negative.

Appendix 2—Supporting Statement of Commissioner Brian D. Quintenz

I support today's proposal to codify how affiliated swap counterparties have, for the past six years, complied with an important provision of one of the Commission's exemptions from the swap clearing requirement. The Commission's swap clearing requirement has accomplished the important task of requiring financial institutions to centrally clear the overwhelming majority of the most commonly-traded interest rate swaps and credit default swaps through CFTC-supervised clearing organizations. According to a Financial Stability Board (FSB) report published in October, at least 80% of interest rate swaps and credit default swaps executed in the U.S. are now cleared.[1] Central clearing, through the posting of initial and variation margin with a clearinghouse, has greatly reduced counterparty credit risk in the swaps market, helping to support confidence in the financial markets. However, carefully considered exceptions should ensure that uncleared products remain economically viable to provide market participants with flexibility in managing risks. For example, entities belonging to the same corporate group regularly execute swaps for internal risk management purposes, and these swaps do not incur the same risks as those executed with unaffiliated counterparties.[2] The Commission has also created exceptions to the swap clearing requirement for *commercial end-users, financial institutions organized as cooperatives,* and *banks with assets of $10 billion or less.* As an additional point, I look forward to the Commission finalizing last year's proposed exemptions for *bank holding companies* and *savings and loan companies* having consolidated assets of $10 billion or less and for *community development financial institutions.*

I believe the proposal before the Commission today strikes an appropriate balance between guarding against evasion, on the one hand, and providing flexibility for cross-border swaps activity on the other. When affiliated financial counterparties exchange variation margin on all of their swaps with one another, on a worldwide basis, the risk that a U.S. firm can amass a critical amount of uncollateralized exposure abroad is greatly reduced. At the same time, the proposal does not disadvantage U.S.-based institutions competing with foreign institutions located in jurisdictions whose swap clearing requirements are narrower in scope than the Commission's. I believe that today's proposal functions rationally with the Commission's rules for margining uncleared swaps on a cross-border basis, including in the context of inter-affiliate transactions, and I look forward to comments on this topic.

In addition, I note that today's proposal would simplify the existing inter-affiliate exemption to reflect current market practices and eliminate complicated provisions that may never have been relied upon. I hope the Commission's next rulemakings similarly rationalize rules so that industry's compliance becomes less burdensome and costly.

[1] FSB OTC Derivatives Market Reforms: 2019 Progress Report on Implementation (Oct. 2019), (Appendix C, Table J), *https://www.fsb.org/2019/10/otc-derivatives-market-reforms-2019-progress-report-on-implementation/.*

[2] *See* the Commission's original proposed inter-affiliate exemption, Clearing Exemption for Swaps Between Affiliated Entities, 77 FR 50425, 50426–50427 (Aug. 21, 2012).

Appendix 3—Concurring Statement of Commissioner Rostin Behnam

I respectfully concur with the Commodity Futures Trading Commission's (the ''Commission'' or ''CFTC'') decision today to issue proposed amendments to the exemption from the swap clearing requirement for certain affiliated entities. The original inter-affiliate exemption rule was issued by the Commission in 2013.[1] Today's proposal reminds us both of how forward thinking the Commission was in implementing the Dodd-Frank Act and the goals envisioned at the 2009 G20 Pittsburgh Summit, and of how we need to be thoughtful and willing to update our rule set when reality differs from what we envisioned.

The impetus for today's proposal boils down to this. In some respects, the world hasn't turned out quite the way the Commission envisioned. When the Commission promulgated the inter-affiliate exemption rule in 2013, the perhaps overly hopeful expectation was that other jurisdictions would quickly follow our lead and adopt swap clearing requirements in short order. While a number of jurisdictions now have clearing mandates for certain swaps, some non-U.S. jurisdictions are still in the process of adopting clearing regimes, and some non-U.S. jurisdictions vary significantly from the Commission's clearing requirement. While the expectation in 2013 was that the Commission would issue comparability determinations for non-U.S. jurisdictions with respect to the clearing requirement, to date the Commission has not issued any comparability determinations.

[1] Clearing Exemption for Swaps Between Certain Affiliated Entities, 78 FR 21750 (Apr. 11, 2013).

Because the Commission in 2013 expected the world to quickly follow with clearing mandates, it established a temporary Alternative Compliance Framework for compliance with the Outward-Facing Swaps Condition of the Inter-Affiliate Exemption.[2] Since that temporary Alternative Compliance Framework expired in 2014, the Division of Clearing and Risk staff has issued a series of no-action letters extending the Alternative Compliance Framework to provide more time for global harmonization.[3] Today, because the global regulatory landscape has not turned out quite like we expected, the Commission proposes to codify and make permanent the Alternative Compliance Framework.

While I support today's proposal and believe that it represents the best path forward to provide legal certainty to market participants regarding the Outward-Facing Swaps Condition of the Inter-Affiliate Exemption, there is one significant aspect of the proposal that gives me pause. In the preamble to the 2013 rule, the Commission stated that the Alternative Compliance Framework provided for the Outward-Facing Swaps Condition is ''not equivalent to clearing and would not mitigate potential losses between swap counterparties in the same manner that clearing would.'' [4] We reiterate this in today's preamble, stating that ''[a]lthough paying and collecting variation margin daily does not mitigate counterparty credit risk to the same extent that central clearing does, the Commission believes, as stated in the 2013 adopting release for the Inter-Affiliate Exemption, that variation margin is an essential risk management tool.'' Despite clearly stating that variation margin does not mitigate counterparty credit risk to the same extent as central clearing, we nonetheless are proposing to exempt certain transactions from central clearing under the theory that variation margin mitigates counterparty credit risk. This may be the right result, but I want to be absolutely certain that we are not injecting unnecessary risk into the system by exempting these transactions from central clearing in the name of focusing on the easiest, cheapest risk management tool. I encourage interested parties to comment on whether the alternative compliance framework that we propose to codify effectively mitigates counterparty credit risk, and the differences in risk mitigation between the alternative compliance framework and central clearing.

In part, I am comfortable with the proposal because the existing rule provides the Commission with the ability to monitor how the exemption is working. Under Regulation 50.52(c) through (d), the election of the Inter-Affiliate Exemption, as well as how the requirements of the exemption are met, must be reported to a Commission-registered swap data repository.[5] Accordingly, the Commission will have a window into which entities elect the exemption, how many swaps are exempted, and how the requirements of the exemption are met. In addition, the Commission retains its special call, anti-fraud, and anti-evasion authorities, which should enable it to discharge its regulatory responsibilities under the CEA. I believe that the Commission should closely monitor SDR data regarding the Inter-Affiliate Exemption going forward in order to be certain that the exemption is not being used to evade central clearing, and to ensure that the exemption is not adding unnecessary and preventable risk to the system.

I thank staff for their thoughtful responses to my questions, and for making edits that reflected comments and suggestions made by me and my staff.

Appendix 4—Statement of Commissioner Dan M. Berkovitz

I support the proposed rule to make permanent the alternative compliance frameworks for certain swaps between the foreign affiliates of U.S. firms and their non-U.S. counterparties.[1] The proposed rule would make permanent, with modifications, anti-evasion provisions for inter-affiliate swaps that the Commission originally adopted in 2013, and then extended through staff no-action letters that remain in effect today. The no-action letters require U.S. firms and their foreign affiliates to exchange variation margin in connection with swaps entered into by the foreign affiliate with non-U.S. counterparties, where such swaps are subject to the Commission's clearing requirement and there is no comparable and comprehensive clearing regime in the foreign jurisdiction. The proposed rule upholds the Dodd-Frank Act's clearing mandate, deters evasion, and helps to protect against systemic risk to the U.S. from swaps executed overseas by foreign affiliates.

The Commission's rules provide a limited, conditional exemption from clearing for swaps between certain affiliate counterparties, including U.S. firms and their foreign affiliates (''Inter-Affiliate Exemption'').[2] At the same time, through both regulation and no-action relief, the Commission has implemented measures designed to prevent U.S. firms from routing swaps through their foreign affiliates to evade the Commission's clearing requirement for such swaps. These anti-evasion provisions condition the Inter-Affiliate Exemption such that foreign affiliates of U.S. firms must clear their outward-facing swaps if such swaps are: (1) Subject to the Commission's clearing requirement and (2) entered into with unaffiliated counterparties in foreign jurisdictions (''Outward-Facing Swaps Condition''). The Outward-Facing Swaps Condition allows outward-facing swaps to be cleared pursuant to a comparable and comprehensive foreign clearing regime, if available.

In jurisdictions where the Commission has not made a comparability determination, the alternative compliance frameworks permit the foreign affiliate to exchange full, daily variation margin for the swap with its U.S. affiliate or its non-U.S. counterparty, rather than clearing the outward-facing swap. The alternative compliance frameworks permit the foreign affiliate to enter into swaps with non-U.S. counterparties in foreign jurisdictions under the same terms and conditions as other non-U.S. persons in those jurisdictions. They preserve the competitiveness of the foreign affiliates of U.S. firms without presenting significant risks to the U.S. affiliate or importing significant risks into the U.S. Today's proposed rule would make the alternative compliance frameworks permanent, with certain modifications.[3]

I support the proposed rule's emphasis on clearing, anti-evasion, and systemic risk by preserving the Outward-Facing Swaps Condition and making permanent the alternative compliance frameworks. The proposed rule would also expand the jurisdictions subject to one of the alternative compliance frameworks to include additional jurisdictions that have adopted and implemented their respective domestic clearing mandates.[4] By extending and making permanent the alternative compliance frameworks, the proposed rule would address the lack of comparability determinations for foreign clearing regimes, while ensuring the continued operation of anti-evasion and anti-systemic risk provisions in the Commission's rules.

The proposed rule seeks public comment on whether the alternative compliance frameworks are sufficient to address potential

[2] The Outward-Facing Swaps Condition requires an eligible affiliate counterparty relying on the Inter-Affiliate Exemption to clear any swap covered by the CFTC's clearing requirement that is entered into with an unaffiliated counterparty, unless the swap qualifies for an exception or exemption from the clearing requirement. Commission regulation 50.52(b)(4)(i).

[3] CFTC Letter Nos. 14–25 (Mar. 6, 2014), 14–135 (Nov. 7, 2014), 15–63 (Nov. 17, 2015), 16–81 (Nov. 28, 2016), 16–84 (Dec. 15, 2016), and 17–66 (Dec. 14, 2017), all available at *https://www.cftc.gov/LawRegulation/CFTCStaffLetters/index.htm.*

[4] *Id.* at 21765.

[5] Commission regulation 50.52(c) through (d).

[1] *See* 7 U.S.C. 2(h)(1), which provides that if the Commission requires a swap to be cleared, then it shall be unlawful for a person to enter into such swap unless it is submitted to a registered derivatives clearing organization (''DCO'') or to a DCO that is exempt from registration. Part 50 of the Commission's regulations sets forth the classes of swaps required to be cleared, as well as certain conditional exemptions to the clearing requirement, including the exemption and conditions under consideration in this proposal.

[2] The Commission has previously found that ''inter-affiliate transactions provide an important risk management role within corporate groups'' and that they may be beneficial to the group as a whole if properly risk managed. *See* Clearing Exemption for Swaps Between Certain Affiliated Entities, 78 FR 21750, 21754 (Apr. 11, 2013).

[3] The original alternative compliance frameworks expired in 2014, but have been repeatedly extended through no-action letters that expire in December 2020.

[4] The proposed alternative compliance frameworks consist of two distinct but similar sets of requirements. Both would require the exchange of full, daily variation margin. However, the first framework, in proposed § 50.52(b)(4)(ii) would apply to eight enumerated jurisdictions that have adopted domestic clearing mandates. The second framework, in proposed § 50.52(b)(4)(iii), would apply in all other jurisdictions. Swaps in this second framework would be limited to the ''five percent test,'' which limits the uncleared swaps activity that a U.S. eligible affiliate counterparty can transact with its affiliates in non-enumerated jurisdictions. The five percent test was also present in the alternative compliance frameworks when they were adopted in 2013.

systemic risk to the U.S. and whether they may produce a permanent residual class of swaps that are not cleared but instead result in the exchange of variation margin between eligible affiliate counterparties (and the risks associated with those swaps). I look forward to public comments on these questions and other aspects of the proposal.

[FR Doc. 2019–27207 Filed 12–20–19; 8:45 am]

BILLING CODE 6351–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 301

[REG–116163–19]

RIN 1545–BP41

Misdirected Direct Deposit Refunds

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: These proposed regulations provide guidance on section 6402(n) of the Internal Revenue Code (Code), concerning the procedures for identification and recovery of a misdirected direct deposit refund. The regulations reflect changes to the law made by the Taxpayer First Act. The proposed regulations affect taxpayers who have made a claim for refund, requested the refund be issued as a direct deposit, but did not receive a refund in the account designated on the claim for refund.

DATES: Comments and requests for a public hearing must be received by February 21, 2020.

ADDRESSES: Submit electronic submissions via the Federal eRulemaking Portal at *www.regulations.gov* (indicate IRS and REG–116163–19) by following the online instructions for submitting comments. Once submitted to the Federal eRulemaking Portal, comments cannot be edited or withdrawn. The Department of the Treasury (Treasury Department) and the IRS will publish for public availability any comment received to its public docket, whether submitted electronically or in hard copy. Send hard copy submissions to: CC:PA:LPD:PR (REG–116163–19), Room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (REG–116163–19), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Concerning the proposed amendments to the regulations, Mary C. King at (202) 317–5433; concerning submissions of comments, or requests for a public hearing, Regina L. Johnson, at (202) 317–6901 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

This document contains proposed amendments to 26 CFR part 301 under section 6402(n) of the Code and provides guidance on the procedures used to identify and recover tax refunds issued by electronic funds transfer (direct deposit) that were not delivered to the account designated to receive the direct deposit refund on the federal tax return or other claim for refund. These proposed regulations implement section 6402(n) of the Code, a new provision added by section 1407 of the Taxpayer First Act, Public Law 116–25, 133 Stat. 981 (2019) (TFA).

Section 6402(a) provides the Secretary of the Treasury or his delegate (Secretary) with the authority to refund the balance of an overpayment after first crediting the overpayment amount against any tax liability of the person who made the overpayment. Before any refund is issued, the balance must also be offset against certain nontax liabilities. Sections 6402(a), (c), (d), (e), and (f) require a taxpayer's overpayment to be applied to any outstanding Federal tax debt, past-due child support, Federal agency non-tax debt, State income tax obligation, or certain unemployment compensation debts owed to a state prior to crediting the overpayment to a future tax or issuing a refund. This application of a tax overpayment is called a refund offset. An offset occurs after a refund is certified by the IRS but prior to the issuance of the refund.

The procedures for making a claim for refund are set out in § 301.6402–2 of the Procedure and Administration Regulations. Those regulations include procedures for the mailing of a check in payment of allowed claims for refund. See § 301.6402–2(f). The procedures for sending a refund by direct deposit are set out in the Treasury Financial Manual, the Bureau of the Fiscal Service Green Book, and the regulations under 31 CFR part 210. The Treasury Financial Manual is available for downloading at the Bureau of the Fiscal Service's website at *https://tfm.fiscal.treasury.gov/home.html.* The Green Book is available for downloading at the Bureau of the Fiscal Service's website at *https://www.fiscal.treasury.gov/reference-guidance/green-book/.*

The IRS generally issues a refund in the manner requested on the claim for refund. This includes splitting a refund by authorizing direct deposits into multiple accounts using Form 8888, ''Allocation of Refund (Including Savings Bond Purchases).'' Under current procedures, if a taxpayer requests that the refund be issued as a direct deposit on a current year tax return, the IRS will generally issue the refund it determines to the account number and routing number designated on the claim. A direct deposit may be stopped or unable to be delivered for a number of reasons, including, but not limited to, an invalid routing number, rejection by a financial institution, or a processing error. If the direct deposit is stopped or returned prior to the delivery of the refund to the account designated on the claim for refund, the IRS will generally issue the refund in the form of a paper check.

Under current procedures, set out in Internal Revenue Manual (I.R.M.) sections 21.4.1, 21.4.2, and 21.4.3 and available at *https://www.irs.gov/irm,* a taxpayer or authorized representative may report a missing refund to the IRS by using an IRS customer service line or filing a Form 3911, ''Taxpayer Statement Regarding Refund.'' A taxpayer or authorized representative may also report a missing refund to the IRS through the Office of the Taxpayer Advocate (commonly referred to as the Taxpayer Advocate Service (TAS)). When a missing refund is reported, the IRS will first determine if a refund was issued to the taxpayer and whether a direct deposit transaction was made. If the refund was issued as a direct deposit, the IRS will verify the accuracy of the taxpayer's account number and routing number.

If the taxpayer reports a missing refund and the IRS confirms a refund was issued, the IRS will generally conduct a refund trace to determine why the refund was not delivered to the account of the taxpayer. A refund trace is the process by which the IRS tracks stolen, lost, or misplaced refund checks or verifies a financial institution received direct deposits and may replace an authorized refund to the taxpayer if warranted. A refund trace will be initiated when a taxpayer reports a missing refund and the IRS confirms a refund was issued as a direct deposit, even if the taxpayer reports that the account information designated on the claim for refund was incorrect. A refund trace is initiated by inputting a trace code into the IRS's Integrated Data Retrieval System (IDRS), which sends a request to the Treasury Department's Bureau of the Fiscal Service (BFS) for

assistance in identifying information about the account into which the refund was made.

When the BFS receives a refund trace request from the IRS for a tax refund issued as a direct deposit, the BFS asks financial institutions for assistance in verifying that the institution received the direct deposit, identifying information about the account where the refund was made, and recovery of such amounts. The correct financial institution is identified by the routing number that appears on the claim for refund. The BFS uses FS Form 150.1, which is an official request from the Treasury Department to the financial institution to recover more information regarding the direct deposit. The information requested includes whether the financial institution received the refund; whether the financial institution returned the refund, will return the refund, or if no funds are available for return; whether the refund was deposited into the account of the taxpayer on whose behalf the request is being made; and the account number and account owner's identifying information.

When the IRS determines that a refund or a portion of a refund was made by direct deposit to an account that is not the account designated on the taxpayer's claim for refund, the refund is considered to be a misdirected direct deposit refund. A misdirected direct deposit refund occurs when the IRS has caused the error, such as when the IRS mistakenly inputs an incorrect account number from the claim for refund, or when a financial institution credits the payment to an account other than the account designated in the IRS's direct deposit instruction. *See* 31 CFR 210.8; *see also* Bureau of the Fiscal Service, Green Book: A Guide to Federal Government ACH Payments, at 2–6 (2016) (where a financial institution has misdirected a payment, the financial institution may be liable to the issuing agency if there is a resulting loss by the agency). When a misdirected direct deposit refund is discovered, the IRS will issue a replacement refund to the taxpayer in the full amount of the refund that was misdirected. This replacement refund is issued regardless of whether the IRS is able to recover the misdirected direct deposit refund that the taxpayer did not receive.

Occasionally, a taxpayer or authorized representative will designate an incorrect account or routing number on the claim for refund that will cause a refund to be disbursed to an account that is not the account of the taxpayer. When the IRS determines that a refund or a portion of a refund was made by direct deposit to the account designated on the taxpayer's claim for refund, the refund is not considered to be a ''misdirected direct deposit refund.'' Nevertheless, the IRS should generally initiate a refund trace for any reported missing refund that is issued as a direct deposit. In some instances, such as when the date of the direct deposit is less than five calendar days from when the missing refund is reported, the IRS will not initiate a refund trace immediately. Through the refund trace procedure, the IRS will coordinate with financial institutions and the BFS to request the return of a refund not deposited into the account of the taxpayer on whose behalf the request is being made. In cases when the taxpayer designates an incorrect account number on the claim for refund, the IRS will issue a replacement refund only after the IRS has recovered the original refund or a portion of the refund that was deposited in the incorrect account from the financial institution. When the financial institution returns the refund, the IRS will issue a replacement refund in the amount recovered. When the IRS has recovered only a portion of the refund that was directed to the incorrect account, only the portion recovered will be refunded to the taxpayer.

In other instances, a refund will be disbursed to the account designated to receive the refund, but the taxpayer will nevertheless not receive the refund that was disbursed. The IRS has separate procedures, reflected in I.R.M. 21.4.1, 21.4.2, and 21.4.3, to assist taxpayers whose refunds are not delivered to them despite the deposit of the refund in the account designated on the return or claim for refund. These procedures also include information on when the IRS will issue a replacement refund to victims of tax return preparer misconduct. See Form 14157–A, Tax Return Preparer Fraud or Misconduct Affidavit. However, refunds that are diverted from the correct taxpayer due to tax return preparer misconduct are not considered to be ''misdirected direct deposit refunds'' because they are deposited into the account listed on the claim for refund.

The TFA added section 6402(n) to the Code. Pursuant to section 6402(n)(1), the Secretary is required to establish procedures to allow taxpayers to report when a refund is not deposited into the taxpayer's account. Section 6402(n)(2) further directs the Secretary to establish procedures for coordination with financial institutions to identify the account to which a misdirected direct deposit refund has been made and to recover such refunds. Finally, under section 6402(n)(3), the Secretary is directed to establish procedures to allow a misdirected direct deposit refund to be delivered to the correct account of the taxpayer. These proposed regulations describe the procedures under section 6402(n) that will be used when a taxpayer or authorized representative notifies the IRS that the requested refund was not received. The proposed regulations adopt current IRS procedures for the reporting, identification, recovery, and delivery of misdirected direct deposit refunds.

Explanation of Provisions

I. Definitions

In § 301.6402–2(g)(1) of the proposed regulations, a misdirected direct deposit refund is defined as any refund of an overpayment of tax that is disbursed as a direct deposit but is not deposited into the account designated on the claim for refund to receive the direct deposit refund. This typically occurs when the IRS mistakenly inputs an incorrect account or routing number from the claim for refund, usually as a result of a processing or computer error. A misdirected direct deposit refund can also occur if a financial institution mistakenly credits the payment to an account other than the account designated in the IRS's direct deposit instruction. These proposed regulations are intended to serve taxpayers as part of the IRS's mission to provide top quality service by increasing awareness of the IRS procedures taxpayers may use to report missing direct deposit refunds and to streamline the identification and recovery of misdirected refunds. *See* H.R. Rep. No. 116–39, pt. 1, at 62 (2019) (although this report is for a prior, un-enacted version of the Taxpayer First Act, H.R. 1957, 116th Cong. (2019), section 1407 of that bill and that of the bill that was passed by the same Congress as Public Law 116–25 are identical).

Not all instances where a taxpayer fails to receive a direct deposit in the account designated on the claim for refund are the result of a misdirected direct deposit refund. The requested tax refund may have instead been issued in the form of a paper check or may not have been issued at all if the IRS adjusted the requested refund amount during the processing of the tax return or offset the requested tax refund to pay certain debts. In some scenarios, the refund is disbursed as a direct deposit, but is not deposited into the account in which the taxpayer expects the refund to be deposited. This includes instances of tax return preparer misconduct and taxpayers designating an incorrect account or routing number on the claim

for refund. There are no significant variances between the proposed regulations and current I.R.M. procedures with regards to refunds that are deposited into the accounts designated on the claims for refund which are ultimately not received by the taxpayer.

The proposed regulations include in the definition of a misdirected direct deposit refund only those refunds which are actually issued as a direct deposit. A misdirected direct deposit refund therefore does not include an overpayment that is credited against another outstanding tax liability of the taxpayer pursuant to section 6402(a) or that is offset pursuant to the law. A refund that is offset or applied as mandated by law is not a misdirected direct deposit refund because these actions are mandated by law.

A refund issued as a check is not a misdirected direct deposit refund merely because the taxpayer requested the refund in the form of a direct deposit. Under current procedures, there are many reasons why a requested direct deposit will be issued as a paper check, including if the financial institution rejects or returns the direct deposit or the claim for refund is filed more than a year after the close of the tax year. Additional information on reasons why a direct deposit may be rejected can be found in I.R.M. 21.4.1.5.8.1, Direct Deposit Reject Reason Codes. If a refund is issued as a check, the taxpayer may then deposit the refund into the correct account.

II. Reporting

Section 301.6402–2(g)(2) of the proposed regulations designates the method of reporting a misdirected direct deposit refund. Under current procedures, taxpayers may submit Form 3911 to the IRS to report a missing refund. The Form 3911, including any future version of the Form, should be filed in accordance with the instructions provided. Alternatively, a taxpayer may report a missing refund orally through an IRS customer service line. If the IRS is unable to verify the identity of the caller through oral statements, the taxpayer may have to submit a written request on the Form 3911 to report a missing refund. Taxpayers may also report a missing refund, after scheduling an appointment, through submission of the Form 3911 in person at a Taxpayer Assistance Center. Where a taxpayer is experiencing a hardship, the taxpayer may report a missing refund to TAS by telephone, facsimile, mail or in person.

The proposed regulations direct taxpayers to use current procedures, including by allowing missing direct deposit refunds to be reported via Form 3911, a customer service line, TAS, and at Taxpayer Assistance Centers. This continuity aids in administering the refund procedures by using processes with which the public and the IRS are familiar. Any taxpayer missing a refund or a portion of a refund made by direct deposit may use the reporting procedures set out in § 301.6402–2(g)(2) of the proposed regulations. If the IRS determines a direct deposit was issued, it will initiate a refund trace for any missing refund in accordance with the procedures set out in § 301.6402–2(g)(3) of the proposed regulations.

III. Coordination With Financial Institutions

Under current procedures, the IRS coordinates with the BFS as well as financial institutions to locate and recover misdirected direct deposit refunds. When a taxpayer reports a missing direct deposit refund, the IRS will review its records to determine if a refund was issued or if there are indicators on the account signifying that an offset may have occurred. If the IRS determines that a refund was issued as a direct deposit, the IRS will initiate a refund trace, which sends a refund trace inquiry to the BFS. The BFS sends an official request on FS Form 150.1 to the financial institution to search for the electronic funds transfer. FS Form 150.1 requests the financial institution to identify the account into which the refund was made, as well as the identifying information of the account holder, including name and Social Security number.

The refund trace will ask for the assistance of the financial institution in the recovery of the refund if the refund was deposited into an account in error. If the financial institution is unable or unwilling to recover the refund, the IRS will separately contact the financial institution to request assistance in recovering the refund. The financial institution may return the refund through the procedures determined by the BFS. *See* Bureau of the Fiscal Service, Green Book: A Guide to Federal Government ACH Payments (2016). If the refund is recovered, a credit will be added to the taxpayer's account to reflect the return of the refund.

Section 301.6402–2(g)(3) of the proposed regulations formalizes current procedures. Where a direct deposit has been misdirected, this section of the regulations proposes to require the IRS to contact banks through the BFS to obtain the information necessary to identify whether the financial institution received the refund and the owner of the deposit account to whom the deposit was disbursed. The regulations further direct the IRS to utilize either BFS procedures or directly seek the assistance of the bank holding the misdirected direct deposit refund to recover the amount.

IV. Delivery of the Refund to the Correct Account

Section 301.6402–2(g)(4) of the proposed regulations establishes that when a misdirected direct deposit refund has been identified by the IRS, the IRS will issue a replacement refund in the full amount of the refund that was misdirected. The refund will generally be issued as soon as possible to make the taxpayer whole and limit credit interest. When a financial institution has indicated that a misdirected direct deposit refund will be returned to the IRS, the IRS generally issues a replacement refund after the misdirected refund is returned. The timing of the replacement refund is calculated to ensure that a replacement refund is not issued twice as a result of a returned refund being credited back to a taxpayer's account after a replacement refund has already been issued, resulting in an erroneous refund to the taxpayer. An erroneous refund is defined as the receipt of any money from the IRS to which the recipient is not entitled.

A replacement refund will generally be issued as a paper check, which the taxpayer may deposit into the correct account. The IRS is generally unable to change the account information for a direct deposit after the information has been input. For example, where the IRS has determined the refund is a misdirected direct deposit refund because it mistakenly input the account number from a claim for refund, the IRS usually cannot correct the incorrect account number. Thus, the taxpayer will receive the refund as a paper check. The check will be sent via postal service to the address listed on the master file. If the taxpayer updates their address through the Form 3911, the check will be mailed to the updated address.

In some limited instances, such as when TAS has worked with a taxpayer to establish hardship criteria, a replacement refund may be issued as a direct deposit. In general, however, to effectively administer the issuance of a replacement refund, the taxpayer will receive the refund in the form of a check. The taxpayer may then deposit the check into the proper account.

V. Application of Procedures to Missing Refunds

Section 301.6402–2(g)(5) of the proposed regulations provides that the

reporting and coordination procedures found in § 301.6402–2(g)(2) through (3)(i) of the proposed regulations for misdirected direct deposit refunds should be used for any refund issued as a direct deposit that the taxpayer believes is missing. As with a misdirected direct deposit refund, once a refund is reporting as missing the IRS will coordinate with the BFS to track the missing refund and gather available information about the account into which the refund was deposited. Section 301.6402–2(g)(5) of the proposed regulations also provides that if a missing refund or a portion of a refund is returned to the IRS resulting in an overpayment on the taxpayer's account, the IRS will issue a refund in accordance with the law. As with a misdirected direct deposit refund, such overpayment may be credited against a federal tax liability or offset against certain non-tax liabilities prior to the issuance of a refund.

Proposed Applicability Date

The applicability date for these proposed regulations applies to claims for refund filed after the date final regulations are published in the **Federal Register**.

Special Analyses

This regulation is not subject to review under section 6(b) of Executive Order 12866 pursuant to the Memorandum of Agreement (April 11, 2018) between the Department of the Treasury and the Office of Management and Budget regarding review of tax regulations.

These proposed regulations do not impose any additional information collection requirements in the form of reporting, recordkeeping requirements, or third-party disclosure requirements related to tax compliance. However, because a taxpayer or a taxpayer's representative may elect to report a missing refund using the procedures described in proposed § 301.6402–2(g)(2)(ii)(B), some taxpayers may use a form to report a missing refund. The collection of information in proposed § 301.6402–2(g)(2)(ii)(B) is through use of a Form 3911, ''Taxpayer Statement Regarding Refund,'' and is the sole collection of information requirement established by the proposed regulations.

For the purposes of the Paperwork Reduction Act, 44 U.S.C. 3501–3520, the reporting burden associated with the collection of information with respect to section 6402(n) will be reflected in Paperwork Reduction Act submissions for IRS Form 3911 (OMB Control Number 1545–1384). The estimated average time to complete Form 3911 is five minutes. However, use of a form is not required. A taxpayer may instead elect to investigate a missing refund over the telephone or in person at a Taxpayer Assistance Center and, after the IRS identifies the tax refund and informs the taxpayer that the refund was issued as a direct deposit, orally report that the already-identified refund is missing. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by the Office of Management and Budget.

It is hereby certified that these proposed regulations will not have a significant economic impact on a substantial number of small entities within the meaning of section 601(6) of the Regulatory Flexibility Act (5 U.S.C. chapter 6). The certification is based on the information that follows. There is no significant impact from these regulations on any small entity utilizing the procedures prescribed by these regulations to report a missing refund because there is no significant cost associated with reporting a missing refund. There is no fee charged in connection with reporting a missing refund, and the estimated time to complete a Form 3911, ''Taxpayer Statement Regarding Refund,'' is five minutes. There are no tax consequences associated with the proposed regulations, as it merely sets forth the procedures for reporting a missing refund and describes the process the IRS uses in locating a missing refund and, in some instances, issuing a replacement refund. The process in these proposed regulations mirrors the existing process and does not change the reporting burden. Accordingly, this regulation is not expected to have a significant economic impact on a substantial number of small entities. Pursuant to section 7805(f) of the Code, this notice of proposed rulemaking will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business entities. The Treasury Department and the IRS invite comments on any impact these proposed regulations would have on small business entities.

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a final rule that includes any Federal mandate that may result in expenditures in any one year by a state, local, or tribal government, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. In 2018, that threshold is approximately $150 million. This rule does not include any Federal mandate that may result in expenditures by state, local, or tribal governments, or by the private sector in excess of that threshold.

Executive Order 13132 (entitled Federalism) prohibits an agency from publishing any rule that has federalism implications if the rule either imposes substantial, direct compliance costs on state and local governments, and is not required by statute, or preempts state law, unless the agency meets the consultation and funding requirements of section 6 of the Executive Order. This proposed rule does not have federalism implications, and does not impose substantial direct compliance costs on state and local governments or preempt state law, within the meaning of the Executive Order.

Comments and Requests for a Public Hearing

Before these proposed amendments to the regulations are adopted as final regulations, consideration will be given to any comments that are submitted timely to the IRS as prescribed in the preamble under the **ADDRESSES** section. The Treasury Department and the IRS request comments on all aspects of the proposed regulations. All comments submitted will be made available at *http://www.regulations.gov* or upon request. A public hearing will be scheduled if requested in writing by any person that timely submits written comments. If a public hearing is scheduled, then notice of the date, time, and place for the public hearing will be published in the **Federal Register**.

Drafting Information

The principal author of these regulations is Mary C. King of the Office of the Associate Chief Counsel (Procedure and Administration). Other personnel from the Treasury Department and the IRS participated in the development of the regulations.

List of Subjects in 26 CFR Part 301

Employment taxes, Estate taxes, Excise taxes, Gift taxes, Income taxes, Penalties, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 301 is proposed to be amended as follows:

PART 301—PROCEDURE AND ADMINISTRATION

■ **Paragraph 1.** The authority citation for part 301 is amended by adding

entries in numerical order to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

* * * * *

Section 301.6402–2(g) also issued under section 6402(n).

* * * * *

■ **Par. 2.** Section 6402–2 is amended by:

■ 1. Redesignating paragraph (g) as paragraph (h) and adding new paragraph (g).

■ 2. Revising the paragraph heading of newly redesignated paragraph (h) and adding a sentence at the end of the paragraph.

The additions and revisions read as follows:

§ 301.6402–2 Claims for credit or refund.

* * * * *

(g) *Misdirected direct deposit refund*—(1) *Definition.* The term *misdirected direct deposit refund* includes any refund of an overpayment of tax that is disbursed as a direct deposit but is not deposited into the account designated on the claim for refund to receive the direct deposit refund. A misdirected direct deposit refund does not include any amount that is credited or offset pursuant to the law in effect immediately prior to the direct deposit being disbursed.

(2) *Procedures for reporting a misdirected direct deposit refund*—(i) *In general.* A taxpayer or a taxpayer's authorized representative may report to the IRS that the taxpayer never received a direct deposit refund and request a replacement refund. The report must include the name of the taxpayer who requested the refund, the taxpayer identification number of the taxpayer, the taxpayer's mailing address, the type of return to which the refund is related, the account number and routing number that the taxpayer requested the refund be directly deposited into, and any other information necessary to locate the misdirected direct deposit refund.

(ii) *How to report a misdirected direct deposit refund.* A reporting described in paragraph (g)(2)(i) of this section may be made in the following ways:

(A) By calling the IRS;

(B) On the form prescribed by the IRS and in accordance with the applicable publications, instructions, or other appropriate guidance;

(C) By contacting the Office of the Taxpayer Advocate by telephone, by mail, facsimile, or in person; or

(D) By submitting the appropriate form in person at a Taxpayer Assistance Center.

(3) *Procedures for coordination with financial institutions*—(i) *Identification of the account that received the misdirected direct deposit refund.* If the IRS receives a report described in paragraph (g)(2)(ii) of this section and confirms that the refund described in the report was issued as a direct deposit, the IRS will initiate a refund trace to request the assistance of the Department of the Treasury's Bureau of the Fiscal Service. In accordance with its own procedures, the Bureau of the Fiscal Service coordinates with the financial institution that holds directly or indirectly the deposit account into which the refund was made, requesting from the financial institution such information as is necessary to identify whether the financial institution received the refund; whether the financial institution returned, or will return, the refund to the IRS, or if no funds are available for return; whether a deposit was made into the account designated on the claim for refund; and the identity of the deposit account owner to whom the deposit was disbursed.

(ii) *Coordination to recover the amounts transferred.* Recovery of the misdirected direct deposit refund from a financial institution shall follow the procedures established by the Bureau of the Fiscal Service. The Bureau of the Fiscal Service shall request the return of the misdirected direct deposit refund from the financial institution that received it. The IRS may contact the financial institution directly to recover the misdirected direct deposit refund.

(4) *Issuance of replacement refund.* When the IRS has determined that a misdirected direct deposit refund has occurred, the IRS will issue a replacement refund in the full amount of the refund that was misdirected. The replacement refund may be issued as a direct deposit or as a paper check sent to the taxpayer's last known address.

(5) *Applicability of this paragraph (g) to missing refunds.* The provisions of paragraphs (g)(2) through (3)(i) of this section should be used for any refund that was disbursed as a direct deposit and that the taxpayer reports as missing. For example, although a refund that was deposited into an incorrect bank account because the taxpayer transposed two digits in their bank account number is not considered to be a misdirected direct deposit refund, the provisions of paragraphs (g)(2) through (3)(i) of this section should be used. If the application of these procedures results in an amount recovered by the IRS, the recovered amount will be refunded or credited as allowed by law.

* * * * *

(h) *Applicability dates.* * * * Paragraph (g) of this section applies to claims for refund filed after [DATE THE FINAL REGULATIONS ARE PUBLISHED IN THE **Federal Register**].

Sunita Lough,

Deputy Commissioner for Services and Enforcement.

[FR Doc. 2019–27653 Filed 12–19–19; 4:15 pm]

BILLING CODE 4830–01–P

POSTAL REGULATORY COMMISSION

39 CFR Part 3017

[Docket No. RM2020–3; Order No. 5353]

Procedures Related to Commission Views

AGENCY: Postal Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Commission proposes revisions to its rules related to the Commission's process for developing views submitted to the Secretary of State on certain international mail matters. The Commission invites public comment on the propose rules.

DATES: *Comments are due:* January 22, 2020.

ADDRESSES: For additional information, Order No. 5353 can be accessed electronically through the Commission's website at *https://www.prc.gov.* Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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I. Relevant Statutory Requirements
II. Background
III. Basis and Purpose of Proposed Rules
IV. Proposed Rules

I. Relevant Statutory Requirements

Section 407(c)(1) of title 39 of the United States Code requires that the Secretary of State, before concluding a treaty, convention, or amendment establishing a market dominant rate or classification, request the Commission's views on the consistency of such rate or classification with the modern rate-setting criteria of 39 U.S.C. 3622. Commission views entail the review and analysis of numerous proposals from the UPU or its member countries, which are typically posted on the UPU website pursuant to a series of deadlines that

begin about 6 months before a Congress convenes.

II. Background

In Docket No. RM2015–14, the Commission adopted rules formalizing its procedures related to Commission views submitted pursuant to 39 U.S.C. 407(c)(1).[1] The adopted rules reflected the Commission's commitment to both transparency and improved public accessibility by establishing dockets that informed the public about the availably of relevant proposals, Commission views, and other related documents, and by allowing all documents to be incorporated into one comprehensive record.

III. Basis and Purpose of Proposed Rules

In the years since the procedures related Commission views were established, the Commission has participated in both traditional UPU Congresses as well as two extraordinary Congresses. In light of that experience, the Commission is proposing minor improvements to enhance transparency and accountability within the Commission views process as well as to improve the accessibility of relevant proposals, Commission views, and related documents. The proposed rules make clarifying changes that are intended to better reflect the Commission's procedures related to the posting of relevant proposals and Commission views.

IV. Proposed Rules

List of Subjects for 39 CFR Part 3017

Administrative practice and procedure, Postal Service, Treaties.

For the reasons stated in the preamble, the Commission proposes to amend chapter III of title 39 of the Code of Federal Regulations as follows:

■ 1. Revise part 3017 to read as follows:

PART 3017—PROCEDURES RELATED TO COMMISSION VIEWS

Sec.
3017.1 Definitions in this part.
3017.2 Purpose.
3017.3 Establishment and scope of docket.
3017.4 Comment deadline(s).
3017.5 Issuance of Commission views.

Authority: 39 U.S.C. 407; 503.

§ 3017.1 Definitions in this part.

(a) *Commission views* refers to the opinion the Commission provides to the Secretary of State pursuant to 39 U.S.C. 407(c)(1) on the consistency of a relevant proposal with modern rate regulation.

(b) *Modern rate regulation* refers to the standards and criteria the Commission has established pursuant to 39 U.S.C. 3622.

(c) *Relevant proposal* means a proposed change to a treaty, convention, or amendment that establishes a market dominant rate or classification.

§ 3017.2 Purpose.

The rules in this part are intended to facilitate public participation in, and promote the transparency of, the development of Commission views.

§ 3017.3 Establishment and scope of docket.

(a) On or about 150 days before a Universal Postal Union Congress convenes or such advance time as the Commission determines for any other 39 U.S.C. 407(c)(1) matter, the Commission shall establish a docket in order to solicit public comments as part of the development of Commission views.

(b) The Commission shall post relevant proposals in the applicable docket established pursuant to paragraph (a) of this section and may also include other materials related to the development of Commission views, such as other documents or related actions.

(c) Public comments should focus on the specific relevant proposals posted by the Commission and the general principles that should guide the development of Commission views as well as any other materials posted in the applicable docket pursuant to paragraph (b) of this section.

(d) The Commission shall arrange for publication in the **Federal Register** of the notice establishing each docket authorized under this part.

§ 3017.4 Comment deadline(s).

(a) The Commission shall establish a deadline for comments upon establishment of the docket that is consistent with timely submission of Commission views to the Secretary of State. The Commission may establish other deadlines for comments as appropriate.

(b) The Commission may suspend or forego solicitation of comments if it determines that such solicitation is not consistent with timely submission of Commission views to the Secretary of State.

§ 3017.5 Commission views.

(a) The Commission will review timely filed comments responding to a Commission solicitation pursuant to § 3017.3(a) prior to submitting its views to the Secretary of State.

(b) After Commission views are developed, the Commission shall post Commission views in the applicable docket established pursuant to § 3017.3(a) and submit Commission views to the Secretary of State pursuant to 39 U.S.C. 407(c)(1).

By the Commission.

Ruth Ann Abrams,

Acting Secretary.

[FR Doc. 2019–27604 Filed 12–20–19; 8:45 am]

BILLING CODE 7710–FW–P

[1] *See generally,* Docket No. RM2015–14, Order Adopting Final Rules on Procedures Related to Commission Views, December 20, 2015 (Order No. 2960).

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 320

[EPA–HQ–OLEM–2019–0087; FRL–10003–10–OLEM]

RIN 2050–AH06

Financial Responsibility Requirements Under CERCLA Section 108(b) for Facilities in the Petroleum and Coal Products Manufacturing Industry

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA (or the Agency) is proposing to not impose financial responsibility requirements for facilities in the Petroleum and Coal Products Manufacturing industry under Section 108(b) of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). Section 108(b) addresses the promulgation of regulations that require classes of facilities to establish and maintain evidence of financial responsibility consistent with the degree and duration of risk associated with the production, transportation, treatment, storage, or disposal of hazardous substances.

DATES: Comments must be received on or before February 21, 2020.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OLEM–2019–0087, at *http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written

comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the Web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: For more information on this document, contact Charlotte Mooney, U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery, Mail Code 5303P, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone (703) 308–7025 or (email) *mooney.charlotte@epa.gov.*

SUPPLEMENTARY INFORMATION:

How can I get copies of this document and other related information?

This **Federal Register** proposed rule and supporting documentation are available in a docket EPA has established for this action under Docket ID No. EPA–HQ–OLEM–2019–0087. All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically at *http://www.regulations.gov* or in hard copy at EPA/DC, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC 20460. This Docket Facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (202) 566–0276. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744.

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I. Executive Summary

A. Overview

Section 108(b) of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) directs EPA to develop regulations that require classes of facilities to establish and maintain evidence of financial responsibility consistent with the degree and duration of risk associated with the production, transportation, treatment, storage, or disposal of hazardous substances. The statute further requires that the level of financial responsibility be established to protect against the level of risk the President, in his discretion, believes is appropriate, based on factors including the payment experience of the Hazardous Substance Superfund (Fund). The President's authority under this section for non-transportation-related facilities has been delegated to the EPA Administrator.

This proposal is based on EPA's interpretation of the statute and analysis of its record developed for this rulemaking.[1] EPA has analyzed the need for financial responsibility based on risk of taxpayer funded cleanups at facilities in the Petroleum and Coal Products Manufacturing Industry operating under modern management practices and modern environmental regulations, *i.e.,* the type of facilities to which financial responsibility regulations would apply.

That risk is identified by examining the management of hazardous substances at such facilities, as well as by examining Federal and state regulatory controls on that management and Federal and state financial responsibility requirements.

Based on that examination, EPA is proposing that, in the context of CERCLA Section 108(b), the degree and duration of risk associated with the modern production, transportation, treatment, storage or disposal of hazardous substances by the Petroleum and Coal Products Manufacturing Industry does not present a level of risk of taxpayer funded response actions that warrant imposition of financial responsibility requirements for this sector.

In August 2014, the Idaho Conservation League, Earthworks, Sierra Club, Amigos Bravos, Great Basin Resource Watch, and Communities for a Better Environment filed a lawsuit in the U.S. Court of Appeals for the District of Columbia Circuit, seeking a writ of mandamus requiring issuance of CERCLA Section 108(b) financial responsibility rules for the hardrock mining industry, and for the three additional industries identified by EPA in the 2010 Advance Notice of Proposed Rulemaking (ANPRM),[2] that is, Chemical Manufacturing; Petroleum and Coal Products Manufacturing; and Electric Power Generation, Transmission, and Distribution. Following oral arguments, EPA and the

[1] EPA's interpretation of the statute was upheld by the D.C. Circuit in *Idaho Conservation League* v. *Wheeler,* No. 18–1141, slip op. at 9–12 (D.C. Cir. July 19, 2019).

[2] 75 FR 816 (Jan. 6, 2010).

petitioners submitted a Joint Motion for an Order on Consent, filed on August 31, 2015, which included a schedule for further administrative proceedings under CERCLA Section 108(b). The court order granting the motion was issued on January 29, 2016. A copy of the order can be found in the docket for this rulemaking.

In addition to requiring EPA to publish a proposed rule on hardrock mining financial requirements by December 1, 2016, the January 2016 Order required EPA to sign for publication in the **Federal Register** a determination whether EPA will issue a notice of proposed rulemaking on financial assurance requirements under Section 108(b) in the (a) chemical manufacturing industry; (b) petroleum and coal products manufacturing industry; and (c) electric power generation, transmission, and distribution industry by December 1, 2016. EPA signed the required determination on December 1, 2016; the notice was published on January 11, 2017,[3] and announced EPA's intent to proceed with rulemakings for all three of the classes.

B. Purpose of This Action

The purpose of today's action is to propose that financial responsibility requirements under CERCLA Section 108(b) at facilities in the Petroleum and Coal Products Manufacturing industry are not necessary, and to solicit comments on this proposal. EPA has reached this conclusion based on the analyses described in Parts VI and VII of this proposal. The evidence provided in these analyses contributed to EPA's proposed finding that the degree and duration of risk posed by the Petroleum and Coal Products Manufacturing industry does not warrant financial responsibility requirements under CERCLA Section 108(b).

The analysis and proposed finding in this proposal are not applicable to and do not affect, limit, or restrict EPA's authority (1) to take a response action or enforcement action under CERCLA with respect to any facility in the Petroleum and Coal Products Manufacturing industry, including any currently operating facilities or those described in this proposal and in the background documents for this proposal, and (2) to include requirements for financial responsibility as part of such response action. The set of facts in the rulemaking record related to the individual facilities discussed in this proposed rulemaking support the Agency's proposal not to issue financial responsibility requirements under Section 108(b) for this class. At the same time, a different set of facts could demonstrate a need for a CERCLA response action at an individual site. This proposed rulemaking also does not affect the Agency's authority under other authorities that may apply to individual facilities, such as the Clean Air Act (CAA), the Clean Water Act (CWA), the Resource Conservation and Recovery Act (RCRA), and the Toxic Substances Control Act (TSCA).

C. Summary of the Major Provisions of the Regulatory Action

EPA is proposing to not require evidence of financial responsibility under CERCLA Section 108(b) at facilities in the Petroleum and Coal Products Manufacturing industry. Thus, there are no proposed regulatory provisions associated with this action.

D. Costs and Benefits of the Regulatory Action

EPA is proposing to not require evidence of financial responsibility under CERCLA Section 108(b) at facilities in the Petroleum and Coal Products Manufacturing industry. EPA, therefore, has not conducted a Regulatory Impact Analysis for this action.

II. Authority

This proposed rule is issued under the authority of Sections 101, 104, 108 and 115 of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended, 42 U.S.C. 9601, 9604, 9608 and 9615, and Executive Order 12580 (52 FR 2923, January 29, 1987).

III. Background Information

A. Overview of Section 108(b) and Other CERCLA Provisions

CERCLA, as amended by the Superfund Amendments and Reauthorization Act of 1986 (SARA), establishes a comprehensive environmental response and cleanup program. Generally, CERCLA authorizes EPA[4] to undertake removal or remedial actions in response to any release or threatened release into the environment of ''hazardous substances'' or, in some circumstances, any other ''pollutant or contaminant.'' As defined in CERCLA Section 101, removal actions include actions to ''prevent, minimize, or mitigate damage to the public health or welfare or to the environment,'' and remedial actions are ''actions consistent with [a] permanent remedy[.]'' Remedial and removal actions are jointly referred to as ''response actions.'' CERCLA Section 111 authorizes the use of the Hazardous Substance Superfund established under title 26, United States Code, to finance response actions undertaken by EPA. In addition, CERCLA Section 106 gives EPA[5] authority to compel action by liable parties in response to a release or threatened release of a hazardous substance that may pose an ''imminent and substantial endangerment'' to public health or welfare or the environment.

CERCLA Section 107 imposes liability for response costs on a variety of parties, including certain past owners and operators, current owners and operators, and certain generators, arrangers, and transporters of hazardous substances. Such parties are liable for certain costs and damages, including all costs of removal or remedial action incurred by the Federal Government, so long as the costs incurred are ''not inconsistent with the national contingency plan'' (the National Oil and Hazardous Substances Pollution Contingency Plan or NCP).[6] Section 107 also imposes liability for natural resource damages and health assessment costs.[7]

Section 108(b) establishes authority to require owners and operators of classes of facilities to establish and maintain evidence of financial responsibility. Section 108(b)(1) directs EPA to develop regulations requiring owners and operators of facilities to establish evidence of financial responsibility ''consistent with the degree and duration of risk associated with the production, transportation, treatment, storage, or disposal of hazardous substances.'' In turn, Section 108(b)(2) directs that the level of financial responsibility shall be initially established, and, when necessary, adjusted, to protect against the level of risk that EPA in its discretion believes is appropriate based on the payment experience of the Fund, commercial insurers, court settlements and judgments, and voluntary claims satisfaction. Section 108(b)(2) does not, however, preclude EPA from considering other factors in addition to those specifically listed. The statute

[3] 82 FR 3512 (Jan. 11, 2017).

[4] Although Congress conferred the authority for administering CERCLA on the President, most of that authority has since been delegated to EPA. *See* Exec. Order No. 12580, 52 FR 2923 (Jan. 23, 1987). The executive order also delegates to other Federal agencies specified CERCLA response authorities at certain facilities under those agencies' ''jurisdiction, custody or control.''

[5] CERCLA Sections 106 authority is also delegated to other Federal agencies in certain circumstances. *See* Exec. Order No. 13016, 61 FR 45871 (Aug. 28, 1996).

[6] CERCLA Section 107(a)(4)(A).

[7] CERCLA Section 107(a)(4)(C)–(D).

prohibited promulgation of such regulations before December 1985.

In addition, Section 108(b)(1) provides for publication within three years of the date of enactment of CERCLA of a ''priority notice'' identifying the classes of facilities for which EPA would first develop financial responsibility requirements. It also directs that priority in the development of requirements shall be accorded to those classes of facilities, owners, and operators that present the highest level of risk of injury.

B. History of Section 108(b) Rulemakings

1. 2009 Identification of Priority Classes of Facilities for Development of CERCLA Section 108(b) Financial Responsibility Requirements

On March 11, 2008, Sierra Club, Great Basin Resource Watch, Amigos Bravos, and Idaho Conservation League filed suit in the U.S. District Court for the Northern District of California against then EPA Administrator Stephen Johnson and then Secretary of the U.S. Department of Transportation Mary E. Peters. *Sierra Club, et al.* v. *Johnson*, No. 08–01409 (N. D. Cal.). On February 25, 2009, that court ordered EPA to publish the Priority Notice required by CERCLA Section 108(b)(1) later that year. The 2009 Priority Notice and supporting documentation presented the Agency's conclusion that hardrock mining facilities would be the first class of facilities for which EPA would issue CERCLA Section 108(b) requirements.[8] Additionally, the 2009 Priority Notice stated EPA's view that classes of facilities outside of the hardrock mining industry may warrant the development of financial responsibility requirements.[9] The Agency committed to gather and analyze data on additional classes of facilities and to consider them for possible regulation. The court later dismissed the remaining claims.

2. Additional Classes 2010 Advance Notice of Proposed Rulemaking

On January 6, 2010, EPA published an Advance Notice of Proposed Rulemaking (ANPRM)[10] in which the Agency identified three additional industrial sectors for the development, as necessary, of proposed Section 108(b) regulation. To develop the list of additional classes for the 2010 ANPRM, EPA used information from the CERCLA National Priorities List (NPL) and analyzed data from the RCRA Biennial Report (BR) and the Toxics Release Inventory (TRI).

EPA specifically requested public comment in the 2010 ANPRM on whether to propose a regulation under CERCLA Section 108(b) for each of the three industries, or any class or classes within those industries, including information demonstrating why such financial responsibility requirements would or would not be appropriate for those particular classes. In addition, the Agency requested information related to the industry categories discussed in the ANPRM, including data on facility operations, information on past and expected future environmental response actions, use of financial responsibility mechanisms by the industry categories, existing financial responsibility requirements, and other information the Agency might consider in setting financial responsibility levels. Finally, EPA requested information from the insurance and financial sectors related to instrument availability and implementation and to potential instrument conditions.[11] Comments received on the ANPRM are summarized in the Additional Classes 2017 Notice of Intent to Proceed with Rulemakings, section III.B.4 below.

3. 2014 Petition for Writ of Mandamus

In August 2014, the Idaho Conservation League, Earthworks, Sierra Club, Amigos Bravos, Great Basin Resource Watch, and Communities for a Better Environment filed a new lawsuit in the U.S. Court of Appeals for the District of Columbia Circuit, seeking a writ of mandamus requiring issuance of CERCLA Section 108(b) financial assurance rules for the hardrock mining industry and for three other industries: Chemical manufacturing; petroleum and coal products manufacturing; and electric power generation, transmission, and distribution. Thirteen companies and organizations representing business interests in the hardrock mining and other sectors sought to intervene in the case.

Following oral argument, the court issued an Order in May 2015 requiring the parties to submit, among other things, supplemental submissions addressing a schedule for further administrative proceedings under CERCLA Section 108(b). Petitioners and EPA requested an Order from the court with a schedule calling for the Agency to sign a proposed rule for the hardrock mining industry by December 1, 2016, and a final rule by December 1, 2017. The joint motion also included a requested schedule for the additional industry classes, which called for EPA to sign by December 1, 2016, a determination on whether EPA would issue a notice of proposed rulemaking for classes of facilities in any or all of the other industries, and a schedule for proposed and final rules for the additional industry classes as follows:

> EPA will sign for publication in the **Federal Register** a notice of proposed rulemaking in the first additional industry by July 2, 2019, and sign for publication in the **Federal Register** a notice of its final action by December 2, 2020.
>
> EPA will sign for publication in the **Federal Register** a notice of proposed rulemaking in the second additional industry by December 4, 2019, and sign for publication in the **Federal Register** a notice of its final action by December 1, 2021.
>
> EPA will sign for publication in the **Federal Register** a notice of proposed rulemaking in the third additional industry by December 1, 2022, and sign for publication in the **Federal Register** a notice of its final action by December 4, 2024.[12]

While the joint motion identified the three additional industries as the Chemical Manufacturing industry, the Petroleum and Coal Products Manufacturing industry, and the Electric Power Generation, Transmission and Distribution industry, and set a rulemaking schedule, the motion did not indicate which industry would be the first, second or third. The Joint Motion specified that it did not alter the Agency's discretion as provided by CERCLA and administrative law.[13]

On January 29, 2016, the court granted the joint motion and issued an order that mirrored the submitted schedule in substance. The order did not mandate any specific outcome of the rulemakings.[14] The order can be found in the docket for this rulemaking. The signing of this proposed rule by December 4, 2019, will satisfy one component of the order.

4. Additional Classes 2017 Notice of Intent To Proceed With Rulemakings

Consistent with the January 2016 court order, EPA signed on December 1, 2016, a determination regarding

[8] 74 FR 37214 (July 28, 2009).

[9] Id. at 37218.

[10] 75 FR 816 (Jan. 6, 2010).

[11] 75 FR 816, 830–831 (Jan. 6, 2010).

[12] *In Re: Idaho Conservation League,* No. 14–1149 (D.C. Cir. Jan. 29, 2016) (order granting joint motion).

[13] *See* Joint Motion at 6 (''Nothing in this Joint Motion should be construed to limit or modify the discretion accorded EPA by CERCLA or the general principles of administrative law'').

[14] In granting the Joint Motion, the court expressly stated that its Order ''merely requires that EPA conduct a rulemaking and then decide whether to promulgate a new rule—the content of which is not in any way dictated by the [Order].'' *In re Idaho Conservation League,* at 17 (quoting *Defenders of Wildlife* v. *Perciasepe,* 714 F.3d 1317, 1324 (D.C. Cir. 2013).

rulemakings for the additional classes—a Notice of Intent to Proceed with Rulemakings for all three of the classes. The notice was published in the **Federal Register** on January 11, 2017.[15]

The notice formally announced EPA's intention to move forward with the regulatory process and to publish a notice of proposed rulemaking for classes of facilities within the three industries identified in the 2010 ANPRM. The announcement in the notice was not a determination that requirements were necessary for any or all of the classes of facilities within the three industries, or that EPA would propose such requirements. In addition, the notice gave an overview of some of the comments received on the 2010 ANPRM and initial responses to those comments. The comments on the ANPRM which specifically addressed the need for CERCLA Section 108(b) regulation for the three additional classes fell into four categories: (1) Other laws with which the industry complies that obviate the need for CERCLA Section 108(b) regulation; (2) the sources of data that EPA used to select the industries; (3) past versus current practices within each industry; and (4) the overall need for financial responsibility for each industry. In discussing the ANPRM comments in the 2017 notice, the Agency stated its intent to use other, more industry-specific and more current sources of data to identify risk; to consider site factors that reduce risks, including those that result from compliance with other regulatory requirements; and to develop a regulatory proposal for each rulemaking.

At the time of the 2017 notice, EPA had not identified sufficient evidence to determine that the rulemaking process was not warranted, nor had EPA identified sufficient evidence to establish CERCLA Section 108(b) requirements. The notice described a process to gather and analyze additional information to support the Agency's ultimate decision, including further evaluation of the classes of facilities within the three industry sectors. The notice stated that EPA would decide whether proposing requirements was necessary and, accordingly, that EPA would propose appropriate requirements or would propose not to impose requirements.

5. CERCLA Section 108(b) Proposal for Facilities in the Electric Power Generation, Transmission, and Distribution Industry

On July 29, 2019, EPA published a notice of proposed rulemaking on the first of the three additional industries. In that notice, the Agency proposed to not impose financial responsibility requirements for the Electric Power Generation, Transmission, and Distribution industry and described the analyses and results that were used to reach that decision. The court's January 2016 order requires that a final action on the first additional industry be signed by December 2, 2020.[16]

IV. Statutory Interpretation

CERCLA Section 108(b) provides general instructions on how to determine what financial responsibility requirements to impose for a particular class of facility. Section 108(b)(1) directs EPA to develop regulations requiring owners and operators of facilities to establish evidence of financial responsibility ''consistent with the degree and duration of risk associated with the production, transportation, treatment, storage, or disposal of hazardous substances.'' Section 108(b)(2) directs that the ''level of financial responsibility shall be initially established and, when necessary, adjusted to protect against the level of risk'' that EPA ''believes is appropriate based on the payment experience of the Fund, commercial insurers, court settlements and judgments, and voluntary claims satisfaction.'' EPA interprets the risk to be addressed by financial assurance under Section 108(b) to be the risk of the need for taxpayer financed response actions. Read together, the statutory language on determining the degree and duration of risk and on setting the level of financial responsibility confers a significant amount of discretion on EPA.

Section 108(b)(1) directs EPA to evaluate risk from a selected class of facilities, but it does not suggest that a precise calculation of risk is either necessary or feasible. Although the cost of response associated with a particular site can be ascertained only once a response action is required, any financial responsibility requirements imposed under Section 108(b) would be imposed before any such response action was identified. The statute thus necessarily confers on EPA wide latitude to determine, in a Section 108(b) rulemaking proceeding, what degree and duration of risk are presented by the identified class.

Section 108(b)(2) in turn directs that EPA establish the level of financial responsibility that EPA in its discretion believes is appropriate to protect against the risk. This statutory direction does not specify a methodology for the evaluation. Rather, this decision is committed to the discretion of the EPA Administrator. While the statute provides a list of information sources on which EPA is to base its decision—the payment experience of the Superfund, commercial insurers, court settlements and judgments, and voluntary claims satisfaction—the statute does not indicate that this list of factors is exclusive, nor does it specify how the information from these sources is to be used, such as by indicating how these categories are to be weighted relative to one another.

EPA believes that Sections 108(b)(1) and (b)(2) are sufficiently interrelated that it is appropriate to evaluate the degree and duration of risk under paragraph (b)(1) by considering the factors enumerated in paragraph (b)(2). EPA therefore concludes that Congress intended the risk associated with a particular class of facilities to mean the risk of future Fund-financed cleanup actions in that industry. This reading is supported by the structure of the statute, as Section 108(b) appears between two provisions related to cost recovery. Section 108(a), concerning financial assurance requirements for certain vessels, refers specifically to cleanup costs. And Section 108(c), concerning recovery of costs from guarantors who provide the financial responsibility instruments, refers specifically to liability for cleanup costs. EPA thus reads ''risk'' in Section 108(b) consistent with its meaning in Sections 108(a) and (c); that is, the risk of Fund-financed cleanup. EPA adopted this interpretation in assessing the need for financial responsibility requirements under CERCLA Section 108(b) for facilities in the first class of facilities it evaluated: The hardrock mining industry.[17] In its opinion deciding the challenge to EPA's Final Action for the hardrock mining industry, the U.S. Court of Appeals for the District of Columbia Circuit held that EPA's interpretation—that the provisions of Section 108(b) ''relate only to ensuring against financial risks associated with cleanup costs''—is reasonable and entitled to deference.[18]

For the Petroleum and Coal Products Manufacturing industry, EPA has investigated the payment history of the Fund, and enforcement settlements and judgments, to evaluate, in the context of this CERCLA Section 108(b) rulemaking, the risk of a Fund-financed response action at facilities that would be subject to CERCLA financial responsibility

[15] 82 FR 3512 (Jan. 11, 2017).

[16] 84 FR 36535 (Jul. 29, 2019).

[17] 83 FR 7556, 7561–62 (Feb. 21, 2018).

[18] *Idaho Conservation League* v. *Wheeler,* No. 18–1141, slip op. at 12 (DC Cir. July 19, 2019).

requirements. The statute also authorizes EPA to consider the existence of Federal and state regulatory requirements, including any financial responsibility requirements. Section 108(b)(1) directs EPA to promulgate financial responsibility requirements ''in addition to those under subtitle C of the Solid Waste Disposal Act and other Federal law.'' According to the 1980 Senate Report on legislation that was later enacted as CERCLA, Congress considered it appropriate for EPA to examine those additional requirements when evaluating the degree and duration of risk under what was later enacted as CERCLA Section 108(b):

> ''The bill requires also that facilities maintain evidence of financial responsibility consistent with the degree and duration of risks associated with the production, transportation, treatment, storage, and disposal of hazardous substances. These requirements are in addition to the financial responsibility requirements promulgated under the authority of Section 3004(6) of the Solid Waste Disposal Act. It is not the intention of the Committee that operators of facilities covered by Section 3004(6) of that Act be subject to two financial responsibility requirements for the same dangers.[19]

While the Senate Report mentions RCRA Section 3004(6) specifically, it is consistent with congressional intent for EPA to consider other potentially duplicative Federal financial responsibility requirements when examining the ''degree and duration of risk'' in the context of CERCLA Section 108(b) to determine whether and what financial responsibility requirements are appropriate. It is also consistent with congressional intent for EPA to consider state laws before imposing additional Federal financial responsibility requirements.

Consideration of state laws *before* developing financial responsibility regulations is consistent with CERCLA Section 114(d), which prevents states from imposing financial responsibility requirements for liability for releases of the same hazardous substances *after* a facility is regulated under Section 108 of CERCLA. Just as Congress intended to prevent states from imposing duplicative financial assurance requirements after EPA had acted to impose such requirements under Section 108, it is reasonable to also conclude that Congress did not mean for EPA to disrupt existing state programs that are successfully regulating industrial operations to minimize risk, including the risk of taxpayer liability for response actions under CERCLA, and that specifically include appropriate financial assurance requirements under state law. Reviews of both state programs and other Federal programs help to identify whether and at what level there is current risk that is appropriate to address under CERCLA Section 108.

EPA also believes that, when evaluating whether and at what level it is appropriate to require evidence of financial responsibility, EPA should examine information on Petroleum and Coal Products Manufacturing facilities operating under modern conditions. In other words, EPA should assess the types of facilities to which any new financial responsibility regulations would apply. Financial responsibility requirements under Section 108(b) would not apply to legacy operations that are no longer operating. Rather, any requirements would apply to facilities that follow current industry practices and are subject to the modern regulatory framework (*i.e.,* the regulations currently in place that apply to this industry). These modern conditions include state and Federal regulatory requirements and financial responsibility requirements that currently apply to operating facilities. This reading of Section 108(b) is consistent with statements in the legislative history of the statute. The 1980 Senate Report states that the legislative language that became Section 108(b) ''requires those engaged in businesses involving hazardous substances to maintain evidence of financial responsibility commensurate with the risk which they present.''[20] This approach is also consistent with the analysis that EPA undertook in developing its Final Action on Financial Responsibility Requirements Under CERCLA Section 108(b) for Classes of Facilities in the Hardrock Mining Industry.[21] EPA's approach was recently upheld by the U.S. Court of Appeals for the District of Columbia Circuit.[22]

This statutory interpretation is reflected in today's proposal. Any financial responsibility requirements imposed under Section 108(b) would apply to currently operating facilities. EPA thus sought to examine the extent to which hazardous substance management at currently operating Petroleum and Coal Products Manufacturing facilities as a class continues to present risk. Moreover, the statutory direction to identify requirements consistent with identified risks guides EPA's interpretation that imposition of financial responsibility requirements under Section 108(b) would not be necessary for currently operating facilities that present minimal current risk of a Fund-financed response action. The interpretation in this proposal does not extend to any site-specific determinations of risk made in the context of individual CERCLA site responses. Those decisions will continue to be made in accordance with preexisting procedures.

EPA thus examined records of releases of hazardous substances from facilities operating under a current regulatory framework and data on the actions taken and expenditures incurred in response to such releases. The data collected do not reflect historical practices, many of which would be illegal under current environmental laws and regulations. Instead, EPA has considered current Federal and state regulation of hazardous substance production, transportation, treatment, storage, or disposal applicable to facilities in the Petroleum and Coal Products Manufacturing industry.

V. Approach To Developing This Proposed Rule

Based on the statutory interpretation described above, EPA developed an analytical approach to determine whether the current risk under the modern regulatory framework within the Petroleum and Coal Products Manufacturing industry rises to the level that warrants imposition of financial responsibility requirements under CERCLA Section 108(b). Specifically, EPA designed the analytical approach to determine the need for financial responsibility for this industry based on the degree and duration of risk of a Fund-financed response action associated with the industry's production, transportation, treatment, storage, or disposal of hazardous substances.

The approach, described in detail below, looks at risks by examining records of releases of hazardous substances from facilities in the industry in combination with the payment history of the Fund and enforcement settlements and judgments. To enable EPA to base its decision on risk posed by facilities operating under modern conditions, *i.e.,* the types of facilities to which financial responsibility requirements would apply, EPA developed an approach to identify and consider relevant state and Federal regulatory requirements and financial responsibility requirements that currently apply to operating facilities, as well as voluntary protective practices.

[19] S. Rept. 96–848 (2d Sess, 96th Cong.), at 92.

[20] S. Rept. 96–848 (2d Sess, 96th Cong.), at 92.

[21] 83 FR 7556 (Feb. 21, 2018).

[22] *Idaho Conservation League* v. *Wheeler,* No. 18–1141 (D.C. Cir. July 19, 2019).

EPA sought to determine the level of risk of a Fund-financed response action at current Petroleum and Coal Products Manufacturing operations. Relevant to this decision are requirements of existing regulatory programs and voluntary practices, including existing financial responsibility requirements, which can reduce costs to the taxpayer; EPA's experience with clean-ups in the Petroleum and Coal Products Manufacturing industry; and enforcement actions, which may reduce the need for Federally-financed response action at facilities in the Petroleum and Coal Products Manufacturing industry.

As part of scoping the Petroleum and Coal Products Manufacturing industry for this proposal, EPA sought to understand general characteristics of the industry that may be relevant to financial responsibility under Section 108(b). To do this, EPA compiled industry features, including the types of activities undertaken and wastes handled or produced. Additionally, EPA looked at the financial condition of the industry to assess the ability of facilities in this class to pay for any environmental obligations they may incur. Discussion of these aspects of the industry is included in section VI of this proposal.

Section VII.A describes EPA's evaluation of cleanup cases at facilities in the Petroleum and Coal Products Manufacturing industry. So-called ''cleanup cases'' are sites in the Petroleum and Coal Products Manufacturing industry where releases and cleanup actions occurred. To perform this evaluation, EPA developed an analytic approach that considered cleanup cases to identify risk at currently operating facilities and where taxpayer funds were expended for response action. EPA first examined each site to determine the nature and timing of release. EPA used this information to determine if releases occurred under current regulations. As an initial screen, releases that occurred prior to 1980 were deemed to be legacy releases that occurred before the advent of the modern environmental regulatory framework and were therefore screened out of our analysis. Once EPA identified those sites with more recent releases occurring under a modern regulatory framework, EPA then focused on those response actions that were paid for by the taxpayer by looking at those sites with Fund-financed cleanup activity.

As described in section VII.B, to understand the modern regulatory framework applicable to currently operating facilities within the Petroleum and Coal Products Manufacturing industry, EPA compiled applicable Federal and state regulations. Specifically, EPA looked to regulations that address the types of releases identified in the cleanup cases. This review also considered industry voluntary programs that could reduce risk of releases. EPA also identified financial responsibility regulations that apply to facilities in the Petroleum and Coal Products Manufacturing industry in section VII.C, and compliance and enforcement history for the relevant regulations in section VII.D.

EPA considered payments from commercial insurers as well, but determined that it was not necessary to conduct a detailed analysis of this potential information source in light of the analyses of cleanup cases and enforcement data. The cleanup cases and enforcement data, in addition to addressing the payment experience of the Fund, court settlements and judgments, and voluntary claims satisfaction, also encompass amounts from commercial insurance payments. For example, at one of the Petroleum and Coal Products Manufacturing sites identified and reviewed, EPA recovered funds from the potentially responsible party's (PRP's) commercial insurers in two separate settlements. Furthermore, payments from commercial insurers may have helped finance the work conducted by PRPs in the cleanup cases identified or may have been included in settlements, judgments, or enforcement cases identified by EPA. However, in the event there were significant payments from commercial insurers associated with facilities in the Petroleum and Coal Products Manufacturing industry that were not already indirectly captured, this information would neither indicate greater risk to the Fund nor suggest a need for financial responsibility requirements under CERCLA Section 108(b).

In considering how to structure its analysis and what data sources to examine, EPA reviewed prior analysis done for selection of industry classes in the 2010 ANPRM and public comments responding to EPA's approach. In the public comment period for the ANPRM, EPA received a total of 67 comments from 30 commenters on the Chemical Manufacturing industry, Petroleum and Coal Products Manufacturing industry, and the Electric Power Generation, Transmission, and Distribution industry. In addition, EPA received five comments to the hardrock mining proposed rule that were related to the additional classes of facilities.

EPA received comments from the American Petroleum Institute, the National Petrochemical & Refiners Association, and the American Coke and Coal Chemicals Institute, as well as individual refineries. Commenters indicated that EPA should concentrate on current practices and not legacy contamination. Commenters also said that EPA should not impose financial responsibility requirements on facilities that are already subject to other Federal laws. One commenter stated that EPA should not include waste oil recycling sites, and that oil refineries and coke production facilities should be analyzed independently from each other. Lastly, many commenters believe that EPA placed too much emphasis on TRI data and RCRA BR data and expressed their opinions that these data sources are not designed or intended to provide risk-based information.

In its 2017 Notice of Intent to Proceed with Rulemakings,[23] EPA acknowledged limitations on information that can be gained from TRI and BR data and announced its intention to use industry-specific and current sources of data to identify risk for the purposes of the rulemakings. EPA also analyzed those limitations in the Final Action for the hardrock mining industry.[24] Accordingly, in the analysis conducted to assess risk in the Petroleum and Coal Products Manufacturing industry for this action, EPA chose not to rely on TRI and BR data. While, at the time of the 2010 ANPRM, the Agency found those data sources appropriate for identifying classes of facilities to examine further, the Agency does not find the data sources valuable for assessing current risk of a Fund-financed response action in the industry.

VI. Petroleum and Coal Products Manufacturing Industry Overview

A. Identification of Petroleum and Coal Products Manufacturing Industry

For this proposal and the associated analyses, EPA reviewed facilities classified under the North American Industry Classification System (NAICS) code 324. The most recent available census data lists the size of the industry at 2,167 establishments nationally.[25] The Petroleum and Coal Products Manufacturing industry is based on the transformation of crude petroleum and coal into usable products. The dominant process, as measured by the value of shipments, is petroleum refining, which involves the separation of crude petroleum into component products through such techniques as cracking

[23] 82 FR 3512 (Jan. 11, 2017).

[24] 83 FR 7570 (Feb. 21, 2018).

[25] 2016 Economic Census of the United States, NAICS 324.

and distillation. As of 2018, there were 135 operating petroleum refineries in the U.S. In 2000, there were 155, indicating that at least 20 refineries have closed since the year 2000.[26] In addition, this industry includes establishments that primarily further process refined petroleum and coal products to produce products, such as asphalt, asphalt roofing materials, coke from coal, and petroleum lubricating oils.

B. Current Industry Practices

Operational and decommissioning practices in industrial sectors and their associated firms can ultimately affect the ability of individual firms to responsibly minimize their impact on human health and the environment. To consider the potential for releases as part of its decision making, EPA prepared a high-level review of industry practices and the environmental profile of the Petroleum and Coal Product Manufacturing industry, which includes a summary of relevant operational and decommissioning materials and wastes in a background document, which is available in the docket for this rulemaking.[27]

Potentially hazardous materials are frequently used in this industry. These materials can include sandblast media, fuels, paints, spent vehicle and equipment fluids (*e.g.,* lubricating oils, hydraulic fluids, battery electrolytes, glycol coolants), among others. Known hazardous materials may include, but are not limited to, asbestos or mercury containing materials, compressed gases, dielectric fluids, boiler bottom ash, and oils. Process fluids can be either hazardous or non-hazardous, and can include oily water, spent solvents, chemical cleaning rinses, cooling water, wash and makeup water, sump and floor discharges, oily water separator fluids, boiler blowdown, and acids.[28] Other materials beyond those listed here may be used in the operation of Petroleum and Coal Product Manufacturing facilities.

Facilities in this industry generate significant amounts of hazardous waste,[29] including but not limited to, primary and secondary sludges, spent catalysts, filter clays and cakes, sour water, heavy ends (distillation bottoms), dissolved air/nitrogen flotation, flotation debris, waste soils, oily sludge, tank bottom sludge, clarified slurry oil, slop oil emulsion solids, spent lime, storm water silt, catalyst and coke fines, and tank bottoms. Additionally, insulating materials (such as asbestos) that are hazardous substances must also be managed properly.

Industry practices in certain subsectors, the Petroleum Refineries (324110), and Other Petroleum and Coal Products Manufacturing (32419), of the Petroleum and Coal Products Manufacturing industry use more hazardous substances and/or generate larger volumes of hazardous waste than the Asphalt Paving, Roofing and Saturated Material Manufacturing (32412), which uses and generates smaller amounts of hazardous substances or wastes. Further information on industry practices is provided in the background document for this section, which is available in the docket for this rulemaking.[30]

Sites contaminated by the industry typically contain a wide variety of contaminants, including but not limited to toxic organics, such as benzene, polychlorinated biphenyls (PCBs), phenol, and volatile organic hydrocarbons (VOCs); and heavy metals, such as barium, cadmium, chromium, copper, lead, selenium, and zinc. Other substances beyond those listed here may also have been released. In terms of sources of contamination, improper landfill/land disposal issues, as well as contaminated soils resulting from process activities, have been the most common sources at contaminated sites. Other examples of sources of contamination included abandoned units/materials and improper wastewater management.

As outlined in the ANPRM, because refineries tend to be operated for decades, there is a long timeframe for potential releases and exposure of hazardous substances to occur. In addition, because of their need for large amounts of cooling water for operations, refineries tend to be located near navigable waterways or on the seashore, which likely increases the potential to impact groundwater, surface water, aquatic biota, and aquatic vegetation. Other impacts to terrestrial vegetation, wetlands, wildlife, soils, air, cultural resources, and humans that use these resources recreationally or for subsistence also are likely.[31]

Contamination of soils from the petroleum refining processes is generally less significant relative to the contamination of water resources.[32] While soil contamination can occur from leaks or spills of spent catalysts or coke dust, tank bottoms, or sludges from the treatment processes, many of the residuals produced during the refining processes are typically recycled through other stages in the process, or collected and disposed of in landfills. Or they may be recovered by other facilities.

Potential impacts to human health and the environment may include large spills that not only contaminate soil and water but may also cause devastating explosions and fires. The consequences and associated releases from refinery accidents can be significant. To ensure immediate responses and to prevent or reduce the likelihood of such incidents, the industry is subject to several Federal regulations and enforcement oversight under various statutes, as discussed in Sections VII.B. and VII.D. below.

C. Industry Economic Profile

Economic trends and financial health in industrial sectors and their associated firms can ultimately affect the ability of individual firms to responsibly address their environmental liabilities. Circumstances in which firms face financial stress can potentially contribute to the abandonment of facilities and the creation of orphan waste sites requiring cleanup. To consider the potential for firms to default on their financial obligations, EPA prepared a high-level economic profile of the Petroleum and Coal Products Manufacturing industry, which includes a summary of relevant financial metrics, industry default statistics and trends, and a broad discussion outlining environmental liabilities under Chapter 11 of the Bankruptcy Code. This analysis, summarized in this section, looked at the industry as a whole and additionally focused on two subsectors individually, providing an industry profile, evaluation of the potential universe of regulated entities, and discussion of the subsector's financial health and relative volatility. The full analysis is found in the background document for this section and is available in the docket for this rulemaking.[33]

Generally, this analysis found the sector to be in a relatively stable financial position with low default risk. Firms in the industry maintain healthy

[26] *CERCLA 108(b) Economic Sector Profile: Petroleum and Coal Products Manufacturing Industry.*

[27] *Petroleum and Coal Products Manufacturing Industry Practices and Environmental Characterization.*

[28] EPA 310–R–95–013 Refinery Sector notebook.

[29] According to the 2017 Hazardous Waste Report, facilities in this sector reported the generation of 5.6 million tons of hazardous waste. *https://rcrapublic.epa.gov/rcrainfoweb/action/modules/br/naics.*

[30] *Petroleum and Coal Products Manufacturing Industry Practices and Environmental Characterization.*

[31] 75 FR 826 (Jan. 6, 2010).

[32] *https://cfpub.epa.gov/ncer_abstracts/index.cfm/fuseaction/display.files/fileID/14522.*

[33] *CERCLA 108(b) Economic Sector Profile: Petroleum and Coal Products Manufacturing Industry.*

credit scores and reasonable levels of debt relative to assets. The report did note that despite a generally healthy financial outlook, intrinsic market volatility due to exogenous factors (*e.g.,* geopolitical unrest) and supply and demand shocks poses an ongoing threat to stability. The report also notes that firms generally remain liable for environmental compliance obligations under Chapter 11 debt restructuring. Sections 101(5) and 1141(d) of the Bankruptcy Code only provide for a discharge of monetary rights to payment and not for compliance obligations where the Federal government has not sought the payment of money. This may serve to temper the impact to the Fund of potential future volatility.

VII. Discussion of Cleanup Sites Analysis

A. Cleanup Site Evaluations

As described in the Approach to Developing the Proposed Rule, Section V above, to evaluate the need for financial responsibility regulations in the Petroleum and Coal Products Manufacturing industry, EPA sought examples of pollution that occurred under a modern regulatory framework and that required a taxpayer-funded CERCLA cleanup. In its evaluation, EPA focused first on identifying response actions at Superfund National Priorities List (NPL) sites and sites using the Superfund Alternative Approach (SAA),[34] as those are generally larger cleanups both in terms of amounts of contaminants removed and in terms of costs to carry out these cleanups. EPA also looked at Superfund removals at non-NPL sites.

To identify the relevant cleanup cases in the Petroleum and Coal Products Manufacturing industry, EPA included the NPL sites already identified in the 2010 ANPRM,[35] and supplemented the dataset with additional NPL sites that had been identified since the ANPRM, sites using the SAA, and non-NPL removal sites identified in EPA's Superfund Enterprise Management System (SEMS) database. EPA collected information on the timing and nature of releases or threatened releases at these sites. Specifically, EPA sought to identify, as applicable, facility operation end dates, release dates, sources of contamination, NPL proposal dates, contaminated media, type of contaminant, cleanup lead, and information on Superfund expenditures at the site, as well as other information. For this collection, EPA relied on information previously collected as part of the ANPRM, information available in Superfund site documents (*e.g.* NPL listing narratives, Records of Decision, Action Memos, Five-Year Reviews) and information in EPA's SEMS, as of March 2018. The cleanup case identification and site information collection processes are described in greater detail in the relevant background documents, which are available in the docket for this rulemaking.[36]

After compiling information about the risks and history of each site, EPA sought to identify instances in which releases occurred under the modern regulatory framework that resulted in Fund-financed response actions. To do so, EPA's methodology applied sequenced screens to the identified sites. EPA first screened out any NPL sites or sites using the SAA where the contaminant release or cleanup activity occurred before 1980. EPA chose 1980 as the cutoff point to initially screen out legacy contamination because it was the year when CERCLA was enacted, as well as the date of the initial regulations under RCRA Subtitle C governing the generation, treatment, storage, and disposal of hazardous waste. EPA chose to give these significant RCRA and CERCLA milestones the greatest consideration due to the large number of issues of waste management, land disposal and soil contamination identified in the review of the NPL and SAA cases. EPA believes the 1980 cutoff date is a conservative screen (*i.e.,* retains more sites in the analysis) in that only the initial RCRA regulations were in place in 1980 and they were refined, expanded and enhanced several times over the next decades. Moreover, the Agency's enforcement authorities expanded in the 1980s as the RCRA program matured. Notably, the passage of the Hazardous and Solid Waste Amendments (HSWA) in 1984 resulted in many regulatory changes and enhanced enforcement mechanisms. More specifically, HSWA created the Land Disposal Restrictions (LDR) program, codified in 40 CFR part 268, which prohibits the land disposal of untreated hazardous wastes. HSWA also substantially expanded corrective action authorities for both permitted RCRA treatment, storage and disposal (TSD) facilities and facilities operating under interim status,[37] requiring facilities to address the release of hazardous wastes and demonstrate financial responsibility for completing the required corrective actions, further reducing the risks that sites would have to be addressed under CERCLA. For further detail on these requirements, see section VII. B below.

Next, EPA sought to remove from the analysis sites where significant Fund expenditures had not occurred, because response actions that were paid for by private parties do not support the need for CERCLA Section 108(b) financial responsibility regulations. Using the ''Action Lead'' field in SEMS associated with each site, EPA screened out the potentially responsible party (PRP) lead sites. This left only the Mixed Lead Construction or Government Performed Construction sites in the analysis, under the assumption that PRP Performed Construction [38] sites did not present significant expenses to the Fund.

EPA then reviewed the remaining sites (*i.e.,* those with both pollution dates of 1980 or later and Mixed Lead Construction or Government Performed Construction designation in SEMS) individually in greater detail. Specifically, EPA considered the site history and each of the contamination sources at the site in the context of the regulations that would be applicable to that facility today. More information on the regulations EPA considered is available in Section VII.B.

Findings from EPA's analysis of the cleanup cases are discussed below, with more detailed information in background documents, which are available in the docket for this rulemaking.[39] These background documents provide the list of sites identified and remaining at each stage of the analysis, as well as the information considered in the screening and review process.

[34] The Superfund Alternative Approach (SAA) uses the same CERCLA authority and investigation and cleanup process and standards that are used for NPL sites. The threshold criteria for using the SAA are: (1) The site must have contamination significant enough to make it eligible for listing on the NPL; (2) the site is anticipated to need remedial action; and, (3) there must be a cooperative, viable, capable PRP that will sign a CERCLA agreement with EPA to perform the necessary cleanup.

[35] 75 FR 816 (Jan.6, 2010).

[36] *Identification and Evaluation of CERCLA 108(b) National Priorities List (NPL) and Superfund Alternative Approach (SAA) Cleanup Case Sites Associated with the Petroleum and Coal Products Manufacturing Industry* and *Identification and Evaluation of CERCLA 108(b) Petroleum and Coal Products Manufacturing Industry non-National Priorities List (NPL) Removal Sites.*

[37] Interim status facilities are facilities that were in existence on the effective date of the regulations and subject to the requirement to have a RCRA permit. The standards for interim status facilities are not as stringent as those for permitted facilities.

[38] These terms are used in the SEMS database to identify the party that had primary responsibility for construction at the sites.

[39] *Identification and Evaluation of National Priorities List (NPL) Sites and sites using the Superfund Alternative Approach (SAA) Cleanup Cases in the Petroleum and Coal Products Manufacturing Industry* and *Identification and Evaluation of CERCLA 108(b) Petroleum and Coal Products Manufacturing non-National Priorities List (NPL) Removal Sites.*

Using the data sources described above for the Petroleum and Coal Products Manufacturing industry, EPA identified 34 NPL or SAA sites, as well as 51 non-NPL CERCLA removal action sites [40] to evaluate according to the methodology described above. As described further below, none of the contamination at NPL sites or sites using the SAA were ultimately considered incidents that occurred under the modern regulatory framework where significant taxpayer funds were relied upon. For the removal sites, one of the 51 cases showed releases of hazardous substances under a modern regulatory framework and required taxpayer expenditures, as described below.

The 34 NPL and SAA sites evaluated include 23 petroleum refineries, nine coke production facilities, and two sites with oil re-refining and/or fuel blending operations. At these 34 sites, improper land disposal was the most prevalent issue.

EPA applied the screens described above to remove any PRP-Performed Construction sites, as well as any sites where the pollution occurred pre-1980, to the 34 NPL and SAA sites. Eight sites remained after those screens that were either Government Performed Construction or Mixed Lead Construction (*i.e.,* a combination of Government and PRP) sites and had at least one source of pollution that arose in 1980 or later. To assess those eight sites, EPA conducted a more detailed review to compare the environmental issues (*e.g.,* contamination) at the sites against the regulations applicable today. Based on the detailed review, EPA concluded that the pollution at six of the eight Petroleum and Coal Products Manufacturing NPL sites reflect legacy practices. That is to say that while the sites had at least one source of pollution that arose in 1980 or later, the detailed review of the sites' histories concluded that, for six of the eight sites, the pollution arose before the RCRA Subtitle C program was fully in place.

Several of the sites had long operational histories pre-1980 that contributed to a portion, if not all, of the pollution. Additionally, at most of the sites it was evident that pollution arose prior to HSWA's implementation. This is relevant because four of these sites had land disposal issues, five of these sites had soil contamination resulting from process activities, and four of these sites had abandoned hazardous substances at their sites. These sites pre-dated the enactment of expanded generator regulations, enhanced land disposal unit technical standards, enhanced enforcement provisions (including facility-wide corrective action), Land Disposal Restrictions, and the Loss of Interim Status deadlines for compliance with groundwater monitoring and financial assurance requirements at land disposal facilities, and other protections afforded by HSWA that would have mitigated these issues. Please see Appendix 4 of the background document for an explanation of how the contamination at these six sites would now be addressed by regulations in place today.[41]

Regarding the other two of the eight NPL sites that remained after the screens, EPA's detailed review indicated that these sites may have had releases under the modern regulatory framework. Both sites had legacy land disposal issues, due primarily to improper disposal of hazardous waste, which contributed significantly to the site's requiring a CERCLA action. However, as detailed below, notwithstanding a designation of mixed or government lead in SEMS, neither of these two sites required a level of taxpayer expenditures high enough to warrant imposing financial responsibility on the whole industry.

The sites, Indian Refinery—Texaco Lawrenceville in Illinois and Koch Refining Co. in Minnesota, had Superfund expenditures to date of $720,511 and $26,659 (2017 USD), respectively. At the Indian Refinery—Texaco Lawrenceville site, which operated from 1907 to 1995, various owners or operators performed cleanup work at the site starting as early as 1983. EPA's primary involvement at the site was oversight of two short-term cleanups, or removal actions, prior to the site's listing on the NPL in 2000. Issues at the site primarily stemmed from a waste disposal area where highly acidic refinery wastes (*e.g.,* lube oil filter clay sludge; acid sludge; and spent filter clays) were improperly disposed. Waste at the site also migrated offsite, requiring cleanup.

At the Koch Refining Co. site, Koch Refining, a Potentially Responsible Party, signed a consent agreement with the State of Minnesota for cleanup of the facility under RCRA authority in 1985. Issues at the site included persistent seepages from ponds, lagoons, and waste piles identified in 1972 as well as leaks, spills, and discharges from active and inactive wastewater lagoons, process areas, internal pipelines, and waste treatment areas identified in investigations conducted between 1986 and 1988. In 1995, EPA deleted the site from the National Priorities List, and determined that no further action under the Superfund law was needed. The refinery at the site is still in operation. The results of the NPL and SAA sites analysis is presented in Table 1, below.

TABLE 1—EVALUATION RESULTS FOR NPL AND SAA SITES IN THE PETROLEUM AND COAL PRODUCTS MANUFACTURING INDUSTRY

Total NAICS 324 NPL & SAA sites evaluated	Number of NAICS 324 NPL & SAA sites screened out based on pre-1980, or PRP lead status	Detailed review concluded release occurred prior to the modern regulatory framework	Detailed review identified a possible modern regulation release but no significant taxpayer expenditures	Cases with release(s) under modern regulation that required taxpayer funded response
34	26	6	2	0

Additionally, EPA looked at the removal cases found in the SEMS database to supplement this analysis. For this sector, EPA identified 51 non-NPL removal sites. Applying the same methodology as above, EPA screened out 30 sites because the environmental releases occurred before 1980 or PRPs led the response action. EPA also excluded an additional 12 sites that were deemed outside the scope of this rulemaking because the industrial

[40] None of the 51 removal sites are associated with an NPL site. Removal actions that have taken place at NPL sites or sites using the SAA, either before or after listing or designation, are tracked in SEMS as NPL or SAA level actions and not as separate removal records.

[41] *Identification and Evaluation of National Priorities List (NPL) Sites and Sites using the Superfund Alternative Approach (SAA) in the Petroleum and Coal Products Manufacturing Industry.*

activities that resulted in release of hazardous substances were neither petroleum refining nor coal products manufacturing. Four other sites were left out of the analysis because of insufficient documentation to fully conduct the evaluation (*i.e.,* not enough to verify whether the sites included pollution attributable to a NAICS 324 facility, or the nature/date of the releases at the site).

To assess the five sites that remained after those screens, EPA first conducted a detailed review of case files to compare the environmental issues at the sites to the regulations applicable today. At two of the five removal sites (United Energy in Evanston, Indiana, and Browns Island Emergency Response in Weirton, West Virginia), while the environmental releases had occurred recently, EPA concluded that they had resulted from legacy waste management practices. For instance, at the United Energy site, the refinery operations ceased during the 1970s and the site was abandoned. Though long abandoned, the presence of former tars pits and waste oil lagoons, PCB stained soil, and PCB oils tanks at the site posed threats to public health and the environment, resulting in EPA's removal response in 2012; total Fund expenditure reported at this site was $583,000.[42] Similarly, at the Browns Island site, although operations at the former coke by-product plant ceased in 1982, a release occurred in March 2008 when 300 gallons of liquid organic chemicals (primarily naphthalene) that had been stored in an abandoned tank leaked during demolition work. The current owner reported the spill to the National Response Center (NRC) and subsequently conducted the cleanup activity with EPA's oversight; total Fund expenditure reported at this site was $6,700.

At two other sites (St. Rose Air Assessment Site in St. Charles Parish, Louisiana, and Benicia Valero Refinery in Benicia, California), EPA concluded that the releases were caused by a one-time incident (malfunctioning of sulfur removal equipment at the former and power outage at the latter) which resulted in release of air pollutants (*e.g.,* sulfur dioxide, other organic vapors).[43] [44] Although not designated as PRP-lead actions in the SEMS database, according to EPA's review of site documents, the PRPs largely financed and performed the response actions with oversight of EPA and state agencies. SEMS expenditure data show EPA incurred $75,000 in Fund expenditures to conduct an air quality monitoring and assessment at the St. Rose site, after the state requested assistance from EPA. No Fund expenditures were reported at the Benicia site.

The remaining removal site was Lake Charles NRG, located in Lake Charles, Louisiana. Petroleum refinery operations occurred at this site from 1983 to 1999. The refinery operations consisted of processing petroleum feedstocks into naphtha, fuel oil, and residual fuel oil. Rebel Energy, Inc. constructed the site and began intermittent operation in 1983. Following several ownership changes and bankruptcies, the site was transferred to NRG in 1998. NRG operated the facility for a short time during 1999 and subsequently abandoned it. Site assessment beginning in 2000 identified hundreds of storage systems (including above-ground tanks, sludge boxes, vessels, and drums) and process equipment containing over 200,000 gallons of hazardous liquids, solid sludge, and liquid acid.[45] A subsequent visit by EPA also revealed a tank that had failed, and oil was leaking from the secondary containment structures.

EPA concludes this site represents a case in which a release or threatened release of hazardous substances took place under the modern regulatory framework and required taxpayer-funded cleanup. As described in more detail in the Role of Federal and State Programs section below, the primary regulations governing Above Ground Storage Tanks (ASTs) used for storing oil and petroleum products are the Spill Prevention, Control, and Countermeasure (SPCC) regulations, 40 CFR 112. These regulations have been in place since 1990. Tank systems used to store hazardous waste have also been regulated under RCRA (40 CFR parts 264 and 265) since 1986.[46] Moreover, according to EPA's records, no financially viable PRPs were identified for this site, and SEMS expenditure data show that EPA incurred an estimated cost of $2.3 million for response and enforcement activities.

More detailed information can be found in the background document [47] and supporting spreadsheets, which are available in the docket for this rulemaking. The background document includes the list of sites identified for analysis, as well as the data and information considered in the screening and review process. Table 2 presents the summarized results of the analysis.

TABLE 2—EVALUATION RESULTS FOR SUPERFUND REMOVAL SITES IN THE PETROLEUM REFINERY AND COKE PRODUCTS MANUFACTURING INDUSTRY

Total NAICS 324 superfund removal cases evaluated	Number of NAICS 324 superfund removal cases screened out based on pre-1980, or PRP lead status	Detailed review concluded release occurred prior to the modern regulatory framework	Detailed review identified a possible modern regulation release but no significant taxpayer expenditures	Cases with release(s) under modern regulation that required taxpayer funded response
51	30(16) [48]	2	2	1

Petroleum Exclusion

In identifying and reviewing cleanup cases in the Petroleum and Coal Products Manufacturing industry, EPA was mindful of the CERCLA petroleum exclusion. CERCLA Section 101 excludes petroleum, or any fraction thereof, from the statutory definition of a hazardous substance unless it is listed

[42] 2012 Action Memorandum—Request for Approval and Funding for Removal Action at the United Energy Site, Spencer County, Evanston, Indiana.

[43] 2017 Pollution Report for Benicia Valero Refinery Site.

[44] 2014 and 2015 Pollution Reports for St. Rosa Air Assessment.

[45] 2012 Pollution Report for Lake Charles NRG site.

[46] 51 FR 25472 (Jul. 14, 1986).

[47] *Identification and Evaluation of CERCLA 108(b) Petroleum and Coal Products Manufacturing non-National Priorities List (NPL) Removal Sites.*

[48] The number in parentheses indicates the sites that were also removed at this stage in the analysis: 12 sites for which EPA determined the industrial activities did not involve either petroleum refining or coal products manufacturing, and four sites for which there was not enough documentation to be included in the analysis.

or designated as a hazardous substance under certain other environmental laws, including RCRA. As a result, some releases of ''petroleum'' are not subject to CERCLA liability or response authority.

Notwithstanding the exclusion, EPA's review of the cleanup sites that had petroleum or coal product manufacturing operations identified numerous instances in which CERCLA responses were taken. Many of these instances pertained to sites where RCRA hazardous wastes had been mishandled; these releases were not excluded by the petroleum exclusion. In reviewing releases at Petroleum and Coal Products Manufacturing sites, EPA was careful to exclude from its analysis petroleum releases at sites where CERCLA authority was used to address other releases. EPA encountered only one release at an NPL site where the petroleum exclusion brought the release's relevance to our analysis in question. At this site, the Falcon Refinery site, the release occurred from a crude oil storage facility that had been operating over a decade after the refinery closed. As such, the release was determined to have occurred at a facility which is outside the scope of NAICS 324 and would better be classified as NAICS 424710—Petroleum Bulk Stations and Terminals. Thus, that specific release was excluded from the analysis on those grounds.

Prevalent Sources of Releases

EPA's analysis of cleanup cases compiled information, where discernable, on the root cause of releases. Across the industry overall, the most prevalent issues were soil and surface water and groundwater contamination from unlined or leaking storage tanks, drums, surface impoundments, and surface water lagoons, and uncontrolled polluted stormwater runoff. Additionally, at NPL sites using the SAA, and non-NPL removal sites, abandoned units (*e.g.,* tank farms, drums) containing hazardous substances and soil contamination resulting from process activities were prevalent sources of contamination. As discussed in the next section, there are regulations in place that address these types of releases.

B. Role of Federal and State Programs and Voluntary Protective Industry Practices at Facilities in the Petroleum and Coal Products Manufacturing Industry

In the 2010 ANPRM, EPA recognized that the NPL data reflects releases arising from activity that, in some cases, predates CERCLA, RCRA, and other modern environmental requirements. The Agency welcomed information about current releases of hazardous substances to the environment to help inform EPA's future actions. As discussed in the Approach section of this proposal, to enable EPA to base its decision on risk posed by facilities operating under modern conditions, *i.e.,* the types of facilities to which financial responsibility requirements would apply, EPA developed an approach to identify and consider relevant state and Federal regulatory requirements and financial responsibility requirements that currently apply to operating facilities, as well as voluntary protective practices. EPA thus undertook an effort to gather information about Federal and state environmental programs and industry voluntary programs that have been implemented and are applicable to currently operating facilities within the Petroleum and Coal Products Manufacturing industry today. EPA evaluated the extent to which activities that contributed to the risk associated with the production, transportation, treatment, storage, or disposal of hazardous substances are now regulated. EPA recognizes that substantial advances have been made in the development of manufacturing, pollution control, and waste management practices, as well as the implementation of Federal and state regulatory programs to prevent and address releases at these facilities. In part, EPA's proposed decision to not issue financial responsibility requirements for this industry is based on EPA's review and analysis of Federal regulations and complemented by state program regulations. EPA's proposed findings and conclusions about the impact of Federal and state environmental programs, along with industry voluntary programs, are discussed in the following section.

Overview of Federal and State Regulatory Programs and Industry Voluntary Practices Applicable to Facilities in the Petroleum and Coal Products Manufacturing Industry

EPA evaluated Federal and state regulations that address the potential for release of hazardous substances to the range of environmental media that may be affected by a release from a facility in the Petroleum and Coal Products Manufacturing industry. EPA found that a comprehensive regulatory framework has developed since the enactment of CERCLA. Federal statutes such as the CAA, CWA, TSCA, RCRA, and the Emergency Planning and Community Right-to-Know Act (EPCRA) are applicable across the entire industry and lay the foundation for this regulatory framework. Specific regulations are discussed in the background document according to the affected media that the regulations address: Air pollution, water pollution, emergency planning and response, hazardous substances management, and hazardous and non-hazardous waste management and disposal. This background document is located in the docket for this rulemaking.[49]

Regulations Addressing Prevalent Sources of Releases Identified in Analysis of Cleanup Cases

EPA's analysis of the cleanup cases found that the most prevalent releases involved:

- Surface and ground water contamination from unlined or leaking storage tanks, drums, surface impoundments, and surface water lagoons, and uncontrolled polluted stormwater runoff;
- Abandonment and disposal of contaminated soil and debris;
- Improper storage of hazardous waste; and
- Soil and water contamination from spills and hazardous substance management practices.

The comprehensive regulations for the management and disposal of hazardous waste, promulgated under the authority of RCRA, were designed to prevent these types of releases and assure that past spills are cleaned up by facility owners and operators. Specifically, Subtitle C of RCRA required EPA to establish a hazardous waste management program, and EPA developed a ''cradle to grave'' approach to control the generation, transportation, treatment, storage, and disposal of hazardous waste.[50] EPA's regulatory approach under RCRA includes standards specific to types of hazardous wastes, types of hazardous waste disposal facilities, and types of hazardous waste disposal activities; EPA enforces these standards through permitting, reporting and inspection programs.[51]

[49] *Summary Report: Federal and State Environmental Regulations and Industry Voluntary Programs in Place to Address CERCLA Hazardous Substances at Petroleum Refineries and Other Petroleum and Coal Products Manufacturing Facilities.*

[50] ''EPA History: Resource Conservation and Recovery Act,'' EPA, at: *https://www.epa.gov/history/epa-history-resource-conservation-and-recovery-act.*

[51] ''EPA History: Resource Conservation and Recovery Act,'' EPA, at: *https://www.epa.gov/history/epa-history-resource-conservation-and-recovery-act;* ''Summary of the Resource Conservation and Recovery Act,'' EPA, at: *https://www.epa.gov/laws-regulations/summary-resource-conservation-and-recovery-act.*

In 1980, under the authority of RCRA Subtitle C, EPA promulgated the initial hazardous waste management and permitting regulations. These regulations included the identification of hazardous wastes that would be regulated under RCRA Subtitle C. Under Subtitle C, generators of hazardous waste are required to ensure and fully document that the hazardous waste they produce is properly identified, managed, tracked, and treated prior to recycling or disposal. The degree of regulation to which each generator is subject depends to a large extent on how much waste each generator produces every calendar month. Early in the development of the RCRA program, EPA recognized that a relatively small number of industrial facilities generated the majority of the nation's hazardous waste. EPA initially focused on these large quantity generators, *i.e.,* those that generate 1,000 kilograms or more of non-acute hazardous waste per month (or more than 1 kilogram of acute hazardous waste per month). These facilities must obtain an EPA identification number and report the quantities and types of hazardous waste they generate, as well as the intended receiving facility for treatment and disposal, unless the waste will be managed onsite. Large quantity generators who send their waste offsite are responsible for the proper packaging and labeling of the waste before transport and the tracking of the waste to the destination facility using the uniform hazardous waste manifest. Large quantity generators may store their waste on site for less than 90 days before transport to a treatment and disposal facility; that storage is subject to the same unit-specific standards (described below) applicable to treatment, storage, and disposal facilities.

RCRA Subtitle C also established standards for hazardous waste treatment, storage, and disposal facilities (TSDFs). Operators that handle or manifest hazardous waste at any point in its lifecycle, including generators and transporters, are required to notify EPA of these activities. To keep track, TSDF owners and operators must keep records and make reports to EPA. TSDFs are required to track hazardous waste they receive through EPA's hazardous waste manifest system, among other recordkeeping and reporting standards.

RCRA Subtitle C regulations created a permitting program for hazardous waste TSDFs. The TSDF permitting regulations include application procedures, permit approval conditions, and monitoring and reporting requirements. TSDFs must have permits for the entirety of the active life of the permitted units, including during closure of waste management units. New and existing hazardous waste TSDFs must submit a RCRA permit application at least 180 days before the commencement of construction and/or hazardous waste management activities.[52] Both permitted and interim status TSDFs must comply with general facility operating standards, preparedness and prevention, contingency plans and emergency procedures, as well as specific technical standards designed to insure that hazardous waste management units such as storage tanks and containers, landfill, surface impoundments, waste piles, land treatment of hazardous waste, and solid waste management units are operated in a manner that prevents releases. To minimize the potential for leachate to threaten human health and the environment, EPA developed design and operating standards that use a combination of different technologies and good operating practices to detect, contain, and clean up any leaks that might occur. To prevent releases of hazardous waste into the environment, containers holding liquid hazardous wastes at a permitted TSDF must have a secondary containment system. Secondary containment is emergency short-term storage designed to hold leaks from hazardous waste management units.

Slightly later in the 1980s, EPA promulgated regulations that set financial assurance requirements for TSDFs.[53] The TSDF standards eventually included air emission standards for process vents, equipment leaks, tank systems, surface impoundments, and containers. The regulations covering proper management of surface impoundments, found in 40 CFR parts 264 and 265, Subpart K, require facilities that store hazardous waste in surface impoundments to meet specific design requirements, which include a double liner system, leachate collection and removal systems, and a leak detection system. The regulations for containers, found in 40 CFR parts 264 and 265, Subpart I, include provisions regarding design and operating requirements, and inspections. Certain 40 CFR part 265 standards also apply to hazardous waste containers at generator sites.

HSWA was enacted in 1984, largely in response to citizen concerns that existing methods of hazardous waste disposal, particularly land disposal, were not safe. With HSWA, Congress sought to minimize waste generation and phase out land disposal of hazardous waste. Accordingly, in 1986, EPA promulgated a suite of regulations that established standards and restrictions for land disposal of hazardous waste. While the regulations set stringent guidelines for the land disposal of hazardous waste, some hazardous wastes and some types of land disposal are prohibited altogether. Although there are exceptions, operators are generally prohibited from diluting hazardous waste as a substitute for treatment. In addition, operators can land dispose hazardous waste only following treatment and only in appropriate land treatment units, landfills and surface impoundments. Further, operators must meet testing, removal, recordkeeping, and design requirements. Additional standards, restrictions, and prohibitions are in place for hazardous waste that exhibited ignitability, corrosivity, reactivity, or toxicity.[54]

HSWA required that all landfills and surface impoundments install groundwater monitoring, comply with technical requirements, such as double liners and leachate collection, and obtain financial assurance. The HSWA amendments also added to RCRA's regulations for small quantity generators, facilities that generated between 100 to 1,000 kilograms per month of hazardous waste, which were previously exempt from RCRA rules. These small quantity generator rules took effect in 1986. Generators of less than 100 kilograms per month of hazardous waste (*i.e.,* conditionally-exempt small quantity generators) remained subject to significantly reduced requirements.[55] EPA amended the hazardous waste generator provisions in 2016, largely to clarify the requirements.[56]

HSWA also established closure and post-closure requirements for hazardous waste TSDF facilities. The regulations require facilities to develop closure plans for all hazardous waste management units. All TSDFs are required to prepare and submit written closure plans. A permitted facility submits this plan as part of its permit application. Once the plan is approved by the permitting agency, it becomes part of the facility's operating permit.

[52] 45 FR 33063 (May 19, 1980).

[53] 45 FR 33063 (May 19, 1980); 47 FR 15047 (Apr. 7, 1982).

[54] 51 FR 40572 (Nov. 7, 1986).

[55] *Id.*

[56] 81 FR 85732 (Nov. 28, 2016).

Interim status facilities [57] must have written closure plans within six months of becoming subject to the closure regulations. Upon the completion of closure of a hazardous waste disposal unit, owners and operators must submit a certification of closure to the relevant state or EPA regional office. Following closure, facilities must implement a post-closure plan that abides by post-closure property use and care guidelines. The standard post-closure care period is 30 years, but this can be shortened or extended on a case-by-case basis by the permitting authority (*i.e.,* the EPA Region or the authorized state regulatory agency). Post-closure notification and security requirements remain in place so long as hazardous waste is present at the facility, even after the 30-year post-closure period.[58]

HSWA provided EPA with authority to develop a broader corrective action program. Under this program, EPA requires owners and operators of facilities that treat, store or dispose of hazardous waste to investigate and clean up hazardous releases into soil, groundwater, surface water and air, thus reducing the likelihood that these facilities would require cleanup under Superfund. RCRA permits issued to TSDFs must include provisions for both corrective action and financial assurance to cover the costs of implementing those cleanup measures. EPA also possesses additional authorities to order corrective action through enforcement orders, which are not contingent upon a facility's permit. In addition, facilities may voluntarily choose to clean up their contamination.

EPA issued regulations under RCRA Subtitle C that were specific to the Petroleum and Coal Products Manufacturing industry in 1980, 1990, and 1998. In 1980, EPA classified the following waste from the petroleum refining industry as RCRA hazardous waste: Dissolved air flotation float; slop oil emulsion solids; heat exchanger bundle cleaning sludge; separator sludge; and leaded tank bottoms. In 1990, EPA classified the following as RCRA hazardous waste: Petroleum refinery primary oil/water/solids separation sludge; and petroleum refinery secondary (emulsified) oil/water/solids separation sludge.

The 1998 regulations categorized four wastes generated during petroleum refining operations as hazardous wastes subject to full Subtitle C regulation, while opting not to categorize an additional ten petroleum refining wastes as hazardous. The wastes that the 1998 rule classified as hazardous wastes under RCRA were: Crude oil storage tank sediment from petroleum refining operations; clarified slurry oil storage tank sediment and/or in-line filter/separation solids from petroleum refining operations; spent hydrotreating catalyst from petroleum refining operations, including guard beds used to desulfurize feeds to other catalytic units; and spent hydrorefining catalyst from petroleum refining operations, including guard beds used to desulfurize feeds to other catalytic units. The rule also changed RCRA regulations to exclude certain oil-bearing residuals from the definition of solid waste—such as oil and oil-bearing residuals that petroleum refineries insert into the refining process and spent caustic from liquid treating operations that are used in chemical production operations—in order to promote the recycling of those materials.[59]

In addition to Subtitle C requirements, RCRA Subtitle D established a program for management and disposal of non-hazardous industrial and municipal solid waste through state solid waste management plans that conform with Federal guidelines. And RCRA Subtitle I requires EPA to promulgate technical standards and corrective action requirements for owners and operators of underground storage tanks (USTs), including underground storage tanks that contain hazardous substances or petroleum products. The UST regulations include requirements for design, installation, notification, operational procedures, release reporting, release response and corrective action procedures for underground storage tank systems that contain petroleum or hazardous substances. The regulations also include financial responsibility requirements for underground storage tank owners and operators. In addition, EPA has established guidelines for the approval of state underground storage tank programs.[60]

In addition to the regulatory scheme that RCRA imposes on the management of hazardous waste in underground storage tanks that store petroleum products and chemicals, petroleum refineries and coal products manufacturing facilities are subject to a number of additional regulatory provisions that reduce the potential for a Federally-financed response action. Catastrophic releases of hazardous substances and the use of toxic chemicals and other hazardous substances are additional environmental and safety concerns for petroleum refineries and coal products manufacturing facilities. Several environmental laws authorize regulations requiring the development of response plans for various emergencies in order to reduce the effects of a release, and to notify local emergency response personnel and facilitate cooperation. For example, EPA implements the Chemical Accident Prevention Provisions of Section 112(r) of the Clean Air Act Amendments, which require certain facilities to generate Risk Management Plans (RMPs) to mitigate the effects of a chemical accident and coordinate with local response personnel. Emergency Action Plan (EAP) regulations under the Occupational Safety and Health Act (OSHA) require that employers prepare a written EAP to create practices to follow during workplace emergencies. EPA implements regulations under the EPCRA that impose emergency planning, reporting, and notification requirements for hazardous and toxic chemicals.

Contamination of surface water is largely addressed by the Clean Water Act. The CWA established the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), which sets a blueprint for responding to oil spills and hazardous substance releases. At its inception in 1968, the NCP provided a comprehensive Federal system of accident reporting, spill containment, and cleanup of oil spills. In 1972, the CWA expanded it to include hazardous substance releases.[61]

The 1990, Oil Pollution Act amended the CWA and authorized regulations requiring facility owners or operators to prepare response plans for worst-case scenario oil discharges. In addition, the Oil Pollution Prevention Regulations require facilities that store or use certain amounts of oil and oil products to develop SPCC Plans to prevent the discharge of oil to navigable waters in case of a spill. EPA finalized the full suite of amendments to the Oil Pollution Prevention Regulation in 2002.[62]

[57] Interim status facilities are facilities that were already in existence at the time of the enactment of the permitting regulations. Interim status facilities must comply with the requirements in 40 CFR part 265 until they receive their permit.

[58] 51 FR 16444 (May 2, 1986).

[59] 63 FR 42110 (Aug. 6, 1998).

[60] 53 FR 37082 and 43322 (Nov. 27, 2018).

[61] ''National Oil and Hazardous Substances Pollution Contingency Plan (NCP) Overview,'' at: *https://www.epa.gov/emergency-response/national-oil-and-hazardous-substances-pollution-contingency-plan-ncp-overview.*

[62] 40 CFR 112; ''Overview of the Spill Prevention, Control, and Countermeasure (SPCC) Regulation,'' EPA, at: *https://www.epa.gov/oil-spills-prevention-*

State Regulatory Programs

Some states impose requirements on the Petroleum and Coal Products Manufacturing industry in addition to requirements related to Federal programs. These stricter or additional standards for emissions, spill prevention, emergency preparedness, and hazardous substance management on facilities that handle toxic or hazardous chemicals can reduce risk at facilities that manage hazardous substances. EPA researched state environmental regulations relevant to the Petroleum and Coal Products Manufacturing industry for a representative sample of states. A discussion of these state regulations, as well as the methodology EPA used in selecting the 11 states that it researched, is in a background document, which is available in the docket for this rulemaking.[63]

States with significant oil and gas refining and manufacturing industries have implemented state regulations applicable to facilities that store or use oil and oil-related materials, including petroleum refineries and petroleum and coal product manufacturing facilities. For example, Alaska has established requirements for owners or operators of petroleum production facilities to prevent the discharge of oil; these regulations include financial responsibility provisions for oil terminal facilities. Alaska also established comprehensive workplace safety standards for the petroleum refining industry, including standards for process equipment maintenance, equipment leakage, and breakage.

Industry Voluntary Practices

EPA reviewed facility RMPs, industry materials, governmental literature, and academic literature to locate voluntary programs that: (1) Attempt to address CERCLA hazardous substance management or disposal, and release prevention, mitigation, and response; (2) are relevant to petroleum refineries and coal products manufacturing facilities; and (3) in which petroleum refineries and coal products manufacturing facilities participate. Industry voluntary programs fall into three categories: Those sponsored by Federal, state or local governmental agencies; those fostered within industry associations or non-governmental organizations; and those implemented by individual firms. These programs set or publish environmental management and safety standards that facilities may follow to supplement Federal and state requirements with additional standards and may come with a certification from the government agency or industry group that establishes the standards. Voluntary programs may also serve as forums for coordination and collaboration among companies, facilities, and government agencies to develop best practice standards and improve emergency preparedness. EPA's review of available studies found that the industry voluntary programs can be effective at reducing both pollution and the frequency of government enforcement actions. A discussion of industry voluntary practices, as well as the methodology used by EPA, is in a background document, which is available in the docket for this rulemaking.[64]

C. Existing State and Federal Financial Responsibility Programs

To help inform the level of risk of a Fund-financed response action associated with classes of facilities in the Petroleum and Coal Products Manufacturing industry, EPA reviewed existing state and Federal financial responsibility programs that may be applicable to the industry and that cover a wide range of liabilities, including liabilities for closure, post-closure care, corrective action, third-party personal injury/property damage, and natural resource damages. EPA focused on these types of financial responsibility programs for two reasons. First, these categories of damages, actions, and costs are like those that could be covered by CERCLA Section 108(b) rulemaking, and thus they help inform the need for CERCLA Section 108(b) financial responsibility for this industry. Secondly, the existence of financial responsibility requirements can help create incentives for sound practices, reducing the risk of releases requiring CERCLA response action. EPA also sought to identify state cleanup funds that are at least partially funded by industry (*e.g.,* through a tax on hazardous wastes generated), and that could cover future CERCLA liabilities that may arise at petroleum and coal product manufacturing facilities. EPA's report focused on the 25 states reviewed in EPA's reports on existing state regulatory and voluntary programs (excluding financial responsibility programs) that may be applicable to petroleum and coal product manufacturing facilities.

Finally, EPA reviewed existing financial responsibility requirements in the following Federal programs: (1) RCRA Subtitle C TSDFs; (2) TSCA commercial PCB waste facilities; and (3) EPA Safe Drinking Water Act Underground Injection Control wells. The report is available in the docket for this rulemaking.[65]

EPA identified a range of existing financial responsibility programs that may be applicable to facilities in the Petroleum and Coal Products Manufacturing industry. The programs include the Federal programs mentioned above, as well as state programs related to:

- Financial responsibility for used oil processing and re-refining facilities,
- Financial responsibility for hazardous waste TSDFs,
- Financial responsibility for underground injection of hazardous wastes,
- Financial responsibility for storage tanks containing hazardous substances,
- Corrective action financial responsibility to address hazardous waste or hazardous constituents,
- Facility remediation financial responsibility associated with transfer in ownership or facility closure, and
- Other authorities to require financial responsibility to assure compliance with orders.

The applicability of these programs will depend on a variety of facility-specific factors, for example, use of a specific piece of equipment (*e.g.,* an underground storage tank that contains regulated substances) or engaging in a specified activity (*e.g.,* a release of a hazardous substance). Furthermore, state financial responsibility programs vary by state and some types of financial responsibility programs exist only in limited subsets of the states reviewed. EPA believes that state and Federal financial responsibility programs help reduce risk of a Fund-financed response action at facilities where they are applicable. While financial responsibility programs vary in structure and function, they may reduce such risk in a myriad of ways. For example, they may help ensure undercapitalized firms do not engage in environmentally risky enterprises, reduce the incentive to abandon properties with extensive contamination, ensure compliance with protective requirements, and incentivize better environmental practices.

and-preparedness-regulations/overview-spill-prevention-control-and.

[63] *Summary Report: Federal and State Environmental Regulations and Industry Voluntary Programs in Place to Address CERCLA Hazardous Substances at Petroleum Refineries and Other Petroleum and Coal Products Manufacturing Facilities.*

[64] *Id.*

[65] *Review of Existing Financial Responsibility Laws Potentially Applicable to Classes of Facilities in the Petroleum and Coal Products Manufacturing Industry.*

D. Compliance and Enforcement History

To understand the experience of court settlements and judgments, EPA looked at compliance and enforcement in the Petroleum and Coal Products Manufacturing industry. EPA believes that compliance assistance, compliance monitoring, and enforcement are important components of the regulatory framework discussed above. Through inspections, compliance monitoring can identify noncompliance at regulated facilities. Enforcement actions may result in legal instruments that ensure correction of deficiencies to achieve compliance with environmental requirements. Some functions of compliance and enforcement actions are particularly pertinent to the risk determination for rulemaking under CERCLA Section 108(b). First, if noncompliance causes release of a hazardous substances EPA can ensure in negotiated agreements that the responsible party carries out or pays for the cleanup. Second, enforcement actions can result in orders and settlements that compel a responsible party to return to compliance. Third, the prospect of financial penalties that can accompany these enforcement instruments can encourage compliance. All of these functions support the regulatory structure in reducing risk of Fund expenditures.

EPA looked at applicable enforcement authorities as well as historical enforcement and compliance data in the development of this proposal. EPA obtained data from the EPA Enforcement and Compliance History Online (ECHO) system and provides a review of the Federal environmental enforcement settlements and judgments data from FY 1974 through FY 2017.[66] Facilities whose primary NAICS codes indicate Petroleum and Coal Products Manufacturing (NAICS 324) were included in EPA's review. ECHO data show that targeted initiatives and routine review or inspection of facilities resulted in over 2500 enforcement cases in the Petroleum and Coal Products Manufacturing industry from FY 1974 through FY 2017. CAA (53%) and CWA (18%) cases were the most common. There are a smaller number of cases in RCRA (9%), CERCLA (8%), EPCRA (6%), and TSCA (4%). Further description of this review is in the background document, which is available in the docket for this rulemaking.[67]

As noted above, the Risk Management Program under Chemical Accident Prevention Provisions of Section 112(r) of the Clean Air Act Amendments requires certain facilities to generate Risk Management Plans (RMPs) to mitigate the effects of a chemical accident and coordinate with local response personnel. Assuring compliance with this program has been a priority of EPA's Office of Enforcement and Compliance Assurance since 2017.

Enforcement cases can include instances in which removal action, release reduction, or return to compliance include the removal of contaminated media by the responsible party. Measures to remove contamination may be required in enforcement orders under the range of environmental statutes and are negotiated to require activities aligned with return to compliance.[68] In this situation, enforcement action directly reduces risks to human health and the environment. During the period FY 2011 through FY 2016, 14 settled Petroleum and Coal Products Manufacturing industry enforcement cases were flagged in ECHO as involving removal of contaminated media. They are primarily CWA (8 of the 14) cases. One Clean Air Act, two RCRA and three CERCLA cases are also included.

The substances removed included metals, hydrocarbons, asbestos, and hazardous chemicals. These cleanups resulting from Federal enforcement actions mitigated risks to human health and the environment, removing contaminated soils, groundwater and a variety of hazardous substances, and reduced likelihood of impact to the Fund.

Settlements and judgments in enforcement cases can result in financial penalties, supplemental environmental projects (SEPs), and activities required to return to compliance.[69] Enforcement settlements and judgments can ensure that the responsible party conducts or pays for cleanup, drive a return to compliance, and incentivize compliance.

As stated in the cleanup site evaluations in Section VII.A, particular consideration was given to CERCLA and RCRA regulations that had relevant components which apply to the Petroleum and Coal Products Manufacturing industry. There have been over 400 CERCLA and RCRA enforcement cases in this industry, beginning in 1981. For context, there are approximately 2,167 establishments currently operating in the industry. The ten largest CERCLA or RCRA enforcement settlements and judgments for the Petroleum and Coal Products Manufacturing industry each have 2017 inflation-adjusted total values ranging from over $13 million to $72 million. Further discussion of the details on the Federal actions for these and additional criminal cases can be found in the background document for this section and is available in the docket for this rulemaking.[70] This document lists facilities where noncompliance was identified and was addressed by means of formal Federal enforcement. The background document does not include facilities where noncompliance was addressed through informal enforcement or facilities where noncompliance was addressed by a state. In addition, it does not include facilities where noncompliance was not identified, either because those facilities were not inspected or because they were inspected and found in compliance.

The compliance and enforcement actions documented here and in the background document show that where noncompliance is identified, the preponderance of industry responsible parties are conducting or paying for cleanups, returning to compliance, and improving public health and the environment. Although enforcement actions alone do not completely supplant the need for Fund-financed response actions in the Petroleum and Coal Products Manufacturing industry (as discussed in section VIII, below), effective criminal, civil and judicial enforcement demonstrates proper functioning of this component of the modern regulatory framework. Enforcement thus serves as a complementary element supporting the overall conclusion that CERCLA Section 108(b) financial assurance is not necessary.

[66] ECHO does not include all of EPA's compliance and enforcement activity because regions are not required to report ''informal actions,'' and it does not consistently capture all state actions.

[67] *Enforcement, Court Settlements and Judgments in the Petroleum and Coal Products Manufacturing Industry.*

[68] These ECHO enforcement removals are separate from the Superfund removals analyzed elsewhere. ECHO system data includes the combined value of total enforcement financial penalties, Supplemental Environmental Projects (SEPs), and associated compliance activity.

[69] Compliance actions ordered can include the removal of contaminated media, installation of new equipment, or implementation of compliant processes.

[70] *Enforcement, Court Settlements and Judgments in the Petroleum and Coal Products Manufacturing Industry.*

VIII. Decision to Not Propose Requirements

Based on consideration of the analyses described in the previous sections, EPA has reached a conclusion that the degree and duration of risk posed by the Petroleum and Coal Products Manufacturing industry does not warrant financial responsibility requirements under CERCLA Section 108(b) and thus is proposing to not issue such requirements. The analysis and proposed finding in this proposal are not applicable to and do not affect, limit, or restrict EPA's authority (1) to take a response action or enforcement action under CERCLA at any facility in the Petroleum and Coal Products Manufacturing industry, including any currently operating facilities or those described in this proposal and in the background documents for this proposal, and (2) to include requirements for financial responsibility as part of such response action. The set of facts in the rulemaking record related to the individual facilities discussed in this proposed rulemaking supports the Agency's proposal not to issue financial responsibility requirements under Section 108(b) for this class, but a different set of facts could demonstrate a need for a CERCLA response action at an individual site. This proposed rulemaking also does not affect the Agency's authority under other authorities that may apply to individual facilities, such as the CAA, CWA, RCRA, and TSCA.

EPA believes the evaluation of the Petroleum and Coal Products Manufacturing industry demonstrates significantly reduced risk of a Fund-financed response action at current operations. The reduction in risks due to the requirements of existing regulatory programs and voluntary practices, combined with reduced costs to the taxpayer—demonstrated by EPA's cleanup case analysis, existing financial responsibility requirements, and enforcement actions—has reduced the need for Federally-financed response action at facilities in the Petroleum and Coal Products Manufacturing industry. EPA looked at current industry practices, market structure and economic performance of the industry; analyzed cleanup cases for facilities in the industry; and evaluated the extent to which the industry and sources of releases are covered by the modern regulatory framework, the degree to which taxpayers have been called upon to pay for cleanup, and EPA enforcement history in the industry.

As discussed in section VII.A, EPA identified only one cleanup case that occurred under the modern regulatory framework and also entailed some Fund expenditure. Overwhelmingly, however, the industry was found to be practicing responsibly within the current regulatory framework, with just one site indicating a significant impact to the Fund while operating under the modern regulatory framework. For context, there are approximately 2,167 establishments currently operating in the industry. The language in Section 108(b) on determining the degree and duration of risk and on setting the level of financial responsibility confers a significant amount of discretion on EPA. In the past, some of the risks associated with spills resulted from, or were exacerbated by, cleanups not being undertaken in a timely fashion. However, under the modern regulatory framework, requirements such as the Risk Management Plan under the CAA, the Emergency Action Plan under OSHA, and as RCRA requirements for TSDFs to detect, contain, and clean up any leaks, including facility-wide corrective action, all help to ensure timely responses to releases. In addition to the requirements for facilities to respond to spills in a timely fashion, the public can alert the Federal government to releases by calling the National Response Center (NRC), which is a part of the Federally established National Response System and staffed 24 hours a day by the U.S. Coast Guard. The NRC is the designated Federal point of contact for reporting all oil, chemical, radiological, biological and etiological discharges into the environment, anywhere in the United States and its territories.

Only one site (discussed in detail in Section VII.A) had significant releases or threatened releases of hazardous substances under the modern regulatory framework and required more than minimal taxpayer-funded cleanups. Additionally, none of the at least 20 refineries that have closed since 2000, under the modern regulatory framework, had releases that resulted in a more than minimal burden to the Fund. It is EPA's assessment that the small set of Federally-funded cleanup cases due to recent contamination does not warrant the imposition of costly financial responsibility requirements on the entire Petroleum and Coal Products Manufacturing industry under CERCLA Section 108(b).

EPA acknowledges that regulations do not always prevent releases, and the risk of a release is lessened but never eliminated by existing Federal and state environmental regulations. However, EPA believes that the network of Federal and state regulations creates a comprehensive framework that applies to prevent releases that could result in a need for a Fund-financed response action. Numerous Federal programs have been established under several environmental statutes since CERCLA was enacted on December 11, 1980. These include programs under RCRA, which requires proper management and disposal of hazardous waste; under TSCA, which regulates the manufacture and sale of chemicals; and under both the CWA and the CAA, which address releases to water and air. In addition to these Federal programs, some states have stricter or additional standards beyond Federal requirements. These Federal and state programs are discussed in detail in Section VII. B and in the background document, which is available in the docket for this rulemaking.[71]

In addition, enforcement settlements and judgments that force return to compliance are important components of the applicable regulatory structure. EPA's analysis of enforcement history shows that enforcement of the applicable regulations provides a lever to monitor compliance, obtain responsible party cleanups, and recover financial penalties. Federal and state regulatory programs, backed up by enforcement and complemented by industry voluntary practices, have improved public health and the environment significantly since CERCLA's initial adoption nearly 40 years ago. EPA believes that within the Petroleum and Coal Products Manufacturing industry, this framework provides effective controls that protect human health and the environment.

Examination of market structures for the Petroleum and Coal Products Manufacturing industry further indicates comparatively low likelihood of default on environmental obligations at the expense of taxpayers and the government by companies in this industry. This economic performance, combined with the low impact to the Fund by facilities with releases that happened under the modern regulatory framework, suggests that the degree of risk to the Fund by this industry does not rise to a level that warrants imposing CERCLA Section 108(b) financial responsibility requirements.

For these reasons, EPA is proposing today to not issue financial responsibility requirements under CERCLA Section 108(b) for this industry.

[71] *Summary Report: Federal and State Environmental Regulations and Industry Voluntary Programs in Place to Address CERCLA Hazardous Substances at Petroleum and Coal Products Manufacturing Facilities.*

A. Solicitation of Public Comment on This Proposal

EPA solicits comments on all aspects of today's proposal. EPA is specifically interested in receiving comments on several issues and requests the following information:

- Examples of Petroleum and Coal Products Manufacturing industry related response actions for releases which took place under the modern regulatory framework where potentially responsible parties (PRPs) did not lead the response at the facility.
- Examples of Petroleum and Coal Products Manufacturing industry related response actions for releases which took place under the modern regulatory framework where PRPs have not taken financial responsibility for their environmental liabilities.
- Information on state-lead or other Federal agency cleanups or instances of natural resource damages associated with this industry that may supplement the information on cleanups gathered and analyzed for this proposal.
- Information about existing Federal, state, tribal, and local environmental requirements applicable to the Petroleum and Coal Products Manufacturing industry relevant to the prevention of releases of hazardous substances that were not evaluated as part of this proposal.
- Information about financial responsibility requirements applicable to the Petroleum and Coal Products Manufacturing industry that were not evaluated as part of this proposal.

IX. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review, because it may raise novel legal or policy issues [3(f)(4)]. Any changes made in response to OMB recommendations have been documented in the docket for this rulemaking. EPA did not prepare an economic analysis for the proposed rule, since this action proposes no regulatory requirements.

B. Executive Order 13771: Reducing Regulation and Controlling Regulatory Costs

This proposed rule is not subject to the requirements of Executive Order 13771 (82 FR 9339, February 3, 2017) because this proposed rule would not result in additional cost.

C. Paperwork Reduction Act (PRA)

This action does not propose an information collection burden under the PRA, because this action does not propose any regulatory requirements.

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action does not propose any new requirements for small entities.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments, because this action does not propose any regulatory requirements.

F. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the Federal Government and the states, or on the distribution of power and responsibilities among the various levels of government, since this action proposes no new regulatory requirements.

G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175, because this action proposes no regulatory requirements. Thus, Executive Order 13175 does not apply to this action.

H. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

This action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866, and because EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children, since this action proposes no regulatory requirements.

I. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This action is not a ''significant energy action'' because it is not likely to have a significant adverse effect on the supply, distribution or use of energy, since this action proposes no regulatory requirements.

J. National Technology Transfer and Advancement Act

This rulemaking does not involve technical standards.

K. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

EPA believes that this action is not subject to Executive Order 12898 because it does not establish an environmental health or safety standard, since this action proposes no regulatory requirements.

List of Subjects in 40 CFR Part 320

Environmental protection, Financial responsibility, Hazardous substances, Petroleum.

Dated: December 4, 2019.

Andrew R. Wheeler,

Administrator.

[FR Doc. 2019–27066 Filed 12–20–19; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 51, 61, and 69

[WC Docket No. 18–155; Report No. 3137; FRS 16323]

Petition for Reconsideration of Action in Proceeding

AGENCY: Federal Communications Commission.

ACTION: Petition for reconsideration.

SUMMARY: A Petition for Reconsideration (Petition) has been filed in the Commission's proceeding listed below by James U. Troup, on behalf of Iowa Network Services, Inc. d/b/a Aureon Network Services.

DATES: Oppositions to the Petition must be filed on or before January 7, 2020. Replies to an opposition must be filed on or before January 17, 2020.

ADDRESSES: Federal Communications Commission, 445 12th Street SW, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Lynne Engledow, Pricing Policy Division, Wireline Competition Bureau, at (202) 418–1540, email: *Lynne.Engledow@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's document, Report No. 3137, released December 10, 2019. The full text of the Petition is available for viewing and copying at the FCC Reference Information Center, 445 12th Street SW, Room CY–A257, Washington, DC 20554.

It also may be accessed online via the Commission's Electronic Comment Filing System at: *http://apps.fcc.gov/ecfs/*. The Commission will not send a Congressional Review Act (CRA) submission to Congress or the Government Accountability Office pursuant to the CRA, 5 U.S.C. 801 because no rules are being adopted by the Commission.

Subject: Updating the Intercarrier Compensation Regime to Eliminate Access Arbitrage, FCC 19–94, published at 84 FR 57629, October 28, 2019, in WC Docket No. 18–155. This document is being published pursuant to 47 CFR 1.429(e). *See also* 47 CFR 1.4(b)(1) and 1.429(f), (g).

Number of Petitions Filed: 1.

Federal Communications Commission.

Marlene Dortch,

Secretary,

[FR Doc. 2019–27608 Filed 12–20–19; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MB Docket Nos. 19–310 and 17–105; FCC 19–122]

Amendment of the Commission's Rules Regarding Duplication of Programming on Commonly Owned Radio Stations, Modernization of Media Initiative

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document seeks comment on whether the Commission should modify or eliminate its rule (the radio duplication rule) that bars same-service (AM or FM) commercial radio stations from duplicating more than 25% of their total hours of programming in an average broadcast week if the stations have 50% or more contour overlap and are commonly owned or subject to a time brokerage agreement.

DATES:

Comments Due: January 22, 2020. *Replies Due:* February 6, 2020.

ADDRESSES: Interested parties may submit comments and replies, identified by MB Docket Nos. 19–310 and 17–105, by any of the following methods:

- *Federal Communications Commission Website: http://apps.fcc.gov/ecfs/*. Follow the instructions for submitting comments.
- *Mail:* Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.
- *People with Disabilities:* Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by email: *FCC504@fcc.gov* or phone: 202–418–0530 or TTY: 202–418–0432.

For more detailed filing instructions for submitting comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Julie Saulnier, Industry Analysis Division, Media Bureau, *Julie.Saulnier@fcc.gov,* (202) 418–1598.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Notice of Proposed Rulemaking* (NPRM) in MB Docket Nos. 19–310 and 17–105, FCC 19–122, that was adopted November 22, 2019 and released November 25, 2019. The full text of this document is available for public inspection during regular business hours in the FCC Reference Center, 445 12th Street SW, Room CY–A257, Washington, DC 20554, or online at *https://docs.fcc.gov/public/attachments/FCC–18–179A1.pdf.* Documents will be available electronically in ASCII, Microsoft Word, and/or Adobe Acrobat. Alternative formats are available for people with disabilities (Braille, large print, electronic files, audio format, etc.) and reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) may be requested by sending an email to *fcc504@fcc.gov* or calling the FCC's Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY).

Synopsis

1. *Background.* In 1964, the Commission first limited radio programming duplication by commonly owned stations in the same local area by prohibiting FM stations in cities with populations over 100,000 from duplicating the programming of a co-owned AM station in the same local area for more than 50% of the FM station's broadcast day. Even though the Commission did not consider programming duplication an efficient use of FM spectrum, it was willing to allow limited duplication ''as a temporary expedient to help establish the [then-new] FM service.'' To minimize the rule's economic impact on radio broadcasters, the Commission allowed for waivers upon a substantial showing that programming duplication would be in the public interest, and provided that compliance would be monitored through the license renewal process. In 1976, the Commission concluded that ''the virtually complete absence of available channels as well as the strengthened economic position of FM'' warranted tightening the restriction to limit FM stations to duplicating only 25% of the average program week of a co-owned AM station in the same local area if either the AM or FM station operated in a community of over 25,000 population. The Commission found that fewer available channels in communities of substantial size could inhibit programming diversity and that programming duplication was a wastefully inefficient use of spectrum. In 1986 the Commission eliminated the cross-service radio duplication rule entirely, finding that FM service had developed, and FM stations were fully competitive. The Commission further found that the rule was no longer necessary to promote spectrum efficiency because market forces would lead stations to provide separate programming where economically feasible, and, where separate programming was not economically feasible, duplication was preferable to a station curtailing programming or going off air entirely to comply with the rule.

2. In 1992, as part of a broad review of radio ownership rules, the Commission adopted a new programming duplication rule barring same-service (AM or FM) commercial radio stations from duplicating more than 25% of the total hours of an average broadcast week of programming if the stations have 50% or more contour overlap and are commonly owned or subject to a time brokerage agreement. Principal community contours are defined as ''predicted or measured 5 mV/m groundwave for AM stations and predicted 3.16 mV/m for FM stations.'' 47 CFR 73.3556. A time brokerage agreement generally involves the sale by one radio licensee of blocks of time to a broker who then supplies programming to fill that time and sells advertising to support it.

3. The Commission saw no public benefit in allowing substantial programming duplication, observing that, ''when a channel is licensed to a particular community, others are prevented from using that channel and six adjacent channels at varying distances of up to hundreds of kilometers. The limited amount of available spectrum could be used more efficiently by other parties to serve

competition and diversity goals.'' The Commission concluded, however, that limited programming duplication had benefits, stating ''we are persuaded that limited simulcasting, particularly where expensive, locally produced programming such as on-the-spot news coverage is involved, could economically benefit stations . . . .''

4. *Discussion.* Overall, the Commission seeks comment on whether it should modify or eliminate the radio duplication rule and asks if the rule has outlived its utility or whether it remains necessary to further the public interest goals of competition, programming diversity and spectrum efficiency for which it was intended. The broadcast industry has changed significantly since the Commission adopted the current rule in 1992. One change promoting competition and programming diversity is the greatly increased number of radio stations licensed and operating across the country: Roughly 11,700 commercial AM and FM and FM translator stations in 1992, but close to 19,500 such stations today. There also are many more non-commercial/educational radio stations (1,588 in 1992 versus 4,122 today) as well as more than two thousand low power FM stations, all adding to diverse programming. Further, radio broadcasters now expand their content offerings by using station websites and mobile applications, allowing users to listen to a variety of programming on multiple devices either for free or with a paid subscription. This significant growth in the number of radio broadcasting outlets, combined with the new and varied formats in which broadcasters disseminate their programming, has led to greater radio broadcasting competition and programming diversity.

5. Broadcast radio technology also has improved with the introduction of digital radio, which enables FM stations to provide clear sound comparable in quality to CDs and enables AM stations to provide sound quality equivalent to standard analog FM sound quality. Stations broadcasting in digital also are able to provide multiple streams of programming as well as other data such as information about music airing on the station, weather updates, traffic reports and other news.

6. Further, the Commission's AM revitalization proceeding has brought AM programming to the FM band and enabled greater competition. The Commission began allowing AM stations (both commercial and noncommercial) to use currently authorized FM translator stations to retransmit their AM service within their AM stations' coverage areas in 2009. In 2016, the Commission opened two exclusive windows for AM stations to apply to relocate FM translator stations, giving them the ability to expand service by broadcasting at night when their signals may be substantially reduced. In response, the Commission granted more than 1,000 such applications. The Commission opened two additional spectrum windows in 2018 and 2019 and awarded licenses for more than 1,700 new FM translator stations to AM stations not participating in the earlier windows. These efforts have helped AM stations to increase their audiences, and potentially their advertising revenues, in an effort to better compete against stronger rivals.

7. Collectively, how do these changes affect the need for the radio duplication rule? Is the rule still needed to promote radio broadcast competition or programming diversity? Is the Commission's assessment of the increased competition and programming diversity within the radio broadcast industry correct? Are there advantages to competition and programming diversity from giving radio broadcasters additional programming freedom? Or, alternatively, is the radio duplication rule needed to ensure continued competition and diversity, and if so, could elimination or modification of this rule potentially harm programming diversity? Do other sources of audio programming, such as satellite radio or digital streaming audio services, impact the analysis of the need for the radio duplication rule, and if so, how? Has there been consolidation in any aspect of the media marketplace, and if so, how does it impact the Commission's analysis? Should the Commission also consider the impact of non-audio sources of information and entertainment, such as video providers, newspapers, and social media outlets, and if so, how? We seek comment on whether elimination of the radio duplication rule would affect any other public interest goals articulated by the Commission; for example, the public interest goals of broadcast localism, competition and diversity. We also seek comment on whether elimination or modification of this rule would impact local news gathering and journalism, and how elimination or modification could impact consumers who rely on local news for information about their community. Would the elimination or modification of this rule have any special impact on current or prospective station owners who are women or people of color and their ability to compete? Commenters should support any assertions on these points with relevant data and analyses.

8. The Commission also seeks comment on whether the radio duplication rule remains necessary to promote spectrum efficiency. Due in part to the increased number of stations, radio broadcast spectrum is now fully utilized. Demand for spectrum for wireless data applications has mushroomed, leading to the first-ever incentive auction to repurpose television broadcast spectrum for wireless broadband and continuous Commission efforts to free more spectrum for wireless applications. Spectrum remains a scarce and valuable resource, and increased demand for spectrum now pushes radio broadcasters, and indeed all spectrum users, to maximize efficiency. Should the Commission be concerned that absent the radio duplication rule, radio broadcasters will use spectrum less efficiently? Or are the increased number of stations and demand for spectrum today sufficient to ensure that radio broadcasters use spectrum efficiently and supply varied programming to the local market so that the current same-service duplication rule can be eliminated or modified? Is there any evidence to show that radio broadcasters currently use their spectrum inefficiently? Would the limited amount of spectrum available be used more efficiently by current licensees broadcasting duplicative content or other parties to serve competition and diversity goals?

9. In 1986, the Commission eliminated the previous cross-service programming duplication rule, which had restricted certain FM stations from rebroadcasting the programming of commonly owned AM stations in the same local market. Initially adopted to encourage the growth of the FM band and foster competition among local stations, the Commission eliminated the rule once it determined that the FM service was sufficiently established and FM stations were fully competitive. The Commission found that the rule was no longer necessary to promote spectrum efficiency because market forces would lead stations to provide separate programming where economically feasible, and where it was not economically feasible, duplication was preferable to a station curtailing programming or going off the air entirely due to failure to comply with the rule. Do the reasons that caused the Commission to eliminate the cross-service programming duplication rule apply equally to our consideration of the current, same-service duplication rule (§ 73.3556)? Is competition among

local broadcast radio stations sufficiently robust to ensure that overlapping, commonly owned same-service stations will provide separate programming where economically feasible? And where not economically feasible, is duplication of programming preferable to a station ceasing operation or curtailing programming?

10. In adopting section 73.3556 in 1992, the Commission noted certain benefits to permitting some level of programming duplication. Specifically, the Commission found that some duplication could save local broadcaster resources invested in producing expensive programming. In setting the limit on programming duplication at 25% of the total hours of a station's average weekly programming, the Commission sought to strike an appropriate balance between affording stations the ability to repurpose costly programming and continuing to foster competition and programming diversity in the local market. Do the benefits previously identified by the Commission related to the duplication of programming still exist in today's market? Given the changes that have occurred over the past twenty-seven years, as discussed above, does permitting duplication of 25% of the total hours of a station's average weekly programming continue to strike the appropriate balance? If we were to retain and modify the rule, should the amount of programming that can be duplicated on commonly owned stations be increased or decreased, and if so, what would that appropriate percentage be? Commenters should substantiate any proposed change in the amount of permitted programming duplication and explain the benefits that they believe would redound to radio stations and their listeners. Further, if the Commission were to modify and retain the radio duplication rule, would the restriction on broadcasters' programming choices raise any First Amendment concerns?

11. Additionally, in the event the rule is retained, does the trigger for the rule, namely, that the overlap between the stations constitutes more than 50% of the principal community contour service area of either station, continue to be the appropriate standard? Does an overlap of principal community contours appropriately identify stations that should be subject to a programming duplication rule? Should the overlap percentage be revised so that the rule applies if there is some greater, or lesser, amount of overlap between the commonly owned stations? And if so, what should that overlap be? Commenters should substantiate any proposed change in the amount of overlap before the program duplication rule would be triggered and explain any potential benefits or harms. For example, would any potential modification of the rule's trigger have differential effects on small entities? What impact could increasing or decreasing the contour overlap trigger have on duplicative programming? For example, could modifying the contour overlap trigger result in some communities receiving more duplicative programming, thereby harming localism and availability of diverse programming? Could modifying the rule so that it is triggered by a larger contour overlap percentage make valued programming available to more listeners?

12. Given the economic and technical challenges facing AM broadcasters, should the programming duplication rule treat the AM service differently than the FM service? For example, should the Commission keep the rule for the FM service but eliminate it for the AM service? Given reception challenges in the AM band, particularly in urban environments, would eliminating or loosening the AM portion of the rule allow more listeners to hear popular programming?

13. Finally, the Commission seeks comment generally on the benefits and costs associated with possible modification or elimination of the radio duplication rule. Commenters supporting retention, modification, or elimination of the rule should explain the anticipated economic impact of any proposed action, including the impact on small entities, and, where possible, quantify benefits and costs of proposed actions and alternatives. Does the current radio duplication rule create benefits or costs for any segment of consumers, advertisers, or broadcasters? If so, how would elimination or modification of the rule alter the benefits and costs? If the rule were eliminated or modified, how could that impact small entities' ability to compete for advertising dollars? What are the comparative benefits and costs of modifying the rule rather than eliminating it entirely?

Procedural Matters

14. *Initial Regulatory Flexibility Analysis.* As required by the Regulatory Flexibility Act of 1980, as amended (RFA), the Commission has prepared an Initial Regulatory Flexibility Analysis (IRFA) relating to this NPRM.

15. *Initial Paperwork Reduction Act Analysis.* This document may result in new or revised information collection requirements subject to the Paperwork Reduction Act of 1995. If the Commission adopts any new or revised information collection requirement, the Commission will publish a notice in the **Federal Register** inviting the public to comment on the requirement, as required by the Paperwork Reduction Act. In addition, pursuant to the Small Business Paperwork Relief Act of 2002, the Commission seeks specific comment on how it might ''further reduce the information collection burden for small business concerns with fewer than 25 employees.''

16. *Ex Parte Rules—Permit-But-Disclose.* The proceeding this NPRM initiates shall be treated as a ''permit-but-disclose'' proceeding in accordance with the Commission's *ex parte* rules. Persons making *ex parte* presentations must file a copy of any written presentation or a memorandum summarizing any oral presentation within two business days after the presentation (unless a different deadline applicable to the Commission's pre-meeting Sunshine period applies). Persons making oral *ex parte* presentations are reminded that memoranda summarizing the presentation must (1) list all persons attending or otherwise participating in the meeting at which the *ex parte* presentation was made, and (2) summarize all data presented and arguments made during the presentation. If the presentation consisted in whole or in part of the presentation of data or arguments already reflected in the presenter's written comments, memoranda or other filings in the proceeding, the presenter may provide citations to such data or arguments in prior comments, memoranda, or other filings (specifying the relevant page and/or paragraph numbers where such data or arguments can be found) in lieu of summarizing them in the memorandum. Documents shown or given to Commission staff during *ex parte* meetings are deemed to be written *ex parte* presentations and must be filed consistent with § 1.1206(b) of the Commission's rules. In proceedings governed by § 1.49(f) of the Commission's rules or for which the Commission has made available a method of electronic filing, written *ex parte* presentations and memoranda summarizing oral *ex parte* presentations, and all attachments thereto, must be filed through the electronic comment filing system available for that proceeding, and must be filed in their native format (*e.g.,* .doc, .xml, .ppt, searchable .pdf). Participants in this proceeding should familiarize

themselves with the Commission's *ex parte* rules.

17. *Filing Comments and Replies.* Pursuant to §§ 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested parties may file comments and reply comments on or before the dates indicated on the first page of this document. Comments may be filed using the Commission's Electronic Comment Filing System (ECFS). *See Electronic Filing of Documents in Rulemaking Proceedings,* 63 FR 24121 (1998).

• *Electronic Filers:* Comments may be filed electronically using the internet by accessing the ECFS: *http://apps.fcc.gov/ecfs/.*

• *Paper Filers:* Parties who choose to file by paper must file an original and one copy of each filing. If more than one docket or rulemaking number appears in the caption of this proceeding, filers must submit two additional copies for each additional docket or rulemaking number.

Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.

▪ All hand-delivered or messenger-delivered paper filings for the Commission's Secretary must be delivered to FCC Headquarters at 445 12th St. SW, Room TW–A325, Washington, DC 20554. The filing hours are 8:00 a.m. to 7:00 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes and boxes must be disposed of *before* entering the building.

▪ Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9050 Junction Drive, Annapolis Junction, MD 20701.

▪ U.S. Postal Service first-class, Express, and Priority mail must be addressed to 445 12th Street SW, Washington, DC 20554.

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

19. *Availability of Documents.* Comments, reply comments, and *ex parte* submissions will be available for public inspection during regular business hours in the FCC Reference Center, Federal Communications Commission, 445 12th Street SW, CY–A257, Washington, DC 20554. These documents will also be available via ECFS. Documents will be available electronically in ASCII, Microsoft Word, and/or Adobe Acrobat.

20. *Additional Information.* For additional information on this proceeding, contact Julie Saulnier, *julie.saulnier@fcc.gov,* of the Industry Analysis Division, Media Bureau, (202) 418–1598.

Initial Regulatory Flexibility Analysis

21. *Need for, and Objective of, the Proposed Rules.* This NPRM seeks comment on whether the Commission should eliminate or modify the radio duplication rule, which limits same-service programming duplication to 25% of total hours in an average broadcast week for commercial AM and FM radio stations with 50% or more contour overlap that are commonly owned or subject to a time brokerage agreement. The radio broadcast industry has seen significant changes since the Commission adopted the rule in 1992, including a greatly increased number of licensed radio stations, the introduction of AM broadcasting to the FM band through FM translator stations, improved digital radio broadcast technology, and new, digital methods for distributing audio content to multiple devices. Based on these changes, the NPRM seeks comment on whether the radio duplication rule has outlived its utility or whether it remains necessary to further the public interest goals of competition, programming diversity and spectrum efficiency for which it was intended.

22. *Legal Basis.* The proposed action is authorized under sections 14(i), 4(j), and 303 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154(i), 154(j), and 303.

23. *Description and Estimate of the Number of Small Entities to Which the Proposed Rules Will Apply.* The RFA directs agencies to provide a description of, and where feasible, an estimate of the number of small entities that may be affected by the proposed rule revisions, if adopted. The RFA generally defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction.'' In addition, the term ''small business'' has the same meaning as the term ''small business concern'' under the Small Business Act (SBA). A small business concern is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the SBA. Below, we provide a description of such small entities, as well as an estimate of the number of such small entities, where feasible.

24. The radio broadcasting U.S. Economic Census category ''comprises establishments primarily engaged in broadcasting aural programs by radio to the public.'' Programming may originate in the establishment's own studio, from an affiliated network, or from external sources. The SBA has created the following small business size standard for such businesses: Those having $38.5 million or less in annual receipts. Economic Census data for 2012 show that 2,849 firms in this category operated in that year. Of that number, 2,806 operated with annual receipts of less than $25 million per year, 17 with annual receipts between $25 million and $49,999,999 million and 26 with annual receipts of $50 million or more. Based on this data, we estimate that the majority of commercial radio broadcast stations were small under the applicable SBA size standard.

25. The Commission has estimated the number of licensed commercial FM radio stations to be 6,728, the number of commercial FM translator stations to be 8,177 and the number of commercial AM stations to be 4601, for a total of 19,505 commercial radio stations. Of this total, 19,496 stations (or 99.9%) had revenues of $38.5 million or less in 2018, according to Commission staff review of the BIA Kelsey Inc. Media Access Pro Radio Database (BIA) on October 7, 2019, and therefore these stations qualify as small entities under the SBA definition.

26. In assessing whether a business concern qualifies as small under the above definition, business (control) affiliations must be included. Our estimate, therefore, likely overstates the number of small entities that might be affected by our action because the revenue figure on which it is based does not include or aggregate revenues from affiliated companies. In addition, an element of the definition of ''small business'' is that the entity not be dominant in its field of operation. We are unable at this time to define or quantify the criteria that would establish whether a specific radio station is dominant in its field of operation. Accordingly, the estimate of small businesses to which the proposed rules may apply does not exclude any radio station from the definition of small business on this basis and is therefore possibly over-inclusive.

27. *Description of Projected Reporting, Recordkeeping and Other Compliance Requirements.* The NPRM seeks comment on whether to modify or eliminate the radio duplication rule. If

the Commission were to eliminate the rule, it would be expected to reduce compliance requirements for radio broadcasters, including small entities. If the rule were retained but modified to increase the contour overlap necessary to trigger the rule or increase the amount of programming permitted to be duplicated on the commonly owned stations, the compliance requirements would be reduced for radio broadcasters, as the current restriction would be made more permissive. Conversely, were the rule to be modified so as to decrease the contour overlap necessary to trigger the rule or to decrease the amount of programming permitted to be duplicated, it could increase the number of radio broadcasters subject to the rule and/or potentially increase the compliance requirements for those broadcasters in situations that are not subject to the existing rule.

28. *Steps Taken to Minimize Significant Economic Impact on Small Entities, and Significant Alternatives Considered.* The RFA requires an agency to describe any significant alternatives that it has considered in reaching its proposed approach, which may include the following four alternatives (among others): (1) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance or reporting requirements under the rule for small entities; (3) the use of performance, rather than design, standards; and (4) an exemption from coverage of the rule, or any part thereof, for small entities. The NPRM seeks comment on eliminating the radio duplication rule, which would relieve radio broadcasters, including small entities, from costs of compliance with the rule. The NPRM also seeks comment on modifying the rule instead of repealing it, alternatives that will minimize any burden on small entities, and on retention of the existing rule.

29. *Federal Rules that May Duplicate, Overlap, or Conflict with the Proposed Rule.* None.

30. *Ordering Clauses.* Accordingly, it is ordered that, pursuant to the authority found in sections 1, 4(j), and 303(r) of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154(i), 154(j), and 303(r), this *Notice of Proposed Rulemaking* is adopted.

31. It is further ordered that, pursuant to applicable procedures set forth in §§ 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415 and 1.419, interested parties may file comments on the Notice of Proposed Rulemaking in MB Docket Nos. 19–310 and 17–105 on or before thirty (30) days after publication in the **Federal Register** and reply comments on or before forty five (45) days after publication in the **Federal Register**.

32. It is further ordered that the Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, shall send a copy of this *Notice of Proposed Rulemaking,* including the Initial Regulatory Flexibility Act Analysis, to the Chief Counsel for Advocacy of the Small Business Administration.

List of Subjects in 47 CFR Part 73

Television; Radio.

Federal Communications Commission.

Cecilia Sigmund,

Federal Register Liaison Officer.

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR part 73 as follows:

PART 73—RADIO BROADCAST SERVICES

■ 1. The Authority citation for Part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 155, 301, 303, 307, 309, 310, 334, 336, 339.

§ 73.3556 [Removed and Reserved]

■ 2. Remove and reserve § 73.3556.

[FR Doc. 2019–27645 Filed 12–20–19; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 73 and 74

[MB Docket No. 03–185; DA 19–1231]

Low Power Television Digital Rules

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In this document, the Media Bureau seeks to update the record in MB Docket No. 03–185 on the operation of analog radio services by digital low power television stations (LPTV) as ancillary or supplementary services.

DATES:

Comments Due: January 22, 2020.

Reply Comments Due: February 6, 2020.

ADDRESSES: You may submit comments, identified by MB Docket No. 03–185, by any of the following methods:

• *Electronic Filers:* Comments may be filed electronically using the internet by accessing the ECFS: *http://fjallfoss.fcc.gov/ecfs2/.*

▪ *Paper Filers:* Parties who choose to file by paper must file an original and one copy of each filing. If more than one docket or rulemaking number appears in the caption of this proceeding, filers must submit two additional copies for each additional docket or rulemaking number.

▪ Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.

▪ All hand-delivered or messenger-delivered paper filings for the Commission's Secretary must be delivered to FCC Headquarters at 445 12th St. SW, Room TW–A325, Washington, DC 20554. The filing hours are 8:00 a.m. to 7:00 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes and boxes must be disposed of *before* entering the building.

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▪ U.S. Postal Service first-class, Express, and Priority mail must be addressed to 445 12th Street SW, Washington, DC 20554.

Availability of Documents. Comments, reply comments, and *ex parte* submissions will be available for public inspection during regular business hours in the FCC Reference Center, Federal Communications Commission, 445 12th Street SW, CY–A257, Washington, DC 20554. These documents will also be available via ECFS. Documents will be available electronically in ASCII, Microsoft Word, and/or Adobe Acrobat.

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

For detailed instructions for submitting comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Shaun Maher, *Shaun.Maher@fcc.gov* of the Media Bureau, Video Division, (202) 418–2324.

SUPPLEMENTARY INFORMATION: This is a summary of the Media Bureau's Notice

of Proposed Rulemaking, DA 19–1231, released December 4, 2019. The full text is available for inspection and copying during regular business hours in the FCC Reference Center, 445 12th Street SW, Room CY–A257, Portals II, Washington, DC 20554, and may also be purchased from the Commission's copy contractor, BCPI, Inc., Portals II, 445 12th Street SW, Room CY–B402, Washington, DC 20554. Customers may contact BCPI, Inc. via their website, *http://www.bcpi.com,* or call 1–800–378–3160. This document is available in alternative formats (computer diskette, large print, audio record, and Braille). Persons with disabilities who need documents in these formats may contact the FCC by email: *FCC504@fcc.gov* or phone: 202–418–0530 or TTY: 202–418–0432.

Synopsis

1. In this document, the Media Bureau (Bureau) seeks to update the record in MB Docket No. 03–185 on the operation of analog radio services by digital low power television stations (LPTV) as ancillary or supplementary services under § 74.790(i) of the Commission's rules. Due to the impending deadline for elimination of the analog LPTV service, and recent developments in the record, the Bureau seek to refresh the record in this proceeding.

2. Historically, some analog LPTV stations licensed on channel 6 have operated with very limited visual programming and an audio signal that is programmed like a radio station. FM radio listeners are able to receive the audio portion of these LPTV stations at 87.76 MHz, which is adjacent to noncommercial educational (NCE) FM channel 201 (88.1 MHz). When these LPTV stations convert to digital, however, they will be unable to continue providing such radio service because the digital audio portion of their signal can no longer be received by standard FM receivers.

3. As part of the transition from analog to digital operations, the Commission sought comment in a 2014 Notice of Proposed Rulemaking in MB Docket No. 03–185, 29 FCC Rcd 12536 (2014) (NPRM) on whether to allow LPTV stations on digital television channel 6 to continue to operate these analog FM radio-type services on an ancillary or supplementary basis. Specifically, the Commission sought comment on whether to permit LPTV stations on digital television channel 6 to operate dual digital and analog transmission systems. The Commission sought to determine whether a digital LPTV station can provide an analog FM radio-type service as an ancillary or supplementary service consistent with the Communications Act of 1934, as amended, and the rules. The Commission also sought comment on the potential for a digital LPTV station's analog FM radio-type service to interfere with or disrupt the LPTV station's digital TV service and/or interfere with primary licensees. Finally, the Commission asked whether such operations should be subject to the Part 73 rules applicable to FM radio stations and whether the analog FM radio-type service should be subject to the five percent fee imposed on revenues generated by ancillary or supplementary services. In a 2015 Report and Order, the Commission declined to decide this issue, and instead noted that it would make a determination at a later date.

4. Given the upcoming deadline for LPTV to transition to digital, the Bureau finds it appropriate to refresh the record in this docket. Several parties have also recently raised some additional issues on which the Bureau seeks comment. For example, Venture Technologies Group, Inc., et al. (Channel 6 Commenters) maintains that LPTV licensees should be allowed to make ''the most efficient use of spectrum'' by providing analog FM radio-type service on an ancillary or supplementary basis. Preserve Community Programming Coalition (PCPC) agrees and recommends that the Commission modify its rules to allow those LPTV stations currently licensed and operating in analog on channel 6 to continue transmitting an analog audio carrier when they transition to digital operations on channel 6. Both commenters claim that the provision of independent aural and visual carriers are allowed under the rules and we seek comment on whether that is an accurate reading of the Commission's technical rules.

5. In addition, Channel 6 Commenters and PCPC maintain that digital LPTV stations can operate with supplementary audio signals pursuant to the existing ancillary or supplementary services rules. The Bureau seeks comment on these matters. Specifically, the Bureau seeks comment on whether analog channel 6 LPTV stations currently operating an analog FM-radio type service should be permitted to continue to provide such service on an ancillary or supplementary basis after they transition to digital. Further, the Bureau seeks comment on whether, and how, the Commission could legally limit the number of stations eligible to offer such a service. Should the Commission determine to limit eligibility, the Bureau seeks comment on the basis for such a limitation. Should eligibility be limited to only those analog channel 6 LPTV stations ''currently operating'' an analog FM radio-type service? How should the Commission define the term ''currently operating?'' Should ''currently operating'' be defined as an analog channel 6 LPTV station providing an analog FM radio-type service as of the release date of this Public Notice? The Bureau seeks comment on this proposal, other cut-off dates, or alternate ways to limit eligibility.

6. Channel 6 Commenters and PCPC also maintain that analog radio signals ''can co-exist on the same 6 MHz channel as a digital [c]hannel 6 LPTV station without harming TV or FM reception.'' Channel 6 Commenters argues that ''no verifiable evidence has ever been produced showing that a channel 6 television station, operating within the lawful parameters of its license, causes harmful interference to an FM radio station.'' PCPC recommends revising the rules so that, ''if the operation of the LPTV station causes any actual interference to the transmission of any authorized FM broadcast station, the LPTV station should be required to eliminate the interference or immediately suspend operations.'' California State University Long Beach Research Foundation (Cal State) disagrees and maintains that the Commission's current rules ignore the potential for interference between LPTV channel 6 analog audio operations and FM radio stations which Cal State describes as ''particularly objectionable since LPTV are left free to propose facilities that are predicted to cause interference to primary service FM radio stations, even though LPTV is a secondary service.'' Cal State asks that the Commission obtain ''much more detailed information'' on this issue and adopt rules to protect other stations from interference. The Bureau seeks comment on the question of whether analog FM-radio type services operated by digital LPTV channel 6 stations will cause impermissible interference to other services. The Bureau requests the submission of any more recent technical studies demonstrating the feasibility of transmitting analog audio signals within a digital television station's spectrum.

7. The Commission rules require FM stations proposing operations on FM reserved band channels 201 through 220 to protect television stations operating on TV channel 6. Commenters should note that the Commission in July 2019 adopted an Notice of Proposed Rulemaking, 34 FCC Rcd 6537 (2019) proposing elimination of these protections entirely as of July 13, 2021 (the deadline for the digital LPTV transition) and adoption of a waiver

process in the interim. The Commission acknowledged those analog LPTV channel 6 television stations providing FM radio type services and specifically sought comment on whether the proposed elimination of channel 6 television protection by FM radio stations would be compatible with LPTV audio operations on 87.7 MHz if such operations were allowed to continue.

8. Finally, given the passage of time since the NPRM was adopted, the Bureau seeks comment on the remaining issues raised in the NPRM. For example, as required by Section 336(b)(1) of the Act, is use of digital LPTV channel 6 for an analog service ''consistent with the technology or method designated by the Commission for the provision of advanced television services''? The Bureau seeks comment on how an ancillary or supplementary analog service is ''consistent with'' digital technology. If the Commission decides to permit analog FM radio-type operations by digital LPTV stations on an ancillary or supplementary basis, the Bureau seeks comment on whether such operations should be subject to the Part 73 rules applicable to FM radio stations. Should channel 6 digital LPTV stations authorized to provide analog FM radio-type operations be prohibited from transferring such authorization and should the right to continue the analog operation terminate with an assignment or transfer?

9. In addition, the Bureau seeks further comment on whether the provision of an analog FM radio-type service on an ancillary or supplementary basis should be subject to a five percent fee on revenues generated by such service. Channel 6 Commenters maintains that ''a supplementary 87.7 MHz audio signal qualifies as an ancillary service, which entitles the government to 5% of its revenue.''

Initial Regulatory Flexibility Act Analysis

The NPRM included an Initial Regulatory Flexibility Analysis (IRFA) pursuant to 5 U.S.C. 603, exploring the potential impact on small entities of the Commission's proposals. The Bureau invites parties to file comments on the IRFA in light of this request to refresh the record. Comments must be identified as responses to the IRFA and must be filed by the deadlines for comments indicated on the first page of this document.

List of Subjects in 47 CFR Parts 73 and 74

Television, Low Power Television.

Federal Communications Commission.

Barbara Kreisman,

Chief, Video Division.

[FR Doc. 2019–27614 Filed 12–20–19; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

49 CFR Parts 172 and 173

[Docket No. PHMSA–2018–0025 (HM–264); Notice No. 2019–14]

RIN 2137–AF40

Hazardous Materials: Liquefied Natural Gas by Rail; Extension of Comment Period

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), Department of Transportation (DOT).

ACTION: Proposed rule; Extension of comment period.

SUMMARY: On October 24, 2019, PHMSA published a notice of proposed rulemaking (NPRM), entitled ''Hazardous Materials: Liquefied Natural Gas by Rail (HM–264)'' proposing changes to the Hazardous Materials Regulations to allow for the bulk transport of Methane, refrigerated liquid, commonly known as liquefied natural gas (LNG), in rail tank cars. In response to a request for an extension of the comment period from the Offices of the Attorneys General of New York and Maryland, PHMSA is extending the comment period for the HM–264 NPRM for an additional 21 days. Comments to the HM–264 NPRM will now be due January 13, 2020.

DATES: Comments should be received on or before January 13, 2020. To the extent possible, PHMSA will consider late-filed comments.

ADDRESSES: Comments should reference Docket No. PHMSA–2018–0025 and may be submitted in the following ways:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 1–202–493–2251.
- *Mail:* Docket Management System; U.S. Department of Transportation, West Building, Ground Floor, Room W12–140, Routing Symbol M–30, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* To the Docket Management System; Room W12–140 on the ground floor of the West Building, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Instructions: All submissions must include the agency name and Docket Number (PHMSA–2018–0025) for this notice at the beginning of the comment. To avoid duplication, please use only one of these four methods. All comments received will be posted without change to the Federal Docket Management System (FDMS) and will include any personal information you provide. If sent by mail, comments must be submitted in duplicate. Persons wishing to receive confirmation of receipt of their comments must include a self-addressed stamped postcard.

Docket: For access to the dockets to read associated documents or comments received, go to *http://www.regulations.gov* or DOT's Docket Operations Office (see **ADDRESSES**).

Privacy Act: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its process. DOT posts these comments, without change, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

Confidential Business Information: Confidential Business Information (CBI) is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' PHMSA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Michael Ciccarone, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590–0001. Any commentary that PHMSA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

FOR FURTHER INFORMATION CONTACT: Michael Ciccarone, Standards and Rulemaking Division, (202) 366–8553, Pipeline and Hazardous Materials Safety Administration, or Mark Maday, Federal

Railroad Administration, (202) 366–2535, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590–0001.

SUPPLEMENTARY INFORMATION:

I. Background

PHMSA, in consultation with the Federal Railroad Administration (FRA), published the HM–264 NPRM [1] on October 24, 2019, in response to a petition for rulemaking from the Association of American Railroads and an internal review of existing regulations. The NPRM proposed to authorize DOT–113C120W tank cars for use in the transportation of LNG by rail, requesting public comment by December 23, 2019.

On December 5, 2019, PHMSA granted a U.S. Department of Transportation Special Permit [2] (DOT–SP) to Energy Transport Solutions, LLC (ETS) authorizing transportation of LNG in DOT–113C120 tank cars between Wyalusing, PA and Gibbstown, NJ, with no intermediate stops, subject to certain operational controls. PHMSA issued DOT–SP 20534 after having completed extensive analysis in response to the request for special permit received from ETS in August 2017.

The special permit, as issued, includes certain operational controls that were not included in the HM–264 NPRM. PHMSA did not propose operational controls in the HM–264 NPRM. However, in the NPRM, PHMSA invited comment on whether PHMSA and FRA should rely on existing regulations and industry standards, or if additional operational controls may be warranted based on an assessment of risk. PHMSA encouraged commenters to provide data on the safety or economic impacts associated with any suggested operational controls, including analysis of the safety justification or cost impact of implementing the operational controls.

PHMSA recognized that the subject matter overlapped between the NPRM and special permit. Therefore, PHMSA published a notice [3] in the **Federal Register** on December 11, 2019, to inform the public that DOT–SP 20534 and documents supporting the special permit decision were being added to the docket for the HM–264 NPRM for consideration by the public. PHMSA invited comments on these operational controls to be submitted to the rulemaking docket (Docket No. PHMSA–2018–0025) by December 23, 2019. We noted our intent to consider any additional comments on the operational controls included in the special permit that are filed in the rulemaking docket to aid in determining what, if any, operational controls may be appropriate for inclusion in the HM–264 final rule.

II. Comment Period Extension

PHMSA initially provided a 60-day comment period for the HM–264 NPRM, which expires on December 23, 2019. In response to a request to extend the comment period an additional 30 days from the Offices of the Attorneys General of New York and Maryland, PHMSA is extending the comment period an additional 21 days. The comment period will now close on January 13, 2020. This extension provides the public with 32 days [4] to review relevant aspects of the special permit, and should provide adequate opportunity for the public to submit additional comments, if necessary.

Issued in Washington, DC, on December 18, 2019, under authority delegated in 49 CFR part 1.97.

William S. Schoonover,

Associate Administrator of Hazardous Materials Safety, Pipeline and Hazardous Materials Safety Administration.

[FR Doc. 2019–27656 Filed 12–20–19; 8:45 am]

BILLING CODE 4910–60–P

[1] See *Hazardous Materials: Liquefied Natural Gas by Rail NPRM* [84 FR 56964] at *https://www.federalregister.gov/documents/2019/10/24/2019-22949/hazardous-materials-liquefied-natural-gas-by-rail.*

[2] See DOT–SP 20534 at *https://www.regulations.gov/document?D=PHMSA-2019-0100-3006.*

[3] See *Hazardous Materials: Notice of Issuance of Special Permit Regarding Liquefied Natural Gas* [84 FR 67768] at *https://www.federalregister.gov/documents/2019/12/11/2019-26614/hazardous-materials-notice-of-issuance-of-special-permit-regarding-liquefied-natural-gas.*

[4] Thirty days from December 11, 2019, would be January 11, 2020, which is a Saturday, therefore PHMSA decided to extend the comment period to the following Monday, January 13, 2020.

Notices

Federal Register

Vol. 84, No. 246

Monday, December 23, 2019

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

Animal and Plant Health Inspection Service

[Docket No. APHIS–2011–0102]

Privacy Act of 1974; System of Records

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of a modified system of records; reopening of comment period.

SUMMARY: We are reopening the comment period for our proposal to modify a system of records titled the Animal Welfare Act and Horse Protection Act, USDA/APHIS–8. This action will allow interested persons additional time to prepare and submit comments.

DATES: The comment period for the notice published on October 24, 2019 (84 FR 56999) is reopened. We will consider all comments that we receive on or before December 26, 2019.

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

- *Federal eRulemaking Portal:* Go to: *http://www.regulations.gov/#!docketDetail;D=APHIS-2011-0102.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2011–0102, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road, Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2011-0102* or in our reading room, which is located in Room 1141 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: For general questions, please contact Mr. Tola Liv, Information Systems Security Manager, Animal Care, APHIS, 4700 River Road Unit 84, Riverdale, MD 20737; (301) 851–3741. For Privacy Act questions concerning this system of records notice, please contact Ms. Tonya Woods, Director, Freedom of Information Act/Privacy Act, 4700 River Road, Unit 50, Riverdale, MD 20737; (301) 851–4076. For USDA Privacy Act questions, please contact the USDA Chief Privacy Officer, Information Security Center, Office of Chief Information Officer, USDA, Jamie L. Whitten Building, 1400 Independence Ave. SW, Washington, DC 20250; email: *USDAPrivacy@ocio.usda.gov.*

SUPPLEMENTARY INFORMATION: On October 24, 2019, we published in the **Federal Register** (84 FR 56999–57004, Docket No. APHIS–2011–0102) a notice of a modified system of records titled Animal Welfare Act and Horse Protection Act, USDA/APHIS–8. In addition to revising the name of the system, we proposed to further modify the system by updating the system location, manager, and system safeguards; expanding the categories of individuals and records included in the system; revising the record source categories; updating policies and practices for storage, retrievability, and retention and disposal of records; updating the notification, record access, and contesting record procedures; and revising, deleting, redesignating, and establishing routine uses.

Comments on the notice were required to be received on or before November 25, 2019. We are reopening the comment period on Docket No. APHIS–2011–0102 for an additional 30 days. This action will allow interested persons additional time to prepare and submit comments.

We will also consider all comments received between November 26, 2019 (the day after the close of the original comment period) and the date of this notice.

Done in Washington, DC, this 19th day of December 2019.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2019–27800 Filed 12–20–19; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

National Institute of Food and Agriculture

Solicitation of Input From Stakeholders on the Federally Recognized Tribes Extension Program—FRTEP

AGENCY: National Institute of Food and Agriculture, USDA.

ACTION: Request for written stakeholder input.

SUMMARY: The National Institute of Food and Agriculture (NIFA) is requesting written stakeholder input on the Federally Recognized Tribes Extension Program (FRTEP).

The purpose of this Notice is to assist NIFA in developing the FY 2021 Request for Applications for the Federally Recognized Tribes Extension Program. NIFA plans to consider all stakeholder input received in response to this Notice.

DATES: Written comments on this Notice must be received by February 15, 2020, to be assured of consideration. Comments received after that date will be considered to the extent practicable.

ADDRESSES: You may submit comments, identified by NIFA–2020–0001, through the Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments. Include NIFA–2020–0001 in the subject line of the message.

Instructions: All submissions received must include the Title, ''Federally Recognized Tribes Extension Program'' and NIFA–2020–0001. All comments received will be posted to *http://www.regulations.gov,* including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Erin Riley 816–926–2131 (phone), *erin.riles@usda.gov.*

SUPPLEMENTARY INFORMATION: The program is authorized under Section 3(d) of the Act of May 8, 1914, Smith-Lever Act, ch. 79, 38, Stat. 372, 7 U.S.C. 341 *et seq.* Section 7609 of the Agriculture Improvement Act of 2018 (Pub. L. 115–334) amended section 3(d) of the Smith-Lever Act to allow 1994 Land-grant Institutions eligibility to receive FRTEP grant funds.

Background and Summary: Section 7609 of the Agriculture Improvement Act of 2018 added 1994 Land-grant Institutions as eligible to receive Smith-

Lever 3(d) funding, including grants under the Federally Recognized Tribes Extension Program (FRTEP).

Previously, only 1862 and 1890 Land-grant Institutions were eligible to receive FRTEP grants. The grant competition for FRTEP is run every four years, and a new competition is scheduled for fiscal year (FY) 2021. NIFA is using this opportunity to gather stakeholder feedback for the next open competition in FY 2021.

The purpose of this program is to establish an Extension presence and support Extension outreach on Federally Recognized Indian Reservations and Tribal jurisdictions of Federally Recognized Tribes. FRTEP seeks to continue the Land Grant mission of inclusion by providing education and research-based knowledge to those who might not otherwise receive it.

Program Priorities Have Included:

a. Tribal Youth and 4–H
b. Indian Farmer and Rancher Productivity and Management
c. Indian Community Development:
- Economic and Workforce Development
- Food Systems, Farm and Community Markets
- Natural Resource Conservation and Adaptation to Environmental Changes
- Human Nutrition and Reduction of Childhood and Adolescent Obesity
- Indian Cultural and Language Preservation

Effective Extension involves identifying and attracting funds and resources to support an ever-changing and growing portfolio of activities in response to identified community needs. As a result, it is understood that applicants will work towards a comprehensive Extension plan and engage in both direct and indirect activities in support of their proposed programs. Examples of funded direct program activities include, but are not limited to, needs assessments, educational workshops, site visits, producer demonstration projects and cultural-learning events. Funded indirect activities have included, but are not limited to: Extending partnerships, expanding communication networks, and acquiring additional resources in support of the overall goals and objectives of the proposed project.

Done at Washington, DC, this 18th day of November 2019.

Stephen Censky,

Deputy Secretary, U.S. Department of Agriculture.

[FR Doc. 2019–27568 Filed 12–20–19; 8:45 am]

BILLING CODE 3410–22–P

DEPARTMENT OF AGRICULTURE

Natural Resources Conservation Service

[Docket ID: NRCS–2019–0021]

The Secretary of Agriculture's Determination of the Primary Purpose of the Nevada Petroleum Claims Fund for the Cleanup of Petroleum Discharge From Storage

AGENCY: Natural Resources Conservation Service (NRCS), U.S. Department of Agriculture (USDA).

ACTION: Notice of Determination.

SUMMARY: NRCS is providing public notice that the Secretary of Agriculture has determined that cost share payments made by the Nevada Division of Environmental Protection (NDEP) are primarily for the purpose of conserving soil and water resources or protecting and restoring the environment. NRCS was assigned technical and administrative responsibility for reviewing NDEP's Petroleum Claims Fund program and for making appropriate recommendations for the Secretary's determination of primary purpose. The Secretary made the determination for the State of Nevada's Petroleum Claims Fund program administered by the Nevada Division of Environmental Protection.

FOR FURTHER INFORMATION CONTACT: Greg Lovato, Division Administrator, Nevada Petroleum Claims Fund, 901 S Stewart Street, Carson City, Nevada 89701 or Maggie Rhodes, Director, Financial Assistance Programs Division, Department of Agriculture, Natural Resources Conservation Service, 1400 Independence Avenue SW, Room 5237 South Building, Washington, DC 20250.

SUPPLEMENTARY INFORMATION: Under Section 126(a) (8) of the Internal Revenue Code, gross income does not include the ''excludable portion'' of payments received under any program of a State, or a political subdivision of a State, under which payments are made to individuals primarily for the purpose of protecting or restoring the environment. In general, a cost share payment for selected conservation practices is exempt from Federal taxation if it meets three tests: (1) It was for a capital expense, (2) it does not substantially increase the operator's annual income from the property for which it is made, and (3) the Secretary of Agriculture certified that the payment was made primarily for conserving soil and water resources, protecting or restoring the environment, improving forests, or providing habitat for wildlife.

The Secretary of Agriculture evaluates a conservation program on the basis of criteria set forth in 7 CFR part 14 and makes a ''primary purpose'' determination for the payments made under the program. The objective of the determination made under part 14 is to provide maximum conservation, environmental, forestry improvement, and wildlife benefits to the general public from the operation of applicable programs. Final determinations are made based on program, category of practices, or individual practices.

Following a primary purpose determination by the Secretary of Agriculture, the Secretary of the Treasury determines if the payments made under the conservation program substantially increases the annual income derived from the property benefited by the payments.

From this Federal action, approving tax deferral will not result in impacts to the environment, therefore, no further National Environmental Policy Act (NEPA) documentation will be prepared.

Determination: As provided for by Section 126 of the Internal Revenue Code, the Secretary examined the authorizing legislation, regulations, and operating procedures regarding the NDEP's Nevada Petroleum Claims Fund program. In accordance with the criteria set out in 7 CFR part 14, the Secretary has determined the primary purpose of cost share payments made under Nevada Petroleum Claims Fund program is conserving soil and water resources or protecting and restoring the environment.

The State of Nevada Petroleum Fund was initially implemented in 1989 by State legislation to assist owners and operators of regulated underground storage tanks in meeting the Federal requirements for financial responsibility, pursuant to the Code of Federal Regulations (CFR) 40 CFR 280.90 through 280.99. The Fund also allows voluntary enrollment of eligible non-regulated petroleum storage tanks and covers the cost of cleanup associated with releases from residential heating oil tanks.

A primary objective when the Nevada legislature authorized the Fund is the protection of the State's environment, specifically the supplies of water. The Nevada legislature made these findings part of the statutory authorization in NRS 445C.290 and charged the Nevada Board to Review Claims (Board) with assisting in the prompt cleanup of any discharge of petroleum from a storage tank located in Nevada.

A ''Record of Decision'' for the Nevada Petroleum Fund Board to

review claims regarding reimbursement for cleanup of petroleum storage tank discharges has been prepared and is available upon request from Maggie Rhodes, Director, Financial Assistance Programs Division, NRCS, 1400 Independence Avenue SW, Room 5237 South Building, Washington, DC 20250.

This determination is in accordance with Section 126 of the Internal Revenue Code of 1954, as amended (26 U.S.C. 126), and permits recipients of cost share payments to exclude such payments from gross income to the extent allowed by the Internal Revenue Service.

Matthew Lohr,

Chief, Natural Resources Conservation Service.

[FR Doc. 2019–27581 Filed 12–20–19; 8:45 am]

BILLING CODE 3410–16–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–489–825]

Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes From the Republic of Turkey: Final Results of Countervailing Duty Administrative Review; 2017

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) determines that countervailable subsidies are not being provided to Ozdemir Boru Profil San. Ve Tic. Ltd. Sti. (Ozdemir), an exporter/producer of heavy walled rectangular welded carbon steel pipes and tubes (HWR pipes and tubes) from the Republic of Turkey (Turkey), during the period of review (POR) January 1, 2017 through December 31, 2017.

DATES: Applicable December 23, 2019.

FOR FURTHER INFORMATION CONTACT: Jaron Moore or Janae Martin, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3640 or (202) 482–0238, respectively.

SUPPLEMENTARY INFORMATION:

Background

On August 21, 2019, Commerce published the *Preliminary Results* of this administrative review.[1] For a description of the events that occurred since the *Preliminary Results, see* the Issues and Decision Memorandum.[2] The deadline for the final results of this administrative review is December 19, 2019.

Scope of the Order

The products covered by the order are certain heavy walled rectangular welded steel pipes and tubes of rectangular (including square) cross section, having a nominal wall thickness of not less than 4 mm. The subject merchandise is currently provided for in item 7306.61.1000 of the Harmonized Tariff Schedule of the United States (HTSUS). Subject merchandise may also enter under HTSUS 7306.61.3000. While the HTSUS subheadings and ASTM specification are provided for convenience and customs purposes, the written description is dispositive.[3]

Analysis of Comments Received

A list of the issues raised by interested parties and to which we responded in the Issues and Decision Memorandum is provided in the appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov,* and to all parties in the Central Records Unit, room B8024 of the main Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/.* The signed and electronic versions of the Issues and Decision Memorandum are identical in content.

Changes From the Preliminary Results

Based on our analysis of the comments received, Commerce made certain revisions to the subsidy rate calculations for Ozdemir. The Issues and Decision Memorandum contains descriptions of these revisions.

Methodology

Commerce conducted this review in accordance with section 751(a)(1)(A) of the Tariff Act of 1930, as amended (the Act). For each of the subsidy programs found countervailable, we find that there is a subsidy, *i.e.,* a government-provided financial contribution that gives rise to a benefit to the recipient, and that the subsidy is specific. For a full description of the methodology underlying Commerce's conclusions, *see* the Issues and Decision Memorandum.

Final Results of Administrative Review

In accordance with 19 CFR 351.221(b)(5), we determine the following net countervailable subsidy rate for Ozdemir during the period January 1, 2017 through December 31, 2017:

Company	Subsidy rate (percent)
Ozdemir Boru Profil San. Ve Tic. Ltd. Sti	0.24 (*de minimis*)

Assessment Rates

Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, countervailing duties on all appropriate entries covered by this review, pursuant to section 751(a)(2)(C) of the Act and 19 CFR 351.212(b).[4] Because we calculated a *de minimis* margin for Ozdemir in the final results of this review, we intend to instruct CBP to liquidate the appropriate entries without regard to countervailing duties.

Commerce intends to issue the appropriate assessment instructions to CBP 15 days after the date of publication of the final results of this review.

Cash Deposit Requirement

Pursuant to section 751(a)(2)(C) of the Act, Commerce also intends to instruct CBP to collect cash deposits of estimated countervailing duties at the appropriate rates. For shipments of subject merchandise by Ozdemir entered, or withdrawn from warehouse, for consumption on or after the date of publication of these final results, the cash deposit rate will be zero. For all non-reviewed firms, we will instruct CBP to continue to collect cash deposits at the most-recent company-specific or all-others rate applicable to the company, as appropriate. These cash deposit requirements, when imposed,

[1] *See Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes from the Republic of Turkey: Preliminary Results of Countervailing Duty Administrative Review; 2017,* 84 FR 43583 (August 21, 2019) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum.

[2] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results: Administrative Review of the Countervailing Duty Order on Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes from the Republic of Turkey,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum), at 2.

[3] For a complete description of the scope of the order, *see* Issues and Decision Memorandum at 2–3.

[4] *See* section 751(a)(2)(C) of the Act; 19 CFR 351.212(b).

shall remain in effect until further notice.

Administrative Protective Order

This notice also serves as a final reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of proceeding. Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

These final results are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(5).

Dated: December 17, 2019.

Christian Marsh,

Deputy Assistant Secretary for Enforcement and Compliance.

APPENDIX

I. Summary
II. Background
III. Scope of the Order
IV. Period of Review
V. Subsidies Valuation Information
VI. Analysis of Programs
VII. Analysis of Comments
Comment 1: Provision of Hot-Rolled Steel (HRS) for Less Than Adequate Renumeration (LTAR): Whether To Include Value-Added Tax (VAT) on Imported HRS
Comment 2: Deduction From Taxable Income for Export Revenue: Whether To Use Amount Listed in Ozdemir's 2016 or 2017 Tax Return
VIII. Recommendation

[FR Doc. 2019–27643 Filed 12–20–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–351–844]

Cold-Rolled Steel Flat Products From Brazil: Rescission of Countervailing Duty Administrative Review; 2018

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) is rescinding its administrative review of the countervailing duty (CVD) order on cold-rolled steel flat products (CRS flat products) from Brazil for the period of review (POR) January 1, 2018, through December 31, 2018.

DATES: Applicable December 23, 2019.

FOR FURTHER INFORMATION CONTACT: William Miller, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3906.

SUPPLEMENTARY INFORMATION:

Background

On September 3, 2019, Commerce published in the **Federal Register** a notice of opportunity to request an administrative review of the CVD order on CRS flat products from Brazil for the POR.[1] Commerce received a timely request from the petitioner, United States Steel Corporation, in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.213(b), to conduct an administrative review of this CVD order for seven companies.[2]

On November 12, 2019, Commerce published in the **Federal Register** a notice of initiation with respect to these companies.[3] On November 19, 2019, the petitioner timely withdrew its request for an administrative review for all seven companies.[4]

Rescission of Administrative Review

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if the parties that requested a review withdraw the request within 90 days of the date of publication of the notice of initiation of the requested review. The petitioner withdrew its request for review before the 90-day deadline, and no other party requested an administrative review of this order. Therefore, we are rescinding the administrative review of the CVD order on CRS flat products from Brazil covering the period January 1, 2018, through December 31, 2018, in its entirety.

Assessment

Commerce will instruct U.S. Customs and Border Protection (CBP) to assess countervailing duties on all appropriate entries. Because Commerce is rescinding this administrative review in its entirety, the entries to which this administrative review pertained shall be assessed at rates equal to the cash deposit of estimated countervailing duties required at the time of entry, or withdrawal from warehouse, for consumption, in accordance with 19 CFR 351.212(c)(1)(i). Commerce intends to issue appropriate assessment instructions directly to CBP 15 days after the date of publication of this notice in the **Federal Register**.

Notification Regarding Administrative Protective Orders

This notice serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Notification to Interested Parties

This notice is published in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.213(d)(4).

Dated: December 17, 2019.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2019–27642 Filed 12–20–19; 8:45 am]

BILLING CODE 3510–DS–P

[1] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review,* 84 FR 45949 (September 3, 2019).

[2] *See* Petitioner's Letter, ''Cold-Rolled Steel Flat Products from Brazil: Request for Administrative Review of Countervailing Duty Order,'' dated September 30, 2019 (request for review of: Aperam Inox America do Sul S.A.; Armco do Brasil S.A.; Arvedi Metalfer do Brasil; Companhia Siderurgica Nacional; NVent do Brasil Eletrometalurgica; Signode Brasileira Ltda.; and Usinas Siderurgicas de Minas Gerais (Usiminas)).

[3] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 84 FR 61011 (November 12, 2019).

[4] *See* Petitioner's Letter, ''Cold-Rolled Steel Flat Products from Brazil: Withdrawal of Request for Administrative Review of Countervailing Duty Order,'' dated November 19, 2019.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–095, C–570–096]

Aluminum Wire and Cable From the People's Republic of China: Antidumping Duty and Countervailing Duty Orders

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: Based on affirmative final determinations by the Department of Commerce (Commerce) and the International Trade Commission (ITC), Commerce is issuing antidumping duty

(AD) and countervailing duty (CVD) orders on imports of aluminum wire and cable from the People's Republic of China (China).

DATES: Applicable December 23, 2019.

FOR FURTHER INFORMATION CONTACT: Nancy Decker or Caitlin Monks at (202) 482–0196 and (202) 482–2670, respectively, AD/CVD Operations, Office VII, Enforcement and Compliance, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

In accordance with sections 705(d) and 735(d) of the Tariff Act of 1930, as amended (the Act), on October 30, 2019, Commerce published its affirmative final determination in the less-than-fair-value (LTFV) investigation of aluminum wire and cable from China, and its affirmative final determination that countervailable subsidies are being provided to producers and exporters of aluminum wire and cable from China.[1] On December 16, 2019, the ITC notified Commerce of its final affirmative determinations that an industry in the United States is materially injured by reason of LTFV imports and subsidized imports of aluminum wire and cable from China, within the meaning of sections 705(b)(1)(A)(i) and 735(b)(1)(A)(i) of the Act.[2]

Scope of the Orders

The products covered by these orders are aluminum wire and cable from China. For a complete description of the scope of the orders, *see* the Appendix to this notice.

AD Order

As stated above, on December 16, 2019, in accordance with section 735(d) of the Act, the ITC notified Commerce of its final determination that an industry in the United States is materially injured within the meaning of section 735(b)(1)(A)(i) of the Act by reason of imports of aluminum wire and cable from China that are sold in the United States at LTFV. Therefore, in accordance with section 735(c)(2) of the Act, we are issuing this AD order. Because the ITC determined that imports of aluminum wire and cable from China are materially injuring a U.S. industry, unliquidated entries of such merchandise from China entered, or withdrawn from warehouse, for consumption are subject to the assessment of antidumping duties.

Therefore, in accordance with section 736(a)(1) of the Act, Commerce will direct U.S. Customs and Border Protection (CBP) to assess, upon further instruction by Commerce, antidumping duties equal to the amount by which the normal value of the merchandise exceeds the export price (or constructed export price) of the merchandise, for all relevant entries of aluminum wire and cable from China. Antidumping duties will be assessed on unliquidated entries of aluminum wire and cable from China entered, or withdrawn from warehouse, for consumption on or after June 5, 2019, the date of publication of the *AD Preliminary Determination,*[3] but will not include entries occurring after the expiration of the provisional measures period and before publication of the ITC's final injury determination, as further described below.

Continuation of Suspension of Liquidation—AD

In accordance with section 736 of the Act, we will instruct CBP to continue the suspension of liquidation on entries of aluminum wire and cable from China, effective on the date of publication in the **Federal Register** of the ITC's final affirmative injury determination. These instructions suspending liquidation will remain in effect until further notice.

We will also instruct CBP to require cash deposits equal to the amounts indicated below. Accordingly, effective on the date of publication in the **Federal Register** of the ITC's final affirmative injury determination, CBP will require, at the same time as importers would normally deposit estimated duties on the subject merchandise, a cash deposit equal to the exporter/producer-specific estimated weighted-average dumping margins listed below. As stated in the *AD Final Determination,* Commerce made certain adjustments for export subsidies from the *CVD Final Determination* to the estimated weighted-average dumping margins to determine each of the cash deposit rates.

Exporter	Producer	Estimated weighted-average dumping margin (percent)	Cash deposit rate (adjusted for subsidy offsets) (percent)
Changfeng Wire & Cable Co., Ltd	Changfeng Wire & Cable Co., Ltd	58.51	47.83
Wuxi Jiangnan Cable Co., Ltd	Wuxi Jiangnan Cable Co., Ltd	58.51	47.83
China-wide entity		63.47	52.79

Provisional Measures—AD

Section 733(d) of the Act states that instructions issued pursuant to an affirmative preliminary determination may not remain in effect for more than four months, except where exporters representing a significant proportion of exports of the subject merchandise request Commerce to extend that four-month period to no more than six months. At the request of exporters that account for a significant proportion of aluminum wire and cable from China, Commerce extended the four-month period to six months in this proceeding.[4] In the underlying investigation, Commerce published the *AD Preliminary Determination* on June 5, 2019. Therefore, the extended period, beginning on the date of publication of the *AD Preliminary Determination,* ended on December 1, 2019. Furthermore, section 737(b) of the Act states that definitive duties are to begin on the date of publication of the ITC's final injury determination.

Therefore, in accordance with section 733(d) of the Act and our practice, Commerce will instruct CBP to

[1] *See Aluminum Wire and Cable from the People's Republic of China: Final Affirmative Determination of Sales at Less Than Fair Value,* 84 FR 58134 (October 30, 2019) (*AD Final Determination*); *see also Aluminum Wire and Cable from the People's Republic of China: Final Affirmative Countervailing Duty Determination,* 84 FR 58137 (October 30, 2019) (*CVD Final Determination*).

[2] *See* ITC's Letter, ''Notification of ITC Final Determinations,'' dated December 16, 2019 (ITC Notification); *see also Aluminum Wire and Cable from China,* Inv. No. 701–TA–611 and 731–TA–1428 (USITC Publication 5001).

[3] *See Aluminum Wire and Cable from the People's Republic of China: Affirmative Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination,* 84 FR 26069 (June 5, 2019) (*AD Preliminary Determination*).

[4] *Id.*

terminate the suspension of liquidation and to liquidate, without regard to antidumping duties, unliquidated entries of aluminum wire and cable from China entered, or withdrawn from warehouse, for consumption after December 1, 2019, the date on which the provisional measures expired, until and through the day preceding the date of publication of the ITC's final injury determination in the **Federal Register**. Suspension of liquidation will resume on the date of publication of the ITC's final determination in the **Federal Register**.

CVD Order

As stated above, on December 16, 2019, in accordance with section 705(d) of the Act, the ITC notified Commerce of its final determination that the industry in the United States producing aluminum wire and cable is materially injured within the meaning of section 705(b)(1)(A)(i) of the Act by reason of subsidized imports of aluminum wire and cable from China.[5] Therefore, in accordance with section 705(c)(2) of the Act, we are issuing this CVD order.

As a result of the ITC's final determination, in accordance with section 706(a) of the Act, Commerce will direct CBP to assess, upon further instruction by Commerce, countervailing duties on unliquidated entries of subject merchandise from China entered, or withdrawn from warehouse, for consumption on or after April 8, 2019, the date on which Commerce published the *CVD Preliminary Determination*[6] and before August 6, 2019, the effective date on which Commerce instructed CBP to discontinue the suspension of liquidation in accordance with section 703(d) of the Act. Section 703(d) of the Act states that the suspension of liquidation pursuant to a preliminary determination may not remain in effect for more than 120 days. Therefore, entries of subject merchandise from China made on or after August 6, 2019, and prior to the date of publication of the ITC's final determination in the **Federal Register**, are not subject to the assessment of countervailing duties due to Commerce's discontinuation of the suspension of liquidation.

Suspension of Liquidation—CVD

In accordance with section 706 of the Act, Commerce will direct CBP to reinstitute the suspension of liquidation of subject merchandise from China, effective on the date of publication of the ITC's final affirmative injury determination in the **Federal Register**, and to assess, upon further instruction by Commerce pursuant to section 706(a)(1) of the Act, countervailing duties for each entry of aluminum wire and cable in an amount based on the net countervailable subsidy rates for the subject merchandise. On or after the date of publication of the ITC's final injury determination in the **Federal Register**, Commerce will instruct CBP to require, at the same time as importers would normally deposit estimated duties on the subject merchandise, a cash deposit for each entry of subject merchandise equal to the subsidy rates listed below.[7] The all-others rate applies to all producers or exporters not specifically listed below, as appropriate.

Producer/exporter	Subsidy rate (percent)
Shanghai Silin Special Equipment Co., Ltd[8]	165.63
Changfeng Wire & Cable Co., Ltd	33.44
Shanghai Yang Pu Qu Gong	165.63
All Others	33.44

Provisional Measures—CVD

Section 703(d) of the Act states that the suspension of liquidation pursuant to an affirmative preliminary determination may not remain in effect for more than four months. Commerce published the affirmative *Preliminary Determination* on April 8, 2019. Therefore, the four-month period beginning on the date of the publication of the *Preliminary Determination* ended on August 5, 2019.

In accordance with section 733(d) of the Act, Commerce instructed CBP to terminate the suspension of liquidation and to liquidate, without regard to CVD duties, unliquidated entries of aluminum wire and cable from China entered, or withdrawn from warehouse, for consumption on or after August 6, 2019, the date on which the provisional CVD measures expired, through the day preceding the date of publication of the ITC final injury determinations in the **Federal Register**. Suspension of liquidation will resume on the date of publication of the ITC final injury determination in the **Federal Register**.

Notification to Interested Parties

This notice constitutes the AD and CVD orders with respect to aluminum wire and cable from China pursuant to sections 706(a) and 736(a) of the Act. Interested parties can find a list of orders currently in effect at *http://enforcement.trade.gov/stats/iastats1.html.*

These orders are published in accordance with sections 706(a) and 736(a) of the Act and 19 CFR 351.211(b).

Dated: December 17, 2019.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix

Scope of the Orders

The scope of these orders covers aluminum wire and cable, which is defined as an assembly of one or more electrical conductors made from 8000 Series Aluminum Alloys (defined in accordance with ASTM B800), Aluminum Alloy 1350 (defined in accordance with ASTM B230/B230M or B609/B609M), and/or Aluminum Alloy 6201 (defined in accordance with ASTM B398/B398M), provided that: (1) At least one of the electrical conductors is insulated; (2) each insulated electrical conductor has a voltage rating greater than 80 volts and not exceeding 1000 volts; and (3) at least one electrical conductor is stranded and has a size not less than 16.5 thousand circular mil (kcmil) and not greater than 1000 kcmil. The assembly may: (1) Include a grounding or neutral conductor; (2) be clad with aluminum, steel, or other base metal; or (3) include a steel support center wire, one or more connectors, a tape shield, a jacket or other covering, and/or filler materials.

Most aluminum wire and cable products conform to National Electrical Code (NEC) types THHN, THWN, THWN–2, XHHW–2, USE, USE–2, RHH, RHW, or RHW–2, and also conform to Underwriters Laboratories (UL) standards UL–44, UL–83, UL–758, UL–854, UL–1063, UL–1277, UL–1569, UL–1581, or UL–4703, but such conformity is not required for the merchandise to be included within the scope.

The scope of the orders specifically excludes aluminum wire and cable products in lengths less than six feet, whether or not included in equipment already assembled at the time of importation.

The merchandise covered by the orders is currently classifiable under subheading 8544.49.9000 of the Harmonized Tariff Schedule of the United States (HTSUS). Products subject to the scope may also enter under HTSUS subheading 8544.42.9090. The HTSUS subheadings are provided for convenience and customs purposes. The written description of the scope of the orders is dispositive.

[FR Doc. 2019–27641 Filed 12–20–19; 8:45 am]

BILLING CODE 3510–DS–P

[5] *See* ITC Notification.

[6] *See Aluminum Wire and Cable from the People's Republic of China: Preliminary Affirmative Countervailing Duty Determination, and Alignment of Final Determination with Final Antidumping Duty Determination,* 84 FR 13886 (April 8, 2019) (*CVD Preliminary Determination*).

[7] *See* section 706(a)(3) of the Act.

[8] As discussed in the *Preliminary Determination* PDM, Commerce has also assigned Silin's rate to the entity named as cross-owned in its affiliation questionnaire response: Jiangxi Silin International Cable Co., Ltd.

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XG910]

Takes of Marine Mammals Incidental To Specified Activities; Taking Marine Mammals Incidental to the Sand Island Pile Dike System Test Piles Project Near the Mouth of the Columbia River; Correction

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

ACTION: Notice; issuance of an incidental harassment authorization; correction.

SUMMARY: This document contains corrections to the **DATES** caption of the notice of issuance of an incidental harassment authorization (IHA) for the take of marine mammals incidental to the Sand Island Pile Dike System Test Piles Project Near the Mouth of the Columbia River. This action is necessary to correct errors in the effective dates of the issued IHA. The scope of the activities and anticipated effects remain the same, authorized take numbers have not changed, and the required mitigation, monitoring, and reporting remain the same.

FOR FURTHER INFORMATION CONTACT: Rob Pauline, Office of Protected Resources, NMFS, (301) 427–8401.

SUPPLEMENTARY INFORMATION:

Background

NMFS published a notice in the **Federal Register** on November 12, 2019 (84 FR 61026) announcing that an IHA had been issued to the U.S. Army Corps of Engineers, Portland District (Corps) authorizing the take of marine mammals incidental to the planned Sand Island Pile Dike System Test Piles Project effective for one year from the date of issuance. NMFS refers the reader to the November 12, 2019, **Federal Register** notice (84 FR 61026) for background information concerning the IHA. The information in the notice of issuance is not repeated here. As published, the notice of issuance contains errors, which need to be clarified.

Correction

1. On page 61026 in the third column, the **DATES** section is corrected to read as follows:

DATES: This Authorization is effective from September 15, 2020, through September 14, 2021.

2. On page 61037 in the third column, the paragraph under the heading ''Authorization'' is corrected to read as follows:

NMFS has issued an IHA to the Corps for conducting test pile installation and removal at the Sand Island Pile Dike system near the MCR, effective from September 15, 2020 through September 14, 2021, provided the mitigation, monitoring, and reporting requirements are incorporated.

Dated: December 16, 2019.

Catherine Marzin,

Deputy Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2019–27570 Filed 12–20–19; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XV154]

North Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: The North Pacific Fishery Management Council (Council) Bering Sea Fishery Ecosystem Plan Climate Change Taskforce will meet January 13, 2020 through January 15, 2020.

DATES: The meeting will be held on Monday, January 13, 2020, from 1 p.m. to 5 p.m.; January 14, from 9 a.m. to 5 p.m.; and on January 15, from 9 a.m. to 2 p.m., Pacific Standard Time.

ADDRESSES: The meeting will be held in the Goodman A at the Mountaineers Club 7700 Sand Point Way NE, Seattle, WA 98115. Teleconference number is (907) 245–3900, pin 2809.

Council address: North Pacific Fishery Management Council, 1007 W 3rd Ave, Anchorage, AK 99501–2252; telephone: (907) 271–2809.

FOR FURTHER INFORMATION CONTACT: Diana Stram, Council staff; telephone: (907) 271–2806.

SUPPLEMENTARY INFORMATION:

Agenda

Monday, January 13 Through Wednesday, January 15, 2020

The agenda will include: (a) Review of Bering Sea Fishery Ecosystem Plan (FEP) establishing Taskforce and Taskforce objectives; (b) Review of existing regional climate change initiatives, research and on-going modeling efforts; (c) the elements and timing of work required to meet Taskforce objectives; (d) development of a workplan; (e) outreach and communication; and (f) other business. The agenda is subject to change, and the latest version will be posted at *https://meetings.npfmc.org/Meeting/Details/1203* prior to the meeting, along with meeting materials.

Public Comment

Public comment letters will be accepted and should be submitted either electronically to *https://meetings.npfmc.org/Meeting/Details/1203* or through the mail: North Pacific Fishery Management Council, North Pacific Fishery Management Council, 1007 W 3rd Ave, Anchorage, AK 99501–2252; telephone: (907) 271–2809.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Shannon Gleason at (907) 271–2809 at least 7 working days prior to the meeting date.

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

Dated: December 18, 2019.

Tracey L. Thompson,

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

[FR Doc. 2019–27639 Filed 12–20–19; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XV157]

North Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: The North Pacific Fishery Management Council (Council) Crab Plan Team will meet January 14, 2020 through January 17, 2020.

DATES: The meetings will be held Tuesday, January 14, 2020 through Friday, January 17, 2020, from 8 a.m. to 5 p.m., Alaska Standard Time.

ADDRESSES: The meetings will be held in the Large Conference Room at the Kodiak Fisheries Research Center, 301 Research Ct, Kodiak, AK 99615.

Council address: North Pacific Fishery Management Council, 1007

West 3rd, Suite 400, Anchorage, AK 99501; telephone: (907) 271–2809.

FOR FURTHER INFORMATION CONTACT: Jim Armstrong, Council staff; telephone: (907) 271–2809.

SUPPLEMENTARY INFORMATION:

Agenda

Tuesday, January 14, 2020 Through Friday, January 17, 2020

The Crab Plan Team will review the final 2020 stock assessment for Norton Sound red king crab. Additionally the Crab Plan Team will discuss fishery catches, ecosystem and socioeconomic profiles, St Matthew blue king crab rebuilding, draft model runs for Aleutian Islands golden king crab, the BSAI crab economic SAFE, various aspects of crab research off Alaska, and plans for the Team's upcoming May 2020 meeting.

The Agenda is subject to change, and the latest version will be posted at *https://meetings.npfmc.org/Meeting/Details/1163* prior to the meeting, along with meeting materials.

Public Comment

Public comment letters will be accepted and should be submitted electronically to *https://meetings.npfmc.org/Meeting/Details/1163* or through the mail: North Pacific Fishery Management Council, 1007 West 3rd Suite 400, Anchorage, AK 99501. In-person oral public testimony will be accepted at the discretion of the chairs.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Shannon Gleason at (907) 271–2809 at least 7 working days prior to the meeting date.

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

Dated: December 18, 2019.

Tracey L. Thompson,

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

[FR Doc. 2019–27638 Filed 12–20–19; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XR076]

Marine Mammals; File No. 23577

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

ACTION: Notice; receipt of application.

SUMMARY: Notice is hereby given that the BBC Studios Ltd., Natural History Unit Productions, Broadcasting House, Whiteladies Road, Bristol, BS8 2LR, UK, (Responsible Party: Rowan Crawford), has applied in due form for a permit to conduct commercial or educational photography of humpback whales (*Megaptera novaeangliae*).

DATES: Written, telefaxed, or email comments must be received on or before January 22, 2020.

ADDRESSES: These documents are available upon written request or by appointment in the Permits and Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 427–8401; fax (301) 713–0376.

Written comments on this application should be submitted to the Chief, Permits and Conservation Division, at the address listed above. Comments may also be submitted by facsimile to (301) 713–0376, or by email to *NMFS.Pr1Comments@noaa.gov.* Please include the File No. in the subject line of the email comment.

Those individuals requesting a public hearing should submit a written request to the Chief, Permits and Conservation Division at the address listed above. The request should set forth the specific reasons why a hearing on this application would be appropriate.

FOR FURTHER INFORMATION CONTACT: Amy Hapeman or Carrie Hubard, (301) 427–8401.

SUPPLEMENTARY INFORMATION: The subject permit is requested under the authority of the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 *et seq.*) and the regulations governing the taking and importing of marine mammals (50 CFR part 216).

The applicant proposes to film humpback whales in Hawaii to obtain footage for an episode of a wildlife television series focusing on female animal behavior. Up to 315 humpback whales will be targeted for filming using a vessel, underwater divers, and an unmanned aircraft system (UAS). Activities would include behavioral observations, photography/videography, UAS operation, and passive acoustic recordings. Filmmakers may incidentally harass up to 30 short-beaked common dolphins (*Delphinus delphis*), 60 bottlenose dolphins (*Tursiops truncatus*), 342 spinner dolphins (*Stenella longirostris*), and 324 short-finned pilot whales (*Globicephala macrorhynchus*) during filming. The permit would expire on March 31, 2020.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), an initial determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Concurrent with the publication of this notice in the **Federal Register**, NMFS is forwarding copies of the application to the Marine Mammal Commission and its Committee of Scientific Advisors.

Dated: December 17, 2019.

Julia Marie Harrison,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2019–27571 Filed 12–20–19; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XV156]

New England Fishery Management Council; Public Meeting

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

ACTION: Notice; public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a public meeting of its Scientific & Statistical Committee to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This meeting will be held on Friday, January 10, 2020 beginning at 9:30 a.m.

ADDRESSES: The meeting will be held at the Hilton Garden Inn, Boston Logan, 100 Boardman Street, Boston, MA 02128; phone: (617) 567–6789.

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION:

Agenda

The Scientific and Statistical Committee will meet to consider the New England Fishery Management Council's remand of the SSC's acceptable biological catch (ABC) recommendations for American plaice, Gulf of Maine and Georges Bank haddock stocks, and Atlantic pollock for fishing years 2020–23. They will also discuss any matters concerning issues with ABC control rules for groundfish and the lack of fish stock status determination criteria. Other business will be discussed as needed.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency. The public also should be aware that the meeting will be recorded, consistent with 16 U.S.C. 1852, a copy of the recording is available upon request.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Thomas A. Nies, Executive Director, at (978) 465–0492, at least 5 days prior to the meeting date.

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

Dated: December 18, 2019.

Tracey L. Thompson,

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

[FR Doc. 2019–27637 Filed 12–20–19; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XR002

Marine Mammals; File No. 22156

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

ACTION: Notice; receipt of application.

SUMMARY: Notice is hereby given that Douglas Nowacek, Ph.D., Nicholas School of the Environment, Duke University Marine Laboratory, 135 Duke Marine Lab Rd, Beaufort, NC 28516, has applied in due form for a permit to conduct research on and import specimens of 31 cetacean species for scientific research.

DATES: Written, telefaxed, or email comments must be received on or before January 22, 2020.

ADDRESSES: The application and related documents are available for review by selecting ''Records Open for Public Comment'' from the ''Features'' box on the Applications and Permits for Protected Species (APPS) home page, *https://apps.nmfs.noaa.gov,* and then selecting File No. 22156 from the list of available applications.

These documents are also available upon written request or by appointment in the Permits and Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 427–8401; fax (301) 713–0376.

Written comments on this application should be submitted to the Chief, Permits and Conservation Division, at the address listed above. Comments may also be submitted by facsimile to (301) 713–0376, or by email to *NMFS.Pr1Comments@noaa.gov.* Please include the File No. in the subject line of the email comment.

Those individuals requesting a public hearing should submit a written request to the Chief, Permits and Conservation Division at the address listed above. The request should set forth the specific reasons why a hearing on this application would be appropriate.

FOR FURTHER INFORMATION CONTACT: Amy Hapeman or Shasta McClenahan, (301) 427–8401.

SUPPLEMENTARY INFORMATION: The subject permit is requested under the authority of the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 *et seq.*), the regulations governing the taking and importing of marine mammals (50 CFR part 216), the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), and the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222–226).

The applicant proposes to conduct a five-year research program on 31 species of cetaceans in U.S. and international waters of the North Atlantic Ocean. Species include endangered blue (*Balaenoptera musculus*), fin (*B. physalus*), sei (*B. borealis*), and sperm (*Physeter macrocephalus*) whales. The purpose of the research is to study variation in cetacean behavior, foraging ecology, body condition, health status, population structure, and use of and response to sounds. Researchers would conduct surveys by vessel and an unmanned aircraft system to approach, count, observe, photograph, remotely measure, and track cetaceans. During surveys, researchers may conduct acoustic playback trials in the presence of animals, collect biological samples, and tag animals, with some species receiving two tags at a time. Non-target cetaceans in the vicinity of research could be incidentally harassed. See the application for take numbers by species. Biological samples collected in international waters would be imported into the United States and cell lines may be developed from tissue samples.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), an initial determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Concurrent with the publication of this notice in the **Federal Register**, NMFS is forwarding copies of the application to the Marine Mammal Commission and its Committee of Scientific Advisors.

Dated: December 17, 2019.

Julia Marie Harrison,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2019–27569 Filed 12–20–19; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XV155

North Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: The North Pacific Fishery Management Council (Council) Bering Sea Fishery Ecosystem Plan Local Knowledge, Traditional Knowledge, and Subsistence Taskforce will meet January 16, 2020 through January 17, 2020.

DATES: The meeting will be held on Thursday, January 16, 2020 through Friday, January 17, 2020, from 8:30 a.m. to 5 p.m., Alaska Standard Time.

ADDRESSES: The meeting will be held in the Birch/Willow Room at the Hilton Hotel, 500 West Third Avenue,

Anchorage, AK 99501. Teleconference number is (907) 245–3900, pin 2809.

Council address: North Pacific Fishery Management Council, 1007 W 3rd Ave., Anchorage, AK 99501–2252; telephone: (907) 271–2809.

FOR FURTHER INFORMATION CONTACT: Kate Haapala, Council staff; telephone: (907) 271–2801.

SUPPLEMENTARY INFORMATION:

Agenda

Thursday, January 16, 2020 to Friday, January 17, 2020

The agenda will include: (a) Establishing Taskforce objectives; (b) the elements and timing of work required to meet Taskforce objectives; (c) development of a workplan; (d) outreach and communication; and (e) other business. The agenda is subject to change, and the latest version will be posted at *meetings.npfmc.org/Meeting/Details/1223* prior to the meeting, along with meeting materials.

Public Comment

Public comment letters will be accepted and should be submitted either electronically to *meetings.npfmc.org/Meeting/Details/1223* or through the mail: North Pacific Fishery Management Council, North Pacific Fishery Management Council, 1007 W 3rd Ave., Anchorage, AK 99501–2252; telephone: (907) 271–2809.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Shannon Gleason at (907) 271–2809 at least 7 working days prior to the meeting date.

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

Dated: December 18, 2019.

Tracey L. Thompson,

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

[FR Doc. 2019–27640 Filed 12–20–19; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Technical Information Service

Submission for OMB Review; Renewal of Currently Approved Information Collection; 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 Technical Information Service (NTIS), Commerce.

Title: Limited Access Death Master File Accredited Conformity Assessment Body Application for Firewalled Status (Firewalled Status Application Form).

OMB Control Number: 0692–0015.

Form Number(s): NTIS FM101.

Type of Request: Renewal of a currently approved information collection.

Number of Respondents: NTIS expects to receive approximately 250 applications and renewals for certification every year for access to the Limited Access Death Master File, of which it expects that approximately 20% of the required assessments will be provided by Accredited Conformity Assessment Bodies that will seek firewalled status in a given year. Accordingly, NTIS estimates that it will receive approximately 50 Firewalled Status Application Forms.

Average Hours per Response: 1 hour.

Burden Hours: 50.

Needs and Uses: NTIS issued a final rule establishing a program through which persons may become eligible to obtain access to Death Master File (DMF) information about an individual within three years of that individual's death. The final rule was promulgated under Section 203 of the Bipartisan Budget Act of 2013, Public Law 113–67 (Act). The Act prohibits the Secretary of Commerce (Secretary) from disclosing DMF information during the three-year period following an individual's death (Limited Access DMF), unless the person requesting the information has been certified to access the Limited Access DMF pursuant to certain criteria in a program that the Secretary establishes. The Secretary delegated the authority to carry out Section 203 to the Director of NTIS.

The final rule requires that, in order to become certified, a Person or Certified Person must submit a written attestation from an ''Accredited Conformity Assessment Body'' (ACAB), as defined in the final rule, that such Person has information security systems, facilities and procedures in place to protect the security of the Limited Access DMF, as required under Section 1110.102(a)(2) of the final rule. A Certified Person also must provide a new written attestation periodically for renewal of its certification as specified in the final rule. The ACAB must be independent of the Person or Certified Person seeking certification, unless it is a third-party conformity assessment body which qualifies for ''firewalled status'' pursuant to Section 1110.502 of the final rule.

The Firewalled Status Application Form collects information that NTIS will use to evaluate whether the respondent qualifies for ''firewalled status'' under the rule, and, therefore, can provide a written attestation in lieu of an independent ACAB's attestation. This information includes specific requirements of Section 1110.502(b) of the final rule, which the respondent ACAB must certify are satisfied, and the provision of specific information by the respondent ACAB, such as the identity of the Person or Certified Person that would be the subject of the attestation and the basis upon which the certifications were made.

Affected Public: ACABs seeking firewalled status under 15 CFR 1110.502 because they are ''owned, managed or controlled'' by the Person or Certified Person for whom they are providing assessment(s) and/or audit(s) under the final rule for ''Certification Program for Access to the Death Master File.''

Frequency: Once per attestation.

Respondent's Obligation: Voluntary.

This information collection request may be viewed at reginfo.gov. Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov* or fax to (202) 395–5806.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2019–27615 Filed 12–20–19; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 19–69]

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: Karma Job at *karma.d.job.civ@mail.mil* or (703) 697–8976.

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 19–69 with attached Policy Justification and Sensitivity of Technology.

Dated: December 18, 2019.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

The Honorable Nancy Pelosi
Speaker of the House
U.S. House of Representatives
H-209, The Capitol
Washington, DC 20515

NOV 2 0 2019

Dear Madam 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. 19-69 concerning the Air Force's proposed Letter(s) of Offer and Acceptance to the Government of New Zealand for defense articles and services estimated to cost $1.4 billion. 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

Transmittal No. 19-69

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 New Zealand

(ii) *Total Estimated Value*:

Major Defense Equipment * ..	$ .6 billion
Other	$ .8 billion
TOTAL	$1.4 billion

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase*:

Major Defense Equipment (MDE):

Five (5) C-130J Aircraft

Twenty-four (24) Rolls Royce AE-2100D3 Turboprop Engines (20 installed, 4 spares)

Fifteen (15) Embedded Global Positioning System (GPS)/Inertial Navigation Systems (INS) (EGIs) with GPS Security Devices, Airborne (10 installed, 5 spares)

Eight (8) Multi-Information Distribution System (MIDS)/Link-16 Low Video Terminal (LVT)-BU2 (5 installed, 3 spares)

Thirteen (13) AN/AAQ-24(V)N LAIRCM (Large Aircraft Infrared Countermeasures) System Processor Replacement (LSPR) (10 installed, 3 spares)

Nineteen (19) Guardian Laser Transmitter Assembly for LAIRCM (15 installed, 4 spares)

Non-MDE: Also includes eight (8) AN/AAR-47 Missile Warning System (MWS); eight (8) AN/APN-241 Low Power Color Radar; eight (8) AN/ALR -56M Missile Warning System Receiver; fifteen (15) AN/ALE-47 Countermeasures Dispensing System; six (6) MX-20HD Electro-Optical/Infrared Imaging System; forty-four (44) Missile Warning Sensor, LAIRCM; Control Interface Unit Replacement, LAIRCM; classified memory cards, LAIRCM; Low Volume Terminal Cryptographic Modules KIV-55; AN/ARC-210 RT-1990A(C) Radio; AN/ARC-164(V) RT-1518 Radio; AN/ARC-153 Tactical Air Navigation; AN/ARN-147 VHF Receiver; AN/ARC-190 HF Radio; AN/ARC-222 VHF Radio w/SINCGARS; Classified Tactical Manuals; Cartridge Activated Devices/Propellant Activated Devices; M206 Flares; MJU-64/B Decoy; BBU-35A/B Impulse Carts; Joint Mission Planning System; Classified Computer Identification Numbers; Electronic Combat International Security Assistance Program (ECISAP) support, support and test equipment, publications and technical documentation, personnel training and training equipment, U.S. Government and contractor engineering, technical and logistics support services; and other related elements of logistical and program support.

(iv) *Military Department*: Air Force (NZ-D-SAB and NZ-D-QAF)

(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*: November 20, 2019

*As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

New Zealand—C-130J Aircraft

The Government of New Zealand has requested to buy five (5) C-130J aircraft; twenty-four (24) Rolls Royce AE-2100D3 turboprop engines (20 installed, 4 spares); fifteen (15) Embedded Global Positioning System (GPS)/Inertial Navigation Systems (INS) (EGIs) with GPS security devices, airborne (10 installed, 5 spares); eight (8) Multi-Information Distribution System (MIDS)/Link-16 Low Video Terminal (LVT)-BU2 (5 installed, 3 spares); thirteen (13) AN/AAQ-24(V)N LAIRCM (Large Aircraft Infrared Countermeasures) System Processor Replacement (LSPR) (10 installed, 3 spares); and nineteen (19) Guardian Laser Transmitter Assembly for LAIRCM (15 installed, 4 spares). Also included are eight (8) AN/AAR-47 Missile Warning System (MWS); eight (8) AN/APN-241 Low Power Color Radar; eight (8) AN/ALR-56M Missile Warning System Receiver; fifteen (15) AN/ALE-47 Countermeasures Dispensing System; six (6) MX-20HD Electro-Optical/Infrared Imaging System; forty-four (44) Missile Warning Sensor, LAIRCM; Control Interface Unit Replacement, LAIRCM; classified memory cards, LAIRCM; Low Volume Terminal Cryptographic Modules KIV-55; AN/ARC-210 RT-1990A(C) Radio; AN/ARC- 164(V) RT-1518 Radio; AN/ARC-153 Tactical Air Navigation; AN/ARN-147 VHF Receiver; AN/ARC-190 HF Radio; AN/ARC-222 VHF Radio w/SINCGARS; Classified Tactical Manuals; Cartridge Activated Devices/Propellant Activated Devices; M206 Flares; MJU-64/B Decoy; BBU-35A/B Impulse Carts; Joint Mission Planning System; Classified Computer Identification Numbers; Electronic Combat International Security Assistance Program (ECISAP) support, support and test equipment, publications and technical documentation, personnel training and training equipment, U.S. Government and contractor engineering, technical and logistics support services; and other related elements of logistical and program support. The total estimated value is $1.40 billion.

This proposed sale will support the foreign policy and national security of the United States by helping to improve the security of a major ally that is a force for political stability, and economic progress in the Asia-Pacific region. The proposed sale will improve New Zealand's capability to meet current and future threats by enhancing its current airlift capability.

This proposed sale will provide the capability to support national, United Nations, and other coalition operations. This purchase also includes sensors and performance improvements that will assist New Zealand during extensive maritime surveillance and reconnaissance as well as improve its search and rescue capability. Additionally, the extra cargo capacity and aircraft performance will greatly increase New Zealand's Antarctic mission capabilities while simultaneously increasing safety margins. New Zealand currently operates the C-l30H aircraft and will have no difficulty absorbing this equipment and support into its armed forces.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

The prime contractor will be Lockheed Martin, Ft Worth, TX. There are no known offset agreements proposed in connection with this potential sale.

Implementation of this sale will require the assignment of up to three U.S. contractor representatives to New Zealand.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 19–69

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 C-130J Hercules with Rolls Royce AE 2100D Turboprop Engines is a military airlift aircraft that performs primarily the tactical portion of the airlift mission. The aircraft is capable of operating from rough, dirt strips and is the prime transport for air dropping troops and equipment into hostile areas. The C-130J improvements over the C-130E include improved maximum

speed, climb time, cruising altitude and range. The C-130J has 55 feet of cargo compartment length, an additional 15 feet over the original ''short'' aircraft. Hardware is UNCLASSIFIED. Technical data and documentation to be provided is UNCLASSIFIED.

2. Embedded GPS-INS (EGI) LN-260 is a sensor that combines GPS and inertial sensor inputs to provide accurate location information for navigation and targeting.

3. Multifunctional Information Distribution System (MIDS) is an advanced Link-16 command, control, communications, and intelligence (C3I) system incorporating high-capacity, jam-resistant, digital communication links for exchange of near realtime tactical information, including both data and voice, among air, ground, and sea elements. The MIDS terminal hardware, publications, performance specifications, operational capability, parameters, vulnerabilities to countermeasures, and software documentation are classified CONFIDENTIAL. The classified information to be provided consists of that which is necessary for the operation, maintenance, and repair (through intermediate level) of the data link terminal, installed systems, and related software.

4. The AN/AAQ-24(V)N LAIRCM is a self-contained, directed energy countermeasures system designed to protect aircraft from infrared-guided surface-to-air missiles. The system features digital technology and micro-miniature solid-state electronics. The system operates in all conditions, detecting incoming missiles and jamming infrared-seeker equipped missiles with aimed bursts of laser energy. The LAIRCM system consists of multiple Missile Warning Sensors, Guardian Laser Turret Assemblies (GLTA), LAIRCM System· Processor Replacement (LSPR), Control Indicator Unit Replacement (CIUR), and a classified User Data Memory (UDM) card containing the laser jam codes. The UDM card is loaded into LAIRCM System Processor Replacement (LSPR) prior to flight; when not in use, the UDM card is removed from the LSPR and put in secure storage. The Missile Warning Sensors (MWS) for AN/AAQ-24 (V)N are mounted on the aircraft exterior to provide omni-directional protection. The MWS detects the rocket plume of missiles and sends appropriate data signals to the LSPR for processing. The LSPR analyzes the data from each sensor and automatically deploys the appropriate countermeasure via the GLTA. The CIUR displays the incoming threat. The LSPR also contains Built-In-Test (BIT) circuitry.

5. The AN/ALE-47 Counter-Measures Dispensing System (CMDS) is an integrated, threat-adaptive, software-programmable dispensing system capable of dispensing chaff, flares, and active radio frequency expendables. The threats countered by the CMDS include radar-directed anti-aircraft artillery, radar command-guided missiles, radar homing guided missiles, and infrared guided missiles. The system is internally mounted and may be operated as a stand-alone system or may be integrated with other on-board EW and avionics systems. The AN/ALE-47 uses threat data received over the aircraft interfaces to assess the threat situation and to determine a response. Expendable routines tailored to the immediate aircraft and threat environment may be dispensed using one of four operational modes. Hardware is UNCLASSIFIED. Technical data and documentation to be provided is UNCLASSIFIED.

6. The AN/AAR-47A(V)2 Missile Warning System is a small, lightweight, passive, electro-optic, threat warning device used to detect surface-to-air missiles fired at helicopters and low-flying fixed-wing aircraft and automatically provide countermeasures, as well as audio and visual-sector warning messages to the aircrew. The basic system consists of multiple Optical Sensor Converter (OSC) units, a Computer Processor (CP) and a Control Indicator (Cl). The set of OSC units, which normally consist of four, is mounted on the aircraft exterior to provide omnidirectional protection. The OSC detects the rocket plume of missiles and sends appropriate signals to the CP for processing. The CP analyses the data from each OSC and automatically deploys the appropriate countermeasures. The CP also contains comprehensive BIT circuitry. The CI displays the incoming direction of the threat, so that the pilot can take appropriate action. Hardware is UNCLASSIFIED. Technical data and documentation to be provided is UNCLASSIFIED.

7. The AN/ALR-56M Advanced Radar Warning Receiver continuously detects and intercepts RF signals in certain frequency ranges and analyzes and separates threat signals from non-threat signals. It contributes to full-dimensional protection by providing individual aircraft probability of survival through improved aircrew situational awareness of the radar guided threat environment. The ALR-56M is designed to provide improved performance in a dense signal environment and improved detection of modern threats signals. Hardware is UNCLASSIFIED. Technical data and documentation to be provided is UNCLASSIFIED.

8. 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.

9. The MX-20HD is a gyro-stabilized, multi-spectral, multi field of view ElectroOptical/ Infrared (EO/IR) system. The system provides surveillance laser illumination and laser designation through use of an externally mounted turret sensor unit and internally mounted master control. Sensor video imagery is displayed in the aircraft real time and may be recorded for subsequent ground analysis.

10. This sale will involve the release of sensitive and/or classified cryptographic equipment for secure communications radios, precision navigation, and cryptographic appliques and keying equipment. The hardware is UNCLASSIFIED, except where systems are loaded with cryptographic software, which may be classified up to SECRET.

11. 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.

12. A determination has been made that New Zealand 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.

13. All defense articles and services listed in this transmittal are authorized for release and export to the Government of New Zealand.

[FR Doc. 2019–27650 Filed 12–20–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 19–29]

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: Karma Job at *karma.d.job.civ@mail.mil* or (703) 697–8976.

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 19–29 with attached Policy Justification.

Dated: December 17, 2019.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

JUL 2 6 2019

The Honorable Nancy Pelosi
Speaker of the House
U.S. House of Representatives
H-209, The Capitol
Washington, DC 20515

Dear Madam 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. 19-29 concerning the Air Force's proposed Letter(s) of Offer and Acceptance to Pakistan for defense services estimated to cost $1 25 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

Transmittal No. 19-29

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 Pakistan

(ii) *Total Estimated Value:*

Major Defense Equipment * ..	$ 0 million
Other	$125 million
TOTAL	$125 million

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:*

Major Defense Equipment (MDE): None

Non-MDE: Continuation of technical support services; U.S. Government and contractor technical and logistics support services; and other related elements of logistics support to assist in the oversight of operations in support of the Pakistan Peace Drive advanced F-16 program.

(iv) *Military Department*: Air Force (PK-D-GAI)

(v) *Prior Related Cases, if any*: PK-D-GAC, PK-D-GAF

(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:* None

(viii) *Date Report Delivered to Congress*: July 26, 2019

* As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Pakistan—Technical Security Team (TST) in Continued Support of the F-16 Program

The Government of Pakistan requested a continuation of technical support services; U.S. Government and contractor technical and logistics support services; and other related elements of logistics support to assist in the oversight of operations in support of the Pakistan Peace Drive advanced F-16 program. The total estimated program cost is $125 million.

This proposed sale will support the foreign policy and national security of the United States by protecting U.S. technology through the continued presence of U.S. personnel that provide 24/7 end-use monitoring.

Congress required 24/7 monitoring of the advanced F-16s and AMRAAMs in the original LOA, which is carried out by the Technical Security Teams (TST) at Shahbaz and Mushaf Air Force bases. The TST exists to protect sensitive U.S technology through 24/7 observation and reporting. TST members are not authorized to train Pakistan Air Force (PAF) service members or perform maintenance on PAF aircraft.

The proposed sale of this support will not alter the basic military balance in the region.

The principal contractor is Booz Allen Hamilton Engineering Services LLC, Fairborn, Ohio.

Implementation of this proposed sale will require the assignment of 60 contractor representatives to Pakistan to assist in the oversight of operations as part of the Peace Drive F-16 program.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

[FR Doc. 2019–27622 Filed 12–20–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 19–0M]

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: Karma Job at *karma.d.job.civ@mail.mil* or (703) 697–8976.

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 19–0M with attached Policy Justification and Sensitivity of Technology.

Dated: December 18, 2019.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

The Honorable Nancy Pelosi
Speaker of the House
U.S. House of Representatives
H-209, The Capitol
Washington, DC 20515

OCT 3 0 2019

Dear Madam 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. 19-0M. This report relates to enhancements or upgrades from the level of sensitivity of technology or capability described in the Section 36(b)(1) AECA certification 16-57 of December 20, 2016.

Sincerely,

Charles W. Hooper
Lieutenant General, USA
Director

Enclosure:
1. Transmittal

Transmittal No. 19-0M

REPORT OF ENHANCEMENT OR UPGRADE OF SENSITIVITY OF TECHNOLOGY OR CAPABILITY (SEC. 36(B)(5)(C), AECA)

(i) *Prospective Purchaser*: Government of Norway
(ii) Sec. 36(b)(1), AECA Transmittal No.: 16-57
Date: December 20, 2016
Military Department: U.S. Navy
(iii) *Description*: On December 20, 2016, Congress was notified by Congressional certification transmittal number 16-57 of the possible sale, under Section 36(b)(1) of the Arms Export Control Act, of five (5) P–8A Patrol Aircraft, each included: Commercial Engines, Tactical Open Mission Software (TOMS), Electro-Optical (EO) and Infrared (IO) MX-20HD, AN/AAQ–2(V)1 Acoustic System, AN/APY–10 Radar, ALQ-240 Electronic Support Measures, forty (40) AIM-120C-7 Advanced Medium Range Air-to-Air Missiles (AMRAAM) and one (1) spare AIM-120C-7 AMRAAM Guidance Section. Also included were eleven (11) Multifunctional Distribution System Joint Tactical Radio Systems (MIDS JTRS); eight (8) Guardian Laser Transmitter Assemblies (GLTA) for the AN/AAQ-24(V)N; eight (8) System Processors for AN/AAQ-24(V)N; forty-two (42) AN/AAR-54 Missile Warning Sensors for the AN/AAQ-24(V)N; fourteen (14) LN-251 with Embedded Global Positioning Systems (GPS)/ Inertial Navigation Systems (EGIs); and two thousand (2,000) AN/SSQ-125 Multi-Static Active Coherent (MAC) Source Sonobouys; spares; spare engine; support equipment; operational support systems; training; maintenance trainer/ classrooms; publications; software; engineering and logistics technical assistance; Foreign Liaison Officer support; contractor engineering technical services; repair and return; transportation; aircraft ferry; and other associated training and support. The

total estimated program cost is $1.75 billion. Major Defense Equipment * (MDE) constituted $1.4 billion of this total.

This transmittal reports one (1) additional P-8 aircraft with commercial engines, Tactical Open Mission Software (TOMS), Electro-Optical (EO) and Infrared (IO) MX-20HD, AN/AAQ-2(V)1 Acoustic System, AN/APY-10 Radar, ALQ-240 Electronic Support Measures, once (1) Multifunctional Distribution System Joint Tactical Radio Systems (MIDS JTRS), one (1) Guardian Laser Transmitter Assemblies (GLTA) for the AN/AAQ-24(V)N; one (1) System Processors for AN/AAQ-24(V)N; and two (2) LN-251 with Embedded Global Positioning Systems (GPS)/Inertial Navigation Systems (EGIs), and associated materiel, support, and services. These additional MDE items will result in an increase in MDE cost of $100 million, for a total MDE value of $1.5 billion. Total case value will increase to $1.85 billion.

(iv) *Significance*: Acquisition of an additional P-8A aircraft will increase Norwegian Maritime Patrol Aircraft (MPA) capability. This sale will strengthen collective NATO defense and further enhance Norway's regional and global allied contributions.

(v) *Justification*: This proposed sale supports the foreign policy and national security objectives of the United States by helping improve the security of a NATO ally that has been, and continues to be, an important force for political stability throughout the world.

(vi) *Sensitivity of Technology*: The Sensitivity of Technology Statement contained in the original notification applies to these additional items.

(vii) *Date Report Delivered to Congress*: October 30, 2019

[FR Doc. 2019–27652 Filed 12–20–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 19–35]

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: Karma Job at *karma.d.job.civ@mail.mil* or (703) 697–8976.

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 19–35 with attached Policy Justification and Sensitivity of Technology.

Dated: December 17, 2019.

Aaron T. 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

JUL 2 9 2019

The Honorable Nancy Pelosi
Speaker of the House
U.S. House of Representatives
H-209, The Capitol
Washington, DC 20515

Dear Madam 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. 19-35 concerning the Navy's proposed Letter(s) of Offer and Acceptance to the Government of Canada for defense articles and services estimated to cost $44 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. 19–35

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 Canada

(ii) *Total Estimated Value*:

Major Defense Equipment * ..	$38 million
Other	$ 6 million
TOTAL	$44 million

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:*

Major Defense Equipment (MDE): One hundred fifty-two (152) MIDS JTRS (5) with Remote Power Supply

Non-MDE: Also included are spare cables and MIDS batteries; Link-16 mobile racks; diagnostic support tools; technical documentation; training and engineering technical support; and other related elements of logistics and program support.

(iv) *Military Department*: Navy (CN–P–LKT)

(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*: July 29, 2019

* As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Canada–Multifunctional Information Distribution System (MIDS)—Joint Tactical Radio System (JTRS) (5)

The Government of Canada has requested to buy one hundred fifty-two (152) MIDS JTRS (5) with Remote Power Supply. Also included are spare cables and MIDS batteries; Link-16 mobile racks; diagnostic support tools; technical documentation; training and engineering technical support; and other related elements of logistics and program support. The total estimated program cost is $44 million.

This proposed sale will support the foreign policy and national security objectives of the United States by helping to improve the military capability of Canada, a NATO ally that is an important force for ensuring political stability and economic progress and a contributor to military, peacekeeping and humanitarian operations around the world.

Canada intends to upgrade its current inventory of CF-18 Aircraft, CC-130J, and the Royal Canadian Air Force's Ground Stations with the purchase of these MIDS JTRS (5) terminals to be fully interoperable with U.S. and allied forces to support and compliment joint operations in a net-enabled environment; have modernized electronic protection and secure, jam-resistant wave forms; and be capable of improved Link 16 message exchange and information fidelity including support to advanced weapon employment. Canada will have no difficulty absorbing this equipment into its armed forces.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

The principal contractors for MIDS JTRS are Viasat, Incorporated, headquartered in Carlsbad, CA and Data Link Solutions, headquartered in Cedar Rapids, IA. The Government of Canada is expected to negotiate an offset agreement with the principal contractor(s), in accordance with Canada's Industrial and Technological Benefits (ITB) Policy, before signing the Letter of Offer and Acceptance (LOA), but details are not known at this time.

Implementation of this proposed sale will not require the assignment of additional U.S. Government or contractor representatives to Canada. However, it is anticipated that engineering and technical support services provided by the U.S. Government may be required on an interim basis for training and technical assistance.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 19–35

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 Multifunctional Information Distribution System (MIDS) Joint Tactical Radio (JTRS) is a software defined radio. The MIDS JTRS Programmable Secure Information Security Architecture Module (PSISAM) is Critical Program Information (CPI). The PSISAM is embedded in a MIDS JTRS Shop Replaceable Unit (SRU) and contains the information security hardware and cryptographic keys necessary to operate the terminal. MIDS JTRS contains embedded COMSEC and is capable of processing up to TOP SECRET information. Each MIDS JTRS contains an embedded SRU that is UNCLASSIFIED Controlled Cryptographic Information (CCI). Un-keyed terminals and de-energized terminals are UNCLASSIFIED CCI. When a terminal is operating on the host platform it is classified up to the level of data being transmitted.

2. 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.

3. A determination has been made that Canada can provide substantially the same degree of protection for the technology being released as the U.S. Government. This sale supports the U.S. foreign policy and national security objectives as outlined in the Policy Justification.

4. All defense articles and services listed in this transmittal have been authorized for release and export to Canada.

[FR Doc. 2019–27603 Filed 12–20–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 19–72]

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: Karma Job at *karma.d.job.civ@mail.mil* or (703) 697–8976.

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 19–72 with attached Policy Justification and Sensitivity of Technology.

Dated: December 18, 2019.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–P

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, SUITE 101
ARLINGTON, VA 22202-5408

The Honorable Nancy Pelosi
Speaker of the House
U.S. House of Representatives
H-209, The Capitol
Washington, DC 20515

OCT 3 0 2019

Dear Madam 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. 19-72 concerning the Army's proposed Letter(s) of Offer and Acceptance to the Government of Croatia for defense articles and services estimated to cost $115 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. 19-72

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*: Republic of Croatia

(ii) *Total Estimated Value*:

Major Defense Equipment * ..	$ 60 million
Other	$ 55 million
TOTAL	$115 million

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase*: The Government of Croatia has requested to buy two (2) UH-60M Black Hawk Helicopters in standard U.S. Government configuration with designated unique equipment and Government Furnished Equipment (GFE).

Major Defense Equipment (MDE):

Two (2) UH-60M Black Hawk Helicopters with Designated Unique Equipment

Up to nine (9) T700-GE-701D Engines (4 installed and up to 5 spares)

Up to nine (9) H-764GU Embedded Global Positioning Systems with Inertial Navigation and Country Unique SAASM (4 installed and up to 5 spares)

Non-MDE: Also, included are two (2) AN/APX-123A Identification Friend or Foe (IFF) transponder, four (4) AN/ARC-201D RT-1478D, and four (4) AN/ARC-231 RT-1808A radios, aircraft warranty, air worthiness support, calibration services, spare and repair parts, support equipment, communication equipment, weapons, ammunition, night vision devices, publications and technical documentation, personnel training and training devices, site surveys, tool and test equipment, U.S. Government and contractor technical and logistics support services, and other related elements of logistical and program support.

(iv) *Military Department*: Army

(v) *Prior Related Cases, if any*: 7L-B-UGK, HR-B-UBQ

(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*: October 30, 2019

*As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Croatia—UH-60M Black Hawk Helicopters

The Government of Croatia has requested a possible sale of two (2) UH-60M Black Hawk Helicopters in standard USG configuration with designated unique equipment and Government Furnished Equipment (GFE), up to nine (9) each T700-GE-70 ID engines, and up to nine (9) each H-764GU/Embedded Global Positioning/Inertial Navigation (EGI). Also included are Communication Security equipment including an AN/APX-123A Identification Friend or Foe (IFF) transponder, AN/ARC-201D RT-1478D, and AN/ARC-231 RT-1808A radios, aircraft warranty, air worthiness support, calibration services, spare and repair parts, support equipment, communication equipment, weapons, ammunition, night vision devices, publications and technical documentation, personnel training and training devices, site surveys, tool and test equipment, U.S. Government and contractor technical and logistics support services, and other related elements of logistical and program support. The total estimated program cost is $115 million.

This proposed sale will support the foreign policy and national security of the United States by helping to improve the security of a NATO ally. The sale of these UH-60 helicopters to Croatia will significantly increase its capability to provide troop lift, border security, counterterrorism, medical evacuation, search and rescue, re-supply/external lift, and combat support. These UH-60 helicopters will allow for interoperability with U.S. and NATO forces in rapid response to a variety of missions and quick positioning of troops with minimal helicopter assets.

Croatia intends to use these defense articles and services to modernize its armed forces and expand its existing army architecture in its efforts to provide multi-mission support in the region as well as combat terrorist threats. Croatia will have no difficulty absorbing these helicopters into its armed forces.

The proposed sale of this equipment will not alter the basic military balance in the region.

The principal contractors will be Sikorsky Aircraft Company, Stratford, Connecticut; and General Electric Aircraft Company (GEAC), Lynn, Massachusetts. There are no known offset agreements in connection with this potential sale.

Implementation of this proposed sale may require the assignment of an additional three U.S. Government and five contractor representatives in country full-time to support the delivery and training for approximately two-five years.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 19-72

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 UH-60M aircraft is a medium lift four bladed aircraft which includes two (2) T-701D Engines. The aircraft has four (4) Multifunction Displays (MFD), which provides aircraft system, flight, mission, and communication management systems. The instrumentation panel includes four (4) Multifunction Displays (MFDs), two (2) Pilot and Co-Pilot Flight Director Panels, and two (2) Data Concentrator Units (DCUs). The Navigation System will have Embedded GPS/INS (EGIs), and two (2) Advanced Flight Control Computer Systems (AFCC), which provide 4 axis aircraft control.

2. The H764-G EGI provides GPS and INS capabilities to the aircraft. The EGI will include Selective Availability anti-Spoofing Module (SAASM) security modules to be used for secure GPS PPS if required. The Embedded GPS/INS within the SAASM contains sensitive technology.

3. The AN/APX-123A, Identification Friend or Foe (IFF) Transponder, is a space diversity transponder and is installed on various military platforms. When installed in conjunction with platform antennas and the Remote Control Unit (or other appropriate control unit), the transponder provides identification, altitude and surveillance reporting in response to interrogations from airborne, ground-based and/or surface interrogators. This item contains sensitive technology.

4. The AN/ARC-201D, Single Channel Ground to Air Radio System (SINCGARS), is a tactical airborne radio subsystem that provides secure, anti-jam voice and data communication. The integration of COMSEC and the Data Rate Adapter (DRA) combines three Line Replaceable Units into one and reduces overall weight of the aircraft. Performance capabilities, ECM/ECCM specification and Engineering Change Orders (ECOs) are classified SECRET.

5. The AN/ARC-231, Very High Frequency/Ultra High Frequency (VHF/UHF), Line-of-Sight (LOS) Radio with frequency agile modes, Electronic counter-countermeasures (ECCM), UHF Satellite Communications (SATCOM), Demand Assigned Multiple Access (DAMA), Integrated Waveform (IW), Air Traffic Control (ATC) channel spacing is operator selectable in 5, 8.33, 12 .5, and 25kHz steps. The antennas associated with this radio contain sensitive technology.

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 or equivalent systems which might reduce weapon system effectiveness or be used in the development of a system with similar or advanced capabilities.

7. This sale is necessary in furtherance of the U.S. foreign policy and national security objectives outlined in the enclosed Policy Justification. A determination has been made that Croatia can provide the same degree of protection for the sensitive technology being released as the U.S. Government.

8. All defense articles and services listed in this transmittal have been

authorized for release and export to Croatia.

[FR Doc. 2019–27648 Filed 12–20–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 19–70]

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: Karma Job at *karma.d.job.civ@mail.mil* or (703) 697–8976.

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 19–70 with attached Policy Justification and Sensitivity of Technology.

Dated: December 18, 2019.

Aaron T. Siegel,

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

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, SUITE 101
ARLINGTON, VA 22202-5408

The Honorable Nancy Pelosi
Speaker of the House
U.S. House of Representatives
H-209, The Capitol
Washington, DC 20515

OCT 0 3 2019

Dear Madam 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. 19-70 concerning the Army's proposed Letter(s) of Offer and Acceptance to the Government of Ukraine for defense articles and services estimated to cost $39.2 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

Transmittal No. 19-70

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 Ukraine

(ii) *Total Estimated Value*:

Major Defense Equipment * ..	$31.0 million
Other	$ 8.2 million
TOTAL	$39.2 million

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase*:

Major Defense Equipment (MDE):

One hundred fifty (150) Javelin Missiles
Ten (10) Javelin Command Launch Units (CLU)

Non-MDE: Also included are training devices, transportation, support equipment, technical data and publications, personnel training and training equipment, U.S. government, engineering, technical, and logistics support services, and other related elements of logistics support tools and test equipment; support equipment; publications and technical documentation; spare and repair parts; equipment training and training

devices; U.S. Government and contractor technical, engineering and logistics support services; and other related elements of logistical, sustainment, and program support.

(iv) *Military Department*: Army (UP-B-UCJ)

(v) *Prior Related Cases, if any*: UP-B-UBT

(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*: October 3, 2019

* As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Ukraine—Javelin Missiles and Command Launch Units

The Government of Ukraine has requested to buy one hundred fifty (150) Javelin missiles and ten (10) Javelin Command Launch Units (CLUs). Also included are training devices, transportation, support equipment, technical data and publications, personnel training and training equipment, U.S. government, engineering, technical, and logistics support services, and other related elements of logistics support tools and test equipment; support equipment; publications and technical documentation; spare and repair parts; equipment training and training devices; U.S. Government and contractor technical, engineering and logistics support services; and other related elements of logistical, sustainment, and program support. The total estimated cost is not to exceed $39.2 million.

This proposed sale will contribute to the foreign policy and national security of the United States by improving the security of Ukraine. The Javelin system will help Ukraine build its long-term defense capacity to defend its sovereignty and territorial integrity in order to meet its national defense requirements. Ukraine will have no difficulty absorbing this system into its armed forces.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

The prime contractor for the Javelin Missile System is Raytheon Company, Waltham, MA. There are no known offset agreements proposed in conjunction with this potential sale.

Implementation of this proposed program will require additional contractor representatives to travel to Ukraine. It is not expected additional U.S. Government personnel will be required in country for an extended period of time.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 19-70

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 Javelin Weapon System is a medium-range, man portable, shoulder-launched, fire and forget, anti-tank system for infantry, scouts, and combat engineers. The system weighs 49.5 pounds and has a maximum range in excess of 2,500 meters. They system is highly lethal against tanks and other systems with conventional and reactive armors. The system possesses a secondary capability against bunkers.

2. Javelin's key technical feature is the use of fire-and-forget technology which allows the gunner to fire and immediately relocate or take cover. Additional special features are the top attack and/or direct fire modes, an advanced tandem warhead and imaging infrared seeker, target lock-on before launch, and soft launch from enclosures or covered fighting positions. The Javelin missile also has a minimum smoke motor thus decreasing its detection on the battlefield.

3. The Javelin Weapon System is comprised of two major tactical components, which are a reusable Command Launch Unit (CLU) and a round contained in a disposable launch tube assembly. The CLU incorporates an integrated day-night sight that provides a target engagement capability in adverse weather and countermeasure environments. The CLU may also be used in a stand-alone mode for battlefield surveillance and target detection. The CLU's thermal sight is a second generation Forward Looking Infrared (FLIR) sensor operating in the 8-10 micron wavelength and has a 240 X 240 pixel scanning array with a Dewar-coolant unit.

4. The missile is autonomously guided to the target using an imaging infrared seeker and adaptive correlation tracking algorithms. This allows the gunner to take cover or reload and engage another target after firing a missile. The missile contains an infrared seeker with a 64 x 64 pixel element Mercury-Cadmium-Telluride (HgCdTE) Focal Plane Array (FPA) operating in the 8-10 micron wavelength. The missile has an advanced tandem warhead and can be used in either the top attack or direct fire modes (for target undercover). An onboard flight computer guides the missile to the selected target.

5. The Javelin Missile System hardware and the documentation are UNCLASSIFIED. The missile software which resides in the CLU is considered SENSITIVE. The sensitivity is primarily in the software programs which instruct the system how to operate in the presence of countermeasures. The overall hardware is also considered SENSITIVE in that the infrared wavelengths could be useful in attempted countermeasure development.

6. If a technologically advanced adversary obtains knowledge of the specific hardware and software elements, the information could be used to develop countermeasures or equivalent systems 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 Ukraine 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 further the U.S. foreign policy and national security objectives outlined in the Policy Justification.

8. All defense articles and services listed on this transmittal are authorized for release and export to the Government of Ukraine.

[FR Doc. 2019–27651 Filed 12–20–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 19–28]

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: Karma Job at *karma.d.job.civ@mail.mil* or (703) 697–8976.

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 19–28 with attached Policy Justification and Sensitivity of Technology.

Dated: December 17, 2019.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–P

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, SUITE 101
ARLINGTON, VA 22202-5408

AUG 2 7 2019

The Honorable Nancy Pelosi
Speaker of the House
U.S. House of Representatives
H-209, The Capitol
Washington, DC 20515

Dear Madam 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. 19-28 concerning the Navy's proposed Letter(s) of Offer and Acceptance to the Republic of Korea for defense articles and services estimated to cost $72 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,

For

Charles W. Hooper
Lieutenant General, USA
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Sensitivity of Technology

BILLING CODE 5001–06–C

Transmittal No. 19-28

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*: Republic of Korea

(ii) *Total Estimated Value*:

Major Defense Equipment * ..	$37 million
Other	$35 million
TOTAL	$72 million

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase*:

Major Defense Equipment (MDE): Up to thirty-one (31) MK 54 All Up Round Lightweight Torpedoes

Non-MDE: Also included are torpedo containers, Recoverable Exercise Torpedoes (REXTORP) with containers, Fleet Exercise Section (FES) and fuel tanks, air launch accessories for fixed wing, torpedo spare parts, training, publications, support and test equipment, U.S. Government and contractor engineering, technical, and logistics support services, and other related elements of logistics and program support.

(iv) *Military Department*: Navy (KS-P-AMP)

(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 Annex Attached

(viii) *Date Report Delivered to Congress*: August 27, 2019

* As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Korea—MK 54 Lightweight Torpedoes

The Republic of Korea (ROK) has requested to buy thirty-one (31) MK 54 All Up Round lightweight torpedoes. Also included are torpedo containers, Recoverable Exercise Torpedoes (REXTORP) with containers, Fleet Exercise Section (FES) and fuel tanks, air launch accessories for fixed wing, torpedo spare parts, training, publications, support and test equipment, U.S. Government and contractor engineering, technical, and logistics support services, and other related elements of logistics and program support. The total estimated program cost is $72 million.

This proposed sale will support the foreign policy and national security objectives of the United States by meeting the legitimate security and defense needs of one of the closest allies in the INDOPACOM Theater. The Republic of Korea is one of the major political and economic powers in East Asia and the Western Pacific and a key partner of the United States in ensuring peace and stability in that region. It is vital to U.S. national interests to assist the Republic of Korea in developing and maintaining a strong and ready self-defense capability.

The Republic of Korea Navy intends to utilize MK 54 Lightweight Torpedoes on its P-8A aircraft. The ROK will have no difficulty absorbing this equipment into its armed forces.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

The principal contractor will be Raytheon Integrated Defense System, Portsmouth, Rhode Island. There are no known offset agreements proposed in connection with this potential sale. Any offset agreement will be defined in negotiations between the Purchaser and the prime contractor.

Implementation of the proposed sale will not require the assignment of any additional U.S. Government or contractor representatives to the ROK. However, U.S. Government Engineering and Technical Services may be required on an interim basis for training and technical assistance.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 19-28

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 54 Torpedo is a conventional torpedo that can be launched from surface ships and rotary and fixed wing aircraft. The MK 54 is an upgrade to the MK 46 Torpedo. The upgrade to the MK 54 entails replacement of the torpedo's sonar and guidance and control systems with more 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 assembled MK 54 torpedo and several of its individual components are classified CONFIDENTIAL. The MK 54 operational software is classified as SECRET. The Republic of Korea has not requested nor will it be provided with the source code for the MK 54 operational software.

2. 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.

3. A determination has been made that the recipient government can provide substantially the same degree of protection for the technology being released as the U.S. Government. This sale supports the U.S. foreign policy and national security objectives as outlined in the Policy Justification.

4. All defense articles and services listed in this transmittal have been authorized for release and export to the Republic of Korea.

[FR Doc. 2019–27623 Filed 12–20–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 19–25]

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: Karma Job at *karma.d.job.civ@mail.mil* or (703) 697–8976.

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 19–25 with attached Policy Justification and Sensitivity of Technology.

Dated: December 17, 2019.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

AUG 2 7 2019

The Honorable Nancy Pelosi
Speaker of the House
U.S. House of Representatives
H-209, The Capitol
Washington, DC 20515

Dear Madam 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. 19-25, concerning the Air Force's proposed Letter(s) of Offer and Acceptance to the Government of Hungary for defense articles and services estimated to cost $500 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

Transmittal No. 19-25

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 Hungary

(ii) *Total Estimated Value*:

Major Defense Equipment* ..	$320 million
Other	$180 million
TOTAL	$500 million

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:*

Major Defense Equipment (MDE):

One hundred eighty (180) AIM-120C-7 Advanced Medium Range Air-to-Air Missiles (AMRAAM)

Four (4) Spare AIM-120C-7 AMRAAM Guidance Sections

Non-MDE: Also included are four (4) spare AIM-120C-7 control sections, six (6) AMRAAM training missiles (CATM-120C), missile containers, classified software (for the AN/MPQ-64F1 Sentinel Radar requested by Hungary through Direct Commercial Sale), spare and repair parts, cryptographic and communication security devices, precision navigation equipment, other software, site surveys, weapons system

equipment and computer software support, publications and technical documentation, common munitions and test equipment, repair and return services and equipment, personnel training and training equipment, integration support and test equipment, and U.S. Government and contractor, engineering, technical and logistics support services, and other related elements of logistical and program support.

(iv) *Military Department*: Air Force (HU-D-YAD); Army (HU-B-UCU)

(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*: August 27, 2019

*As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Hungary—AIM-120C-7 Advanced Medium-Range Air-to-Air Missiles (AMRAAM)

The Government of Hungary has requested to buy one hundred and eighty (180) AIM-120C-7 Advanced Medium Range Air-to-Air Missiles (AMRAAM), and four (4) spare AIM-120C-7 AMRAAM guidance sections. Also included are four (4) spare AIM-120C-7 control sections, six (6) AMRAAM training missiles (CATM-120C), missile containers, classified software (for the AN/MPQ-64F1 Sentinel Radar requested by Hungary through Direct Commercial Sale), spare and repair parts, cryptographic and communication security devices, precision navigation equipment, other software, site surveys, weapons system equipment and computer software support, publications and technical documentation, common munitions and test equipment, repair and return services and equipment, personnel training and training equipment, integration support and test equipment, and U.S. Government and contractor, engineering, technical and logistics support services, and other related elements of logistical and program support. The total estimated cost is $500 million.

This proposed sale will support the foreign policy and national security of the United States by improving the security of a NATO ally which is an important force for political stability and economic progress in Europe. This sale is consistent with U.S. initiatives to provide key allies in the region with modern systems that will enhance interoperability with U.S forces and increase security.

Hungary intends to use these defense articles and services to modernize its armed forces and expand its capability to deter regional threats and strengthen its homeland defense. This sale will contribute to Hungary's interoperability with the United States and other allies. Hungary should not have any difficulties absorbing this equipment into its armed forces.

The proposed sale of this equipment and support does not alter the basic military balance in the region.

The prime contractor and integrator will be Raytheon Missile Systems of Tucson, AZ. There are no known offset agreements proposed in connection with this potential sale.

Implementation of this proposed sale will not require the assignment of additional U.S. Government and contractor representatives to Hungary.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 19-25

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. AIM-120C Advance Medium Range Air-to-Air Missile (AMRAAM) is a radar guided missile featuring digital technology and micro-miniature solid-state electronics. AMRAAM capabilities include look-down/shoot-down, multiple launches against multiple targets, resistance to electronic counter measures, and interception of high flying and low flying and maneuvering targets. AIM-120 Captive Air Training Missiles are non-functioning, inert missile rounds used for armament load training, and which also simulate the correct weight and balance of live missiles during captive carry on training sorties. Although designed as an air-to-air missile, the AMRAAM can also be employed in a surface-launch mode when integrated on systems such as the National Advanced Surface-to-Air System (NASAMS). The AIM-120C7, as employed on NASAMS, protects national assets from imminent hostile air threats. The AMRAAM All Up Round is classified CONFIDENTIAL, major components and subsystems range from UNCLASSIFIED to CONFIDENTIAL, and technology data and other documentation are classified up to SECRET.

2. The classified radar operational software utilized with the exportable AN/MPQ-4F1 Sentinel Radar contains specific Electronic Counter-Counter Measures (ECCM) capability, but it does not contain Non-Cooperative Target Recognition (NCTR)/classification capabilities. This software will only be released for export in an executable format with no source code. Without source code, the ability of a foreign entity to analyze the operating software, its processes, and its algorithms is slowed. The highest classification of this software is SECRET.

3. 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.

4. This sale is necessary in furtherance of the U.S. foreign policy and national security objectives outlined in the enclosed Policy Justification. A determination has been made that Hungary can provide the same degree of protection for the sensitive technology being released as the U.S. Government.

5. All defense articles and services listed in this transmittal have been authorized for release and export to Hungary.

[FR Doc. 2019–27634 Filed 12–20–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF ENERGY

[EERE–2019–BT–PET–0019–0008]

Energy Efficiency Program for Industrial Equipment: Interim Determination Classifying North Carolina Advanced Energy Corporation as a Nationally Recognized Certification Program for Electric Motors and Small Electric Motors

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Notice of interim determination and request for public comments.

SUMMARY: This notice announces an interim determination classifying North Carolina Advanced Energy Corporation as a nationally recognized certification program under the Department of Energy's (DOE's) regulations regarding recognition of nationally recognized certification programs and procedures for recognition and withdrawal of

recognition of accreditation bodies and certification programs for electric and small electric motors.

DATES: DOE will accept comments, data, and information with respect to the Advanced Energy Petition until January 22, 2020.

ADDRESSES: You may submit comments, identified by docket number ''EERE–2019–BT–PET–0019–0008,'' by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Email: AdvEnergyElecMotorsPet2019PET0019@ee.doe.gov. Include the docket number and/or RIN in the subject line of the message.

Postal Mail: Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Office, Mailstop EE–5B, 1000 Independence Avenue SW., Washington, DC, 20585–0121. Telephone: (202) 287–1445. If possible, please submit all items on a compact disc (''CD''), in which case it is not necessary to include printed copies.

No telefacsimilies (faxes) will be accepted.

Hand Delivery/Courier: Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Office, 950 L'Enfant Plaza, SW, Suite 600, Washington, DC, 20024. Telephone: (202) 287–1445. If possible, please submit all items on a CD, in which case it is not necessary to include printed copies.

Docket: The docket for this activity, which includes **Federal Register** notices, comments, and other supporting documents/materials, is available for review at *http://www.regulations.gov.* All documents in the docket are listed in the *http://www.regulations.gov* index. However, some documents listed in the index, such as those containing information that is exempt from public disclosure, may not be publicly available.

The docket web page can be found at *https://www.regulations.gov/docket?D=EERE-2019-BT-PET-0019.* The docket web page contains instructions on how to access all documents, including public comments, in the docket.

FOR FURTHER INFORMATION CONTACT: Mr. Jeremy Dommu, U.S. Department of Energy, Building Technologies Program, EE–5B, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 586–9870. Email: *Jeremy.Dommu@ee.doe.gov.*

Mr. Michael Kido, U.S. Department of Energy, Office of the General Counsel, GC–33, 1000 Independence Avenue SW, Washington, DC 20585–0103. Telephone: (202) 586–8145. Email: *Michael.Kido@hq.doe.gov.*

For further information on how to submit a comment, review other public comments and the docket, or to request a public meeting, contact the Appliance and Equipment Standards Program staff at (202) 287–1445 or by email: *ApplianceStandardsQuestions@ee.doe.gov.*

SUPPLEMENTARY INFORMATION:

I. Background and Authority

Part C of Title III of the Energy Policy and Conservation Act, as amended (''EPCA'') contains energy conservation requirements for, among other things, electric motors and small electric motors, including test procedures, energy efficiency standards, and compliance certification requirements. 42 U.S.C. 6311–6316.[1] Section 345(c) of EPCA directs the Secretary of Energy to require manufacturers of electric motors ''to certify through an independent testing or certification program nationally recognized in the United States, that [each electric motor subject to EPCA efficiency standards] meets the applicable standard.'' 42 U.S.C. 6316(c). The United States Department of Energy (''DOE'' or, in context, ''the Department'') codified this requirement at 10 CFR 431.17(a)(5). DOE also established certain compliance testing requirements for manufacturers of small electric motors. 77 FR 26608 (May 4, 2012) Manufacturers of small electric motors have the option of either self-certifying the efficiency of their small electric motors or they can use a certification program nationally recognized in the U.S to certify them. (10 CFR 431.445) DOE developed a regulatory process for the recognition, and withdrawal of recognition, for certification programs nationally recognized in the U.S. The criteria and procedures for national recognition of an energy efficiency certification program for electric motors are codified at 10 CFR 431.20—10 CFR 431.21 for electric motors and at 10 CFR 431.447—10 CFR 431.448 for small electric motors. Each step of the process and evaluation criteria are discussed below.

For a certification program to be classified by DOE as being nationally recognized in the United States for the testing and certification of electric motors and small electric motors, the organization operating the program must submit a petition to the Department requesting such classification, in accordance with the aforementioned sections.

For the Department to grant such a petition, the petitioner's certification program must:

(1) Have satisfactory standards and procedures for conducting and administering a certification system, and for granting a certificate of conformity;

(2) Be independent of electric motor and small electric motor manufacturers (as applicable), importers, distributors, private labelers or vendors;

(3) Be qualified to operate a certification system in a highly competent manner; and

(4) Be expert in the following test procedures and methodologies:

(a) For electric motors, it must be expert in the content and application of the test procedures and methodologies in IEEE Std 112–2004 Test Method B or CSA C390–10. It must have satisfactory criteria and procedures for the selection and sampling of electric motors tested for energy efficiency. (10 CFR 431.20(b)); and

(b) For small electric motors, it must be expert in the content and application of the test procedures and methodologies in IEEE Std 112–2004 Test Methods A and B, IEEE Std 114–2010, CSA C390–10, and CSA C747, or similar procedures and methodologies for determining the energy efficiency of small electric motors. It must have satisfactory criteria and procedures for the selection and sampling of electric motors tested for energy efficiency. (10 CFR 431.447(b))

The petition requesting classification as a nationally recognized certification program must contain a narrative statement explaining why the organization meets the above criteria, be accompanied by documentation that supports the narrative statement, and be signed by an authorized representative. (10 CFR 431.20(c), and 10 CFR 431.447(c)).

II. Discussion

Pursuant to §§ 431.20, 431.21, 431.447 and 431.448, on February 11, 2019, North Carolina Advanced Energy Corporation Efficiency Verification Services (''Advanced Energy'') submitted to DOE a Petition for Recognition related to the group's motor efficiency verification services. That petition, titled, ''Energy Efficiency Evaluation of Electric Motors and Small Electric Motors to US Department of Energy Regulations as stipulated in 10 CFR part 431, subpart B and Subpart X'' (''Petition'' or ''Advanced Energy Petition''), was accompanied by a cover letter from Advanced Energy to the

[1] For editorial reasons, upon codification in the U.S. Code, Part C was re-designated Part A–1.

Department containing four separate sections including individual narrative statements—(1) Standards and Procedures, (2) Independent Status, (3) Qualification of Advanced Energy to Operate a Certification System, and (4) Expertise in Electric Motor Test Procedures. The petition included supporting documentation on these subjects. The Department is required to publish in the **Federal Register** such petitions for public notice and solicitation of comments, data and information as to whether the Petition should be granted. 10 CFR 431.21(b) and 10 CFR 431.448(b). In accordance with requirements in 10 CFR 431.21(b) and 10 CFR 431.448(b), DOE published Advanced Energy's petition in the **Federal Register** on July 8, 2019 and requested public comments. 84 FR 32437.

In response to the notice of petition, DOE did not receive any comments. In addition, based on DOE's review of Advanced Energy's certification program, DOE has tentatively determined that Advanced Energy meets the requirements at 10 CFR 431.20–10 CFR 431.21 for electric motors and at 10 CFR 431.447–10 CFR 431.448 for small electric motors because they (1) have satisfactory standards and procedures for conducting and administering a certification system, (2) are independent of electric motor and small electric motor manufacturers, and (3) have expertise with both the electric motors and small electric motors test procedures. Therefore, after reviewing the materials submitted by Advanced Energy and comparing them against the required criteria under the relevant regulations, DOE finds no specific cause to reject Advanced Energy's request for recognition as a nationally recognized certification program for electric motors and small electric motors.

The Department hereby announces its interim determination pursuant to 10 CFR 431.21(d) and 10 CFR 431.448(d) that Advanced Energy is classified as a nationally recognized certification program for electric motors and small electric motors and will accept comments on this interim determination until January 22, 2020. Any person submitting written comments to DOE with respect to the Advanced Energy Petition must also, at the same time, send a copy of such comments to Advanced Energy. As provided under §§ 431.21(c) and 431.448(c), Advanced Energy may submit to the Department a written response to any such comments. After receiving any such comments and responses, the Department will issue a final determination on the Advanced Energy Petition, in accordance with § 431.21(e), and § 431.448(e) of 10 CFR part 431.

Signed in Washington, DC, on December 6, 2019.

Alexander N. Fitzsimmons,

Acting Deputy Assistant Secretary for Energy Efficiency, Energy Efficiency and Renewable Energy.

[FR Doc. 2019–27630 Filed 12–20–19; 8:45 am]

BILLING CODE 6450–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–10003–58-Region 2]

Territory of the U.S. Virgin Islands; Final Determination of Adequacy of U.S. Virgin Islands' Municipal Solid Waste Landfill Permitting Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of final determination of adequacy of the Territory of the U.S. Virgin Islands' municipal solid waste landfill permit program.

SUMMARY: The Territory of the U.S. Virgin Islands (USVI) applied for a Determination of Adequacy of its Municipal Solid Waste Landfill (MSWLF) Permit Program under Section 4005 of the Resource Conservation and Recovery Act (RCRA). The components of authority and capability were contained in the USVI's application and its revisions. EPA reviewed the USVI's application, and revisions thereto, including its revised solid waste regulations. After consideration of all public comments received regarding the Tentative Determination of Adequacy, EPA is today issuing a Final Determination that the U.S. Virgin Islands' MSWLF permit program is adequate to ensure compliance with the revised MSWLF permit program criteria.

DATES: The Final Determination of Adequacy of the USVI MSWLF Permit Program shall be effective immediately upon publication of this **Federal Register** Notice, December 23, 2019.

FOR FURTHER INFORMATION CONTACT: Kimiko Link, Sustainable Materials Management Section, Land, Chemicals and Redevelopment Division, *link.kimiko@epa.gov,* 212–637–4182.

SUPPLEMENTARY INFORMATION:

A. Background

Section 4005(c)(l)(B) of the Resource, Conservation and Recovery Act (RCRA) Subtitle D, as amended by the Hazardous and Solid Waste Amendments (HSWA) of 1984, requires states to develop and implement permit programs or other systems of prior approval to ensure that MSWLFs, which may receive hazardous household waste or small quantity generator waste, will comply with the revised federal MSWLF regulations codified in 40 CFR part 258.

RCRA section 4005(c)(l)(C) requires the EPA to determine whether states have adequate permit programs for MSWLFs. Pursuant to RCRA, the term ''State'' includes the Territory of the U.S. Virgin Islands. Title 40 CFR part 239 specifies the minimum requirements that state landfill permit programs must satisfy to be determined to be adequate by EPA, including: the state must have legally adopted enforceable standards for new and existing MSWLFs that are technically comparable to EPA' s revised MSWLF landfill criteria; the state must have an adequate compliance monitoring program and the legal authority to issue permits or other forms of prior approval to all new and existing MSWLFs in its jurisdiction; the state must provide for public participation in permit issuance and enforcement as required in Section 7004(b) of RCRA, 42 U.S.C. 6974(b); and the state must also demonstrate that it has sufficient compliance monitoring and enforcement authorities to take specific action against any owner or operator who fails to comply with applicable regulations or its landfill permit.

The EPA regions are authorized to determine whether a state has submitted an adequate program based on the statute and the regulations summarized above. EPA expects each state to meet all of these requirements for its MSWLF program before it gives full approval of the adequacy of a MSWLF program. As a general matter, the Agency believes that approvals of state programs have an important benefit. Approved state permit programs establish procedures for interaction between a state and an owner/operator regarding site-specific permit conditions. Also, EPA approval of state MSWLF programs provides directors of approved states with various flexibilities including: The authority to approve expansion of an existing landfill or siting a new landfill in a seismic zone; application of alternative daily cover; and alternate financial assurance mechanisms. EPA notes that regardless of the approval status of a state and the permit status of any facility, the federal landfill criteria apply to all permitted and unpermitted MSWLF facilities. EPA also notes that Section 4005(a) of RCRA, 42 U.S.C. 6945(a), provides that citizens may use the citizen suit provisions of Section 7002 of RCRA to enforce the federal MSWLF criteria in 40 CFR part 258

independent of any state enforcement program.

B. U.S. Virgin Islands

The Territory of the U.S. Virgin Islands originally applied for a Determination of Adequacy of its MSWLF Permit Program in October 1993. EPA reviewed the application and published in the **Federal Register** a Tentative Determination of Adequacy on June 16, 1995. However, the public hearings and public comments contained many adverse statements concerning deficiencies in the USVI solid waste program. In addition, the USVI did not promulgate revised solid waste regulations that met EPA requirements. Accordingly, EPA did not publish a Final Determination of Adequacy. Based on continuing deficiencies in the USVI solid waste management program, on May 8, 2000 (65 FR 26546), EPA published in the **Federal Register** a Tentative Determination of Inadequacy and held two public hearings on St. Thomas and St. Croix. After review of public comments, EPA decided not to proceed with a Final Determination of Inadequacy and to allow the USVI additional time to develop its solid waste management program, which EPA believes has now occurred. The EPA has continued to work with the USVI both on its day-to-day landfill operations practices and the development of appropriate solid waste regulations. In addition, in 2004, the USVI established the Waste Management Authority (WMA) and in recent years has pursued various efforts to improve its solid waste management program. The USVI WMA is the USVI agency charged with implementing solid waste management, and it oversees the operation of the Bovoni landfill on St. Thomas, the Anguilla landfill on St. Croix, and the Susanaberg Transfer Station on St. John. The WMA has a Solid Waste Director as well as landfill managers for the Bovoni and Anguilla landfills and the Susanaberg Transfer Station. Also, scheduling the work for the final closure of both the Anguilla and Bovoni landfills is now under the supervision of a federal judge and the Department of Justice, pursuant to federal Consent Decrees which became effective in 2013 and 2014.

The USVI submitted revised program application material to EPA in 2008, and in 2017 and 2018 submitted additional information that EPA had requested. EPA has reviewed all relevant materials concerning the USVI's MSWLF program including revised solid waste regulations.

Based on this documentation, EPA determined that: the USVI solid waste regulations are in conformance with the minimum requirements of 40 CFR part 258 criteria; the Department of Planning and Natural Resources had sufficient authority and responsibility for implementing and enforcing solid waste management regulations, including establishing a permit program, maintaining inspection authority and pursuing enforcement activities; and that the USVI committed to ensuring that adequate technical support and legal personnel would be assigned to implement its permit program. Hence, on June 7, 2019, EPA published in the **Federal Register** a Tentative Determination of Adequacy of the USVI MSWLF Permit Program that concluded all portions of the USVI MSWLF permit program were adequate to ensure compliance with the revised federal criteria.

C. Public Comment

The public comment period for the Tentative Determination of Adequacy commenced with the publication of the action on June 7, 2019. Although RCRA does not require EPA to hold a hearing on any determination to approve a State/Tribe's MSWLF program, the Region held three public hearings in the Territory on July 23rd in St. Croix, July 24th in St. Thomas, and July 25th in St. John. The public comment period ended on August 2, 2019. EPA considered all public comments received during the public comment period and the public hearings in determining whether to publish in the **Federal Register**, a Final Determination of Adequacy of the USVI's RCRA Subtitle D MSWLF Permit Program. Included below is a summary of responses to all major comments received at the public hearings and during the written comment period.

Fifteen comments were received during the three public hearings on consecutive days in St. Croix, St. Thomas and St. John on July 23rd, 24th and 25th, respectively, and the written comment period which closed on August 2, 2019. Most were supportive of the action. Several commenters requested clarification on the authorities, responsibilities and roles associated with solid waste management in the USVI. Clarification was also sought on the implications of approval or disapproval and how the approval would increase the USVI's solid waste management options while ensuring human health and environmental protection. EPA provided responses including the overview of the statutory role of the USVI and the federal government with respect to solid waste management and the required compliance with Part 258 landfill regulations established to protect human health and the environment. Several comments received were related to the need for the USVI's solid waste regulations and future solid waste management plan to include recycling and organics management, the results of the waste characterization study, and the siting of landfills. EPA' s response clarified that the USVI Government is responsible for its solid waste management planning, including any organics diversion programs as well as the siting of any new landfills. EPA also indicated that the waste characterization report funded on behalf of the USVI would be provided to the USVI Government and be made available to the public when finalized.

D. Decision

The USVI Attorney General has certified that the current laws and regulations, which are part of the Virgin Islands' solid waste management program, are in full force and effect, including an appropriate technical correction to the solid waste regulations which has been officially promulgated.

After reviewing the public comments, I conclude that the USVI's application for adequacy determination meets all the statutory and regulatory requirements established by RCRA. Accordingly, the U.S. Territory of Virgin Islands is granted a determination of adequacy for all portions of its municipal solid waste landfill permit program.

Section 4005(a) of RCRA provides that citizens may use the citizen suit provisions of section 7002 of RCRA to enforce the federal MSWLF criteria in 40 CFR part 258 independent of any state/tribal enforcement program. As EPA explained in the preamble to the final MSWLF criteria, EPA expects that any owner or operator complying with provisions in a state/tribal permit program approved by EPA at a MSWLF will adequately reflect the federal criteria. See 56 FR 50978, 50995 (October 9, 1991).

Today's action takes effect immediately with the publication of this Final Determination of Adequacy of the USVI MSWLF Permit Program.

EPA believes it has good cause under section 553(d) of the Administrative Procedure Act, 5 U.S.C 553(d), to put this action into effect less than 30 days after publication in the **Federal Register**.

All the requirements and obligations in the Territory's program are already in effect as a matter of USVI law. EPA's action today does not impose any new

requirements that the regulated community must begin to comply with. Nor do these requirements become enforceable by EPA as federal law. Consequently, EPA finds that it does not need to give notice prior to making its approval effective. Authority: This notice is issued under the authority of sections 2002, 4005 and 4010(c) of the Solid Waste Disposal Act as amended; 42 U.S.C. 6912, 6945, 6949a(c).

Dated: November 27, 2019.

Peter D. Lopez,

Regional Administrator, U.S. Environmental Protection Agency, Region 2.

[FR Doc. 2019–27666 Filed 12–20–19; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0311, OMB 3060–0433, OMB 3060–0863; FRS 16335]

Information Collections Being Submitted for Review and Approval to Office of Management and Budget

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal Agencies to take this opportunity to comment on the following information collection. Pursuant to the Small Business Paperwork Relief Act of 2002, the FCC seeks specific comment on how it might ''further reduce the information collection burden for small business concerns with fewer than 25 employees.'' The Commission may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written comments should be submitted on or before January 22, 2020. If you anticipate that you will be submitting comments but find it difficult to do so with the period of time allowed by this notice, you should advise the contacts listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicholas A. Fraser, OMB, via email *Nicholas_A._Fraser@OMB.eop.gov;* and to Cathy Williams, FCC, via email *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.* Include in the comments the OMB control number as shown in the **SUPPLEMENTARY INFORMATION** below.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection, contact Cathy Williams at (202) 418–2918. To view a copy of this information collection request (ICR) submitted to OMB: (1) Go to the web page *http://www.reginfo.gov/public/do/PRAMain,* (2) look for the section of the web page called ''Currently Under Review,'' (3) click on the downward-pointing arrow in the ''Select Agency'' box below the ''Currently Under Review'' heading, (4) select ''Federal Communications Commission'' from the list of agencies presented in the ''Select Agency'' box, (5) click the ''Submit'' button to the right of the ''Select Agency'' box, (6) when the list of FCC ICRs currently under review appears, look for the Title of this ICR and then click on the ICR Reference Number. A copy of the FCC submission to OMB will be displayed.

SUPPLEMENTARY INFORMATION: As part of its continuing effort to reduce paperwork burdens, as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the FCC invited the general public and other Federal Agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimates; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology. Pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, see 44 U.S.C. 3506(c)(4), the FCC seeks specific comment on how it might ''further reduce the information collection burden for small business concerns with fewer than 25 employees.''

OMB Control Number: 3060–0311.

Title: 47 CFR 76.54, Significantly Viewed Signals; Method to be followed for Special Showings.

Form Number: Not applicable.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents and Responses: 500 respondents, 1,274 responses.

Frequency of Response: On occasion reporting and third-party disclosure requirements.

Estimated Time per Response: 1–15 hours (average).

Total Annual Burden: 20,610 hours.

Total Annual Cost: $300,000.

Nature of Response: Required to obtain or retain benefits. The statutory authority for this information collection is contained in Section 4(i) and 340 of the Communications Act of 1934, as amended.

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

Privacy Impact Assessment: No impact(s).

Needs and Uses: The information collection requirements contained in 47 CFR 76.54(b) state significant viewing in a cable television or satellite community for signals not shown as significantly viewed under 47 CFR 76.54(a) or (d) may be demonstrated by an independent professional audience survey of over-the-air television homes that covers at least two weekly periods separated by at least thirty days but no more than one of which shall be a week between the months of April and September. If two surveys are taken, they shall include samples sufficient to assure that the combined surveys result in an average figure at least one standard error above the required viewing level.

The information collection requirements contained in 47 CFR 76.54(c) are used to notify interested parties, including licensees or permittees of television broadcast stations, about audience surveys that are being conducted by an organization to demonstrate that a particular broadcast station is eligible for significantly viewed status under the Commission's rules. The notifications provide interested parties with an opportunity to review survey methodologies and file objections.

Lastly, 47 CFR 76.54(e) and (f), are used to notify television broadcast stations about the retransmission of significantly viewed signals by a satellite carrier into these stations' local market.

OMB Control Number: 3060–0433.

Title: Basic Signal Leakage Performance Report.

Form Number: FCC Form 320.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents and Responses: 3,413 respondents and 3,413 responses.

Frequency of Response: Recordkeeping requirement, Annual reporting requirement.

Estimated Time per Hour: 20 hours.

Total Annual Burden: 68,260 hours.

Total Annual Cost: None.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this collection is contained in Sections 4(i), 302 and 303 of the Communications Act of 1934, as amended.

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

Privacy Impact Assessment(s): No impact(s).

Needs and Uses: Cable television system operators and Multichannel Video Programming Distributors (MPVDs) who use frequencies in the bands 108–137 and 225–400 MHz (aeronautical frequencies) are required to file a Cumulative Signal Leakage Index (CLI) derived under 47 CFR 76.611(a)(1) or the results of airspace measurements derived under 47 CFR 76.611(a)(2). This filing must include a description of the method by which compliance with basic signal leakage criteria is achieved and the method of calibrating the measurement equipment. This yearly filing of FCC Form 320 is done in accordance with 47 CFR 76.1803. The records must be retained by cable operators.

OMB Control Number: 3060–0863.

Title: Satellite Delivery of Network Signals to Unserved Households for Purposes of the Satellite Home Viewer Act.

Form Number: Not applicable.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents and Responses: 848 respondents; 250,000 responses.

Estimated Time per Response: 0.50 hours.

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

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection action is contained in the Satellite Home Viewer Act, 17 U.S.C. 119. The Satellite Home Viewer Act is an amendment of the Copyright Act; and Satellite Television Extension and Localism Act of 2010, Title V of the ''American Workers, State, and Business Relief Act of 2010,'' Public Law 111–175, 124 Stat. 1218 (2010) (STELA), see footnote 3.

Total Annual Burden to Respondents: 125,000 hours.

Total Annual Cost: None.

Privacy Impact Assessment(s): No impact(s).

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

Needs and Uses: The information collection requirements contained in 47 CFR 73.686 describes a method for measuring signal strength at a household so that the satellite and broadcast industries would have a uniform method for making an actual determination of the signal strength that a household received. The information gathered as part of the Grade B contour signal strength tests will be used to indicate whether a household is ''unserved'' by over-the-air network signals.

Satellite and broadcast industries making field strength measurements for formal submission to the Commission in rulemaking proceedings, or making such measurements upon the request of the Commission, shall follow the procedure for making and reporting such measurements which shall be included in a report to the Commission and submitted in affidavit form, in triplicate. The report shall contain the following information:

(a) Tables of field strength measurements, which for each measuring location; (b) U.S. Geological Survey topographic maps; (c) All information necessary to determine the pertinent characteristics of the transmitting installation; (d) A list of calibrated equipment used in the field strength survey; (e) A detailed description of the calibration of the measuring equipment, and (f) Terrain profiles in each direction in which measurements were made.

The information collection requirements contained in 47 CFR 73.686 also requires satellite and broadcast companies to maintain a written record describing, for each location, factors which may affect the recorded field (*i.e.,* the approximate time or measurement, weather, topography, overhead wiring, heights and types of vegetation, buildings and other structures, the orientation of the measuring location, objects of such shape and size that cause shadows or reflections, signals received that arrived from a direction other than that of the transmitter, survey, list of the measured value field strength, time and date of the measurements and signature of the person making the measurements).

The information collection requirements contained in 47 CFR 73.686(e) describes the procedures for measuring the field strength of digital television signals. These procedures will be used to determine whether a household is eligible to receive a distant digital network signal from a satellite television provider, largely rely on existing, proven methods the Commission has already established for measuring analog television signal strength at any individual location, as set forth in Section 73.686(d) of the existing rules, but include modifications as necessary to accommodate the inherent differences between analog and digital TV signals. The new digital signal measurement procedures include provisions for the location of the measurement antenna, antenna height, signal measurement method, antenna orientation and polarization, and data recording.

Therefore, satellite and broadcast industries making field strength measurements shall maintain written records and include the following information: (a) A list of calibrated equipment used in the field strength survey, which for each instrument specifies the manufacturer, type, serial number and rated accuracy, and the date of the most recent calibration by the manufacturer or by a laboratory. Include complete details of any instrument not of standard manufacture; (b) A detailed description of the calibration of the measuring equipment, including field strength meters, measuring antenna, and connecting cable; (c) For each spot at the measuring site, all factors which may affect the recorded field, such as topography, height and types of vegetation, buildings, obstacles, weather, and other local features; (d) A description of where the cluster measurements were made; (e) Time and date of the measurements and signature of the person making the measurements; (f) For each channel being measured, a list of the measured value of field strength (in units of dBμ after adjustment for line loss and antenna factor) of the five readings made during the cluster measurement process, with the median value highlighted.

Federal Communications Commission.

Cecilia Sigmund,

Federal Register Liaison Officer, Office of the Secretary.

[FR Doc. 2019–27620 Filed 12–20–19; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0548; FRS 16336]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act of 1995 (PRA), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written PRA comments should be submitted on or before February 21, 2020. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams, (202) 418–2918.

OMB Control Number: 3060–0548.

Title: Sections 76.1709 and 76.1620, Availability of Signals; Section 76.56, Signal Carriage Obligations; Section 76.1614, Identification of Must-Carry Signals.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents and Responses: 4,103 respondents; 49,236 responses.

Estimated Time per Response: 0.5—1.0 hour.

Frequency of Response: Recordkeeping requirement, Third party disclosure requirement, On occasion reporting requirement.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this collection is contained in Sections 4(i), 614 and 615 of the Communications Act of 1934, as amended.

Total Annual Burden: 24,618 hours.

Total Annual Cost: No cost.

Privacy Act Impact Assessment: No impact(s).

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

Needs and Uses: On January 31, 2017, the Commission adopted a Report and Order (Public Inspection File R&O) in MB Docket No. 16–161, FCC 17–3, In the Matter of Revisions to Public Inspection File Requirements—Broadcaster Correspondence File and Cable Principal Headend Location which eliminated the requirement in former 47 CFR 76.1708 that cable operators maintain for public inspection the designation and location of the cable system's principal headend. The Public Inspection File R&O removed and reserved 47 CFR.76.1708.

This collection is being revised to reflect the removal of 47 CFR 76.1708 made in the *Public Inspection File R&O.*

The other information collection requirements contained under this collection and have not changed are as follows:

47 CFR 76.56 requires cable television systems to carry signals of all qualified local commercial and Noncommercial Educational (NCE) stations requesting carriage. As a result of this requirement, the following information collection requirements are needed for this collection:

47 CFR 76.1709(a) states that the operator of every cable television system shall maintain for public inspection a file containing a list of all broadcast television stations carried by its system in fulfillment of the must-carry requirements pursuant to 47 CFR 76.56. Such list shall include the call sign; community of license, broadcast channel number, cable channel number, and in the case of a noncommercial educational broadcast station, whether that station was carried by the cable system on March 29, 1990.

47 CFR 76.1709(c) states that a cable operator shall respond in writing within 30 days to any written request by any person for the identification of the signals carried on its system in fulfillment of the requirements of 47 CFR 76.56.

47 CFR 76.1614 states that a cable operator shall respond in writing within 30 days to any written request by any person for the identification of the signals carried on its system in fulfillment of the requirements of 47 CFR 76.56. The required written response may be delivered by email, if the consumer used email to make the request or complaint directly to the cable operator, or if the consumer specifies email as the preferred delivery method in the request or complaint.

Additionally, 47 CFR 76.1620 states that if a cable operator authorizes subscribers to install additional receiver connections, but does not provide the subscriber with such connections, or with the equipment and materials for such connections, the operator shall notify such subscribers of all broadcast stations carried on the cable system which cannot be viewed via cable without a converter box and shall offer to sell or lease such a converter box to such subscribers. Such notification must be provided by June 2, 1993, and annually thereafter and to each new subscriber upon initial installation. The notice, which may be included in routine billing statements, shall identify the signals that are unavailable without an additional connection, the manner for obtaining such additional connection and instructions for installation.

Federal Communications Commission.

Cecilia Sigmund,

Federal Register Liaison Officer, Office of the Secretary.

[FR Doc. 2019–27621 Filed 12–20–19; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0506; FRS 16333]

Information Collection Being Reviewed by the Federal Communications Commission Under Delegated Authority

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act of 1995 (PRA), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written PRA comments should be submitted on or before February 21, 2020. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams, (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0506.

Title: FCC Form 2100, Schedule 302–FM—FM Station License Application.

Form Number: FCC Form 2100, Schedule 302–FM.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities; Not-for-profit institutions.

Number of Respondents and Responses: 925 respondents; 925 responses.

Estimated Time per Response: 1–2 hours.

Frequency of Response: On occasion reporting requirement.

Total Annual Burden: 3,135 hours.

Total Annual Costs: $640,000.

Obligation To Respond: Required to obtain or retain benefits. The statutory authority for this collection of information is contained in Sections 154(i), 303 and 308 of the Communications Act of 1934, as amended.

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

Privacy Impact Assessment(s): No impact(s).

Needs and Uses: FCC Form 2100, Schedule 302–FM is required to be filed by licensees and permittees of FM broadcast stations to request and obtain a new or modified station license and/or to notify the Commission of certain changes in the licensed facilities of these stations. Data is used by FCC staff to confirm that the station is built to the terms specified in the outstanding construction permit and to ensure that any changes made to the station will not have any impact on other stations and the public. Data is extracted from FCC Form 2100, Schedule 302–FM for inclusion in the license to operate the station.

Federal Communications Commission.

Cecilia Sigmund,

Federal Register Liaison Officer, Office of the Secretary.

[FR Doc. 2019–27619 Filed 12–20–19; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice of the FDIC's Response to Exception Requests Pursuant to Recordkeeping for Timely Deposit Insurance Determination

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice of the FDIC's response to exception requests pursuant to the Recordkeeping for Timely Deposit Insurance Determination rule.

SUMMARY: In accordance with its rule regarding recordkeeping for timely deposit insurance determination, the FDIC is providing notice to covered institutions that it has granted a time-limited exception concerning the requirement to maintain official custodian information in deposit account records for government deposit accounts, a time-limited exception concerning the requirement to maintain accurate beneficiary information in deposit account records for informal revocable trust accounts, and an indefinite exception concerning the requirement to maintain certain identifying information for beneficial owners of deposits in low balance, short-term prepaid card accounts.

DATES: The FDIC's grants of exception relief were effective as of November 26, 2019.

FOR FUTHER INFORMATION CONTACT: Peter Miller, Assistant Director, Division of Complex Institution Supervision and Resolution; telephone 917–320–2589.

SUPPLEMENTARY INFORMATION: The FDIC has granted three exception requests pursuant to the FDIC's rule entitled ''Recordkeeping for Timely Deposit Insurance Determination,'' codified at 12 CFR part 370 (part 370).[1] Part 370 generally requires covered institutions to implement the information technology system and recordkeeping capabilities needed to quickly calculate the amount of deposit insurance coverage available for each deposit account in the event of failure. Pursuant to section 370.8(b)(1), one or more covered institutions may submit a request in the form of a letter to the FDIC for an exception from one or more of the requirements of part 370 if circumstances exist that would make it impracticable or overly burdensome to meet those requirements. Pursuant to section 370.8(b)(3), a covered institution may rely upon another covered institution's exception request which the FDIC has previously granted by notifying the FDIC that it will invoke relief from certain part 370 requirements and demonstrating that the covered institution has substantially similar facts and circumstances to those of the covered institution that has already received the FDIC's approval. The notification letter must also include the information required under section 370.8(b)(1) and cite the applicable notice published pursuant to section 370.8(b)(2). Unless informed otherwise by the FDIC within 120 days after receipt of a complete notification for exception, the exception will be deemed granted subject to the same conditions set forth in the FDIC's published notice.

These grants of relief may be rescinded or modified upon material change of circumstances or conditions related to the subject accounts, or upon failure to satisfy conditions applicable to each. These grants of relief will be subject to ongoing FDIC review, analysis, and verification during the FDIC's routine part 370 compliance tests. The following exceptions were

[1] 12 CFR part 370.

granted by the FDIC as of November 26, 2019.

I. Government Deposit Accounts for Which the Covered Institution Does Not have the Requisite Information Regarding the Official Custodian

A covered institution was granted a time-limited exception from the general recordkeeping requirements set forth in section 370.4(a) to obtain official custodian information needed to calculate deposit insurance available for government deposit accounts and maintain that information in its deposit account records. The covered institution did not collect, or have a mechanism to collect such information prior to the FDIC's adoption of part 370 and anticipates that it may not be able to collect such information for all government accounts before its April 1, 2020 compliance date.

In connection with the FDIC's grant of relief, the covered institution will implement an outreach plan to obtain the requisite information directly from the government account holders; update its electronic deposit account records and make other IT system enhancements as needed; ensure that, from and after the April 1, 2020 compliance date, holds can be placed on government deposit accounts in the event of its failure until sufficient information is provided by the account holder to enable calculation of deposit insurance coverage; submit a status report to the FDIC at the midpoint of the exception relief period; and immediately notify the FDIC of any change in relevant circumstances or conditions.

II. Informal Revocable Trust Accounts for Which the Covered Institution Needs Additional Time To Integrate Beneficiary Information

A covered institution was granted a time-limited exception from the general recordkeeping requirements set forth in section 370.4(a) to identify accurate beneficiary information needed to calculate deposit insurance coverage for informal revocable trust accounts (also known as ''payable-on-death'' or ''in-trust-for'' accounts) and maintain that information in a systematic manner that can be used by its IT system to calculate deposit insurance coverage.

In connection with the FDIC's grant of relief, the covered institution will implement and complete review of paper-based documents or contact account holders to obtain the necessary beneficiary information; update its electronic deposit account records and make other IT system enhancements as needed; submit a status report to the FDIC at the midpoint of the period for which relief is granted; and immediately notify the FDIC of any change in relevant circumstances or conditions.

III. Deposits Held in Connection With Low Balance, Short-Term Prepaid Cards

A covered institution was granted an indefinite exception from section 370.4(a)(1)(ii) for deposit accounts held in connection with low balance, short-term prepaid cards issued for rebates, refunds, incentives, and per diem payments. These cards are issued by the covered institution on behalf of a commercial customer and have been registered by the cardholders. Although the prepaid cards are registered, the cardholders do not provide social security numbers, which are necessary for the covered institution's IT system to aggregate deposits by owner for deposit insurance calculation purposes. The covered institution asserts that a certain small population of prepaid cardholders will not provide personally identifiable information for a low dollar prepaid card that will be used within months of issuance. This exception does not include deposit accounts held in connection with payroll or government prepaid cards, certain types of loyalty or rebate cards where the cardholder is not the actual owner of the funds, or per diem cards for which the covered institution has a social security number.

The covered institution stated that it has not collected social security numbers prior to issuance of these prepaid cards, nor does it have a business purpose or mechanism to do so. It also stated that doing so would jeopardize the commercial viability of the product or service and that the deposit accounts subject to the exception were a small subset of the covered institution's prepaid card portfolio and have low balances and high turnover.

In connection with the FDIC's grant of relief, the covered institution will: maintain the capability to restrict access to the deposit accounts subject to the exception to ensure no uninsured funds leave the covered institution in the event of its failure; maintain at least one method for the cardholder to register his or her name, address, and social security number through, for example, a website or call center; receive daily reports from the prepaid card processor(s) with customer name, address, transaction data, and end-of-day customer balances; document the resources, methods, and estimated time needed at failure to collect social security numbers related to the subject accounts; include in the institution's current prepaid cardholder disclosure notices that access to funds will be withheld in the event of failure pending receipt of sufficient information, including, at a minimum, government identification, to complete a deposit insurance calculation; demonstrate the IT system's ability to timely generate the customer file and process the deposit insurance calculation; and immediately bring to the FDIC's attention any change of circumstances or conditions.

Federal Deposit Insurance Corporation.

Dated at Washington, DC on December 18, 2019.

Annmarie H. Boyd,

Assistant Executive Secretary.

[FR Doc. 2019–27626 Filed 12–20–19; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL RESERVE SYSTEM

Agency Information Collection Activities: Announcement of Board Approval under Delegated Authority and Submission to OMB

AGENCY: Board of Governors of the Federal Reserve System.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) is adopting a proposal to extend for three years, without revision, the Savings Association Holding Company Report (FR LL–(b)11; OMB No. 7100–0334).

FOR FURTHER INFORMATION CONTACT:

Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551, (202) 452–3829.

Office of Management and Budget (OMB) Desk Officer—Shagufta Ahmed—Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395–6974.

A copy of the Paperwork Reduction Act (PRA) OMB submission, including the reporting form and instructions, supporting statement, and other documentation will be placed into OMB's public docket files. These documents also are available on the Federal Reserve Board's public website at *https://www.federalreserve.gov/apps/reportforms/review.aspx* or may be requested from the agency clearance officer, whose name appears above.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the PRA to approve and assign OMB control numbers to

collections of information conducted or sponsored by the Board. Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. Copies of the PRA Submission, supporting statements, and approved collection of information instrument(s) are placed into OMB's public docket files.

Final Approval under OMB Delegated Authority of the Extension for Three Years, Without Revision, the Following Information Collection:

Report title: Savings Association Holding Company Report.

Agency form number: FR LL–(b)11.[1]

OMB control number: 7100–0334.

Frequency: Quarterly,[2] annually, and event-generated.

Respondents: Certain savings and loan holding companies (SLHCs).

Estimated number of respondents: Quarterly: 6; annually: 6; event-generated: 1.

Estimated average hours per response: Quarterly: 2; annually: 2; event-generated: 2.

Estimated annual burden hours: Quarterly: 36; annually: 12; event-generated: 2.

General description of report: Title III of the Dodd-Frank Wall Street Reform and Consumer Protection Act transferred to the Board the supervisory functions of the former Office of Thrift Supervision related to SLHCs and their non-depository subsidiaries. Pursuant to section 10(b) the Home Owners' Loan Act (HOLA), the Board may require SLHCs to file reports concerning their operations. Following the transfer to the Board of authority to supervise SLHCs, the Board determined to exempt certain SLHCs (known as ''exempt SLHCs'') from regulatory reporting using the Board's existing regulatory reports, including the Consolidated Financial Statements for Holding Companies (FR Y–9C; OMB No. 7100–0128) and the Parent Company Only Financial Statements for Small Holding Companies (FR Y–9SP; OMB No. 7100–0128). Exempt SLHCs must file the FR LL–(b)11 quarterly report in order for the Board to obtain the information that is necessary to supervise such SLHCs, monitor their financial condition, and assess their regulatory compliance. An SLHC is exempt from filing the FR Y–9C or FR Y–9SP if it: (1) Meets the requirements of section 10(c)(9)(C) of HOLA (*i.e.,* a ''grandfathered'' unitary SLHC) and has primarily commercial assets, with thrift assets making up less than 5 percent of the SLHC's consolidated assets;[3] or (2) primarily holds insurance-related assets and does not otherwise submit financial reports with the U.S. Securities and Exchange Commission pursuant to sections 13 or 15(d) of the Securities Exchange Act of 1934.

The FR LL–(b)11 collects the following six categories of information:

(1) Information about U.S. Securities and Exchange Commission filings;

(2) Reports provided by Nationally Recognized Statistical Rating Organizations and Securities Analysts;

(3) Supplemental information for the Quarterly Savings and Loan Holding Company Report (FR 2320; OMB No. 7100–0345);

(4) Information about other materially important events;

(5) Financial statements; and

(6) Other exhibits required by the Board.

Legal authorization and confidentiality: The FR LL–10(b)11 is authorized pursuant to section 10 of the Home Owners' Loan Act, which requires SLHCs to file ''such reports as may be required by the Board.''[4] The FR LL–(b)11 is mandatory.

Information provided through the FR LL- (b)11 that corresponds to a ''yes'' answer to questions 24, 25, and 26 of the FR 2320 is generally considered to be confidential under exemption 4 of the Freedom of Information Act (FOIA), which protects privileged or confidential commercial or financial information.[5] If it should be determined subsequently that any information collected on these three items must be released, respondents will be notified. Individual respondents may request that other information submitted to the Board through the FR LL–(b)11 be kept confidential, and the Board will determine whether the information is entitled to confidential treatment on a case-by-case basis. Information may be kept confidential under FOIA exemption 4 or exemption 8, which exempts from disclosure information ''related to examination, operating, or condition reports prepared by, on behalf of, or for the use of an agency responsible for the regulation or supervision of financial institutions.''[6]

Current actions: On September 10, 2019, the Board published an initial notice in the **Federal Register** (84 FR 47514) requesting public comment for 60 days on the extension, without revision, of the FR LL–(b)11. The comment period for this notice expired on November 12, 2019. The Board did not receive any comments.

Board of Governors of the Federal Reserve System, December 17, 2019.

Michele Taylor Fennell,

Assistant Secretary of the Board.

[FR Doc. 2019–27599 Filed 12–20–19; 8:45 am]

BILLING CODE 6210–01–P

[1] The internal Agency Tracking Number previously assigned by the Board to this information collection was ''FR H–(b)11.'' The Board is changing the internal Agency Tracking Number to ''FR LL–(b)11'' for the purpose of consistency.

[2] The FR LL–(b)11 is filed quarterly except for the fourth quarter when the respondent is required to file its annual report.

[3] Specifically, a grandfathered unitary SLHC is exempt if (1) as calculated annually as of June 30th, using the four previous quarters (which includes the quarter-ended June 30th reporting period), its savings association subsidiaries' consolidated assets make up less than 5 percent of the total consolidated assets of the grandfathered SLHC on an enterprise-wide basis for any of these four quarters; and (2) as calculated annually as of June 30th, using the assets reported as of June 30th, where more than 50 percent of the assets of the grandfathered unitary SLHC are derived from activities that are not otherwise permissible under HOLA on an enterprise-wide basis.

[4] 12 U.S.C. 1467a(b)(2)(A).

[5] 5 U.S.C. 552(b)(4).

[6] 5 U.S.C. 552(b)(4) and (8).

FEDERAL RESERVE SYSTEM

Agency Information Collection Activities: Announcement of Board Approval under Delegated Authority and Submission to OMB

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Approval of Information Collection.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) is adopting two proposals to extend for three years, with revision, the Capital Assessments and Stress Testing Reports (FR Y–14A/Q/M; OMB No. 7100–0341). The revisions are applicable with as of dates ranging from December 31, 2019, to December 31, 2020. This final notice is adopting two proposals previously published separately: One proposing to incorporate current expected credit loss (CECL) methodology revisions into the FR Y–14A/Q/M reports (CECL proposal), and the other proposal to incorporate non-CECL methodology revisions into the FR Y–14A/Q/M reports (non-CECL proposal).

FOR FURTHER INFORMATION CONTACT: Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551, (202) 452–3829.

Office of Management and Budget (OMB) Desk Officer—Shagufta Ahmed—Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building,

Room 10235, 725 17th Street, NW, Washington, DC 20503, or by fax to (202) 395–6974.

A copy of the Paperwork Reduction Act (PRA) OMB submission, including the reporting form and instructions, supporting statement, and other documentation will be placed into OMB's public docket files. These documents also are available on the Federal Reserve Board's public website at *https://www.federalreserve.gov/apps/reportforms/review.aspx* or may be requested from the agency clearance officer, whose name appears above.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the PRA to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. Copies of the PRA Submission, supporting statements, and approved collection of information instrument(s) are placed into OMB's public docket files.

Final Approval Under OMB Delegated Authority of the Extension for Three Years, With Revision, of the Following Information Collection

Report title: Capital Assessments and Stress Testing Reports.

Agency form number: FR Y–14A/Q/M.

OMB control number: 7100–0341.

Effective dates: Ranges from December 31, 2019, to December 31, 2020.

Frequency: Annually, semi-annually, quarterly, and monthly.

Respondents: The respondent panel consists of U.S. bank holding companies (BHCs), U.S. intermediate holding companies (IHCs) of foreign banking organizations (FBOs), and covered savings and loan holding companies (SLHCs) [1] with $100 billion or more in total consolidated assets, as based on: (i) the average of the firm's total consolidated assets in the four most recent quarters as reported quarterly on the firm's Consolidated Financial Statements for Holding Companies (FR Y–9C); or (ii) if the firm has not filed an FR Y–9C for each of the most recent four quarters, then the average of the firm's total consolidated assets in the most recent consecutive quarters as reported quarterly on the firm's FR Y–9Cs.[2] Reporting is required as of the first day of the quarter immediately following the quarter in which the respondent meets this asset threshold, unless otherwise directed by the Board.

Estimated number of respondents: FR Y–14A: 35; FR Y–14Q: 35; [3] FR Y–14M: 33.

Estimated average hours per response: FR Y–14A: 1,030 hours; FR Y–14Q: 1,944 hours; FR Y–14M: 1,075 hours; FR Y–14 Implementation and On-going Automation Revisions, 540 hours; FR Y–14 Attestation On-going Audit and Review, 2,560 hours.

Estimated annual burden hours: FR Y–14A: 72,100 hours; FR Y–14Q: 272,160 hours; FR Y–14M: 425,700 hours; FR Y–14 On-going Automation Revisions, 18,900 hours; FR Y–14 Attestation On-going Audit and Review, 33,280 hours.

General description of report: This family of information collections is composed of the following three reports:

- The semi-annual FR Y–14A collects quantitative projections of balance sheet, income, losses, and capital across a range of macroeconomic scenarios and qualitative information on methodologies used to develop internal projections of capital across scenarios.[4]
- The quarterly FR Y–14Q collects granular data on various asset classes, including loans, securities, trading assets, and pre-provision net revenue (PPNR) for the reporting period.
- The monthly FR Y–14M is comprised of three retail portfolio- and loan-level schedules, and one detailed address-matching schedule to supplement two of the portfolio and loan-level schedules.

The data collected through the FR Y–14A/Q/M reports provide the Board with the information needed to help ensure that large firms have strong, firm-wide risk measurement and management processes supporting their internal assessments of capital adequacy and that their capital resources are sufficient given their business focus, activities, and resulting risk exposures. The reports are used to support the Board's annual Dodd-Frank Act Stress Test (DFAST) and Comprehensive Capital Analysis and Review (CCAR) exercises, which complement other Board supervisory efforts aimed at enhancing the continued viability of large firms, including continuous monitoring of firms' planning and management of liquidity and funding resources, as well as regular assessments of credit, market and operational risks, and associated risk management practices. Information gathered in this data collection is also used in the supervision and regulation of respondent financial institutions. Compliance with the information collection is mandatory.

Legal authorization and confidentiality: The Board has the authority to require BHCs to file the FR Y–14 reports pursuant to section 5 of the Bank Holding Company Act (''BHC Act'') (12 U.S.C. 1844), to require SLHCs to file the FR Y–14 reports pursuant to section 10 of the Home Owners' Loan Act (12 U.S.C. 1467a(b)), and to require the U.S. IHCs of FBOs to file the FR Y–14 reports pursuant to section 5 of the BHC Act, in conjunction with section 8 of the International Banking Act (12 U.S.C. 3106). The FR Y–14 reports are mandatory.

The information collected in these reports is collected as part of the Board's supervisory process, and therefore is afforded confidential treatment pursuant to exemption 8 of the Freedom of Information Act (''FOIA'') (5 U.S.C. 552(b)(8)). In addition, individual respondents may request that certain data be afforded confidential treatment pursuant to exemption 4 of the FOIA, which exempts from disclosure ''trade secrets and commercial or financial information obtained from a person [that is] privileged or confidential'' (5 U.S.C. 552(b)(4)). Determinations of confidentiality based on FOIA exemption 4 would be made on a case-by-case basis.

Current actions: On July 31, 2019, the Board published two notices in the **Federal Register** (84 FR 37285 and 84 FR 37292) requesting public comment for 60 days on the extension, with revision, of the Capital Assessments and Stress Testing Reports. The Board proposed to implement a number of changes to schedules of the FR Y–14A,

[1] SLHCs with $100 billion or more in total consolidated assets become members of the FR Y–14A/Q/M panel effective June 30, 2020. *See* 84 FR 59032 (November 1, 2019).

[2] The Board had separately revised the respondent panel for the FR Y–14 reports in connection with the Board's rule regarding Prudential Standards for Large Bank Holding Companies and Savings and Loan Holding Companies (the ''Tailoring Rule''). See 84 FR 59230 (November 1, 2019) and 84 FR 50932 (November 1, 2019). Under the Tailoring Rule, the respondent panel for the FR Y–14 reports is BHCs with total consolidated assets of $100 billion or more, IHCs with total consolidated assets of $50 billion or more that are subsidiaries of an FBO, and covered SLHCs with $100 billion or more in total consolidated assets. See 12 CFR 217.2 (defining ''covered savings and loan holding company'').

[3] The estimated number of respondents for the FR Y–14M is lower than for the FR Y–14A and FR Y–14Q because, in recent years, certain respondents to the FR Y–14A and FR Y–14Q have not met the materiality thresholds to report the FR Y–14M due to their lack of mortgage and credit activities. The Board expects this situation to continue for the foreseeable future.

[4] In certain circumstances, a BHC or U.S. IHC may be required to re-submit its capital plan. *See* 12 CFR 225.8(e)(4). Firms that must re-submit their capital plan generally also must provide a revised FR Y–14A in connection with their resubmission.

FR Y–14Q, and FR Y–14M reports. The proposed revisions consisted of deleting or adding items, adding or expanding schedules or sub-schedules, and modifying or clarifying the instructions for existing data items, primarily on the FR Y–14Q and FR Y–14M reports. The Board proposed most of these changes in an effort to reduce reporting burden for firms, clarify reporting instructions and requirements, address inconsistencies between the FR Y–14 reports and other regulatory reports, and to account for revised rules and accounting principles. A limited number of proposed revisions would have modified the reporting requirements and added or expanded sub-schedules to improve the availability and quality of data to enhance supervisory modeling and for use in DFAST.

The proposed revisions also were meant to address revised accounting for credit losses under the Financial Accounting Standards Board's (FASB) Accounting Standards Update (ASU) No. 2016–13, ''Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments'' (ASU 2016–13) and implement the CECL accounting methodology across all of the FR Y–14 reports. The proposed changes to the FR Y–14 reports paralleled the related changes to the Consolidated Financial Statements for Holding Companies (FR Y–9C) for CECL, as appropriate.[5] The proposed reporting changes related to CECL also were consistent with the revisions indicated in the interagency final rule that incorporated the CECL transition.[6]

The comment period for the two notices regarding the Capital Assessments and Stress Testing Reports expired on September 30, 2019. The Board received four comment letters from banking organizations and one comment letter from a banking industry group on its non-CECL proposal. The Board received one comment letter from a banking organization and one comment letter from a banking industry group on its CECL proposal. All comments and responses are delineated below based on whether the comment was related to the non-CECL or CECL proposal.

Detailed Discussion of Public Comments

Timing of Proposed Changes

The Board proposed that all revisions associated with these proposals to be effective for September 30, 2019. Four commenters stated that those revisions should be delayed so that there would be time for FR Y–14 filers to set up or update, as well as adequately test, their internal reporting systems to adopt the reporting changes. For the FR Y–14A, two commenters suggested adjusting the effective date for most of the revisions to December 31, 2019, with the exception of the proposals to eliminate the deposit funding threshold from the PPNR schedule and to require IHCs to provide a cost allocation as a supplement to their PPNR schedules, which two commenters proposed to become effective December 31, 2020. Another commenter suggested that all revisions associated with FR Y–14A become effective December 31, 2020. For the FR Y–14Q, two commenters suggested adjusting the effective date to delay most of the revisions to December 31, 2019, with the exception of certain proposed changes to the Counterparty (Schedule L), Trading (Schedule F), and Retail (Schedule A) schedules, which the commenters suggested to delay until June 30, 2020. One commenter suggested delaying all proposed revisions associated with the FR Y–14Q to March 31, 2020. Finally, for the FR Y–14M, three commenters suggested delaying all proposed revisions to become effective March 31, 2020.

In light of the rationale for delaying implementation to allow firms adequate time to set up, update, and test their internal systems, as well as due to the fact that the proposed effective date has already passed, the Board has revised the effective date from September 30, 2019, to dates ranging from December 31, 2019, to December 31, 2020, for different aspects of the proposal. The December 31, 2019, date was chosen as some revisions are necessary for the DFAST 2020 stress test cycle, and so could not have been delayed to a later date. The effective dates for the other revisions were chosen as a balance between data needed by the Board and industry burden.

Timing of Non-CECL Revisions

For non-CECL revisions associated with the FR Y–14A, all revisions will be effective for December 31, 2020, except the revisions to schedule A.1.d (Capital), the revisions to schedule A.2.a (Retail Balance and Loss Projections), the revisions to schedule A.4 (Trading), and the revisions made to conform to changes previously made to the FR Y–9C. The revisions to schedule A.1.d, A.2.a, and A.4 will be effective for December 31, 2019, as they are critical for the DFAST 2020 stress test cycle.

For non-CECL revisions associated with the FR Y–14Q, all revisions will be effective for March 31, 2020, with the exception of the revisions to Schedule D (Regulatory Capital), the addition of the fair value option (FVO) hedges sub-schedule to Schedule F (Trading), certain revisions to Schedule H (Wholesale), the elimination of Schedule I ([Mortgage Servicing Rights] MSR Valuation Schedule), and the revisions made to conform to changes previously made to the FR Y–9C, which will be effective for December 31, 2019, as well as the revisions to the Counterparty schedule, which will be effective for June 30, 2020. The non-CECL FR Y–14Q revisions that are effective for December 31, 2019, are needed then because they are critical for the DFAST 2020 stress test cycle. For the December 31, 2019, as of date, the Board will allow firms to submit the FVO hedges sub-schedule to Schedule F by March 6, 2020, as opposed to the February due date for the rest of the FR Y–14Q. The Board recognizes that one commenter requested delaying proposed revisions to the Trading schedule and the proposal to add a weighted-average life (WAL) segment variable to the Retail schedules to June 30, 2020. However, the Board feels that extending the effective date by six months will provide adequate time to set up or update, as well as adequately test, pertinent internal systems. In addition, firms already provide a WAL item on the FR Y–14A, PPNR schedule (schedule A.7) at the portfolio level. The instructions for the new WAL item at the loan segment level are similar to the existing WAL items on the PPNR schedule, and so the Board has added the item as proposed, except with a March 31, 2020, effective date.

For non-CECL revisions associated with the FR Y–14M, all revisions will be effective for March 31, 2020.

Timing of CECL Revisions

As indicated in the final CECL rule and as outlined in FR Y–14 CECL proposal, an institution may reflect the adoption of ASU 2016–13 on the FR Y–14 reports beginning with the 2020 stress test cycle. Therefore, all CECL-related items need to be incorporated into the FR Y–14 reports for December 31, 2019.

Consistency of Numbering Across the Two Proposals

The Board also received several comments about inconsistent numbering of items across the FR Y–14 reports between the non-CECL and CECL proposals. Since the Board is adopting both proposals at once, the

[5] *See* 84 FR 11783 (March 28, 2019).

[6] *See* 84 FR 4222 (February 14, 2019).

numbering is consistent in the forms and instructions provided with this notice.

Non-CECL Proposal Comments

General

The Board issues technical instructions so firms know how to configure their systems and files to submit the FR Y–14A and FR Y–14Q. One commenter asked for the Board to provide these technical instructions before year-end 2019 so firms have sufficient time to make any necessary adjustments. The Board seeks to provide firms technical instructions in a timely manner, and seeks to do so with respect to the technical instructions for these reporting changes.

FR Y–14A

Schedule A.1.d (Capital)

The Board proposed to revise the instructions to the FR Y–14A to provide guidance on how firms should reflect the impact of the ''global market shock'' [7] on items subject to adjustment or deduction from capital. Specifically, if a firm were to adjust its projection of an item to reflect the impact of the global market shock, the instructions would indicate that the firm must also report an adjusted starting value that reflects the global market shock for applicable items. One commenter questioned whether this revision conflicts with guidance previously issued through a CCAR frequently asked question (FAQ SHK0030),[8] in which the Board stated that firms should not assume a related decline in portfolio positions or risk-weighted assets as a result of global market shock losses. Another commenter suggested that this treatment is a significant policy question that should be separately clarified by the Board. The Board notes that the proposed revisions reflect a departure from the guidance issued in FAQ SHK0030. In the past, the Board required firms to report capital using post-stress losses, but pre-stress values of certain capital deductions. The Board is now requiring firms to adjust their capital deductions to reflect the impact of the global market shock in order to make their capital calculation further reflect post-stress values.[9] The Board has adopted this revision as proposed. To mitigate confusion, the Board is rescinding FAQ SHK0030, as that historical guidance is inconsistent with the new instructions.

The Board proposed to rename item 109 (Potential net operating loss carrybacks) to ''Taxes previously paid that the bank holding company could recover if the bank holding company's temporary differences (both deductible and taxable) fully reverse at the report date.'' The Board also proposed to revise the instructions for this item to state that firms should report the amount of taxes previously paid that the firm could recover through loss carrybacks if the firm's temporary differences (both deductible and taxable) fully reverse at the report date. The Board proposed these revisions to reflect provisions in the Tax Cuts and Jobs Act (TCJA) that changed the treatment of deferred tax assets (DTAs).[10] One commenter pointed out that the revisions to this item did not include taxes previously paid that the firm could recover through carrybacks of projected negative taxable income (*i.e.,* net operating loss and credits) over the planning horizon. The commenter further noted that, although the TCJA eliminated net operating loss (NOL) carrybacks in the U.S., certain carrybacks are still allowed (*e.g.,* credits and capital losses in U.S., as well as NOL carrybacks in various jurisdictions like the United Kingdom and certain U.S. states). The commenter requested the Board rename item 109 as a result. To better reflect the applicable provisions of the TCJA, the Board is renaming item 109 to ''Taxes previously paid that the bank holding company could recover through allowed carrybacks if the bank holding company's DTAs on net operating loss, tax credits and temporary differences (both deductible and taxable) fully reverse at the report date,'' and is revising the instructions accordingly.

Schedule A.2.a (Retail Balance and Loss Projections)

CECL replaced the concept of purchased credit-impaired (PCI) with that of purchased credit-deteriorated (PCD). As a result, the Board proposed to revise FR Y–14A, Schedule A.2.a, to include PCD breakouts for all mortgage categories. One commenter pointed out that the draft instructions provided with the proposal specify that these new PCD fields only apply to home equity items. Consistent with the language used in the description of the initial proposal, the intent of the proposal was to make these fields applicable to all mortgage line items. The Board is revising the instructions accordingly.

Schedule A.7 (Pre-Provision Net Revenue (PPNR))

The Board proposed eliminating the deposit funding threshold for the FR Y–14A, Schedule A.7.b (Net Interest Income), which is currently optional for firms with deposits comprising less than 25 percent of total liabilities for any period reported in any of the four most recent FR Y–14Q reports. For the reports as of June 30, 2016, the deposit-funding threshold was eliminated from the FR Y–14Q, Schedule G (PPNR). Two commenters said that removing this threshold would impose significant burden on the small subset of firms that are not currently required to report this schedule. The commenters recommended that the Board postpone this revision until December 31, 2020, so that firms that are not currently required to file have ample time to set up and adequately test their reporting systems. Given the time necessary for these firms to set up and adequately test their reporting systems, the Board has adopted the revision and has postponed implementation until December 31, 2020.

The Board proposed adding further specification surrounding the requirements for supporting information provided by U.S. IHCs. Specifically, the proposal would add instructions to the supporting documentation requirements clarifying that IHCs with material transfer pricing or cost allocation items with related entities should report these revenues and expenses in the appropriate business-line category, rather than the ''other'' category. In addition, the proposal would have required U.S. IHCs to provide supporting documentation that disaggregates the impact of transfer pricing and cost allocations on revenue and expense projections to allow the Board to understand the revenue impact of these arrangements.

Two commenters said there would have been insufficient time for IHCs to provide the proposed cost allocation breakout items for September 30, 2019, as these firms are still in the early stages of shared cost structures. Both commenters proposed delaying implementation of these revisions until December 31, 2020. One commenter further requested that the Board provide additional clarification on the proposed change regarding the granularity required for the cost allocation, and that this information not be required for

[7] The global market shock is a set of instantaneous, hypothetical shocks to a large set of risk factors. Generally, these shocks involve large and sudden changes in asset prices, interest rates, and spreads, reflecting general market dislocation and heightened uncertainty. The global market shock impacts the Trading and Counterparty schedules of the FR Y–14A and FR Y–14Q.

[8] *https://www.federalreserve.gov/publications/comprehensive-capital-analysis-and-review-questions-and-anwers.htm.*

[9] *See* 84 FR 6664 (April 1, 2019) for more information on disclosure methodology.

[10] Public Law 115–97, 131 Stat. 2054 (2017).

stressed scenarios as that would require substantial investment in IHCs' models. Given the concerns posed by the commenters, the Board has provided clarification regarding cost allocation in the FR Y–14A instructions, has added this clarifying language to the FR Y–14Q, Schedule G instructions, and has delayed implementation until December 31, 2020. The Board believes this new effective date provides sufficient time for IHCs to gather the necessary information.

The Board proposed to revise several items on the PPNR schedules of the FR Y–14A and FR Y–14Q (Schedule G) to indicate how dividend income on equity products should be reported. The proposed revisions were intended to align with reporting on the FR Y–9C. In doing this, the Board proposed that dividend income on equity products with readily determinable fair values not held for trading be reported as interest income and that dividend income on equity products held for trading be reported as noninterest income. One commenter pointed out that the FR Y–9C is not explicit as to how dividend income on equity products should be reported. The commenter also pointed out that items impacted by these revisions flow through to other PPNR items, specifically those that relate to the earned average rate of trading assets. The Board notes that, under the proposal, the reporting of dividend income on equity products may not be consistent between the FR Y–9C and the FR Y–14, as the FR Y–9C instructions are not explicit as to how this income should be reported. As a result, the Board has revised the language for item 5B (''Other [sales and trading interest income]'') on the FR Y–14A, Schedule A.7.a and FR Y–14Q, Schedule G.1, to include equity trading activity not reported in item 5A (Prime Brokerage [sales and trading noninterest income]), instead of a direct reference to dividend income on equity products with readily determinable fair values not held for trading. The Board has also revised the language for item 18C (''Other [sales and trading noninterest income]'') on Schedules A.7.a and G.1 to remove references to dividend income on equity securities held for trading.

The Board proposed to revise item 15 (''Other Interest/Dividend-Bearing Assets'') on FR Y–14A, Schedule A.7.b and FR Y–14Q, Schedule G.2, to include balances from equity securities with readily determinable fair values not held for trading. One commenter pointed out that this is not consistent with the FR Y–9C, in which equity securities with readily determinable fair values are reported as ''All other debt securities and equity securities with readily determinable fair values not held for trading purposes'' (item 1.c), and not as ''Other earning assets'' (item 4.b), on Schedule K (Quarterly Averages). Given this, the commenter recommended moving balances from equity securities with readily determinable fair values not held for trading from item 15 to item 12 (''Securities AFS and HTM—Other''). The Board notes that item 12 is a more appropriate location for equity securities with readily determinable fair values not held for trading, as they share more risk characteristics with non-equity securities than with other earning assets. As a result, the Board is updating the instructions accordingly.

The Board proposed to revise the PPNR schedules of the FR Y–14A and FR Y–14Q, as well as Schedule A (Retail) of the FR Y–14Q, so that loans (and associated income) in U.S. territories (including Puerto Rico) would be treated as international. The intent of this proposal was to align the reporting of loans in U.S. territories between the FR Y–14 and the FR Y–9C. However, one commenter pointed out that the reporting of these loans is more nuanced on the FR Y–9C, as the treatment can differ within and across schedules, and so the proposed FR Y–14 revisions would still result in inconsistencies between the items on the PPNR schedules and similar items on the FR Y–9C. In response, the Board is revising the proposed instructions to the PPNR schedules to require firms to refer to the FR Y–9C for the definition of domestic and international. This will result in the classification of loans as international or domestic on the FR Y–14 PPNR schedules truly aligning with those of the FR Y–9C.

For the FR Y–14Q, Schedule A (Retail), the Board proposed to remove an exception for loans in U.S. territories from the international loan-reporting requirement. However, in contrast to the PPNR schedules, the existing instructions for Schedule A already directed firms to refer to the FR Y–9C definitions for international and domestic for applicable loan categories. Therefore, the Board has adopted the revisions to the FR Y–14Q, Schedule A (Retail), as proposed, so that the definitions of international and domestic align, without exception, with those on the FR Y–9C.

Schedule E (Operational Risk)

The Board proposed several revisions to Schedule E.2 (Material Risk Identification), one of which was to rename the ''Risk segment'' variable to ''Business line(s)/firm-wide.'' One commenter pointed out that the name ''Risk segment'' provided a clear linkage to FR Y–14A, Schedule A.6 (BHC or IHC Operational Risk Scenario Inputs and Projections), as this schedule also had a variable named ''Risk segment.'' The commenter asked whether the Board still expects this clear linkage despite the name change. The Board notes that the proposed revisions to Schedule E.2 allow for better linkage between the categories of the difference schedules, as firms will now have to identify and list the methodology used to estimate operational risk model. The Board has adopted the revisions as proposed.

FR Y–14Q

Schedule D (Regulatory Capital)

The Board proposed to eliminate most items on Schedule D, as they are duplicative of reporting elsewhere because the common equity tier 1 (CET1) capital deductions are now fully phased-in. One commenter asked for clarification as to whether the proposed changes to Schedule D apply to all firms, or only to non-advanced approaches firms. The Board notes that the changes apply to all firms that file the FR Y–14Q, as there are no exemptions listed in the proposed instructions.

While the Board proposed to eliminate most of the items on Schedule D, it did retain a limited number of items that are not reported elsewhere and proposed to add a handful of items relating to non-significant investments subject to a threshold deduction from CET1 capital. One commenter asked how one of the new items (item 15—''DTAs arising from temporary differences, net of DTLs'') differs from a retained item (item 18—''DTAs arising from temporary differences that could not be realized through net operating loss carrybacks, net of related valuation allowances and net of DTLs''). The difference between these two items is that item 15 is reported before netting of carrybacks and valuation allowance, whereas item 18 is inclusive of valuation allowance and carryback netting. The Board believes this reporting is clear based on the instructions, and has adopted the revisions as proposed.

The Board proposed to add a new memoranda item to Schedule D (item M1—''Taxes paid through the as-of date of the current fiscal year''). The instructions for this item require respondents to report the amount of taxes paid during the current fiscal year through the as-of date that are included in Schedule D, item 17, ''Potential net

operating loss carrybacks,'' assuming that fiscal years align with calendar years. One commenter asked whether the data from this item can be appropriately sourced from FR Y–9C, Schedule HI (Income Statement), item 9 (Applicable income taxes (foreign and domestic)). The Board notes that, based on the instructions for item M1, firms should only report income taxes paid that are included in item 17, which may not equal the income taxes reported in FR Y–9C, Schedule HI, item 9. The Board has adopted the revisions as proposed.

Schedule F (Trading)

The Board proposed to delineate reporting of private equity investments between those reported at fair value and those reported using accounting methods other than fair value (non-fair value). Two commenters asked the Board to clarify whether the intended population of the private equity investments reported at fair value includes investments required to be held at fair value, as well as (1) investments in which FVO accounting treatment has been elected and (2) fund positions measured at net asset value (NAV). In response, the Board notes that the intended population of the private equity investments reported at fair value consists of investments required to be reported at fair value, including investments where fair value is estimated using NAV or where FVO has been elected. The commenters also suggested excluding all non-fair value investments from Schedule F because they believe the macro scenario is more appropriate than the global market shock scenario for capital planning purposes for these positions. The Board notes that private equity is the only asset type where non-fair value exposures are required to be reported on Schedule F. Further, the Board notes that fair value and non-fair value private equity investments have different risk characteristics, and so believes it is essential that these exposures are separately reported. Since the Board now has a breakout between fair value and non-fair value private equity investments, the Board will be able to assess whether the macro scenario is more appropriate than the global market shock for non-fair value exposures. If the macro scenario is more appropriate, then the Board will propose an alternative treatment in a future notice.[11] The Board has adopted the revisions as proposed.

The Board proposed to add a sub-schedule that captures FVO loan hedges. One commenter asked the Board to expand this sub-schedule to include all non-trading hedges, regardless of accounting treatment, as including these hedges would portray a more accurate picture of risk and because it may be difficult for firms to segment hedging activity that is directly correlated to a specific accounting treatment. The Board has been collecting FVO loan hedge information as a supplement to the supervisory stress test for several years, and this proposal was a formalization of this supplemental collection. FVO loan hedge information is critical to adequately assessing the risks posed by FVO loans. Without this information, the Board would have no way to determine whether firms are mitigating FVO loan risks through hedging. The Board has adopted the revisions as proposed, and will consider expanding the sub-schedule in a future proposal. The same commenter asked the Board to clarify whether the as-of date the FVO loan hedges sub-schedule should be at quarter end. Consistent with the instructions published with the initial proposal, the as-of date for the FVO loan hedges sub-schedule is quarter end.

One commenter asked whether the Board could provide examples of what should be included in the FVO loan hedge sub-schedule. The Board is revising the instructions to add a non-exhaustive list of examples of what should be included in this sub-schedule.

The Board proposed to exclude mandated investments, such as those in government or government-sponsored entities and stock exchanges, from Schedule F. One commenter asked the Board to further clarify the definition of mandated investments. The Board believes the proposed definition is sufficient, and therefore has adopted the revisions as proposed. The Board encourages firms to seek guidance from the Federal Reserve if they have specific questions related to bespoke investments.

The Board did not propose to revise the list of examples for what to include the Other Fair Value Assets Sub-schedule that is currently in the instructions. However, due to the placement of the list in the instructions, one commenter asked that the Board clarify whether the list applies only to the Other Fair Value Assets sub-schedule. The Board is revising the instructions to make it clear that this list applies only to the Other Fair Value Assets sub-schedule.

Schedule H (Wholesale)

The Board proposed to add two additional Schedules, H.3 (Line of Business) and H.4 (Internal Risk Rating Scale), which would allow for mapping of each firm's internal risk ratings and line of business values to a consistent benchmark for use in modeling. One commenter suggested the Board expand Schedule H.4 to ask for additional items, such as probability of default information. The commenter also suggested expanding Schedule H.4 to correspond to FR Y–14Q, Schedule L (Counterparty), instead of just Schedule H, as both schedules require an internal and external rating equivalent factor. At this time, the Board does not need any additional fields on these schedules, but will consider expanding Schedule H.4 as part of a future proposal. Additionally, the Board will not expand Schedule H.4 to correspond with the Counterparty schedule at this time, as the data between the two schedules do not readily align.

The Board proposed to revise Schedule H.1 (Corporate Loan Data), item 25 (''Utilized Exposure Global''), and Schedule H.2 (Commercial Real Estate), item 3 (''Outstanding Balance''), to align reporting with the FR Y–9C definition of loan and lease financing receivables. This would cause the exposure amounts reported in Schedule H.1, item 25, and Schedule H.2, item 3, to be netted by deferred fees and costs. One commenter stated that while this would align with the FR Y–9C, firms would need significant time to accurately implement these revisions, and requested the proposal be dropped or delayed. These two fields are critical for modeling, and the Board believes that aligning the definitions between the FR Y–14Q and FR Y–9C will enhance reporting accuracy and improve clarity. The Board also acknowledges that unlike the FR Y–9C, the Wholesale schedule is reported at the facility level, and so firms need time to adequately capture the deferred fees and costs. Therefore, the Board has adopted the revisions as proposed, but is delaying implementation until December 31, 2019, so that these fields can be updated in time for CECL implementation on the FR Y–14Q, as these fields are critical for CECL.

The Board proposed to revise the line of business items (Schedule H.1, item 27; Schedule H.2, item 22) to not require that the line of business be reported at origination, as they typically change over time. One commenter requested the Board expand the description of these items to clarify that the current line of business should be reported. The Board

[11] *See* 84 FR 6664 (February 28, 2019) for more information about the Federal Reserve's model development and validation practices.

believes its proposed revision captures this point because firms will no longer be required to report the line of business at origination, and is more consistent with the existing instructions for other items. The Board has adopted the revision as proposed.

The Board proposed to revise several Schedule H items to align with the definition of loans and lease financing receivables on the FR Y–9C. One commenter noted that the Board should also align the definition of major modification in origination date fields of Schedules H.1 and H.2 (items 18 and 10, respectively), with that of the FR Y–9C. While the Board strives to align reporting definitions when appropriate, the definition of a major modification on Schedule H is much broader than that of the FR Y–9C and is used to assess whether there has been a change in the origination date for all types of loans. The Board does not believe it is appropriate to use the FR Y–9C or GAAP definition of ''modification'' because this definition is mainly associated with troubled debt. The Board has adopted the revision as proposed.

The Board proposed to revise the definition of ''country'' on Schedule H.1 (item 6) to refer to the definition of ''domicile,'' as defined in the FR Y–9C glossary. One commenter suggested the Board also revise Schedule H.1, items 5 (''City'') and 7 (''Zip Code''), to reference the borrower's domicile in assigning the obligor's country in Schedule H.1, (item 6). The Board strives to align the definitions of related items where applicable, and so is revising the instructions accordingly.

The Board proposed to revise the maturity date fields of Schedules H.1 and H.2 (item 19 for both) to eliminate the implied requirement to test compliance with the terms of the credit agreement each quarter. One commenter asked whether this revision means that firms would now have to factor in the extension options that are solely at the discretion of the borrower from inception, or alternatively, whether it means that the extended date is only reported during the extension option window provided that the borrower has requested an extension and an assessment has been made that the conditions outlined in the agreement have been complied with. The Board has adopted the proposed revisions to the maturity date fields, which is inclusive of all extension options that are solely at the borrower's discretion regardless of the timing of the extension option window, including extension options that are conditional on certain terms being met without any need to assess compliance with the terms of the credit agreement.

The Board proposed to add items 65 (''Committed Exposure Global Fair Value'') and 66 (''Outstanding Balance Fair Value'') to Schedule H.2. One commenter questioned whether these two new items were capturing duplicative information, as items 5 (''Committed Exposure Global'') and 3 (''Outstanding Balance''), respectively, seem to capture similar information for held-for-sale and FVO exposures. The Board notes that Schedule H.2, items 5 and 3, represent different concepts from the newly-proposed fair value items 65 and 66. Although there may be cases where values in items 5 and 3 coincide with the values in the newly proposed fair value items (65 and 66, respectively), in other instances the values may differ between these fields (specifically for held-for-sale (HFS) loans reported at lower of cost or fair value, when amortized cost is lower than fair value). The Board has adopted the revisions as proposed.

The Board proposed to add several fields related to committed exposure and utilized exposure global par values, as well as fair values, to Schedules H.1 (items 102 through 105) and H.2 (items 63 through 66). One commenter had several questions about these new items. First, the commenter wanted the Board to clarify whether firms should report their share of the global commitments or the total global commitment of the entire facility. The Board notes that firms are expected to report their pro-rata commitments in the committed exposure fields. The pro-rata share is net of adjustments that are noted in the FR Y–14Q instructions. The ''Committed Exposure Global'' fields should include the total commitment amount, including any unused portfolio of the commitment. Second, the commenter asked how to report these items for facilities that include held-for-sale loans or loans accounted for under a fair value option and held-for-investment loans. The Board notes that for loans reported in Schedule H.1, if the firm reports a value of 3 (''NA'') in the ''Lower of Cost or Market Flag'' (item 86), then it should report ''NA'' for items 102 (''Committed Exposure Global Par Value'') and 103 (''Utilized Exposure Global Par Value''). In cases where there are multiple loans in the same facility, firms should report the consolidated exposure based on the accounting type for loans that make up the predominant share of the facility. Third, the commenter asked whether firms should continue to report commitment balances on a trade date basis. The Board notes that firms should continue to report commitment balances on a trade date basis. The Board has adopted the revision as proposed.

The Board did not propose any changes to the treatment of disposed loans on Schedule H. However, one commenter suggested that the Board revise the instructions to allow disposed facilities to be reported with data as of the prior reporting cycle rather than the day of disposition. The Board believes collecting loan disposition information as it existed at the point of disposition is critical, and so will not revise the current requirements.

Schedule L (Counterparty)

The Board proposed to expand the scope of granularity of a firm's reporting of credit valuation adjustment (CVA) related data fields from the top 95 percent to all counterparties at the legal entity level for several sub-schedules. Four commenters expressed that this change would cause significant burden on firms not only from a data perspective, but also from a technical perspective, as firms' and vendors' systems may not be capable of handling data sets of that size. The Board acknowledges the operational concerns raised by the industry. In doing so, the Board has adopted a modification of the proposed revision that limits the scope of counterparty legal entity identifier (LEI) level reporting requirements in Schedules L.1–L.3 [12] to top 95% stressed CVA, in addition to the existing 95% unstressed CVA. For the remaining counterparties that are not required to be reported at an individual LEI level, a new Schedule will be added to collect summary metrics with respect to their key attributes, for example by industry, rating, and region.

Two commenters requested the Board clarify whether this increased scope applied to all counterparties, or only counterparties with CVA. The Board confirms the scope of the counterparty population under the adopted modification of the proposed revision should apply only to counterparties with CVA.

In addition to the increased scope in CVA related fields, the Board proposed revisions to several definitions throughout Schedule L. Two commenters asked for additional clarification regarding the consistency of the ''Netting Set ID'' field throughout the Schedules, the definition of the ''Trades Not Captured'' field, as well as

[12] Sub-schedules L.1.a through L.1.d.2 capture information regarding derivatives profile by counterparty and aggregate across all counterparties. Sub-schedule L.2 captures expected exposure profile by counterparty and sub-schedule L.3 captures credit quality by counterparty.

whether securities financing transactions (SFTs) should be included with derivatives in the same counterparty data sets. ''Netting Set ID'' and ''Sub-netting Set ID'' are optional fields for certain schedules. To ensure consistency across Schedule L, the Board is revising the instructions to require these field to be reported for all schedules, and is requiring that they be reported using the same granularity across Schedule L. Further, the Board is revising the instructions to indicate that the ''Trades Not Captured'' field should incorporate types of trades or counterparties for which CVA is computed offline (*i.e.,* outside of the main CVA systems). This is effectively equivalent to the scope of counterparties and/or types of trades for which the firm is unable to submit data requirements associated with Schedule L.2 that relate to the components of the CVA. Finally, the Board is revising the instructions to clarify that fair-valued SFTs should be reported in aggregate under Schedule L.1.e.2 (Additional/Offline CVA Reserves), as opposed to at the granular counterparty LEI level reporting under Schedules L.1, L.2, and L.3. In doing so, a new line item will be added to collect fair-valued SFTs separately under Schedule L.1.e.2.

The Board proposed to require firms to report certain counterparties on Schedule L.1.a–L.1.d at a counterparty legal entity level, rather than a consolidated parent level. One commenter recommended that the reporting of sovereign counterparties remain unchanged since the proposed instructions would require incremental data on whether sovereign counterparties are state-owned enterprises, which are backed by the full faith and credit of a sovereign entity, and that data is not readily available. The commenter added that if this change were required, then the Board should clarify the definition of ''full faith and credit of a sovereign entity'' and how to determine that using North American Industry Classification System (NAICS) codes. The commenter further suggested that the Board confirm whether the determination of designated central counterparties (CCPs) not located in the U.S. is consistent with those CCPs identified as Qualifying Central Counterparty (QCCP) under 12 CFR 217. If this is not the intended population, the commenter recommended that the Board specify the supervisory provisions that would constitute an international CCP being regulated and supervised in a manner equivalent to the designated financial market utilities. The Board notes that the proposed change to the instructions on sovereign and designated CCP counterparties is a codification of how the Board requires firms to calculate their largest counterparty as part of the large counterparty default (LCPD) component. However, the Board does acknowledge the benefit of using the definitions of sovereign and CCPs that are consistent with those in the regulatory capital rules. Given this, the Board is revising the definitions of sovereign and CCPs, including the scope of QCCPs vs non-QCCPs, to correspond with the definitions in section .2 of the regulatory capital rules (12 CFR 217), as recommended by the commenter. As a result of the Board revising the instructions to use the definition of sovereign in regulatory capital rules and the delaying of the effective date until June 30, 2020, the Board believes the concerns raised by the commenter have been mitigated.

The Board proposed to revise Schedule L.1.a (Individual Counterparties—Credit Valuation Adjustment (CVA)) to clarify that individual counterparties should be captured at the legal entity level, rather than at the aggregated parent or consolidated level. Two commenters asked the Board to clarify how this change impacts Schedule L.1.e (Aggregate CVA Data by Ratings and Collateralization) and Schedule L.4 (Aggregate and Top 10 CVA Sensitivities by Risk Factor). The Board is revising the instructions to show that Schedule L.1.e should be reported based on the immediate counterparty LEI facing the firm and that Schedule L.4 should continue to be reported at the aggregated parent or consolidated counterparty level.

The Board received a comment recommending that language be added to the Schedule L instructions specifying how the schedule should relate to data reported in FR Y–14A, Schedule A.5 (Counterparty Credit Risk). The Board strives to align or otherwise connect related data fields, where applicable, and is including language in the technical instructions to clarify how the data should reconcile between these two schedules with regards to both CVA and LCPD.

FR Y–14M

Schedule A (Domestic First Lien Closed-End 1–4 Family Residential Loan) and Schedule B (Domestic Home Equity Loan and Home Equity Line)

The Board proposed to revise Schedules A and B to indicate that in cases of involuntary terminations, loans should be reported for up to 24 months following termination until data in the four loss severity fields are available to report. The Board notes that this change should apply to loans that have experienced an involuntary termination within the past 12 months of the date of the revised instructions and for which the four loss severity fields are available. One commenter asked whether this revision should only be applied to accounts where the event (*i.e.,* charge-off and involuntary termination) occurred in the first month after the revision became effective, and which accounts should now be included in these schedules. The Board clarifies that the reporting of accounts where the event occurred 12 months prior to the date of the revised instruction is not changing, and firms are not required to include accounts where the event occurred 24 months prior to the date of the revised instructions.

The Board received two other comments on its proposal regarding reporting cases of involuntary terminations on Schedule A and B. The first comment states that this proposal will create additional operational burden, specifically as it relates to loans serviced by others. Per the comment, loan servicers are responsible for tracking non-performing loans/lines, regardless of lien position, through the full loss mitigation process. When a loan/line is involuntary liquidated, the servicer is responsible for recording all of the loss severity information and passing that information to the bank that owns the loan/line. When this happens, the owning bank removes the liquidated loan/line from its system. The commenter points out that this revision should only be applied prospectively (*i.e.,* for accounts with involuntary terminations from the date of the revised instructions forward). The second comment asks that certain commercial and serviced loans be exempt from this treatment, and asks to confirm whether all fields on Schedules A and B need to be filled out for these loans/lines, or whether only the loss severity fields need to be filled out.

The Board notes that only a portion of recoveries are realized within the first 12 months after charge-off, and so moving to a 24 month window would portray a more complete picture of applicable recoveries. The Board further notes that in the case of involuntary terminations, loans should be reported for up to 24 months following termination, until the data on specified fields (items 93 (''Total Debt at Time of any Involuntary Termination''), 94 (''Net Recovery Amount''), 95 (''Credit Enhanced Amount''), and 121 (''Sales Price of Property'')) are available to

report. If the data are available sooner, the firm does not have to continue reporting these loans in the following months. Moreover, these fields should only be reported for any portfolio or private securitized loans that experienced involuntary terminations. Per the proposal, the Board will require firms to carry involuntary liquidated loans/lines up to 24 months to fully populate all fields up until all the fields are captured or 24 months. A firm does not need to change its reporting conventions for loans before and after the involuntary liquidations. The Board has adopted the revision as proposed.

The Board proposed to revise item 65 (''Foreclosures Status'') of Schedule A to clarify that in the month a loan liquidates, a firm should report the loan as a post-sale foreclosure. One commenter noted that a loan could have moved from a post-sale foreclosure to real estate owned in the month a loan liquidates, and suggested the Board clarify in the instructions that item 65 should be reported as of the month end in the month the loan liquidates. The Board notes that the instructions for this item already require reporting as of the end of the reporting month. However, for clarification purposes, the Board is revising the instructions to indicate that if a loan was in foreclosure in the prior month, and the loan liquidates during the current month, then it should be reported as a post-sale foreclosure.

The Board proposed to revise Schedule A, item 59, and Schedule B, item 43 (both ''Principal and Interest (P&I) Amount Current''), to clarify that firms should report the principal and interest due from the borrower in the reporting month, even in cases of balloon loans that mature in the reporting month. One commenter pointed out that this clarification contradicts other parts of these items instructions, which state that a loan in the process of paying off in a reporting month can be reported with a value of zero. As a result, the Board is revising the instructions for these two items to state that for balloon loans in the process of paying off in a reporting month, firms should report the full amount due.

The Board proposed to add two new items to Schedule B (items 118 (''Charge-off Amount'') and 119 (''Charge-off Date'')). A commenter asked whether similar fields should have been added to Schedule A. The Board did not propose to add these fields to Schedule A, as it does not need this information for that loan population.

Schedule D (Domestic Credit Card)

The Board proposed to revise the instructions for Schedule D to state if an account at the time of closure or charge-off had a positive unpaid balance that needed to be repaid or recovered, then information on that account should be reported up to 24 months after the closure or charge-off. Previously, information on that account would have only been reported up to 12 months after the closure or charge-off. A commenter noted that this requirement should only be applied prospectively due to the burden of retrieving data from the past 24 months. The Board notes that only a portion of recoveries are realized within the first 12 months after charge-off, and so moving to a 24 month window would portray a more complete picture of applicable recoveries. The Board notes that this reporting change should only apply to loans that have experienced a charge-off or termination event within the past 12 months of the date of the revised instructions. The Board has adopted this revision as proposed.

The same commenter asked the Board to clarify when closed accounts should be excluded in cases when they have a zero balances at closure and in cases where they do not. The Board clarifies that charge-off and non-charge off accounts should be have a zero balance reported in the month they close, and should be excluded in the month after they close. Accounts that have a balance greater than zero when closed should be reported up to 24 months after they close.

The Board proposed to update the instructions for items 17 (''Managed Recoveries'') and 18 (''Booked Recoveries'') on Schedule D to clarify that all gross charge-offs, including those related to acquired impaired loans, should be included. One commenter asked why charge-offs should be included in amounts related to recoveries. The Board is revising the instructions to make it clear that these items should be capturing the recovery of the charged-off amount for acquired impaired loans.

The Board proposed to add a clause to the instructions for item 68 (''Account Sold Flag'') on Schedule D to indicate that firms must start to report this item from the sale announcement date. The instructions were previously ambiguous as to when to begin to report this item. One commenter asked how this item should be reported if the sale has been announced but the accounts in the portfolio to be sold have not yet been finalized. The commenter asked the Board to allow for firms to not report this item if the information needed to report is not available as of the sale announcement date. The Board needs the information reported in this item as soon as it is available in order to adequately assess the risk effects of portfolios that are in the process of being sold, and so has adopted the revision as proposed.

One commenter requested revising the FR Y–14M to be reported quarterly instead of monthly, citing reporting burden of monthly filing as a rationale. Monthly data collection allows the Board's financial models to be sensitive to high-frequency changes in risk drivers, and so the Board will continue to require monthly data.

The Board did not propose revising how retired fields on the FR Y–14M should be reported. However, a commenter requested the Board confirm whether retired fields should be removed from the report or remain in the schedules but reported with null values. The Board confirms that due to previously received industry feedback regarding the burden of renumbering items, retired fields should continue to reported and reported with null values.

CECL Proposal Comments

General

The Board proposed to add items and update references to the FR Y–14 reports to incorporate CECL. One commenter expressed concern that firms would be required to produce additional information in order to demonstrate how their projections incorporating CECL differ from what the projections would have been under the incurred-loss methodology, even if the firms intend to retire their incurred-loss models upon adoption of CECL and do not intend to maintain parallel processes. The commenter referenced CCAR FAQ GEN0207,[13] in which the Board stated that firms should prepare to submit documentation on the methodology used to produce the capital plan submission in accordance with the capital plan rule. CCAR FAQ GEN0207 further stated that examiners may request any additional documentation necessary to understand and support the firm's estimated stressed capital insomuch as the firm relied upon that information to create and approve that plan. Per the response to CCAR FAQ GEN0207, firms are not required to maintain parallel methodologies (*i.e.,* CECL and incurred-loss). Firms only need to provide documentation on the methodology

[13] *https://www.federalreserve.gov/publications/comprehensive-capital-analysis-and-review-questions-and-anwers.htm.*

used in their projections and capital plans.

The Board received a comment regarding whether the effective dates for CECL filers will be revised based on FASB's recent proposal to delay CECL effective dates for certain institutions (FASB approved this proposal on October 17, 2019).[14] The Board had initially proposed to remove incurred-loss model items and references from the FR Y–14 reports by March 31, 2022, at the latest, as that was the anticipated time by which all filers would have adopted CECL. However, given this extension, the Board is delaying the removal of these items until March 31, 2023.

The Board received a comment asking how the implementation of CECL would impact the disclosure of DFAST/CCAR results. The commenter points out that the fundamental inconsistencies between how the Board and participating firms will calculate credit loss allowances over the projection horizon will present challenges in comparing the risk profiles and capital planning capabilities of firms. Further, per the comment, stakeholders may have difficulty evaluating and understanding firms' stress-test disclosures, as well as the DFAST and CCAR results, because of the different methodologies used among firms and by the Board. To avoid potential confusion for stakeholders, the commenter recommends that the Board explain in its DFAST and CCAR results publications that its projections for the supervisory severely adverse scenario are not comparable to firms' projections for the same scenario because of the fundamentally different methodologies used by the Board and firms to project credit loss allowances, and that firms' own projections may not be comparable to one another's because of differences in how they incorporated CECL into their projection methodologies. Finally, the commenter recommends that to further promote clear communication to stakeholders and stakeholders' understanding of the stress test results, the Board should provide a template disclosure that firms could include in their own DFAST disclosures explaining that their projections may not be comparable to those of other firms, and are not comparable to those of the Board because of methodological differences relating to the projections of credit loss allowances. In response, the Board understands the concerns posed by the commenter, and will consider this comment as part of its results disclosure process.

FR Y–14A

General

In the initial proposal, the Board mentioned that it would update applicable reporting instructions to account for the exclusion of unconditionally cancelable commitments from the allowance for credit losses off-balance sheet exposures. One commenter pointed out that the Board did not make any such revisions. The Board notes that the reference to updating applicable instructions should not have been made in the initial proposal because the only instructions that mention unconditionally cancelable commitments refer to the definition on the FR Y–9C, and so no additional updates were necessary.

Schedule A.1.a (Income Statement)

The Board proposed to add items that capture the provisions, net charge-offs, and allowances for held-to-maturity (HTM) and available-for-sale (AFS) debt securities to Schedule A.1.a. However, the Board did not add items that capture these fields for all other financial assets that fall within the scope of CECL, such as securities purchased under agreements to resell and other assets. One commenter pointed out that without adding these items, net income as reported on Schedule A.1.a would not be accurate. The Board notes that under the proposed instructions, net income would not reconcile across the FR Y–14 and FR Y–9C reports, and is revising the form and instructions to add applicable items to capture all other financial assets that fall within the scope of CECL.

Schedule A.1.b (Balance Sheet)

The Board proposed to revise the instructions for ''Other assets'' (item 129) to change the FR Y–9C items referenced in the definition. Specifically, the Board proposed to remove references to FR Y–9C, Schedule HC (Balance Sheet), items 8 (''Investments in unconsolidated subsidiaries and associated companies'') and 9 (''Direct and indirect investments in real estate ventures''). One commenter noted that if the references to items 8 and 9 were removed, then the total assets balances would not reconcile between the FR Y–14A and FR Y–9C. The Board notes the total balances would not reconcile under the proposed revision, and is revising the instructions to add back these references.

Schedule A.1.d (Capital)

The Board proposed several revisions to Schedule A.1.d to mirror those made to FR Y–9C, Schedule HC–R (Regulatory Capital), Part I (Regulatory Capital Components and Ratios), to incorporate the adoption of CECL. One commenter pointed out that in the proposed revisions for item 54 (''Allowance for loan and lease losses includable in tier 2 capital''), the Board did not properly mirror the revisions to the equivalent item on the FR Y–9C, Schedule HC–R, Part I (item 30.a), in that it did not add a clause to the instructions for item 54 specifying that firms should only include the portion of allowance for loan and lease losses (ALLL) or adjusted allowances for credit losses (AACL) that is includable in tier 2 capital, per the regulatory capital rule. The Board notes that this clause should be added to the instructions, as only the ALLL or AACL that is included in tier 2 capital should be included in item 54, and is revising the instructions for item 54 to use language in the equivalent FR Y–9C item.

The Board did not propose to revise the instructions for item 96 (''Supplementary leverage ratio exposure'') to state that firms that have adopted ASU 2016–13 and have elected to apply the transition provision should incorporate the effects of this transition. One commenter pointed out that per the regulatory capital rules, the transitional amount should also be applied to the supplementary leverage ratio, and suggested the Board revise the instructions for item 96 to indicate so. The Board confirms that the transitional amount should be applied to the supplementary leverage ratio. However, the current instructions for item 96 directly reference the regulatory capital rules, which describe the items to which the transitional amount applies. Given this, the Board does not believe any further clarification is necessary.

The Board did not propose to add an item to separately capture the AACL on PCD assets on the FR Y–14. One commenter asked the Board to confirm it will not ask firms to provide this information through a supplemental request. The Board does not intend to add an item to separately capture this value on the FR Y–14.

Schedules A.3.f and A.3.g (Expected Credit Loss and Provision for Credit Loss—HTM and AFS Securities, Respectively)

The Board proposed to add Schedules A.3.f and A.3.g to capture allowance for credit loss information on HTM and AFS securities. One commenter asked

[14] *https://www.fasb.org/jsp/FASB/Document_C/DocumentPage?cid=117617376157&acceptedDisclaimer=true.*

whether the ''Total allowance for credit loss'' items on both schedules should be reported as of the prior quarter, the current quarter, or a projected quarter. The Board is revising the instructions to clarify that these items should be reported as of the report date (*i.e.,* current quarter).

One commenter requested that the Board specify what the ''Expected loss'' item in both schedules consists of, whether it corresponds to any FR Y–9C item, and how it differs from the ''Provision for credit loss'' item that is also on both schedules. The ''Expected loss'' item is the expected credit losses as defined by ASU 2016–13 and before applying the ''fair value floor'' that limits the amount of the allowance for credit losses to the amount by which fair value is below amortized cost. This item should equal FR Y–9C, Schedule HI–B (Charge-offs and Recoveries on Loans and Leases and Changes in Allowances for Credit Losses), Part 2 (Change in Allowances for Credit Losses), item 5 (''Provision for credit losses''). To avoid confusion, the Board is renaming the ''Expected loss'' item to ''Expected credit loss before applying the fair value floor,'' and is revising the instructions to indicate this as well. Also in response to this comment, the Board is removing the ''Amortized cost of securities intended to sell or will be required to sell before recovery of amortized cost'' item from Schedule A.3.g, as it is no longer necessary.

Finally, one commenter asked the Board to confirm that the sum of provision for credit loss items reported on Schedules A.3.f and A.3.g should equal proposed items 91.b (''Provisions for credit losses on held-to-maturity debt securities during the quarter'') and 91.c (''Provisions for credit losses on available-for-sale securities during the quarter'') on Schedule A.1.a, respectively. The Board confirms these values should be equal.

Collection of Supplemental CECL Information

The Board proposed to add a collection of supplemental CECL information to be reported by institutions that adopt ASU 2016–13 that captures the timing and impact of CECL adoption as of December 31. This collection would require firms to report actual values (*i.e.,* not projected) that incorporate the adoption of CECL on the FR Y–14A, in the stress test cycle year of adoption. One commenter notes that the collection of supplemental CECL information would not require reporting of information on the stressed impact of CECL on either existing portfolios or on newly originated exposures during the stress test horizon. The commenter is also concerned that this proposed collection would not provide the Board with the insight it is seeking into the stressed impacts of CECL since these potential losses are important components of overall CECL estimates. The commenter further suggested that the Board provide a description of the relationship between each item on Collection of Supplemental CECL information and items on the FR Y–14A, Summary sub-schedules. Finally, the commenter pointed out that the instructions for item 6 (''Total allowance for credit losses'') refer to sub-items 5.a and 5.b, which do not exist.

The Board notes that it intends to collect information of the day 1 unstressed impact; that is, the effect of the change in accounting principles on the effective date of CECL (*i.e.,* not the impact over the entire projection horizon). The Board also notes that because this collection is a pro-forma estimate of the effect of the change in accounting principles, there is no relationship between items on this schedule and other FR Y–14A items corresponding to prior quarter end financial statement data. The Board believes that it will have sufficient data under the collection to reflect the impact of stress losses under CECL accounting. Therefore, the Board has adopted this revision as proposed, except that it is revising the heading on the form to make it clear that the Board is asking for the effect of changes in accounting principles, and it is revising the instructions for item 6 to refer to the sub-items of item 6. For clarification purposes, the Board is also updating the FR Y–14A instructions to include language about when this schedule should be filed and which items need to be reported for certain firms.

FR Y–14Q

Schedule B (Securities)

The Board proposed to add two items to Schedule B that would only be completed by firms that have adopted CECL (''Amount of allowance for credit losses'' and ''Writeoffs''). One commenter asked whether the Board will specify that reporting debt securities on a trade-lot level will continue to apply to firms that have adopted CECL if they calculate their credit loss allowances for AFS debt securities on security-level basis or for HTM debt securities on either a security-level or pool-level basis. The Board is revising the instructions for these two items to instruct firms that if a given allowance measurement or specific writeoff applies to more than one row on the reporting form, to allocate the allowances across the relevant investments on a pro rata basis, based on amortized cost.

The Board proposed instructions for ''Writeoffs'' to require firms to report any writeoffs of the security during the quarter. One commenter asked the Board to clarify whether that means on a quarter-to-date, year-to-date, or lifetime-to-date basis. The Board is revising the instructions to clarify that this item should be reported on a quarter-to-date basis.

Schedule D (Regulatory Capital)

The Board proposed minor revisions to Schedule D in the CECL proposal, but substantial revisions to the schedule in the non-CECL proposal. Two firms commented as to how to reconcile revisions in the event that certain text and items were eliminated in one proposal but not the other. Since the Board has adopted both proposals at the same time, the combined instructions document should clear up any ambiguity. Further, the Board clarifies that Schedule D should be reported by all firms that file the FR Y–14Q, and not just advanced approaches firms.

Schedule H (Wholesale)

The Board proposed to revise the instructions to Schedule H.1, item 24 (''Committed Exposure Global'') to require firms to report the total commitment amount as the sum of loan and lease financing receivables recorded in FR Y–9C, Schedule HC–C (reported in field 25—''Utilized Exposure Global'') and any unused portion of the commitment recorded in Schedules HC–F (Other Assets), HC–G (Other Liabilities), and HC–L (Derivatives and Off-Balance Sheet Items). One commenter said that this revision made it unclear what to report in this item, and recommended the Board clarify the types of unused loan commitments that should be reported instead of referencing other FR Y–14Q or FR Y–9C items. The Board does not believe further clarification is necessary for two reasons. First, the Schedule H instructions already define the reportable facilities. Second, the Board believes it is better to leverage existing instructions within or across reports in order to reduce burden and improve data accuracy. The Board has adopted the revision as proposed.

The Board proposed to add additional items to Schedules H.1 and H.2 that are only reported by firms that have adopted CECL. Two of these items, ''ASC326–20'' and ''Purchased Credit Deteriorated Noncredit Discount'' (Schedule H.1—items 102 and 103;

Schedule H.2—items 63 and 64, respectively), require firms to report the information at the credit facility level, if available, or if not, at a pro-rated allocation from the collective (pool) basis. One commenter stated it was unclear which basis should be used for the proposed allocation. Further, the commenter is concerned that without a prescribed allocation methodology, methods could vary broadly across firms. Per the comment, this inconsistency would weaken comparability and reduce the value of this schedule. Finally, the commenter requested the Board remove the requirements proposed in these two items, and instead prescribe a clear allocation methodology. The Board believes that the reporting firm is in the best position to determine the appropriate allocation methodology, and does not want to impose additional burden by prescribing a single allocation methodology. The Board has adopted the revision as proposed.

FR Y–14M

Generally, institutions subject to filing the FR Y–14 reports would reflect the CECL standard in data reported on the FR Y–14A, FR Y–14Q, and FR Y–14M, with as-of dates following the start of the firm's fiscal year and the adoption of the standard, beginning with the FR Y–14 reports as of December 31, 2019. In the initial proposal, the Board instructed firms to refer the final CECL rule for specifics surrounding inclusion of credit losses in a given stress test cycle. One commenter asked if a firm that adopts CECL January 1, 2020, could report CECL-related FR Y–14M items on a best effort basis for its January and February 2020 FR Y–14M submissions. The rationale for this request is that a firm will be required to file other regulatory reports reflecting CECL for the first time as of March 31, 2020 (FR Y–9C, FR Y–14Q, Securities and Exchange Commission (SEC) reports, etc.). In light of the concerns posed in this comment, the Board is allowing CECL-related FR Y–14M items to be reported on a best effort basis for the January and February 2020 submissions.

Board of Governors of the Federal Reserve System, December 18, 2019.

Michele Taylor Fennell,

Assistant Secretary of the Board.

[FR Doc. 2019–27655 Filed 12–20–19; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Agency Information Collection Activities: Announcement of Board Approval Under Delegated Authority and Submission to OMB

AGENCY: Board of Governors of the Federal Reserve System.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) is adopting a proposal to extend without revision, the Notice of Branch Closure (FR 4031; OMB No. 7100–0264).

FOR FURTHER INFORMATION CONTACT:

Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551, (202) 452–3829.

Office of Management and Budget (OMB) Desk Officer—Shagufta Ahmed—Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395–6974.

A copy of the Paperwork Reduction Act (PRA) OMB submission, including the reporting form and instructions, supporting statement, and other documentation will be placed into OMB's public docket files. These documents also are available on the Federal Reserve Board's public website at *https://www.federalreserve.gov/apps/reportforms/review.aspx* or may be requested from the agency clearance officer, whose name appears above.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the PRA to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. Copies of the PRA Submission, supporting statements, and approved collection of information instrument(s) are placed into OMB's public docket files.

Final Approval Under OMB Delegated Authority of the Extension for Three Years, Without Revision, of the Following Information Collection:

Report title: Notice of Branch Closure.

Agency form number: FR 4031.

OMB control number: 7100–0264.

Frequency: On occasion.

Respondents: State member banks (SMBs).

Estimated number of respondents: Reporting: Regulatory notice, 91; Disclosure: Customer mailing, 91 and posted notice, 91; Recordkeeping: Adoption of policy, 1.

Estimated average hours per response: Reporting: Regulatory notice, 2 hours; Disclosure: Customer mailing, 0.75 hour and posted notice, 0.25 hour; Recordkeeping: Adoption of policy, 8 hours.

Estimated annual burden hours: Reporting: Regulatory notice, 182 hours; Disclosure: Customer mailing, 68 hours and posted notice, 23 hours; and Recordkeeping: Adoption of policy, 8 hours.

General description of report: The reporting, recordkeeping, and disclosure requirements regarding the closing of any branch of an insured depository institution are contained in section 42 of the Federal Deposit Insurance Act (FDI Act), as supplemented by an interagency policy statement on branch closings. There is no reporting form associated with the reporting portion of this information collection; SMBs notify their appropriate Reserve Bank by letter prior to closing a branch.

Legal authorization and confidentiality: The FR 4031 is authorized pursuant to Section 42(a)(1) of the FDI Act and section 11 of the Federal Reserve Act, which authorizes the Board to require SMBs to submit information as the Board deems necessary.[1] The reporting requirements associated with FR 4031 are mandatory. Generally, individual respondent data submitted pursuant to the FR 4031 is not considered to be confidential; however, a SMB may request confidential treatment pursuant to exemption 4 of the Freedom of Information Act, which protects trade secrets and privileged or confidential commercial or financial information.[2]

Current actions: On September 10, 2019, the Board published a notice in the **Federal Register** (84 FR 47516) requesting public comment for 60 days on the extension, without revision, of the FR 4031. The comment period for this notice expired on September 12, 2019. The Board did not receive any comments.

Board of Governors of the Federal Reserve System, December 17, 2019.

Michele Taylor Fennell,

Assistant Secretary of the Board.

[FR Doc. 2019–27601 Filed 12–20–19; 8:45 am]

BILLING CODE 6210–01–P

[1] 12 U.S.C. 1831r–1(a)(1); 12 U.S.C. 248(a).

[2] 5 U.S.C. 552(b)(4).

FEDERAL RESERVE SYSTEM

Agency Information Collection Activities: Announcement of Board Approval Under Delegated Authority and Submission to OMB

AGENCY: Board of Governors of the Federal Reserve System.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) is adopting a proposal to extend for three years, with revision, the Notice of Mutual Holding Company Reorganization (FR MM–10(*o*)–1), Application for Approval of a Stock Issuance by a Subsidiary Holding Company of a Mutual Holding Company (FR MM–10(*o*)–2), Application for Conversion of a Mutual Holding Company to Stock Form (FR MM–AC), Proxy Statement (FR MM–PS), Offering Circular (FR MM–OC), and Order Form (FR MM–OF) (OMB No. 7100–0340). The revisions are applicable as of January 1, 2020.

FOR FURTHER INFORMATION CONTACT:

Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551, (202) 452–3829.

Office of Management and Budget (OMB) Desk Officer—Shagufta Ahmed—Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395–6974.

A copy of the Paperwork Reduction Act (PRA) OMB submission, including the reporting form and instructions, supporting statement, and other documentation will be placed into OMB's public docket files. These documents also are available on the Federal Reserve Board's public website at *https://www.federalreserve.gov/apps/reportforms/review.aspx* or may be requested from the agency clearance officer, whose name appears above.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the PRA to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. Copies of the PRA Submission, supporting statements, and approved collection of information instrument(s) are placed into OMB's public docket files.

Final Approval Under OMB Delegated Authority of the Extension for Three Years, With Revision, of the Following Information Collection

Report title: Notice of Mutual Holding Company Reorganization, Application for Approval of a Stock Issuance by a Subsidiary Holding Company of a Mutual Holding Company, Application for Conversion of a Mutual Holding Company to Stock Form, Proxy Statement, Offering Circular, and Order Form.

Agency form number: FR MM–10(*o*)–1, FR MM–10(*o*)–2, FR MM–AC, FR MM–PS, FR MM–OC, and FR MM–OF.

OMB control number: 7100–0340.

Effective date: January 1, 2020.

Frequency: On occasion.

Respondents: Savings associations that wish to reorganize to form a mutual holding company under the Home Owners' Loan Act (HOLA), subsidiary holding companies of a mutual holding company, mutual holding companies, and members of applying mutual organizations.

Estimated number of respondents: FR MM–10(o)–1: 4; FR MM–10(o)–2: 1; FR MM–AC: 2; FR MM–PS: 1; FR MM–OC: 1; and FR MM–OF: 1.

Estimated average hours per response: FR MM–10(o)–1: 60; FR MM–10(o)–2: 30; FR MM–AC: 60; FR MM–PS: 50; FR MM–OC: 50; and FR MM–OF: 1.

Estimated annual burden hours: FR MM–10(o)–1: 240; FR MM–10(o)–2: 30; FR MM–AC: 120; FR MM–PS: 50; FR MM–OC: 50; and FR MM–OF: 1.

General description of report: The Mutual Holding Company (MHC) Forms consist of information that must be filed in connection with certain proposals involving savings and loan holding companies (SLHCs) that are organized in mutual form (MHCs), including the reorganization of a savings association into MHC form, stock issuances of holding company subsidiaries of MHCs, and conversions of MHCs to stock form. The Board requires the submission of these filings to allow the Board to fulfill its obligations to review such transactions under section 10(*o*) of the HOLA, as amended,(12 U.S.C. 1467a(*o*)), and the Board's Regulation MM (12 CFR part 239). The Board uses the information submitted by an applicant or notificant to evaluate these transactions with respect to the relevant statutory and regulatory factors.

Legal authorization and confidentiality: The MHC Forms are authorized pursuant to section 10(o) of the HOLA, as amended, (12 U.S.C. 1467a(o)). That section requires the Board to review transactions involving the reorganization of a savings association into MHC form, stock issuances of holding company subsidiaries of MHCs, and conversions of MHCs to stock form. The Board also has the authority to require reports from SLHCs under Section 10(a) and (b) of the HOLA (12 U.S.C. 1467a(b) and (g)). The MHC Forms are mandatory.

Individual respondents may request that certain information submitted on the MHC Forms be kept confidential on a case-by-case basis. If a respondent requests confidential treatment, the Board will determine whether the information is entitled to confidential treatment on an ad hoc basis. Requests may include information related to the SLHC's business operations, such as terms and sources of the funding for dividends and pro forma balance sheets. This information may be kept confidential under exemption 4 of the Freedom of Information Act, which protects privileged or confidential commercial or financial information (5 U.S.C. 552(b)(4)).

Current actions: On August 12, 2019, the Board published an initial notice in the **Federal Register** (84 FR 39841) requesting public comment for 60 days on the extension, with revision, of the MHC Forms. The Board proposed numerous revisions to the MHC Forms, which were originally drafted by the Office of Thrift Supervision (OTS) when it supervised MHCs. Since supervisory functions of the OTS relating to SLHCs and MHCs were transferred to the Board, many of the changes modify the MHC Forms to make the forms consistent with the format of other Board forms. Additionally, the proposal includes revisions meant to (1) reduce the amount and types of data requested, (2) incorporate information on the Board's policies and procedures for processing applications, (3) improve the clarity of the information requests, (4) reflect the impact of new laws, regulations, capital requirements, and accounting rules, (5) delete unnecessary information requests, and (6) improve or update grammar, comprehension, citations, and mailing addresses. The revisions are also intended to ensure that initial filings include the information the Board requires to evaluate a transaction and thereby reduce the need for subsequent information requests. The comment period for this notice expired on October 11, 2019. The Board did not receive any comments. The revisions will be implemented as proposed.

Board of Governors of the Federal Reserve System, December 17, 2019.

Michele Taylor Fennell,

Assistant Secretary of the Board.

[FR Doc. 2019–27597 Filed 12–20–19; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Agency Information Collection Activities: Announcement of Board Approval Under Delegated Authority and Submission to OMB

AGENCY: Board of Governors of the Federal Reserve System.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) is adopting a proposal to extend for three years, without revision, the Transfer Agent Registration and Amendment Form (Form TA–1; OMB No. 7100–0099).

FOR FURTHER INFORMATION CONTACT:

Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551, (202) 452–3829.

Office of Management and Budget (OMB) Desk Officer—Shagufta Ahmed—Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395–6974.

A copy of the Paperwork Reduction Act (PRA) OMB submission, including the reporting form and instructions, supporting statement, and other documentation will be placed into OMB's public docket files. These documents also are available on the Federal Reserve Board's public website at *https://www.federalreserve.gov/apps/reportforms/review.aspx* or may be requested from the agency clearance officer, whose name appears above.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the PRA to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. Copies of the PRA Submission, supporting statements, and approved collection of information instrument(s) are placed into OMB's public docket files.

Final Approval Under OMB Delegated Authority of the Extension for Three Years, Without Revision, of the Following Information Collection

Report title: Transfer Agent Registration and Amendment Form.

Agency form number: Form TA–1.

OMB control number: 7100–0099.

Frequency: On occasion.

Respondents: State member banks (SMBs) and subsidiaries thereof, bank holding companies (BHCs) and covered subsidiaries thereof, and savings and loan holding companies (SLHCs).

Estimated number of respondents: Registrations, 1; amendments, 2; de-registrations, 1.

Estimated average time per response: Registrations, 1.25 hours; amendments, 10 minutes (0.16 hours); de-registrations 30 minutes (0.5 hours).

Estimated annual burden hours: Registrations, 1.25 hours; amendments, 0.33 hours; de-registrations, 0.5 hours.

General description of report: The Securities Exchange Act of 1934 (Exchange Act) requires any person acting as a transfer agent [1] to register as such with the appropriate regulatory agency (ARA). The Board is the ARA for the respondents listed above. Transfer agents for which the Board is the ARA must register with the Board using Form TA–1.

Legal authorization and confidentiality: Section 17A(c) of the Exchange Act [2] requires all transfer agents for securities registered under section 12 of the Exchange Act to register ''by filing with the appropriate regulatory agency . . . an application for registration in such form and containing such information and documents . . . as such appropriate regulatory agency may prescribe as necessary or appropriate in furtherance of the purposes of this section.'' [3] Under section 3(a)(34)(B)(ii) of the Exchange Act,[4] the Board is the appropriate regulatory agency with respect to any transfer agent that is a state member bank or a subsidiary thereof, a BHC or a covered subsidiary thereof, or a SLHC (together, ''Board-Registered Transfer Agents''). In addition, the Form TA–1 is authorized pursuant to sections 2, 17(a)(3), and 23(a) of the Exchange Act,[5] which, among other things, authorize the Board to promulgate regulations and establish recordkeeping and reporting requirements with respect to Board-Registered Transfer Agents. Additionally, the Board also has broad authority to require reports from BHCs, SLHCs, and SMBs.[6]

The Form TA–1 is mandatory. The information collected in the Form TA–1 is available to the public upon request and is not considered confidential.

Current actions: On September 10, 2019, the Board published an initial notice in the **Federal Register** (84 FR 47512) requesting public comment for 60 days on the extension, without revision, of the Form TA–1. The comment period for this notice expired on November 12, 2019. The Board did not receive any comments.

Board of Governors of the Federal Reserve System, December 17, 2019.

Michele Taylor Fennell,

Assistant Secretary of the Board.

[FR Doc. 2019–27598 Filed 12–20–19; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Agency Information Collection Activities: Announcement of Board Approval Under Delegated Authority and Submission to OMB

AGENCY: Board of Governors of the Federal Reserve System.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) is adopting a proposal to extend for three years, with revision, the Notice by Financial Institutions of Government Securities Broker or Government Securities Dealer Activities and the Notice by Financial Institutions of Termination of Activities as a Government Securities Broker or Government Securities Dealer (Form G–FIN and Form G–FINW; OMB No. 7100–0224). The revisions are effective immediately.

FOR FURTHER INFORMATION CONTACT:

Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551, (202) 452–3829.

Office of Management and Budget (OMB) Desk Officer—Shagufta Ahmed—Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395–6974.

[1] Transfer agents are institutions that provide securities transfer, registration, monitoring, and other specified services on behalf of securities issuers. *See* 15 U.S.C. 78c(25) (defining ''transfer agent'').

[2] 15 U.S.C. 78q–1(c).

[3] *See* 15 U.S.C. 78q–1(c)(1).

[4] 15 U.S.C. 78c(a)(34)(B)(ii).

[5] 15 U.S.C. 78b, 78q(a)(3), and 78w(a).

[6] *See* 12 U.S.C. 1844(c), 12 U.S.C. 1467a(b) and (g), and 12 U.S.C. 248(a) and 324.

A copy of the Paperwork Reduction Act (PRA) OMB submission, including the reporting form and instructions, supporting statement, and other documentation will be placed into OMB's public docket files. These documents also are available on the Federal Reserve Board's public website at *https://www.federalreserve.gov/apps/reportforms/review.aspx* or may be requested from the agency clearance officer, whose name appears above.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the PRA to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. Copies of the PRA Submission, supporting statements, and approved collection of information instrument(s) are placed into OMB's public docket files.

Final Approval Under OMB Delegated Authority of the Extension for Three Years, With Revision, of the Following Information Collections:

Report title: Notice by Financial Institutions of Government Securities Broker or Government Securities Dealer Activities.

Agency form number: Form G–FIN.

OMB control number: 7100–0224.

Effective Date: The revisions are effectively immediately.

Frequency: On occasion.

Respondents: State member banks, foreign banks, uninsured state branches or state agencies of foreign banks, commercial lending companies owned or controlled by foreign banks, and Edge corporations.

Estimated number of respondents: Reporting, 34; Recordkeeping, 2.

Estimated average hours per response: Reporting, 1; Recordkeeping, 0.25.

Estimated annual burden hours: 35.

General description of report: The Securities Exchange Act of 1934, as amended (the Act),[1] requires financial institutions to notify their appropriate regulatory agency (ARA) prior to using the mails or any means or instrumentality of interstate commerce to engage in government securities broker or dealer activities. The Board is the ARA for state member banks, foreign banks, uninsured state branches or state agencies of foreign banks, commercial lending companies owned or controlled by foreign banks, and Edge corporations (collectively, ''Board regulated financial institutions''). A Board regulated financial institution must use Form G–FIN to register as a government securities broker or dealer or to amend a previously submitted G–FIN.

Form G–FIN collects such information as the company name, all business addresses, names and titles of managers of government securities activities, and the names of any persons involved in disciplinary proceedings related to the sale of securities. The Board uses the information collected by Form G–FIN to measure compliance with the Act.

An important function of the Form G–FIN is to help financial institutions determine whether they must file notices pursuant to the Act. The definitions of government securities broker and government securities dealer in the Act are very broad and, if read literally, would encompass most banks and many thrift institutions. The Treasury has the authority to exempt institutions from this requirement if it is consistent with the intent of the Act. When the Treasury regulations were first drafted to implement the reporting requirements of the Act, the ARAs worked closely to narrow the class of financial institution required to file the Form G–FIN (reflected in Part B of the instructions, Who Must File).

In addition to incorporating the Treasury's exemptions from the notice requirement in the reporting instructions, these exemptions are prominently summarized on the cover sheet of the Form G–FIN in order to provide a simpler and easier means for financial institutions to determine if they are exempt.

Report title: Notice by Financial Institutions of Termination of Activities as a Government Securities Broker or Government Securities Dealer.

Agency form number: Form G–FINW.

OMB control number: 7100–0224.

Effective Date: The revisions are effectively immediately.

Frequency: On occasion.

Respondents: State member banks, foreign banks, uninsured state branches or state agencies of foreign banks, commercial lending companies owned or controlled by foreign banks, and Edge corporations.

Estimated number of respondents: Reporting, 2; Recordkeeping, 1.

Estimated average hours per response: Reporting, 0.25; Recordkeeping, 0.25.

Estimated annual burden hours: 1.

General description of report: The Act requires financial institutions to notify their ARA upon terminating government securities broker or dealer activities. A Board regulated financial institution must use Form G–FINW to notify the Board of its termination of such activities. Form G–FINW collects information such as the company name, address, and contact person responsible for the records associated with the government securities broker or dealer activities. The Board uses the information collected by Form G–FINW to measure compliance with the Act. The information collected by Form G–FINW is not available from other sources.

The instructions for Form G–FINW state that a notificant should retain one exact copy of each completed Form G–FINW for the notificant's records. These records must be kept until at least three years after the financial institution has notified the Board that it has ceased to function as a government securities broker or dealer.

Legal authorization and confidentiality: Forms G–FIN and G–FINW are authorized under the Act, 15 U.S.C. 78o–5(a)(l)(B)(i), which requires a financial institution that is a broker or dealer of government securities to submit a written notice advising its ARA that it is a government securities broker or a government securities dealer or that it has ceased to act as such. The Act also directs the Board, in consultation with the other ARAs (the Federal Deposit Insurance Corporation and the Office of the Comptroller of the Currency),[2] as well as the Securities and Exchange Commission (SEC), to prescribe the form of and the information collected in these notices (15 U.S.C. 78o–5(a)(l)(B)(ii)). Further support for the creation and collection of these notices by the Board is found in the Treasury regulations, authorized by 15 U.S.C. 78o–5(b)(l), which instruct that the Form G–FIN and Form G–FINW are promulgated by the Board and that such forms are to be used by non-exempt[3] financial institutions to notify the ARA of their status as government securities brokers or dealers or the termination of such status.[4]

Section 15C of the Act, 15 U.S.C. 78o–5(b)(1)(C), also instructs the Secretary of the Treasury to promulgate recordkeeping requirements regarding the forms and records to be retained by government securities brokers and dealers and to specify the time period for which such records shall be

[1] 15 U.S.C 78o–5.

[2] A copy of the form filed with each ARA is also made available by the ARA to the SEC under the Act (15 U.S.C. 78o–5(a)(1)(B)(iii)).

[3] The Act permits the Secretary of the Treasury to exempt certain government securities brokers or dealers, 15 U.S.C. 78o–5(a)(5), and the Secretary of the Treasury has promulgated regulations exempting certain types of firms. See 17 CFR part 401.

[4] See 17 CFR 400.1(d), 449.1, and 449.2; see also 17 CFR 400.5(b) (requiring that any amendments or corrections to the notice of status of government securities broker or dealer be filed by the financial institution on Form G–FIN within 30 days).

preserved. Accordingly, the recordkeeping requirement associated with these forms is contained in 17 CFR 404.4, which requires state member banks and uninsured state branches or state agencies of foreign banks, as well as other institutions, to retain these forms for three years after the financial institution notifies its ARA that it has ceased to function as a government securities broker or dealer. Although Treasury's recordkeeping requirement does not explicitly apply to foreign banks, Edge corporations, or commercial lending companies that are owned or controlled by foreign banks, the Board has the authority to ''issue such rules and regulations with respect to transactions in government securities as may be necessary to prevent fraudulent and manipulative acts and practices and to promote just and equitable principles of trade'' (15 U.S.C. 78o–5(b)(3)(A)). Imposing a recordkeeping requirement on foreign banks, Edge corporations, and commercial lending companies owned or controlled by foreign banks is necessary for the public interest and protection of investors in order to ensure that the proper notification has been provided when these institutions are transacting in government securities (15 U.S.C. 78o–5(a)(1)(B)). In addition, the Board is authorized to impose a recordkeeping requirement on foreign banking organizations [5] (12 U.S.C. 3108), on Edge corporations (12 U.S.C. 625), and on commercial lending companies that are owned or controlled by foreign banks (12 U.S.C. 3106, as applied through 12 U.S.C. 1844(c)).

The obligation to file the Form G–FIN and Form G–FINW with the Board, and the obligation for the government securities broker or dealer to retain a copy of the Form G–FIN and Form G–FINW, is mandatory for those financial institutions for which the Board serves as the ARA, unless the financial institution is exempt from the reporting requirement under Treasury's regulations. The filing of these forms and the records retention period is event-generated.

Under the Act, each ARA is instructed to make these forms available to the SEC, and the SEC is instructed to make the notices available to the public (15 U.S.C. 78o-5(a)(l)(B)(iii)). Thus, the information collected on Form G–FIN and Form G–FINW is ordinarily not treated as confidential. However, given that Item 6 of Form G–FIN instructs the filer to attach copies of the confidential Form G–FIN–4, or if applicable, to attach copies of any previously filed confidential Form MSD–4 or confidential Form U–4, these attachments may be treated as confidential under exemptions 4 and/or 6 of the Freedom of Information Act, which protect, respectively, ''trade secrets and commercial or financial information obtained from a person [that is] privileged or confidential'' and information about individuals in ''personnel and medical files and similar files'' when the disclosure of such information ''would constitute a clearly unwarranted invasion of personal privacy'' (5 U.S.C. 552(b)(4) and 5 U.S.C. 552(b)(6)).

Current actions: On August 29, 2019, the Board published a notice in the **Federal Register** (84 FR 45491) requesting public comment for 60 days on the extension, with revision, of the Notice by Financial Institutions of Government Securities Broker or Government Securities Dealer Activities and the Notice by Financial Institutions of Termination of Activities as a Government Securities Broker or Government Securities Dealer (Form G–FIN and Form G–FINW). The changes proposed include revising the Form G–FIN and Form G–FINW to (1) require respondents to submit PDF versions of the forms and any attachments to a designated email address, and (2) to correct cross-references on the following forms: G–FIN–4, Form MSD–4, and Form U–4, which are incorporated by reference in Item 7 of the Form G–FIN. The comment period for this notice expired on October 28, 2019. One public comment was received, but it was outside the scope of the Board's review under the PRA.

Board of Governors of the Federal Reserve System, December 17, 2019.

Michele Taylor Fennell,

Assistant Secretary of the Board.

[FR Doc. 2019–27600 Filed 12–20–19; 8:45 am]

BILLING CODE 6210–01–P

[5] A foreign banking organization is a foreign bank that operates a branch, agency, or commercial lending company subsidiary in the United States; controls a bank in the United States; or controls an Edge corporation acquired after March 5, 1987; and any company of which the foreign bank is a subsidiary.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[30Day–20–19ACF]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Agency for Toxic Substances and Disease Registry (ATSDR) has submitted the information collection request titled ''Human Health Effects of Drinking Water Exposures to Per- and Polyfluoroalkyl Substances (PFAS): A Multi-site Cross-sectional Study (The Multi-site Study)'' to the Office of Management and Budget (OMB) for review and approval. ATSDR previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on April 23, 2019 to obtain comments from the public and affected agencies. ATSDR received two comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

ATSDR will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) 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;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) 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; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570 or send an email to *omb@cdc.gov.* Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Human Health Effects of Drinking Water Exposures to Per- and Polyfluoroalkyl Substances (PFAS): A Multi-site Cross-sectional Study (The Multi-site Study)—NEW—Agency for

Toxic Substances and Disease Registry (ATSDR).

Background and Brief Description

Per- and polyfluoroalkyl substances (PFAS) are a family of chemicals used in industrial applications and consumer products. PFAS contamination of drinking water is widespread in the U.S. Some estimates indicate that at least sixty million residents were served by 66 public water supplies that had at least one sample at or above the US Environmental Protection Agency (EPA) Lifetime Health Advisory for perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS) (individually or combined), which is 70 nanograms per liter (ng/L) of water. Industrial facilities that manufacture or use PFAS have contaminated drinking water in surrounding communities in several states. In addition, PFOS, PFOA, perfluorohexane sulfonic acid (PFHxS) and other PFAS chemicals are constituents in aqueous film-forming foam (AFFF), used to extinguish flammable liquid fires. The use of AFFF at military bases and other sites may have resulted in the migration of PFAS chemicals through soils to ground water and/or surface water sources of drinking water for the bases and/or surrounding communities around the country.

In response to growing awareness of the extent of PFAS contamination across the U.S., the Section 316(a) of the 2018 National Defense Authorization Act (Pub. L. 115–91), as amended by Section 315 of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Pub. L. 115–232), authorized and appropriated funds for the Agency for Toxic Substances and Disease Registry (ATSDR) to conduct a study on the human health effects of PFAS contamination in drinking water. The existence of widespread contamination at many sites across the U.S. makes this a paramount effort in addressing the health effects of exposures to PFAS from contaminated drinking water. Consequently, ATSDR is requesting a three-year Paperwork Reduction Act (PRA) clearance for the Multi-site Study.

The Multi-site Study builds on activities undertaken in preparing and conducting the data collection for the proof-of-concept study at the Pease International Tradeport in Portsmouth, New Hampshire (the Pease Study) (OMB Control No. 0923–0061; expiration date 08/31/2022). These activities included developing data management systems and community engagement materials, modifying the childhood neurobehavioral test battery, adjusting blood collection volume, and modifying data collection materials such as the childhood questionnaire and medical records abstraction forms. Based on peer reviewer and OMB comments on the Pease Study, the Multi-site Study protocol now includes additional data analyses to address potential biases such as selection bias and confounding.

ATSDR will conduct this research using a cooperative agreement titled ''Multi-site Study of the Health Implications of Exposure to PFAS-Contaminated Drinking Water'' (Notice of Funding Opportunity [NOFO] No. CDC–RFA–TS–19–002). Seven research recipients have been selected: University of Colorado School of Public Health, Michigan State Department of Health and Human Services, Pennsylvania Department of Health and RTI International, Rutgers School of Public Health, Silent Spring Institute, SUNY at Albany and the New York State Department of Health, and the University of California at Irvine.

The Multi-site Study is designed to aggregate data across all recipient sites and is designed to compare data between sites. The main goal of this cross-sectional study is to evaluate associations between measured and reconstructed historic serum levels of PFAS including PFOA, PFOS, and PFHxS, and selected health outcomes. The health outcomes of interest include lipids, renal function and kidney disease, thyroid hormones and disease, liver function and disease, glycemic parameters and diabetes, as well as immune response and function in both children and adults. In addition, the study will investigate PFAS differences in sex hormones and sexual maturation, vaccine response, and neurobehavioral outcomes in children. In adults, additional outcomes of interest include cardiovascular disease, osteoarthritis and osteoporosis, endometriosis, and autoimmune disease.

Under the cooperative agreement, each recipient proposed candidate study sites at communities whose drinking water was impacted by AFFF use or by industrial PFAS releases. Site selection considered the documented levels of PFAS drinking water concentrations. The aim was to include sites so that a wide range in PFAS exposures levels were included in the study. This will enable the evaluation of exposure-response trends including effects at the lower range of exposures. Ground water contaminant fate and transport models and water distribution system models may be necessary to identify the areas with contaminated drinking water, to determine the period when the drinking water was contaminated, and to reconstruct historical PFAS contaminant concentrations.

For exposure estimation, participants will be categorized based on their measured serum concentration of PFAS compounds or on modeled estimated historical serum levels (*e.g.,* referent or low, medium, high). Measured and estimated PFAS serum levels will also be evaluated as continuous variables. At sites with prior PFAS biomonitoring data, the study will evaluate changes in PFAS concentration over time.

Each recipient shall reconstruct historic serum PFAS concentrations. This may be done by estimating half-lives and elimination rates as well as by water contamination modeling to inform pharmacokinetic (PK) or physiologically based pharmacokinetic (PBPK) models. Historical serum PFAS reconstruction will enable the evaluation of exposure lags and vulnerable periods as well as statistical analyses that can control for confounding and reverse causation due to physiological factors.

If feasible, each recipient shall identify and enumerate all households served by the contaminated drinking water supply in the selected community to recruit potential participants and to meet the sample size requirements for children and adults. If the selected community is served by a PFAS-contaminated public water system, then the recipient will obtain a list of households served by the water purveyor from its billing records. If the community is served by contaminated private wells, then the recipient will obtain a list of households with contaminated wells from the local and/or state health and environmental agencies.

Statistical sampling methods (*e.g.,* a two-stage cluster sample) may be used for recruitment of study participants if all the affected households can be enumerated. If the PFAS drinking water concentrations vary widely across the community, then the recipient should consider using targeted sampling approaches—including oversampling of areas with higher PFAS concentrations—to ensure a sufficiently wide distribution of exposure levels among study participants to evaluate exposure-response trends. If enumeration of all households is not feasible, or if participation rates are expected to be low, then the recipient can consider non-probabilistic sampling approaches such as ''judgment'' and ''snowball'' sampling approaches.

The recipients should consider requesting assistance from local and state health departments in their recruitment efforts. In addition, the recipients should engage community organizations to assist in conducting outreach about the study and

recruitment of participants and consider establishing a community assistance panel (CAP). The CAP could provide comments on any additional investigator-initiated research questions and hypotheses and facilitate the involvement of the affected community in decisions related to outreach about the study, participant recruitment strategies, and study logistics. The CAP could also assist the recipient in the dissemination of study findings to the community.

In total, ATSDR seeks to enroll approximately 9,100 participants (7,000 adults and 2,100 children and their parents) from communities exposed to PFAS-contaminated drinking water over the first three years of the five-year cooperative agreement program. In total, each recipient will attempt to meet a target recruitment of 1,000 adults and 300 children. Annualized estimates are 3,033 participants (2,333 adults and 700 children).

To restrict this study to drinking water exposures, adults occupationally exposed to PFAS will not be eligible for the study (*e.g.,* ever firefighters or ever workers in an industry using PFAS chemicals in its manufacturing process). Likewise, children whose birth mothers were occupationally exposed will not be eligible.

Assuming a 95 percent eligibility rate and a 40 percent response rate, ATSDR estimates that the recipients will screen 7,982 people (6,140 adults and 1,842 children) each year across all sites in order to recruit the target sample size of 3,033 participants (2,333 adults and 700 children), using an annual time burden of 1,330 hours. The recipients will provide appointment reminder calls for each eligible person who agrees to be enrolled (n=3,033 per year).

At enrollment, each recipient will obtain adult consent, parental permission, and child assent before data collection begins. For each participant, the recipient will take body measures, collect blood samples to measure PFAS serum levels and several effect biomarkers such as lipids, and thyroid, kidney, immune and liver function. The recipient will also obtain urine samples from participants to measure PFAS levels and kidney function biomarkers. The study will archive leftover serum and urine samples for additional analyses of PFAS chemicals and specific effect biomarkers. The National Center for Environmental Health (NCEH) laboratory will perform blood and urine PFAS analyses for all Multi-site Study participants. Thus, issues of inter-laboratory variability for exposure measures will be eliminated.

Adult participants and a parent of child participants will complete a questionnaire that includes residential history, medical history, occupational history, and water consumption habits (n=3,033 adults and 700 children per year). Ideally, the parent will be the child's birth mother, as ATSDR will ask details about the child's exposure, pregnancy, and breastfeeding history. For purposes of time burden estimation, ATSDR assumes that 20 percent of parents (n=140 per year) will also enroll as adults and can take the child short form questionnaire; therefore, 560 parents will take the child long form questionnaire per year. Parents and children, with administration by trained professionals, will also complete neurobehavioral assessments of the child's attention and behaviors (n=700 per year). The time burden for responding to questionnaires is 1,482 hours, and for neurobehavioral assessments is 1,225, per year.

To facilitate access to medical and school records, each recipient will reach out to local medical societies, public school systems, and private schools, to enlist their cooperation with the study. The recipient will ask for permission to abstract participants' medical records to confirm self-reported health outcomes. The recipient will also seek permission to abstract and compare children's school records to their behavioral assessment results. Based on ATSDR's experience from the Pease Study (OMB Control No. 0923–0061; expiration date 08/31/2022), ATSDR estimates that it will take 30 school administrators, 48 education specialists, 70 medical office administrators, and 150 adult and 50 pediatric medical record specialists to complete record abstractions across all study sites. The annual time burden for medical and educational record abstraction is estimated to be 2,490 hours.

The total annualized time burden requested is 7,960 hours. There is no cost to the respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Multi-site Study Participants	Eligibility Screening Script	7,982	1	10/60
	Appointment Reminder Telephone Script	3,033	1	5/60
	Update Contact Information Hardcopy Form	3,033	1	5/60
	Medication List	3,033	1	3/60
	Body and Blood Pressure Measures Form	3,033	1	5/60
	Blood Draw and Urine Collection Form	3,033	1	10/60
	Adult Questionnaire	2,333	1	30/60
	Child Questionnaire—Long Form	560	1	30/60
	Child Questionnaire—Short Form	140	1	15/60
	Parent Neurobehavioral Test Battery	700	1	15/60
	Child Neurobehavioral Test Battery	700	1	90/60
Medical Office Administrators	Request for Medical Record Abstraction	70	43	20/60
Medical Record Specialists	Medical Record Abstraction Form—Adult	150	16	20/60
	Medical Record Abstraction Form—Child	50	14	20/60
School Administrators	Request for Child School Record Abstraction	30	23	20/60
Education Specialists	Child School Record Abstraction Form	48	15	20/60

Jeffrey M. Zirger,
Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2019–27550 Filed 12–20–19; 8:45 am]
BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substance and Disease Registry

[60Day–20–0057; Docket No. ATSDR–19–0009]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Agency for Toxic Substances and Disease Registry (ATSDR), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Agency for Toxic Substances and Disease Registry (ATSDR), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled ''APPLETREE Performance Measures,'' which ATSDR will use to manage its next three-year cooperative agreement program under Notice of Funding Opportunity (NOFO) No. CDC–RFA–TS20–2001.

DATES: ATSDR must receive written comments on or before February 21, 2020.

ADDRESSES: You may submit comments, identified by Docket No. ATSDR–2019–0009 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. ATSDR will post, without change, all relevant comments to *Regulations.gov*.

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.
5. Assess information collection costs.

Proposed Project

APPLETREE Performance Measures (OMB Control No. 0923–0057, Exp. 07/31/2020)—Revision—Agency for Toxic Substances and Disease Registry (ATSDR).

Background and Brief Description

The Agency for Toxic Substances and Disease Registry (ATSDR) seeks to build and sustain the capacity to evaluate exposures to hazardous waste across the country. Releases from hazardous waste sites are a major source of harmful exposures in homes, schools, workplaces, and communities. These exposures are often complex and may be difficult to identify and control. Hazardous waste sites may involve various toxic substances, exposure pathways, and health impacts. ATSDR's primary goal is to keep communities safe from harmful exposures and related diseases. To accomplish this goal, the agency works closely with partnering agencies to evaluate exposures at hazardous waste sites, educate communities, and seek new ways to better protect public health.

ATSDR's Partnership to Promote Local Efforts to Reduce Environmental Exposure (APPLETREE) Program is critical to ATSDR's success in accomplishing its mission in communities nationwide. ATSDR's recipients will use APPLETREE funding to advance ATSDR's primary goal of keeping communities safe from harmful environmental exposures and related diseases. APPLETREE gives recipients the resources to build their capacity to assess and respond to site-specific issues involving human exposure to hazardous substances in the environment. APPLETREE helps recipients identify exposure pathways at specific sites; educate affected communities about site contamination and potential health effects; make recommendations to prevent exposure; review health outcome data to evaluate potential links between site contaminants and community health outcomes. APPLETREE facilitates the implementation of state-level programs to ensure that potential early care and education facilities are in areas free from harmful environmental exposures. It also encourages recipients in the innovation of progressive public health interventions that prevent exposures to environmental contamination. Because of APPLETREE recipients' local connections and partnerships, community engagement and implementation of recommendations is improved. This program is authorized under Sections 104(i)(15) of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended by the Superfund Amendments and Reauthorization Act (SARA) of 1986 [42 U.S.C. 9604(i)(15)].

Under the next three-year APPLETREE cooperative agreement (NOFO No. CDC–RFA–TS20–2001), eligible applicants include federally recognized American Indian/Alaska Native tribal governments; American Indian/Alaska native tribally designated organizations; political subdivisions of states (in consultation with states); and

state and local governments or their bona fide agents. ATSDR technical project officers (TPOs) will assist approximately 25 APPLETREE recipients to address site-specific issues involving human exposure to hazardous substances. Key capacities include identification of human exposure pathways at ATSDR sites, education of affected communities and local health professionals about site contamination and potential health effects; making appropriate recommendations to prevent exposure; reviewing health outcome data to evaluate potential links between site contaminants and community health; and documenting the effects of environmental remediation on health.

This is a revision of an information collection request (ICR) titled ''APPLETREE Performance Measures,'' previously approved under OMB Control No. 0923–0057 (expiration date 07/31/2020). ATSDR will continue to collect information related to recipient activities, and the process and outcome performance measures outlined by the cooperative agreement program. Information will be used to monitor progress toward program goals and objectives, and for program quality improvement. The first five forms were previously approved by OMB (''APPLETREE Performance Measures'' under OMB Control No. 0923–0057, expiration date 07/31/2020). The first three forms, formerly reported in SharePoint, will be migrated to a new information technology (IT) system called ATSDR's Request Management System (ARMS).

1. *ATSDR Health Education Activity Tracking (HEAT) Form:* For each environmental health assessment and health education activity conducted at ATSDR sites, APPLETREE Recipients shall quantitatively assess and report efforts to educate community members about site recommendations and health risks using indicators to assess community understanding of site findings about health risks and community understanding of agency recommendations to reduce health risks. This information will be entered in to the ATSDR HEAT system for each activity at ATSDR sites.

2. *ATSDR Technical Assistance (TA) Activity Form:* Throughout the budget year, this form will be used to record the routine requests made of the recipients and their program responses. These responses do not evaluate environmental data and do not make health calls, but are monitored by ATSDR as part of the recipients' performance.

3. *ATSDR Site Impact Assessment (SIA) Form:* For each environmental health assessment and health education activity conducted at ATSDR sites, recipients shall estimate and report the number of people protected from exposure to toxic substances at each site where implementation of agency recommendations has taken place and at each child care center where safe siting guidelines have been implemented. To the extent possible, recipients shall estimate and report the disease burden prevented due to the implementation of site recommendations and safe siting guidelines.

Recipients will continue to submit the following form to ATSDR via SharePoint:

4. *ATSDR Success Story Form:* Recipients will provide one success story per quarter (four success stories total per year) that highlights an impact of any of their programs. Recipients will report a brief summary, background, intervention/action taken, and accomplishment/impact for each story. Optionally, they may include a photo or quote.

Recipients will submit the following five forms to ATSDR via email. As part of the revision request, the last four forms are new.

5. *APPLETREE Annual Performance Report (APR) Template:* Recipients will continue to provide an APR each year and at the end of the funding cycle, which summarizes their annual and funding cycle performances, respectively. APRs will be due in December of each year to coincide with the CDC Grants Management annual reports to reduce overall reporting burden and the final report will be due at the end of the funding cycle. The purpose of the performance reports will be to assess Partners based on performance measures and evaluation projects. The reports should include a summary of performance measures, results of any evaluation projects, accompanying narrative of progress and interpretation of results, optional successes, challenges, and updated work plan. These reports will be entered into a Microsoft Word form.

6. *Choose Safe Places for Early Care and Education (CSPECE) Qualitative Narrative Form:* Recipients will now provide a narrative report of their CSPECE Programs to document descriptive details of their state's landscape, program plan, program implementation, and results that cannot be captured through numbers. Recipients will complete and submit the narrative once a year as a supplement with their APRs in a Microsoft Word form.

7. *CSPECE Quantitative Form:* Recipients will also now provide data on their CSPECE Programs to quantify aspects of their program such as children reached, target audiences educated, early care and education programs referred and screened, and recommendations implemented. To supplement their APRs, recipients will complete and submit a Microsoft Excel form once a year as a supplement with their APRs.

In addition to the required annual reporting, at the end of the three-year program, each recipient will report cumulative three-year performance measures for three forms: The APR, the CSPECE Qualitative Narrative Form, and the CSPECE Quantitative Form. This will result in four total responses in a three-year period for each form. The estimated annualized number of required responses is thus rounded to once per year for these three forms, as 4 hours divided by three years equals 1.33 hours per year.

8. *ATSDR SoilSHOP Form:* SoilSHOPs are not a required activity; however, if conducted, a recipient will need to complete the ATSDR SoilSHOP Form in Word. This form gathers data on the inputs, activities, outputs, and outcomes of the event, such as the number of soil samples screened, number of elevated soil samples, number of individuals receiving health consultations, and number of individuals receiving referrals. The form should be provided back to ATSDR via email within two weeks of the SoilSHOP completion.

9. *ATSDR Recommendation Follow-up Form:* For each environmental health assessment, recipients will provide an update on the status of acceptance and implementation of all recommendations to understand whether and how recommendations have been implemented, and the subsequent impact on communities. Recipients will complete a Microsoft Excel reporting form annually on the anniversary date of the release of each health assessment. Initially recipients will provide to ATSDR via email, but the form will be migrated into the ARMS system in the future.

ATSDR is seeking a three-year Paperwork Reduction Act (PRA) clearance for this revision information collection request. The total annual time burden requested is 240 hours. This reflects a reduction in requested time burden compared to the 272 hours previously approved in 2017. This revision also requests approval for an increase in the annual number of responses from 1,575 in 2017, to 1,685 in this current request. ATSDR will

continue to fund 25 recipients. Recipient reporting is required to receive funding under the APPLETREE cooperative agreement.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
APPLETREE Recipients	ATSDR Health Education Activity Tracking (HEAT) Form.	25	37	3/60	47
	ATSDR Technical Assistance (TA) Activity Form	25	15	5/60	32
	ATSDR Site Impact Assessment (SIA) Form	25	4	7/60	12
	ATSDR Success Story Form	25	4	30/60	50
	APPLETREE Annual Performance Report (APR) Template.	25	1	2	50
	Choose Safe Places for Early Care and Education (CSPECE) Qualitative Narrative Form.	25	1	1	25
	CSPECE Quantitative Form	25	1	15/60	6
	ATSDR SoilSHOP Form	10	1	7/60	1
	ATSDR Recommendation Follow-up Form	25	4	10/60	17
Total					240

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2019–27556 Filed 12–20–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60–Day–20–1180; Docket No. CDC–2019–0092]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Airline and Vessel and Traveler Information Collection (42 CFR part 71) that enables CDC to order air carriers and maritime vessels to provide certain contact information for travelers in the event there is a confirmed illness onboard that poses a public health risk.

DATES: CDC must receive written comments on or before February 21, 2020.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2020–0092 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *Regulations.gov.*

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) *or by U.S. mail to the address listed above.*

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, of the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.
5. Assess information collection costs.

Proposed Project

Airline and Vessel and Traveler Information Collection (42 CFR part 71) (0920–1180 expires 05/31/2020)—Revision—Division of Global Migration and Quarantine (DGMQ), National Center for Emerging Zoonotic and Infectious Diseases (NCEZID), Centers

for Disease Control and Prevention (CDC).

Background and Brief Description

Under the Public Health Service Act (42 United States Code 264), and under 42 Code of Federal Regulations (CFR) 71.4 and 71.5, CDC can order air carriers and maritime vessels arriving from another country to submit a certain information related to passengers and crew that CDC believes were exposed to co-traveler infected with a communicable disease of public health concern.

Stopping a communicable disease outbreak—whether it is naturally occurring or intentionally caused—requires the use of the most rapid and effective public health tools available. Basic public health practices, such as collaborating with airlines in the identification and notification of potentially exposed contacts, are critical tools in the fight against the introduction, transmission, and spread of communicable diseases in the United States.

The collection of pertinent contact information enables Quarantine Public Health Officers in CDC's Division of Global Migration and Quarantine (DGMQ) to notify state and local health departments in order for them to make contact with individuals who may have been exposed to a contagious person during travel and identify appropriate next steps.

In the event that there is a confirmed case of communicable disease of public health concern aboard an aircraft or maritime vessel, CDC collects manifest information for those passengers and crew at risk for exposure. This specific manifest information collection differs depending on the communicable disease that is confirmed during air or maritime travel. CDC then uses this passenger and crew manifest information to coordinate with state and local health departments so they can follow-up with residents who live or are currently located in their jurisdiction. In general, state and local health departments are responsible for the contact investigations. In rare cases, CDC may use the manifest data to perform the contact investigation directly. In either case, CDC works with state and local health departments to ensure individuals are contacted and provided appropriate public health follow-up.

CDC estimates that for each traveler manifest ordered, airlines require approximately six hours to review the order, search their records, and send those records to CDC. There is no cost to respondents other than their time perform these actions. The total estimated hourly burden to respondents as a result of this information collection is 600 hours per year. While CDC has included maritime conveyance manifest orders in the public health rationale for this information collection, these orders are rare and are not included in the burden table.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Airline Medical Officer or Equivalent/Computer and Information Systems Manager.	International TB Manifest Template.	51	1	360/60	306
Airline Medical Officer or Equivalent/Computer and Information Systems Manager.	International Non-TB Manifest Template.	49	1	360/60	294
Total					600

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2019–27557 Filed 12–20–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–20–20EC; Docket No. CDC–2019–0115]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Enterprise Laboratory Information Management System which is a system used to record specimen metadata and patient data related to test order requests submitted by external partners (state public health laboratories, International organizations, federal institutions, hospitals, doctor's offices, etc.) to the CDC Infectious Diseases testing laboratories.

DATES: CDC must receive written comments on or before February 21, 2020.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2019–0115 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *Regulations.gov.*

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) *or by U.S. mail to the address listed above.*

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffery M. Zirger, of the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

5. Assess information collection costs.

Proposed Project

Enterprise Laboratory Information Management System (ELIMS)—Existing Collection in Use without an OMB Control Number—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The collection of specimen information designated for testing by the CDC occurs on a regular and recurring basis (multiple times per day) using an electronic PDF file called the *CDC Specimen Submission 50.34 Form* or an electronic XSLX file called the *Global File Accessioning Template.*

Hospitals, doctor's offices, medical clinics, commercial testing labs, universities, state public health laboratories, U.S. federal institutions and foreign institutions use the *CDC Specimen Submission Form 50.34* when submitting a single specimen to CDC Infectious Diseases laboratories for testing. The *CDC Specimen Submission 50.34 Form* consists of over 200 data entry fields (of which five are mandatory fields that must be completed by the submitter) that captures information about the specimen being sent to the CDC for testing. The type of data captured on the *50.34 Form* identifies the origin of the specimen (human, animal, food, environmental, medical device or biologic), CDC test order name/code, specimen information, patient information (as applicable), animal information (as applicable) information about the submitting organization requesting the testing, patient history (as applicable), owner information and animal history (as applicable) and epidemiological information. The collection of this type of data is pertinent in ensuring a specimen's testing results are linked to the correct patient and the final test reports are delivered to the appropriate submitting organization to aid in making proper health-related decisions related to the patient. Furthermore, the data provided on this form may be used by the CDC to identify sources of potential outbreaks and other public-health related events. When the form is filled out, a user in the submitting organization prints a hard copy of it that will be included in the specimen's shipping package sent to the CDC. The printed form has barcodes on it that allow the CDC testing laboratory to scan its data directly into ELIMS where the specimen's testing lifecycle is tracked and managed.

Likewise, the *Global File Accessioning Template* records the same data as the *50.34 Form* but provides the capability to submit information for a batch of specimens (typically 50–1,000 specimens per batch) to a specific CDC laboratory for testing. The CDC testing laboratory electronically uploads the *Global File Accessioning Template* into ELIMS where the batch of specimens are then logged and are ready to be tracked through their respective testing and reporting workflow. CDC requests approval for 2,047 annual burden hours. There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Medical Assistant, Doctor's Office/Hospital	*CDC Specimen Submission 50.34 Form.*	2,000	3	5/60	480
19–1042 Medical Scientists, Except Epidemiologists, State Public Health Lab.	*CDC Specimen Submission 50.34 Form.*	98	193	5/60	1,513
Medical Assistant, Doctor's Office/Hospital	*Global File Accessioning Template.*	15	11	20/60	54
Total					2,047

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2019–27555 Filed 12–20–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–20–20DV; Docket No. CDC–2019–0114]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled ''Chronic Q Fever in the United States: Enhanced Clinical Surveillance.'' This enhanced medical surveillance for chronic Q fever will collect specific clinical data not otherwise collected during routine public health surveillance to allow for better characterization of the clinical presentation and risk factors of chronic Q fever in the United States.

DATES: CDC must receive written comments on or before February 21, 2020.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2019–0114 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *Regulations.gov.*

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) *or by U.S. mail to the address listed above.*

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, of the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.
5. Assess information collection costs.

Proposed Project

Chronic Q Fever in the United States: Enhanced Clinical Surveillance—New—National Center for Emerging Zoonotic and Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Q fever is a worldwide zoonosis caused by *Coxiella burnetii* with acute and chronic disease presentations. Chronic Q fever can manifest months to years after the primary infection and is rare, occurring in <5% of persons with an acute infection. Chronic Q fever can take on several clinical forms, including endocarditis, chronic hepatitis, chronic vascular infections, osteomyelitis, and osteoarthritis. In the United States, Q fever cases are reported via the National Notifiable Disease Surveillance System; however, limited information is collected on the various clinical manifestation of chronic Q fever or patients pre-existing risk factors. Data on outcomes other than death or hospitalizations are not collected by the current surveillance.

Because of this lack of data, the true burden and proportion of cases exhibiting endocarditis and other forms of chronic Q fever in the United States is unknown. We plan to establish an enhanced medical surveillance for chronic Q fever by working with consulting clinicians to gather additional and more specific clinical data not otherwise collected during routine public health surveillance for chronic Q fever. This information will allow for better characterization of the clinical presentation and risk factors of chronic Q fever in the United States. The results will help characterize an under-recognized disease and provide valuable data to educate physicians on identifying and diagnosing these cases. CDC is requesting approval for five burden hours annually. There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Physician	Chronic Q fever enhanced surveillance report form.	15	1	20/60	5
Total					5

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2019–27554 Filed 12–20–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–20–20DC; Docket No. CDC–2019–0113]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled ''2019 Lung Injury Response Understanding Vaping Practices In the United States.'' This is a formative study to identify why people are getting sick after vaping/dabbing, in order to narrow the list of products, substances, and risk factors requiring further public health action.

DATES: CDC must receive written comments on or before February 21, 2020.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2019–0113 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *Regulations.gov*.

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) *or by U.S. mail to the address listed above.*

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.
5. Assess information collection costs.

Proposed Project

2019 Lung Injury Response Understanding Vaping Practices In the United States—New—National Center for Injury Prevention and Control (NCIPC), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC), National Center for Injury Prevention and Control (NCIPC) requests approval for a New Information Collection, ''2019 Lung Injury Response Understanding Vaping Practices In the United States.''

In early August 2019, initial cases of e-cigarette, or vaping, product use associated lung injury (EVALI) were reported to CDC. As of November 13, 2019, 2,172 EVALI cases have been reported to CDC from 49 states, the District of Columbia, the US Virgin Islands, and Puerto Rico; 42 deaths have been reported among these cases. A multi-state centrally coordinated response for this severe pulmonary injury was established at CDC to assist each state/local/territory jurisdiction in making rapid, practical decisions for actions to prevent and control this public health problem.

To date, all EVALI patients have reported a history of using e-cigarette, or vaping, products. The latest national and state findings suggest products containing THC, particularly from informal sources like friends, or family, or in-person or online dealers, are linked to most of the cases and play a major role in the outbreak. In addition, vitamin E has been identified as a chemical of concern among people with e-cigarette, or vaping, product use associated lung injury (EVALI). However, while it appears that vitamin E acetate is associated with EVALI, evidence is not yet sufficient to rule out contribution of other chemicals of concern to EVALI. Many different substances and product sources are still under investigation, and it may be that there is more than one cause of this outbreak. At present, there is very little data on which to compare EVALI cases to individuals who are vaping the same products at the same frequency but have not developed EVALI. Comparing EVALI cases to people who vape but have not developed EVALI in a timely way is very important for narrowing the list of products, substances, and risk factors requiring further public health action (*e.g.,* continuing to refine communication messages) and additional studies (*e.g.,* prioritizing samples for laboratory testing). Further, there is insufficient data for guiding the selection of controls for a rigorous case control study (lack of uniformity in demographic characteristics and product brands and types).

The data collected will be used to identify product types, ''brands'', devices, and frequency of use (collectively referred to as use characteristics) from a geographically diverse convenience sample of individuals who report vaping THC but have not developed EVALI. These data will enable CDC to compare the

frequency of use characteristics between the convenience sample and EVALI cases to prioritize follow up on hypotheses about potential risk factors and causes of the outbreak as well as to refine, target, and prioritize additional information gathering, *e.g.,* epidemiological analyses, laboratory testing, and analysis of pathological specimen.

The proposed approach leverages on an opt-in internet panel survey to rapidly collect specific information on a demographically and geographically diverse convenience sample of individuals who report vaping THC but have not developed EVALI. Because such sampling frame is not population representative and not suitable for generalizing about populations, only unweighted data will be obtained from the opt-in internet panel survey and only unweighted, aggregate results will be shared with partners or publicly. The data collected will not be used to produce national, regional, or state-representative estimates; rather, the data will be used to help prioritize hypotheses for future epidemiological, laboratory, and clinical analyses as part of CDC's ongoing lung injury response.

There is no cost to respondents other than the time to participate. The annualized burden is estimated at 5,000 hours. Authorizing legislation comes from Section 301 of the Public Health Service Act (42 U.S.C. 241).

ESTIMATED TOTAL BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number responses per respondent	Average burden per response (in hrs.)	Total burden (in hrs.)
Individuals	Understanding Vaping Practices in the United States Survey—screening questions.	120,000	1	2/60	4,000
Individuals	Understanding Vaping Practices in the United States Survey—full survey.	6,000	1	10/60	1,000
Total					5,000

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2019–27553 Filed 12–20–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–20–19BDE]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled ''The Maternal Mortality Review Information Application (MMRIA)'' to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on June 20, 2019 to obtain comments from the public and affected agencies. CDC received four comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) 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;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) 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; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570 or send an email to *omb@cdc.gov.* Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

The Maternal Mortality Review Information Application (MMRIA)—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC) seeks OMB approval to collect information through the Maternal Mortality Review Information Application (MMRIA) for three years. MMRIA is a standardized data collection system that allows Maternal Mortality Review Committees (MMRCs) across the country to abstract relevant data (clinical and non-clinical) from a variety of sources, document committee decisions, and analyze data in order to better understand the contributing factors and preventability of maternal deaths and thus to develop recommendations for prevention.

About 700 women die each year in the United States as a result of pregnancy or delivery complications, a chain of events initiated by pregnancy, or the aggravation of an unrelated condition by the physiologic effects of pregnancy. Furthermore, considerable racial disparities exist, with black women almost four times more likely to die from pregnancy-related complications than white women.

Findings from MMRCs indicate that more than half of maternal deaths are preventable.

Maternal Mortality Review is a process by which a multidisciplinary committee at the jurisdiction level identifies and reviews cases of maternal death within one year of end of pregnancy. Members of MMRCs typically represent public health, obstetrics and gynecology, maternal-fetal medicine, nursing, midwifery, forensic pathology, mental and behavioral health, and other relevant stakeholders. Through a partnership among the MMRC, state vital records office, and epidemiologists, deaths among women of reproductive age are examined to determine if they occurred during pregnancy or within one year of the end of pregnancy (*i.e.,* pregnancy-associated deaths). Through this process, potential cases of pregnancy-related deaths (*i.e.,* maternal death from any cause related to or aggravated by pregnancy or its management) are then identified. Review committees access multiple sources of clinical and non-clinical information to understand the circumstances surrounding a maternal death in order to develop recommendations for action to prevent similar deaths in the future.

MMRIA is a standardized data collection system designed to collect timely, accurate, and standardized information about deaths to women during pregnancy and within one year of end of pregnancy, including opportunities for prevention, within and across jurisdictions. Data will be abstracted and entered into MMRIA from various sources, including death certificates, autopsy reports, birth certificates, prenatal care records, emergency room visit records, hospitalization records, records from other medical office visits, medical transport records, social and environmental profiles, mental health profiles, and informant interviews. Case narratives for committee reviews are auto-populated from the abstracted data entered into MMRIA to facilitate committee review, and committee decisions will also be entered into MMRIA.

The data collected in MMRIA will be used to facilitate an understanding of the drives of maternal mortality and complications of pregnancy and associated disparities; determine what interventions at patient, provider, facility, system, and community levels will have the most impact; and implement data driven recommendations.

The burden estimates presented here are applicable to the estimated 25 awardees of the cooperative agreement *Preventing Maternal Deaths: Supporting Maternal Mortality Review Committees* (CDC–RFA–DP19–1908); these awardees are required to compile a defined set of information about maternal deaths into MMRIA. It is estimated that information will be collected for a total of 740 pregnancy-associated deaths on average, annually, among the 25 awardees. Burden is estimated based on each awardee's total staff time to enter the abstracted data into MMRIA and enter the committee decision. The annual burden is estimated to be 11,550 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Types of respondents	Form name	Number of respondents	Number of responses per respondent	Average hours per response (in hours)
Awardees	Data abstraction	25	30	15
	Committee decision	25	30	24/60

Jeffery M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2019–27551 Filed 12–20–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60–Day–20–1186; Docket No. CDC–2019–0098]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Information Collection for Tuberculosis Data from Referring Entities to CureTB, which enables CDC to coordinate continuity of care services for individuals with tuberculosis.

DATES: CDC must receive written comments on or before February 21, 2020.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2019–0098 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *Regulations.gov.*

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) *or by U.S. mail to the address listed above.*

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, of the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of

information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

5. Assess information collection costs.

Proposed Project

Information Collection for Tuberculosis Data from Referring Entities to CureTB (OMB Control No. 0920–1186, Exp. 06/30/2020)—Revision—National Center for Emerging Zoonotic and Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CureTB at the Centers for Disease Control and Prevention (CDC), works with domestic and international programs to protect the U.S. public by preventing TB disease transmission domestically and internationally, as well as preventing the development of drug resistant TB. These goals are accomplished through CureTB referral and continuity of care services for mobile TB patients.

Lack of treatment adherence and inappropriate selection of medications are prime reasons for the continued emergence and spread of resistant strains of tuberculosis. To combat this, CureTB ensures that patients understand how to remain adherent to treatment regimens, despite moving between nations. CureTB also provides information to the health care team that will be continuing care about each patient's TB strain and tailored medication regimen. CureTB gathers demographic and clinical information for each patient and connects that individual to appropriate clinical care. This information is also provided on a real-time basis to medical providers and public health authorities in receiving nations so follow-up with the patient can be expedited.

The respondents for the CureTB referral services are nurse practitioners, registered nurses, and physicians working for organizations within the United States and other countries who provide diagnostic and treatment services to individuals affected by TB. The organizations are primarily state and local health departments, but include immigration detention centers, correctional facilities, and foreign national TB programs. All 50 U.S. states and territories may refer TB patients to the CureTB program. To date, CureTB has also received referrals from Mexico and Guatemala.

Registered nurses or nurse practitioners will submit CureTB referral forms as they request referral services. The number of referrals varies widely between respondents. To ensure adequate referral to treatment occurs, CDC CureTB may need to follow-up with an individual to complete missing data fields concerning clinical or contact information. This is done to ensure continuity of care. Therefore, individuals with TB are also respondents in this information collection. CDC's CureTB program will also continue working with our public health partners in notifications and referrals for contacts of TB cases. This is a lesser used function of CureTB, but burden is included below. These respondents are registered nurses or nurse practitioners working in health departments.

Finally, CDC staff in the CureTB program also contact the new treating physicians to determine patient outcomes using CureTB Clinician Public Health Department Follow-up Script. The physicians are generally contacted every two months over the course of standard six month TB treatment, for a total of three follow-up contacts per patient. There are no costs to respondents other than the time required to complete the referral documents and respond to CDC requests for TB patient outcomes. The total burden requested is 1,117 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Registered Nurses/Nurse Practitioners	CureTB Transnational Notification	100	3	30/60	150
TB patients	CureTB Transnational Notification	200	1	5/60	17
TB patients (ICE referrals)	CureTB Transnational Notification	600	1	45/60	450
TB treating physicians	Clinician Public Health Department Follow-up Script.	900	3	10/60	450
Registered Nurses/Nurse Practitioners	CureTB Contact/Source Investigation (CI/SI) Notification.	20	5	30/60	50
Total					1,117

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2019–27559 Filed 12–20–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–287–19]

Agency Information Collection Activities: Submission for OMB Review; Comment Request;

ACTION: Partial Withdrawal.

On Tuesday, December 17, 2019 (84 FR 68936), the Centers of Medicare & Medicaid Services (CMS) published a Notice document titled ''Agency Information Collection Activities: Submission for OMB Review; Comment Request.'' That notice invited public comments on four separate information collection requests. Through the publication of this document, we are withdrawing the portion of the notice requesting public comment on the information collection request titled ''Home Office Cost Statement'' Form number: CMS–287–19 (OMB control number: 0938–0202). The notice for CMS–287–19 published in error. We will resubmit it for public comment at a later date. The original comment period for the other notices that published on December 17, 2019 (84 FR 68936) remains in effect and ends January 16, 2020.

Dated: December 18, 2019.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2019–27667 Filed 12–20–19; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–5743]

Importation of Certain Food and Drug Administration-Approved Human Prescription Drugs, Including Biological Products, Under Section 801(d)(1)(B) of the Federal Food, Drug, and Cosmetic Act; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a draft guidance for industry entitled ''Importation of Certain FDA-Approved Human Prescription Drugs, Including Biological Products, under Section 801(d)(1)(B) of the Federal Food, Drug, and Cosmetic Act.'' This draft guidance describes procedures to obtain a National Drug Code (NDC) for an FDA-approved prescription drug that is imported into the United States in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act), which would provide an additional avenue through which drugs could be sold at a lower cost in the U.S. market. This draft guidance is intended to address certain challenges in the private market faced by manufacturers seeking to sell their drugs at lower costs.

DATES: Submit either electronic or written comments on the draft guidance by February 21, 2020 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

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–2019–D–5743 for ''Importation of Certain FDA-Approved Human Prescription Drugs, Including Biological Products, under Section 801(d)(1)(B) of the Federal Food, Drug, and Cosmetic Act.'' Received comments 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.govinfo.gov/content/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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002 or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Lyndsay Hennessey, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–7605, or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Importation of Certain FDA-Approved Human Prescription Drugs, Including Biological Products, under Section 801(d)(1)(B) of the Federal Food, Drug, and Cosmetic Act,'' which, when finalized, will represent the Agency's current thinking on the importation of multi-market approved (MMA) products. This draft guidance describes procedures to obtain an NDC for an FDA-approved prescription drug that is imported into the United States in compliance with section 801 of the FD&C Act (21 U.S.C. 381), which would provide an additional avenue through which drugs could be sold at a lower cost in the U.S. market. In recent years, FDA has become aware that some drug manufacturers may be interested in offering certain of their drugs at lower costs and that obtaining additional NDCs for these drugs may help them to address certain challenges in the private market. This guidance is not intended to address the applicability of the Medicaid drug rebate program for manufacturers. This guidance is intended to outline a potential pathway by which manufacturers could obtain an additional NDC for an FDA-approved drug that was originally intended to be marketed in a foreign country. This guidance specifically addresses the importation of FDA-approved drugs that were also authorized for sale in a foreign country in which the drugs were originally intended to be marketed (''MMA product''). This guidance describes: (1) The process for submitting a supplement to an approved FDA application for an MMA product; (2) the recommended labeling for an MMA product; (3) the process for registration and listing and for obtaining an NDC for the MMA product; (4) the requirements of section 582 of the FD&C Act (21 U.S.C. 360eee–1) as added by the Drug Supply Chain Security Act (DSCSA) (Title II of Pub. L. 113–54); (5) recommendations related to procedures for importation of the MMA product; and (6) other FDA requirements applicable to MMA products.

This guidance, when finalized, will help ensure manufacturers are aware of procedures to provide access to lower-cost drugs in the United States.[1] The guidance details procedures that will enable manufacturers to obtain an additional NDC for the MMA product, which could allow greater pricing flexibility for a drug or biological product. The additional NDC also will support pharmacovigilance, accurate billing and reimbursement, and facilitate clearance of the MMA products through customs. This draft guidance is not final nor is it in effect at this time.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on the importation of MMA products. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Issues for Consideration

As previously noted, FDA is interested in receiving comments on the draft guidance. Regarding the approach set forth in the draft guidance, in addition to any other issues addressed, FDA requests that commenters consider the following issues when submitting comments:

1. Are there additional considerations for certain types of drug products with special handling, such as sterile injectables, drugs with boxed warnings, drugs with REMS (Risk Evaluation and Mitigation Strategy), controlled substances, or drugs that do not meet the definition of ''product'' under the DSCSA (21 U.S.C. 360eee(13))? Are there additional considerations for combination products related to the content of the guidance (*e.g.,* supplement, labeling, NDC) that would warrant additional guidance for use of this approach for those products? To the extent that interested parties believe that different or additional considerations from those described in the draft guidance should apply to such an approach for combination products, we are interested in input on that, as well.

2. The draft guidance uses ''MMA product'' to describe FDA-approved drugs that were originally intended to be marketed in a foreign country and also authorized for sale in that foreign country. Is this new term adequate and understandable? Is there another term that would provide more clarity regarding the products discussed in the guidance?

3. The draft guidance describes how an NDC could be obtained for MMA products. What is the effect of a manufacturer using a new labeler code as opposed to a new product code to distinguish these products, such as for reimbursement?

4. The draft guidance recommends a labeling statement in the FDA-approved labeling for the MMA product, including the carton and container label, to assist pharmacists and others in accurately identifying, dispensing, and billing for these products. FDA seeks comment on the specific wording that could be included in the statement to differentiate MMA products from other drugs that are not the subject of the guidance, if finalized, and to help ensure MMA products are easily identifiable to pharmacists and not confusing to patients. FDA also seeks comment on other types of distinguishing characteristics on the carton and container label that would further enable pharmacists to identify an MMA product and distinguish it from other packages of the FDA-approved drug, without confusing patients and consistent with other applicable requirements relating to carton and container labeling. Additionally, would other possible mechanisms, such as a Dear Healthcare Provider letter, provide further clarity and reduce confusion for pharmacists and other healthcare providers as well as patients?

5. We request comment about how much, on average, the labeling and packaging changes described in the draft guidance would cost drug manufacturers and repackagers or relabelers. Are there other ways to

[1] Elsewhere in this issue of the **Federal Register**, FDA is issuing a Notice of Proposed Rulemaking under 21 U.S.C. 384 to offer a pathway for importation of drugs from Canada without the authorization of the manufacturer.

distinguish the appearance of an MMA product? We also request comment about alternative labeling approaches that would display the required information with equal prominence but may result in lower costs.

6. The draft guidance describes procedures for manufacturers of drug products approved under new drug applications or biologics license applications to obtain an additional NDC for an MMA product. FDA is interested as to whether manufacturers of generic drugs approved under an abbreviated new drug application confront similar pricing issues such that it would be appropriate to provide guidance on a similar approach for generic drugs. To the extent that interested parties believe that different considerations should apply to such an approach for generic drugs from those described in the draft guidance, input is requested on that as well.

7. There are complex considerations that impact biosimilar development, market entry, and uptake. We are interested in the possible impacts of MMA products that are biological products on biosimilar development, market entry, and uptake.

8. Similarly, there are complex considerations impacting generic drug market entry. We are interested in the possible impacts of MMA products on generic drug development and market entry.

9. Are there voluntary steps a manufacturer may take in addition to the requirements in the DSCSA to ensure the security of the supply chain for products imported pursuant to the guidance?

10. Are there any potential risks associated with the importation of products as described in the draft guidance that could be addressed by a rulemaking? For example, to what extent, if any, are there additional procedures that might better protect against entities seeking to introduce counterfeit drugs in the United States? If so, please be specific about the potential risk and how it could be addressed through rulemaking.

III. Paperwork Reduction Act of 1995

FDA has tentatively concluded that there are no new collections of information in this draft guidance. This draft guidance refers to previously approved collections of information found in the FD&C Act and 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). In accordance with the Paperwork Reduction Act, if FDA's tentative conclusion changes, prior to publication of any final guidance document FDA intends to solicit public comment and obtain OMB approval for any information collections recommended in this guidance that are new or that would represent material modifications to those previously approved collections of information found in FDA regulations or guidances.

The collections of information in 21 CFR part 314 (new drug applications) have been approved under OMB control number 0910–0001; the collections of information in 21 CFR part 601 (biologics license applications) have been approved under OMB control number 0910–0338; the collections of information in 21 CFR part 207 (domestic and foreign facility registration, including assignment of an NDC) have been approved under OMB control number 0910–0045; the collections of information in 21 CFR part 1 (general enforcement regulations) have been approved under OMB control number 0910–0046; the collections of information in 21 CFR part 201 (labeling) have been approved under OMB control number 0910–0572; the collections of information pertaining to current good manufacturing practice requirements for finished pharmaceuticals and combination products under 21 CFR parts 4, 210, 211, 610, and 680 have been approved under OMB control numbers 0910–0139 and 0910–0834; and the collections of information pertaining to suspect product identification and notification under section 582 of the FD&C Act have been approved under OMB control number 0910–0806.

IV. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances,* or *https://www.regulations.gov.*

Dated: December 11, 2019.

Brett P. Giroir,

Acting Commissioner of Food and Drugs.

[FR Doc. 2019–27475 Filed 12–18–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Cancer Institute Clinical Trials and Translational Research Advisory Committee.

The meeting will be open to the public. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting website (*http://videocast.nih.gov/*).

Name of Committee: National Cancer Institute Clinical Trials and Translational Research Advisory Committee.

Date: March 12, 2020.

Time: 11:00 a.m. to 1:00 p.m.

Agenda: Strategic Discussion of NCI's Clinical and Translational Research Programs.

Place: National Institutes of Health, Building 31, Room 11A01, 31 Center Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Sheila A. Prindiville, M.D., M.P.H. Director, Coordinating Center for Clinical Trials, National Institutes of Health, National Cancer Institute, Coordinating Center for Clinical Trials, 9609 Medical Center Drive, Room 6W136, Rockville, MD 20850, 240–276–6173, *prindivs@mail.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *http://deainfo.nci.nih.gov/advisory/ctac/ctac.htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: December 17, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–27582 Filed 12–20–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel; P41 BTRC Review E SEP.

Date: January 24, 2020.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: John P. Holden, Ph.D., Scientific Review Officer, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, 6707 Democracy Blvd., Suite 920, Bethesda, MD 20892, (301) 496–8775, *john.holden@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, HHS)

Dated: December 17, 2019.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–27583 Filed 12–20–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[1651–0025]

Agency Information Collection Activities: Report of Diversion

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security.

ACTION: 30-Day Notice and request for comments; Extension of an existing collection of information.

SUMMARY: The Department of Homeland Security, U.S. Customs and Border Protection will be 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 (PRA). The information collection is published in the **Federal Register** to obtain comments from the public and affected agencies.

DATES: Comments are encouraged and must be submitted (no later than January 22, 2020) to be assured of consideration.

ADDRESSES: Interested persons are invited to submit written comments on this proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the OMB Desk Officer for Customs and Border Protection, Department of Homeland Security, and sent via electronic mail to *dhsdeskofficer@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional PRA information should be directed to Seth Renkema, Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, 90 K Street NE, 10th Floor, Washington, DC 20229–1177, Telephone number 202–325–0056 or via email *CBP_PRA@cbp.dhs.gov.* Please note that the contact information provided here is solely for questions regarding this notice. Individuals seeking information about other CBP programs should contact the CBP National Customer Service Center at 877–227–5511, (TTY) 1–800–877–8339, or CBP website at *https://www.cbp.gov/.*

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on the proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This proposed information collection was previously published in the **Federal Register** (84 FR 55167) on October 15, 2019, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.8. Written comments and suggestions from the public and affected agencies should address one or more of the following four points: (1) 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) 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) suggestions to enhance the quality, utility, and clarity of the information to be collected; and (4) suggestions to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. The comments that are submitted will be summarized and included in the request for approval. All comments will become a matter of public record.

Overview of this Information Collection:

Title: Report of Diversion

OMB Number: 1651–0025

Form Number: CBP Form 26

Current Actions: This submission is being made to extend the expiration date with no change to the burden hours or to the information collected on Form 26.

Type of Review: Extension (without change)

Abstract: CBP Form 26, *Report of Diversion,* is used to track vessels traveling coastwise from U.S. ports to other U.S. ports when a change occurs in scheduled itineraries. This form is initiated by the vessel owner or agent to notify and request approval by CBP for a vessel to divert while traveling coastwise from a U.S. port to another U.S. port, or a vessel traveling to a foreign port having to divert to a U.S. port when a change occurs in the vessel itinerary. CBP Form 26 collects information such as the name and nationality of the vessel, the expected port and date of arrival, and information about any related penalty cases, if applicable. This information collection is authorized by 46 U.S.C. 60105 and 19 CFR 4.91. CBP Form 26 is accessible at *https://www.cbp.gov/newsroom/publications/forms?title=26&=Apply.*

Affected Public: Businesses.

Estimated Number of Respondents: 1,400.

Estimated Number of Annual Responses per Respondent: 2.

Estimated Number of Total Annual Responses: 2,800.

Estimated Time per Response: 5 minutes.

Estimated Total Annual Burden Hours: 233.

Dated: December 18, 2019.

Seth D. Renkema,

Branch Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection.

[FR Doc. 2019–27662 Filed 12–20–19; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[1651–0002]

Agency Information Collection Activities: General Declaration

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security.

ACTION: 60-Day notice and request for comments; extension of an existing collection of information.

SUMMARY: The Department of Homeland Security, U.S. Customs and Border Protection will be 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 (PRA). The information collection is published in the **Federal Register** to obtain comments from the public and affected agencies.

DATES: Comments are encouraged and must be submitted (no later than February 21, 2020) to be assured of consideration.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice must include the OMB Control Number 1651–0002 in the subject line and the agency name. To avoid duplicate submissions, please use only *one* of the following methods to submit comments:

(1) *Email.* Submit comments to: *CBP_PRA@cbp.dhs.gov.*

(2) *Mail.* Submit written comments to CBP Paperwork Reduction Act Officer, U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, Economic Impact Analysis Branch, 90 K Street NE, 10th Floor, Washington, DC 20229–1177.

FOR FURTHER INFORMATION CONTACT: Requests for additional PRA information should be directed to Seth Renkema, Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, 90 K Street NE, 10th Floor, Washington, DC 20229–1177, Telephone number 202–325–0056 or via email *CBP_PRA@cbp.dhs.gov.* Please note that the contact information provided here is solely for questions regarding this notice. Individuals seeking information about other CBP programs should contact the CBP National Customer Service Center at 877–227–5511, (TTY) 1–800–877–8339, or CBP website at *https://www.cbp.gov/.*

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on the proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This process is conducted in accordance with 5 CFR 1320.8. Written comments and suggestions from the public and affected agencies should address one or more of the following four points: (1) 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) 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) suggestions to enhance the quality, utility, and clarity of the information to be collected; and (4) suggestions to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. The comments that are submitted will be summarized and included in the request for approval. All comments will become a matter of public record.

Overview of This Information Collection

Title: General Declaration (Outward/Inward) Agriculture, Customs, Immigration, and Public Health.

OMB Number: 1651–0002.

Form Number: Form 7507.

Action: CBP proposes to extend the expiration date of this information collection with no change to the burden hours. There is no change to the information collected or CBP Form 7507.

Type of Review: Extension (without change).

Abstract: As provided in 19 CFR 122.43, an aircraft commander or agent must file CBP Form 7507, *General Declaration (Outward/Inward) Agriculture, Customs, Immigration, and Public Health* at the time of arrival for all aircraft required to enter pursuant to 19 CFR 122.41. As provided in 19 CFR 122.72 and 122.73, an aircraft commander or agent must file this form at the departure airport for all aircraft departing to a foreign area with commercial airport cargo. As provided in 19 CFR 122.144, this form must be presented to CBP for signature by the inspecting officer in the U.S. Virgin Islands for flights from the U.S. Virgin Islands to the U.S. This form is used to document clearance and inspections by appropriate regulatory agency staffs. CBP Form 7507 collects information about the flight routing, the number of passengers embarking and disembarking, the number of crew members, a declaration of health for the persons on board, and details about disinfecting and sanitizing treatments during the flight. This form also includes a declaration attesting to the accuracy, completeness, and truthfulness of all statements contained in the form and in any document attached to the form.

CBP Form 7507 is authorized by 42 U.S.C 268, 19 U.S.C. 1431, 1433, and 1644a; and provided for by 19 CFR 122.43, 122.52, 122.54, 122.73, 122.144, 42 CFR 71.21 and 71.32. This form is accessible at: *https://www.cbp.gov/newsroom/publications/forms?title=7507&=Apply.*

Affected Public: Businesses.

Estimated Number of Respondents: 500.

Estimated Number of Responses per Respondent: 2,644.

Estimated Number of Total Annual Responses: 1,322,000.

Estimated Time per Response: 5 minutes.

Estimated Annual Burden Hours: 110,123.

Dated: December 18, 2019.

Seth D. Renkema,

Branch Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection.

[FR Doc. 2019–27663 Filed 12–20–19; 8:45 am]

BILLING CODE P

DEPARTMENT OF HOMELAND SECURITY

Agency Information Collection Activities: Vulnerability Discovery Program

AGENCY: Officer of the Chief Information Security Officer, Department of Homeland Security.

ACTION: 30-Day notice and request for comments; New Collection, 1601–NEW.

SUMMARY: The Department of Homeland Security (DHS), Office of the Chief Information Security Officer, DHS will submit the following information collection request (ICR) to the Office of Management and Budget (OMB) for

review and clearance in accordance with the Paperwork Reduction Act of 1995. DHS previously published this information collection request (ICR) in the **Federal Register** on Wednesday, August 28, 2019 for a 60-day public comment period. Two (2) comments were received by DHS. The purpose of this notice is to allow additional 30-days for public comments.

DATES: Comments are encouraged and will be accepted until January 22, 2020. This process is conducted in accordance with 5 CFR 1320.10.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to OMB Desk Officer, Department of Homeland Security and sent via electronic mail to *dhsdeskofficer@omb.eop.gov.*

The Office of Management and Budget is particularly interested in comments which:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

SUPPLEMENTARY INFORMATION: Security vulnerabilities, defined in section 102(17) of the Cybersecurity Information Sharing Act of 2015, are any attribute of hardware, software, process, or procedure that could enable or facilitate the defeat of a security control. Security vulnerability mitigation is a process starting with discovery of the vulnerability leading to applying some solution to resolve the vulnerability. There is constantly a search for security vulnerabilities within information systems, from individuals or nation states wishing to bypass security controls to gain invaluable information, to researchers seeking knowledge in the field of cyber security. Bypassing such security controls in the DHS information systems can cause catastrophic damage including but not limited to loss in Personally Identifiable Information (PII), sensitive information gathering, and data manipulation.

Pursuant to section 101 of the Strengthening and Enhancing Cyber-capabilities by Utilizing Risk Exposure Technology Act commonly known as the SECURE Technologies Act individuals, organizations, and companies will be able to submit discovered security vulnerabilities on the Department of Homeland Security (DHS) Information Systems. This collection would be used by these individuals, organizations, and companies who choose to submit a discovered vulnerability in the information system of the DHS.

The form will include the following essential information:

- Vulnerable host(s)
- Necessary information for reproducing the security vulnerability
- Remediation or suggestions for remediation of the vulnerability
- Potential impact on host, if not remediated

This form will allow the DHS to do two things (1) allow the individuals, organizations, and companies who discover vulnerabilities in the information systems of DHS to report their findings to the DHS. (2) give DHS first insight into newly discovered vulnerabilities, as well as zero-day vulnerabilities in order to mitigate the security issues prior to malicious actors acting on the vulnerability for malicious intent. The form will benefit researchers as it will provide a safe and lawful way for them to practice and discover new skills while discovering the vulnerabilities. Meanwhile, it will provide the same benefit to the DHS, in addition to enhanced information system security following the vulnerability mitigation.

Respondents will be able to fill the form out online at *https://www.dhs.gov* and submit it thereafter. Links to the form will also be available at any of the DHS components websites (*https://www.tsa.gov/, https://www.ice.gov/,* etc.)

The collection of this information regarding to discovered security vulnerabilities by individuals, organizations, and companies is needed to fulfil the congressional mandate in Section 101 of the SECURE Technologies Act regarding a Vulnerability Disclosure Policy. In addition, without the ability to collect information on newly discovered security vulnerabilities in DHS information systems, the DHS will rely solely on the internal security personnel and or discovery through post occurrence of such a breach on security controls.

The is new collection.

Analysis

Agency: The Department of Homeland Security, Officer of the Chief Information Security Officer.

Title: Vulnerability Discovery Program.

OMB Number: 1601—New.

Frequency: On Occasion.

Affected Public: Private Sector.

Number of Respondents: 3000.

Estimated Time Per Respondent: 3 Hours.

Total Burden Hours: 9000.

Dated: December 3, 2019.

Melissa Bruce,

Executive Director, Business Management Office.

[FR Doc. 2019–27127 Filed 12–20–19; 8:45 am]

BILLING CODE 9112–fl–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R8–ES–2019–N111; FXES11140000–189–FF08E00000]

Proposed Upper Santa Ana River Habitat Conservation Plan and Draft Environmental Impact Statement; San Bernardino County, CA; Correction

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice; correction.

SUMMARY: The U.S. Fish and Wildlife Service published a document in the December 9, 2019, **Federal Register** that announced the availability of a proposed habitat conservation plan (HCP) and a draft environmental impact statement for public comment. The subject heading of the document incorrectly referred to the ''Upper Santa Ana River Habitat Conservation Plan'' instead of the ''Upper Santa Ana River Wash Habitat Conservation Plan,'' which is the correct name of the HCP.

FOR FURTHER INFORMATION CONTACT: Karin Cleary-Rose, 760–322–2070.

SUPPLEMENTARY INFORMATION:

Correction

In notice document 2019–26478, appearing at 84 FR 67292 in the issue of Monday, December 9, 2019, make the following correction: On page 67292, the subject heading should read ''Proposed Upper Santa Ana River Wash Habitat Conservation Plan and Draft

Environmental Impact Statement; San Bernardino County, CA''.

Sara Prigan,

Federal Register Liaison.

[FR Doc. 2019–27673 Filed 12–20–19; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–HQ–IA–2019–0112; FXIA16710900000–201–FF09A30000]

Foreign Endangered Species; Marine Mammals; Receipt of Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of permit applications; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), invite the public to comment on applications to conduct certain activities with foreign species that are listed as endangered under the Endangered Species Act (ESA) and foreign or native species for which the Service has jurisdiction under the Marine Mammal Protection Act (MMPA). With some exceptions, the ESA and the MMPA prohibit activities with listed species unless Federal authorization is issued that allows such activities. The ESA and MMPA also require that we invite public comment before issuing permits for any activity otherwise prohibited by the ESA or MMPA with respect to any endangered species or marine mammals.

DATES: We must receive comments by January 22, 2020.

ADDRESSES: *Obtaining Documents:* The applications, application supporting materials, and any comments and other materials that we receive will be available for public inspection at *http://www.regulations.gov* in Docket No. FWS–HQ–IA–2019–0112.

Submitting Comments: When submitting comments, please specify the name of the applicant and the permit number at the beginning of your comment. You may submit comments by one of the following methods:

- *Internet: http://www.regulations.gov.* Search for and submit comments on Docket No. FWS–HQ–IA–2019–0112.
- *U.S. mail or hand-delivery:* Public Comments Processing, Attn: Docket No. FWS–HQ–IA–2019–0112; U.S. Fish and Wildlife Service Headquarters, MS: PERMA; 5275 Leesburg Pike; Falls Church, VA 22041–3803.

For more information, see Public Comment Procedures under **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Brenda Tapia, by phone at 703–358–2104, via email at *DMAFR@fws.gov,* or via the Federal Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION:

I. Public Comment Procedures

A. How do I comment on submitted applications?

We invite the public and local, State, Tribal, and Federal agencies to comment on these applications. Before issuing any of the requested permits, we will take into consideration any information that we receive during the public comment period.

You may submit your comments and materials by one of the methods in **ADDRESSES**. We will not consider comments sent by email or fax, or to an address not in **ADDRESSES**. We will not consider or include in our administrative record comments we receive after the close of the comment period (see **DATES**).

When submitting comments, please specify the name of the applicant and the permit number at the beginning of your comment. Provide sufficient information to allow us to authenticate any scientific or commercial data you include. The comments and recommendations that will be most useful and likely to influence agency decisions are: (1) Those supported by quantitative information or studies; and (2) those that include citations to, and analyses of, the applicable laws and regulations.

B. May I review comments submitted by others?

You may view and comment on others' public comments at *http://www.regulations.gov,* unless our allowing so would violate the Privacy Act (5 U.S.C. 552a) or Freedom of Information Act (5 U.S.C. 552).

C. Who will see my comments?

If you submit a comment at *http://www.regulations.gov,* your entire comment, including any personal identifying information, will be posted on the website. If you submit a hardcopy comment that includes personal identifying information, such as your address, phone number, or email address, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. Moreover, all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public disclosure in their entirety.

II. Background

To help us carry out our conservation responsibilities for affected species, and in consideration of section 10(c) of the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), and section 104(c) of the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 *et seq.*), we invite public comments on permit applications before final action is taken. With some exceptions, the ESA and MMPA prohibit certain activities with listed species unless Federal authorization is issued that allows such activities. Permits issued under section 10(a)(1)(A) of the ESA allow otherwise prohibited activities for scientific purposes or to enhance the propagation or survival of the affected species. Service regulations regarding prohibited activities with endangered species, captive-bred wildlife (CBW) registrations, and permits for any activity otherwise prohibited by the ESA with respect to any endangered species are available in title 50 of the Code of Federal Regulations in part 17. Service regulations regarding permits for any activity otherwise prohibited by the MMPA with respect to any marine mammals are available in title 50 of the Code of Federal Regulations in part 18. Concurrent with publishing this notice in the **Federal Register**, we are forwarding copies of the marine mammal applications to the Marine Mammal Commission and the Committee of Scientific Advisors for their review.

III. Permit Applications

We invite comments on the following applications.

A. Endangered Species

Applicant: Purdue University Fort Wayne, Fort Wayne, IN; Permit No. 57460D

The applicant requests authorization for a permit to import samples of wild green sea turtle (*Chelonia mydas*), loggerhead sea turtle (*Caretta caretta*), and Hawksbill sea turtle (*Eretmochelys imbricata*) for the purpose of scientific research. This notification is for a single import.

Applicant: The San Diego Zoo, San Diego, CA; Permit No. 49913D

The applicant requests authorization for a permit to export two male babirusa (*Babyrousa celebensis*) to Tierpark

Berlin, Berlin, Germany, for the purpose of enhancing the propagation or survival of the species. This notification is for a single export.

Applicant: Marc Papiernik, Romeoville, IL; Permit No. 34678D

The applicant requests a captive-bred wildlife (CBW) registration under 50 CFR 17.21(g) for Madagascar radiated tortoise (*Astrochelys radiata*), to enhance the propagation or survival of the species. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Christian Ryder, Greenwich, CT; Permit No. 52946D

The applicant requests a CBW registration under 50 CFR 17.21(g) for Grand Cayman blue iguana (*Cyclura lewisi*), to enhance the propagation or survival of the species. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Russell Johnson, Scottsdale, AZ; Permit No. 53009D

The applicant requests a CBW registration under 50 CFR 17.21(g) for Grand Cayman blue iguana (*Cyclura lewisi*), to enhance the propagation or survival of the species. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Ryan Combs, Peoria, AZ; Permit No. 59845D

The applicant requests a permit to import a sport-hunted trophy of one sport-hunted trophy of male bontebok (*Damaliscus pygargus pygargus*) culled from a captive herd maintained under the management program of the Republic of South Africa, for the purpose of enhancing the propagation or survival of the species.

B. Endangered Marine Mammals and Marine Mammals

Applicant: SeaWorld LLC d/b/a SeaWorld San Diego, San Diego, CA; Permit No. 16657D

The applicant requests a permit to import one female captive-bred Pacific walrus (*Odobenus rosmarus*) from Kamogawa Sea World, Chiba, Japan, for the purpose of public display. This notification is for a single import.

IV. Next Steps

After the comment period closes, we will make decisions regarding permit issuance. If we issue permits to any of the applicants listed in this notice, we will publish a notice in the **Federal Register**. You may locate the notice announcing the permit issuance by searching *http://www.regulations.gov* for the permit number listed above in this document. For example, to find information about the potential issuance of Permit No. 12345A, you would go to regulations.gov and search for ''12345A''.

V. Authority

We issue this notice under the authority of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*), and its implementing regulations, and the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), and its implementing regulations.

Brenda Tapia,

Program Analyst/Data Administrator, Branch of Permits, Division of Management Authority.

[FR Doc. 2019–27624 Filed 12–20–19; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Office of the Secretary

[20XD4523WC DWCFO0000.000000 DS68664000 DQ.QSO00.20WC0000]

Proposed Renewal of Information Collection: OMB Control Number 1084–0033, Private Rental Survey

AGENCY: Office of Acquisition and Property Management. Office of the Secretary, Interior.

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Office of Acquisition and Property Management, Office of the Secretary, Department of the Interior, has submitted an information collection request to the Office of Management and Budget (OMB) to continue the collection of information for the ''Private Rental Survey'' OMB Control No. 1084–0033. The information collection request (ICR) describes the nature of the information collection and the expected burden and cost.

DATES: OMB has up to 60 days to approve or disapprove the information collection request, but may respond after 30 days; therefore, public comments should be submitted to OMB by January 22, 2020, in order to be assured of consideration.

ADDRESSES: Submit comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for the Department of the Interior (1084–0033), by telefax at (202) 395–5806 or via email to *OIRA_submission@omb.eop.gov.* Also, please send a copy of your comments to Laura Walters, Quarters Rental Program Manager, Interior Business Center, 7301 W Mansfield Ave, MS D–2910, Denver, CO 80235, or fax 303–969–6336, or by email to *laura_a_walters@ibc.doi.gov.* Individuals providing comments should reference ''Private Rental Survey'' OMB Control No. 1084–0033.

FOR FURTHER INFORMATION CONTACT: To request more information on this information collection or to obtain a copy of the collection instrument, please write or call Laura Walters, Quarters Rental Program Manager, Interior Business Center, 7301 W Mansfield Ave, MS D–2910, Denver, CO 80235, or fax 303–969–6336, or by email to *laura_a_walters@ibc.doi.gov.* Individuals providing comments should reference ''Private Rental Survey'' OMB Control No. 1084–0033. To see a copy of the entire ICR submitted to OMB, go to: *http://www.reginfo.gov* and select Information Collection Review, Currently Under Review.

SUPPLEMENTARY INFORMATION:

I. Abstract

Office of Management and Budget (OMB) regulations at 5 CFR 1320, which implement the Paperwork Reduction Act of 1995 (Pub. L. 104–131), require that interested members of the public and affected parties have an opportunity to comment on information collection and recordkeeping activities. This notice identifies an information collection activity that the Office of Acquisition and Property Management has submitted to OMB for renewal.

Title 5 of the U.S. Code section 5911 authorizes Federal agencies to provide housing for Government employees under specified circumstances. In compliance with OMB Circular A–45 (Revised), Rental and Construction of Government Quarters, a review of private rental market housing rates is required at least once every 5 years to ensure that the rental, utility charges, and charges for related services to occupants of Government Furnished Housing (GFH) are comparable to corresponding charges in the private sector. To avoid unnecessary duplication and inconsistent rental rates, the Department of the Interior, Office of the Secretary, Interior Business Center (on behalf of the Office of Acquisition and Property Management), conducts housing surveys in support of employee housing management programs for the Departments of the Interior (DOI), Agriculture, Commerce, Homeland Security, Justice, Transportation, Health and Human Services, Veterans Affairs, and other

agencies. In this survey, two collection forms are used for rental unit data: OS–2000 covering ''Houses–Apartments–Mobile Homes,'' and OS–2001 covering ''Trailer Spaces.''

Respondents are typically property management companies or significant property owners in specific communities, and are contacted by email or telephone. They may provide the rental unit information requested in OS–2000 and OS–2001 verbally, update rental data collected during a previous survey, enhance/complete rental data gathered from published sources, or provide printouts/lists of rental units they manage.

This collection of information provides data that is essential for DOI and the other Federal agencies to manage GFH in accordance with the requirements of OMB Circular A–45 (Revised). If this information were not collected from the public, DOI and the other Federal agencies providing GFH would be required to use professional real estate appraisals of private market rental costs, again, in accordance with OMB Circular A–45, but at an increased cost to the taxpayer.

II. Data

(1) Title: Private Rental Survey.

OMB Control Number: 1084–0033.

Type of Review: Extension without change of a currently approved collection

Affected Entities: Businesses and other for-profit institutions.

Estimated annual number of unique respondents: 1,883

Obligation to Respond: Voluntary.

Estimated annual average number of responses (rental units): OS–2000: 3,180; OS–2001: 359; Total: 3,539.

Frequency of response: Once per respondent every fourth year. Three or four of 16 total survey regions are surveyed every year. Therefore a respondent or business may potentially be surveyed every fourth year, if exact same unit is surveyed again four years later. In addition, if an individual respondent or business is a significant rental property manager or rental property owner in the community, they may provide multiple responses in the same survey. Approximately 63% of respondents furnish more than one rental unit (OS–2000 and OS–2001). About 60% of respondents validate published data (tax records, advertisement, etc.), 30% update their previous survey data, and 10% furnish a new OS–2000 or OS–2001. Participation is optional.

(2) Annual reporting and recordkeeping burden:

Total annualized reporting per response: 6 minutes for OS–2000 and 4 minutes for OS–2001.

Total annualized reporting: 342 hours.

(3) Description of the need and use of the information: This information collection provides the data that enables DOI to determine open market rental costs for GFH. These rates in turn enable DOI to set GFH rental rates for other Federal agencies, as a shared federal service, in accordance with the requirements of OMB Circular A–45 (Revised). The information collection enables government employee rental rates to be established that comply with A–45 for several agencies cost-effectively.

(4) As required under 5 CFR 1320.8(d), a **Federal Register** notice soliciting comments on the information collection was published on May 5, 2016 (81 FR 27171). No comments were received. This notice provides the public with an additional 30 days in which to comment on the proposed information collection activity.

III. Request for Comments

The Department of the Interior invites comments on:

(a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) The accuracy of the agency's estimate of the burden of the collection and the validity of the methodology and assumptions used;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(d) Ways to minimize the burden of the collection of information on respondents, including through the use of appropriate automated, electronic, mechanical, or other collection techniques or other forms of information technology.

''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.

While you can ask us in your comment to withhold your personal information from public review, we cannot guarantee that we will be able to do so. 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 Office of Management and Budget control number.

Jeffrey Parrillo,

Departmental Information Collection Clearance Officer, Office of the Secretary, Department of the Interior.

[FR Doc. 2019–27617 Filed 12–20–19; 8:45 am]

BILLING CODE 4334–63–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. TA–201–75 (Modification)]

Crystalline Silicon Photovoltaic Cells, Whether or Not Partially or Fully Assembled into Other Products: Advice on the Probable Economic Effect of Certain Modifications to the Safeguard Measure

AGENCY: United States International Trade Commission.

ACTION: Notice of investigation.

SUMMARY: Following receipt on December 6, 2019, of a request from the United States Trade Representative (USTR), the Commission instituted Investigation No. TA–201–75 (Modification), *Crystalline Silicon Photovoltaic Cells, Whether or Not Partially or Fully Assembled Into Other Products: Advice on the Probable Economic Effect of Certain Modifications to the Safeguard Measure* under section 204(a)(4) of the Trade Act of 1974 (Trade Act) to advise the President of the probable economic effect on the domestic crystalline silicon photovoltaic (CSPV) cell and module manufacturing industry of modifying the safeguard measure on imports of CSPV products, as described in Proclamation 9693 of January 23, 2018.

DATES:

January 6, 2020: Deadline for filing written submissions.

January 13, 2020: Deadline for filing responses to written submissions.

FOR FURTHER INFORMATION CONTACT: Project Leader Dylan Carlson of the Office of Industries (202–205–3457 or *dylan.carlson@usitc.gov*) or Deputy Project Leader Lauren Gamache of the Office of Economics (202–205–3489 or *lauren.gamache@usitc.gov*) for information specific to this investigation. For information on the

legal aspects of this investigation, contact William Gearhart of the Commission's Office of the General Counsel (202–205–3091 or *william.gearhart@usitc.gov*). The media should contact Margaret O'Laughlin, Office of External Relations (202–205–1819 or *margaret.olaughlin@usitc.gov*). Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its website (*https://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.—On January 23, 2018, the President, pursuant to section 203 of the Trade Act (19 U.S.C. 2253), issued Proclamation 9693, imposing a safeguard measure on imports of CSPV products, in the form of (a) a tariff-rate quota (TRQ) on certain imports of solar cells not partially or fully assembled into other products and (b) an increase in duties on certain imports of modules. The proclamation was published in the **Federal Register** on January 25, 2018 (83 FR 3541). The measure took effect on February 7, 2018, for a period of four years, or through February 6, 2022. The President imposed the measure following receipt of a report from the Commission in November 2017 under section 202 of the Trade Act (19 U.S.C. 2252) that contained an affirmative determination, remedy recommendations, and certain additional findings (see Crystalline Silicon Photovoltaic Cells (Whether or not Partially or Fully Assembled into Other Products), investigation No. TA–201–75, USITC Publication 4739, November 2017).

Section 204(a)(4) of the Trade Act (19 U.S.C. 2254(a)(4)) requires the Commission, upon request of the President, to advise the President of its judgment as to the probable economic effect on the industry concerned of any reduction, modification, or termination of the action taken under section 203 of the Trade Act which is under consideration. In his letter of December 6, 2019, the USTR, under authority delegated by the President and pursuant to section 204(a)(4) of the Trade Act, requested that the Commission provide its advice regarding the probable economic effect on the domestic CSPV cell and module manufacturing industry of modifying the safeguard measure. Specifically, the USTR requested that the Commission analyze the effect of increasing the level of the tariff-rate quota applicable to imports of CSPV cells from the current 2.5 gigawatts (GW) to 4, 5, or 6 GW, without other changes to the remedy. As requested, the Commission will provide its report to the USTR by no later than 30 days from the date of the report currently being prepared by the Commission under section 204(a)(2) of the Trade Act (Investigation No. TA–201–75 (Monitoring), *Crystalline Silicon Photovoltaic Cells, Whether or Not Partially or Fully Assembled into Other Products: Monitoring Developments in the Domestic Industry*).

For further information concerning the conduct of this investigation and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 206, subparts A and F (19 CFR part 206).

Limited disclosure of confidential business information (CBI).—The Commission may include CBI in the report it sends to the President and to the USTR. Additionally, all information, including CBI, submitted in this investigation may be disclosed to and used by (i) the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel for cybersecurity purposes.

The Commission will not release information which the Commission considers to be confidential business information unless the party submitting the confidential business information had notice, at the time of submission, that such information would be released by the Commission, or such party subsequently consents to the release of the information. The Commission will not otherwise disclose any CBI in a manner that would reveal the operations of the firm supplying the information.

The Commission will not release CBI obtained in this investigation to representatives of other interested parties under an administrative protective order (APO). Interested parties who may have obtained CBI under the APO issued in the ongoing Investigation No. TA–201–75 (Monitoring), *Crystalline Silicon Photovoltaic Cells, Whether or Not Partially or Fully Assembled Into Other Products: Report on Monitoring of Developments in the Domestic Industry,* should be aware that they may not use CBI obtained under the APO in that monitoring investigation in this modification proceeding. Such use in this modification proceeding will likely constitute a breach of the APO that they signed in the monitoring investigation. Any person with questions should contact the Office of the Secretary at 202–205–2000.

Written submissions.—Interested parties are invited to file written submissions concerning this investigation with the Commission. The Commission requests, in particular, that domestic producers of CSPV cells and/or modules provide in their written submissions estimates and projections for their production, capacity, number of production workers, and exports of cells and modules separately in 2019, 2020, and 2021, as well as any information, estimates, or projections on the price or production cost per watt of U.S. manufactured cells. In addition, the Commission requests that domestic producers describe how modifications to the TRQ, as described in USTR's request letter, would affect current and future investments in U.S. cell and module manufacturing. Written submissions must not exceed twenty (20) pages of textual material, double-spaced and singled-sided, when printed on pages measuring 8.5 × 11 inches. All written submissions must be addressed to the Secretary, and should be received not later than 5:15 p.m., January 6, 2020.

Persons wishing to have a summary of their written submission included in the report should include a summary along with their written submission and should specifically identify the summary as being for this purpose. Summaries should not include CBI. The summaries will be published in an appendix to the report. The summary may not exceed 500 words and should be in MS Word format or a format that can be easily converted to MS Word. The summary will be published as provided if it meets these requirements and is germane to the subject matter of the investigation. The Commission will list the name of the organization furnishing the summary and will include a link to the Commission's Electronic Document Information System (EDIS) where the full written submission can be found. The summary and additional exhibits with relevant factual information will not count toward the 20-page limit of the full written submission.

Interested parties are also invited to file a response to written submissions

made by other interested parties. Such responses must not contain any new factual information, and must only address information and arguments in written submissions filed by other interested parties. Responses to written submissions must not exceed five (5) pages of textual material, double-spaced and singled-sided, when printed on pages measuring 8.5 x 11 inches. All responses to written submissions should be addressed to the Secretary, and must be received no later than 5:15 p.m., January 13, 2020.

All written submissions and subsequent responses must conform with the provisions of section 201.8 of the Commission's rules; any submissions that contain CBI must also conform with the requirements of section 201.6 of the Commission's rules. Any CBI that is provided may be included in the report that the Commission sends to the President and the U.S. Trade Representative. The Commission's *Handbook on E-Filing,* available on the Commission's website at *https://edis.usitc.gov,* elaborates upon the Commission's rules with respect to electronic filing. Persons with questions regarding electronic filing should contact the Office of the Secretary, Docket Services Division (202–205–1802).

Additional written submissions to the Commission, including requests pursuant to section 201.12 of the Commission's rules, will not be accepted unless good cause is shown for accepting such submissions, or unless the submission is pursuant to a specific request by a Commissioner or Commission staff.

Authority: This investigation is being conducted under the authority of section 204(a)(4) of the Trade Act of 1974; this notice is published pursuant to section 206.3 of the Commission's rules.

By order of the Commission.
Issued: December 18, 2019.

Lisa Barton,
Secretary to the Commission.

[FR Doc. 2019–27627 Filed 12–20–19; 8:45 am]
BILLING CODE 7020–02–P

DEPARTMENT OF LABOR

Office of Labor-Management Standards

Information Collection Request; comment request

ACTION: Notice.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA). Currently, the Office of Labor-Management Standards (OLMS) of the Department of Labor (Department) is soliciting comments concerning the proposed extension of the collection of information requirements implementing the Labor-Management Reporting and Disclosure Act of 1959, as amended (LMRDA). A copy of the proposed information collection request can be obtained by contacting the office listed below in the **ADDRESSES** section of this Notice.

DATES: Written comments must be submitted to the office using the method below by February 21, 2020.

ADDRESSES: Andrew R. Davis, Chief of the Division of Interpretations and Standards, Office of Labor-Management Standards, U.S. Department of Labor, 200 Constitution Avenue NW, Room N–5609, Washington, DC 20210, *olms-public@dol.gov,* (202) 693–0123 (this is not a toll-free number), (800) 877–8339 (TTY/TDD).

Please use only one method of transmission (submission via email to *olms-public@dol.gov*) to submit comments or to request a copy of this information collection and its supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden. You may also request a copy of this information collection and its supporting documentation by sending an email to *olms-public@dol.gov.*

SUPPLEMENTARY INFORMATION: This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Office of Labor-Management Standards (OLMS) of the Department of Labor (Department) is soliciting comments concerning the proposed extension of the collection of information requirements implementing the Labor-Management Reporting and Disclosure Act of 1959, as amended (LMRDA). In particular, the Department seeks to revise the existing ICR in order to ensure a fully comprehensive estimate of such burden associated with the LMRDA, by including the recordkeeping burden associated with union officer elections. See 29 U.S.C. 481. Under 29 U.S.C. 481, election officials designated in the constitution and bylaws or the secretary, if no other official is designated, shall preserve for one year the ballots and all other records pertaining to a labor organization's election of officers. Additionally, the revision is necessary in order to incorporate the reporting burden associated with the voluntary submission of collective bargaining agreements to OLMS pursuant to Labor Management Relations Act section 211(a) and Secretary's Order 4–2007. Finally, the revision is necessary due to electronic filing changes associated with the Forms LM–1, LM–3, LM–4, LM–10, LM–20, and LM–21. The Department proposes to remove the continuing hardship exemption for Form LM–3 and LM–4 filers, and also seeks to make mandatory electronic filing for labor organizations that file the Form LM–1, labor relations consultants that file the Form LM–20 and Form LM–21, and employers that file the Form LM–10.

I. *Background:* Congress enacted the Labor-Management Reporting and Disclosure Act of 1959, as amended (LMRDA), to provide for the disclosure of information on the financial transactions and administrative practices of labor organizations. The statute also provides, under certain circumstances, for reporting by labor organization officers and employees, employers, labor relations consultants, and surety companies. Section 208 of the LMRDA authorizes the Secretary to issue rules and regulations prescribing the form of the required reports. The reporting provisions were devised to implement a basic tenet of the LMRDA: the guarantee of democratic procedures and safeguards within labor organizations, which are designed to protect the basic rights of union members.

Pursuant to section 201 of the LMRDA, the Department established the initial Form LM–1 Labor Organization Information Report, as well as the annual financial disclosure reports: The Forms LM–2, LM–3, and LM–4. These reports detail the receipts, disbursements, assets, and liabilities of covered labor organizations during their previous fiscal year. The Form LM–2 is the most detailed report, for those labor organizations with $250,000 or more in total annual receipts. The Form LM–3 is available for those labor organizations with fewer than $250,000 in total annual receipts, and the Form LM–4 is available for those labor organizations

with fewer than $10,000 in total annual receipts.[1]

Section 205 of the LMRDA provides that the reports are public information. Filers submit the reports to the Department's Office of Labor-Management Standards (OLMS), pursuant to the OLMS Information Collection Request (ICR), OMB # 1245–0003 (Form LM–1, LM–2, LM–3, LM–4, Simplified Annual Report, LM–10, LM–15, LM–15A, LM–16, LM–20, LM–21, LM–30, and S–1). Currently, filers can submit the Forms LM–2, LM–3, LM–4, LM–10, LM–20, LM–21, and LM–30 electronically through the OLMS free and web-based Electronic Forms System (EFS). EFS does not rely on third-party software or require the purchase of digital signatures; instead, EFS is a secure, web-based system that uses electronic signatures, which the filing organization's two principal officers register for, along with the union, obtaining a personal identification number (PIN) each year.[2] Currently, Form LM–2, LM–3, and LM–4 filers must use EFS, with the Form LM–2 instructions providing a temporary hardship exemption, and the Form LM–3 and LM–4 instructions providing a temporary and continuing hardship exemption process. Form LM–10, LM–20, Form LM–21, and Form LM–30 filers can choose instead to print off the completed form, sign manually, and mail the form to OLMS.

In response to requests from union members, the media, members of Congress, and other interested parties for internet access to reports filed by unions under the LMRDA, OLMS developed a website (*www.unionreports.gov*) where individuals may now view union annual financial reports and conduct data searches, displaying the results in a number of preformatted listings, free of charge. OLMS can instantaneously post reports submitted via EFS. Reports submitted via mail must be scanned and then posted, with certain data manually entered.

[1] Pursuant to LMRDA Titles II and III, the Department also established eight other reporting and disclosure forms: the Form LM–10 Employer Report; Forms LM–15, 15–A, and 16 trusteeship reports; Form LM–20 Agreement and Activities Report; Form LM–21 Receipts and Disbursement Report; Form LM–30 Officer and Employee Report; and Form S–1 Surety Report.

[2] In May 2011, EFS first became available for LM–3 and LM–4 filers, and those unions with fiscal years ending after June 30, 2011 began to take advantage of electronic filing. Prior to this implementation of EFS, few Form LM–3 and LM–4 unions utilized EFS, since they would be required to purchase a digital signature. As stated, EFS is free of charge.

Authority

The legal authority for this notice is set forth in 35 U.S.C. 3506(c)(2), and sections 203 and 208 of the LMRDA, 29 U.S.C. 432, 438. Section 208 of the LMRDA provides that the Secretary of Labor shall have authority to issue, amend, and rescind rules and regulations prescribing the form and publication of reports required to be filed under Title II of the Act and such other reasonable rules and regulations as he may find necessary to prevent the circumvention or evasion of the reporting requirements. 29 U.S.C. 438. The Secretary has delegated his authority under the LMRDA to the Director of the Office of Labor-Management Standards and permits re-delegation of such authority. *See* Secretary's Order 8–2009, 74 FR 58835 (Nov. 13, 2009).

LMRDA Election Recordkeeping Requirements

In addition to the LMRDA's reporting and disclosure requirements, the Act requires covered labor organizations to hold periodic elections for their officers. See LMRDA section 401, 29 U.S.C. 481. Under 29 U.S.C. 481(e), election officials designated in the constitution and bylaws or the secretary, if no other official is designated, shall preserve for one year the ballots and all other records pertaining to the election. This provision advances Congress' goal of promoting union democracy by protecting employees' rights to choose their own representatives. The enactment of this Act was necessary to eliminate or prevent improper practices on the part of labor organizations, employers, labor relations consultants, and their officers and representatives which distorted and defeated the policies of the Labor Management Relations Act (LMRA), 1947, as amended, and the Railway Labor Act, as amended.

The revised ICR would provide an estimate for the burden associated with labor unions maintaining such union officer election records.

Voluntary Submission of Collective Bargaining Agreements

The Department maintains a collective bargaining agreement (CBA) file pursuant to Section 211(a) of the LMRA and Secretary's Order 4–2007, issued in May 2007. The authority for maintaining the Department of Labor's CBA file was transferred to OLMS from the Bureau of Labor Statistics (BLS), pursuant to Secretary's Order 4–2007. The CBA file has been maintained by the Department since 1947, pursuant to Section 211(a) of the LMRA, which directs the Department of Labor to collect these agreements ''for the guidance and information of interested representatives of employers, employees, and the general public.''

The revised ICR would provide an estimate for the burden associated with unions and employers submitting these CBAs to the Department.

Mandatory Electronic Filing of the Forms LM–1, LM–3, LM–4, LM–10, LM–20, and LM–21

The Department seeks to amend ICR 1245–0003, as well as the Forms LM–1, LM–10, LM–20 and LM–21 instructions, to require mandatory electronic filing of these reports, with a temporary hardship exemption process for the annual Forms LM–10 and LM–21 modeled after the existing one for the annual Form LM–2 filers, as well as modify the Form LM–3 and Form LM–4 hardship exemption process to eliminate the continuing hardship exemption process and correspond with that of the Form LM–2, which only permits temporary hardship exemption submissions, not continuing. The Department believes that reasonable changes must be made to the means by which the forms required under LMRDA Title II are filed. The most efficient way to provide meaningful access to this information by interested members of the public is to require that the reports filed by employers and labor relations consultants be filed in electronic form. This change will benefit the filers, employees, employers, union members, and the public, as well as the Department. Labor organizations of all sizes have generally accounted no difficulties in submitting the forms electronically, and Form LM–2 filers have filed electronically since 2005, with no continuing hardship exemption since 2017. Some consultants have also already filed electronically in 2019, with little difficulty.

The Department invites comments regarding any alternative procedures that might better address problems associated with mandatory electronic filing of the Forms LM–1, LM–3, LM–4, LM–10-, LM–20, and LM–21.

The mandatory Forms LM–1 and LM–20 e-filing, as well as the changes to the Forms LM–3 and LM–4, would begin immediately after the Department finalizes this ICR revision. Mandatory Form LM–21 and Form LM–10 e-filing, however, would begin for reports due in 2021.

While no other changes to any other forms covered by this ICR are contemplated at this time, the agency seeks comments on any aspect of this

information collection. The Department will use the comments as it seeks to revise and extend OMB authorization under the PRA for this information collection.

II. *Review Focus:* The Department is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- enhance the quality, utility and clarity of the information to be collected; and
- minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

III. *Current Actions:* The Department seeks to revise this information collection to provide for electronic filing. The information collected by OLMS is used by union members to help self-govern their unions, by workers making decisions regarding their collective bargaining rights, by the general public, and as research material for both outside researchers and within the Department. The information is also used to assist the Department and other government agencies in detecting improper practices on the part of labor organizations, their officers and/or representatives, and is used by Congress in oversight and legislative functions.

Burden Statement: The Department updated its ICR by providing estimates for the burden associated with the LMRDA Title IV election recordkeeping requirements and the voluntary CBA submission program. The Department also updated its estimates for LM report responses and total burden hours, as the Department revised its estimates based upon an average of the LM reports received over the most recent five-year period (FY14–18). See: *https://www.dol.gov/olms/regs/compliance/enforcement_data.htm.* The Department did not change the hourly burden estimates for Forms LM–1, LM–3, LM–4, LM–10, LM–20, and LM–21, due to the mandatory e-filing changes, since the changes will have little if any impact on filers. Form LM–3 and LM–4 filers submitted very few continuing hardship requests (just 33) in 2018, and just 1 so far in 2019, with all of them rejected by the Department. Further, electronic filing is already available for Form LM–10, LM–20, and LM–21 filers, and will become available shortly for Form LM–1 filers, and the Department expects such filers to adapt quickly to EFS, due to the ease of the system and convenience of e-filing. Indeed, many have already filed electronically.

The total burden for the Labor Organization and Auxiliary Reports information collection is summarized as follows:

Type of Review: Revision.

Agency: DOL–OLMS.

Title of Collection: Labor Organization and Auxiliary Reports.

OMB Control Number: 1245–0003.

Affected Public: Private Sector—businesses or other for-profits, farms, and not-for-profit institutions; and Individuals or Households.

Total Estimated Number of Responses: 35,297.

Total Estimated Annual Burden Hours: 4,644,849

Total Estimated Annual Other Costs Burden: $0.

Comments submitted in response to this notice will be summarized and/or included in the request for the Office of Management and Budget (OMB) approval of the information collection request; they will also become a matter of public record.

Dated: December 11, 2019.

Andrew R. Davis,

Chief of the Division of Interpretations and Standards, Office of Labor-Management Standards, U.S. Department of Labor.

[FR Doc. 2019–27578 Filed 12–20–19; 8:45 am]

BILLING CODE P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

Petition for Modification of Application of Existing Mandatory Safety Standard

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Notice.

SUMMARY: This notice is a summary of a petition for modification submitted to the Mine Safety and Health Administration (MSHA) by the parties listed below.

DATES: All comments on the petition must be received by MSHA's Office of Standards, Regulations, and Variances on or before January 22, 2020.

ADDRESSES: You may submit your comments, identified by ''docket number'' on the subject line, by any of the following methods:

1. *Email: zzMSHA-comments@dol.gov* Include the docket number of the petition in the subject line of the message.

2. *Facsimile:* 202–693–9441.

3. *Regular Mail or Hand Delivery:* MSHA, Office of Standards, Regulations, and Variances, 201 12th Street South, Suite 4E401, Arlington, Virginia 22202–5452, Attention: Sheila McConnell, Director, Office of Standards, Regulations, and Variances. Persons delivering documents are required to check in at the receptionist's desk in Suite 4E401. Individuals may inspect a copy of the petition and comments during normal business hours at the address listed above.

MSHA will consider only comments postmarked by the U.S. Postal Service or proof of delivery from another delivery service such as UPS or Federal Express on or before the deadline for comments.

FOR FURTHER INFORMATION CONTACT: Sheila McConnell, Office of Standards, Regulations, and Variances at 202–693–9440 (voice), *McConnell.Sheila.A@dol.gov* (email), or 202–693–9441 (facsimile). [These are not toll-free numbers.]

SUPPLEMENTARY INFORMATION: Section 101(c) of the Federal Mine Safety and Health Act of 1977 and Title 30 of the Code of Federal Regulations Part 44 govern the application, processing, and disposition of petitions for modification.

I. Background

Section 101(c) of the Federal Mine Safety and Health Act of 1977 (Mine Act) allows the mine operator or representative of miners to file a petition to modify the application of any mandatory safety standard to a coal or other mine if the Secretary of Labor (Secretary) determines that:

1. An alternative method of achieving the result of such standard exists which will at all times guarantee no less than the same measure of protection afforded the miners of such mine by such standard; or

2. The application of such standard to such mine will result in a diminution of safety to the miners in such mine.

In addition, the regulations at 30 CFR 44.10 and 44.11 establish the requirements for filing petitions for modification.

II. Petition for Modification

Docket Number: M–2019–057–C.

Petitioner: Marfork Coal Company, LLC, P.O. Box 457, Whitesville, WV 25209.

Mine: Black Eagle, MSHA I.D. No. 46–09550, located in Raleigh County, West Virginia.

Regulation Affected: 30 CFR 75.1700 (Oil and gas wells).

Modification Request: The petitioner requests a modification of the existing standard, 30 CFR 75.1700, as it relates to vertical oil and gas wells at the Black Eagle mine. The operator is petitioning in order to mine through existing wells as they are met.

The petitioner states that:

(1) The Black Eagle mine extracts coal from the Eagle coal seam. The Black Eagle mine operates one continuous miner section that produces coal 5 to 6 days per week.

(2) There are many vertical oil and gas wells which exist in the reserve area of the Black Eagle mine.

(3) The Black Eagle mine will employ the continuous mining room and pillar method of mining. It is expected that each vertical wellbore will only be mined through once in any seam.

The petitioner proposes the following alternative method:

(a) With respect to vertical mines, the petitioner proposes to modify 30 CFR 75.1700 to allow mining through vertical wellbores as encountered and whenever the safety barrier diameter is reduced to a distance less than the MSHA District Manager would approve pursuant to 30 CFR 75.1700 for plugged oil or gas wells penetrating the Eagle Coal Seam and other mineable coal seams.

(b) The petitioner proposes to use the following procedures when cleaning out and preparing oil and gas wells prior to plugging:

(1) A diligent effort will be made to clean the borehole to the original total depth. If this depth cannot be reached, and the depth of the well is less than 4,000 feet, the operator will clean the well from the surface to at least 200 feet below the lowest mineable coal seam's base. If the well depth is equal to or greater than 4,000 feet, the operator must clean out the well from the surface to at least 400 feet below the lowest mineable coal seam's base. The operator must remove all materials that are within the well, throughout the entire diameter of the well, and from wall to wall.

(2) Down-hole logs will be prepared by the operator for each well. The logs, which collect subsurface information for each well, will use the following data measurement tools: a caliper survey, a gamma log, a bond log, and a deviation survey for determining the top and bottom of the lowest mineable coalbed, potential hydrocarbon producing strata, and the location for the bridge plug. If approved by the MSHA District Manager, down-hole camera surveys may be approved used instead of down-hole logs. A journal will be maintained to describe the depth and nature of material(s) encountered, the drilling information, the length of the plug, casing(s) effected, and other information related to cleaning and sealing the well. This information will be kept for MSHA to inspect, should MSHA request it.

(3) When cleaning the well, a diligent effort will be made to remove all the casing in the well. Once it is cleaned and the casings are removed, the well must be plugged by pumping cement slurry and pressurizing to 200 psi. If the casing cannot be removed, the remaining casing which remains will be cut, milled, perforated, or ripped to facilitate removing remaining casings. Any remaining casing must be perforated or ripped to allow cement to be injected in order to fill in voids throughout the well. Remaining casings must be perforated or ripped a minimum of 5 feet from 10 feet below to 10 feet above the coal seam. Perforations or rips are required at intervals spaced close enough (at least every 50 feet) to permit expanding cement slurry to infiltrate the annulus between the casing and the well wall for a distance of at least 200 feet below the base of the lowest mineable coalbed, for wells less than 4,000 feet deep and 400 feet below the lowest mineable coal seam, up to 100 feet above the uppermost part of the coal seam. If it is not possible to remove the casing, the operator will contact the MSHA District Manager before continuing work. If the well cannot be cleaned or the casing cannot be removed, then the operator must prepare the well as described above (if the well is less than 4,000 feet in depth) from the surface to at least 200 feet below the base of the lowest mineable seam; if the seam well is 4,000 feet or greater, then it must be prepared from the surface to 400 feet below the lowest mineable coal seam, unless the MSHA District Manager requires cleaning out the well due to a greater depth. If the operator can show, to the satisfaction of the MSHA District Manager, that the well is sealed properly, then the operator will not be required to perforate or rip the casings. A casing bond log is required for each casing and tubing string in lieu of ripping or perforating strings.

(4) In the event that the cleaned-out well produces excessive gas, a mechanical bridge plug will be placed in the borehole in a competent stratum at least 200 feet below the base of the lowest mineable coalbed, but above the top of the uppermost hydrocarbon-producing stratum, unless the MSHA District Manager requires a larger distance. If it is not possible to set a mechanical bridge plug, an appropriately sized packer may be used in place of the mechanical bridge plug. The mine operator must provide the MSHA District Manager will any information on the geological formation of the strata and the well pressure. The mine operator must record what actions have been taken to plug the hydrocarbon producing strata.

(5) If the uppermost hydrocarbon-producing stratum is within 300 feet of the base of the lowest mineable coalbed, properly placed mechanical bridge plugs or a suitable brush plug, described in subparagraph (b)(4) above, will be used to isolate the hydrocarbon-producing stratum from the expanding cement plug. A minimum of 200 feet of expanding cement will be placed below the lowest mineable coalbed.

(c) After cleaning out the well, as specified above, the petitioner proposes to use the following procedures when plugging or replugging oil and gas wells to the surface:

(1) A cement plug will be set in the wellbore by pumping an expanding cement slurry down the well to create a plug that runs from at least 200 feet below the base of the coal seam that is being mined. The cement must be placed in the well under a pressure of at least 200 pounds per square inch. Portland cement or a light-weight cement mixture may be used to fill in the area from approximately 100 feet above the top of the lowest mineable coalbed to the surface.

(2) A small quantity of steel turnings, or other small magnetic particles, will be embedded in the top of the cement near the surface to serve as a permanent magnetic monument of the borehole.

(d) The petitioner proposes to use the following procedures when plugging oil or gas wells for subsequent use as degasification boreholes:

(1) A cement plug will be set in the wellbore by pumping an expanding cement slurry down the tubing to displace the gel and provide at least 200 feet of expanding cement (400 feet if the depth is 4,000 feet or greater) below the lowest mineable coalbed at a pressure of at least 200 pounds per square inch. The top of the expanding cement will extend upward at least 50 feet above the top of the coalbed being mined, unless the MSHA District Manager requires a greater distance.

(2) The operator must grout a suitable casing into the bedrock of the upper part of the degasification well in order to protect it.

(3) The operator must fit a wellhead to the top of the degasification casing, as required by the MSHA District Manager in the approved ventilation plan. This equipment can include check valves, shut-in valves, sampling ports,

flame arrestor equipment, and security fencing.

(4) The degasification well must be addressed in the approved ventilation plan, including periodic tests of methane levels and limits on the minimum methane concentrations extracted.

(5) Once an area of the coal mine is degassed by a sealed well or if the coal mine is abandoned, the operator must plug all degasification wells using the following procedures:

(i) The operator must insert a tube to the bottom of the well, or at least to 100 feet above the coal seam being mined; blockage must be removed to allow the tube to reach this depth.

(ii) The operator will set a cement plug in the well, pumping Portland cement or a lightweight cement mixture until the well is filled to the surface.

(iii) The operator must embed steel turnings or other small magnetic particles in the top of the cement near the surface as permanent magnetic monuments for the well. An alternative is a 4 inch or larger casing, set in cement, which extends 36 or more inches above the ground level with the API number engraved or welded on the casing.

(e) As an alternative procedure for preparing and plugging or replugging oil or gas wells that cannot be cleaned completely:

(1) The operator must drill a hole adjacent and parallel to the well, at least 200 feet deep, below the coal seam to be mined or at the lowest mineable coal seam (whichever is lower). The operator will locating remaining casings using geophysical sensing devices.

(2) If casings are detected then the operator must drill into the well from the parallel hole. Between 10 feet above to 10 feet below the coal seam, the operator must perforate or rip all casings every 5 feet. Beyond that distance, the operator must perforate or rip at every 50 feet from at least 200 feet below the base of the coal seam to be mined or the lowest mineable coal seam, whichever is lower, up to 100 feet above the seam that is being mined.

(3) The annulus between the degasification casing and the borehole wall will be cemented.

(4) If there is insufficient casings in the well to allow for (e)(3) to be completed, the operator must use a horizontal hydrolic fracturing technique to intercept the original well.

(5) The operator must prepare down-hole logs for each well consisting of a caliper survey, gamma log, a bond log, and a deviation survey for determining the diameters of the coal seam to be mined or the lowest mineable coal seam, whichever is lower.

(6) A journal must be maintained to describe the depth and nature of material encountered, the drilling information, length of plug, casing(s) effected, and other information related to cleaning and sealing the well. This information will be kept for MSHA to inspect, should MSHA request it.

(7) After the operator has plugged the well described in (e), the operator must plug the adjacent hole using Portland cement or a lightweight cement mixture.

(8) The operator must embed steel turnings or other small magnetic particles in the top of the cement near the surface as permanent magnetic monuments for the well. An alternative is a 4 inch or larger casing, set in cement, which extends 36 or more inches above the ground level with the API number engraved or welded on the casing.

(f) Once mining has been granted by the MSHA District Manager, the following procedures will take place:

(1) A conference may be requested by any of the following: The representative of the miners, a state agency, or the MSHA District Manager. The conference will be scheduled by the MSHA District Manager, to review, evaluate, and accommodate any abnormal or unusual circumstances that relate to the condition of the well or surrounding strata.

(2) The intersection of a well by the operator must be conducted on a shift approved by the MSHA District Manager. The operator must notify the MSHA District Manager and the miners' representative prior to the intersection so that representatives can be present.

(3) Drivage sites must be installed by the operator not more than 50 feet from the well, at the last open crosscut near the area to be mined to ensure intersection of the well. For longwall mining, distance markers will be installed on 5-foot centers 50 feet in advance of the well in the headgate entry and in the tailgate entry.

(4) Firefighting equipment, including fire extinguishers, rock dust, and sufficient fire hose to reach the working face area of the mining-through will be available when either the conventional or continuous mining method is used. The fire hose will be located in the last open crosscut of the entry or room. The operator will maintain the water line to be able to reach the farthest point of penetration on the section.

(5) Sufficient supplies of roof support and ventilation materials will be available and located at the last open crosscut. In addition, an emergency plug and/or plugs will be available in the immediate area of the mine-through.

(6) Equipment will be checked for permissibility and serviced on the shift prior to mining-through the well; water sprays, water pressures and water flow rates will be checked and any issues will be corrected.

(7) The methane monitor on the continuous mining machine will be calibrated on the shift prior to mining-through the well.

(8) When mining is in progress, tests for methane will be made with a hand-held methane detector at least every 10 minutes from the time that mining with the continuous mining machine is within 30 feet of the well until the well is intersected and immediately prior to mining through. During the actual cutting through process, no individual will be allowed on the return side until mining-through has been completed and the area has been examined and declared safe.

(9) The working place will be free from accumulations of coal dust and coal spillages, and rock dust will be placed on the roof, rib and floor within 20 feet of the face when mining through or near the well on the shift or shifts during which the cut-through will occur.

(10) When the wellbore is intersected, all equipment will be deenergized and the area thoroughly examined and determined safe before mining is resumed.

(11) After a well has been intersected and the working place determined safe, mining will continue inby the well at a sufficient distance to permit adequate ventilation around the area of the wellbore.

(12) When a torch is necessary for poorly cut or milled casings, no open flames will be permitted in the area until adequate ventilation has been established around the wellbore and methane levels of less than 1 percent are present in all areas affected by flames or sparks from the torch.

(13) Non-sparking (brass) tools will be used only to expose and examine cased wells. These tools will be located on the working section.

(14) No person will be permitted in the area of the mining-through operation except for those actually engaged in the operation, company personnel, representatives of the miners, personnel from MSHA, and personnel from the appropriate State agency.

(15) The operator must alert all personnel in the mine of a planned intersection of the well before going underground if it is to occur during the shift.

(16) The mining-through operation will be under the direct supervision of a certified official. Instructions concerning the mining-through operation will be issued only by the certified official in charge.

(17) If the mine operator cannot find the well or if the anticipated intersection is missed, the operator must cease mining to assess for hazardous conditions, notify the MSHA District Manager, and use reasonable methods of locating the well. If the well cannot be located, the mine operator must notify the MSHA District Manager to resolve issues before mining resumes.

(18) This modification does not affect the ability for MSHA representatives to interrupt or halt well intersection or to issue a withdrawal notice when deemed necessary. MSHA may issue a withdrawal of persons in the mine or a cessation of the well intersection verbally or by written order, including the basis for the order. The MSHA representative then needs to permit resumption for mining operations in the affected area to restart.

(19) If the well is not plugged to the depth of all mineable coal seams that have been identified in the core hole logs, then any coal seams below the lowest plug will remain subject to the barrier requirements dictated by 30 CFR 75.1700, if developed in the future.

(20) All involved miners will be trained on the contents of this petition prior to starting the process of plugging or re-plugging.

(21) Mechanical bridge plugs will utilize the best available technologies required or recognized by the state regulatory agency and/or the oil and gas industry.

(22) Within 30 days after the Proposed Decision and Order (PDO) becomes final, the operator will submit proposed revisions to be approved by the MSHA District Manager, as part of the 30 CFR 48 training plan. This will include initial and refresher training. The revisions are to include training on the above terms for all miners involved in well intersection prior to mining within 150 feet of the well which is to be mined through.

(23) The required person under 30 CFR 75.1501 Emergency Evacuations is responsible for emergencies relating to the intersection and this person will review intersection procedures before the intersection occurs.

(24) Within 30 days of when this PDO is finalized, the operator will submit a revised emergency evacuation and firefighting training program, required by 30 CFR 75.1502. The operator must revise the program to incorporate hazards and evacuation plans used for well intersection. All underground miners will be trained in the above plan revisions within 30 days of submittal.

(25) The petitioner asserts that the proposed alternative method will at all times guarantee no less than the same measure of protection from the potential hazards against which the existing standard for 30 CFR 75.1700 is intended to guard.

Sheila McConnell,

Director, Office of Standards, Regulations, and Variances.

[FR Doc. 2019–27574 Filed 12–20–19; 8:45 am]

BILLING CODE 4520–43–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2009–0042]

OSHA's Conflict of Interest and Disclosure Form; 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 the proposal to extend the Office of Management and Budget's (OMB) approval of the information collection requirements contained in the proposed Conflict of Interest (COI) and Disclosure Form, which will be used to determine whether or not a conflict of interest exists for a potential peer review panel member.

DATES: Comments must be submitted (postmarked, sent, or received) by February 21, 2020.

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, OSHA Docket No. OSHA–2009–0042, 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 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–2009–0042) for the Information Collection Request (ICR). All comments, including any personal information you provide, such as social security numbers and dates of birth, 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 above address. 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 below phone number to obtain a copy of the ICR.

FOR FURTHER INFORMATION CONTACT: Seleda Perryman 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 the 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 OSHA to 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).

OSHA conducts peer reviews of a draft product for quality by specialists in the field who were not involved in producing the draft. The selection of participants in a peer review is based on expertise, with due consideration of independence. The Office of Management and Budget published the Final Information Quality Bulletin for Peer Review on December 15, 2004. The Bulletin states ''. . . the agency must address reviewers' potential conflicts of interest (including those stemming from ties to regulated businesses and other stakeholders) and independence from the agency.'' The Bulletin requires agencies to adopt or adapt the committee selection policies employed by the National Academy of Sciences (NAS) when selecting peer reviewers who are not Government employees. To fulfill this requirement, OSHA has developed a Conflict of Interest (COI) and Disclosure Form, based on NAS' Conflict of Interest Disclosure form. This form will be used to determine whether or not a conflict exists for a potential peer review panel member.

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

There are no changes in burden hours from the previous Information Collection Request for obtaining the necessary background information and disclosure of conflict of interest information to ensure that invited experts are not compromised. There are no costs as discussed under Item 13 of the Supporting Statement.

Type of Review: Extension of a currently approved collection.

Title: OSHA's Conflict of Interest (COI) and Disclosure Form.

OMB Control Number: 1218–0255.

Affected Public: Individuals and Households.

Number of Respondents: 36.

Frequency of Responses: On occasion.

Total Responses: 36.

Average Time per Response: OSHA estimates it will take one-half hour (0.5) to complete the COI Short form, and one (1) hour to complete the COI Long form.

Estimated Total Burden Hours: 27.

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–2009–0042). 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, Principal 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 December 17, 2019.

Loren Sweatt,

Principal Deputy Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2019–27576 Filed 12–20–19; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF LABOR

Veterans' Employment and Training Service

Advisory Committee on Veterans' Employment, Training and Employer Outreach (ACVETEO): Meeting

ACTION: Notice of open meeting.

SUMMARY: This notice sets forth the schedule and proposed agenda of a forthcoming meeting of the ACVETEO. The ACVETEO will discuss the DOL core programs and services that assist veterans seeking employment and raise employer awareness as to the advantages of hiring veterans. There will be an opportunity for individuals or organizations to address the committee. Any individual or organization that wishes to do so should contact Mr. Gregory Green at 202–693–4734.

Individuals who will need accommodations for a disability in order to attend the meeting (*e.g.,* interpreting services, assistive listening devices, and/or materials in alternative format) should notify the Advisory Committee no later than Monday, January 6, 2020 by contacting Mr. Gregory Green at 202–693–4734. Requests made after this date will be reviewed, but availability of the requested accommodations cannot be guaranteed. The meeting site is accessible to individuals with disabilities. This Notice also describes the functions of the ACVETEO. Notice of this meeting is required under Section 10(a)(2) of the Federal Advisory

Committee Act. This document is intended to notify the general public.

DATES: Thursday, January 16, 2020 beginning at 9:00 a.m. and ending at approximately 11:30 a.m. (EST).

ADDRESSES: The meeting will take place at the U.S. Department of Labor, Frances Perkins Building, 200 Constitution Avenue NW, Washington, DC 20210, Conference Room N–4437 A, B & C. Members of the public are encouraged to arrive early to allow for security clearance into the Frances Perkins Building.

FOR FURTHER INFORMATION CONTACT: Mr. Gregory Green, Designated Federal Official for the ACVETEO, (202) 693–4734.

SUPPLEMENTARY INFORMATION:

Security Instructions: Meeting participants should use the visitor's entrance to access the Frances Perkins Building, one block north of Constitution Avenue at 3rd and C Streets, NW. For security purposes meeting participants must:

1. Present a valid photo ID to receive a visitor badge.
2. Know the name of the event being attended: The meeting event is the Advisory Committee on Veterans' Employment, Training and Employer Outreach (ACVETEO).
3. Visitor badges are issued by the security officer at the Visitor Entrance located at 3rd and C Streets NW. When receiving a visitor badge, the security officer will retain the visitor's photo ID until the visitor badge is returned to the security desk.
4. Laptops and other electronic devices may be inspected and logged for identification purposes.
5. Due to limited parking options, Metro's Judiciary Square station is the easiest way to access the Frances Perkins Building.

Notice of Intent to Attend the Meeting: All meeting participants should submit a notice of intent to attend by Friday, January 3, 2020, via email to Mr. Gregory Green at *green.gregory.b@dol.gov,* subject line ''January 2020 ACVETEO Meeting.''

The ACVETEO is a Congressionally mandated advisory committee authorized under Title 38, U.S. Code, Section 4110 and subject to the Federal Advisory Committee Act, 5 U.S.C. App. 2, as amended. The ACVETEO is responsible for: Assessing employment and training needs of veterans; determining the extent to which the programs and activities of the U.S. Department of Labor meet these needs; assisting to conduct outreach to employers seeking to hire veterans; making recommendations to the Secretary, through the Assistant Secretary for Veterans' Employment and Training Service, with respect to outreach activities and employment and training needs of veterans; and carrying out such other activities necessary to make required reports and recommendations. The ACVETEO meets at least quarterly.

Agenda

9:00 a.m. Welcome and remarks, Sam Shellenberger, Deputy Assistant Secretary, Veterans' Employment and Training Service
9:05 a.m. Introduction of John Lowry, Assistant Secretary, Veterans' Employment and Training Service
9:15 a.m. Administrative Business, Gregory Green, Designated Federal Official
9:20 a.m. Discussion on Fiscal Year 2019 Report Recommendations, Eric Eversole, Committee Chairman
10:00 a.m. Subcommittees discussion/development Fiscal Year 2020 work plan, Eric Eversole, Committee Chairman
11:00 a.m. Break
11:10 p.m. Public Forum, Gregory Green, Designated Federal Official
11:30 a.m. Adjourn

Signed in Washington, DC, this 12th day of December 2019.

Joseph Shellenberger,

Deputy Assistant Secretary, Veterans' Employment and Training Service.

[FR Doc. 2019–27565 Filed 12–20–19; 8:45 am]

BILLING CODE 4510–79–P

OFFICE OF MANAGEMENT AND BUDGET

Discount Rates for Cost-Effectiveness Analysis of Federal Programs

AGENCY: Office of Management and Budget

ACTION: Revisions to Appendix C of OMB Circular A–94.

SUMMARY: The Office of Management and Budget (OMB) revised Circular A–94 in 1992. With this action, OMB has revised the Circular and specified certain discount rates to be updated annually when the interest rate and inflation assumptions used to prepare the Budget of the United States Government were changed. These updated discount rates are found in Appendix C of the revised Circular and are to be used for cost-effectiveness analysis, including lease-purchase analysis, as specified in the revised Circular. These rates do not apply to regulatory analysis.

The revised Circular can be accessed at *https://www.whitehouse.gov/wp-content/uploads/2019/12/Appendix-C.pdf.*

DATES: The revised discount rates will be in effect through December 2020.

FOR FURTHER INFORMATION CONTACT: Rachel Hernández, Office of Economic Policy, Office of Management and Budget, (202) 395–3585.

Vance Ginn,

Associate Director for Economic Policy, Office of Management and Budget.

[FR Doc. 2019–27575 Filed 12–20–19; 8:45 am]

BILLING CODE 3110–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–293; NRC–2019–0247]

Holtec Decommissioning International, LLC; Pilgrim Nuclear Power Station

AGENCY: Nuclear Regulatory Commission.

ACTION: Exemption; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has issued exemptions in response to a request from the licensee regarding certain emergency planning (EP) requirements. The exemptions eliminate the requirements to maintain an offsite radiological emergency preparedness plan and reduce the scope of onsite EP activities at the Pilgrim Nuclear Power Station, based on the reduced risks of accidents that could result in an offsite radiological release at a decommissioning nuclear power reactor.

DATES: The exemption was issued on December 18, 2019.

ADDRESSES: Please refer to Docket ID NRC–2019–0247 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2019–0247. Address questions about NRC docket IDs in *Regulations.gov* to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov.* For technical questions, contact the individual 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

https://www.nrc.gov/reading-rm/adams.html. To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.

• 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: Scott P. Wall, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington DC 20555–0001; telephone: 301–415–2855, email: *Scott.Wall@nrc.gov.*

SUPPLEMENTARY INFORMATION: The text of the exemption is attached.

Dated at Rockville, Maryland, this 18th day of December, 2019.

For the Nuclear Regulatory Commission.

Scott P. Wall,

Senior Project Manager, Plant Licensing Branch III, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

Attachment—Exemption

NUCLEAR REGULATORY COMMISSION

Docket No. 50–293

Holtec Decommissioning International, LLC

Pilgrim Nuclear Power Station

Exemption

I. Background

By letter dated November 10, 2015 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML15328A053), Entergy Nuclear Operations, Inc. (ENOI) certified to the U.S. Nuclear Regulatory Commission (NRC) that it planned to permanently cease power operations at Pilgrim Nuclear Power Station (Pilgrim) no later than June 1, 2019. On May 31, 2019, ENOI permanently ceased power operations at Pilgrim. By letter dated June 10, 2019 (ADAMS Accession No. ML19161A033), ENOI certified to the NRC that the fuel was permanently removed from the Pilgrim reactor vessel and placed in the spent fuel pool (SFP) on June 9, 2019. Based on the docketing of these certifications for permanent cessation of operations and permanent removal of fuel from the reactor vessel, as specified in Title 10 of the *Code of Federal Regulations* (10 CFR) Section 50.82(a)(2), the 10 CFR part 50 license for Pilgrim no longer authorizes operation of the reactor or emplacement or retention of fuel into the reactor vessel. The facility is still authorized to possess and store irradiated (*i.e.,* spent) nuclear fuel. Spent fuel is currently stored onsite at the Pilgrim facility in the SFP and in a dry cask independent spent fuel storage installation (ISFSI).

Many of the accident scenarios postulated in the updated safety analysis reports (USARs) for operating power reactors involve failures or malfunctions of systems, which could affect the fuel in the reactor core and, in the most severe postulated accidents, would involve the release of large quantities of fission products. With the permanent cessation of power operations at Pilgrim and the permanent removal of the fuel from the reactor vessel, many accidents are no longer possible. The reactor, reactor coolant system, and supporting systems are no longer in operation and have no function related to the storage of the spent fuel. Therefore, emergency planning (EP) provisions for postulated accidents involving failure or malfunction of the reactor, reactor coolant system, or supporting systems are no longer applicable.

The EP requirements of 10 CFR 50.47, ''Emergency plans,'' and Appendix E to 10 CFR part 50, ''Emergency Planning and Preparedness for Production and Utilization Facilities,'' continue to apply to nuclear power reactors that have permanently ceased operation and have permanently removed all fuel from the reactor vessel. There are no explicit regulatory provisions distinguishing EP requirements for a power reactor that is permanently shut down and defueled from those for a reactor that is authorized to operate. To reduce or eliminate EP requirements that are no longer necessary due to the decommissioning status of the facility, the Pilgrim licensee must obtain exemptions from those EP regulations. Only then can the Pilgrim licensee modify the facility emergency plan to reflect the reduced risk associated with the permanently shutdown and defueled condition of Pilgrim.

II. Request/Action

By letter dated July 3, 2018 (ADAMS Accession No. ML18186A635), as supplemented by letters dated November 30 and December 4, 2018, and February 14 and February 18, 2019 (ADAMS Accession Nos. ML18338A205, ML18341A219, ML19050A298, and ML19056A260, respectively), ENOI requested exemptions from certain EP requirements in 10 CFR part 50 for Pilgrim. Specifically, ENOI requested exemptions from certain planning standards in 10 CFR 50.47(b) regarding onsite and offsite radiological emergency preparedness plans for nuclear power reactors; from certain requirements in 10 CFR 50.47(c)(2) that require establishment of plume exposure and ingestion pathway EP zones for nuclear power reactors; and from certain requirements in 10 CFR part 50, Appendix E, Section IV, which establish the elements that comprise the content of emergency plans. In the letters dated November 30 and December 4, 2018, and February 14 and February 18, 2019, ENOI provided supplemental information and responses to the NRC staff's requests for additional information concerning the proposed exemptions.

By letter dated November 16, 2018 (ADAMS Accession No. ML18320A031), ENOI, on behalf of itself and Entergy Nuclear Generation Company (ENGC) (to be known as Holtec Pilgrim, LLC), Holtec International (Holtec), and Holtec Decommissioning International, LLC (HDI, the licensee) (together, Applicants), requested that the NRC consent to: (1) The indirect transfer of control of Renewed Facility Operating License No. DPR–35 for Pilgrim, as well as the general license for the Pilgrim ISFSI (together, the Licenses), to Holtec; and (2) the direct transfer of ENOI's operating authority (*i.e.,* its authority to conduct licensed activities at Pilgrim) to HDI. In addition, the Applicants requested that the NRC approve a conforming administrative amendment to the Licenses to reflect the proposed direct transfer of the Licenses from ENOI to HDI; a planned name change for ENGC from ENGC to Holtec Pilgrim, LLC; and deletion of certain license conditions to reflect satisfaction and termination of all ENGC obligations after the license transfer and equity sale.

By Order dated August 22, 2019 (ADAMS Accession No. ML19170A265), the NRC staff approved the direct and indirect transfers requested in the November 16, 2018, application. Additionally, on August 22, 2019, HDI informed the NRC (ADAMS Accession No. ML19234A357) that:

HDI will assume responsibility for all ongoing NRC regulatory actions and reviews currently underway for Pilgrim Nuclear Power Station. HDI respectfully requests NRC continuation of these regulatory actions and reviews.

On August 26, 2019, ENOI informed the NRC that the license transfer transaction closed on August 26, 2019 (ADAMS Accession No. ML19239A037). On August 27, 2019 (ADAMS Accession

No. ML19235A050), the NRC staff issued Amendment No. 249 to reflect the license transfer. Accordingly, HDI is now the licensee for decommissioning operations at Pilgrim.

The information provided by the licensee included justifications for each exemption requested. The exemptions requested would eliminate the requirements to maintain formal offsite radiological emergency preparedness plans reviewed by the Federal Emergency Management Agency (FEMA) under the requirements of 44 CFR, ''Emergency Management and Assistance,'' part 350, ''Review and Approval of State and Local Radiological Emergency Plans and Preparedness,'' and would reduce the scope of onsite EP activities at Pilgrim. The licensee stated that the application of all the standards and requirements in 10 CFR 50.47(b), 10 CFR 50.47(c), and 10 CFR part 50, Appendix E is not needed for adequate emergency response capability, based on the substantially lower onsite and offsite radiological consequences of accidents still possible at the permanently shutdown and defueled facility, as compared to an operating facility. If offsite protective actions were needed for a highly unlikely beyond-design-basis accident that could challenge the safe storage of spent fuel at Pilgrim, provisions exist for offsite agencies to take protective actions using a comprehensive emergency management plan (CEMP) under the National Preparedness System to protect the health and safety of the public. A CEMP in this context, also referred to as an emergency operations plan, is addressed in FEMA's Comprehensive Preparedness Guide 101, ''Developing and Maintaining Emergency Operations Plans,'' which is publicly available at *http://www.fema.gov/pdf/about/divisions/npd/CPG_101_V2.pdf.* Comprehensive Preparedness Guide 101 is the foundation for State, territorial, Tribal, and local EP in the United States. It promotes a common understanding of the fundamentals of risk-informed planning and decision-making and helps planners at all levels of government in their efforts to develop and maintain viable, all-hazards, all-threats emergency plans. An emergency operations plan is flexible enough for use in all emergencies. It describes how people and property will be protected; details who is responsible for carrying out specific actions; identifies the personnel, equipment, facilities, supplies and other resources available; and outlines how all actions will be coordinated. A CEMP is often referred to as a synonym for ''all-hazards planning.''

III. Discussion

In accordance with 10 CFR 50.12, ''Specific exemptions,'' the Commission may, upon application by any interested person or upon its own initiative, grant exemptions from the requirements of 10 CFR part 50 when: (1) The exemptions are authorized by law, will not present an undue risk to public health and safety, and are consistent with the common defense and security; and (2) any of the special circumstances listed in 10 CFR 50.12(a)(2) are present. These special circumstances include, among other things, that the application of the regulation in the particular circumstances would not serve the underlying purpose of the rule or is not necessary to achieve the underlying purpose of the rule.

As noted previously, the EP regulations contained in 10 CFR 50.47(b) and Appendix E to 10 CFR part 50 apply to both operating and shutdown power reactors. The NRC has consistently acknowledged that the risk of an offsite radiological release at a power reactor that has permanently ceased operations and permanently removed fuel from the reactor vessel is significantly lower, and the types of possible accidents are significantly fewer, than at an operating power reactor. However, the EP regulations do not recognize that once a power reactor permanently ceases operation, the risk of a large radiological release from credible emergency accident scenarios is significantly reduced. The reduced risk for any significant offsite radiological release is based on two factors. One factor is the elimination of accidents applicable only to an operating power reactor, resulting in fewer credible accident scenarios. The second factor is the reduced short-lived radionuclide inventory and decay heat production due to radioactive decay. Due to the permanently defueled status of the reactor, no new spent fuel will be added to the SFP and the radionuclides in the current spent fuel will continue to decay as the spent fuel ages. The irradiated fuel will produce less heat due to radioactive decay, increasing the available time to mitigate a loss of water inventory from the SFP. The NRC's NUREG/CR–6451, ''A Safety and Regulatory Assessment of Generic BWR [Boiling Water Reactor] and PWR [Pressurized Water Reactor] Permanently Shutdown Nuclear Power Plants,'' dated August 1997 (ADAMS Accession No. ML082260098), and the NRC's NUREG–1738, ''Technical Study of Spent Fuel Pool Accident Risk at Decommissioning Nuclear Power Plants,'' dated February 2001 (ADAMS Accession No. ML010430066), confirmed that for permanently shutdown and defueled power reactors that are bounded by the assumptions and conditions in the report, the risk of offsite radiological release is significantly less than for an operating power reactor.

In the past, EP exemptions similar to those requested for Pilgrim, have been granted to permanently shutdown and defueled power reactor licensees. However, the exemptions did not relieve the licensees of all EP requirements. Rather, the exemptions allowed the licensees to modify their emergency plans commensurate with the credible site-specific risks that were consistent with a permanently shutdown and defueled status. Specifically, the NRC's approval of these prior exemptions was based on the licensee's demonstration that: (1) The radiological consequences of design-basis accidents would not exceed the limits of the U.S. Environmental Protection Agency (EPA) early phase Protective Action Guides (PAGs) of one roentgen equivalent man (rem) at the exclusion area boundary; and (2) in the highly unlikely event of a beyond-design-basis accident resulting in a loss of all modes of heat transfer from the fuel stored in the SFP, there is sufficient time to initiate appropriate mitigating actions, and if needed, for offsite authorities to implement offsite protective actions using a CEMP approach to protect the health and safety of the public.

With respect to design-basis accidents at Pilgrim, the licensee provided analysis demonstrating that 10 months following permanent cessation of power operations, the radiological consequences of the only remaining design-basis accident with potential for offsite radiological release (the fuel handling accident in the Auxiliary Building, where the SFP is located) will not exceed the limits of the EPA PAGs at the exclusion area boundary.

With respect to beyond-design-basis accidents at Pilgrim, the licensee analyzed a drain down of the SFP water that would effectively impede any decay heat removal. The analysis demonstrates that at 10 months after permanent cessation of power operations, there would be at least 10 hours after the assemblies have been uncovered until the limiting fuel assembly (for decay heat and adiabatic heatup analysis) reaches 900 degrees Celsius (°C), the temperature used to assess the potential onset of fission product release. The analysis conservatively assumed that

the heat up time starts when the SFP has been completely drained, although it is likely that site personnel will start to respond to an incident when drain down starts. The analysis also does not consider the period of time from the initiating event causing loss of SFP water inventory until cooling is lost.

The NRC staff reviewed the licensee's justification for the requested exemptions against the criteria in 10 CFR 50.12(a) and determined, as described below, that the criteria in 10 CFR 50.12(a) will be met, and that the exemptions should be granted 10 months after Pilgrim has permanently ceased power operations. An assessment of the licensee's EP exemptions is described in SECY–19–0078, ''Request by the Entergy Nuclear Operations, Inc. for Exemptions from Certain Emergency Planning Requirements for the Pilgrim Nuclear Power Station,'' dated August 9, 2019 (ADAMS Accession No. ML18347A717). The Commission approved the NRC staff's recommendation to grant the exemptions in the staff requirements memorandum to SECY–19–0078, dated November 4, 2019 (ADAMS Accession No. ML19308A034). Descriptions of the specific exemptions requested by the licensee and the NRC staff's basis for granting each exemption are provided in SECY–19–0078. The NRC staff's detailed review and technical basis for the approval of the specific EP exemptions requested by the licensee are provided in the NRC staff's safety evaluation dated December 18, 2019 (ADAMS Accession No. ML19142A043).

A. The Exemption Is Authorized by Law

The licensee has proposed exemptions from certain EP requirements in 10 CFR 50.47(b), 10 CFR 50.47(c)(2), and 10 CFR part 50, Appendix E, Section IV, that would allow the licensee to revise the Pilgrim Emergency Plan to reflect the permanently shutdown and defueled condition of the facility. As stated above, in accordance with 10 CFR 50.12, the Commission may, upon application by any interested person or upon its own initiative, grant exemptions from the requirements of 10 CFR part 50. The NRC staff has determined that granting of the licensee's proposed exemptions will not result in a violation of the Atomic Energy Act of 1954, as amended, or the NRC's regulations. Therefore, the exemptions are authorized by law.

B. The Exemption Presents No Undue Risk to Public Health and Safety

As stated previously, the licensee provided analyses that show that the radiological consequences of design-basis accidents will not exceed the limits of the EPA early phase PAGs at the exclusion area boundary. Therefore, formal offsite radiological emergency preparedness plans required under 10 CFR part 50 will no longer be needed for protection of the public beyond the exclusion area boundary, based on the radiological consequences of design-basis accidents still possible at Pilgrim 10 months after the plant has permanently ceased power operations.

Although highly unlikely, there is one postulated beyond-design-basis accident that might result in significant offsite radiological releases. However, NUREG–1738 confirms that the risk of beyond-design-basis accidents is greatly reduced at permanently shutdown and defueled reactors. The NRC staff's analyses in NUREG–1738 conclude that the event sequences important to risk at permanently shutdown and defueled power reactors are limited to large earthquakes and cask drop events. For EP assessments, this is an important difference relative to operating power reactors, where typically a large number of different sequences make significant contributions to risk. As described in NUREG–1738, relaxation of offsite EP requirements in 10 CFR part 50 a few months after shutdown resulted in only a small change in risk. The report further concludes that the change in risk due to relaxation of offsite EP requirements is small because the overall risk is low, and because even under current EP requirements for operating power reactors, EP was judged to have marginal impact on evacuation effectiveness in the severe earthquakes that dominate SFP risk. All other sequences including cask drops (for which offsite radiological emergency preparedness plans are expected to be more effective) are too low in likelihood to have a significant impact on risk.

Therefore, granting exemptions to eliminate the requirements of 10 CFR part 50 to maintain offsite radiological emergency preparedness plans and to reduce the scope of onsite EP activities will not present an undue risk to the public health and safety.

C. The Exemption Is Consistent With the Common Defense and Security

The requested exemptions by the licensee only involve EP requirements under 10 CFR part 50 and will allow the licensee to revise the Pilgrim Emergency Plan to reflect the permanently shutdown and defueled condition of the facility. Physical security measures at Pilgrim are not affected by the requested EP exemptions. The discontinuation of formal offsite radiological emergency preparedness plans and the reduction in scope of the onsite EP activities at Pilgrim will not adversely affect the licensee's ability to physically secure the site or protect special nuclear material. Therefore, the proposed exemptions are consistent with common defense and security.

D. Special Circumstances

Special circumstances, in accordance with 10 CFR 50.12(a)(2)(ii), are present whenever application of the regulation in the particular circumstances is not necessary to achieve the underlying purpose of the rule. The underlying purpose of 10 CFR 50.47(b), 10 CFR 50.47(c)(2), and 10 CFR part 50, Appendix E, Section IV, is to provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency, to establish plume exposure and ingestion pathway emergency planning zones for nuclear power plants, and to ensure that licensees maintain effective offsite and onsite radiological emergency preparedness plans. The standards and requirements in these regulations were developed by considering the risks associated with operation of a power reactor at its licensed full-power level. These risks include the potential for a reactor accident with offsite radiological dose consequences.

As discussed previously in Section III, because Pilgrim is permanently shut down and defueled, there will no longer be a risk of a significant offsite radiological release from a design-basis accident exceeding EPA early phase PAGs at the exclusion area boundary and the risk of a significant offsite radiological release from a beyond-design-basis accident is greatly reduced when compared to an operating power reactor. The NRC staff has confirmed the reduced risks at Pilgrim by comparing the generic risk assumptions in the analyses in NUREG–1738 to site-specific conditions at Pilgrim and determined that the risk values in NUREG–1738 bound the risks presented at Pilgrim. As indicated by the results of the research conducted for NUREG–1738, and more recently for NUREG–2161, ''Consequence Study of a Beyond-Design-Basis Earthquake Affecting the Spent Fuel Pool for a U.S. Mark I Boiling Water Reactor,'' dated September 2014 (ADAMS Accession No. ML14255A365), while other consequences can be extensive, accidents from SFPs with significant decay time have little potential to cause offsite early fatalities, even if the formal offsite radiological EP requirements were relaxed. The licensee's analysis of a beyond-design-basis accident

involving a complete loss of SFP water inventory, based on an adiabatic heatup analysis of the limiting fuel assembly for decay heat, shows that within 10 months after permanent cessation of power operations, the time for the limiting fuel assembly to reach 900 °C is 10 hours after the assemblies have been uncovered assuming a loss of all cooling means.

The only analyzed beyond-design-basis accident scenario that progresses to a condition where a significant offsite release might occur, involves the highly unlikely event where the SFP drains in such a way that all modes of cooling or heat transfer are assumed to be unavailable, which is referred to as an adiabatic heatup of the spent fuel. The licensee's analysis of this beyond-design-basis accident shows that within 10 months after permanent cessation of power operations, more than 10 hours would be available between the time the fuel is initially uncovered (at which time adiabatic heatup is conservatively assumed to begin), until the fuel cladding reaches a temperature of 900 °C, which is the temperature associated with rapid cladding oxidation and the potential for a significant radiological release. This analysis conservatively does not include the period of time from the initiating event causing a loss of SFP water inventory until all cooling means are lost.

The NRC staff has verified the licensee's analyses and its calculations. The analyses provide reasonable assurance that in granting the requested exemptions to the licensee, there is no design-basis accident that will result in an offsite radiological release exceeding the EPA early phase PAGs at the exclusion area boundary. In the highly unlikely event of a beyond-design-basis accident affecting the SFP that results in a complete loss of heat removal via all modes of heat transfer, there will be over 10 hours available before an offsite release might occur and, therefore, at least 10 hours to initiate appropriate mitigating actions to restore a means of heat removal to the spent fuel. If a radiological release were projected to occur under this highly unlikely scenario, a minimum of 10 hours is considered sufficient time for offsite authorities to implement protective actions using a CEMP approach to protect the health and safety of the public.

Exemptions from the offsite EP requirements in 10 CFR part 50 have previously been approved by the NRC when the site-specific analyses show that at least 10 hours is available following a loss of SFP coolant inventory with no air cooling (or other methods of removing decay heat) until cladding of the hottest fuel assembly reaches the rapid oxidation temperature. The NRC staff concluded in its previously granted exemptions, as it does with the licensee's requested EP exemptions, that if a minimum of 10 hours is available to initiate mitigative actions consistent with plant conditions, or if needed, for offsite authorities to implement protective actions using a CEMP approach, then formal offsite radiological emergency preparedness plans, required under 10 CFR part 50, are not necessary at permanently shutdown and defueled facilities.

Additionally, Pilgrim committed to maintaining SFP makeup strategies in its letters to the NRC dated November 30 and December 4, 2018, and February 14 and February 18, 2019. The multiple strategies for providing makeup to the SFP include: Using existing plant systems for inventory makeup; an internal strategy that relies on the fire protection system with redundant pumps (one diesel-driven and electric motor-driven); and onsite diesel fire truck that can take suction from the Cape Cod Bay. These strategies will continue to be required as License Condition 3.K, ''Mitigation Strategy License Condition,'' of Renewed Facility License No. DPR–35 for Pilgrim. Considering the very low probability of beyond-design-basis accidents affecting the SFP, these diverse strategies provide multiple methods to obtain additional makeup or spray to the SFP before the onset of any postulated offsite radiological release.

For all of the reasons stated above, the NRC staff finds that the licensee's requested exemptions meet the underlying purpose of all of the standards in 10 CFR 50.47(b), and requirements in 10 CFR 50.47(c)(2) and 10 CFR part 50, Appendix E, and satisfy the special circumstances provision in 10 CFR 50.12(a)(2)(ii) in view of the greatly reduced risk of offsite radiological consequences associated with the permanently shutdown and defueled state of the Pilgrim facility 10 months after the facility permanently ceases operation.

The NRC staff has concluded that the exemptions being granted by this action will maintain an acceptable level of emergency preparedness at Pilgrim and, if needed, that there is reasonable assurance that adequate offsite protective measures can and will be taken by State and local government agencies using a CEMP approach in the highly unlikely event of a radiological emergency at Pilgrim. Since the underlying purpose of the rules, as exempted, would continue to be achieved, even with the elimination of the requirements under 10 CFR part 50 to maintain formal offsite radiological emergency preparedness plans and the reduction in the scope of the onsite EP activities at Pilgrim, the special circumstances required by 10 CFR 50.12(a)(2)(ii) exist.

E. Environmental Considerations

In accordance with 10 CFR 51.31(a), the Commission has determined that the granting of this exemption will not have a significant effect on the quality of the human environment as discussed in the NRC staff's Finding of No Significant Impact and associated Environmental Assessment published in the **Federal Register** on December 18, 2019 (84 FR 69396).

IV. Conclusions

Accordingly, the Commission has determined that, pursuant to 10 CFR 50.12, the licensee's request for exemptions from certain EP requirements in 10 CFR 50.47(b), 10 CFR 50.47(c)(2), and 10 CFR part 50, Appendix E, Section IV, and as summarized in Enclosure 2 to SECY–19–0078, are authorized by law, will not present an undue risk to the public health and safety, and are consistent with the common defense and security. Also, special circumstances are present. Therefore, the Commission hereby grants the licensee's exemptions from certain EP requirements in 10 CFR 50.47(b), 10 CFR 50.47(c)(2), and 10 CFR part 50, Appendix E, Section IV, as discussed and evaluated in detail in the NRC staff's safety evaluation dated December 18, 2019. The exemptions are effective as of 10 months after permanent cessation of power operations.

Dated at Rockville, Maryland, this 18th day of December, 2019.

For the Nuclear Regulatory Commission.

Craig G. Erlanger,

Director, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2019–27658 Filed 12–20–19; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2019–0233]

Target set Identification and Development for Nuclear Power Plants

AGENCY: Nuclear Regulatory Commission.

ACTION: Regulatory guide; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing Revision 1 to Regulatory Guide (RG) 5.81, ''Target set Identification and Development for Nuclear Power Plants,'' as a final RG. RG 5.81 provides guidance the NRC considers acceptable for applicant or licensee analysis, development, documentation, and reevaluation of target set elements and target sets, including preventive operator actions that may be credited to prevent core damage (*e.g.,* non-localized fuel melting, and/or core destruction) or loss of spent fuel coolant and exposure of spent fuel. This revision of the guide (Revision 1) clarifies issues that have been identified through interactions with stakeholders and inspection activities since the original publication of the guide.

DATES: Revision 1 to RG 5.81 is available on December 23, 2019.

ADDRESSES: Revision 1 to RG 5.81 contains Official Use Only—Security Related Information (OUO–SRI). Therefore, this RG is being withheld from public disclosure, but is available to those affected licensees, stakeholders who have established a need to know and cleared stakeholders who have access authorization. For access to RG 5.81, contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Wesley Held, Office of Nuclear Security and Insident Response, U.S. Nuclear Regulatory Commission, telephone: 301–287–3591, email: *Wesley.Held@nrc.gov;* or Mekonen Bayssie,Office of Nuclear Regulatory Research; telephone: 301–415–1699, email: *Mekonen.Bayssie@nrc.gov.* Alternatively, you may make suggestions or comments on RG 5.81 via email to: *RegulatoryGuideDevelopmentBranch.Resource@nrc.gov.* Please do not include any potentially classified or sensitive information in your email.

SUPPLEMENTARY INFORMATION:

I. Discussion

The NRC is issuing a revision to an existing guide in the NRC's ''Regulatory Guide'' series. This series was developed to describe and make available to the public information regarding methods that are acceptable to the NRC staff for implementing specific parts of the agency's regulations, techniques that the NRC staff uses in evaluating specific issues or postulated events, and data that the NRC staff needs in its review of applications for permits and licenses.

Regulatory Guide 5.81 provides licensees with guidance on meeting the requirements described in section 73.55(f) of title 10 of the *Code of Federal Regulations* (10 CFR),''Target Sets.'' Specifically, it sets forth approaches that the NRC considers acceptable for use by applicants or licensees in analyzing, developing, documenting, and evaluating target set elements and target sets, including operator actions that may be credited to prevent core damage (*e.g.,* non-localized fuel melting, and/or core destruction) or loss of spent fuel coolant and exposure of spent fuel.

This revision of RG 5.81 (Revision 1) incorporates lessons learned from operating experience. Specifically, this revision clarifies issues that have been identified through interactions with stakeholders and inspection activities since the original publication of the guide.

II. Additional Information

Regulatory Guide 5.81 contains OUO–SRI information. Accordingly, this RG is being withheld from public disclosure. It will be made available to those affected licensees and stakeholders who have an established need-to-know for access to the RG. The NRC did not announce the availability of the draft RG for public comment because the guide contains OUO–SRI information. Nonetheless, the NRC is issuing this notice to inform the public of the issuance of this revision to the RG.

On August 14, 2018, the NRC issued a memorandum (ADAMS Accession No. ML19324F694) transmitting the draft regulatory guide for comment to stakeholders who have an established need-to-know for access to the document. The stakeholders' comment period closed on October, 15, 2018. The NRC received 20 comments from stakeholders. The comments and the associated agency responses to the publc comments contain OUO–SRI information and are not available to the public. These comment responses can be obtained by those licensees and stakeholders who have established a need-to-know for access to the regulatory guide. For access to RG 5.81 or the comments and comment resolution documment, contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section.

III. Congressional Review Act

This RG 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.

IV. Backfitting

This RG provides applicants or licensees with guidance to meet the requirements set forth in 10 CFR 73.55, ''Requirements for Physical Protection of Licensed Activities in Nuclear Power Reactors Against Radiological Sabotage.'' Issuance of this regulatory guide does not constitute backfitting as defined in 10 CFR 50.109, ''Backfitting,'' or affect issue finality of any approval issued under 10 CFR part 52, Licenses, Certificates, and Approvals for Nuclear Power Plants,'' because as explained in Section D., ''Implementation,'' of the regulatory guide, NRC staff does not intend to use the guidance in this regulatory guide to support NRC staff actions in a manner that would constitute backfitting. If, in the future, the NRC seeks to impose a position in this regulatory guidein a manner that constitutes backfitting or affects the issue finality for a Part 52 approval, then the NRC will address the backfitting provision in 10 CFR 50.109 or the applicable issue finality provision in Part 52 respectively.

Dated at Rockville, Maryland, this 17th day of December 2019.

For the Nuclear Regulatory Commission.

Thomas H. Boyce,

Chief, Regulatory Guidance and Generic Issues Branch, Division of Engineering, Office of Nuclear Regulatory Research.

[FR Doc. 2019–27606 Filed 12–20–19; 8:45 am]

BILLING CODE 7590–01–P

OFFICE OF PERSONNEL MANAGEMENT

President's Commission on White House Fellowships Advisory Committee: Closed Meeting

AGENCY: President's Commission on White House Fellowships, Office of Personnel Management.

ACTION: Notice of meeting.

SUMMARY: The President's Commission on White House Fellowships (PCWHF) was established by an Executive Order in 1964. The PCWHF is an advisory committee composed of Special Government Employees appointed by the President.

The meeting is closed.

Name of Committee: President's Commission on White House Fellowships Mid-Year Meeting.

Date: January 15–16, 2020.

Time: 8:00 a.m.–5:30 p.m.

Place Eisenhower Executive Office Building, 1650 Pennsylvania Ave. NW, Washington, DC 20502.

Agenda: The Commission holds a mid-year meeting to talk with current

Fellows on how their placements are going and discuss preparation for future events.

FOR FURTHER INFORMATION CONTACT: Elizabeth D. Pinkerton, 712 Jackson Place NW, Washington, DC 20503, Phone: 202–395–4522.

President's Commission on White House Fellowships.

Alexys Stanley,

Regulatory Affairs Analyst.

[FR Doc. 2019–27612 Filed 12–20–19; 8:45 am]

BILLING CODE 6325–38–P

OFFICE OF PERSONNEL MANAGEMENT

Federal Prevailing Rate Advisory Committee; Open Committee Meetings

AGENCY: Office of Personnel Management.

ACTION: Notice of Federal Prevailing Rate Advisory Committee meeting dates in 2020. According to the provisions of section 10 of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given that meetings of the Federal Prevailing Rate Advisory Committee will be held on—

Thursday, January 16, 2020
Thursday, February 20, 2020
Thursday, March 19, 2020
Thursday, April 16, 2020
Thursday, May 21, 2020
Thursday, June 18, 2020
Thursday, July 16, 2020
Thursday, August 20, 2020
Thursday, September 17, 2020
Thursday, October 15, 2020
Thursday, November 19, 2020
Thursday, December 17, 2020

The meetings will start at 10 a.m. and will be held in Room 5A06A, Office of Personnel Management Building, 1900 E Street NW, Washington, DC.

The Federal Prevailing Rate Advisory Committee is composed of a Chair, five representatives from labor unions holding exclusive bargaining rights for Federal prevailing rate employees, and five representatives from Federal agencies. Entitlement to membership on the Committee is provided for in 5 U.S.C. 5347.

The Committee's primary responsibility is to review the Prevailing Rate System and other matters pertinent to establishing prevailing rates under subchapter IV, chapter 53, 5 U.S.C., as amended, and from time to time advise the Office of Personnel Management.

These scheduled meetings are open to the public with both labor and management representatives attending. During the meetings either the labor members or the management members may caucus separately to devise strategy and formulate positions. Premature disclosure of the matters discussed in these caucuses would unacceptably impair the ability of the Committee to reach a consensus on the matters being considered and would disrupt substantially the disposition of its business. Therefore, these caucuses will be closed to the public because of a determination made by the Director of the Office of Personnel Management under the provisions of section 10(d) of the Federal Advisory Committee Act (Pub. L. 92–463) and 5 U.S.C. 552b(c)(9)(B). These caucuses may, depending on the issues involved, constitute a substantial portion of a meeting.

Annually, the Chair compiles a report of pay issues discussed and concluded recommendations. These reports are available to the public. Reports for calendar years 2008 to 2018 are posted at *www.opm.gov/FPRAC.* Previous reports are also available, upon written request to the Committee.

The public is invited to submit material in writing to the Chair on Federal Wage System pay matters felt to be deserving of the Committee's attention. Additional information on these meetings may be obtained by contacting the Committee at Office of Personnel Management, Federal Prevailing Rate Advisory Committee, Room 5H27, 1900 E Street NW, Washington, DC, 20415, (202) 606–2858.

Office of Personnel Management.

Alexys Stanley,

Regulatory Affairs Analyst.

[FR Doc. 2019–27613 Filed 12–20–19; 8:45 am]

BILLING CODE 6325–49–P

POSTAL REGULATORY COMMISSION

[Docket No. MC2020–73; Order No. 5354]

Transfer of Market Dominant Negotiated Service Agreement

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service request to transfer five negotiated service agreements from the market dominant product list in the Mail Classification Schedule to the competitive product list. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* January 3, 2020.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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I. Introduction
II. Commission Action
III. Ordering Paragraphs

I. Introduction

On December 13, 2019, the Postal Service filed a notice with the Commission pursuant to 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.,* requesting the transfer of five negotiated service agreements (NSAs) from the market dominant product list in the Mail Classification Schedule (MCS) to the competitive product list.[1] These five agreements include: Inbound Market Dominant Exprès Service Agreement 1, Inbound Market Dominant Registered Service Agreement 1, Inbound Market Dominant PRIME Tracked Service Agreement, Australian Postal Corporation (Australia Post)—United States Postal Service Bilateral Agreement, and Canada Post Corporation (Canada Post)—United States Postal Service Bilateral Agreement NSAs. Request at 1–2. In support of its Request, the Postal Service filed the following documents:

- Attachment 1—Statement of Supporting Justification;
- Attachment 2—Governors Resolution No. 19–5;
- Attachment 3—Draft MCS language;
- Attachment 4—Redacted copy of the most recent Inbound Market Dominant Exprès Service Agreement 1;
- Attachment 5—Redacted copy of the most recent Inbound Market Dominant Registered Service Agreement 1;
- Attachment 6—Redacted copy of the most recent Inbound Market Dominant PRIME Tracked Service Agreement;
- Attachment 7—Redacted copy of the most recent list of parties to the

[1] United States Postal Service Request to Transfer the Inbound Market Dominant Exprès Service Agreement 1, Inbound Market Dominant Registered Service Agreement 1, Inbound Market Dominant PRIME Tracked Service Agreement, Australian Postal Corporation—United States Postal Service Bilateral Agreement, and Canada Post Corporation—United States Postal Service Bilateral Agreement to the Competitive Product List, December 13, 2019, at 1–2 (Request).

Inbound Market Dominant Exprès Service Agreement 1, the Inbound Market Dominant Registered Service Agreement 1, and the Inbound Market Dominant PRIME Tracked Service Agreement;

- Attachment 8—Redacted copy of the Australia Post Bilateral Agreement;
- Attachment 9—Redacted copy of the Canada Post Bilateral Agreement; and
- Attachment 10—Application for non-public treatment.

The Postal Service asserts that these products fulfill all of the criteria for competitive products. *See id.* at 11–15. Specifically, the Postal Service states that ''the market power provisions of 39 U.S.C. [ ] 3642(b)(1) do not prevent the transfer'' of these products, that they satisfy the standards for competitive products under 39 U.S.C. 3633, and that the Request's content is sufficient, pursuant to 39 CFR 3020.31. *Id.*

The Postal Service states that transfer is appropriate for three primary reasons: ''[b]ecause (i) the Commission conditionally approved the removal of Inbound Letter Post small packets and bulky letters from the Inbound Letter Post product on the market dominant product list and the addition of the Inbound Letter Post Small Packets and Bulky Letters product to the competitive product list [in Docket No. MC2019–17], (ii) the items to which the services provided under the three PRIME agreements and Australia Post bilateral five agreements are applied are treated as E format items, and (iii) all of the inbound portions of the Canada Post bilateral that are currently included in the market dominant product list concern Inbound Letter Post Small Packets and Bulky Letters items.'' *Id.* at 8–9 (footnotes omitted). For these reasons, the Postal Service concludes that the Commission should transfer these products from the market dominant product list to the competitive product list. *Id.* at 15.

II. Commission Action

The Commission establishes Docket No. MC2020–73 to consider the Postal Service's proposals described in its Request. Interested persons may submit comments on whether the Request is consistent with the policies of 39 U.S.C. 3632, 3633, and 3642 and 39 CFR 3020.30 *et seq.* Comments are due by January 3, 2020.

The Request and related filings are available on the Commission's website (*http://www.prc.gov*). The Commission encourages interested persons to review the Request for further details.

The Commission appoints Anne C. O'Connor to serve as Public Representative in this proceeding.

III. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket No. MC2020–73 for consideration of the matters raised by the United States Postal Service Request to Transfer the Inbound Market Dominant Exprès Service Agreement 1, Inbound Market Dominant Registered Service Agreement 1, Inbound Market Dominant PRIME Tracked Service Agreement, Australian Postal Corporation—United States Postal Service Bilateral Agreement, and Canada Post Corporation—United States Postal Service Bilateral Agreement to the Competitive Product List, filed December 13, 2019.
2. Pursuant to 39 U.S.C. 505, Anne C. O'Connor is appointed to serve as an officer of the Commission (Public Representative) to represent the interests of the general public in this proceeding.
3. Comments by interested persons are due by January 3, 2020.
4. The Secretary shall arrange for publication of this Order in the **Federal Register**.

By the Commission.

Ruth Ann Abrams,

Acting Secretary.

[FR Doc. 2019–27605 Filed 12–20–19; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2020–77 and CP2020–76]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning negotiated service agreements. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* December 26, 2019.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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I. Introduction
II. Docketed Proceeding(s)

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the market dominant or the competitive product list, or the modification of an existing product currently appearing on the market dominant or the competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3007.301.[1]

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern market dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3010, and 39 CFR part 3020, subpart B. For request(s) that the Postal Service states concern competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s).:* MC2020–77 and CP2020–76; *Filing Title:* USPS Request to Add Priority Mail & First-Class Package Service Contract 139 to Competitive Product List and Notice of

[1] *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

Filing Materials Under Seal; *Filing Acceptance Date:* December 16, 2019; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3020.30 *et seq.,* and 39 CFR 3015.5; *Public Representative:* Christopher C. Mohr; *Comments Due:* December 26, 2019.

This Notice will be published in the **Federal Register**.

Ruth Ann Abrams,

Acting Secretary.

[FR Doc. 2019–27654 Filed 12–20–19; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL SERVICE

Product Change—First-Class Package Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* December 23, 2019.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 17, 2019, it filed with the Postal Regulatory Commission a *USPS Request to Add First-Class Package Service Contract 106 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2020–78, CP2020–77.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2019–27566 Filed 12–20–19; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* December 23, 2019.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 18, 2019, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Contract 586 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2020–79, CP2020–78.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2019–27677 Filed 12–20–19; 8:45 am]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87773; File No. SR–LTSE–2019–04]

Self-Regulatory Organizations; Long-Term Stock Exchange; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Dual Listing

December 17, 2019.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on December 5, 2019, Long-Term Stock Exchange (''LTSE'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

LTSE proposes to add two definitions to Rule 1.160 to clarify the meaning of two amended terms—LTSE-Primary-Listed Security and Non-LTSE-Primary-Listed Security—in the Rule 11 Series (Trading Rules) in the context of an exchange that provides for dually-listed securities.

The text of the proposed rule change is available at the Exchange's website at *https://longtermstockexchange.com/,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

II. Self-Regulatory Organization's Statement on the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The self-regulatory organization 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 on the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The rules of the Exchange provide for dual listings.[4] The concept of dual listing is not new. Companies have dually listed their securities on NYSE and Nasdaq,[5] and more recently, companies dual list their securities on a foreign and U.S. exchange.[6] One of the reasons a company may dual list is to commit to comply with a more stringent regulatory regime, such as an exchange's listing standards.[7] The Commission recently approved LTSE Rule 14.425, in which the Exchange enhanced its listing standards to require companies that list with the Exchange to adopt and publish a Long-Term Stakeholder Policy, a Long-Term Strategy Policy, a Long-Term

[4] *See* Rule 14.210 (Dually-Listed Securities).

[5] *See* Craig Karmin, *Nasdaq Draws 6 Dual Listings, Including H–P and Schwab,* **WALL ST. J.** (Jan. 13, 2004), *https://www.wsj.com/articles/SB107391401136003100.*

[6] Dual listing in the United States and a foreign jurisdiction allows a company to more easily reach a global set of investors and benefit from a multitude of trading venues. *See International Investing,* Sec. & Exch. Comm'n (Dec. 7, 2016), *available at https://www.sec.gov/reportspubs/investor-publications/investorpubsininvesthtm.html* (''Although most foreign stocks trade in the U.S. markets as ADRs, some foreign companies list their stock directly here as well as in their local market. For example, some Canadian stocks that are listed and trade on Canadian markets are also listed and trade directly in U.S. markets, rather than as ADRs. Some foreign companies list their securities in multiple markets, which may include U.S. markets.'').

[7] *See* Securities Exchange Act Release No. 50741 (Nov. 29, 2004), 69 FR 70296, 70298 (Dec. 3, 2004) (''Nasdaq believes issuers that become dually listed voluntarily undertake a second set of regulations and therefore demonstrate their commitment to regulatory excellence.''). *See generally* Cecilia Caglio, et al., *Going Public Abroad* 3 (DERA, Working Paper, Nov. 2013), *available at https://www.sec.gov/files/rsfi-wp2013-01.pdf* (''[G]oing public in a market with more stringent securities laws can also maximize proceeds by enabling the issuing firm to credibly commit to greater ongoing disclosure.'').

Compensation Policy, a Long-Term Board Policy and a Long-Term Investor Policy (collectively, ''Long-Term Policies'').[8]

Dually-Listed Securities as defined in the Exchange Rule 14.210 refers to securities that also are listed on another national securities exchange registered with the Commission under Section 6(a) of the Act. Inasmuch as Dually-Listed Securities, by virtue of already being listed on another national securities exchange are eligible to trade on each of the registered national securities exchanges under Unlisted Trading Privileges (''UTP''), the primary benefit to an issuer from such a dual listing flows from its commitment to adhere to the Exchange's differentiated listing standards, *e.g.,* the Long-Term Policies. The Long-Term Policies are intended to better enable companies to focus on long-term value creation, potentially enhancing opportunities for capital formation, including capital from long-term focused institutional investors and index funds that have established long-term focused mandates.

The decision to offer companies the option of dually listing is not aimed at displacing the role of the primary listing market in the opening and closing auctions. Indeed, the Commission recently noted the role of the primary listing market in working with the Nasdaq and NYSE to provide transparency on how a closing price would be determined if a systems or technical issue prevented normal exchange operations.[9] In that approval order, the Commission noted ''that the primary listing market's closing price for a security is relied upon by market participants for a variety of reasons, including, but not limited to, calculation of index values, calculation of the net asset value of mutual funds and exchange-traded products, and the price of derivatives that are based on the security.'' [10]

To maintain the status quo and ensure that dual listings do not interfere with the primary listing market in various market operations, including managing the opening and closing auctions as well as addressing intra-day auctions as a result of market pauses or halts, the Exchange proposes to amend the term ''LTSE-listed security'' as used throughout the Rule 11 Series to ''LTSE-Primary-Listed Security'' and define it in Rule 1.160 (Definitions) to mean ''a class of securities listed on the Exchange for which the Exchange is the primary listing market.'' Likewise, the Exchange proposes to amend the term ''non-LTSE-listed security'' as used throughout the Rule 11 Series to ''Non-LTSE-Primary-Listed Security'' and define it in Rule 1.160 to mean ''(i) any UTP Security; and (ii) any Dually-Listed Securities, as provided for in Rule 14.210, which are not LTSE-Primary-Listed Securities.'' [11] These proposed clarifications are already implemented in part in the supplementary material to Rule 14.210, which excludes the applicability of various provisions in Rule 11.282 (Regulatory Trading Halts) to Dually-Listed Securities where LTSE is not the primary listing market. In reviewing the Rule 11 Series, the Exchange observed that there are other provisions in the Rule 11 Series that would benefit from similar clarity in the context of dual listings. In particular, the provisions applicable to a Market Maker's request to withdraw quotations in a security and terminate its registration in a security as contained in Rules 11.152(c)(1) and (e)(3), and in Rule 11.153(a), pertain to activity for LTSE-Primary-Listed Securities and are proposed to be amended accordingly. Additionally, the provisions in Rule 11.190 describing the handling of market orders submitted before the open of the Regular Market Session are proposed to be amended in paragraphs (a)(2)(E)(ii) and (f)(1) to distinguish between the Auction process provided for in Rule 11.350, which applies to LTSE-Primary-Listed Securities, and the Opening Process provided for in Rule 11.231, which applies to Non-LTSE-Primary-Listed Securities.[12]

Although Supplementary Material .01 to Rule 14.210 states that the Exchange shall continue to honor the trade halt authority of the primary listing market under the CQ and CTA Plans or the UTP Plan, as applicable, the proposed rule change would amend Rule 11.281(a)(8) to use the new proposed definitions in place of the more generic LTSE-listed and non-LTSE-listed securities rule text. Similar amendments are proposed to Rule 11.282(a)(1) and (a)(4) with respect to Regulatory Trading Halts, with the latter addressing, in addition, American Depository Receipts (''ADRs'') that are LTSE-Primary-Listed Securities.

Rule 11.330 describes various data products to be offered by the Exchange, and the proposed rule change would amend paragraph (a)(1) to clarify that the Auction Information to be provided via the LTSE Web Platform pertains to LTSE-Primary-Listed Securities. Lastly, as previously noted above, Rule 11.350 governs how auctions are conducted on the Exchange. To clarify that these provisions apply to primary listed securities, the term ''LTSE-listed security'' is proposed to be replaced with ''LTSE-Primary-Listed Security'' in Rule 11.350 paragraphs (a)(1)(E)(i), (a)(10)–(13), (c)(2), (c)(2)(B), (c)(2)(D), (c)(2)(E), (c)(2)(F), (d)(2), (d)(2)(B), (d)(2)(D), (e), (e)(2)(C), (f), (f)(1)(A), (f)(2)(C)(iii), (f)(2)(E), (f)(3), (f)(3)(B)(ii), and Supplementary Material .02.

In creating these two new definitions, the Exchange desires to maintain the definitions in Rule 1.160 in alphabetical order. However, to maintain flexibility to add or delete defined terms in the future, the Exchange proposes to remove specific cross-references to defined terms throughout the rule book, while keeping the cross-references to Rule 1.160, more generally.[13] These proposed changes would remove the cross-reference to ''Rule 1.160(m)'' in Rule 14.202(h), and the 26 cross-references to ''Rule 1.160(qq)'' in Rules 14.207(b)(1)-(2), 14.501(c), and 14.505(k), and in the Supplementary Material to Rule 14.207.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[14] in general, and furthers the objectives of Section 6(b)(5) of the Act,[15] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanisms of a free and open market

[8] *See* Securities Exchange Act Release No. 86722 (Aug. 21, 2019), 84 FR 44952 (Aug. 27, 2019).

[9] *See* Securities Exchange Act Release No. 78014 (June 8, 2016), 81 FR 38755 (June 14, 2016).

[10] *Id.* at 38757. *See also Research Note: Equity Market Volatility on August 24, 2015,* Sec. & Exch. Comm'n (Dec. 2015), *available at https://www.sec.gov/marketstructure/research/equity_market_volatility.pdf* (discussing the impact of the opening and re-opening process at the primary listing market, noting that S&P Dow Jones Indices LLP (''S&P DJI'') generally uses prices from only the primary listing exchange for calculating index values, including the S&P 500 Index that provides the reference for triggering market-wide circuit breakers and the that the price of the opening cross on the primary listing exchange (if it occurs before 9:35) is used as a reference price for calculation of the first Limit Up-Limit Down price bands of a trading day).

[11] ''UTP Security'' is defined in Rule 1.160 as ''any security that is not listed on the Exchange, but is traded on the Exchange pursuant to unlisted trading privileges.'' ''Dually-Listed Securities,'' as provided for in Rule 14.210, means ''a class of securities that has been approved for listing on another national securities exchange registered with the Commission pursuant to Section 6(a) of the Act.''

[12] The proposed rule change also would amend the title of Rule 11.231.

[13] Very few of the definitions are cross-referenced to Rule 1.160, and even fewer are done at the paragraph or subparagraph level.

[14] 15 U.S.C. 78f.

[15] 15 U.S.C. 78f(b)(5).

and a national market system and, in general, to protect investors and the public interest. In this respect, the proposed rule change would help ensure that issuers, investors and the public more easily understand the meaning and operation of the Exchange's trading rules as applied to dually-listed securities.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the 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 prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, it has become effective pursuant to Section 19(b)(3)(A) of the Act [16] and Rule 19b–4(f)(6) thereunder.[17]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) [18] of the Act to determine whether the proposed rule change should be approved or disapproved.

[16] 15 U.S.C. 78s(b)(3)(A).

[17] 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 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.

[18] 15 U.S.C. 78s(b)(2)(B).

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–LTSE–2019–04 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–LTSE–2019–04. 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–LTSE–2019–04 and should be submitted on or before January 13, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2019–27588 Filed 12–20–19; 8:45 am]

BILLING CODE 8011–01–P

[19] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87771; File No. SR–ICEEU–2019–019]

Self-Regulatory Organizations; ICE Clear Europe Limited; Notice of Filing of Proposed Rule Change Relating to the ICE Clear Europe Collateral and Haircut Policy and Collateral and Haircut Procedures

December 17, 2019.

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 4, 2019, ICE Clear Europe Limited (''ICE Clear Europe'' or the ''Clearing House'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule changes described in Items I, II, and III below, which Items have been prepared primarily by ICE Clear Europe. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

ICE Clear Europe proposes to adopt a new Collateral and Haircut Policy (the ''Revised Policy'') to replace the existing Collateral and Haircut Policy (the ''Existing Policy'') and to adopt new Collateral and Haircut Procedures (the ''Collateral Procedures''). The revisions would not involve any changes to the ICE Clear Europe Clearing Rules or Procedures.[3]

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, ICE Clear Europe 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. ICE

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Capitalized terms used but not defined herein have the meanings specified in the ICE Clear Europe Clearing Rules (the ''Rules'').

Clear Europe has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

(a) Purpose

ICE Clear Europe is proposing to adopt the Revised Policy and new Collateral Procedures. Together, the Revised Policy and Collateral Procedures would supersede the Existing Policy, which would be retired. The new documents would provide certain clarifications and better separate policy-level documentation and implementation-level documentation, such that high-level policy details would be in the Revised Policy and supporting detail for the Revised Policy would be contained in the new Collateral Procedures. Accordingly, relevant parts of the Existing Policy would be split between the Revised Policy and the Collateral Procedures. The amendments also remove certain operational details in the Existing Policy which ICE Clear Europe has determined are not needed in the Revised Policy and Collateral Procedures. Nonetheless, ICE Clear Europe does not expect that the new documentation would itself result in material changes to its underlying haircut model, or to the eligible collateral, haircuts and concentration limitations that the Clearing House currently imposes.

Collateral and Haircut Policy

The Revised Policy would set out the Clearing House's overall approach to defining the types, amounts and composition of cash and non-cash collateral that ICE Clear Europe accepts from Clearing Members (''CMs'') to cover their guaranty fund and margin requirements (referred to generally as ''collateral''). The Revised Policy would set out the Clearing House overall goal of mitigating price risk it may face when liquidating collateral of a defaulting CM by: (i) Setting and enforcing a list of acceptable collateral (also referred to as ''Permitted Cover''); (ii) setting and applying risk-based haircuts to the value of the collateral (''Haircuts''); (iii) setting and enforcing concentration limits on the amount of collateral a CM may post, to provide diversification of the collateral pool (''Concentration Limits''); and (iv) ensuring Permitted Cover, Haircuts and Concentration Limits are aligned to the Clearing House's risk appetite and compliant with applicable legal and regulatory requirements.

The Revised Policy would set out overall requirements that Permitted Cover assets: (i) Are highly liquid with low credit and market risk; (ii) are priced in an Eligible Currency; and (iii) entail risks limited to those that ICE Clear Europe is able to identify, measure, monitor and mitigate. (The specific list of Permitted Cover would not be contained in the Revised Policy itself but would continue to be available on the ICE Clear Europe website.)

The Revised Policy would set overall requirements that Haircuts would be based on a model that includes: (i) The creditworthiness of the issuer; (ii) the asset's market risk and liquidity risk; and (iii) market conditions and volatility. Certain further details relating to Haircuts (including the determination of minimum haircuts) would be specified in the Collateral Procedures, or in related model documentation. The Revised Policy would also establish the general principal that wrong way risk (''WWR'') with respect to posting of collateral (*i.e.,* the risk that the value of a particular CM's collateral is likely to decline at the same time the Clearing House's risk to the CM increases) would be mitigated through member-specific restrictions and actions rather than Haircuts.

The Revised Policy would address the overall framework for setting CM Concentration Limits. It would provide that ICE Clear Europe may limit (i) the absolute amount of each type of collateral that CMs may lodge to minimize concentration and enable liquidity and (ii) the relative amount of each collateral type in a CM's collateral portfolio to prevent overexposure to price movements in individual asset classes. Collateral exceeding Concentration Limits would not count towards a CM's total margin requirements. As discussed below, details regarding collateral management, data and reporting and legal review of enforceability of collateral found in the Existing Policy would be split across the Revised Policy, Collateral Procedures, ICE Clear Europe Collateral and Haircut Schedule of Parameters and Reviews (the ''Parameters'') and the Model Documentation for the ICE Clear Europe Collateral Haircut Model (the ''Model''). Where details are included in other Clearing House policies, procedures and documentation, such as the Treasury & Banking Services Policy, Investment Management Policy, F&O Risk Policy, Document Governance Schedule and Risk Appetite Framework, to avoid duplication, they would not be covered in the Revised Policy.

The Revised Policy would describe overall arrangements for policy governance, reviews and exception handling. Pursuant to the Revised Policy, the document owner would be responsible for ensuring that it remains up-to-date and appropriately reviewed and would report material breaches and deviations to their Head of Department, the Chief Risk Officer and the Head of Compliance (or their delegates), who together would then consider further escalation to relevant senior executives, the Board and/or competent authorities. Exceptions to the Revised Policy would be approved in accordance with applicable governance processes.

Collateral and Haircut Procedures

The new Collateral Procedures would set out the application of the Revised Policy through describing the operational activities and related governance processes for Permitted Cover, Haircuts and Concentration Limits. Certain details contained in the Existing Policy have been incorporated in the Collateral Procedures, rather than the Revised Policy, as discussed herein.

Permitted Cover

The Collateral Procedures would provide more detail regarding requirements relating to Permitted Cover. These requirements are generally consistent with the Existing Policy, and ICE Clear Europe does not expect that the adoption of the new Collateral Procedures would result in a change in the list of Eligible Permitted Cover. The Collateral Procedures would apply the following general eligibility criteria to Permitted Cover:

- The assets must be highly liquid with an active sale or repurchase agreement market with a diverse group of buyers and sellers;
- The market for the assets must have sufficient price history to permit ICE Clear Europe to analyze the statistical returns of the assets;
- The assets must be capable of daily revaluation and must be quoted intraday by financial market news information providers;
- ICE Clear Europe must be capable of managing the assets operationally; and
- The assets must be in an Eligible Currency.

Where the asset is a financial instrument, generally the following additional criteria would apply:

- The asset must be a vanilla form of that instrument;
- The asset must have low credit risk and low market risk, based on ICE Clear Europe's internal assessment based on credit and bond yield and CDS spread relative to the maximum set by ICE Clear Europe and

• The asset must be freely transferable and without any regulatory or legal constraint or third party claims that impair liquidation;

• The asset must not be issued by a CM, or an affiliate of a CM; and

• The asset must not be issued by a central clearing counterparty or entity providing services critical to the functioning of ICE Clear Europe (unless it is a central bank in the European Economic Area or that issues a currency in which ICE Clear Europe has exposures).

Where the asset is gold, one of the following additional criteria would apply:

• It must be owned as allocated gold (where ICE Clear Europe directly holds an interest in specific bars of gold); or

• It must be owned as unallocated gold (where ICE Clear Europe holds an interest in a pool of gold bars) through a firm with low credit risk based on ICE Clear Europe's own assessment.

The eligibility criteria described above, combined with the description of the concentration limits, basis for haircuts and steps to mitigate price risk set out in the Revised Policy, are consistent with the general principles for accepting Permitted Cover set out in the Existing Policy, other than the sovereign rating model criteria. The sovereign rating model has been retired by ICE Clear Europe and instead, the Procedures and related Parameters address sovereign quality. The elements related to sovereign rating are the same in the Existing Policy and in the new Collateral Procedures and Parameters.

Consistent with current practice, letters of credit and bank guarantees would not be eligible as Permitted Cover. Certain additional details and parameters would be set out in an annex to the Procedure or in the List of Permitted Cover, which is an operational document that is published on the ice.com website.[4] Unlike the Existing Policy, the Collateral Procedures would not have a section specifically addressing restrictions on Guaranty Fund collateral as this is already be addressed in the Finance Procedures and List of Permitted Cover.

Haircuts

Pursuant to the proposed Collateral Procedures, ICE Clear Europe would continue to apply conservative haircuts to Permitted Cover to ensure that, even in stressed market conditions, the collateral could be liquidated at least at the value of the requirement it would be used to cover, and would also continue to apply cross-currency haircuts to mitigate foreign exchange risk where the currency applicable to the collateral would be different from the currency of the requirements it would be covering.

ICE Clear Europe would determine Haircuts using a combination of a model, analytical tools and/or qualitative overlays. The model would be described in the collateral and haircut model documentation and related parameters maintained by the Clearing House and be back-tested periodically. Consistent with the existing model, Haircuts would further be based on a number of factors, including, but not limited to:

• A credit assessment of the issuer;

• The maturity of the asset;

• Historical and current market conditions and volatility;

• Stressed market conditions, including both historical and forward looking (hypothetical) scenarios based on macroeconomic or political events;

• Expectations of future volatility;

• The liquidity of the underlying market, including bid/ask spreads; and

• Any other factors that may affect the liquidity or the value of the asset in stressed market conditions.

These factors are substantially the same as those set out in the Existing Policy, other than the wrong way risk factor, which is addressed through an operational report, and as noted above is addressed through CM-specific measures rather than Haircuts. The Haircuts would be subject to minimum values which would be addressed in the Parameters, instead of the Revised Policy or Collateral Procedures, and the final Haircut value would be rounded up to the nearest ''Haircut Rounding Interval''. Certain additional requirements relating to Haircuts on bonds and gold bullion, as well as collateral pricing, which are currently addressed in the Existing Policy, would be removed from the Existing Policy as they are already addressed, and will continue to be addressed, in the Model and the Parameters. Other aspects of the haircut calculation methodology would also move to the related collateral haircut model documentation. The list of data used in collateral pricing that is currently set out in the Existing Policy would instead be set out in the Parameters. The description of exceptions would be set out in Clearing House operational documentation.

Consistent with the Existing Policy, the Collateral Procedures would call for ICE Clear Europe to limit the likelihood of procyclical impact from Haircuts as issuer creditworthiness deteriorates and haircuts increase by:

• Applying a conservative minimum haircut level to all collateral types, regardless of issuer and tenor;

• Including stressed market conditions in the Haircuts;

• Pre-emptively identifying and incorporating potential future events into the Haircuts via the qualitative overlays and analytical tools; and

• Providing advance notice of changes in haircuts to CMs and competent authorities, where practicable.

Concentration Limits

The approach to Concentration Limits contained in the proposed Collateral Procedures would be substantially similar to the Existing Policy. However, certain details regarding the collateral breakdown report currently in the Existing Policy would not be included in the Collateral Procedures (as they are inconsistent with the level of detail in the Collateral Procedures generally) but would instead be set out in operational documentation. The report itself, which details how collateral values are produced at an operational level, will continue to be produced as part of the normal reporting cycle. As under current practice, ICE Clear Europe would be able to set Absolute Limits and Relative Limits.

With respect to the absolute amount of each type of collateral that can be accepted from a CM (''Absolute Limits''), the Collateral Procedures would set the framework for how this level is set. ICE Clear Europe would limit the absolute amount of each type of collateral such that if two CM groups were to default, ICE Clear Europe's total holdings of a particular type of collateral (across all of ICE Clear Europe's markets) could be liquidated with minimal impact on prices. As compared to the Existing Policy, the Collateral Procedures would clarify that all markets cleared by ICE Clear Europe would be included in the calculation methodology for Absolute Limits. The description of the Absolute Limits in the Collateral Procedures would otherwise generally be consistent with the description of the Absolute Limits set out in the Existing Policy, including the description of the calculation of Absolute Limits for bonds lodged as Permitted Cover.

The Absolute Limits would be set as a percentage of the Daily Traded Volume, which is an average market volume for each asset and converted from the reported currency to the currency of the asset (where required) using the previous end of day foreign exchange rate. The Absolute Limits could be adjusted based on certain

[4] Available at: *https://www.theice.com/publicdocs/clear_europe/list-of-permitted-covers.pdf.*

qualitative considerations and must be approved by senior management. Absolute Limits would be specified in the currency of the issuer, based on the market values of the collateral, and apply at a CM group level. Unlike the Existing Policy, the Collateral Procedures would not take into account ICE Clear Europe's committed repo facility as a basis for allowing Clearing Members to exceed otherwise applicable Absolute Limits.

With respect to the relative amount of each type of collateral within a CM's collateral portfolio (''Relative Limits''), the Collateral Procedures would describe the general framework for setting these limits, which would be set so that an individual CM's collateral portfolios would be balanced between different assets based on a qualitative assessment of the different types of collateral, taking into account factors such as the types of issuers, issuer credit risk and collateral liquidity and price volatility. The Relative Limits would be based on the post-haircut value of the collateral applied at the individual CM level.

Further Restrictions

Pursuant to the proposed Collateral Procedures, and consistent with current practice, ICE Clear Europe would apply additional restrictions and measures with respect to collateral as follows:

- Reducing Absolute Limits once the CDS spread of the issuer breaches pre-defined levels;
- analyzing CMs' non-cash collateral to identify WWR daily and where ICE Clear Europe identifies material WWR, requiring the CM to take mitigating actions, such as substituting the lodged Permitted Cover with alternative Permitted Cover; and
- not placing Concentration Limits on certain Permitted Cover because of the liquidity of the asset's market, its behavior under stress and wider risk management considerations.

The Collateral Procedures would address cross clearing house concentration limits consistently with the manner in which they are addressed in the Existing Policy

Data Management

Consistent with existing practice, the sources of data used for collateral valuation and for Haircuts and Concentration Limits would be approved and reviewed periodically at a senior level, though data could be excluded or corrected without senior approval to correct stale or incorrect prices where reliable updated values have been supplied or to exclude data in the observation period for the Absolute Limits credit risk percentage reduction if it is unduly volatile due to low trading volumes. The list of exclusions and corrections and related justifications would be reviewed periodically. ICE Clear Europe would monitor the end of day and intraday market data that it uses to value collateral against thresholds to ensure that the data is not 'stale', investigate breaches of these thresholds and take action to resolve them.

The existing F&O Risk Procedures covers all aspects of collateral requirements and collateral valuation (and provides for issuance of margin calls accordingly). Therefore data and reporting requirements for valuation purposes have been removed from the Revised Policy as the content is covered in the Intraday Shortfall section of the F&O Risk Procedures. In addition, the formula for collateral valuation is publicly available on the ICE Clear Europe website.[5] The scope of the collateral documentation is limited to setting collateral haircuts and limits, and monitoring them against market performance.

Daily Monitoring

Pursuant to the proposed Collateral Procedures, ICE Clear Europe would continue daily monitoring processes to ensure the eligibility of the list of Permitted Cover, to ensure the adequacy of Haircuts and to enforce the Concentration Limits. ICE Clear Europe would monitor: (i) Publically available sources for information affecting the eligibility of collateral on the list of Permitted Cover; (ii) the adequacy of its Haircuts daily, in near real time, by comparing each asset's price movement since the previous day to the Haircut for that asset; and (iii) collateral against the Concentration Limits, which, in the case of a breach, would require the collateral to be replaced with alternative Permitted Cover or allow ICE Clear Europe to call for additional margin. Certain provisions of the Existing Policy relating to intraday valuation of collateral and the description of collateral composition reporting would not be included in the Collateral Procedures, as the topic is already covered in the F&O Risk Procedures, which describe the valuation methodology of collateral and the related monitoring undertaken through the margin call process. The CDS Risk Procedures will be updated as part of the Policy and Procedures documentation review cycle to align with the F&O Risk Procedures with respect to this matter.

Certain details under Data and Reporting in the Existing Policy concerning the reports that are available to various stakeholders in the form of periodic Collateral Reports, will not be included in the Revised Policy or Collateral Procedures. In ICE Clear Europe's view, these reports have evolved since the adoption of the Existing Policy, and in order to facilitate their continued development ICE Clear Europe does not believe they should be specified in detail in Clearing House procedures. Internal tools instead would describe how the reports would be built in greater detail and may be adjusted over time, without affecting the Revised Policy or Collateral Procedures. The back testing of the haircut parameters currently set out in the Existing Policy would be instead set out in the Parameters (and the substance of those parameters is not proposed to be changed). The description of the Risk Committee collateral reporting would be governed through the Terms of Reference for committees instead of through the Revised Policy or Collateral Procedures (and is not otherwise proposed to be changed).

Governance

Governance relating to Permitted Cover, collateral and Haircuts would generally remain the same as in the Existing Policy, though the Collateral Procedures would add that competent authorities would be notified of any material breaches. Pursuant to the proposed Collateral Procedures, proposals to add, remove, change or set Permitted Cover, Haircuts or Concentration Limits would also reviewed at a senior level and existing levels would be reviewed at least monthly, but could also be reviewed and changed ad hoc if needed. Amendments would be published by circular in advance of taking effect (where practicable) to CMs and relevant competent authorities.

The governance requirements relating to reviews, breach management and exception handling would be the same as those under the Revised Policy.

Requirements under the Existing Policy relating to independent validation and policy review are covered in the Model Risk Governance Framework and Documentation Governance Schedule, and would not be addressed in the Revised Policy or Collateral Procedures.

Other Existing Policy Matters

A number of additional details currently set out in the Existing Policy

[5] Available at: *https://www.theice.com/clear-europe/treasury-and-banking.*

would be removed and addressed in documentation other than the Revised Policy or Collateral Procedures. Collateral management would be set out in the Treasury and Banking Services Policy and the Investment Management Procedures. The monitoring schedule would be set out in the Parameters. The description of the legal review of enforceability of collateral that was set out in the Existing Policy is generally considered to be business as usual work for the legal team and would no longer be covered through policies.

(b) Statutory Basis

ICE Clear Europe believes that the changes described herein are consistent with the requirements of Section 17A of the Act [6] and the regulations thereunder applicable to it. Section 17A(b)(3)(F) of the Act [7] in particular requires, among other things, that the rules of the clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions and, to the extent applicable, derivative agreements, contracts and transactions, to assure the safeguarding of securities and funds in the custody or control of the clearing agency or for which it is responsible and, in general, protect investors and the public interest. Through ensuring that liquidity risks associated with the collateral it collects are managed and minimized through clear policies and procedures, the amendments would promote ICE Clear Europe's ability to ensure prompt and accurate clearing and settlement of transactions in the event that it becomes necessary for ICE Clear Europe to use or liquidate collateral collected from CMs. As discussed above, ICE Clear Europe does not expect the amendments, as an initial matter, to change its list of Permitted Cover, Haircuts or Concentration Limits, but rather to clarify and simplify the policies and procedures under which such measures are currently determined and applied. Enhancing management of its collateral liquidation risks in this way also generally enhances the stability of the Clearing House and therefore ICE Clear Europe's ability to safeguard securities and funds in its custody and control and generally better protects investors and the public interest, within the meaning of Section 17A(b)(3)(F).

Rule 17Ad–22(e)(3)(i) [8] requires clearing agencies to maintain a sound risk management framework that identifies, measures, monitors and manages the range of risks that it faces. The new Revised Policy and Collateral Procedures (the ''Documents'') are intended to clearly describe the manner in which ICE Clear Europe mitigates collateral price and liquidation risk through setting acceptable Permitted Cover, Haircuts and Concentration Limits and monitoring these measures and managing any deviations or related issues. Further, in compliance with Rule 17 Ad–22(e)(5),[9] the Documents clearly describe (i) the manner in which ICE Clear Europe would set eligibility criteria for Permitted Cover to limit the assets it accepts as collateral to those with low liquidity and market risks, (ii) the basis on which it would set Haircuts and Concentration Limits to ensure that they are sufficiently conservative, and (iii) the requirement that Haircuts and Concentration Limits be reviewed at least monthly at a senior level.

Rule 17Ad–22(e)(2) [10] requires clearing agencies to establish reasonably designed policies and procedures to provide for governance arrangements that are clear and transparent and specify clear and direct lines of responsibility. To facilitate compliance with this requirement, the proposed Documents more clearly define the roles and responsibilities of the document owner, and their Head of Department, the Chief Risk Officer and the Head of Compliance. The Collateral Procedures also set out the role of senior personnel in reviewing Haircuts, Concentration Limits and Permitted Cover.

(B) Clearing Agency's Statement on Burden on Competition

ICE Clear Europe does not believe the proposed rule changes would have any impact, or impose any burden, on competition not necessary or appropriate in furtherance of the purpose of the Act. As an initial matter, ICE Clear Europe does not anticipate that the amendments would in themselves result in a change to the list of Permitted Cover or the Haircuts or Concentration Limits. Rather, the amendments are intended to clarify the documentation of the relevant policies and procedures that are currently in effect. The amendments apply to all Contracts and are intended to strengthen risk management relating to these products primarily through providing greater clarity. ICE Clear Europe does not believe the amendments would have any direct effect on Clearing Members, other market participants or the market for cleared products generally. As a result, ICE Clear Europe does not believe the amendments would materially affect the cost of, or access to, clearing. Therefore, ICE Clear Europe does not believe the proposed rule changes impose any burden on competition that is not appropriate in furtherance of the purposes of the Act.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments relating to the proposed rule changes have not been solicited or received. ICE Clear Europe will notify the Commission of any written comments received by ICE Clear Europe.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which

[6] 15 U.S.C. 78q–1.

[7] 15 U.S.C. 78q–1(b)(3)(F).

[8] 17 CFR 240.17 Ad–22(e)(3)(i). The rule states that: ''[e]ach covered clearing agency shall establish, implement, maintain and enforce written policies and procedures reasonably designed to, as applicable: (3) Maintain a sound risk management framework for comprehensively managing legal, credit, liquidity, operational, general business, investment, custody, and other risks that arise in or are borne by the covered clearing agency, which:

(i) Includes risk management policies, procedures, and systems designed to identify, measure, monitor, and manage the range of risks that arise in or are borne by the covered clearing agency, that are subject to review on a specified periodic basis and approved by the board of directors annually;''

[9] 17 CFR 240.17 Ad–22(e)(5). The rule states that: ''[e]ach covered clearing agency shall establish, implement, maintain and enforce written policies and procedures reasonably designed to, as applicable: (5) Limit the assets it accepts as collateral to those with low credit, liquidity, and market risks, and set and enforce appropriately conservative haircuts and concentration limits if the covered clearing agency requires collateral to manage its or its participants' credit exposure; and require a review of the sufficiency of its collateral haircuts and concentration limits to be performed not less than annually;''

[10] 17 CFR 240.17 Ad–22(e)(2). The rule states that ''[e]ach covered clearing agency shall establish, implement, maintain and enforce written policies and procedures reasonably designed to, as applicable: (2) Provide for governance arrangements that:

(i)Are clear and transparent

(ii) Clearly prioritize the safety and efficiency of the covered clearing agency;

(iii) Support the public interest requirements in Section 17A of the Act (15 U.S.C. 78q–1) applicable to clearing agencies, and the objectives of owners and participants;

(iv) Establish that the board of directors and senior management have appropriate experience and skills to discharge their duties and responsibilities;

(v) Specify clear and direct lines of responsibility; and

(vi) Consider the interests of participants' customers, securities issuers and holders, and other relevant stakeholders of the covered clearing agency.''''

the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove the proposed rule change or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

The proposal shall not take effect until all regulatory actions required with respect to the proposal are completed.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change, security-based swap submission or advance notice 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–ICEEU–2019–019 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–ICEEU–2019–019. 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 filings will also be available for inspection and copying at the principal office of ICE Clear Europe and on ICE Clear Europe's website athttps://*www.theice.com/clear-europe/regulation.*

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–ICEEU–2019–019 and should be submitted on or before January 13, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2019–27587 Filed 12–20–19; 8:45 am]

BILLING CODE 8011–01–P

[11] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87769; File No. SR-CboeBZX–2019–057]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Designation of a Longer Period for Commission Action on Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change To List and Trade Shares of the American Century Focused Dynamic Growth ETF and American Century Focused Large Cap Value ETF Under Currently Proposed Rule 14.11(k)

December 17, 2019.

On June 6, 2019, Cboe BZX Exchange, Inc. 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 list and trade shares of the American Century Focused Dynamic Growth ETF and American Century Focused Large Cap Value ETF under proposed Rule 14.11(k) (Managed Portfolio Shares). The proposed rule change was published for comment in the **Federal Register** on June 25, 2019.[3] On August 2, 2019, pursuant to Section 19(b)(2) of the Act,[4] the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.[5] On September 23, 2019, the Commission instituted proceedings under Section 19(b)(2)(B) of the Act[6] to determine whether to approve or disapprove the proposed rule change.[7] The Commission has received no comment letters on the proposed rule change.

Section 19(b)(2) of the Act[8] provides that, after initiating disapproval proceedings, the Commission shall issue an order approving or disapproving the proposed rule change not later than 180 days after the date of publication of notice of filing of the proposed rule change. The Commission, however, may extend the period for issuing an order approving or disapproving the proposed rule change by not more than 60 days if the Commission determines that a longer period is appropriate and publishes reasons for such determination. The proposed rule change was published for notice and comment in the **Federal Register** on June 25, 2019. December 22, 2019, is 180 days from that date, and February 20, 2020, is 240 days from that date.

The Commission finds it appropriate to designate a longer period within which to issue an order approving or disapproving the proposed rule change so that it has sufficient time to consider the proposed rule change. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[9] designates February 20, 2020, as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change (File Number SR–CboeBZX–2019–057).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[10]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2019–27586 Filed 12–20–19; 8:45 am]

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b-4.

[3] *See* Securities Exchange Act Release No. 86155 (June 19, 2019), 84 FR 29912.

[4] 15 U.S.C. 78s(b)(2).

[5] *See* Securities Exchange Act Release No. 86557, 84 FR 39024 (August 8, 2019). The Commission designated September 23, 2019, as the date by which the Commission shall approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change.

[6] 15 U.S.C. 78s(b)(2)(B).

[7] *See* Securities Exchange Act Release No. 87059, 84 FR 51215 (September 27, 2019).

[8] 15 U.S.C. 78s(b)(2).

[9] *Id.*

[10] 17 CFR 200.30–3(a)(31).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87775; File No. SR–NYSEArca–2019–81]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change To Establish Generic Listing Standards for Derivative Securities Products That Are Permitted To Operate in Reliance on Rule 6c–11 Under the Investment Company Act of 1940

December 17, 2019.

On November 1, 2019, NYSE Arca, Inc. 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, among other things, establish generic listing standards for Exchange-Traded Fund Shares that are permitted to operate in reliance on Rule 6c-11 under the Investment Company Act of 1940. The proposed rule change was published for comment in the **Federal Register** on November 20, 2019.[3] The Commission has received no comment letters on the proposed rule change.

Section 19(b)(2) of the Act [4] provides that within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding, or as to which the self-regulatory organization consents, the Commission will either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is January 4, 2020. The Commission is extending this 45-day time period.

The Commission finds it appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[5] designates February 18, 2020 as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change (File No. SR–NYSEArca–2019–81).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[6]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2019–27590 Filed 12–20–19; 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. 87542 (Nov. 14, 2019), 84 FR 64170.

[4] 15 U.S.C. 78s(b)(2).

[5] *Id.*

[6] 17 CFR 200.30–3(a)(31).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87778; File No. SR–NASDAQ–2019–098]

Self-Regulatory Organizations; The Nasdaq Stock Market, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Relocate Rules From Its Current Rulebook Into Its New Rulebook Shell

December 17, 2019.

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 6, 2019, The Nasdaq Stock Market LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I 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 relocate rules from its current Rulebook into its new Rulebook shell.

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

The purpose of this rule change is to relocate Nasdaq rules, including The Nasdaq Stock Market LLC (''NOM''), into the new Rulebook shell with some amendments to the shell.[3] Nasdaq ISE, LLC (''ISE''), Nasdaq GEMX, LLC (''GEMX'') and Nasdaq MRX, LLC (''MRX'') recently relocated their rules.[4] NOM proposes to relocate its rules to align with the ISE, GEMX, MRX and BX Rulebooks. Phlx will also relocate its Rulebook in order to harmonize its rule structure, where applicable, across Nasdaq markets. The relocation and harmonization of the Nasdaq Rule structure is part of the Exchange's continued effort to promote efficiency and structural conformity of its rules with those of its Affiliated Exchanges. The Exchange believes that the placement of the Nasdaq Rules into their new location in the shell will facilitate the use of the Rulebook by Members and Members of Affiliated Exchanges.

The Exchange notes that the entire Rulebook is not being relocated at this time. Specifically, the Equity Rules are not being relocated.

The Exchange proposes to update all cross-references within the Rule to the new relocated rule cites and also proposes to correct certain citations. The Exchange proposes to replace internal rule references to simply state ''this Rule'' where the rule is citing itself without a more specific cite included in the Rule. For example, if NOM Chapter VI, Section 3 refers currently to

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Previously, the Exchange added a shell structure to its Rulebook with the purpose of improving efficiency and readability and to align its rules closer to those of its five sister exchanges, The Nasdaq Stock Market LLC; Nasdaq PHLX LLC; Nasdaq ISE, LLC (''ISE''); Nasdaq GEMX, LLC; and Nasdaq MRX, LLC (''Affiliated Exchanges''). The shell structure currently contains eight (8) General sections which, once complete, will apply a common set of rules to the Affiliated Exchanges. The shell structure currently contains eight (8) Chapters which, once complete, will apply a common set of rules to the Affiliated Exchanges. *See* Securities Exchange Act Release No. 82174 (November 29, 2017), 82 FR 57492 (December 5, 2017) (SR–NOM–2017–054).

[4] *See* Securities Exchange Act Release Nos. 86138 (June 24, 2019), 84 FR 29567 (June 18, 2019) (SR–ISE–2019–17); 86346 (July 10, 2019) 84 FR 33999 (July 16, 2019) (SR–GEMX–2019–08); and 86424 (July 22, 2019), 84 FR 36134 (July 22, 2019) (SR–MRX–2019–15). SR–BX–2019–36 was filed on October 1, 2019.

''Chapter VI, Section 3'' the Exchange will amend the phrase to simply ''this Rule.'' The Exchange proposes to conform numbering and lettering in certain rules to the remainder of the Rulebook. The Exchange proposes to reflect the use of the General Equity and Options Rules in place of Equity Rules, where applicable. Finally, the Exchange proposes to delete any current Rules that are reserved in the Rulebook.

General 1

The Exchange proposes to relocate and alphabetize rule text from Rule 0111, ''Adoption of Rules'', Rule 0112, ''Effective Date'', Rule 0113 ''Interpretation'', Rule 0120 ''Definitions,'' and certain definitions from Rule 0121, ''Definitions in Nasdaq By-Laws'' into General 1. The Exchange proposes to relocate certain definitions from Chapter VI, Section 1 into General 1.[5] The Exchange proposes to delete certain definitions which are repetitive.[6] The Exchange will also alphabetize the definitions within General 1 and conform the text where applicable. Definitions related to the equities rules[7] will be relocated into Equity 1. The Exchange is conforming the format of all definitions. Finally, the Exchange notes that the description of ''MarketWatch'' was amended to remove the phrase ''a unit of Nasdaq Regulation.''

General 2

General 2 would be comprised of the following rules:

Proposed new rule No.	Current rule No.
Section 1	Reserved.
Section 2	Chapter VI, Section 16, Fees, Dues and Other Charges.
Section 3	Reserved.
Section 4	2130, Nasdaq Ownership Restriction (re-title as Limitation on Affiliation between the Exchange and Members).
Section 5	0130, Regulation of the Exchange and Its Members.
Section 6	0115, Applicability.
Section 7	0150, Regulatory Independence.
Section 8	Reserved.
Section 9	1130, Reliance on Current Membership List.
Section 10	1150, Executive Representative.
Section 11	1160. Contact Information Requirements.
Section 12	1170, Nasdaq's Business Continuity and Disaster Recovery Plan Testing Requirements for Members and Options Participants Pursuant to Regulation SCI (re-title as ''Business Continuity and Disaster Recovery'').
Section 13	0140, Fingerprint-Based Background Checks of Employees and Independent Contractors.
Section 14	2160, Restrictions on Affiliation.
Section 15	3510, Business Continuity Plans.
Section 16	3520, Emergency Contact Information.

The Exchange is reserving Sections 1 and 3 at this time. The Exchange is reserving Sections 1 and 3 at this time. The Exchange proposes to relocate Chapter VI, Section 16, Fees, Dues and Other Charges, into the General section because this rule applies to both the equity and options products. This rule describes the power of Nasdaq's Board of Directors. The Exchange notes that the Board of Directors of Nasdaq has the power to set fees for the Nasdaq market, which includes fees for both options and equities.[8] The Exchange notes that Section 7, Regulatory Independence, was amended to remove the placeholder for a date. Finally Rule 2170, Disruptive Quoting and Trading Activity Prohibited, is not being relocated as this rule applies to equities. There is a similar rule within Chapter III, Section 16 related to options, which is being relocated to Options 9, Section 4. As noted above, the equity rules are not being relocated at this time.

General 4

The Exchange proposes to rename General 4 from ''Regulation'' to ''Registration Requirements.''

General 5

The Exchange proposes to relocate Nasdaq Series 8000 and 9000 into General 5 Discipline and not change the rule numbers. The Exchange is proposing to delete reserved sections.

General 9

The Exchange proposes to adopt a new General 9, titled ''Regulation.'' The Exchange proposes to relocate the following rules into General 9:

Proposed new rule No.	Current rule No.
Section 1	2010A, Standards of Commercial Honor and Principles of Trade; 5320A, Prohibition Against Trading Ahead of Customer Orders; IM–2110–4, Trading Ahead of Research Reports; IM–2110–5, Anti-Intimidation/Coordination; IM–2110–6, Confirmation of Callable Common Stock; 2120, Use of Manipulative, Deceptive or Other Fraudulent Devices; and 2140, Interfering With the Transfer of Customer Accounts in the Context of Employment Disputes.
Section 2	2150, Customers' Securities or Funds; and IM–2150, Segregation of Customers' Securities.
Section 3	2210, Communications with the Public; IM–2210–1. Guidelines to Ensure That Communications With the Public Are Not Misleading; and IM–2210–4, Limitations on Use of the Exchange's Name.
Section 4	2211, Institutional Sales Material and Correspondence.

[5] *See* note 14 below.

[6] The Exchange proposes to delete the term ''Exchange Act'' and ''SEC'' or ''Commission.''

[7] The terms ''Customer'' and ''Security'' are being relocated into Equity 1 of the Rulebook as these terms are specific to the equity market. Further, the following definitions are being relocated from Chapter I, Section 1 and Chapter VI, Section 1 into General 1, Section: ''associated person,'' ''Board,'' ''Exchange,'' ''Exchange Act,'' ''he,'' ''him,'' or ''his,'' ''MarketWatch,'' ''Nasdaq Rules,'' ''Nasdaq Regulation,'' ''primary market,'' and ''SEC'' or ''Commission.''

[8] *See* NOM By-Law Article XII, Section 12.4 which provides the Board authority to set fees. In addition, the Exchange proposes to amend the word ''Participant'' in this rule to ''member'' to clearly indicate all members are subject to the Rule.

Proposed new rule No.	Current rule No.
Section 5	2212, Telemarketing.
Section 6	2251, Forwarding of Proxy and Other Issuer-Related Materials.
Section 7	2261, Disclosure of Financial Condition; 2262, Disclosure of Control Relationship with Issuer; and 2269, Disclosure of Participation or Interest in Primary or Secondary Distribution (re-title as ''Disclosure of Financial Condition, Control Relationship with Issuer and Participation or Interest in Primary or Secondary Distribution'').
Section 8	2266, SIPC Information.
Section 9	2290, Fairness Opinions.
Section 10	2090A, Know Your Customer, 2111A. Suitability (re-title ''Recommendations to Customers (Suitability)'').
Section 11	5310A, Best Execution and Interpositioning.
Section 12	2340, Customer Account Statements.
Section 13	2341, Margin Disclosure Statement.
Section 14	2360, Approval Procedures for Day-Trading Accounts; and 2361, Day-Trading Risk Disclosure Statement (re-title as ''Approval Procedures for Day-Trading Accounts'').
Section 15	2370, Borrowing From or Lending to Customers.
Section 16	2430, Charges for Services Performed.
Section 17	2441, Net Transactions with Customers.
Section 18	2460, Payments for Market Making.
Section 19	2510, Discretionary Accounts.
Section 20	3010, Supervision; IM–3010–1, Standards for Reasonable Review; and IM–3010–2, Guidance on Heightened Supervision Requirements (re-title as ''Supervision'').
Section 21	3012, Supervisory Control System.
Section 22	3013, Annual Certification of Compliance and Supervisory Processes; and IM–3013. Annual Compliance and Supervision Certification (re-title as ''Annual Certification of Compliance and Supervisory Processes'').
Section 23	3030, Outside Business Activities of an Associated Person.
Section 24	3040, Private Securities Transactions of an Associated Person.
Section 25	3050, Transactions for or by Associated Persons.
Section 26	3220A, Influencing or Rewarding Employees of Others.
Section 27	3070, Reporting Requirements.
Section 28	3080, Arbitration Disclosure to Associated Persons When Signing Form U4 (re-titled ''Disclosure to Associated Persons When Signing Form U4'').
Section 29	2070A, Transactions Involving Nasdaq Employees.
Section 30	3110A, Books and Records.
Section 31	3120, Use of Information Obtained in Fiduciary Capacity.
Section 32	3140, Approval of Change in Exempt Status Under SEC Rule 15c3–3.
Section 33	3150, Reporting Requirements for Clearing Firms and IM–3150, Exemptive Relief.
Section 34	3160, Extensions of Time Under Regulation T and SEC Rule 15c3–3.
Section 35	2040, Nonregistered Foreign Finders.
Section 36	IM–2460–1, Market Quality Program.
Section 37	3011, Anti-Money Laundering Compliance Program.
Section 38	2520, Margin Requirements.
Section 39	3020, Fidelity Bonds.
Section 40	4110A, Capital Compliance.
Section 41	4120A, Regulatory Notification and Business Curtailment.
Section 42	4140A, Audit.
Section 43	4511A, General Requirements.
Section 44	4513A, Records of Written Customer Complaints.
Section 45	4512A, Customer Account Information.
Section 46	4514A, Authorization Records for Negotiable Instruments Drawn From a Customer's Account.
Section 47	4515A, Approval and Documentation of Changes in Account Name or Designation.
Section 48	4521A, Notifications, Questionnaires and Reports.
Section 49	5230A, Payments Involving Publications that Influence the Market Price of a Security.
Section 50	1090, Foreign Member.
Section 51	1050, Research Analysts.

The word ''FINRA'' is being added in certain places for greater clarity. The Exchange is amending Rule 2212, Telemarketing, to update the Rule reference to NASD Rule 2212 to FINRA Rule 3230 in light of a FINRA rule change.[9] The Exchange is amending Rule 3010, Supervision, as well as IM–3010–1, Standards for Reasonable Review, to update the Rule reference to NASD Rule 3010 to FINRA Rule 3170 and 3110, respectively, in light of a FINRA rule change.[10] The Exchange proposes to amend NASD Rule 3070 references within Rule 3070, Reporting Requirements, to FINRA Rule 4530 pursuant to a FINRA rule change.[11] The Exchange proposes to amend NASD Rule 3110A, Books and Records, to amend the rule references to FINRA Rule 4511 pursuant to a FINRA rule change.[12]

Equity Rules

The Exchange proposes some changes to the Equity Rules to re-title certain chapters in the new Rulebook. The Exchange proposes to relocate certain definitions currently within Rule 0121 ''Definitions in the By-Laws of the

[9] *See* Securities Exchange Act Release No. 66279 (January 30, 2012), 77 FR 5611 (February 3, 2012) (SR–FINRA–2011–059).

[10] *See* Securities Exchange Act Release No. 71179 (December 23, 2013), 78 FR 79542 (December 30, 2013) (SR–FINRA–2013–025).

[11] *See* Securities Exchange Act Release No. 63260 (November 5, 2010), 75 FR 69508 (November 12, 2010) (SR–FINRA–2010–034).

[12] *See* Securities Exchange Act Release No. 63784 (January 27, 2011), 76 FR 5850 (February 2, 2011) (SR–FINRA–2010–052).

Exchange'' into Equity 1.[13] The Exchange proposes to re-title Equity 2 from ''Equity Trading Rules'' to ''Equity Market Participants.'' The Exchange proposes to re-title Equity 3 from ''Equity Market Participants'' to ''Equity Trading Rules.'' The Exchange proposes to title Equity 4, which is currently reserved, as ''Limit Up-Limit Down.'' The Exchange proposes to reserve Equity 6, which is currently titled ''Limit Up-Limit Down.'' The Exchange proposes to reserve Equity 10, which is titled ''Qualification, Listing and Delisting of Companies.'' Finally, the Exchange proposes to remove Equity 11, which is currently reserved.

Options 1

The Exchange proposes to rename current Options 1 from ''Options Definitions'' to ''General Provisions.'' The Exchange proposes to relocate and alphabetize certain definitions from Chapter I, Section 1 into proposed General 1, Section 1. The Exchange also proposes to relocate definitions from Chapter VI, Section 1(a)–(c) and (h) into General 1, Section 1. Certain definitions within Chapter 1, Section 1 and Chapter VI, Section 1 apply to both equities and options. These definitions [14] will be relocated to General 1, Section 1 from Chapter I, Section 1 and Chapter VI, Section 1. The Exchange proposes to conform the definitions by adding ''the term'' where necessary. The Exchange proposes to amend the term ''System'' from Chapter VI, Section 1 and apply that term to both ''System'' and ''Trading System'' and remove the separate definition for ''Trading System'' in Chapter I, Section I(a)(61) which creates a circular reference to the term ''System.'' The Exchange also proposes to eliminate the defined term ''Participant'' from Chapter VI, Section 1. The Exchange defines an ''Options Participant'' or ''Participant'' within its rules today. The separate defined term ''Participant'' is confusing and unnecessary. The terms ''Nasdaq Regulation'' and ''Nasdaq Rules'' are redundant of the same terms that was already being relocated to General 1 from the Equity Rules. The Exchange proposes to delete the terms ''Nasdaq Regulation'' ''Nasdaq Rules'' in this rule. The term ''Exchange'' is redundant of the same terms that was already being relocated to General 1 from the Equity Rules. The Exchange proposes to delete the terms ''Exchange'' and ''Order Entry Firms'' in this rule because they are duplicative.

In addition the Exchange proposes to relocate the following rules into Options 1:

Proposed new rule No.	Current rule No.
Section 1	Chapter I, Section 1, Definitions and Chapter VI, Section 1(a)–(c) and (h).
Section 2	Chapter I, Section 2, Applicability.
Section 3	Chapter I, Section 3, Regulation of Nasdaq and its Members.

The Exchange proposes to relocate Chapter V, Section 2, MarketWatch, to the end of the defined term within Options 1, Section 1, which is currently within Chapter I, Options 1, Section 1 and is being relocated to General 1 as that term applies to both options and equities. The sentence is merely descriptive and adds to the already defined term. The Exchange proposes to relocate Chapter VII, Section 1, Customer Orders and Order Entry Firms, into a definition for Order Entry Firms within Options 1, Section 1.

Options 2

The Exchange proposes to rename Options 2 from ''Options Trading Rules'' to ''Options Market Participants'' and relocate the following rules into this chapter:

Proposed new rule No.	Current rule No.
Section 1	Chapter VII, Section 2, Market Maker Registration; and Section 3 Continuing Market Maker Registration (re-title as Registration of Market Makers).
Section 2	Reserved.
Section 3	Reserved.
Section 4	Chapter VII, Section 5, Obligations of Market Makers.
Section 5	Chapter VII, Section 6, Market Maker Quotations.
Section 6	Reserved.
Section 7	Chapter VII, Section 7, Securities Accounts and Orders of Market Makers.
Section 8	Chapter VII, Section 9, Financial Requirements for Market Makers.
Section 9	Chapter VII, Section 4, Good Standing for Market Makers.
Section 10	Reserved.

The Exchange proposes to reserve certain rules. The Exchange proposes to relocate Chapter VII, Section 8, Letters of Guarantee, to Options 6, Section 4. The Exchange proposes to relocate Chapter VII, Sections 11, Mass Cancellation of Trading Interest to Options 3, Section 19, and Section 12, Order Exposure Requirements, to Options 3, Section 22. Chapter VII, Section 1 was relocated to the definitions as described herein.

Options 2A

The Exchange proposes a new Options Section 2A titled ''Options Participation'' and proposes to relocate the following rules into this chapter:

Proposed new rule No.	Current rule No.
Section 1	Chapter II, Section 1, Options Participation.
Section 2	Chapter II, Section 2, Requirements for Options Participation.
Section 3	Chapter II, Section 3, Persons Associated with Options Participants.

[13] *See* note 5 above. The term ''Nasdaq Manual'' is being eliminated.

[14] The following definitions are being relocated from Chapter I, Section 1 and Chapter VI, Section 1 into General 1, Section 1: ''associated person,'' ''Board,'' ''Exchange,'' ''Exchange Act,'' ''he,'' ''him,'' or ''his,'' ''MarketWatch,'' ''Nasdaq Rules,'' ''Nasdaq Regulation,'' ''primary market,'' and ''SEC'' or Commission.''

Proposed new rule No.	Current rule No.
Section 4	Chapter II, Section 4, Good Standing for Options Participants.

The Exchange proposes to reserve Sections 5–7.

Options 3

The Exchange proposes to rename Options 3 from ''Options Market Participants'' to ''Options Trading Rules'' and relocate the following rules into this chapter:

Proposed new rule No.	Current rule No.
Section 1	Chapter VI, Section 2, Days and Hours of Business.
Section 2	Chapter VI, Section 3, Units of Trading; and Section 4, Meaning of Premium Quotes and Orders (combined into one rule and retitle as ''Units of Trading and Meaning of Premium Quotes and Orders'').
Section 3	Chapter VI, Section 5, Minimum Increments.
Section 4.	Chapter VI, Section 6, Entry and Display of Quotes.
Section 5	Chapter VI, Section 7, Entry and Display of Orders.
Section 6	Chapter V, Section 5, Unusual Market Conditions.
Section 7	Chapter VI, Section 1(d)–(g), Definitions; and Chapter VI, Section 21, Order and Quote Protocols (re-title as ''Types of Orders and Quote Protocols'').
Section 8	Chapter VI, Section 8, Nasdaq Opening and Halt Cross (re-title as ''Opening and Halt Cross'').
Section 9	Chapter V, Section 3, Trading Halts; and Section 4, Resumption of Trading After a Halt (re-title as ''Trading Halts'').
Section 10	Chapter VI, Section 10, Book Processing (re-title as ''Order Book Allocation'').
Section 11	Reserved.
Section 12	Reserved.
Section 13	Reserved.
Section 14	Reserved.
Section 15	Chapter VI, Section 18, Risk Protections.
Section 16	Reserved.
Section 17	Chapter VI, Section 22, Kill Switch.
Section 18	Chapter VI, Section 23, Detection of Loss of Communication.
Section 19	Chapter VII, Section 11, Mass Cancellation of Trading Interest.
Section 20	Chapter V, Section 6, Nullification and Adjustment of Options Transactions including Obvious Errors.
Section 21	Chapter V, Section 1, Access to and Conduct on the NOM Market; and Chapter VI, Section 20, Exchange Sharing of Participant-Designated Risk Settings (re-title as ''Access to and Conduct on NOM'').
Section 22	Chapter VII, Section 12, Limitations on Order Entry.
Section 23	Chapter VI, Section 19, Data Feeds and Trade Information.
Section 24	Chapter VI, Section 13, Transaction Price Binding
Section 25	Chapter VI, Section 12, Anonymity.
Section 26	Chapter VI, Section 17, Message Traffic Mitigation.
Section 27	Chapter V, Section 9, Limitation of Liability.
Section 28	Reserved.

The Exchange proposes to combine the NOM Rules and retitle them as indicated herein. The Exchange proposes to reserve certain rules. Chapter VI, Section 16, Fees, Dues and Other Charges, was relocated to General 2 and Chapter VI, Sections 14, Authorization to Give Up and Section 15, Submission for Clearance, were relocated to Options 6. The Exchange amended Options 3, Section 21(b)(8) to refer to Section 22 with describes the limitation on orders on NOM.

Options 4

The Exchange proposes to amend Options 4, Options Listing Rules, to remove Section 5, which is reserved, and renumber Section 6, Series of Options Contracts Open for Trading, as Section 5.[15] The Exchange also proposes to reserve Section 6 and reserve a new Section 10.

Options 4A

The Exchange proposes to relocate rules within new proposed Options 4A, which is proposed to be titled ''Options Index Rules'' as follows:

Proposed new rule No.	Current rule No.
Section 1	Chapter XIV, Section 1, Application of Index Rules.
Section 2	Chapter XIV, Section 2, Definitions.
Section 3	Chapter XIV, Section 3, Designation of a Broad-Based Index.
Section 4	Chapter XIV, Section 6, Designation of Narrow-Based and Micro-Narrow-Based Index Options.
Section 5	Chapter XIV, Section 4, Dissemination of Information.
Section 6	Chapter XIV, Section 5, Position Limits for Broad-Based Index Options.
Section 7	Chapter XIV, Section 7, Position Limits for Industry and Micro-Narrow Based Index Options.
Section 8	Reserved.
Section 9	Chapter XIV, Section 8, Exemptions from Position Limits.
Section 10	Chapter XIV, Section 9, Exercise Limits
Section 11	Chapter XIV, Section 10, Trading Sessions.
Section 12	Chapter XIV, Section 11, Terms of Index Options Contracts.

[15] The corresponding rule numbers are changing for removals of certain sections.

Proposed new rule No.	Current rule No.
Section 13	Chapter XIV, Section 12, Debit Put Spread Cash Account Transactions.
Section 14	Chapter XIV, Section 13, Disclaimers.
Section 15	Chapter XIV, Section 14, Exercise of American-Style Index Options.
Section 16	Reserved.

Options 5

The Exchange proposes to rename Options 5 from ''Options Trade Administration'' to ''Order Protection and Locked and Crossed Markets.'' The current rules [16] within Options 5 are being relocated into Options 6B.

The Exchange proposes to relocate the following rules within Options 5 as follows:

Proposed new rule No.	Current rule No.
Section 1	Chapter XII, Section 1, Definitions.
Section 2	Chapter XII, Section 2, Order Protection.
Section 3	Chapter XII, Section 3, Locked and Crossed Markets.
Section 4	Chapter VI, Section 11(a), Order Routing.
Section 5	Chapter VI, Section 11(b) to be titled ''Cancellation of Orders and Error Account''.

The definitions of ''Exchange Act'' and ''SEC are being removed from Chapter XII, Section 1, ''Definitions'' as these terms are repetitive of definitions within General 1.

Options 6

The Exchange proposes to rename Options 6 from ''Order Protection and Locked and Cross Markets'' to ''Options Trade Administration'' and relocate rules within Options 6 as follows:

Proposed new rule No.	Current rule No.
Section 1	Chapter VI, Section 14, Authorization to Give Up.
Section 2	Chapter VI, Section 15, Submission for Clearance.
Section 3	Reserved.
Section 4	Chapter VII, Section 8, Letters of Guarantee.

Options 6A

The Exchange proposes to relocate rules within new proposed Options 6A titled ''Closing Transactions'' as follows:

Proposed new rule No.	Current rule No.
Section 1	Chapter X, Section 6, Contracts of Suspended Participants.
Section 2	Chapter V, Section 8, Failure to Pay Premium.

Options 6B

The Exchange proposes to relocate rules within new proposed Options 6B titled ''Exercises and Deliveries'' as follows:

Proposed new rule No.	Current rule No.
Section 1	Options 5, Section 101, Exercise of Options Contracts.
Section 2	Options 5, Section 102, Allocation of Exercise Notices.
Section 3	Options 5, Section 103, Delivery and Payment.

Options 6C

The Exchange proposes to relocate rules within new proposed Options 6C titled ''Exercises and Deliveries'' as follows:

[16] Options 5 currently includes the following rules: Section 101 Exercise of Options Contracts, Section 102 Allocation of Exercise Notices, and Section 103, Delivery and Payment.

Proposed new rule No.	Current rule No.
Section 1	Chapter XIII, Section 1, General Rule.
Section 2	Chapter XIII, Section 2, Time Margin Must Be Obtained.
Section 3	Chapter XIII, Section 3, Margin Requirements.
Section 4	Reserved.
Section 5	Chapter XIII, Section 4, Margin Required Is Minimum.
Section 6	Reserved.

Chapter XIII, Section 5, Joint Back Office Participants, is being relocated to Options 6D.

Options 6D

The Exchange proposes to relocate rules within new proposed Options 6D titled ''Net Capital Requirements'' as follows:

Proposed new rule No.	Current rule No.
Section 1	Reserved.
Section 2	Reserved.
Section 3	Reserved.
Section 4	Chapter XIII, Section 5, Joint Back Office Participants.

With respect to the relocation of Joint Back Office Participants, the Supplementary Material .01 titled was removed and the text was retained as part of the main rule in paragraph (c) of Section 4.

Options 6E

The Exchange proposes to relocate rules within new proposed Options 6E titled ''Records, Reports and Audits'' as follows:

Proposed new rule No.	Current rule No.
Section 1	Chapter IX, Section 1, Maintenance, Retention and Furnishing of Books, Records and Other Information.
Section 2	Chapter IX, Section 2, Reports of Uncovered Short Positions.
Section 3	Chapter IX, Section 3, Financial Reports and Audits.
Section 4	Reserved.
Section 5	Chapter IX, Section 4, Automated Submission of Trade Data.
Section 6	Chapter IX, Section 6, Risk Analysis of Market Maker Accounts.
Section 7	Chapter IX, Section 5, Regulatory Cooperation.
Section 8	Reserved.
Section 9	Chapter V, Section 7, Audit Trail.

The Exchange proposes to relocate Chapter IX, Section 7, Anti-Money Laundering Compliance Program, to Options 9, Section 21.

Options 7

The Exchange is updating cross-references within Options 7 to the introductory section of the Rule as well as Options 7, Section 4 Nasdaq Options Market Data Distributor Fees.

Options 9

The Exchange proposes to relocate rules within new proposed Options 9, which is currently reserved, and title the chapter as ''Business Conduct.'' The following rules will be relocated within Options 9 with certain rules reserved:

Proposed new rule No.	Current rule No.
Section 1	Reserved.
Section 2	Chapter III, Section 1, Adherence to Law and Section 2 Conduct and Compliance with the Rules.
Section 3	Reserved.
Section 4	Chapter III, Section 16, Disruptive Quoting and Trading Activity Prohibited.
Section 5	Reserved.
Section 6	Reserved.
Section 7	Reserved.
Section 8	Chapter III, Section 3, Rumors.
Section 9	Chapter III, Section 4, Prevention of the Misuse of Material Nonpublic Information.
Section 10	Chapter III, Section 5, Disciplinary Action by Other Organizations.
Section 11	Chapter III, Section 6, Other Restrictions on Participants.
Section 12	Chapter III, Section 15, Significant Business Transactions of Options Clearing Participants.
Section 13	Chapter III, Section 7, Position Limits.
Section 14	Chapter III, Section 8, Exemptions from Position Limits.
Section 15	Chapter III, Section 9, Exercise Limits.
Section 16	Chapter III, Section 10, Reports Related to Position Limits.
Section 17	Chapter III, Section 11, Liquidation Positions.
Section 18	Chapter III, Section 14, Limit on Outstanding Uncovered Short Positions.
Section 19	Chapter III, Section 12, Other Restrictions on Options Transactions and Exercises.
Section 20	Chapter III, Section 13, Mandatory Systems Testing.

Proposed new rule No.	Current rule No.
Section 21	Chapter IX, Section 7, Anti-Money Laundering Compliance Program.
Section 22	Reserved.
Section 23	Reserved.

Options 10

The Exchange proposes to relocate rules within new proposed Options 10 titled ''Doing Business with the Public'' as follows:

Proposed new rule No.	Current rule No.
Section 1	Chapter XI, Section 1, Eligibility.
Section 2	Chapter XI, Section 2, Registration of Options Principals.
Section 3	Chapter XI, Section 3, Registration of Representatives.
Section 4	Chapter XI, Section 5, Discipline, Suspension, Expulsion of Registered Persons.
Section 5	Chapter XI, Section 6, Branch Offices.
Section 6	Chapter XI, Section 7, Opening of Accounts.
Section 7	Chapter XI, Section 8, Supervision of Accounts.
Section 8	Chapter XI, Section 9, Suitability of Recommendations.
Section 9	Chapter XI, Section 10, Discretionary Accounts.
Section 10	Chapter XI, Section 11, Confirmation to Public Customers.
Section 11	Chapter XI, Section 12, Statement of Accounts to Public Customers.
Section 12	Chapter XI, Section 13, Statements of Financial Condition to Customers.
Section 13	Chapter XI, Section 15, Delivery of Current Options Disclosure Documents and Prospectus.
Section 14	Chapter XI, Section 16, Restrictions on Pledge and Lending of Customers' Securities.
Section 15	Chapter XI, Section 17, Transactions of Certain Customers.
Section 16	Chapter XI, Section 18, Guarantees.
Section 17	Chapter XI, Section 19, Profit Sharing.
Section 18	Chapter XI, Section 20, Assuming Losses.
Section 19	Chapter XI, Section 21, Transfer of Accounts.
Section 20	Chapter XI, Section 22, Communications with Public Customers; and Section 14, Addressing of Communications to Public Customers (re-title ''Communications with Public Customers'').
Section 21	Chapter XI, Section 23, Fidelity Bond.
Section 22	Chapter XI, Section 24, Public Customer Complaints.
Section 23	Chapter XI, Section 25, Telephone Solicitation.
Section 24	Chapter XI, Section 4, Other Affiliations of Registered Persons.
Section 25	Reserved.

The Exchange proposes to reserve Options 10, Section 25.

Options 11

The Exchange proposes to relocate Chapter X, Section 7 titled ''Penalty for Minor Rule Violations'' to Options 11 titled ''Minor Rule Plan Violations'' at Section 1. The Exchange proposes to relocate Chapter X, Section 1, ''Imposition of Suspension,'' Section 2, ''Investigation Following Suspension Violations,'' Section 3, ''Reinstatement Following Suspension,'' Section 4, ''Failure to Obtain Reinstatement,'' Section 5, ''Termination of Rights by Suspension'' and Section 6, ''Contracts of Suspended Participants'' into Options 11, Section 2, titled ''Suspension.''

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[17] in general, and furthers the objectives of Section 6(b)(5) of the Act,[18] in particular, in that it is designed to promote just and equitable principles of trade and to protect investors and the public interest by bringing greater transparency to its rules by relocating its Rules into the new Rulebook shell together with other rules which have already been relocated. The Exchange's proposal is consistent with the Act and will protect investors and the public interest by harmonizing its rule structure, where applicable, across Nasdaq markets so that Members can readily locate rules which cover similar topics. The relocation and harmonization of the Nasdaq Rule structure is part of the Exchange's continued effort to promote efficiency and conformity of its processes with those of its Affiliated Exchanges. The Exchange believes that the placement of the Nasdaq Rules into their new location in the shell will facilitate the use of the Rulebook by Members. Specifically, the Exchange believes that market participants that are members of more than one Nasdaq market will benefit from the ability to compare Rulebooks.

The Exchange is not substantively amending rule text unless noted otherwise within this rule change. The renumbering, re-lettering, deleting reserved rules, amending cross-references and other minor technical changes will bring greater transparency to Nasdaq's Rule structure. ISE, GEMX and MRX have already relocated their Rulebooks. BX recently filed to relocate its Rulebook.[19] Phlx will also relocate its Rulebook in order to harmonize its rule structure, where applicable, across Nasdaq markets. The Exchange believes its proposal will benefit investors and the general public by increasing the transparency of its Rulebook and promoting easy comparisons among the various Nasdaq Rulebooks.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that the proposed amendments do not impose an undue

[17] 15 U.S.C. 78f(b).

[18] 15 U.S.C. 78f(b)(5).

[19] SR–BX–2019–036 filed on October 1, 2019.

burden on competition because the amendments to relocate the Rules are non-substantive. This rule change is intended to bring greater clarity to the Exchange's Rules. Renumbering, re-lettering, deleting reserved rules and amending cross-references will bring greater transparency to Nasdaq's Rule structure.

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 [20] and Rule 19b–4(f)(6) thereunder.[21]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act [22] normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii) [23] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative delay so that the Exchange could immediately relocate its rules. According to the Exchange, the proposal is intended to make it easier for members to locate the various Exchange rules, and is part of a larger effort to reorganize the Exchange's rules and those of its Affiliated Exchanges. For these reasons, the Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the operative delay and designates the proposed rule change operative upon filing.[24]

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 change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NASDAQ–2019–098 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–2019–098. 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–2019–098, and should be submitted on or before January 13, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[25]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2019–27593 Filed 12–20–19; 8:45 am]

BILLING CODE 8011–01–P

[20] 15 U.S.C. 78s(b)(3)(A).

[21] 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 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.

[22] 17 CFR 240.19b–4(f)(6).

[23] 17 CFR 240.19b–4(f)(6)(iii).

[24] For purposes only of waiving the 30-day operative delay, the Commission also has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[25] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87777; File No. SR–CboeBZX–2019–097]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change To Adopt BZX Rule 14.11(l) to Permit the Listing and Trading of Exchange-Traded Fund Shares That Are Permitted To Operate in Reliance on Rule 6c–11 Under the Investment Company Act of 1940

December 17, 2019.

On November 15, 2019, Cboe BZX Exchange, Inc. (''BZX'') 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, among other things, adopt BZX Rule 14.11(l) to permit the listing and trading of Exchange-Traded Fund Shares that are permitted to operate in reliance on Rule 6c–11 under the Investment Company Act of 1940. The proposed rule change was published for comment in the **Federal Register** on November 22, 2019.[3] The Commission has received no comment letters on the proposed rule change.

Section 19(b)(2) of the Act [4] provides that within 45 days of the publication of

[1] 15 U.S.C.78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 87560 (Nov. 18, 2019), 84 FR 64607.

[4] 15 U.S.C. 78s(b)(2).

notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding, or as to which the self-regulatory organization consents, the Commission will either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is January 6, 2020. The Commission is extending this 45-day time period.

The Commission finds it appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[5] designates February 20, 2020 as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change (File No. SR–CboeBZX–2019–097).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[6]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2019–27592 Filed 12–20–19; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87779; File No. SR–NYSEAMER–2019–57]

Self-Regulatory Organizations; NYSE American LLC; Notice of Filing and Immediate Effectiveness of Proposed Change To Amend the NYSE American Options Fee Schedule Relating to the MM FAANG Credit

December 17, 2019.

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 9, 2019, NYSE American LLC (''NYSE American'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the NYSE American Options Fee Schedule (''Fee Schedule'') relating to the MM FAANG Credit. The Exchange proposes to implement the fee change effective December 9, 2019. The proposed change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this filing is to modify an incentive program (described below), which is designed to encourage Market Makers to provide more competitive prices and deeper liquidity in options on the NYSE FANG+ Index (''NYSE FANG+''), which trades under the symbol FAANG. FAANG is an acronym for the market's five most popular and best-performing tech stocks, namely Facebook, Apple, Amazon, Netflix and Alphabet's Google.

Currently, the Exchange offers a $5,000 credit to Market Maker organizations—specifically, NYSE American Options Market Maker, Specialist, e-Specialist or Directed Order Market Makers—that execute at least 500 total monthly contract sides that open a position in FAANG on the Exchange (the ''MM FAANG Credit'' or ''Credit''). The Credit, which is applied against all Exchange fees charged to a Market Maker, is currently capped at $50,000, so if more than ten Market Maker organizations qualify for a MM FAANG Credit in a calendar month, the MM FAANG Credit for each qualifying firm will be a pro rata share of $50,000.[3]

The Exchange proposes to continue to provide $50,000 in Credits to encourage Market Maker organizations to provide liquidity in FAANG, but provide for two different qualifying levels with different monthly credits. As proposed, the Exchange proposes to add an alternative, higher monthly credit of $10,000 for Market Maker Organizations that execute at least 2,000 total monthly contract sides that open a position in FAANG on the Exchange. This credit would be capped at $25,000. Accordingly, if more than two firms qualify, they must share $25,000 pro rata. The Exchange also proposes to reduce the total credits available for firms that qualify for the current Credit from $50,000 to $25,000, and similarly reduce the fewest number of qualifying firms that would be entitled to the full Credit from eleven to six. The Exchange believes that the proposed change would incent firms that have historically qualified for the Credit to trade greater volume to earn the higher (proposed) Credit. And, believes that the lower (existing) volume threshold should still attract firms (including those that have never achieved the Credit) to trade the requisite volume in FAANG to earn the Credit.

The Exchange proposes to implement the fee change effective December 9, 2019.

Background

The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.''[4]

There are currently 16 registered options exchanges competing for order flow. Based on publicly-available information, and excluding index-based options, no single exchange has more than 16% of the market share of executed volume of multiply-listed

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[5] *Id.*

[6] 17 CFR 200.30–3(a)(31).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Fee Schedule, Section I.A., Options Transaction Fees and Credits, Rates for Options Transactions, note 7 (Options on NYSE FANG+ Index (''FAANG'') transactions), *available here: https://www.nyse.com/publicdocs/nyse/markets/american-options/NYSE_American_Options_Fee_Schedule.pdf.*

[4] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (S7–10–04) (''Reg NMS Adopting Release'').

equity and ETF options trades.[5] Therefore, no exchange possesses significant pricing power in the execution of multiply-listed equity & ETF options order flow. More specifically, in the first quarter of 2019, the Exchange had less than 10% market share of executed volume of multiply-listed equity & ETF options trades.[6]

With respect to FAANG, this index is listed and traded only on the Exchange and NYSE Arca, Inc. (''NYSE Arca''). However, this index product competes with market participants that choose to create their own synthetic index product by trading in the basket of securities that comprise the FAANG index. This proposed fee change is designed to increase liquidity for market participants that would like to trade FAANG by encouraging Market Maker organizations to open more positions in FAANG on the Exchange.

Proposed Fee Change

The Exchange proposes to modify the existing Credit and add an alternative that offers a higher credit for firms that execute a higher number of total monthly contract sides that open a position in FAANG on the Exchange, as set forth in more detail below. With this proposed change, the total amount available under the Credit would not be changing. Rather, the Exchange would make available a higher per-firm credit for firms that provide more liquidity in FAANG. The Exchange believes the proposed modifications would further the Exchange's goal of encouraging Market Makers to make a market in these (relatively) new products, which would in turn, benefit market participants that are interested in trading FAANG.

To effect this change, the Exchange proposes to modify the Credit to reduce the cap on the credits available for the existing qualification from $50,000 to $25,000. With this change, if more than five (as opposed to more than ten) firms execute at least 500 total monthly FAANG contract sides in a calendar month, the Credit for each qualifying firm would be a pro rata share of $25,000 (down from $50,000).[7] The Exchange also proposes to make clear that the limitation of five firms qualifying for the MM FAANG Credit applies to the $5,000 credit.[8]

The Exchange also proposes to add an alternative Credit to the same Market Maker organizations described above. As proposed, any such firm that executes at least 2,000 total monthly contract sides that open a position in FAANG on the Exchange would qualify for a credit of $10,000; provided, however, that if more than two firms qualify for the proposed (higher) FAANG Credit in a calendar month, the MM FAANG Credit for each qualifying firm would be a pro rata share of $25,000.[9] As further proposed, a Market Maker firm that qualified for both Credits would be eligible for only one of the two alternatives (*i.e.,* the higher). As proposed, the Exchange's maximum exposure under the Credit would continue to be $50,000, but this cap would be split between the two different qualifying rates.

The Exchange believes the proposed modified MM FAANG Credit would further the Exchange's goal of encouraging trading in this (relatively) new index product, in particular by encouraging Market Makers to provide increased liquidity in tighter markets, which would in turn, benefit all market participants through more opportunities to trade.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[10] in general, and furthers the objectives of Sections 6(b)(4) and (5) of the Act,[11] in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Proposed Rule Change Is Reasonable

The Exchange operates in a highly competitive market. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [12]

There are currently 16 registered options exchanges competing for order flow. Based on publicly-available information, and excluding index-based options, no single exchange has more than 16% of the market share of executed volume of multiply-listed equity and ETF options trades.[13] Therefore, no exchange possesses significant pricing power in the execution of multiply-listed equity & ETF options order flow. More specifically, in the third quarter of 2019, the Exchange had less than 10% market share of executed volume of multiply-listed equity & ETF options trades.[14]

The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can shift order flow, or discontinue or reduce use of certain categories of products, in response to fee changes. Accordingly, competitive forces constrain options exchange transaction fees. Stated otherwise, changes to exchange transaction fees can have a direct effect on the ability of an exchange to compete for order flow.

While FAANG lists and trades only on the Exchange and NYSE Arca, this index product competes with market participants that choose to create their own synthetic index product by trading in the basket of securities that comprise the FAANG index. This proposed fee change is designed to increase liquidity for market participants that would like to trade FAANG by encouraging Market Maker organizations to open more positions in FAANG on the Exchange.

More specifically, the Exchange believes that the proposed modification to the MM FAANG Credit is designed to generate additional order flow to the Exchange by creating incentives to transact in FAANG, which increased liquidity would benefit all market participants, including non-Market

[5] The OCC publishes options and futures volume in a variety of formats, including daily and monthly volume by exchange, *available here: https://www.theocc.com/market-data/volume/default.jsp.*

[6] Based on OCC data, *see id.,* the Exchange's market share in equity-based options declined from 9.82% for the month of January to 7.86% for the month of September.

[7] *See* proposed Fee Schedule, Section I.A., Options Transaction Fees and Credits, Rates for Options Transactions, note 7 (Options on NYSE FANG+ Index (''FAANG'') transactions).

[8] *See id.* In light of the proposed changes, to make the Fee Schedule easier to navigate, the Exchange also proposes to describe each alternative credit in bullet points, with typographical edits to the current rule text for clarity, and to remove reference to ''$5,000'' where it appears in the current rule and to add the concept of a ''specified minimum number'' of ''eligible contract sides.'' *See id.*

[9] *See id.* As with the current Credit, only those FAANG transactions marked as ''open'' would be eligible to be counted towards the MM FAANG Credit. To add clarity and transparency to the Fee Schedule, the Exchange also proposes to add the word ''FAANG'' prior to the word contracts to make clear that this MM FAANG Credits applies only to such contracts. *See id.*

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(4) and (5).

[12] *See* Reg NMS Adopting Release, *supra* note 4, at 37499.

[13] *See supra* note 5.

[14] Based on OCC data, *see supra* note 6, in 2019, the Exchange's market share in equity-based options declined from 9.82% for the month of January to 7.86% for the month of September.

Makers that are interested in trading FAANG. The Exchange believes that the proposed change would incent firms that have historically qualified for the Credit to trade greater volume to earn the higher (proposed) Credit. And, believes that the lower (existing) volume threshold should still attract firms (including those that have never achieved the Credit) to trade the requisite volume in FAANG to earn the Credit. To the extent that the proposed change attracts more FAANG transactions to the Exchange, this increased order flow would continue to make the Exchange a more competitive venue for order execution, which, in turn, promotes just and equitable principles of trade and removes impediments to and perfects the mechanism of a free and open market and a national market system.

To the extent the proposed change continues to attract greater volume and liquidity (to the Floor or otherwise), the Exchange believes the proposed change would improve the Exchange's overall competitiveness and strengthen its market quality for all market participants. In the backdrop of the competitive environment in which the Exchange operates, the proposed rule change is a reasonable attempt by the Exchange to increase the depth of its market and improve trading opportunities to better compete with other exchange offerings.

The Exchange cannot predict with certainty whether any firms would avail themselves of this proposed fee change, as historically, whether or when a firm qualifies for the MM FAANG Credit has varied month to month. Assuming historical behavior can be predictive of future behavior, the Exchange cannot predict the number of firms that may qualify for the alternative MM FAANG Credit, but believes that firms would be encouraged to take advantage of the modified Credit.

Finally, the Exchange believes that the technical changes to the rule text (*i.e.,* clarifying ''FAANG contract sides'' and including concept of a specified minimum number of ''eligible contract sides'') is reasonable as it would streamline the Fee Schedule, adding clarity and transparency, thereby making the Fee Schedule easier for market participants to navigate.[15]

The Proposed Rule Change Is An Equitable Allocation of Credits and Fees

The Exchange believes the proposed rule change is an equitable allocation of its fees and credits. The proposal is based on the amount and type of business transacted on the Exchange and Market Makers can opt to avail themselves of the MM FAANG Credit or not. To the extent that the proposed change attracts more FAANG transactions to the Exchange, this increased order flow would continue to make the Exchange a more competitive venue for, among other things, order execution. Thus, the Exchange believes the proposed rule change would improve market quality for all market participants on the Exchange and, as a consequence, attract more order flow to the Exchange thereby improving market-wide quality and price discovery.

The Proposed Rule Change Is Not Unfairly Discriminatory

The Exchange believes it is not unfairly discriminatory to modify the MM FAANG Credit because the proposed modification would be available to all similarly-situated market participants on an equal and non-discriminatory basis.

The proposal is based on the amount and type of business transacted on the Exchange and Market Maker organizations are not obligated to try to achieve the MM FAANG Credit. In addition, Market Maker organizations have increased obligations with respect to trading on the Exchange, and the Exchange believes that making this this Credit available to Market Maker organizations would more likely result in increased liquidity in FAANG on the Exchange. To the extent that the proposed change attracts a variety of transactions to the Exchange, this increased order flow would continue to make the Exchange a more competitive venue for, among other things, order execution. Thus, the Exchange believes the proposed rule change would improve market quality for all market participants on the Exchange and, as a consequence, attract more order flow to the Exchange thereby improving market-wide quality and price discovery. The resulting increased volume and liquidity would provide more trading opportunities and tighter spreads to all market participants and thus would promote just and equitable principles of trade, 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.

Finally, the Exchange believes that it is subject to significant competitive forces, as described below in the Exchange's statement regarding the burden on competition.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act, the Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Instead, as discussed above, the Exchange believes that the proposed changes would encourage the submission of additional liquidity to a public exchange, thereby promoting market depth, price discovery and transparency and enhancing order execution opportunities for all market participants. As a result, the Exchange believes that the proposed change furthers the Commission's goal in adopting Regulation NMS of fostering integrated competition among orders, which promotes ''more efficient pricing of individual stocks for all types of orders, large and small.''[16]

Intramarket Competition. The proposed change is designed to attract additional order flow to the Exchange by improving quote quality. The Exchange also believes the proposed Credit, as modified, is procompetitive as it would further the Exchange's goal of introducing (relatively) new products to the marketplace and encouraging Market Makers to provide liquidity in these products, which would in turn, benefit all market participants. Market participants that do not wish to trade in FAANG are not obliged to do so. To the extent that there is an additional competitive burden on market participants that are not eligible for the modified MM FAANG Credit (*i.e.,* non-Market Maker organizations), the Exchange believes that this is appropriate because the proposal would incent Market Makers to transact in FAANG, which would enhance the quality of the Exchange's markets and increases the volume of contracts traded here. To the extent that this purpose is achieved, all of the Exchange's market participants should benefit from the improved market liquidity. Enhanced market quality and increased transaction volume that results from the anticipated increase in order flow directed to the Exchange will benefit all market participants and improve competition on the Exchange. Further, the proposed Credit would be applied to all similarly situated participants (*i.e.,* Market Maker organizations), and, as such, the proposed change would not impose a disparate burden on

[15] *See supra* notes 8, 9.

[16] *See* Reg NMS Adopting Release, *supra* note 4, at 37499.

competition either among or between classes of market participants.

Finally, the Exchange believes that the technical changes to the rule text (*i.e.,* clarifying ''FAANG contract sides'' and including concept of a specified minimum number of ''eligible contract sides'') do not impose an undue burden on competition. Instead, the proposed changes would add clarity and transparency making the Fee Schedule easier for market participants to navigate.[17]

Intermarket Competition. While there is limited intermarket competition with respect to FAANG, as it lists and trades only on the Exchange and NYSE Arca, this index product competes with market participants that choose to create their own synthetic index product by trading in the basket of securities that comprise the FAANG index on other exchanges. This proposed fee change would therefore promote intermarket competition because it is designed to increase liquidity for market participants that would like to trade FAANG by encouraging Market Maker organizations to open more positions in FAANG on the Exchange. The Exchange believes that the proposed change could promote competition between the Exchange and other execution venues, by encouraging additional orders to be sent to the Exchange for execution. The Exchange does not believe that the proposed change will impair the ability of any market participants or competing order execution venues to maintain their competitive standing in the financial markets.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A)[18] of the Act and subparagraph (f)(2) of Rule 19b–4[19] thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[20] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEAMER–2019–57 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–NYSEAMER–2019–57. 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–NYSEAMER–2019–57, and should be submitted on or before January 13, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[21]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2019–27594 Filed 12–20–19; 8:45 am]

BILLING CODE 8011–01–P

[17] *See supra* notes 8, 9.

[18] 15 U.S.C. 78s(b)(3)(A).

[19] 17 CFR 240.19b–4(f)(2).

[20] 15 U.S.C. 78s(b)(2)(B).

[21] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87774; File No. SR–OCC–2019–011]

Self-Regulatory Organizations; The Options Clearing Corporation; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Concerning an Agreement for Clearing and Settlement Services Between The Options Clearing Corporation and Small Exchange, Inc.

December 17, 2019.

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 6, 2019, the Options Clearing Corporation (''OCC'') 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 OCC. OCC filed the proposed rule change pursuant to Section 19(b)(3)(A)[3] of the Act and Rule 19b–4(f)(4)(ii)[4] thereunder so that the proposal was effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

OCC is proposing to execute an Agreement for Clearing and Settlement Services (''Clearing Agreement'') between OCC and Small Exchange, Inc. (''Small'') in connection with Small's intention to operate as a designated contract market (''DCM'') regulated by the Commodity Futures Trading

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(4)(ii).

Commission (''CFTC''). There are no proposed changes to OCC's By-Laws or Rules.

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, OCC 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. OCC has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of these statements.

A. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

(1) Purpose

OCC is proposing to provide clearance and settlement services to Small pursuant to the terms set forth in the Clearing Agreement. Small has applied for designation as a DCM by the CFTC.[5] The purpose of this proposed rule change is to adopt a new Clearing Agreement so that OCC may begin providing clearing and settlement services for Small after Small has received the requisite regulatory approvals.

Clearing Agreement Proposal

On December 4, 2018, Small applied for designation as a DCM by the CFTC.[6] Contingent on the CFTC approving Small's application, OCC is now proposing to provide the clearance and settlement services as described in the Clearing Agreement.

The terms of the Clearing Agreement are based on the terms of the Agreement for Clearing and Settlement Services entered into with Nasdaq Futures, Inc. (''NFX Clearing Agreement''), which has been approved by the Commission.[7] The Clearing Agreement is substantially similar to the NFX Clearing Agreement with several differences discussed in more detail below.

The Clearing Agreement includes new provisions that are designed to protect OCC and the holders of outstanding contracts listed on Small. These new provisions would enable OCC to better manage the risks associated with a clearing relationship with a DCM such as the one OCC proposes to enter into with Small. More specifically, the following provisions would be added:

- Section 12 of the Clearing Agreement, ''Information Sharing by Market,'' would be revised to require Small to provide OCC with audited financial statements (i) on an annual basis and (ii) upon request by OCC. OCC believes this reporting will enable OCC to better monitor the financial resources of Small.[8]
- Section 18(d) of the Clearing Agreement, ''Financial Resources or Agreement with Another Exchange,'' would be added to require that Small either (i) maintain at all times at least one year of projected operating expenses, as updated on an annual basis[9] or (ii) maintain an arrangement with another DCM to provide a listing and trading venue for contracts that would be listed by Small and cleared by OCC in the event Small becomes unavailable to provide a trading venue for its contracts.[10] OCC believes this will better enable it to manage the potential risk of Small not being available to provide a trading venue for contracts listed on the exchange.

In addition to the above, the Clearing Agreement would include several other differences from the NFX Clearing Agreement, which include:

- Section 3 ''Selection of Underlying Interests; Classes and Series of Commodity Contracts'' would be revised to clearly reflect that security futures would not be cleared by OCC pursuant to the Clearing Agreement, as Small is not planning to list such contracts.
- Section 3 would also be revised to: (i) Add the condition that OCC be satisfied that it is able to appropriately process contracts proposed for clearing by Small using commercially reasonable efforts, (ii) describe the manner in which Small initially would notify OCC of proposed new products, (iii) require Small to submit a certificate to OCC detailing certain information on a new product as specified in Section 3(c) no later than ten trading days before Small plans to commence trading the product, and (iv) specify expectations around the clearance and settlement of a contract with a new maturity or expiration date not set forth in the certificate described in Section 3(c).
- Section 5(a) of the Clearing Agreement, ''Confirmed Trade Reports,'' would be amended to eliminate the reference to exchange-for-physical transactions, as the exchange is not planning to provide for such transactions in its rules. Section 26 from NFX Clearing Agreement also would be deleted for this reason as well as the fact that Article XII, Section VII of OCC's By-Laws already contains provisions regarding block trades that mirror what was in Section 26.
- Section 10 of the Clearing Agreement, ''Margin Requirements of Corporation,'' would be revised to clarify that OCC maintains the exclusive right to enforce its margin requirements with respect to its Clearing Members, but will maintain good faith communications with Small concerning OCC's establishment and communication of margin requirements. Section 10 also would be revised to remove a provision that would have required the exchange's consent prior to a listed product being made fungible with other products.
- Section 11 of the Clearing Agreement, ''Financial Requirements for Clearing Members,'' would be revised to provide that OCC would have the exclusive authority to establish in its By-Laws and Rules financial responsibility standards with which its Clearing Members must comply.
- Section 13 of the Clearing Agreement, ''Fees for Clearing Services and Changes Related to Commodity Contracts,'' would be revised to clarify that in the future, OCC would have the ability to charge Small fees reasonably related to OCC's costs to make any change(s) necessary to clear a product for Small, with the condition that prior to imposing any such fee, OCC would provide Small with advance written notice of the fee.[11]
- Section 15(c) of the Clearing Agreement, ''Indemnification in Respect of Intellectual Property,'' would be amended to provide that only Small would indemnify OCC if Small were alleged to have violated the patent or

[5] *See https://www.cftc.gov/filings/documents/2018/orgsmfecoverletter181212.pdf.*

[6] *Id.*

[7] *See* Securities Exchange Act Release No. 74747 (April 16, 2015), 80 FR 22591 (April 22, 2015) (SR–OCC–2015–03).

[8] Section 12 of the NFX Clearing Agreement provided that the rights and obligations of purchasers and sellers of contracts subject to that agreement are as set forth in the By-Laws and Rules of OCC. This is a reiteration of provisions that already exist in OCC's By-Laws and OCC therefore determined to replace it with the provision noted above in the proposed Clearing Agreement. *See, e.g.,* Article XII, Section 2(a).

[9] OCC notes that 17 CFR 38.1101(a) requires a DCM to maintain minimum financial resources ''equal to a total amount that would enable the designated contract market, or applicant for designation as such, to cover its operating costs for a period of at least one year, calculated on a rolling basis.''

[10] It is anticipated that any such DCM would be cleared by OCC.

[11] If OCC ever made a decision to charge Small fees reasonably related to OCC's costs to make any change(s) necessary to clear a product for Small, OCC would provide Small ample prior written notice (*e.g.,* 30 days) of any such fees. It is also anticipated that OCC would make a determination as to whether a proposed rule change would be needed in connection with any such fee.

other intellectual property rights of others.

• Section 18(b) of the Clearing Agreement, ''Other Grounds for Termination,'' would be amended to provide that there would be a 365-day period in which to transfer contracts to another DCO if either party to the Clearing Agreement voluntarily terminated it. Under this amended provision, OCC also would have the right to terminate the agreement earlier if such a transfer were accomplished prior to this 365-day period.

In addition to the foregoing, various minor and administrative changes have been made throughout the document including, but not limited to, updated references to the names of the parties and clean-up of outdated terms.

(2) Statutory Basis

OCC believes the proposed rule change is consistent with Section 17A of the Act [12] and the rules thereunder applicable to OCC. Section 17A(b)(3)(F) of the Act [13] requires, among other things, that the rules of a clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions and, to the extent applicable, derivative agreements, contracts, and transactions, to assure the safeguarding of securities and funds which are in the custody or control of the clearing agency or for which it is responsible, and, in general, to protect investors and the public interest. The proposed rule change is designed to promote the prompt and accurate clearance and settlement of derivatives contracts traded on Small by providing that such contracts will be cleared through OCC's existing clearance and settlement processes for futures contracts, which have functioned efficiently for many years with regard to other futures markets for which OCC provides clearance and settlement services. Similarly, OCC believes that the proposed rule change is designed to assure the safeguarding of securities and funds which are in the custody or control of the clearing agency by bringing contracts traded on Small and funds associated with those contracts within the scope of OCC's existing custody and control arrangements, which have effectively served OCC's Clearing Members and their customers for many years. Finally, OCC believes the proposed rule change is designed to the protect investors and the public interest. By providing that futures contracts traded on Small and cleared by OCC are risk managed under OCC's risk management framework, which is designed to provide protections to customers and other market participants in the event of a Clearing Member default, OCC believes the proposed rule change contributes to the protection of investors and the public interest.

Rule 17Ad–22(e)(20) [14] requires that a covered clearing agency ''establish, implement, maintain and enforce written policies and procedures reasonably designed to . . . [i]dentify, monitor, and manage risks related to any link the covered clearing agency establishes with one or more other clearing agencies, financial market utilities, or trading markets.'' OCC believes that the proposed rule change is also consistent with Rule 17Ad–22(e)(20) [15] because the proposed Clearing Agreement is designed to help OCC identify, monitor, and manage the risks associated with providing clearance and settlement services for Small, which is a trading market. For example, the Clearing Agreement would require Small to report financial information to OCC, which would enable OCC to monitor for changes in Small's financial condition. It also would require Small to maintain sufficient financial resources or arrangements with another DCM to mitigate the impact to the marketplace should Small become unavailable as a trading venue for its contracts.

B. Clearing Agency's Statement on Burden on Competition

Section 17A(b)(3)(I) of the Act [16] requires that the rules of a clearing agency not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. OCC does not believe the proposed rule change would impose any burden on competition. The purpose of the proposed rule change is to adopt a Clearing Agreement between OCC and Small. The adoption of such an agreement would not affect Clearing Members' access to OCC's services, nor would it disadvantage or favor any particular user in relationship to another user. As such, OCC believes that the proposed rule change would not impose any burden on competition.

C. Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments on the proposed rule change were not and are not intended to be solicited with respect to the proposed rule change and none have been received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Pursuant to Section 19(b)(3)(A) of the Act,[17] and Rule 19b–4(f)(4)(ii) thereunder,[18] the proposed rule change is filed for immediate effectiveness because it effects a change in an existing service of OCC that (i) primarily affects the clearing operations of OCC with respect to products that are not securities, *i.e.,* options on futures that are not security futures, and (ii) does not significantly affect any securities clearing operations of OCC or any rights or obligations of OCC with respect to securities clearing or persons using such securities clearing services.

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.[19]

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 Exchange 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–OCC–2019–011 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–OCC–2019–011. 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/*

[12] 15 U.S.C. 78q–1.

[13] 15 U.S.C. 78q–1(b)(3)(F).

[14] 17 CFR 240.17Ad-22(e)(20).

[15] *Id.*

[16] 15 U.S.C. 78q–1(b)(3)(I).

[17] 15 U.S.C. 78s(b)(3)(A).

[18] 17 CFR 240.19b–4(f)(4)(ii).

[19] Notwithstanding its immediate effectiveness, implementation of this rule change will be delayed until this change is deemed certified under CFTC Rule 40.6.

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 OCC and on OCC's website at *https://www.theocc.com/about/publications/bylaws.jsp.*

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–OCC–2019–011 and should be submitted on or before January 13, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[20]

J. Matthew DeLesDernier,

Assistant Secretary.

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[20] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87768; File No. SR–Phlx–2019–53]

Self-Regulatory Organizations; Nasdaq PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Adopt a New Rule 1059

December 17, 2019.

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 4, 2019, Nasdaq PHLX LLC (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to adopt a new Rule 1059 titled ''In-Kind Exchange of Options Positions and ETF Shares.''

The text of the proposed rule change is available on the Exchange's website at *http://nasdaqphlx.cchwallstreet.com/,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to adopt a new Rule 1059 titled ''In-Kind Exchange of Options Positions and ETF Shares,'' based on recent changes proposed by Cboe Exchange, Inc. (''Cboe'') and approved by the Commission.[3]

Background

As discussed further below, the ability to effect ''in kind'' transfers is a key component of the operational structure of an exchange-traded fund (''ETF''). Currently, in general, ETFs can effect in-kind transfers with respect to equity securities and fixed-income securities. The in-kind process is a major benefit to ETF shareholders and, in general, the means by which assets may be added to or removed from ETFs. In-kind transfers protect ETF shareholders from the undesirable tax effects of frequent ''creations and redemptions'' (described below) and improve the overall tax efficiency of the products. However, currently, the Exchange Rules do not provide for ETFs to effect in-kind transfers of options off of the Exchange, resulting in tax inefficiencies for ETFs that hold them. As a result, the use of options by ETFs is substantially limited.

Currently, Rule 1058(a) permits members or member organizations to transfer their positions off of the Exchange in specified, limited circumstances. The circumstances currently listed include: (1) The dissolution of a joint account in which the remaining member or member organization assumes the positions of the joint account; (2) the dissolution of a corporation or partnership in which a former nominee of that corporation or partnership assumes the positions; (3) positions transferred as part of a member or member organization's capital contribution to a new joint account, partnership, or corporation; (4) the donation of positions to a not-for-profit corporation; (5) the transfer of positions to a minor under the Uniform Gifts to Minors Act; (6) a merger or acquisition resulting in a continuity of ownership or management; and (7) consolidation of accounts within a member or member organization.[4] At present, the list of limited circumstances in Rule 1058(a) that allows members to transfer their options positions off the Exchange does not include an exception for in-kind transfers.

The Exchange proposes to add a new circumstance under which off-Exchange transfers of options positions would be permitted to occur. Specifically, under proposed Rule 1059, positions in options listed on the Exchange would be permitted to be transferred off the Exchange by a member or member organization in connection with transactions to purchase or redeem ''creation units'' of ETF shares between an ''authorized participant'' [5] and the

[3] *See* Cboe Rule 6.9. *See also* Securities Exchange Act Release No. 87340 (October 17, 2019) (SR–CBOE–2019–048) (Order Approving on an Accelerated Basis a Proposed Rule Change, as Modified by Amendment Nos. 2 and 3, to Adopt Rule 6.9 (In-Kind Exchange of Options Positions and ETF Shares)).

[4] The Exchange notes that other options exchanges have adopted rules that provide for off-Exchange transfers under similar circumstances. *See, e.g.,* Cboe Rule 6.7(a); and NYSE Arca, Inc. Rule 6.78–O(d)(1).

[5] The Exchange is proposing that, for purposes of proposed Rule 1059, the term ''authorized participant'' would be defined as an entity that has a written agreement with the issuer of ETF shares or one of its service providers, which allows the authorized participant to place orders for the purchase and redemption of creation units (*i.e.,* specified numbers of ETF shares). While an authorized participant may be a member or member organization and directly effect transactions in options on the Exchange, an authorized participant that is not a member or member organization may

Continued

issuer[6] of such ETF shares,[7] which transfers would occur at the price used to calculate the net asset value (''NAV'') of such ETF shares. The NAV for ETF shares is represented by the traded price for ETFs holding options positions on days of creation or redemption, and an options pricing model on days in which creations and redemptions do not occur. This proposed new exception, although limited in scope, would have a significant impact in that it would help protect ETF shareholders from undesirable tax consequences and facilitate tax-efficient operations. The frequency with which ETFs and authorized participants would rely on the proposed exception would depend upon such factors as the number of ETFs holding options positions traded on the Exchange, the market demand for the shares of such ETFs, the redemption activity of authorized participants, and the investment strategies employed by such ETFs.

As described in further detail below, while ETFs do not sell and redeem individual shares to and from investors, they do sell large blocks of their shares to, and redeem them from, authorized participants in conjunction with what is known as the ETF creation and redemption process. Under the proposed exception, ETFs that hold options listed on the Exchange would be permitted to effect creation and redemption transactions with authorized participants on an ''in-kind'' basis, which is the process that may generally be utilized by ETFs for other asset types. This ability would allow such ETFs to function as more tax-efficient investment vehicles to be benefit of investors that hold ETF shares. In addition, it may also result in transaction cost savings for the ETFs, which may be passed along to investors.

While the Exchange recognizes that, in general, the execution of options transactions on exchanges provides certain benefits, such as price discovery and transparency, based on the circumstances under which proposed Rule 1059 would apply, the Exchange does not believe that such benefits would be compromised. In this regard, as discussed more fully below, the Exchange notes that in conjunction with the creation and redemption process, positions would be transferred at a price(s) used to calculate the NAV of such ETF shares. In addition, although options positions would be transferred off of the Exchange, they would not be closed or ''traded.'' Rather, they would reside in a different clearing account until closed in a trade on the Exchange or until they expire. Further, as discussed below, proposed Rule 1059 would be clearly delineated and limited in scope, given that the proposed exception would only apply to transfers of options effected in connection with the creation and redemption process.

The ETF Creation and Redemption Process[8]

Due to their ability to effect in-kind transfers with authorized participants in conjunction with the creation and redemption process described below, ETFs have the potential to be significantly more tax-efficient than other pooled investment products, such as mutual funds. ETFs issue shares that may be purchased or sold during the day in the secondary market at market-determined prices. Similar to other types of investment companies, ETFs invest their assets in accordance with their investment objectives and investment strategies, and ETF shares represent interests in an ETF's underlying assets. ETFs are, in certain respects, similar to mutual funds in that they continuously offer their shares for sale. In contrast to mutual funds, however, ETFs do not sell or redeem individual shares. Rather, through the creation and redemption process referenced above, authorized participants have contractual arrangements with an ETF and/or its service provider (*e.g.,* its distributor) purchase and redeem shares directly from that ETF in large aggregations known as ''creation units.'' In general terms, to purchase a creation unit of ETF shares from an ETF, in return for depositing a ''basket'' of securities and/or other assets identified by the ETF on a particular day, the authorized participant will receive a creation unit of ETF shares. The basket deposited by the authorized participant is generally expected to be representative of the ETF's portfolio[9] and, when combined with a cash balancing amount (*i.e.,* generally an amount of cash intended to account for any difference between the value of the basket and the NAV of a creation unit), if any, will be equal in value to the aggregate NAV of the shares of the ETF comprising the creation unit. After purchasing a creation unit, an authorized participant may then hold individual shares of the ETF and/or sell them in the secondary market. In connection with effecting redemptions, the creation process described above is reversed. More specifically, the authorized participant will redeem a creation unit of ETF shares to the ETF in return for a basket of securities and/or other assets (along with any cash balancing account).

The ETF creation and redemption process, coupled with the secondary market trading of ETF shares, facilitates arbitrage opportunities that are intended to help keep the market price of ETF shares at or close to the NAV per share of the ETF. Authorized participants play an important role because of their ability, in general terms, to add ETF shares to, or remove them from, the market. In this regard, if shares of an ETF are trading at a discount (*i.e.,* below NAV per share), an authorized participant may purchase ETF shares in the secondary market, accumulate enough shares for a creation unit and then redeem them from the ETF in exchange for the ETF's more valuable redemption basket. Accordingly, the authorized participant will profit because it paid less for the ETF shares than it received for the underlying assets. The reduction in the supply of ETF shares available on the secondary market, together with the sale of the ETF's basket assets, may cause the price of ETF shares to increase, the price of the basket assets to decrease, or both, thereby causing the market price of the ETF shares and the value of the ETF's holdings to move closer together. In contrast, if the ETF shares are trading at a premium (*i.e.,* above NAV per share), the transactions are reversed (and the authorized participant would deliver the creation basket in exchange for ETF shares), resulting in an increase in the supply of ETF shares which may also

effect transactions in options on the Exchange through a member or member organization on its behalf.

[6] The Exchange is proposing that, for purposes of proposed Rule 1059, any issuer of ETF shares would be registered with the Commission as an open-end management investment company under the Investment Company Act of 1940 (the ''1940 Act'').

[7] An ETF share is a share or other security traded on a national securities exchange and defined as an NMS stock, which includes interest in open-end management investment companies. *See* Commentary .06 to Rule 1009.

[8] The following summary of the ETF creation and redemption process is based largely on portions of the discussion set forth in Investment Company Act Release No. 33140 (June 28, 2018), 83 FR 37332 (July 31, 2018) (the ''Proposed ETF Rule Release'') in which the Commission proposed a new rule under the 1940 Act that would permit ETFs registered as open-end management investment companies that satisfy certain conditions to operate without the need to obtain an exemptive order. The proposed rule was adopted on September 25, 2019. *See* Investment Company Act Release No. 33646 (September 25, 2019).

[9] Under certain circumstances, however, and subject to the provisions of its exemptive relief from various provisions of the 1940 Act obtained from the Commission, an ETF may substitute cash and/or other instruments in lieu of some or all of the ETF's portfolio holdings. For example, today, positions in options traded on the Exchange would be generally substituted with cash.

help to keep the price of the shares of an ETF close to the value of its holdings.

In comparison to other pooled investment vehicles, one of the significant benefits associated with an ETF's in-kind redemption feature is tax efficiency. In this regard, by effecting redemptions on an in-kind basis (*i.e.,* delivering certain assets from the ETF's portfolio instead of cash), there is no need for the ETF to sell assets and potentially realize capital gains that would be distributed to shareholders. As indicated above, however, because Exchange Rules currently do not allow ETFs to effect in-kind transfers of options off of the Exchange, ETFs that invest in options traded on the Exchange are generally required to substitute cash in lieu of such options when effecting redemption transactions with authorized participants. Because they must sell the options to obtain the requisite cash, such ETFs (and therefore, investors that hold shares of those ETFs) are not able to benefit from the tax efficiencies afforded by in-kind transactions.

An additional benefit associated with the in-kind feature is the potential for transaction cost savings. In this regard, by transacting on an in-kind basis, ETFs may avoid certain transaction costs they would otherwise incur in connection with purchases and sales of securities and other assets. Again, however, this benefit is not available today to ETFs with respect to their options holdings.

Proposal

The Exchange notes that the Commission approved Rule 1058 in 2011 because the Exchange recognized, and the Commission agreed, that under certain circumstances, off-Exchange transfers were justified.[10] The Exchange believes that it is appropriate to permit off-Exchange transfers of options positions in connection with the creation and redemption process and recognizes that the prevalence and popularity of ETFs have increased greatly since the adoption of Rule 1058. Currently, ETFs serve both as popular investment vehicles and trading tools [11] and, as discussed above, the creation and redemption process, along with the arbitrage opportunities that accompany it, are key ETF features. Accordingly, the Exchange believes that providing for an additional, narrow circumstance to make it possible for ETFs that invest in options to effect creations and redemptions on an in-kind basis is justified.

The Exchange submits that its proposal is clearly delineated and limited in scope and not intended to facilitate ''trading'' options off of the Exchange. In this regard, the proposed circumstance would be available solely in the context of transfers of options positions effected in connection with transactions to purchase or redeem creation units of ETF shares between ETFs and authorized participants.[12] As a result of this process, such transfers would occur at the price(s) used to calculate the NAV of such ETF shares (as discussed above), which removes the need for price discovery on an Exchange for pricing these transfers. Moreover, as described above, ETFs and authorized participants are not seeking to effect the opening or closing of new options positions in connection with the creation and redemption process. Rather, the options positions would reside in a different clearing account until closed in a trade on the Exchange or until they expire.

The proposed transfers, while occurring between two different parties, will occur off the Exchange and will not be considered transactions (as is the case for current off-Exchange transfers permitted by Rule 1058(a)). While the prices of options transactions effected on the Exchange are disseminated to OPRA, back-office transfers of options positions in clearing accounts held at The Options Clearing Corporation (''OCC'') (in accordance with OCC Rules) [13] are not disseminated to OPRA or otherwise publicly available, as they are considered position transfers, rather than executions.[14] The Exchange believes that price transparency is important in the options markets. However, the Exchange expects any transfers pursuant to the proposed rule will constitute a minimal percentage of the total average daily volume of the combined standardized and FLEX options [15] with the same underlying security or index.[16] Today, the trading of ETFs that invest in options is substantially limited on the Exchange, primarily because the current rules do not permit ETFs to effect in-kind transfers of options off the Exchange. The Exchange continues to expect that any impact this proposal could have on price transparency in the options market is minimal because the proposed rule change is limited in scope, and is intended to provide market participants with an efficient and effective means to transfer options positions under clearly delineated, specified circumstances. Additionally, as noted above, the NAV for transfers will generally be based on the disseminated closing price for an options series on the day of a creation or redemption, and thus the price (although not the time or quantity of the transfer) at which these transfers will generally be effected will be publicly available.[17] Further, the Exchange generally expects creations or redemptions to include corresponding transactions by the authorized participant that will occur on an exchange and be reported to OPRA.[18] Therefore, the Exchange expects that any impact the proposed rule change

[10] *See* Securities Exchange Act Release No. 66023 (December 21, 2011), 76 FR 81553 (December 28, 2011) (SR-Phlx–2011–118).

[11] As noted in the Proposed ETF Rule Release, during the first quarter of 2018, trading in U.S.-listed ETFs comprised approximately 18.75% of U.S. equity trading by share volume and 28.2% of U.S. equity trading by dollar volume (based on trade and quote data from the New York Stock Exchange and Trade Reporting Facility data from the Financial Industry Regulatory Authority, Inc. (FINRA)). *See* Proposed ETF Rule Release at 83 FR 37334.

[12] *See supra* note 5. The term ''authorized participant'' is specific and narrowly defined. As noted in the Proposed ETF Rule Release, the requirement that only authorized participants of an ETF may purchase creation units from (or sell creation units to) an ETF ''is designed to preserve an orderly creation unit issuance and redemption process between ETFs and authorized participants.'' Furthermore, an ''orderly creation unit issuance and redemption process is of central importance to the arbitrage mechanism.'' *See* Proposed ETF Rule Release at 83 FR 37348.

[13] OCC has informed the Exchange that it has the operational capabilities to effect the proposed position transfers. All transfers pursuant to proposed Rule 1059 would be required to comply with OCC rules. *See* Rules 1000(b)(3) and 1046 (which, taken together, requires all members and member organizations that are OCC members to comply with OCC's rules).

[14] For example, any transfers effected pursuant to the current limited circumstances specified in Rule 1058(a) are not disseminated to OPRA.

[15] *See* Options 8, Section 34 for FLEX options provisions.

[16] The Exchange notes that the price discovery process in standardized options contracts in a particular class of options generally provides meaningful guideposts for pricing FLEX options with the same underlying security or index.

[17] If there is no disseminated closing price, the ETF would price according to a pricing model or procedure as described in the fund's prospectus.

[18] The Exchange notes that for in-kind creations, an authorized participant will acquire the necessary options positions in an on-exchange transaction that will be reported to OPRA. For in-kind redemptions, the Exchange generally expects that an authorized participant will acquire both the shares necessary to effect the redemption and an options position to offset the position that it will receive as proceeds for the redemption. Such an options position would likely be acquired in an on-exchange transaction that would be reported to OPRA. Such transactions are generally identical to the way that creations and redemptions work for equities and fixed income transactions—while the transfer between the authorized participant and the fund is not necessarily reported, there are generally corresponding transactions that would be reported, providing transparency into the transactions.

could have on price transparency in the options market would be de minimis.

Other than the transfers covered by the proposed rule, transactions involving options, whether held by an ETF or an authorized participant, would be fully subject to all applicable trading Rules.[19] Accordingly, the Exchange does not believe that the proposed new exception would compromise price discovery or transparency.

Further, the Exchange believes that providing an additional exception to make it possible for ETFs that invest in options to effect creations and redemptions on an in-kind basis is justified because, while the proposed exception would be limited in scope, the benefits that may flow to ETFs that hold options and their investors may be significant. Specifically, the Exchange expects such ETFs and their investors would benefit from increased tax efficiencies and potential transaction cost savings. By making such ETFs more attractive to both current and prospective investors, the proposed rule change would enable them to compete more effectively with other ETFs that, due to their particular portfolio holdings, may effect in-kind creations and redemptions without restriction.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[20] in general, and furthers the objectives of Section 6(b)(5) of the Act,[21] 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.

The Exchange believes that permitting off-Exchange transfers in connection with the in-kind ETF creation and redemption process promotes just and equitable principles of trade and helps remove impediments to and perfect the mechanism of a free and open market and a national market system, as it would permit ETFs that invest in options traded on the Exchange to utilize the in-kind creation and redemption process that is available for ETFs that invest in equities and fixed-income securities. This process represents a significant feature of the ETF structure generally, with advantages that distinguish ETFs from other types of pooled investment vehicles. In light of the associated tax efficiencies and potential transaction cost savings, the Exchange believes the ability to utilize an in-kind process would make such ETFs more attractive to both current and prospective investors and enable them to compete more effectively with other ETFs that, based on their portfolio holdings, may effect in-kind creations and redemptions without restriction. In addition, the Exchange believes that because it would permit ETFs that invest in options traded on the Exchange to benefit from tax efficiencies and potential transaction cost savings afforded by the in-kind creation and redemption process, which benefits the Exchange expects would generally be passed along to investors that hold ETF shares, the proposed rule change would protect investors and the public interest.

Moreover, the Exchange submits that the proposed exception is clearly delineated and limited in scope and not intended to facilitate ''trading'' options off the Exchange. Other than the transfers covered by the proposed exception, transactions involving options, whether held by an ETF or an authorized participant, would be fully subject to the applicable trading Rules. Additionally, the transfers covered by the proposed exception would occur at a price(s) used to calculate the NAV of the applicable ETF shares, which removes the need for price discovery on the Exchange. Accordingly, the Exchange does not believe that the proposed rule change would compromise price discovery or transparency.

When Congress charged the Commission with supervising the development of a ''national market system'' for securities, Congress stated its intent that the ''national market system evolve through the interplay of competitive forces as unnecessary regulatory restrictions are removed.''[22] Consistent with this purpose, Congress and the Commission have repeatedly stated their preference for competition, rather than regulatory intervention to determine products and services in the securities markets.[23] This consistent and considered judgment of Congress and the Commission is correct, particularly in light of evidence of robust competition among exchanges. The fact that an exchange proposed something new is a reason to be receptive, not skeptical—innovation is the life-blood of a vibrant competitive market—and that is particularly so given the continued internalization of the securities markets, as exchanges continue to implement new products and services to compete not only in the United States but throughout the world. Exchanges continuously adopt new and different products and trading services in response to industry demands in order to attract order flow and liquidity to increase their trading volume. This competition has led to a growth in investment choices, which ultimately benefits the marketplace and the public.

Currently, the Exchange Rules do not allow ETFs to effect in-kind transfers of options off of the Exchange, resulting in tax inefficiencies for ETFs that hold them. As a result, the use of options by ETFs is substantially limited. While the proposed exception would be limited in scope, the Exchange believes the benefits that may flow to ETFs that hold options and their investors may be significant. Specifically, the Exchange expects that such ETFs and their investors could benefit from increased tax efficiencies and potential transaction cost savings. By making such ETFs more attractive to both current and prospective investors, the proposed rule change would enable them to compete more effectively with other ETFs that, due to their particular portfolio holdings, may effect in-kind creations and redemptions without restriction. This may lead to further development of ETFs that invest in options, thereby fostering competition and resulting in additional choices for investors, which ultimately benefits the marketplace and the public.

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

[19] As indicated above, the operation of the arbitrage mechanism accompanying the creation and redemption process generally contemplates ongoing interactions between authorized participants and the market in transactions involving both ETF shares and the assets comprising an ETF's creation/redemption basket.

[20] 15 U.S.C. 78f(b).

[21] 15 U.S.C. 78f(b)(5).

[22] *See* H.R. Rep. 94–229, at 92 (1975) (Conf. Rep.).

[23] *See* S. Rep. No. 94–75, 94th Cong., 1st Sess. 8 (1975) (''The objective [in enacting the 1975 amendments to the Exchange Act] would be to enhance competition and to allow economic forces, interacting within a fair regulatory field, to arrive at appropriate variations in practices and services.''); Order Approving Proposed Rule Change Relating to NYSE Arca Data, Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770 (December 9, 2008) (''The Exchange Act and its legislative history strongly support the Commission's reliance on competition, whenever possible, in meeting its regulatory responsibilities for overseeing the [self-regulatory organizations] and the national market system. Indeed, competition among multiple markets and market participants trading the same products is the hallmark of the national market system.''); and Regulation NMS, 70 FR at 37499 (observing that NMS regulation ''has been remarkably successful in promoting market competition in [the] forms that are most important to investors and listed companies'').

necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe the proposed rule change will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. Utilizing the proposed exception would be voluntary. As an alternative to the normal auction process, the proposed rule change would provide market participants with an efficient and effective means to transfer positions under the specified circumstances. The proposed exception would enable all ETFs that hold options to enjoy the benefits of in-kind creations and redemptions already available to other ETFs (and to pass these benefits along to investors). The proposed rule change would apply in the same manner to all entities that meet the definition of ''authorized participant.''

The Exchange does not believe the proposed rule change will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. As indicated above, it is intended to provide an additional clearly delineated and limited circumstance in which options positions can be transferred off an exchange. Further, the Exchange believes the proposed rule change will eliminate a significant competitive disadvantage for ETFs that invest in options. Furthermore, as indicated above, in light of the significant benefits provided (*e.g.,* tax efficiencies and potential transaction cost savings), the proposed exception may lead to further development of ETFs that invest in options, thereby fostering competition and resulting in additional choices for investors, which ultimately benefits the marketplace and the public. Lastly, the Exchange notes that proposed rule change is based on a recent Cboe rule change approved by the Commission.[24] As such, the Exchange believes that its proposal enhances fair competition between markets by providing for additional listing venues for ETFs that hold options to utilize the in-kind transfers proposed herein.

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[25] and subparagraph (f)(6) of Rule 19b–4 thereunder.[26]

A proposed rule change filed under Rule 19b–4(f)(6)[27] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[28] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange requests that the Commission waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange believes that waiver of the operative delay is consistent with the protection of investors and the public interest because it would increase competition by allowing the Exchange to adopt a transfer rule similar to Cboe Rule 6.9. The Exchange asserts that adoption of this rule may lead to further development of ETFs that invest in options. The Exchange represents that OCC has informed the Exchange that it has the operational capabilities to effect the proposed position transfers. All transfers pursuant to proposed Rule 1059 would be required to comply with OCC rules.[29]

The Commission believes that proposed Phlx Rule 1059 is designed to protect investors and the public interest because it should facilitate in-kind creations and redemptions by options-based ETFs, which should lower taxable gains of shareholders of such ETFs. The Commission further believes that, by facilitating in-kind creations and redemptions by options-based ETFs, the proposed rule may also lower such funds' transaction costs. The Commission notes that the proposed rule change does not raise any new or novel issues not previously considered by the Commission. For the reasons above, the Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission waives the 30-day operative delay and designates the proposed rule change operative upon filing.[30]

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–Phlx–2019–53 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–Phlx–2019–53. 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

[24] *See supra* note 3.

[25] 15 U.S.C. 78s(b)(3)(A)(iii).

[26] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires the Exchange to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and 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.

[27] 17 CFR 240.19b–4(f)(6).

[28] 17 CFR 240.19b–4(f)(6)(iii).

[29] *See supra* note 13.

[30] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

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–Phlx–2019–53 and should be submitted on or before January 13, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[31]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2019–27585 Filed 12–20–19; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87776; File No. SR–NASDAQ–2019–090]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change To Adopt Nasdaq Rule 5704 and Other Related Amendments

December 17, 2019.

On November 8, 2019, The Nasdaq Stock Market LLC (''Nasdaq'') 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, among other things, adopt new Nasdaq Rule 5704 to list and trade Exchange Traded Fund Shares. The proposed rule change was published for comment in the **Federal Register** on November 22, 2019.[3] The Commission has received no comment letters on the proposed rule change.

Section 19(b)(2) of the Act [4] provides that within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding, or as to which the self-regulatory organization consents, the Commission will either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is January 6, 2020. The Commission is extending this 45-day time period.

The Commission finds it appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[5] designates February 20, 2020 as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change (File No. SR–NASDAQ–2019–090).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[6]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2019–27591 Filed 12–20–19; 8:45 am]

BILLING CODE 8011–01–P

[31] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C.78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 87559 (Nov. 18, 2019), 84 FR 64574.

[4] 15 U.S.C. 78s(b)(2).

[5] *Id.*

[6] 17 CFR 200.30–3(a)(31).

SOCIAL SECURITY ADMINISTRATION

[Docket No: SSA–2019–0055]

Agency Information Collection Activities: Proposed Request and Comment Request

The Social Security Administration (SSA) publishes a list of information collection packages requiring clearance by the Office of Management and Budget (OMB) in compliance with Public Law 104–13, the Paperwork Reduction Act of 1995, effective October 1, 1995. This notice includes revisions of OMB-approved information collections.

SSA is soliciting comments on the accuracy of the agency's burden estimate; the need for the information; its practical utility; ways to enhance its quality, utility, and clarity; and ways to minimize burden on respondents, including the use of automated collection techniques or other forms of information technology. Mail, email, or fax your comments and recommendations on the information collection(s) to the OMB Desk Officer and SSA Reports Clearance Officer at the following addresses or fax numbers.

(OMB) Office of Management and Budget, Attn: Desk Officer for SSA, *Fax:* 202–395–6974, *Email address: OIRA_Submission@omb.eop.gov*

(SSA) Social Security Administration, OLCA, Attn: Reports Clearance Director, 3100 West High Rise, 6401 Security Blvd., Baltimore, MD 21235, *Fax:* 410–966–2830, *Email address: OR.Reports.Clearance@ssa.gov.* Or you may submit your comments online through *www.regulations.gov,* referencing Docket ID Number [SSA–2019–0055].

I. The information collections below are pending at SSA. SSA will submit them to OMB within 60 days from the date of this notice. To be sure we consider your comments, we must receive them no later than February 21, 2020. Individuals can obtain copies of the collection instruments by writing to the above email address.

1. Continuing Disability Review Report—20 CFR 404.1589 & 416.989—0960–0072. Sections 221(i), 1614(a)(3)(H)(ii)(I) and 1633(c)(1) of the Social Security Act requires SSA to periodically review the cases of individuals who receive benefits under Title II or Title XVI, based on disability, to determine if disability continues. SSA uses Form SSA–454, Continuing Disability Review Report to complete the review for continued disability. SSA considers adults eligible for payment if they continue to be unable to do substantial gainful activity because of their impairments; and we consider Title XVI children eligible for payment if they have marked and severe functional limitations due to their impairments. SSA also uses Form SSA–454 to obtain information on sources of medical treatment; participation in vocational rehabilitation programs (if any); attempts to work (if any); and the opinions of individuals regarding whether their conditions have improved. The respondents are Title II or Title XVI disability recipients or their representatives.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Total annual opportunity cost (dollars) **
SSA–454–BK (Paper version)	270,500	1	60	270,500	* $10.22	** $2,764,510
Electronic Disability Collect System (EDCS)	270,500	1	60	270,500	* 10.22	** 2,764,510
Totals	541,000			541,000		** 5,529,020

* We based this figure on average DI payments, as reported in SSA's disability insurance payment data.
** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

2. Supplemental Security Income (SSI)—Quality Review Case Analysis—0960–0133. To assess the Supplemental Security Income (SSI) program and ensure the accuracy of its payments, SSA conducts legally mandated periodic SSI case analysis quality reviews. SSA uses Form SSA–8508–BK, and the electronic Excel application version, e8505, to conduct these reviews, collecting information on operating efficiency; the quality of underlying policies; and the effect of incorrect payments. SSA also uses the data to determine SSI program payment accuracy rate, which is a performance measure for the agency's service delivery goals. Respondents are the recipients of SSI payments which SSA randomly selects for quality reviews. Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Total annual opportunity cost (dollars) **
SSA–8508–BK (paper interview)	230	1	60	230	* $10.22	** $2,351
e8508 (electronic interview)	4,370	1	60	4,370	* 10.22	** 44,661
Totals	4,600			4,600		** 47,012

* We based this figure on average DI payments, as reported in SSA's disability insurance payment data.
** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

3. Employer Reports of Special Wage Payments—20 CFR 404.428—404.429—0960–0565. SSA collects information on the SSA–131 to prevent earnings-related overpayments, and to avoid erroneous withholding of benefits. SSA field offices and program service centers also use Form SSA–131 for awards and post-entitlement events requiring special wage payment verification from employers. While we need this information to ensure the correct payment of benefits, we do not require employers to respond. The respondents are large and small businesses that make special wage payments to retirees. Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Total annual opportunity cost (dollars) **
Paper Version: SSA–131 (without #6)	105,000	1	20	35,000	* $36.65	$1,282,750
Paper Version: SSA–131 (#6 only)	1,050	1	2	35	* 36.65	** 1,283
Electronic Version: Business Services Online Special Wage Payments	26	1	5	2	* 36.65	** 73
Totals	106,076			35,037		** 1,284,106

* We based this figure on average Budget Analysts hourly salary, as reported by Bureau of Labor Statistics data.
** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

4. Consent Based Social Security Number Verification Process—20 CFR 400.100—0960–0760. The Consent Based Social Security Number Verification (CBSV) process is a fee-based automated Social Security number (SSN) verification service available to private businesses and other requesting parties. To use the system, private businesses and requesting parties must register with SSA and obtain valid consent from SSN holders prior to verification. We collect the information to verify if the submitted name and SSN match the information in SSA records. After completing a registration process and paying the fee, the requesting party can use the CBSV process to submit a file containing the names of number holders who gave valid consent, along with each number holder's accompanying SSN and date of birth (if available) to obtain real-time results using a web service application or SSA's Business Services Online (BSO) application. SSA matches the information against the SSA master file

of SSNs, using SSN, name, date of birth, and gender code (if available). The requesting party retrieves the results file from SSA, which indicates only a match or no match for each SSN submitted.

Under the CBSV process, the requesting party does not submit the consent forms of the number holders to SSA. SSA requires each requesting party to retain a valid consent form for each SSN verification request. The requesting party retains the consent forms in either electronic or paper format.

SSA added a strong audit component to ensure the integrity of the CBSV process. At the discretion of the agency, we require audits (called ''compliance reviews'') with the requesting party paying all audit costs. Independent certified public accounts (CPAs) conduct these reviews to ensure compliance with all the terms and conditions of the party's agreement with SSA, including a review of the consent forms. CPAs conduct the reviews at the requesting party's place of business to ensure the integrity of the process. In addition, SSA reserves the right to perform unannounced onsite inspections of the entire process, including review of the technical systems that maintain the data and transaction records. The respondents to the CBSV collection are the participating companies; members of the public who consent to the SSN verification; and CPAs who provide compliance review services.

Type of Request: Revision of an OMB-approved information collection.

Time Burden

Requirement	Number of respondents	Frequency of response	Number of responses	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Total annual opportunity cost (dollars) **
Participating Companies							
Registration process for new participating companies.	*** 10	1	10	120	20	* $36.98	** $740
Creation of file with SSN holder identification data; maintaining required documentation/forms	80	**** 251	20,080	60	20,080	* 36.98	** 742,558
Using the system to upload request file, check status, and download results file	80	251	20,080	5	1,673	* 36.98	** 61,868
Storing Consent Forms	80	251	20,080	60	20,080	* 36.98	** 742,558
Activities related to compliance review	80	251	20,080	60	20,080	* 36.98	** 742,558
Totals	330	.....	80,330	.....	61,933	.....	** 2,290,282
Participating Companies Who Opt for External Testing Environment (ETE)							
ETE Registration Process (includes reviewing and completing ETE User Agreement)	30	1	1	180	90	* 36.98	** 3,328
Web Service Transactions	30	50	1,500	1	25	* 36.98	** 925
Reporting Issues Encountered on Web service testing (e.g., reports on application's reliability)	30	50	1,500	1	25	* 36.98	** 925
Reporting changes in users' status (e.g., termination or changes in users' employment status; changes in duties of authorized users)	30	1	1	60	30	* 36.98	** 1,109
Cancellation of Agreement	30	1	1	30	15	* 36.98	** 555
Dispute Resolution	30	1	1	120	60	* 36.98	** 2,219
Totals	180	.....	3,004	.....	245	.....	** 9,061
People Whose SSNs SSA Will Verify							
Reading and signing authorization for SSA to release SSN verification (Form SSA–89)	2,500,000	1	2,500,000	3	125,000	* 10.22	** 1,277,500
Responding to CPA re-contact	4,000	1	4,000	5	333	* 36.98	** 12,314
Totals	2,504,000	.....	2,504,000	.....	125,333	.....	** 1,289,814

* We based these figures on average Business and Financial operations occupations hourly salaries, as reported by Bureau of Labor Statistics data, and per average DI payments, as reported in SSA's disability insurance payment data.

** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

*** One-time registration process/approximately 10 new participating companies per year.

**** Please note there are 251 Federal business days per year on which a requesting party could submit a file.

There is one CPA respondent conducting compliance reviews and preparing written reports of findings. The average burden per the 80 responses is 4,800 minutes for a total burden of 6,400 hours annually.

Cost Burden

The public cost burden is dependent upon the number of companies and transactions per year. In FY 2019, 80 companies enrolled; 80 companies submitted an advance; and 70 actually performed verifications. The cost estimates below are based upon 80 participating companies in FY 2019 (includes an average of 10 new companies per year since 2016) submitting a total of 2,500,000 transactions.

One-Time Per Company Registration Fee: $5,000.

Estimated Per SSN Transaction Fee: $1.00.

Estimated Per Company Cost to Store Consent Forms: $300.

II. SSA submitted the information collections below to OMB for clearance. Your comments regarding these information collections would be most useful if OMB and SSA receive them 30 days from the date of this publication. To be sure we consider your comments, we must receive them no later than January 22, 2020. Individuals can obtain copies of the OMB clearance packages by writing to *OR.Reports.Clearance@ssa.gov.*

1. Missing and Discrepant Wage Reports Letter and Questionnaire—26 CFR 31.6051–2—0960–0432. Each year employers report the wage amounts they

paid their employees to the Internal Revenue Service (IRS) for tax purposes, and separately to SSA for retirement and disability coverage purposes. Employers should report the same figures to SSA and the IRS; however, each year some of the employer wage reports SSA receives show wage amounts lower than those employers report to the IRS. SSA uses Forms SSA–L93–SM, SSA–L94–SM, SSA–95–SM, and SSA–97–SM to ensure employees receive full credit for their wages. Respondents are employers who reported lower wage amounts to SSA than they reported to the IRS.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Total annual opportunity cost (dollars) **
SSA–95–SM and SSA-97-SM (and accompanying cover letters SSA–L93, L94)	360,000	1	30	180,000	* $22.50	** $4,050,000

* We based this figure on average U.S. citizen's hourly salary, as reported by Bureau of Labor Statistics data.

** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

2. Request for Proof(s) from Custodian of Records—20 CFR 404.703, 404.704, 404.720, 404.721, 404.723, 404.725, & 404.728—0960–0766. SSA sends Form SSA–L707, Request for Proof(s) from Custodian of Records, to records custodians on behalf of individuals who need help obtaining evidence of death, marriage, or divorce in connection with claims for benefits. SSA uses the information from the SSA–L707 to determine eligibility for benefits. The respondents are records custodians including statistics and religious entities, coroners, funeral directors, attending physicians, and State agencies.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Total annual opportunity cost (dollars) **
State or Local Government	94	1	10	16	* $18.00	** $288
Private Sector	24	1	10	4	* 37.60	** 150
Totals	118			20		** 438

* We based these figures on average records custodians in the local/state government, and records custodians in the private sectors hourly salary, as reported by Bureau of Labor Statistics data.

** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

Dated: December 18, 2019.

Naomi Sipple,

Reports Clearance Officer, Social Security Administration.

[FR Doc. 2019–27664 Filed 12–20–19; 8:45 am]

BILLING CODE 4191–02–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

[Docket No. USTR–2019–0023]

Request for Comments and Notice of a Public Hearing Regarding the 2020 Special 301 Review

AGENCY: Office of the United States Trade Representative.

ACTION: Request for comments and notice of public hearing.

SUMMARY: Each year, the Office of the United States Trade Representative (USTR) conducts a Special 301 review to identify countries that deny adequate and effective protection of intellectual property (IP) rights or deny fair and equitable market access to U.S. persons who rely on IP protection. Based on this review, the United States Trade Representative (Trade Representative) determines which, if any, of these countries to identify as Priority Foreign Countries. USTR requests written comments that identify acts, policies, or practices that may form the basis of a country's identification as a Priority Foreign Country or placement on the Priority Watch List or Watch List. USTR also requests notices of intent to appear at the public hearing.

DATES: February 6, 2020 at 11:59 p.m. EST: Deadline for submission of written comments, hearing statements, and notices of intent to appear at the hearing from the public.

February 20, 2020 at 11:59 p.m. EST: Deadline for submission of written comments, hearing statements, and notices of intent to appear at the hearing from foreign governments.

February 26, 2020: The Special 301 Subcommittee will hold a public hearing at the Office of the United State Trade Representative, 1724 F Street NW, Rooms 1&2, Washington DC. If necessary, the hearing may continue on the next business day. Those who intend to testify at the public hearing must submit a notice of intent to appear by the deadlines stated above. Please consult the USTR website at *https://ustr.gov/issue-areas/intellectual-property/Special-301,* for confirmation of the date and location and the schedule of witnesses.

March 5, 2020 at 11:59pm EST: Deadline for submission of post-hearing written comments from persons who testified at the public hearing.

On or about April 30, 2020: USTR will publish the 2020 Special 301

Report within 30 days of the publication of the National Trade Estimate (NTE) Report.

ADDRESSES: USTR strongly encourages electronic submissions made through the Federal eRulemaking Portal: *https://www.regulations.gov.* Follow the submission instructions in section IV below. The docket number is USTR–2019–0023. For alternatives to on-line submissions, please contact USTR at *Special301@ustr.eop.gov* before transmitting a comment and in advance of the relevant deadline.

FOR FURTHER INFORMATION CONTACT: Jacob Ewerdt, Director for Innovation and Intellectual Property, at *Special301@ustr.eop.gov.* You can find information about the Special 301 Review at *https://www.ustr.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 182 of the Trade Act of 1974 (Trade Act) (19 U.S.C. 2242), commonly known as the ''Special 301'' provisions, requires the Trade Representative to identify countries that deny adequate and effective IP protections or fair and equitable market access to U.S. persons who rely on IP protection. The Trade Act requires the Trade Representative to determine which, if any, of these countries to identify as Priority Foreign Countries. Acts, policies or practices that are the basis of a country's identification as a Priority Foreign Country can be subject to the procedures set out in sections 301–305 of the Trade Act (19 U.S.C. 2411–2415).

In addition, USTR has created a ''Priority Watch List'' and ''Watch List'' to assist the Administration in pursuing the goals of the Special 301 provisions. Placement of a trading partner on the Priority Watch List or Watch List indicates that particular problems exist in that country with respect to IP protection, enforcement, or market access for persons that rely on intellectual property protection. Trading partners placed on the Priority Watch List are the focus of increased bilateral attention concerning the problem areas.

USTR chairs the Special 301 Subcommittee (Subcommittee) of the Trade Policy Staff Committee. The Subcommittee reviews information from many sources, and consults with and makes recommendations to the Trade Representative on issues arising under Special 301. Written submissions from the public are a key source of information for the Special 301 review process. In 2020, USTR will conduct a public hearing as part of the review process and will allow hearing participants to provide additional information relevant to the review. At the conclusion of the process, USTR will publish the results of the review in a Special 301 Report. USTR requests that interested persons identify through the process outlined in this notice those countries whose acts, policies, or practices deny adequate and effective protection for IP rights or deny fair and equitable market access to U.S. persons who rely on IP protection.

The Special 301 provisions also require the Trade Representative to identify any act, policy, or practice of Canada that affects cultural industries, was adopted or expanded after December 17, 1992, and is actionable under Article 2106 of the North American Free Trade Agreement (NAFTA). USTR invites the public to submit views relevant to this aspect of the review.

The Special 301 provisions require the Trade Representative to identify all such acts, policies, or practices within 30 days of the publication of the NTE Report. In accordance with this statutory requirement, USTR will publish the annual Special 301 Report about April 30, 2020.

II. Public Comments

To facilitate this year's review, written comments should be as detailed as possible and provide all necessary information to identify and assess the effect of the acts, policies, and practices. USTR invites written comments that provide specific references to laws, regulations, policy statements, including innovation policies, executive, presidential, or other orders, and administrative, court, or other determinations that should factor in the review. USTR also requests that, where relevant, submissions mention particular regions, provinces, states, or other subdivisions of a country in which an act, policy, or practice is believed to warrant special attention. Finally, submissions proposing countries for review should include data, loss estimates, and other information regarding the economic impact on the United States, U.S. industry, and the U.S. workforce caused by the denial of adequate and effective intellectual property protection. Comments that include quantitative loss claims should include the methodology used to calculate the estimated losses.

III. Public Hearing

The Special 301 Subcommittee will convene a public hearing on February 26, 2020, in Rooms 1 and 2, 1724 F Street NW, Washington DC, at which interested persons, including representatives of foreign governments, may appear to provide oral testimony. If necessary, the hearing may continue on the next business day. Because the hearing will take place in Federal facilities, attendees must show photo identification and will be screened for security purposes. Please consult the USTR website at *https://ustr.gov/issue-areas/intellectual-property/Special-301,* to confirm the date and location of the hearing and to obtain copies of the hearing schedule. USTR also will post the transcript and recording of the hearing on the USTR website as soon after the hearing as possible. Witnesses must deliver prepared oral testimony, which is limited to five minutes, before the Special 301 Subcommittee in person and in English. Subcommittee member agencies may ask questions following the prepared statement.

Witnesses not from foreign governments must submit a notice of intent to testify and a hearing statement by February 6, 2020, and foreign government witnesses must submit a notice of intent to testify and a hearing statement by February 20, 2020. The submissions must be in English and must include: (1) The name, address, telephone number, fax number, email address, and firm or affiliation of the individual wishing to testify, and (2) a hearing statement that is relevant to the Special 301 review.

IV. Submission Instructions

All submissions must be in English and sent electronically via *https://www.regulations.gov* using docket number USTR–2019–0023. To submit comments, locate the docket (folder) by entering the number USTR–2019–0023 in the 'Enter Keyword or ID' window at the *https://www.regulations.gov* home page and click 'Search.' The site will provide a search-results page listing all documents associated with this docket. Locate the reference to this notice by selecting 'Notice' under 'Document Type' on the left side of the search-results page, and click on the link entitled 'Comment Now!'.

USTR requests that you provide comments in an attached document, and that you name the file according to the following protocol, as appropriate: Commenter Name, or Organization_ 2020 Special 301_Review_Comment, or Notice of Intent to Testify or Hearing Statement. Please include the following information in the 'Type Comment' field: ''2020 Special 301 Review'' and whether the submission is a comment, a request to testify at the hearing, or a hearing statement. Please submit documents prepared in (or compatible with) Microsoft Word (.doc) or Adobe Acrobat (.pdf) formats. If you prepare

the submission in a compatible format, please indicate the name of the relevant software application in the 'Type Comment' field. For further information on using the *https://www.regulations.gov* website, please select 'How to Use Regulations.gov' on the bottom of any page.

Please do not attach separate cover letters to electronic submissions; rather, include any information that might appear in a cover letter in the comments themselves. Similarly, to the extent possible, please include any exhibits, annexes, or other attachments in the same file as the comment itself, rather than submitting them as separate files.

For any comments that contains business confidential information, the file name of the business confidential version should begin with the characters 'BC'. Any page containing business confidential information must be clearly marked ''BUSINESS CONFIDENTIAL'' on the top of that page and the submission should clearly indicate, via brackets, highlighting, or other means, the specific information that is business confidential. A filer requesting business confidential treatment must certify that the information is business confidential and that they would not customarily released it to the public. Additionally, the filer should type 'Business Confidential' in the 'Type Comment' field.

Filers of comments containing business confidential information also must submit a public version of their comments. The file name of the public version should begin with the character 'P'. The 'BC' and 'P' should be followed by the name of the person or entity submitting the comments. Filers submitting comments containing no business confidential information should name their file using the name of the person or entity submitting the comments.

As noted, USTR strongly urges commenters to submit comments through *https://www.regulations.gov.* You must make any alternative arrangements before transmitting a document and in advance of the relevant deadline by contacting USTR at *Special301@ustr.eop.gov.*

USTR will place comments in the docket and they will be open to public inspection, except business confidential information. You can view comments on the *https://www.regulations.gov* website by entering Docket Number USTR–2019–0023 in the 'Search' field on the home page.

Daniel Lee,

Assistant U.S. Trade Representative for Innovation and Intellectual Property (Acting), Office of the United States Trade Representative.

[FR Doc. 2019–27572 Filed 12–20–19; 8:45 am]

BILLING CODE 3290–F0–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Procurement Thresholds for Implementation of the Trade Agreements Act of 1979

AGENCY: Office of the United States Trade Representative.

ACTION: Notice.

SUMMARY: The U.S. Trade Representative has determined the U.S. dollar procurement thresholds to implement certain U.S. trade agreement obligations, as of January 1, 2020, for calendar years 2020 and 2021.

DATES: This notice is applicable on January 1, 2020, for calendar years 2020 and 2021.

FOR FURTHER INFORMATION CONTACT: Kate Psillos, Director of International Procurement Policy at (202) 395–9581 or *Kathryn.W.Psillos@ustr.eop.gov.*

SUPPLEMENTARY INFORMATION: Executive Order 12260 (E.O.) requires the U.S. Trade Representative to set the U.S. dollar thresholds for application of Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. 2511 *et seq.*). These obligations apply to covered procurements valued at or above specified U.S. dollar thresholds. In conformity with the provisions of the E.O., and in order to carry out U.S. trade agreement obligations, the U.S. Trade Representative has determined the U.S. dollar procurement thresholds, effective on January 1, 2020, for calendar years 2020 and 2021 as follows:

I. World Trade Organization (WTO) Agreement on Government Procurement

A. *Central Government Entities listed in U.S. Annex 1:*

(1) Procurement of goods and services—$182,000; and

(2) Procurement of construction services—$7,008,000.

B. *Sub-Central Government Entities listed in U.S. Annex 2:*

(1) Procurement of goods and services—$498,000; and

(2) Procurement of construction services—$7,008,000.

C. *Other Entities listed in U.S. Annex 3:*

(1) Procurement of goods and services—$561,000; and

(2) Procurement of construction services—$7,008,000.

II. Chapter 15 of the United States-Australia Free Trade Agreement

A. *Central Government Entities listed in the U.S. Schedule to Annex 15–A, Section 1:*

(1) Procurement of goods and services—$83,099; and

(2) Procurement of construction services—$7,008,000.

B. *Sub-Central Government Entities listed in the U.S. Schedule to Annex 15–A, Section 2:*

(1) Procurement of goods and services—$498,000; and

(2) Procurement of construction services—$7,008,000.

C. *Other Entities listed in the U.S. Schedule to Annex 15–A, Section 3:*

(1) Procurement of goods and services for List A Entities— $415,495;

(2) Procurement of goods and services for List B Entities— $561,000;

(3) Procurement of construction services—$7,008,000.

III. Chapter 9 of the United States-Bahrain Free Trade Agreement

A. *Central Government Entities listed in the U.S. Schedule to Annex 9–A–1:*

(1) Procurement of goods and services—$182,000; and

(2) Procurement of construction services—$10,802,884.

B. *Other Entities listed in the U.S. Schedule to Annex 9–A–2:*

(1) Procurement of goods and services for List B entities—$561,000; and

(2) Procurement of construction services—$13,296,478.

IV. Chapter 9 of the United States–Chile Free Trade Agreement

A. *Central Government Entities listed in the U.S. Schedule to Annex 9.1, Section A:*

(1) Procurement of goods and services—$83,099; and

(2) Procurement of construction services—$7,008,000.

B. *Sub-Central Government Entities listed in the U.S. Schedule to Annex 9.1, Section B:*

(1) Procurement of goods and services—$498,000; and

(2) Procurement of construction services—$7,008,000.

C. *Other Entities listed in the U.S. Schedule to Annex 9.1, Section C:*

(1) Procurement of goods and services for List A Entities— $415,495;

(2) Procurement of goods and services for List B Entities— $561,000;

(3) Procurement of construction services—$7,008,000.

V. Chapter 9 of the United States-Colombia Trade Promotion Agreement

A. *Central Government Entities listed in the U.S. Schedule to Annex 9.1, Section A:*

(1) Procurement of goods and services—$83,099; and

(2) Procurement of construction services—$7,008,000.

B. *Sub-Central Government Entities listed in the U.S. Schedule to Annex 9.1, Section B:*

(1) Procurement of goods and services—$498,000; and

(2) Procurement of construction services—$7,008,000.

C. *Other Entities listed in the U.S. Schedule to Annex 9.1, Section C:*

(1) Procurement of goods and services for List B Entities— $561,000;

(2) Procurement of construction services—$7,008,000.

VI. Chapter 9 of the Dominican Republic-Central American-United States Free Trade Agreement

A. *Central Government Entities listed in the U.S. Schedule to Annex 9.1.2(b)(i), Section A:*

(1) Procurement of goods and services—$83,099; and

(2) Procurement of construction services—$7,008,000.

B. *Sub-Central Government Entities listed in the U.S. Schedule to Annex 9.1.2(b)(i), Section B:*

(1) Procurement of goods and services—$498,000; and

(2) Procurement of construction services—$7,008,000.

C. *Other Entities listed in the U.S. Schedule to Annex 9.1.2(b)(i), Section C:*

(1) Procurement of goods and services for List B Entities— $561,000;

(2) Procurement of construction services—$7,008,000.

VII. Chapter 17 of the United States-Korea Free Trade Agreement

A. *Central Government Entities listed in the U.S. Schedule to Annex 17–A, Section A:*

(1) Procurement of construction services—$7,008,000.

VIII. Chapter 9 of the United States–Morocco Free Trade Agreement

A. *Central Government Entities listed in the U.S. Schedule to Annex 9–A–1:*

(1) Procurement of goods and services—$182,000; and

(2) Procurement of construction services—$7,008,000.

B. *Sub-Central Government Entities listed in the U.S. Schedule to Annex 9–A–2:*

(1) Procurement of goods and services—$498,000; and

(2) Procurement of construction services—$7,008,000.

C. *Other Entities listed in the U.S. Schedule to Annex 9–A–3:*

(1) Procurement of goods and services for List B Entities— $561,000;

(2) Procurement of construction services—$7,008,000.

IX. Chapter 10 of the North American Free Trade Agreement

A. *Federal Government Entities listed in the U.S. Schedule to Annex 1001.1a-1:*

(1) Procurement of goods and services—$83,099; and

(2) Procurement of construction services—$10,802,884.

B. *Government Enterprises listed in the U.S. Schedule to Annex 1001.1a-2:*

(1) Procurement of goods and services—$415,495; and

(2) Procurement of construction services—$13,296,479.

X. Chapter 9 of the United States–Oman Free Trade Agreement

A. *Central Level Government Entities listed in the U.S. Schedule to Annex 9, Section A:*

(1) Procurement of goods and services—$182,000; and

(2) Procurement of construction services—$10,802,884.

B. *Other Covered Entities listed in the U.S. Schedule to Annex 9, Section B:*

(1) Procurement of goods and services for List B Entities— $561,000;

(2) Procurement of construction services—$13,296,478.

XI. Chapter 9 of the United States-Panama Trade Promotion Agreement

A. *Central Government Entities listed in the U.S. Schedule to Annex 9.1, Section A:*

(1) Procurement of goods and services—$182,000; and

(2) Procurement of construction services—$7,008,000.

B. *Sub-Central Government Entities listed in the U.S. Schedule to Annex 9.1, Section B:*

(1) Procurement of goods and services—$498,000; and

(2) Procurement of construction services—$7,008,000.

C. *Other Entities listed in the U.S. Schedule to Annex 9.1, Section C:*

(1) Procurement of goods and services for List B Entities— $561,000;

(2) Procurement of construction services—$7,008,000.

D. *Autoridad del Canal de Panamá*

(1) Procurement of goods and services—$561,000.

XII. Chapter 9 of the United States–Peru Trade Promotion Agreement

A. *Central Government Entities listed in the U.S. Schedule to Annex 9.1, Section A:*

(1) Procurement of goods and services—$182,000; and

(2) Procurement of construction services—$7,008,000.

B. *Sub-Central Government Entities listed in the U.S. Schedule to Annex 9.1, Section B:*

(1) Procurement of goods and services—$498,000; and

(2) Procurement of construction services—$7,008,000.

C. *Other Entities listed in the U.S. Schedule to Annex 9.1, Section C:*

(1) Procurement of goods and services for List B Entities— $561,000;

(2) Procurement of construction services—$7,008,000.

XIII. Chapter 13 of the United States-Singapore Free Trade Agreement

A. *Central Government Entities listed in the U.S. Schedule to Annex 13A, Schedule 1, Section A:*

(1) Procurement of goods and services—$83,099; and

(2) Procurement of construction services—$7,008,000.

B. *Sub-Central Government Entities listed in the U.S. Schedule to Annex 13A, Schedule 1, Section B:*

(1) Procurement of goods and services—$498,000; and

(2) Procurement of construction services—$7,008,000.

C. *Other Entities listed in the U.S. Schedule to Annex 13A, Schedule 1, Section C:*

(1) Procurement of goods and services—$561,000;

(2) Procurement of construction services—$7,008,000.

Jamieson Greer,

Chief of Staff, Office of the United States Trade Representative.

[FR Doc. 2019–27647 Filed 12–20–19; 8:45 am]

BILLING CODE 3290–F0–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Notice of Product Exclusion Extensions: China's Acts, Policies, and Practices Related to Technology Transfer, Intellectual Property, and Innovation

AGENCY: Office of the United States Trade Representative.

ACTION: Notice of product exclusion extensions.

SUMMARY: The initial set of exclusions from the additional duties imposed in this investigation are scheduled to expire on December 28, 2019. On October 31, 2019, the U.S. Trade Representative established a process for the public to comment on whether to

extend particular exclusions for up to 12 months. This notice announces the U.S. Trade Representative's determination to extend certain exclusions for 12 months.

DATES: The product exclusion extensions announced in this notice will apply as of December 28, 2019 and extend for one year.

FOR FURTHER INFORMATION CONTACT: For general questions about this notice, contact Assistant General Counsels Philip Butler or Benjamin Allen, or Director of Industrial Goods Justin Hoffmann, at (202) 395–5725. For specific questions on customs classification or implementation of the product exclusions identified in the Annex to this notice, contact *traderemedy@cbp.dhs.gov.*

SUPPLEMENTARY INFORMATION:

A. Background

For background on the proceedings in this investigation, please see the prior notices issued in the investigation, including 82 FR 40213 (August 23, 2017), 83 FR 14906 (April 6, 2018), 83 FR 28710 (June 20, 2018), 83 FR 32181 (July 11, 2018), 83 FR 67463 (December 28, 2018), 84 FR 11152 (March 25, 2019), 84 FR 16310 (April 18, 2019), 84 FR 21389 (May 14, 2019), 84 FR 25895 (June 4, 2019), 84 FR 32821 (July 9, 2019), 84 FR 46212 (September 3, 2019), 84 FR 49564 (September 20, 2019), 84 FR 52567 (October 2, 2019), and 84 FR 58427 (October 31, 2019).

Effective July 6, 2018, the U.S. Trade Representative imposed additional 25 percent duties on goods of China classified in 818 8-digit subheadings of the Harmonized Tariff Schedule of the United States (HTSUS), with an approximate annual trade value of $34 billion. *See* 83 FR 28710 (the $34 billion action). The U.S. Trade Representative's determination included a decision to establish a process by which U.S. stakeholders could request exclusion of particular products classified within an 8-digit HTSUS subheading covered by the $34 billion action from the additional duties. The U.S. Trade Representative issued a notice setting out the process for the product exclusions, and opened a public docket. *See* 83 FR 32181 (the July 11 notice).

In December 2018, the U.S. Trade Representative granted an initial set of exclusion requests, which are scheduled to expire on December 28, 2019. *See* 83 FR 67463 (the December 28 notice). On October 31, 2019, the U.S. Trade Representative invited the public to comment on whether to extend, by up to twelve months, particular exclusions granted in the December 28 notice. *See* 84 FR 58427 (the October 31 notice).

Under the October 31 notice, commenters were asked to address whether the particular product and/or a comparable product is available from sources in the United States and/or in third countries; any changes in the global supply chain since July 2018 with respect to the particular product, or any other relevant industry developments; and efforts, if any, importers or U.S. purchasers have undertaken since July 2018 to source the product from the United States or third countries.

In addition, commenters who were importers and/or purchasers of the products covered by an exclusion were asked to provide information regarding their efforts since July 2018 to source the product from the United States or third countries; the value and quantity of the Chinese-origin product covered by the specific exclusion request purchased in 2018, the first half of 2018, and the first half of 2019, and whether these purchases are from a related company; whether Chinese suppliers have lowered their prices for products covered by the exclusion following the imposition of duties; the value and quantity of the product covered by the exclusion purchased from domestic and third country sources in 2018, the first half of 2018 and the first half of 2019; the commenter's gross revenue for 2018, the first half of 2018, and the first half of 2019; whether the Chinese-origin product of concern is sold as a final product or as an input; whether the imposition of duties on the products covered by the exclusion will result in severe economic harm to the commenter or other U.S. interests; and any additional information in support or in opposition of the extending the exclusion.

The October 31 notice required the submission of comments no later than November 30, 2019.

B. Determination To Extend Certain Exclusions

Based on the information received in response to the October 31 notice, an evaluation of the factors set out in the July 11 notice and October 31 notice, which are summarized above, and in accordance with the advice of the interagency Section 301 Committee, the U.S. Trade Representative has determined, pursuant to sections 301(b), 301(c), and 307(a) of the Trade Act of 1974, as amended, to extend for 12 months certain product exclusions covered by the December 28 notice. As set out in the Annex to this notice, the U.S. Trade Representative has determined to extend the following exclusions under U.S. note 20(h) to subchapter III of chapter 99 of the HTSUS: (2), (7), (11), (29), (30), and (31). U.S. Customs and Border Protection will issue instructions on entry guidance and implementation.

In accordance with the July 11 notice, the exclusions are available for any product that meets the description in the Annex, regardless of whether the importer filed an exclusion request. Further, the scope of each exclusion is governed by the scope of the 10-digit HTSUS headings and product descriptions in the Annex to this notice, and not by the product descriptions set out in any particular request for exclusion.

Joseph Barloon,

General Counsel, Office of the U.S. Trade Representative.

Annex

The U.S. Trade Representative has determined to extend the following exclusions granted under the December 28, 2018 notice under heading 9903.88.05 and U.S. note 20(h) to subchapter III of chapter 99 of the HTSUS:

(2) 8418.69.0120

(7) 8525.60.1010

(11) Roller machines with dies for embossing paper, manually powered (described in statistical reporting number 8420.10.9080)

(29) Angle cock handle assemblies, of iron and steel, each measuring 11.43 cm by 21.59 cm by 5.08 cm and weighing 0.748 kg (described in statistical reporting number 8481.90.9040)

(30) Radiation therapy systems, each encased by steel-based structural shell with gantry cover comprising three pairs of plastics-based panels (described in statistical reporting number 9022.14.0000)

(31) Thermostats designed for air conditioning or heating systems, not designed to connect to the internet, the foregoing designed for wall mounting (described in statistical reporting number 9032.10.0030)

With respect to goods entered for consumption, or withdrawn from warehouse for consumption, on or after 12:01 a.m. eastern daylight time on July 6, 2018, and before December 28, 2020, the additional duties provided for in heading 9903.88.01 shall not apply to products which are provided for in heading 9903.88.05 and U.S. notes 20(h)(2), 20(h)(7), 20(h)(11), 20(h)(29), 20(h)(30) and 20(h)(31) to subchapter III of chapter 99 of the HTSUS.

[FR Doc. 2019–27611 Filed 12–20–19; 8:45 am]

BILLING CODE 3290–F0–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. FAA–2019–82]

Petition for Exemption; Summary of Petition Received; Spirit Airlines

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

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Federal Aviation Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before January 13, 2020.

ADDRESSES: Send comments identified by docket number FAA–2019–0826 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at (202) 493–2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Justin Barcas (202) 267–7023, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on December 17, 2019.

Brandon Roberts,

Acting Executive Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2019–0826.

Petitioner: Spirit Airlines (Spirit).

Section(s) of 14 CFR Affected: § 121.571(b)(3).

Description of Relief Sought: Spirit is seeking relief from 14 CFR 121.571(b)(3), which mandates that each certificate holder must carry on each passenger-carrying airplane printed cards supplementing the oral briefing that contain the following information pertinent only to the type and model of airplane used for that flight:

''Final assembly of this airplane was completed in [INSERT NAME OF COUNTRY].'' Spirit is proposing to list all possible countries of final assembly for the type and model of airplane operated by Spirit on each required printed safety information card.

[FR Doc. 2019–27660 Filed 12–20–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Final Federal Agency Actions on Proposed Highway in Kentucky and Tennessee

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of Limitation on Claims for Judicial Review of Actions by FHWA and Other Federal Agencies.

SUMMARY: This notice announces actions taken by FHWA and other Federal agencies that are final. The actions relate to a proposed highway project for the construction of US–641/State Route (SR) 54 from just north of Puryear in Henry County, Tennessee to just south of Murray in Calloway County, Kentucky. Those actions grant licenses, permits, and approvals for the project. The FHWA's Finding of No Significant Impact (FONSI) provides details on the Selected Alternative for the proposed improvements.

DATES: By this notice, FHWA is advising the public of final agency actions subject to 23 U.S.C. 139(*l*)(1). A claim seeking judicial review of the Federal agency actions on the highway project will be barred unless the claim is filed on or before May 21, 2020. If the Federal law that authorizes judicial review of a claim provides a time period of less than 150 days for filing such claim, then that shorter time period still applies.

FOR FURTHER INFORMATION CONTACT: For FHWA in Kentucky: Mr. Todd Jeter; Division Administrator; Federal Highway Administration; Kentucky Division Office; 330 West Broadway, Frankfort, Kentucky 40601; Telephone (502) 223–6720; email: *Todd.Jeter@dot.gov.* The FHWA Kentucky Division Office's normal business hours are 8:00 a.m. to 5:00 p.m. (Eastern Time). For FHWA in Tennessee: Ms. Theresa Claxton; Program Development Team Leader; Federal Highway Administration; Tennessee Division Office; 404 BNA Drive, Building 200, Suite 508; Nashville, Tennessee 37217; Telephone (615) 781–5770; email: *Theresa.Claxton@dot.gov.* FHWA Tennessee Division Office's normal business hours are 7:30 a.m. to 4 p.m. (Central Time). You may also contact Mr. Daniel Peake, Director of the Division of Environmental Analysis, Kentucky Transportation Cabinet, 200 Mero Street, Frankfort, Kentucky 40622; Telephone (502) 564–7250, *Danny.Peake@ky.gov.* The Kentucky Transportation Cabinet (KYTC) Division of Environmental Analysis's normal business hours are 8 a.m. to 4:30 p.m. (Eastern Time). The contact at the Tennessee Department of Transportation (TDOT) is Ms. Susannah Kniazewycz, Environmental Division Director, James K. Polk Building, Suite 900, 505 Deaderick Street, Nashville, Tennessee 37243–0334; Telephone (615) 741–3655, *Susannah.Kniazewycz@tn.gov.* The TDOT Environmental Division's normal business hours are 8 a.m. to 5 p.m. (Central Time).

SUPPLEMENTARY INFORMATION: Notice is hereby given that FHWA and other Federal agencies have taken final agency actions subject to 23 U.S.C. 139(*l*)(1) by issuing licenses, permits, and approvals for the following highway project located in northwestern Tennessee and southwestern Kentucky, more specifically described as: Construction of US 641/SR–54, KYTC Item Number 1–314.20 and TDOT Project Number 101886.05, Calloway County, Kentucky and Henry County, Tennessee. The

proposed action will provide a facility for safe and efficient movement of traffic and freight in the region, particularly between I–24, I–40, and I–69. The Selected Alternative proposes the construction of two roadway sections within the project. The southern portion constructs US–641/SR–54 from north of Howard Road to the Tennessee-Kentucky State Line and consists of two 12-foot travel lanes in each direction, a 14-foot turning lane, and 8-foot outside shoulders, within an approximate 300-foot right-of-way (ROW). Construction will be phased to initially build a three-lane section with intent for future widening to the ultimate five-lane configuration. The northern portion of the project constructs US–641 from the Tennessee-Kentucky State Line to just south of the bridge over the Middle Fork of the Clarks River and consists of two 12-foot travel lanes in each direction, 4-foot inside shoulders, 10-foot outside shoulders, and a 48-foot depressed median, within an approximate 330-foot ROW.

The actions by the Federal agencies, and the laws under which such actions were taken, are described in the Environmental Assessment (EA) for the project, approved on July 17, 2019, and in the FHWA FONSI issued on November 15, 2019, and in other documents in the FHWA project records. The EA, FONSI, and other project records are available by contacting FHWA, TDOT, or KYTC at the addresses provided above. The FHWA EA and FONSI can be viewed and downloaded from the project website at *https://transportation.ky.gov/DistrictOne/Pages/US-641-Calloway-.aspx* or viewed at the TDOT Central Office; James K. Polk Building, Suite 700, 505 Deaderick Street, Nashville, Tennessee 37243; the TDOT Region 4, Administrative Building, 300 Benchmark Place, Jackson, Tennessee 38301; the KYTC Central Office, 200 Mero Street, Frankfort, Kentucky 40622; or the KYTC District 1 Office, 5501 Kentucky Dam Road, Paducah, Kentucky 42003.

This notice applies to all Federal agency decisions that are final as of the issuance date of this notice and all laws under which such actions were taken, including but not limited to:

1. *General:* National Environmental Policy Act (NEPA) [42 U.S.C. 4321–4351]; Federal-Aid Highway Act [23 U.S.C. 109 and 23 U.S.C. 128].

2. *Air:* Clean Air Act [42 U.S.C. 7401–7671(q)].

3. *Land:* Section 4(f) of the Department of Transportation Act of 1966 [23 U.S.C. 138 and 49 U.S.C. 303].

4. *Wildlife:* Endangered Species Act [16 U.S.C. 1531–1544 and Section 1536]; Fish and Wildlife Coordination Act [16 U.S.C. 661–667(d)]; Migratory Bird Treaty Act [16 U.S.C. 703–712].

5. *Historic and Cultural Resources:* Section 106 of the National Historic Preservation Act of 1966, as amended [54 U.S.C. 300101 *et seq.*].

6. *Social and Economic:* Civil Rights Act of 1964 [42 U.S.C. 2000(d)–2000(d)(1)]; Farmland Protection Policy Act (FPPA) [7 U.S.C. 4201–4209].

7. *Wetlands and Water Resources:* Clean Water Act (Section 404, Section 401, and Section 319) [33 U.S.C. 1251–1377].

8. *Hazardous Materials:* Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) [42 U.S.C. 9601–9675].

9. *Executive Orders:* E.O. 11990 Protection of Wetlands; E.O. 11988 Floodplain Management; E.O. 13112 Invasive Species; E.O. 12898 Federal Actions to Address Environmental Justice in Minority Populations and Low Income Populations; E.O. 13175 Consultation and Coordination with Indian Tribal Governments; E.O. 11514 Protection and Enhancement of Environmental Quality.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Authority: 23 U.S.C. 139(*l*)(1).

Issued on: December 5, 2019.

Todd Jeter,

Division Administrator, Frankfort, Kentucky.

[FR Doc. 2019–27021 Filed 12–20–19; 8:45 am]

BILLING CODE 4910–RY–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2019–0108]

Agency Information Collection Activities; Approval of a Renewal Information Collection Request: Commercial Driver's License Drug and Alcohol Clearinghouse

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FMCSA announces its plan to submit the Information Collection Request (ICR) described below to the Office of Management and Budget (OMB) for review and approval. The FMCSA requests to renew an ICR titled, ''Commercial Driver's License Drug and Alcohol Clearinghouse.'' The Agency's final rule, published December 5, 2016, titled ''Commercial Driver's License Drug and Alcohol Clearinghouse'' (Clearinghouse) established the regulatory requirements for the Clearinghouse. The compliance date of the final rule is January 6, 2020. Since the original ICR was approved, FMCSA has opened the Clearinghouse to user registration, resulting in the collection of user contact information. With the upcoming compliance date, this ICR is needed to ensure that Clearinghouse querying and reporting requirements are met to improve compliance with the existing requirement that Commercial Driver's License (CDL) or Commercial Learner's Permit (CLP) holders who have drug or alcohol testing violations cannot perform safety-sensitive functions, including driving a commercial motor vehicle (CMV), without participating in the required return-to-duty process.

DATES: Please send your comments by January 22, 2020. OMB must receive your comments by this date.

ADDRESSES: All comments should reference Federal Docket Management System (FDMS) Docket Number FMCSA–2019–0108. Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the attention of the Desk Officer, Department of Transportation/Federal Motor Carrier Safety Administration, and sent via electronic mail to *oira_submission@omb.eop.gov,* or faxed to (202) 395–6974, or mailed to the Office of Information and Regulatory Affairs, Office of Management and Budget, Docket Library, Room 10102, 725 17th Street, NW, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Juan Moya, Compliance Division, Department of Transportation, Federal Motor Carrier Safety Administration, 6th Floor, West Building, 1200 New Jersey Avenue SE., Washington, DC 20590–0001. Telephone: 202–366–4844; Email Address: *clearinghouse@dot.gov.* Office hours are from 9 a.m. to 5 p.m., Monday through Friday, except Federal Holidays.

SUPPLEMENTARY INFORMATION:

Title: Commercial Driver's License Drug and Alcohol Clearinghouse.

OMB Control Number: 2126–0057.

Type of Request: Renewal

Respondents: Motor carriers (employers), drivers, medical review officers (MRO), substance abuse professionals (SAP), consortia/third-party administrators (C/TPAs), and State Drivers Licensing Agencies (SDLAs).

Estimated Number of Respondents: 11,038,986.

Estimated Time per Response: 20 minutes.

Expiration Date: January 31, 2020.

Frequency of Response: On occasion.

Estimated Total Annual Burden: 1,864,251.

An authorized user's role will determine the frequency of the response in the Clearinghouse.

• *Employers, or C/TPAs acting on behalf of an employer:* At a minimum, employers are required to query the Clearinghouse for each driver they currently employ at least once a year. Employers must query the Clearinghouse for all prospective employees. In addition, employers report to the Clearinghouse alcohol confirmation test, with a concentration of 0.04 or higher, refusal to test (alcohol), refusal to test (drug) that is not determined by an MRO, actual knowledge of a driver's conduct prohibited by 49 CFR part 382, subpart B, negative return-to-duty (RTD) test results, and the driver's completion of follow-up testing. Employer reporting must be completed by the close of the third business day following the date they obtained the information.

• *MROs:* Verified positive, adulterated or substituted drug test result and refusals to tests (drug) must be entered to the Clearinghouse no later than two business days of making a determination or verification.

• *SAPs:* Must enter the initial assessment date and the date the driver successfully complied with return-to-duty (RTD) requirements. SAPs are required to enter this information on occasion by the close of business day following the date of the initial assessment or compliance with the RTD process.

• SDLAs will be required to query the Clearinghouse prior to specified licensing transactions to determine if there are existing drug or alcohol violations.[1]

• Drivers must provide their specific consent to pre-employment queries electronically through the Clearinghouse.

Background

Agency regulations at 49 CFR part 382 apply to persons and employers of such persons who operate CMVs in commerce in the United States and who are subject to the CDL requirements in 49 CFR part 383 or the equivalent CDL requirements for Canadian and Mexican drivers (49 CFR 382.103(a)). Part 382 requires that employers conduct pre-employment drug testing, post-accident testing, random drug and alcohol testing, and reasonable suspicion testing, as well as RTD testing and follow-up testing for those drivers who test positive or otherwise violate DOT drug and alcohol program requirements. Motor carrier employers are prohibited from allowing an employee to perform safety-sensitive functions, which include operating a CMV, if the employee tests positive on a DOT drug or alcohol test, refuses to take a required test, or otherwise violates the DOT or FMCSA drug and alcohol testing regulations.

Section 32402 of the Moving Ahead for Progress in the 21st Century Act (MAP–21) requires that the Secretary of Transportation establish, operate, and maintain a national clearinghouse for records relating to alcohol and controlled substances testing of CMV operators to improve compliance with the Department of Transportation's (DOT) alcohol and controlled substances testing program and to enhance the safety of our roadways by reducing crashes and injuries involving the misuse of alcohol or use of controlled substances by operators of CMVs. As noted above, FMCSA published a final rule on December 5, 2016, with an effective date of January 4, 2017, and a compliance date of January 6, 2020, to implement these statutory requirements.

On June 20, 2019, the FMCSA published a 60-day ICR notice (84 FR 28882). The Agency received 24 comments in response to the ICR notice. These comments are summarized below. Thirteen commenters recommended an application programming interface (API) to reduce the burden of manual entries by employers or their designated C/TPAs, MROs, and employee-designated SAPs. In addition, several commenters stated an API would increase efficiency when querying the Clearinghouse for current and prospective employees. Some commenters suggested that the API would reduce errors in reporting of information, as well as reduce cost to employers and service agents. One commenter recommended delaying the implementation of the Clearinghouse until the development of an API has been completed.

FMCSA Response: The Agency believes that conducting mandatory pre-employment and annual Clearinghouse queries will impose the most significant burden on employers or their designated C/TPAs. In order to alleviate this burden, FMCSA developed a bulk query template allowing employers or their designated C/TPAs to submit multiple queries at one time rather than querying each individual driver. FMCSA will consider the development of an API as a future enhancement to the system.

One commenter noted increased burden during registration due to the establishment of two-factor authentication methods through *login.gov. Login.gov* is a shared service which provides the public secure and private online access to participating Federal government programs, such as the Clearinghouse.

FMCSA Response: A two-factor authentication for all Clearinghouse users is necessary to ensure the security of sensitive driver-specific information. Once the *login.gov* account has been created, there is no additional burden to authorized users during the registration.

One commenter recommended that the comment period for the ICR be extended until after implementation of the Clearinghouse.

FMCSA Response: In accordance with information collection requirements established by the Paperwork Reduction Act of 1995 and related regulations, the public is invited to respond to this **Federal Register** Notice (FRN) during the 30-day comment period. All comments will be considered before publishing the final FRN for the ICR.

The remaining comments were not relevant to the subject matter of the ICR.

FMCSA opened the Clearinghouse to user registration on October 1, 2019. Information stored in the Clearinghouse includes the user name, point of contact information, email address, system role, CDL information (as applicable), credential information (as applicable) and company information (as applicable). This information collected is covered under the existing Clearinghouse ICR (2126–0057).

The Clearinghouse will function as a repository for records relating to the positive test results and test refusals of CMV operators and other violations by such operators of prohibitions set forth in part 382, subpart B, of title 49, Code of Federal Regulations. An employer will utilize the Clearinghouse to determine whether current and

[1] On September 6, 2019, FMCSA published a Notice of Proposed Rulemaking (NPRM) to extend the compliance date for the States' mandatory query of the Clearinghouse, as set forth in the Clearinghouse final rule, from January 6, 2020 to January 6, 2023. (84 FR 46923 (Sept. 6, 2019)) The NPRM proposed that, in the interim, States be permitted to voluntarily query the Clearinghouse beginning January 6, 2020. The Agency expects that a final rule will be published before the end of 2019.

prospective employees have incurred a drug or alcohol violation that would prohibit them from performing safety-sensitive functions, including operating a CMV.

The Clearinghouse will provide FMCSA and employers the necessary tools to identify drivers who are prohibited from operating a CMV and ensure that such drivers receive the required evaluation and treatment before resuming safety-sensitive functions. Specifically, information maintained in the Clearinghouse will ensure that drivers who commit a drug or alcohol violation while working for one employer and attempt to find work with another employer, can no longer conceal their drug and alcohol violations merely by moving on to the next job or the next state. Drug and alcohol violation records maintained in the Clearinghouse will follow the driver regardless of how many times he or she changes employers, seeks employment or applies for a CDL in a different State.

The information in the Clearinghouse will be used by FMCSA and its State partners for enforcement purposes:

- Ensure employers are meeting their pre-employment investigation and reporting requirements.
- Place drivers out of service if drivers are found to be operating a CMV without completing the RTD process.
- Ensure medical review officers (MROs) and substance abuse professionals (SAPs) meet their reporting requirements.

Only authorized users, including employers and their service agents, and highway safety personnel, and State Driver Licensing Agencies (SDLAs), will be able to register and access the Clearinghouse for designated purposes. State enforcement personnel will receive the driver's eligibility status to operate a CMV, based on Clearinghouse information, when they check Query Central or NLets for driver information. FMCSA will share a driver's drug and alcohol violation information with the National Transportation Safety Board when it is investigating a crash involving that driver.

Drivers will be able to access their own information, but not information of other drivers. The Clearinghouse will meet all relevant federal security standards and FMCSA will continuously monitor compliance with applicable security regulations.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including: (1) Whether the proposed collection is necessary for the FMCSA to perform its functions; (2) the accuracy of the estimated burden; (3) ways for the FMCSA to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized without reducing the quality of the collected information.

Issued under the authority delegated in 49 CFR 1.87 on: December 17, 2019.

G. Kelly Regal,

Associate Administrator for Office of Research and Information Technology.

[FR Doc. 2019–27635 Filed 12–20–19; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2019–0287]

Driver Qualification Files: Application for Exemption; Knight-Swift Transportation Holdings, Inc.

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of application for exemption; request for comments.

SUMMARY: FMCSA announces that Knight-Swift Transportation Holdings, Inc. (Knight-Swift) has applied for an exemption from regulations requiring motor carriers to obtain the motor vehicle record (MVR) of its drivers holding a commercial driver's license (CDL) whenever the driver's MVR is updated by a new medical examination. Knight-Swift seeks exemption only when a newly-hired driver undergoes a medical examination. Knight-Swift suggests that in these cases it be permitted to satisfy this requirement by obtaining other proof of the results of the medical examination. FMCSA requests public comments on the request for exemption. The application is available in the docket.

DATES: January 22, 2020.

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) Docket ID FMCSA–2019–0287 using any of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Follow the online instructions for submitting comments.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* 1–202–493–2251.

Each submission must include the Agency name and the docket number for this notice. Note that DOT posts all comments received without change to *www.regulations.gov,* including any personal information included in a comment. Please see the *Privacy Act* heading below.

Docket: For access to the docket to read background documents or comments, go to *www.regulations.gov* at any time or visit Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. The on-line FDMS is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

Privacy Act: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

FOR FURTHER INFORMATION CONTACT: For information concerning this notice contact Ms. La Tonya Mimms, Chief, Driver and Carrier Operations Division; Office of Carrier, Driver and Vehicle Safety Standards; Telephone: 202–366–9220. Email: *MCPSD@dot.gov.* If you have questions on viewing or submitting material to the docket, contact Docket Services, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation and Request for Comments

FMCSA encourages you to participate by submitting comments and related materials.

Submitting Comments

If you submit a comment, please include the docket number for this notice (FMCSA–2019–0287), indicate the specific section of this document to which the comment applies, and provide a reason for suggestions or recommendations. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so the Agency

can contact you if it has questions regarding your submission.

To submit your comment online, go to *www.regulations.gov* and put the docket number, ''FMCSA–2019–0287'' in the ''Keyword'' box, and click ''Search.'' When the new screen appears, click on ''Comment Now!'' button and type your comment into the text box in the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party and then submit. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to *www.regulations.gov* and insert the docket number, ''FMCSA–2019–0287'' in the ''Keyword'' box and click ''Search.'' Next, click ''Open Docket Folder'' button and choose the document listed to review. If you do not have access to the internet, you may view the docket online by visiting the Docket Management Facility in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., e.t., Monday through Friday, except Federal holidays.

II. Legal Basis

FMCSA has authority under 49 U.S.C. 31136(e) and 31315 to grant exemptions from certain parts of the Federal Motor Carrier Safety Regulations. FMCSA must publish a notice of each exemption request in the **Federal Register** (49 CFR 381.315(a)). The Agency must provide the public an opportunity to inspect the information relevant to the application, including any safety analyses that have been conducted. The Agency must also provide an opportunity for public comment on the request.

The Agency reviews the safety analyses and the public comments, and determines whether granting the exemption would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved by the current regulation (49 CFR 381.305). The decision of the Agency must be published in the **Federal Register** (49 CFR 381.315(b)) with the reason for the grant or denial and, if granted, the specific person or class of persons receiving the exemption, and the regulatory provision or provisions from which exemption is granted. The notice must also specify the effective period of the exemption (up to 5 years), and explain the terms and conditions of the exemption. The exemption may be renewed (49 CFR 381.300(b)).

Issued on: December 17, 2019.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2019–27632 Filed 12–20–19; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Notice of Final Federal Agency Actions on Proposed Highway Projects in Texas

AGENCY: Texas Department of Transportation (TxDOT), Federal Highway Administration (FHWA), U.S. Department of Transportation.

ACTION: Notice of limitation on claims for judicial review of actions by TxDOT and Federal Agencies.

SUMMARY: This notice announces actions taken by TxDOT and Federal agencies that are final. The environmental review, consultation, and other actions required by applicable Federal environmental laws for these projects are being, or have been, carried-out by TxDOT pursuant to an assignment agreement executed by FHWA and TxDOT. The actions relate to various proposed highway projects in the State of Texas. These actions grant licenses, permits, and approvals for the projects.

DATES: By this notice, TxDOT is advising the public of final agency actions subject to 23 U.S.C. 139(l)(1). A claim seeking judicial review of TxDOT and Federal agency actions on the highway projects will be barred unless the claim is filed on or before the deadline. For the projects listed below, the deadline is May 21, 2020. If the Federal law that authorizes judicial review of a claim provides a time period of less than 150 days for filing such a claim, then that shorter time period still applies.

FOR FURTHER INFORMATION CONTACT: Carlos Swonke, Environmental Affairs Division, Texas Department of Transportation, 125 East 11th Street, Austin, Texas 78701; telephone: (512) 416–2734; email: *carlos.swonke@txdot.gov.* TxDOT's normal business hours are 8:00 a.m.–5:00 p.m. (central time), Monday through Friday.

SUPPLEMENTARY INFORMATION: The environmental review, consultation, and other actions required by applicable Federal environmental laws for these projects are being, or have been, carried-out by TxDOT pursuant to 23 U.S.C. 327 and a Memorandum of Understanding dated December 16, 2014, and executed by FHWA and TxDOT.

Notice is hereby given that TxDOT and Federal agencies have taken final agency actions by issuing licenses, permits, and approvals for the highway projects in the State of Texas that are listed below.

The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Categorical Exclusion (CE), Environmental Assessment (EA), or Environmental Impact Statement (EIS) issued in connection with the projects and in other key project documents. The CE, EA, or EIS and other key documents for the listed projects are available by contacting TxDOT at the address provided above.

This notice applies to all TxDOT and Federal agency decisions as of the issuance date of this notice and all laws under which such actions were taken, including but not limited to:

1. *General:* National Environmental Policy Act (NEPA) [42 U.S.C. 4321–4351]; Federal-Aid Highway Act [23 U.S.C. 109].

2. *Air:* Clean Air Act, 42 U.S.C. 7401–7671(q).

3. *Land:* Section 4(f) of the Department of Transportation Act of 1966 [49 U.S.C. 303]; Landscaping and Scenic Enhancement (Wildflowers), 23 U.S.C. 319.

4. *Wildlife:* Endangered Species Act [16 U.S.C. 1531–1544 and Section 1536], Marine Mammal Protection Act [16 U.S.C. 1361], Fish and Wildlife Coordination Act [16 U.S.C. 661–667(d)], Migratory Bird Treaty Act [16 U.S.C. 703–712].

5. *Historic and Cultural Resources:* Section 106 of the National Historic Preservation Act of 1966, as amended [54 U.S.C. 300101 *et seq.*]; Archeological Resources Protection Act of 1977 [16 U.S.C. 470(aa)–11]; Archeological and Historic Preservation Act [54 U.S.C. 312501 *et seq.*]; Native American Grave Protection and Repatriation Act (NAGPRA) [25 U.S.C. 3001–3013].

6. *Social and Economic:* Civil Rights Act of 1964 [42 U.S.C. 2000(d)–2000(d)(1)]; American Indian Religious Freedom Act [42 U.S.C. 1996]; Farmland Protection Policy Act (FPPA) [7 U.S.C. 4201–4209].

7. *Wetlands and Water Resources:* Clean Water Act, 33 U.S.C. 1251–1377 (Section 404, Section 401, Section 319); Land and Water Conservation Fund (LWCF), 16 U.S.C. 4601–4604; Safe Drinking Water Act (SDWA), 42 U.S.C. 300(f)–300(j)(6); Rivers and Harbors Act of 1899, 33 U.S.C. 401–406; Wild and

Scenic Rivers Act, 16 U.S.C. 1271–1287; Emergency Wetlands Resources Act, 16 U.S.C. 3921, 3931; TEA–21 Wetlands Mitigation, 23 U.S.C. 103(b)(6)(m), 133(b)(11); Flood Disaster Protection Act, 42 U.S.C. 4001–4128.

8. *Executive Orders:* E.O. 11990 Protection of Wetlands; E.O. 11988 Floodplain Management; E.O. 12898, Federal Actions to Address Environmental Justice in Minority Populations and Low Income Populations; E.O. 11593 Protection and Enhancement of Cultural Resources; E.O. 13007 Indian Sacred Sites; E.O. 13287 Preserve America; E.O. 13175 Consultation and Coordination with Indian Tribal Governments; E.O. 11514 Protection and Enhancement of Environmental Quality; E.O. 13112 Invasive Species. (Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction.)

The projects subject to this notice are:

1. FM 471 from SH 211 to Old FM 471, Bexar and Medina Counties, Texas. The project would expand the existing FM 471 from a two-lane roadway to a four-lane roadway with raised medians, turn lanes, dedicated bike lanes and sidewalks. The project is approximately 4.44 miles in length. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Categorical Exclusion Determination issued on July 8, 2019 and other documents in the TxDOT project file. The Categorical Exclusion determination and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT San Antonio District Office at 4615 NW Loop 410, San Antonio, TX 78229; telephone (210) 615–5839.

2. Business (BU) 71E over the Colorado River in LaGrange, Fayette County, Texas. The proposed project consists of the construction of a new concrete and steel girder bridge over the Colorado River approximately 54 feet downstream (centerline to centerline) of the existing historic truss bridge. The new bridge would be 1,400 feet long and 53 feet wide and would carry two 12 feet travel lanes with 10 feet shoulders and a 6 feet wide sidewalk. The purpose of the project is to provide a bridge crossing that meets current design and safety standards, as well as allow for the future rehabilitation and continued use of the existing historic truss bridge. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Categorical Exclusion Determination issued on July 10, 2019, and other documents in the TxDOT project file. The Categorical Exclusion Determination and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Yoakum District Office at 403 Huck St., Yoakum, TX 77995; telephone (361) 293–4436.

3. State Loop 250 at CR 1140, Midland County Texas. The proposed improvements include the construction of main lanes through the entirety of the project limits. An overpass would be constructed at the intersection with CR 1140 with ramps to and from the bridge overpass. Turnaround lanes would also be constructed at both bridges. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Categorical Exclusion Determination issued on July 12, 2019, and other documents in the TxDOT project file. The Categorical Exclusion Determination and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Odessa District Office at 3901 East Highway 80, Odessa, Texas 79761; telephone (432) 498–4746.

4. SH 276 from FM 549 to CR 2472 in Rockwall County, Texas. The proposed project would reconstruct and widen SH 276 from a two-lane undivided rural roadway to a four-lane divided urban roadway within the project limits. The proposed facility would include four lanes, two 12-foot inside lanes and two 14-foot outside shared-use lanes, with a raised median and two-foot inside and outside shoulders. Five-foot sidewalks would be included on both sides of the roadway. The length of the proposed project is approximately 7.22 miles. The purpose of the proposed project is to improve traffic mobility and reduce congestion. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Categorical Exclusion Determination issued on July 31, 2019, and other documents in the TxDOT project file. The Categorical Exclusion Determination and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Dallas District Office at 4777 E Highway 80, Mesquite, TX 75150; telephone (214) 320–4480.

5. Pellicano Drive from Joe Battle Blvd. to Darrington (Berryville St.) in El Paso County, Texas. The project will reconstruct/widen from a two-lane roadway to a six-lane divided facility with sidewalk, illumination, landscaping, dedicated bicycle lanes and a shared-use path. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Categorical Exclusion Determination issued on August 7, 2019 and other documents in the TxDOT project file. The Categorical Exclusion Determination and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT El Paso District Office at 13301 Gateway West, El Paso, TX 79928; telephone (915) 790–4340.

6. Landing Boulevard from FM 518 to Interstate Highway 45 (I–45) in Harris and Galveston Counties, Texas. The approximately 1.7-mile-long project will extend Landing Boulevard and the NASA Road 1 Bypass (NASA 1) as a four-lane divided roadway to a proposed roundabout with the proposed NASA 1 Bypass extension, which would connect to the existing NASA 1 Bypass at I–45. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Categorical Exclusion Determination approved on August 14, 2019 and other documents in the TxDOT project file. The Categorical Exclusion Determination and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Houston District Office located at 7600 Washington Avenue, Houston, Texas 77007; telephone (713) 802–5076.

7. I–10 from Loop 1604 to US 90, Bexar and Guadalupe Counties, Texas. The project includes widening the existing facility from four lanes to six lanes and upgrading existing interchanges. The existing two-way frontage roads would be modified to one-way on either side of the I–10 main lanes. Continuous 6-foot sidewalks would be added adjacent to the outside of the northern (westbound) and southern (eastbound) frontage roads for the entire project length. The project is approximately 13.35 miles in length. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Categorical Exclusion Determination issued on August 15, 2019 and other documents in the TxDOT project file. The Categorical Exclusion determination and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT San Antonio District Office at 4615 NW Loop 410, San Antonio, TX 78229; telephone (210) 615–5839.

8. FM 2818 from 0.5 miles North of FM 60 to FM 2154 in Brazos County, Texas. The proposed project would add capacity to FM 2818 by constructing an

additional travel lane in each direction. Additionally, congestion would be addressed at the intersections of FM 2347, Luther Street and Holleman Drive by converting the corridor to a ''Super Street'' design. The length of the project is approximately 3.25 miles. The purpose of the proposed project is to relieve congestion by adding capacity and improving safety. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Categorical Exclusion Determination issued on August 28, 2019, and other documents in the TxDOT project file. The Categorical Exclusion Determination and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Bryan District Office at 2591 North Earl Rudder Freeway, Bryan, TX 77803; telephone (979) 778–2165.

9. FM 565 from 0.30 miles West of FM 2354 to 0.16 miles East of FM 1405, Chambers County, Texas. The existing roadway consists of two 11-foot lanes with 1-foot shoulders. The proposed roadway will be widened to two 12-foot lanes with two 10-foot shoulders. From approximately 1.02 miles west of FM 2354 to 0.36 miles east of FM 1405, the roadway will be realigned to eliminate an undesirable ''S'' curve that does not meet current standards. The length of the proposed project is approximately 1.86 miles. The purpose of the proposed project is to improve traffic mobility, reduce congestion and bring the existing roadway up to current safety standards by removing the ''s'' curve. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in, the Categorical Exclusion Determination issued on August 28, 2019, and other documents in the TxDOT project file. The Categorical Exclusion Determination and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Beaumont District Office at 8350 Eastex Freeway, Beaumont TX 77708; telephone (409) 892–7311.

10. Interstate Highway 10 (I–10) at the San Jacinto River in Harris County, Texas. The 0.5-mile-long project will complete an emergency repair of the navigation system associated with the existing bridge which was damaged as a result of Hurricane Harvey. The project would replace the damaged dolphin structures and navigation fender system, and add rip-rap to protect the navigation fender system and bridge bents from future natural disasters or extreme high-water events. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Categorical Exclusion Determination approved on October 11, 2019 and other documents in the TxDOT project file. The Categorical Exclusion Determination and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Houston District Office located at 7600 Washington Avenue, Houston, Texas 77007; telephone (713) 802–5076.

11. US 83 at FM 3034 in Jones County, Texas. The project will consist of a new overpass on US 83 with a project length of 1 mile. FM 3034 will be realigned to the north of the existing alignment with a project length of 0.27 miles. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Categorical Exclusion approved on October 15, 2019, and other documents in the TxDOT project file. The Categorical Exclusion Determination and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Abilene District Office at 4250 North Clack Street, Abilene, TX 79601; telephone (325) 643–6817.

12. FM 2275 from FM 3272 to SH 300, in Gregg County, Texas. The purpose of the proposed project is to improve safety and mobility by reconstructing and widening the freeway from two to four lanes with flush median (continuous left turn lane), including shared use paths, bike lanes, and sidewalks. The proposed project length is approximately 4.04 miles in length. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the final Environmental Assessment (EA) approved on July 18, 2019, the Finding of No Significant Impact (FONSI) issued on July 18, 2019, and other documents in the TxDOT project file. The Final EA, FONSI, and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Tyler District Office at 2709 West Front Street St., Tyler, TX 75702; telephone (903) 510–9267.

13. US 59 from FM 2914 to south of SL 573, in San Jacinto and Liberty Counties, Texas. The purpose of the proposed project is to improve safety and mobility on US 59 between FM 2914 and SL 573 to accommodate current and future traffic volumes by upgrading US 59 to interstate standards which would include converting it to a controlled access highway with frontage roads and two main lanes in each direction, and frontage road shoulders to accommodate bicycles in the Liberty County portion of the project. The proposed project length is approximately 6.63 miles in length. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Final Environmental Assessment (EA) approved on August 14, 2019, the Finding of No Significant Impact (FONSI) issued on August 14, 2019, and other documents in the TxDOT project file. The Final EA, FONSI, and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Lufkin District Office at 1805 North Timberland Dr., Lufkin, TX 75901; telephone (936) 633–4395.

14. US 183A Toll Road Phase III, From Hero Way to SH 29, Williamson County, Texas. The build alternative would extend the six-lane, controlled-access, grade separated 183A tolled main lanes from their current terminus approximately 0.4 mile north of Hero Way to approximately 0.4 mile north of SH 29. The 183A tolled main lanes would be located in the median between the existing northbound and southbound US 183 four-lane divided roadway. The existing US 183 four-lane divided roadway within the project limits would serve as frontage roads north to SH 29, and transition back to the existing, undivided US 183 approximately 1.1 miles north of SH 29. The project is approximately 5.63 miles in length. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Final EA approved on August 19, 2019, the Finding of No Significant Impact (FONSI) issued on August 19, 2019, and other documents in the TxDOT project file. The Final EA, FONSI and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Austin District Office at 7901 North I–35, Austin, TX 78753; telephone (512) 832–7000.

15. FM 552 from SH 205 to SH 66 in Rockwall County, Texas. The proposed project would consist of widening FH 552 from a two-lane rural section to a four-lane urban section. The two inside travel lanes would be 12-foot wide and the outside travel lanes would be 14-foot wide to accommodate shared-use of bicycles and vehicles. The length of the proposed project is approximately 5.19 miles. The purpose of the proposed project is to improve mobility and providing a facility that meets current roadway design standards. The actions by TxDOT and Federal agencies and the laws under which such actions were

taken are described in the Final Environmental Assessment (EA) approved on August 23, 2019, Finding of No Significant Impact (FONSI) issued on August 23, 2019 and other documents in the TxDOT project file. The Final EA, FONSI, and other documents are available by contacting TxDOT at the address provided above or the TxDOT Dallas District Office at 4777 E Highway 80, Mesquite, TX 75150; telephone (214) 320–4480.

16. SH 286 from FM 43 to south of FM 2444, in Nueces County, Texas. The purpose of the proposed project is to improve safety and mobility on SH 286 between FM 43 and FM 2444 and to accommodate current and future traffic volumes by reconstructing and widening SH 286 from a two-lane undivided highway to a controlled access four-lane freeway, including frontage roads with 12-foot shoulders, and sidewalks. The proposed project length is approximately 3.2 miles. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Final Environmental Assessment (EA) approved on September 24, 2019, the Finding of No Significant Impact (FONSI) issued on September 25, 2019 and other documents in the TxDOT project file. The Final EA, FONSI, and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Corpus Christi District Office at 1701 South Padre Island Drive, Corpus Christi, TX 78416; telephone (361) 808–2544.

17. US 82 from FM 1197/Bridge Street in Henrietta to SH 175/Montague Street in Nocona in Clay and Montague Counties, Texas. The proposed project would consist of widening the existing 2-lane undivided highway to a 4-lane divided highway. Some areas of proposed US 82 would be divided by a depressed grassy median and other areas would be divided by a center left turn lane. The proposed project would be approximately 26.6 miles in length. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Final Environmental Assessment (EA) approved on September 24, 2019, the Finding of No Significant Impact (FONSI) issued on October 3, 2019, and other documents in the TxDOT project file. The Final EA, FONSI, and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or at the TxDOT Wichita Falls District Office at 1601 Southwest Parkway, Wichita Falls, TX 76302; telephone (940) 720–7728.

18. FM 1461 from SH 289 to CR 123 in Collin County, Texas. The proposed improvements would consist of reconstructing and widening the roadway from a two-lane rural highway to a four-lane urban highway. Expansion would consist of one 12-foot wide travel lane and one 14-foot wide outside shared-use lane in each direction, a proposed median to accommodate a future ultimate six-lane facility, and sidewalks. The length of the proposed project is approximately 7.10 miles. The purpose of the proposed project is to accommodate expanding transportation demands, increase mobility and accessibility in the region, and provide an east-west transportation facility to serve the communities in the project area. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Final Environmental Assessment (EA) approved on October 1, 2019, Finding of No Significant Impact (FONSI) issued on October 3, 2019 and other documents in the TxDOT project file. The Final EA, FONSI, and other documents are available by contacting TxDOT at the address provided above or the TxDOT Dallas District Office at 4777 E Highway 80, Mesquite, TX 75150; telephone: (214) 320–4480.

19. IH 35 from US 380 to 0.7 Mile North of FM 3002 in Denton and Cooke Counties, Texas. The proposed project would widen and reconstruct IH 35 within the proposed limits. The proposed project would construct three main lanes in each direction and two frontage road lanes in each direction. Existing interchanges would be reconstructed and the existing two-way frontage roads would be converted to one-way operation. In addition, existing ramps would generally be configured from a ''diamond'' to an ''X'' configuration. The length of the proposed project is approximately 15.1 miles. The purpose of the proposed project is to improve traffic mobility, enhance access, reduce traffic congestion, and improve safety. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Final Environmental Assessment (EA) approved on October 3, 2019, Finding of No Significant Impact (FONSI) issued on October 7, 2019 and other documents in the TxDOT project file. The EA and other documents are available by contacting TxDOT at the address provided above or the TxDOT Dallas District Office at 4777 E Highway 80, Mesquite, TX 75150; telephone: (214) 320–4480.

20. Alliance Texas/Haslet Accessibility Improvement Project, from approximately 3,500 feet west of FM 156 to I–35W, Tarrant County. TxDOT proposes reconstructing and widening approximately 0.75 mile of Avondale-Haslet Road to a 4-lane divided roadway. Also, the project includes the extension of Avondale-Haslet Road (4-lane divided roadway) from FM 156 to I–35W (Proposed Haslet Parkway) and the extension of Intermodal Parkway (6-lane divided roadway) southward from its current southern terminus to the proposed Haslet Parkway. The proposed right-of-way (ROW) width varies between 120 to 170 feet. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Final Environmental Assessment approved on October 28, 2019, the Finding of No Significant Impact issued on December 2, 2019, and other documents in the TxDOT project file. The Final Environmental Assessment and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Fort Worth District Office at 2501 S W Loop 820, Fort Worth, Texas 76133; telephone (817) 370–6744.

21. SH 21 Widening from 2.01 miles west of FM 2865 to Martin Luther King, Jr. Street in the City of Madisonville, in Madison County, Texas. The proposed project would widen SH 21 from 2.01 miles west of FM 2865 to Martin Luther King, Jr. Street in the City of Madisonville, and construct a relief route on new location south of the community of North Zulch. The section of SH 21 through North Zulch would not be widened. Beginning 2.01 miles west of FM 2865, SH 21 would be widened for approximately 5 miles before diverging south of North Zulch on new location near County Road 439 (approximately 1 mile west of North Zulch). The proposed relief route south of North Zulch would continue on new location for approximately 3.2 miles before merging with the existing SH 21 facility east of North Zulch approximately 0.75 mile east of County Road 426 (Cleveland Road). From this point, the proposed project would widen SH 21 for approximately 10 miles, ending at Martin Luther King, Jr. Street in Madisonville. The proposed SH 21 facility, including the new-location relief route, would consist of four 12-foot wide travel lanes with a 56-foot to 68-foot wide median. The proposed project would require approximately 384 acres of additional ROW, including approximately 160 acres of ROW for the new location relief route. The ROW width would vary from 100 feet to 324 feet wide, with a typical

width of 224 feet. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Final Environmental Assessment (EA) October 10, 2019, the Finding of No Significant Impact (FONSI) was issued on December 6, 2019, and other documents in the TxDOT project file. The EA, and FONSI, and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Bryan District Office at 2591 North Earl Rudder Freeway, Bryan, TX 77803; telephone (979) 778–9764.

(Authority: 23 U.S.C. 139(l)(1))

Issued on: December 13, 2019.

Michael T. Leary,

Director, Planning and Program Development, Federal Highway Administration.

[FR Doc. 2019–27380 Filed 12–20–19; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Actions

AGENCY: Office of Foreign Assets Control, Department of the Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the name of a person who has been removed from the list of Specially Designated Nationals and Blocked Persons (SDN List). Their property and interests in property are no longer blocked, and U.S. persons are no longer generally prohibited from engaging in transactions with them.

DATES: See **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: OFAC: Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490; Assistant Director for Licensing, tel.: 202–622–2480; or Assistant Director for Regulatory Affairs, tel.: 202–622–4855.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The Specially Designated Nationals and Blocked Persons List (SDN List) and additional information concerning OFAC sanctions programs are available on OFAC's website (*https://www.treasury.gov/ofac*).

Notice of OFAC Actions

OFAC previously determined on December 9, 2019 that the entity listed below met one or more of the criteria under Executive Order 13818 of December 20, 2017, ''Blocking the Property of Persons Involved in Serious Human Rights Abuse or Corruption,'' 82 FR 608329, 3 CFR, 2017 Comp., p. 399 (E.O. 13818).

On December 18, 2019, the Director of OFAC determined that circumstances no longer warrant the inclusion of the following entity on the SDN List under this authority. This entity is no longer subject to the blocking provisions of Section 1(a) of E.O. 13818.

Entity

1. VENTSPILS FREEPORT AUTHORITY (a.k.a. FREEPORT OF VENTSPILS; a.k.a. FREEPORT OF VENTSPILS AUTHORITY; a.k.a. VENTSPILS FREE PORT; a.k.a. VENTSPILS FREEPORT), Jana 19, Ventspils LV–3601, Latvia [GLOMAG] (Linked To: LEMBERGS, Aivars).

Dated: December 18, 2019.

Andrea Gacki,

Director, Office of Foreign Assets Control.

[FR Doc. 2019–27668 Filed 12–20–19; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF VETERANS AFFAIRS

Allowance for Private Purchase of an Outer Burial Receptacle in Lieu of a Government-Furnished Graveliner for a Grave in a VA National Cemetery

AGENCY: Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Department of Veterans Affairs (VA) is updating the monetary allowance payable for qualifying interments that occur during Calendar Year (CY) 2020, which applies toward the private purchase of an outer burial receptacle (or ''graveliner'') for use in a VA national cemetery. The allowance is equal to the average cost of Government-furnished graveliners less any administrative costs to VA. The purpose of this notice is to notify interested parties of the average cost of Government-furnished graveliners, administrative costs that relate to processing and paying the allowance and the amount of the allowance payable for qualifying interments that occur CY 2020.

FOR FURTHER INFORMATION CONTACT: William Carter, Chief of Budget Execution Division, National Cemetery Administration, Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420. Telephone: 202–461–9764 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: Section 2306(e)(3) and (4) of title 38, United States Code authorizes VA to provide a monetary allowance for the private purchase of an outer burial receptacle for use in a VA national cemetery where its use is authorized. The allowance for qualified interments that occur during CY 2020 is the average cost of Government-furnished graveliners in fiscal year 2019, less the administrative costs incurred by VA in processing and paying the allowance in lieu of the Government-furnished graveliner.

The average cost of Government-furnished graveliners is determined by taking VA's total cost during a fiscal year for single-depth graveliners that were procured for placement at the time of interment and dividing it by the total number of such graveliners procured by VA during that FY. The calculation excludes both graveliners procured and pre-placed in gravesites as part of cemetery gravesite development projects and all double-depth graveliners. Using this method of computation, the average cost was determined to be $342.00 for FY 2019.

The administrative costs incurred by VA consist of those costs that relate to processing and paying an allowance in lieu of the Government-furnished graveliner. These costs have been determined to be $9.00 for CY 2020.

The allowance payable for qualifying interments occurring during CY 2020, therefore, is $333.00.

Signing Authority

The Secretary of Veterans Affairs 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. Pamela Powers, Chief of Staff, Department of Veterans Affairs, approved this document on December 16, 2019, for publication.

Luvenia Potts,

Regulation Development Coordinator, Office of Regulation Policy & Management, Office of the Secretary, Department of Veterans Affairs.

[FR Doc. 2019–27616 Filed 12–20–19; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 486

Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organization; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 486

[CMS–3380–P]

RIN 0938–AU02

Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organization

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the Organ Procurement Organization (OPO) Conditions for Coverage (CfCs) to increase donation rates and organ transplantation rates by replacing the current measures with new transparent, reliable, and objective measures.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. EST on February 21, 2020.

ADDRESSES: In commenting, please refer to file code CMS–3380–P when commenting on the issues in this proposed rule. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. Electronically. You may (and we encourage you to) submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the instructions under the ''submit a comment'' tab.

2. By regular mail. You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3380–P, P.O. Box 8010, Baltimore, MD 21244–1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments via express or overnight mail to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3380–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, we refer readers to the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Diane Corning (410) 786–8486, Eric Laib (410) 786–9759, Jesse Roach (410) 786–1000, Alpha-Banu Wilson (410) 786–8687, or CAPT Hui-Hsing Wong (410) 786–9007.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments.

I. Background

A. The Importance of Organ Procurement Organizations and the Need To Reform the Organ Procurement System

Organ procurement organizations (OPOs) are vital partners in the procurement, distribution, and transplantation of human organs in a safe and equitable manner for all potential transplant recipients. The role of OPOs is critical to ensuring that the maximum possible number of transplantable human organs is available to seriously ill people who are on a waiting list for an organ transplant. There are currently 58 OPOs that are responsible for identifying eligible donors and recovering organs from deceased donors in the United States (U.S.). Therefore, OPO performance is a critical element of the organ transplantation system in the U.S.

As of September 2019, a total of 112,846 people were on the waiting lists for a lifesaving organ transplant.[1] Many people face tremendous quality of life burdens or even death while on the waiting list. An OPO that is efficient in procuring organs and delivering them to recipients will help more people on the waiting list receive lifesaving organ transplants, which could ultimately save more lives.

Given OPOs' important role in the organ donation system in the U.S., some stakeholders have argued that underperformers have faced few consequences for poor performance. These stakeholders, mainly from advocacy organizations, have noted that ''Performance varies across the OPO network, with many persistent underperformers failing to improve over the last decade.'' [2] They further note that there are serious negative impacts to both organ transplantation and donation when OPOs are underperforming, in that ''[w]hen OPOs are inefficient or ineffective, donor hospitals are reluctant to refer potential donors, and transplant centers have fewer organ offers for patients on the waiting list. The end result is a bottleneck within the system that leads to avoidable deaths and increased national health care spending.'' [3]

Some stakeholders, including members of the OPO industry, agree that the OPO outcome measures should be reformed. Some of these stakeholders note that ''[e]xisting regulations need dramatic improvement to remove perverse incentives to organ procurement (for example, OPOs are evaluated on the number of organs procured per donor, which leads to older single-organ donors being overlooked) and increase continuous performance accountability.'' [4] Reforming the outcome measures can be achieved, they indicated, through metrics that improve accountability and ''by replacing current ineffective metrics for OPO performance with a simplified transparent metric that enables independent performance measurement.'' [5]

Based on public feedback and our own internal analysis of organ donation and transplantation rates, we agree that the current OPO outcome measures are not sufficiently objective and transparent to ensure public trust in assessing OPO performance, nor do they properly incentivize the adoption of

[1] Organ Procurement and Transplantation Network (OPTN) Data. *https://optn.transplant.hrsa.gov/data/.*

[2] The Bridgespan Group. Reforming Organ Donation in America. *https://www.bridgespan.org/bridgespan/Images/articles/reforming-organ-donation-in-america/reforming-organ-donation-in-america-12-2018.pdf.*

[3] ORGANIZE. Organ Donation Reform Report. 2019.

[4] The Bridgespan Group. Reforming Organ Donation in America. *https://www.bridgespan.org/bridgespan/Images/articles/reforming-organ-donation-in-america/reforming-organ-donation-in-america-12-2018.pdf.*

[5] The Bridgespan Group. Reforming Organ Donation in America. *https://www.bridgespan.org/bridgespan/Images/articles/reforming-organ-donation-in-america/reforming-organ-donation-in-america-12-2018.pdf.*

best practices and optimization of donation and organ placement rates.

B. Statutory and Regulatory Provisions

To be an OPO, an entity must meet the applicable requirements of both the Social Security Act (the Act) and the Public Health Service Act (the PHS Act). Section 1138(b) of the Act provides the statutory qualifications and requirements that an OPO must meet in order for organ procurement costs to be paid under the Medicare program or the Medicaid program. Section 1138(b)(1)(A) of the Act specifies that payment may be made for organ procurement costs only if the agency is a qualified OPO operating under a grant made under section 371(a) of the PHS Act or has been certified or re-certified by the Secretary of the Department of Health and Human Services (the Secretary) as meeting the standards to be a qualified OPO within a certain time period. Section 1138(b)(1)(C) of the Act provides that payment may be made for organ procurement costs ''only if'' the OPO meets the performance-related standards prescribed by the Secretary. Section 1138(b)(1)(F) of the Act requires that to receive payment under the Medicare program or the Medicaid program for organ procurement costs, the entity must be designated by the Secretary. The requirements for such designation are set forth in 42 CFR 486.304 and include being certified as a qualified OPO by CMS.

Pursuant to section 371(b)(1)(D)(ii)(II) of the PHS Act, the Secretary is required to establish outcome and process performance measures for OPOs to meet based on empirical evidence, obtained through reasonable efforts, of organ donor potential and other related factors in each service area of the qualified OPO. Section 1138(b)(1)(D) of the Act requires an OPO to be a member of, and abide by the rules and requirements of, the Organ Procurement and Transplantation Network (OPTN). OPOs must also comply with the regulations governing the operation of the OPTN (42 CFR part 121). The Department has explained that only those policies approved by the Secretary will be considered ''rules and requirements'' of the OPTN for purposes of section 1138 of the Act. The OPTN is a membership organization that links all professionals in the U.S. organ donation and transplantation system. Currently, the United Network for Organ Sharing (UNOS) serves as the OPTN under contract. OPOs are required under the OPTN final rule (42 CFR 121.11(b)(2)) and 42 CFR 486.328 of the OPO Conditions for Coverage (CfCs) to report specific information to the OPTN, including the data used to calculate the outcome measures for OPOs.

In addition, OPOs are required to comply with Section 504 of the Rehabilitation Act of 1973, 29 U.S.C. 794, and section 1557 of the Patient Protection and Affordable Care Act, 42 U.S.C. 18116, which protects qualified individuals with a disability, including prospective organ recipients with a disability and prospective organ donors with a disability, from unlawful discrimination in the administration of organ transplant programs. Under these laws, OPOs must ensure that qualified individuals with a disability are afforded opportunities to participate in or benefit from the organ transplant program that are equal to opportunities afforded others. Decisions to approve or deny organ transplants must be made based on objective facts related to the individual in question. ''Individuals with disabilities are also entitled to reasonable accommodations needed to participate in and benefit from a program, and auxiliary aids and services needed for effective communication. These rights extend in some circumstances to family members of a prospective organ donor or recipient. For example, health care providers and organ donation programs are required to provide auxiliary aids and services (including sign language interpreters) when necessary for effective communication between a relative involved in a prospective donor or recipient's care and a health care provider or donation program.''

We established CfCs for OPOs at 42 CFR part 486, subpart G, and OPOs must meet these requirements in order to be able to receive payments from the Medicare and Medicaid programs. These regulations set forth the certification and re-certification processes, outcome requirements, and process performance measures for OPOs and became effective on July 31, 2006 (71 FR 30982).

Section 486.322 requires that an OPO must have a written agreement with 95 percent of the Medicare- and Medicaid-participating hospitals and critical access hospitals in its service area that have both a ventilator and an operating room, and have not been granted a waiver by CMS to work with another OPO. Meanwhile, 42 CFR 482.45 requires a hospital have written protocols that incorporate an agreement with an OPO under which it must notify, in a timely manner, the OPO or a third party designated by the OPO, of individuals whose death is imminent or who have died in the hospital. Potential organ donors may encounter Medicare- and Medicaid-certified providers prior to an emergency department visit or hospital admission to a critical care unit. Therefore, we expect that each OPO's responsibilities and work began long before a hospital notified the OPO of an impending death—through, but not limited to, extensive training and education of all Medicare and Medicaid-certified providers along the continuum of care and by fostering a collaborative relationship among them.

C. HHS Initiatives Related to OPO Services and Executive Order 13879

In 2000, the Secretary's Advisory Committee on Organ Transplantation (ACOT) was established under the general authority of section 222 of the PHS Act, as amended, and implementing regulations under 42 CFR 121.12. ACOT is charged to (1) advise the Secretary, acting through the Administrator, Health Resources and Services Administration (HRSA) on all aspects of organ donation, procurement, allocation, and transplantation, and on such other matters that the Secretary determines; (2) advise the Secretary on federal efforts to maximize the number of deceased donor organs made available for transplantation and to support the safety of living organ donation; (3) at the request of the Secretary, review significant proposed OPTN policies submitted for the Secretary's approval to recommend whether they should be made enforceable; and (4) provide expert input to the Secretary on the latest advances in the science of transplantation, the OPTN's system of collecting, disseminating and ensuring the validity, accuracy, timeliness and usefulness of data, and additional medical, public health, patient safety, ethical, legal, financial coverage, social science, and socioeconomic issues that are relevant to transplantation.[6]

A 2012 recommendation by ACOT stated: ''The ACOT recognizes that the current CMS and HRSA/OPTN structure creates unnecessary burdens and inconsistent requirements on transplant centers (TCs) and OPOs and that the current system lacks responsiveness to advances in TCs and OPO performance metrics. The ACOT recommends that the Secretary direct CMS and HRSA to confer with the OPTN, Scientific Registry of Transplant Recipients (SRTR), the OPO community, and TCs representatives to conduct a comprehensive review of regulatory and other requirements, and to promulgate regulatory and policy changes to requirements for OPOs and TCs that

[6] *https://www.organdonor.gov/about-dot/acot/charter.html.*

unify mutual goals of increasing organ donation, improving recipient outcomes, and reducing organ wastage and administrative burden on TCs and OPOs. These revisions should include, but not be limited to, improved risk adjustment methodologies for TCs and a statistically sound method for yield measures for OPOs—. . . .'' [7]

On July 10, 2019, President Trump issued Executive Order 13879 titled Advancing American Kidney Health. The Executive Order 13879 states that it is the policy of the U.S. to ''prevent kidney failure whenever possible through better diagnosis, treatment, and incentives for preventive care; increase patient choice through affordable alternative treatments for ESRD by encouraging higher value care, educating patients on treatment alternatives, and encouraging the development of artificial kidneys; and increase access to kidney transplants by modernizing the organ recovery and transplantation systems and updating outmoded and counterproductive regulations.''

Further, the Executive Order aims to increase the utilization of available organs by ordering that, within 90 days of the date of the order, the Secretary propose a regulation to enhance the procurement and utilization of organs available through deceased donation by revising OPO rules and evaluation metrics to establish more transparent, reliable, and enforceable objective measures for evaluating an OPO's performance. In conjunction with the Executive Order, the Department set a goal to deliver more organs for transplantation and aims to double the number of kidneys available for transplant by 2030.[8]

In accordance with the Executive Order and in response to ACOT's recommendations and stakeholder feedback, we are proposing to revise the OPO outcome and process measures so that they are more transparent, reliable, and objective measures of OPO performance. We believe that these changes will lead to increased procurement opportunities for transplantation, increased organ utilization, and as a result, more lives saved.

II. Provisions of the Proposed Regulations

A. Proposed Changes to Outcome Requirements (§ 486.318)

On May 31, 2006, CMS published the final rule, ''Medicare and Medicaid Programs: Conditions for Coverage for Organ Procurement Organizations (OPOs)'' in the **Federal Register** (71 FR 30982). That final rule established the CfCs that OPOs must comply with in order to receive Medicare and Medicaid reimbursement for organ procurement costs. It also set forth outcome measures at 42 CFR 486.318 and specifies the condition for reporting of data, 42 CFR 486.328. OPOs must report data to the OPTN in accordance with 42 CFR 121.11(b)(2) (describing data specified by the Secretary) and 42 CFR 486.328 (describing data required by the Secretary) for the operations of the OPTN and for CMS's assessment of OPO performance. Under these authorities, OPOs must report data to the OPTN or the SRTR specified by the Secretary (including on OMB-approved forms pursuant to the Paperwork Reduction Act of 1995). The CfCs for OPOs at 42 CFR 486.318(a) and (b) have required that an OPO must meet two of the three following outcome measures:

- The OPO's donation rate of eligible donors as a percentage of eligible deaths is no more than 1.5 standard deviations below the mean national donation rate of eligible donors as a percentage of eligible deaths, averaged over the 4 years of the re-certification cycle. Both the numerator and denominator of an individual OPO's donation rate ratio are adjusted by adding a 1 for each donation after cardiac death donor and each donor over the age of 70;
- The observed donation rate is not significantly lower than the expected donation rate for 18 or more months of the 36 months of data used for re–certification, as calculated by SRTR;
- The OPO data reports, averaged over the 4 years of the re-certification cycle, must meet the rules and requirements of the most current OPTN aggregate donor yield measure.

For the 2022 re-certification cycle only however, under 42 CFR 486.316(a)(3), OPOs are not required to meet the second outcome measure (the observed donation rate is not significantly lower than the expected donation rate for 18 or more months of the 36 months of data used for re–certification, as calculated by SRTR). OPOs must instead meet one out of the two outcome measure requirements described in § 486.318(a)(1) and (3) for OPOs not operating exclusively in the noncontiguous States, Commonwealths, Territories, or possessions; or § 486.318(b)(1) and (3) for OPOs operating exclusively in noncontiguous States, Commonwealths, Territories, and possessions (84 FR 61434 through 61436).

We have heard concerns from some stakeholders within the organ donation and transplantation community about these outcome measures since finalization in 2006. Some stakeholders contend that the current outcome measures are not reliable and transparent indicators of OPO performance. Most comments have centered on the self-defined and self-reported nature of the data on ''eligible deaths'' that are used for the evaluation of the outcome measures. Stakeholders increasingly have brought to our attention that the interpretation of ''eligible deaths'' appears to be inconsistent across donation service areas (DSAs), and that ''all OPO data is unaudited and self-reported'' and therefore, ''the accuracy and consistency of that data cannot be assured.'' [9]

In addition, there were concerns about the donor yield outcome measure. According to stakeholders, there are ''pressures from donor yield reporting'' that ''drives OPOs to walk away from cases in which the donor only has one organ viable for transplant (such as for older patients, where it is common that only the liver is medically viable), even in cases where next of kin consents to donation.'' [10] As a result, some commenters have suggested that ''the regulations may be causing OPOs to 'game' the process of meeting [this] standard by only targeting 'high-yield' organ candidates.'' [11] Given these comments, we are concerned that potentially transplantable organs may be wasted, exacerbating the organ shortage problem.

To address some of these stakeholder concerns, we made several changes to these outcome measures since we finalized the CfCs for OPOs in 2006. In 2012, we modified the definition of ''donor document'' (that is, the document that an individual can sign to authorize the procurement of their own

[7] Available at: *https://www.organdonor.gov/about-dot/acot/acotrecs55.html.*

[8] *https://aspe.hhs.gov/system/files/pdf/262046/AdvancingAmericanKidneyHealth.pdf.*

[9] Letter from Helen Irving, President and CEO, New York Organ Donor Network, to Howard Shelanksi, Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget. Oct. 2013. Available at: *https://obamawhitehouse.archives.gov/sites/default/files/omb/assets/oira_0938/0938_10292013b-1.pdf*

[10] ORGANIZE. Organ Donation Reform Report. 2019.

[11] Letter from Helen Irving, President and CEO, New York Organ Donor Network, to Howard Shelanksi, Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget. Oct. 2013. Available at: *https://obamawhitehouse.archives.gov/sites/default/files/omb/assets/oira_0938/0938_10292013b-1.pdf.*

organs after their death) (77 FR 29020). In 2013, we changed the requirement that an OPO had to meet three outcome measures to requiring that the OPO had to meet only two out of the three outcome measures (78 FR 75141). In 2016, we modified our definition of ''eligible death'' to be consistent with the OPTN definition, modified current requirements for documentation of donor information that is sent to the transplant center with the organ, and modified the yield measure to the most current OPTN aggregate donor yield measure (81 FR 79830).

In addition, in November 2019, we finalized a proposal to reconcile the definition of ''expected donation rate'' in the OPO CfCs with the definition currently used by the SRTR. The rule also finalized a policy that requires OPOs to meet one out of the two outcome measures for the 2022 re-certification cycle only. OPOs therefore are not required to meet the second outcome measure (the observed donation rate is not significantly lower than the expected donation rate for 18 or more months of the 36 months of data used for re–certification, as calculated by SRTR) for the 2022 re-certification cycle. Absent additional regulatory changes, an OPO would be required to meet 2 of the 3 regulatory requirements for future evaluation cycles (84 FR 61434 through 61436). We also published a Request for Information (RFI) in the CY 2020 OPPS/ASC proposed rule that solicited comments regarding what revisions may be appropriate for the current CfCs for OPOs that are set forth at 42 CFR 486.301 through 486.360 and the current Conditions of Participation (CoPs) for TCs that are set forth at 42 CFR 482.68 through 482.104 (84 FR 39595 through 39598). That RFI also requested comments on two potential outcome measures, which we now describe in more detail in this proposed rule.

In a continued effort to respond to these concerns and as required by Executive Order 13879 and controlling statutes, we are proposing to revise the outcome measures for re-certification at § 486.318 to replace the existing outcome measures with two new outcome measures that would be used to assess an OPO's performance: ''donation rate'' and ''organ transplantation rate'' effective for CY 2022. The ''donation rate'' would be measured as the number of actual deceased donors as a percentage of total inpatient deaths in the DSA among patients 75 years of age or younger with any cause of death that would not be an absolute contraindication to organ donation; and the ''organ transplantation rate'' would be measured as the number of organs procured within the DSA and transplanted as a percentage of total inpatient deaths in the DSA among patients 75 years of age or younger with any cause of death that would not be an absolute contraindication to organ donation.

The first measure, ''donation rate'', would demonstrate the OPO's percentage of possible deceased donors who become actual donors and the second measure, ''organ transplantation rate'', would demonstrate the percentage of organs transplanted after procurement. We have chosen this combination of measures to reflect our view that OPOs should be expanding their efforts on both converting potential donors into actual donors and successfully placing all possible organs for transplantation. We chose to include actual organ donors who had at least one organ transplanted in our measure to encourage the pursuit of single-organ donors because we believe that these donors are the greatest opportunity for growth; it is our understanding that transplant centers have recently been willing to expand the definition of traditional organ donors and accept organs from these donors. We also chose the total number of organs transplanted to emphasize the role of the OPO in successful organ placement. We acknowledge concerns that donation rate and transplant rate measures may seem redundant and highly correlated; however, we believe that evidence of the high level of correlation is due to our current outcome measures that include both donation rates and organ transplant yield. We selected both donation rates and transplantation rates in order to reduce the risk that resources would be diverted to focus on one measure rather than increasing overall efforts to address both types of measures, which we believe could result in more single-organ donors and minimize discarding of transplantable organs. We are cautious in creating outcome measures that inadvertently decrease one or the other type of measure. For example, if we choose measures based only on donation rates, we are concerned whether there would be sufficient incentives to place as many as possible organs from each donor, which can be time-consuming. Conversely, if we chose measures based solely on organ transplantation rates, we would be concerned that there would be fewer incentives to procure single organs from older donors or donors after cardiac death, as there would be to procure multiple organs from the younger, healthier donor after brain death.

For the first measure, donation rate, the numerator is defined as the number of actual deceased donors in the DSA who had at least one organ transplanted based on data reported to the OPTN. In the current § 486.302 Definitions, we define ''Donor'' to mean a deceased individual from whom at least one vascularized organ (heart, liver, lung, kidney, pancreas, or intestine) is recovered for the purpose of transplantation. We are proposing to change this definition to require that the organ be transplanted, not just recovered. There are three primary reasons for requiring that the organ be actually transplanted: (1) To discourage the discarding of procured organs, (2) to encourage transplantation of every organ, including those from single-organ donors, and (3) because it is easier to verify the existence of a donor who had at least one organ transplanted compared with donors who did not have an organ transplanted. We are seeking comments on the change in definition of ''donor.''

For the second measure, organ transplantation rate, we are not changing the definition of ''Organ,'' but propose to provide clarification as to how the organs are counted (see Table 1) for purposes of determining the organ transplantation rate (as our current regulations do not provide the specificity that we now propose to more accurately track donations). We are excluding organs procured for research, but not transplanted, from our definition, except for pancreata that are procured for islet cell transplantation or research (transplanted or not transplanted), as this is required by section 371(c) of the PHS Act. The numerator is defined as the number of actual organs transplanted based on data obtained from the OPTN. We are seeking comments on this proposed change and clarification.

TABLE 1—ORGANS TRANSPLANTED COUNT

Organ type	Number of organs transplanted
Right or Left Kidney	1
Right and Left Kidney	2
Double/En-Bloc Kidney	2
Heart	1
Intestine	1
Intestine Segment 1 or Segment 2	1
Intestine Segment 1 and Segment 2	2
Liver	1

TABLE 1—ORGANS TRANSPLANTED COUNT—Continued

Organ type	Number of organs transplanted
Liver Segment 1 or Segment 2	1
Liver Segments 1 and Segment 2	2
Right or Left Lung	1
Right and Left Lung	2
Double/En-bloc Lung	2
Pancreas (transplanted whole, research, islet transplant)	1
Pancreas Segment 1 or Segment 2	1
Pancreas Segment 1 and Segment 2	2

Some members of the OPO community have stated that the proposed measure, organ transplantation rate, reflects the transplant hospitals' acceptance practices and that OPOs should not be held accountable for the transplant hospitals' decisions. We understand the role of transplant hospitals in the organ transplantation rate measure; however, we also recognize the influence OPOs have on transplant hospital practice through OPO advisory boards (§ 486.324(a)(5)), which include a transplant surgeon from every transplant hospital in the DSA. Although the historical basis of this requirement was so that transplant hospitals could advise OPOs about transplant practices and have input into their policies,[12] we believe the relationship has evolved bilaterally, such that OPOs can educate transplant hospitals in the DSA about the performance of organs that were turned down by one hospital, but accepted by another. By serving on the OPO advisory board, transplant surgeons can learn more about the practices of the other transplant surgeons on the board, as well as about acceptance practices at transplant hospitals outside the DSA, and share that information with their own transplant hospitals. We also note that OPOs are often expected to place their organs outside of their DSA; our understanding of organ transplant practice is that there are numerous transplant hospitals throughout the country that successfully transplant ''less than perfect'' organs. It is our belief that given the unacceptable number of patients dying on the waiting list or on dialysis waiting for a transplant, there are transplant hospitals in the U.S. that will accept ''less than perfect,'' but still transplantable organs. As such, we believe it is the OPO's responsibility to ensure that those organs are transplanted, instead of discarded. Our goal for this rule and the organ transplantation rate measure is to incentivize the ''system'' to establish efficiencies that will result in substantial improvement of organ placement and transplantation.

The numerators for these measures will be based on the actual donors who had at least one organ transplanted and the number of organs procured and transplanted from those donors in the DSA. Since the data for the numerators for both of these measures are already being submitted by the OPOs and verified by the transplant hospitals when they perform the transplant, we do not believe that these proposed changes create additional reporting burdens for the OPOs or the transplant hospitals.[13] Also, we are confident in the veracity of the information as it can be corroborated by the OPTN, which has a record of all organs in which a match is run for allocation, and requires reporting of the transplantation by the OPO, as well as the transplant program, and requires documentation of the disposition of the organ.

For both measures, the denominator (that is, donor potential) is defined as the number of total inpatient deaths within the DSA among patients 75 years of age or younger with a cause of death that would not be an absolute contraindication to organ donation. For calculating the denominator, we would use data obtained from state death certificates. Currently, this information can be obtained from the Center for Disease Controls' (CDC), National Center for Health Statistics' (NCHS's) Detailed Multiple Cause of Death (MCOD) as described in more detail in this section. The MCOD is published annually and is publicly available upon request. The MCOD meets NCHS data privacy and security requirements.

The MCOD comprises county-level national mortality data that include a record for every death of a U.S. resident recorded in the U.S. The MCOD files contain an extensive set of variables derived from the death certificates which are standardized across the 57 jurisdictions that provide CDC with the data (50 states, New York City, the District of Columbia and the five territories). The jurisdictions use the U.S. Standard Certificate of Death as a template for their forms.[14]

Within the standard certificate of death are key variables relevant to our measures such as where the death occurred: Hospital (inpatient, emergency room/outpatient, and dead on arrival) or somewhere other than a hospital (hospice facility, nursing home/long-term care facility, decedent's home, other). In addition, there is information on the cause of death. The information on the cause of death is based on free text entered by the certifier, usually a physician, medical examiner, or coroner. Based on the causes of death on the certificate, NCHS assigns a code from the International Classification of Diseases, Tenth Revision (ICD–10) to each cause of death reported. This coding is done centrally at NCHS with software designed for this purpose or manually using expert coders; they have been using ICD–10 codes since 1999. In addition to the underlying cause of death, each record has space for up to 20 multiple cause codes. The ICD–10 codes that could be assigned are found in CDC's Instruction Manual, Part 2e, Volume 1: *ICD–10, International Statistical Classification of Diseases and Related Health Statistical Classification of Diseases and Related Health Problems. Tabular List, 2017;* modified by the National Center for Health Statistics for use in the classification and analysis of medical mortality data in the U.S.[15] Although there may be inaccuracies in the description of the causes of deaths in these death certificates, we have no evidence that there are differences in the rate of errors on inpatient death certificates based on the DSA and that any particular DSA would be disproportionately affected.

Deaths that are not an absolute contraindication to organ donation are calculated from those ICD–10 codes and would exclude clinical causes of death in which organs would never be used for transplantation. Our definition of ''a death that is not an absolute contraindication to organ donation'' means all deaths except those identified by the specific ICD–10 codes that would preclude donation under any circumstance. This information would be obtained from the state death certificates, and include both immediate cause of death and contributing causes of death. We have listed the three character categories of ICD–10 codes in Table 2 to be absolute contraindications to organ donation which was generated

[12] Senate Report 104–256—Organ and Bone Marrow Transplant Program Reauthorization Act of 1995 and § 486.324.

[13] The data submitted to the OPTN has already been accounted for in the OPTN final rule's Paperwork Reduction Act analysis.

[14] *https://www.cdc.gov/nchs/data/dvs/DEATH11-03final-acc.pdf.*

[15] *https://www.cdc.gov/nchs/data/dvs/2e_volume1_2017.pdf.*

from and reviewed by several sources (the current list of eligible deaths, public stakeholder input, and HHS medical advisors). We are interested in comments on whether all appropriate subcategories are included and whether other ICD–10 codes should also be excluded from the denominator.

TABLE 2—ICD–10 CODES EXCLUDED FROM THE DENOMINATOR

Tuberculosis	All.
Other bacterial diseases	A39 Meningococcal infection.
	A40 Streptococcal septicaemia.
	A41 Other septicaemia.
Viral infections of the central nervous system	A82 Rabies.
Viral infections characterized by skin and mucous membrane lesions	B03 Smallpox.
Human immunodeficiency virus [HIV] disease	B20 Human immunodeficiency virus [HIV] disease with infectious and parasitic diseases.
	B21 Human immunodeficiency virus [HIV] disease with malignant neoplasms.
Sequelae of infectious and parasitic diseases	B90 Sequelae of tuberculosis.
Malignant neoplasms of lip, oral cavity and pharynx	All.
Malignant neoplasms of digestive organs	All.
Malignant neoplasms of respiratory and intrathoracic organs	All.
Melanoma and other malignant neoplasms of skin	C43 Malignant melanoma of skin.
Malignant neoplasms of bone and articular cartilage	All.
Melanoma and other malignant neoplasms of skin	All.
Malignant neoplasms of methothelial and soft tissue	All.
Malignant neoplasm of breast	All.
Malignant neoplasms of female genital organs	All.
Malignant neoplasms of male genital organs	All.
Malignant neoplasms of thyroid and other endocrine glands	All.
Malignant neoplasms of ill-defined, secondary and unspecified sites	All.
Malignant neoplasms of lymphoid, haematopoietic and related tissue	All.
Malignant neoplasms of independent (primary) multiple sites	All.
Neoplasms of uncertain or unknown behavior	D44 Neoplasm of uncertain or unknown behaviour of endocrine glands.
	D46 Meylodysplastic syndromes.
	D47 Other neoplasms of uncertain or unknown behavior of lymphoid, haematopietic and related tissue.
	D48 Neoplasms of uncertain or unknown behavior of other and unspecified sites.
Coagulation defects, purpura and other haemorrhagic conditions	D65 Disseminated intravascular coagulation [defibrination syndrome].
	D69 Purpura and other haemorrhagic conditions.
Metabolic disorders	E84 Cystic fibrosis.
Infections specific to the perinatal period	P36 Bacterial sepsis of newborn.

One of our current measures used to measure OPO performance relies upon measuring the donation rate based on eligible deaths. While the ''eligible death'' definition allows for a more narrow and definitive estimation of the organ donation potential, it also limits the pool of potential organ donors by which OPOs are evaluated and does not take into account the advances in medicine that could expand the pool of potential donors (such as, very effective treatments for hepatitis C allowing hepatitis C positive donors to donate to patients who do not have hepatitis C);[16] further, it is subject to bias in interpretation and reporting. By using inpatient deaths from this objective data source and eliminating causes of death that are absolute contraindications to organ donation, we are targeting a specific population that is more likely to be organ donors and mitigating concerns that the data could be manipulated based upon varying interpretations of an eligible death.

The denominator will be the number of inpatient deaths of someone 75 years old or younger identified using the most recent prior 12 months of available data from the state death certificates from the DSA, and the numerators will be based on the number of donors and organs transplanted during the same corresponding time period. We chose to calculate our measures based on the most recent prior 12 months of available data from the DSA because we do not want to penalize OPOs that have improved their performance by using older data. Also, since the purpose of our performing this assessment is to re-certify an OPO for another 4 years, historical performance from more than two years prior may be less reflective of current performance or less predictive of future performance. Finally, we are interested in comments on whether there are alternative or additional data sources or types we should consider, including those already being collected, when assessing OPO performance. As stated earlier, we acknowledge that there are certain limitations of the CDC Multiple Cause of Death File. We are therefore interested in whether there are additional data sources, such as those collected by the OPTN, which could supplement the precision of outcome measures. We are also interested in the availability and utility of additional types of data, such as donor enrollment practices, discarded organs, or referral management.

In the regulatory impact analysis (RIA) section of this proposed rule, we present tables reflecting the results of our proposed measures using data from January 1, 2017 to December 31, 2017. We found a wide range of donation rates (1.65 to 6.45 donors/100 inpatient deaths) and organ transplantation rates (4.47 to 21.14 transplants/100 inpatient deaths). We did not find a correlation between the performance of OPOs and the number of deaths (reflecting experience with larger volumes of potential donors) or the number of patients on the waiting list (reflecting the demand for organs) in the DSA.

[16] Woolley, AE, et al, ''Heart and Lung Transplants from HCV-Infected Donors to Uninfected Recipients,'' *NEJM,* 2019; 390:1606–1617.

Although Cannon et al. found statistically significant clustering of the top 5 causes of death in organ donors (blunt trauma, gunshot wounds, drug overdose, cerebrovascular accidents, and cardiovascular disease), we compared the donation rates and organ transplantation rates using these proposed measures to the geographic variability in those top five causes of death and found no correlation between high OPO performance and distribution or incidence of those causes of death.[17] We examined the characteristics of the DSAs among the top 25 percent performing OPOs and found that they include geographic areas representative of all parts of the U.S. and diverse racial and ethnic populations. Despite this seemingly broader definition of potential organ donors, we did not notice any particular geographic patterns (including urban vs. rural) distinguishing the top performing OPOs from the rest of the cohort, leading us to conclude that our broad definition, inpatient deaths among those 75 and younger within the DSA, excluding causes of deaths that are an absolute contraindication for organ donation, appropriately describes the donor potential in a DSA and that the primary factors for differences in OPO performance using these measures are within the control of the OPOs to change. We are seeking comments as to the accuracy of our assessment and whether additional research is necessary to ensure that all DSAs will be impacted equally under the new measures. Specifically, we are requesting public comments that provide evidence-based support, such as peer-reviewed literature, that we should consider to inform our conclusion that our proposed definitions would not disadvantage any particular OPO as a result of population demographics or incidence of disease within a DSA.

Since our criteria for the denominator takes into consideration many of the clinical characteristics associated with possible organ donation (the age of the potential donor, the inpatient hospitalization, and contraindication to donation), we believe all appropriate risk-adjustments to the clinical characteristics of the donor potential have been made. We are aware of literature identifying racial disparities among organ donors, specifically that African Americans were less willing to donate their own organs compared with whites (72.6% v. 88.3%).[18] However, we are concerned regarding the applicability of that study, given it was from 2000, and more recent evidence suggesting that the racial concordance of the OPO requester plays a role in the rate of authorization for organ donation.[19] Further, we are not aware of any validated coefficients that reflect the likelihood of a particular racial/ethnic group to donate organs and we are concerned that any current risk-adjustments factors being used include the historical poorer performances. Based on the most recent literature and our internal analyses, we have decided not to risk-adjust for race. We seek comments as to whether there is other literature or data regarding race or other demographics or other public health factors that warrant the consideration of further risk adjustment.

Similarly, we are not proposing any additional risk-adjustments to our measures other than the exclusion of the ICD–10 codes that are absolute contraindications to organ donation, the age of 75 and younger, and the requirement that the death occurred as an inpatient in the hospital. However, we are seeking comments on whether other risk-adjustments are necessary and which ones, such as donor demographic characteristics (race, gender, age, disease condition) or DSA characteristics (number of ICU beds or level I and II trauma centers), would be significant and clinically appropriate in the context of our proposed approach to identifying OPOs in need of improved performance. If risk adjustment were to be implemented, it would likely be done retrospectively by identifying risk factors that have a statistically significant impact on transplantation rates using regression analysis. We are interested in comments on specific risk adjustment public health emergencies or other local activities (for example, legislative changes on presumed consent). We are also requesting that commenters provide evidence and data sources that would be necessary to calculate the risk-adjustments recommended. Finally, we are seeking comments about any potential unintended consequence of using risk-adjustments to our measures. Depending on the substance of the public comments received, we could establish a risk adjustment methodology in the final rule.

In order to ensure that our measures adjust to changes in medical technology and causes of death and in order to achieve the goal of doubling the number of kidneys available for transplantation by 2030, we are proposing to use our measures in the context of a comparative donation rate and organ transplantation rate relative to the highest-performing OPOs. By using comparative rates, we assume that the highest performing OPOs are adjusting their practices to reflect medical technology and other factors that may impact the number of donors and organs transplanted. Our ultimate definition of success, however, is to encourage the performance of all OPOs to cluster around the highest performers. Therefore, our proposed definition of success will be based on how OPOs perform on the outcome measures of donation rate and organ transplantation rate compared with the top 25 percent of donation and transplantation rates for OPOs. We acknowledge that there may be other success factors for assessing performance of OPOs outside of the two outcome measures of donation rate and organ transplantation rate. Thus, we are soliciting public comments on whether or not comparing OPO performance should be based solely on the performance of the top 25 percent of OPOs within these two outcome measures, whether a different percentile or calculation of OPO performance should be used, or whether additional outcome, structure, or process criteria could be used to inform stakeholders of OPO performance over time.

In determining our calculations, we will establish a threshold donation rate and organ transplantation rate based on the lowest rate among the top 25 percent of donation rates and organ transplantation rates during the 12-month period prior to the time period that is being evaluated. For example, if we are doing an assessment on December 31, 2024 and using data from January 1, 2023 to December 31, 2023, the threshold rates would be based on the lowest donation rate and organ transplantation rate of the top 25 percent donation and organ transplantation rates for the time period of January 1, 2022 to December 31, 2022. Since there are currently 58 OPOs, there are 15 OPO rates (rounded to the closest integer) in the top 25 percent. There are two primary benefits for using this separate cohort to establish the threshold rates: (1) The predetermined threshold rate obtained from an external source would be known to OPOs before their evaluation cycle and (2) from a

[17] Cannon RM, Jones CM, et al, ''Patterns of geographic variability in mortality and eligible deaths between organ procurement organizations,'' *AmJTransplant.* 2019;00:4 (Fig. 2).

[18] Siminoff, LA, et al, ''Racial Disparities in Preferences and Perceptions Regarding Organ Donation,'' *JGIM,* 2006; 21:995–100.

[19] Bodenheimer, HC, et al, ''The Impact of Race on Organ Donation Authorization Discussed in the Context of Liver Transplantation,'' *Transactions of the American Clinical and Climatological Association,* Vol. 123, 2012.

statistical standpoint, such a predetermined threshold rate would be considered a known constant, not subject to random variation. If we were to use a threshold rate based on the same time period being evaluated, then the threshold rate would not be known to OPOs before their evaluation cycle. From a statistical standpoint, such a threshold rate would not be considered a constant; in that case, its uncertainty would need to be accounted for in the testing procedure, resulting in lower statistical power. To avoid this problem, we instead use a predetermined threshold rate obtained from an external source.

Then, we will determine whether the donation rates and organ transplantation rates for each of the OPOs are statistically significantly lower than the predetermined threshold rate by calculating the 95 percent confidence interval (CI) for each OPO and flagging those OPOs whose upper limit of the one-sided 95 percent CI is lower than the threshold rate. By using this approach, we allow all OPOs the opportunity to re-certify as long as their performance is not statistically significantly different from the top 25 percent.

Importantly, Executive Order 13879 recognizes the problem of organ discards. In choosing the 25 percent cutoff, we hope to encourage OPOs to successfully place every organ they procure and to improve their donation rates. We analyzed the impact of these new outcome measures on data from January 1, 2017 to December 31, 2017 and determined that if all underperforming OPOs reached the threshold rate for that time period, we would have approximately 4,900 more organs transplanted. According to the OPTN data, from that same time period, there were a total of 4,905 organs discarded, of which 3,542 were kidneys.[20] A recent study showed that if U.S. transplant centers expanded the type of deceased donor kidneys that they transplanted to include the lower quality kidneys, similar to those transplanted in France, there would be 17,435 more kidneys transplanted, resulting in 132,445 allograft years over an 11-year period.[21]

However, eliminating all inappropriate organ discards alone will not be enough to achieve the 4,900 more organs transplanted that we hope to achieve in setting the top 25 percent threshold. The reason we believe a top 25 percent threshold rate is appropriate is that we also found a wide variation in donation rates among OPOs, suggesting that there is significant opportunity, especially among the lower- performing OPOs, to increase their donation rates and subsequently, their organ transplantation rates. If we had not seen such a wide variation in donation rates, we would have aligned our expected increase in organs transplanted with the number of organs discarded that we believed could be transplantable and set a lower threshold rate, such as 30 percent or 40 percent. We are seeking comments on the threshold rate cutoffs for determining success and our methodology for calculating the threshold rates.

Our proposed measures are similar to the measures presented in the study, ''Importance of incorporating standardized, verifiable, objective metrics of organ procurement organization performance into discussions about organ allocation.'' [22] This study describes a similar approach using the NCHS data, but uses a cause, age, and location consistent (CALC) donation measure. We are actively considering this approach as well as other alternatives and have described them in greater detail in the RIA, Section G: Alternatives Considered.

We believe that the consistency and quality of these proposed measures would be a significant improvement over the current measures because they would rely on independent data to measure donor potential. Stakeholders have increasingly brought to CMS' and HHS' attention that the self-reporting of data could inadvertently reward poor performance, suggesting that OPOs who are less proficient at identifying eligible deaths in their donation service area could have lower denominators, resulting in higher rates of donations. The current outcome measures also include potentially burdensome OPO self-defined and self-reported ''eligible deaths'' for evaluation purposes. We believe that using CDC data on inpatient deaths from the state death certificates as the denominator would greatly reduce reporting burdens on OPOs and allow them to more efficiently utilize their resources to improving donation rates and organ transplantation rates.

By establishing a definition of success that is compared with the top performing OPOs, we hope to increase the number of organs, particularly kidneys, to achieve the goal of doubling kidney transplantations by 2030. Therefore, we do not think it is appropriate for us to include a measure that assesses the OPO's actual donation or transplantation rates based on their expected donation or transplantation rates since that measure relies on average performances to assess OPOs. Our new measures are designed to drive OPOs to perform optimally by motivating them to pursue every organ, every time, rather than setting standards at or near the current average performance. For all the reasons stated above, we believe that the proposed changes to our outcome measures would standardize the assessment of OPO performance, reduce reporting burdens on OPOs, and increase the number of transplantable organs. We would expect OPOs to continue their quality improvement efforts through their Quality Assurance and Performance Improvement (QAPI) program, as required by our rules at § 486.348, and they would continue to seek and implement best practices for organ procurement. We note that OPOs are already required to develop, implement, and maintain a comprehensive, data-driven QAPI program designed to monitor and evaluate performance of all donation services, and we expect them to use the data provided as part of their QAPI program.

In the current regulations, we have specifically separated OPOs operating exclusively in noncontiguous States, Commonwealths, Territories, or possessions from the other OPOs. In this proposed rule, we are not proposing different outcome measures for these OPOs because we believe the residents of those areas deserve every opportunity for organ transplantation and that OPOs servicing those areas should perform at the same level as the top 25 percent of OPOs. Although these OPOs may not be in a DSA with transplant hospitals capable of transplanting all organs that possibly could be procured, organs are frequently offered to hospitals outside of the DSAs in which they are procured. Further, we believe that geographical distances may not be as much of a hurdle as previously believed. For example, the OPO in Puerto Rico is geographically proximal to the continental U.S. where there are numerous transplant hospitals. The OPO in Hawaii may have more difficulty placing all organs given how long it takes to reach the continental

[20] OPTN databased accessed on August 28, 2019 (*https://optn.transplant.hrsa.gov/data/view-data-reports/build-advanced/*).

[21] Aubert, Reese, et al, ''Disparities in Acceptance of Deceased Donor Kidneys Between the United States and France and Estimated Effects of Increased US Acceptance, *JAMA Intern Med.* Published online August 26, 2019. Doi:10.1001/jamainternmed.2019.2322.

[22] Goldberg D, Karp S, et al, ''Importance of incorporating standardized, verifiable, objective metrics of organ procurement organization performance into discussions about organ allocation,'' *Am J Transplant.* 2019;00:1–6.

U.S. from there; however, we understand that there are new technologies that could be employed to allow for transport for organs that cannot tolerate longer transport time (such as for kidneys, livers, and lungs) and that the geographic distance may be less of a barrier to placement of these organs. We are seeking comments on this proposed change, particularly the burden and unique challenges that may face OPOs in the noncontiguous States, Commonwealths, Territories, or possessions, and whether using just the kidney transplantation rate for the Hawaii OPO would be an appropriate measure of performance as discussed in the RIA, Section G: Alternatives Considered.

B. Proposed Changes to Definitions (§ 486.302) and Re-Certification and Competition Processes (§ 486.316)

In line with our proposal to change the outcome measures at § 486.318, as discussed in section II.A. of this document, we are proposing to modify language in § 486.316(a)(1) that an OPO must meet two out of the three outcome measures at § 486.318 and at § 486.316 (a)(3) that for the 2022 re-certification cycle only that an OPO must meet one out of the two outcome measures described in § 486.318 (a)(1) and (3) and (b)(1) and (3). We are also proposing to remove several definitions from § 486.302, since these terms would no longer apply. Specifically, we are proposing to remove the definitions of ''eligible death,'' ''eligible donor,'' ''expected donation rate,'' ''observed donation rate'', and ''Standard criteria donor (SCD)''. Finally, we are proposing to modify the definition of ''donor'' as described in section II.A of this rule and are proposing to add the terms ''death that is not an absolute contraindication to organ donation,'' ''donation rate,'' ''donor potential,'' and ''organ transplantation rate.'' We are proposing to define these terms as follows:

- ''Death that is not an absolute contraindication to organ donation'': All deaths from the state death certificates except those with any cause of death identified by the specific ICD–10 codes that would preclude donation under any circumstance.
- ''Donor potential'': Is the number of inpatient deaths with in the DSA among patients 75 and younger with any cause of death that is not an absolute contraindication to organ donation.
- ''Donation rate'': Is the number of donors as a percentage of the donor potential.
- ''Organ transplantation rate'': The number of organs transplanted as a percentage of the donor potential.

Accordingly, we are proposing to modify the reporting requirements in § 486.328 to eliminate the reporting of the ''Number of eligible deaths'' and modifying the reporting of ''Number of eligible donors'' to ''Number of donors.'' In addition, we are proposing to revise the language that incorrectly refers to the ''Scientific Registry of Transplant Beneficiaries'' and ''DHHS'' in this section. We would instead include the terms ''Scientific Registry of Transplant Recipients'' and ''HHS.'' We are requesting comments on these proposals.

Sections 486.316 (c) and (d) describe the criteria that an OPO must meet in order to compete for an open service area and the criteria for selection of an OPO for an open service area, respectively. Once an OPO is de-certified and their agreement is terminated, either voluntarily or involuntarily as described in § 486.312, the OPO's service area is open to competition from other OPOs. Under § 486.316(b), the OPO that has been de-certified is not permitted to compete for its service area or any other service area. If an OPO is interested in competing for an open service area, the OPO must submit information and data that describe the barriers in its service area, how they affected organ donation, what steps the OPO took to overcome them, and the results. These current requirements for competition once an OPO is de-certified will continue to apply if we finalize the changes to the outcome measures described in this proposed rule. If no OPO applies to compete for a de-certified OPO's open area, § 486.316 (e) allows for CMS to select a single OPO to take over the entire open area or adjust the service area boundaries of two or more contiguous OPOs to incorporate the open area. CMS would select the new OPO to take over the entire open area based on the criteria set out at § 486.316(d); however, our regulations do not require that the DSAs merge when a new OPO takes over. However, we acknowledge that decertification of multiple OPOs could require changes to OPTN policies. We are soliciting comments on our current regulations related to assigning an open DSA in the case where no OPO applies to compete for that open area or in the case where CMS selects an OPO to take over the entire open DSA, but the OPO refuses to do so.

Our goal is to ensure continuous coverage of an OPO service area in the event an OPO is decertified. Although we would attempt to minimize disruptions to organ procurement services in an open service area as much as possible, we acknowledge that there is the potential for disruption when one or multiple OPOs are decertified. We are therefore seeking comments on ways that we can reduce any potential disruptions when an OPO is decertified and their service area is open to competition. We are particularly interested in comments on such potential options including ways that we could improve or ease the process of transitioning an open service area from the decertified OPO to another OPO and other related factors that may impact organ donation or the OPO's ability to meet the outcome measures.

OPOs are also required to meet certain criteria in order to compete for an open service area. In general, OPOs must meet two out of the three outcome measures requirements at § 486.318 (with the exception of the 2022 re-certification cycle where OPOs are required to meet one out of two outcome measures) and the OPO must be in compliance with the requirements for certification at § 486.303, including the conditions for coverage at §§ 486.320 through 486.360. The OPO that is applying to compete for the open service area must also meet additional criteria, including that the OPO's:

- Performance on the donation rate outcome measure and yield outcome measure is at or above 100 percent of the mean national rate averaged over the 4 years of the re-certification cycle; and
- Donation rate is at least 15 percentage points higher than the donation rate of the OPO currently designated for the service area.
- The OPO must also compete for the entire service area.

These existing requirements, however, are not consistent with our proposed method of assessing an OPO's performance, which would compare OPOs to an established threshold rate (using the lowest rate among the top 25 percent of donation rates and organ transplantation rates during the 12-month period prior to the time period that is being evaluated). We therefore are proposing to remove the additional requirement for an OPO's performance on the donation rate outcome measure and yield outcome measure (is at or above 100 percent of the mean national rate averaged over the 4 years of the re-certification cycle) and the requirement that an OPO's donation rate be at least 15 percentage points higher than the donation rate of the OPO currently designated for the service area. We believe that OPOs will be held to a high standard of performance under the new proposed outcome measures. This would ensure that any OPO that is seeking to compete for an open service

area performs significantly better than the de-certified OPO. By meeting the outcome measure requirements, an OPO would also demonstrate its ability to perform well in its own DSA. We are soliciting comments on whether there should be additional criteria beyond what we are proposing to include here to demonstrate that an OPO is performing significantly better than the de-certified OPO. We are not proposing to eliminate the requirement that OPOs compete for the entire service area. Maintaining this requirement will prevent competition of partial service areas, which may lead to OPOs attempting to obtain certain neighboring service areas purely for business reasons, with no regard to whether the OPO can increase organ donation in those areas.

Finally, the current requirements list certain criteria for selection of an OPO for designation of an open service area including:

- Performance on the outcome measures at § 486.318;
- Relative success in meeting the process performance measures and other conditions at §§ 486.320 through 486.360;
- Contiguity to the open service area; and
- Success in identifying and overcoming barriers to donation within its own service area and the relevance of those barriers to barriers in the open area. An OPO competing for an open service area must submit information and data that describe the barriers in its service area, how they affected organ donation, what steps the OPO took to overcome them, and the results.

We are proposing to make a clarifying change to these requirements to emphasize that CMS will consider the current criteria when determining which OPO to designate for an open service area. Our original intent was to list these criteria as guidelines as opposed to requirements that an OPO must meet in order to be selected. For example, we could select a high performing OPO that meets the outcome measures and other CfC requirements, but may not be contiguous to the open service area. This change would provide clarity to the circumstances under which CMS would select an OPO to take over an open service area.

We are soliciting comments on all of our proposed changes to § 486.316. We are especially interested in comments on whether the contiguity of an OPO to the open service area is still an important factor to consider when selecting an OPO to take over an open service area. Since we implemented the OPO CfCs in 2006, there have been advances in technology that have improved organ procurement and transplantation and that have changed the way and the speed, in which OPOs and transplant centers communicate with each other. It may be the case that an OPO that is taking over an open service area may no longer need to be contiguous to the open service, especially if that OPO is a high performer that could increase the number of organs procured and eventually transplanted in an open service area. We are seeking comments on whether this specific criterion is still applicable.

We are also soliciting comments on whether we should reconsider opening the service area of every OPO for competition at the conclusion of every re-certification cycle, regardless of whether the OPO met the outcome performance standards for the prior re-certification cycle. Under our current regulations, OPOs that successfully pass the outcome and process performance measures and comply with our CfCs are automatically renewed. Only OPOs that are unsuccessful in meeting these regulatory requirements could be de-certified. We are seeking comments on an alternative approach where all OPO service areas would be open for competition at the end of each agreement cycle. Any OPO seeking to renew the agreement could face competition from another OPO that wanted to take over that DSA.

In 2005, we proposed opening every OPO's service area for competition at the end of every re-certification cycle. Specifically, we proposed that once we determined that an OPO met the outcome measures at proposed § 486.318 for the previous re-certification cycle and was found to be in compliance with the process performance measures at §§ 486.320 through 486.360, that we would open the OPO's service area for competition from other OPOs. Some of the comments we received at the time included concerns that such a proposal would threaten cooperation and collaboration between OPOs, and would impact the sharing of best practices and change strategies between OPOs (71 FR 30996). In response to this feedback, we finalized a modified version of this proposal whereby this process would only occur in the service areas of OPOs that have been de-certified. We are seeking comments as to whether circumstances in the past 15 years have changed that would warrant our reconsidering our policy of limiting the competition to just open service areas. If we were to consider a policy to open the service areas of all OPOs, we seek comment on how much effort it would take to prepare a bid for the open service area, how this type of competition may affect organ donation, and how it would affect cooperation when transplant centers are receiving organs from outside the service area.

C. Proposed Changes to the Re-Certification Cycle (§ 486.302 and § 486.318)

In accordance with our rules at § 486.308(b)(1), OPOs are re-certified on a four-year cycle. Currently, OPOs are assessed based on 36 months of data analysis. This data period begins six months after the certification period starts and ends six months prior to the end of the certification cycle. CMS analyzes these data and determines if the OPO is out of compliance with outcomes prior to the end of the current cycle and prior to the start of the next cycle. OPOs are given interim reports every six months during the certification period to gauge performance. The survey and certification administrative enforcement actions begin six months before the end of the certification period. For instance, the data collection period for the previous re-certification cycle ended on December 31, 2017. Re-certification surveys were conducted January 1, 2018 through July 31, 2018 and outcomes measures were assessed for the 36 month period beginning January 1, 2015 through December 31, 2017, with the next certification cycle beginning on August 1, 2018. We recognize that waiting a full 36 months to assess and take actions to improve OPO performance would result in numerous lost opportunities to procure and transplant potentially viable organs. Therefore, we propose that the outcome measures assessment occur at least every year and be based on data from the most recent 12 months of data from the state death certificates. OPOs that are flagged as having donation rates or organ transplantation rates that are statistically significantly less than the threshold rates established by the top 25 percent of OPOs are expected to take actions to improve their performance and include the specific actions that they will undertake to improve their outcome measures in their QAPI program. Currently, OPOs receive data on their performance from the SRTR every six months, so our proposed methodology would not provide assessments as frequently. But, this approach could provide for a continuous assessment of OPO performance and allow for more responsive performance improvement actions from low performers because of

the role of the QAPI program. In the spirit of transparency, we intend make these outcome measures public at each assessment.

Although the assessments would occur at least once every 12 months, no OPO may be de-certified until the end of the re-certification cycle, except in cases of urgent need.[23] We are proposing to use the most recent prior 12 months of data at the last assessment cycle before re-certification to be the basis for de-certification. The reason we are proposing to use only the prior 12 months of data is that we do not want to penalize an OPO who has made legitimate and successful efforts to improve their performance by including the older data, nor do we want to reward an OPO whose recent performance has fallen to be able to rely on past performance as the basis for a subsequent four-year re-certification. In the past, we have used 36 months of data to determine re-certification, so we are seeking comments on the use of the shorter length of data as opposed to all the data during the re-certification cycle. Although using the longer period of time would include data that does not reflect the OPO's current status, it would allow OPOs who had been performing adequately through most of the four-year cycle to remain certified even if they had a lapse in performance at the last cycle. We are also seeking comments on other approaches to use the data to identify high-performing OPOs for re-certification.

After considering public comments and finalizing this rule, we expect to begin calculations of the outcomes measures before the beginning of the next re-certification cycle in 2022. We are requesting comments on this proposed change to the applicability of the outcome measure requirements for the cycle beginning in 2022 and ending in 2026.

D. Proposed Change to the Quality Assessment and Performance Improvement Requirement (§ 486.348)

QAPI requirements for OPOs were first established in 2006 (71 FR 31054). OPOs are required to develop, implement, and maintain a comprehensive, data-driven QAPI program designed to monitor and evaluate performance of all donation services, including services provided under contract or arrangement under § 486.348. In addition, an OPO's QAPI program must include objective measures to evaluate and demonstrate improved performance with regard to certain OPO activities, and the OPO must take actions that result in performance improvements and track performance to ensure that improvements are sustained.

A QAPI program is an important, data driven process that allows health care entities to assess their functioning continuously and make changes to improve their quality and efficiency over time. Since we are proposing to revise the outcome measure requirements at § 486.318 and the re-certification process at § 486.316, we believe that OPOs should also be required to include a process to address and improve poor performance on their outcome measures as part of their QAPI program. We currently do not have such a requirement for an OPO's QAPI program, but because OPOs are re-certified every 4 years, it is important that OPOs continuously strive to improve outcomes over the course of the re-certification cycle. An OPO's QAPI program provides a process to achieve these improvements. We, therefore, are proposing to require that OPOs include a process to evaluate and address their outcome measures in their QAPI program if their rates are statistically significantly lower than the top 25 percent at each assessment, for each assessment period except the final assessment. Failure to meet the outcome measure in the final assessment period would result in de-certification. For all other assessment periods, if the OPO does not meet the outcome measures, the OPO must identify opportunities for improvement and implement changes that lead to improvement in these measures.

As we have previously described in this proposed rule, we are proposing that an OPO's performance on the outcome measures be assessed at least every 12 months, based on the most recent prior 12 months of data. We would expect OPOs to use the data that are obtained from each assessment to drive changes to their QAPI program in order to improve their performance on the outcome measures. If proactive changes are made early in the re-certification cycle, an OPO would be able to begin to address poor performance on the outcome measures early in the re-certification cycle and prior to the re-certification determination. We are additionally interested in whether the QAPI process is sufficiently robust to capture year over year improvements, as well as other quantitative factors that may not be captured in our proposed outcome metrics. As such, we encourage commenters to consider ways the QAPI process may be modified or enhanced to better assess OPO performance relative to past performance and to other OPOs. As proposed in this rule, an OPO that was deemed compliant on its QAPI, but did not meet one or both of the proposed outcome measures would be subject to decertification.

E. Solicitation of Comments

In addition to our requests for comments throughout the preamble, we are specifically seeking the public's input on the following questions:

- Should OPO outcome measures also include an assessment of organ transplantation rates by type of organ transplanted?
- We are proposing to use a performance measure that is based on the OPO's performance relative to the top 25 percent of donation rates and organ transplantation rates. Should CMS use a static level or a different criterion from what is being proposed? What statistical approach to the data or incentives can we use to encourage all OPOs to strive to be high performers? Can the current performance parameter, which requires that the donation rate be no more than 1.5 standard deviations below the mean national donation rate, be appropriately applied to achieve this goal? We are requesting that commenters explain and include any evidence or data they have to support their comments.
- What are the benefits, consequences, or unintended consequences, of using these two proposed measures and what are their potential impact on OPOs, transplant centers, organ donation, patient access, and transplant recipients?
- Are there potential additional compliance burdens on OPOs or transplant centers if the two proposed measures were finalized? Please explain.

In § 486.316(c)(3), we require an OPO to compete for an entire service area as a criterion to compete for an open service area. At this time, we are not proposing to change this requirement but would like comments as to whether we should consider revising this subsection and redefining the open service area for competition. Although we have proposed eliminating the definition of ''eligible deaths,'' we have not proposed to remove the requirement that OPOs conduct monthly death record reviews. We are seeking comments as to whether § 486.348(b)

[23] The Organ Procurement Organization Certification Act of 2000 changed the re-certification cycle from every 2 years to every 4 years; § 486.312(d) and § 486.302 states that CMS can give written notice of de-certification in cases of urgent need and defines urgent need as occurring when an OPO's noncompliance with one or more conditions for coverage has caused, or is likely to cause, serious injury, harm, impairment, or death to a potential or actual donor or an organ beneficiary.

should be revised or removed altogether to eliminate such reviews. Please include justifications and explanations in your comments.

We encourage detailed comments that answer all of the aforementioned questions. Additionally, in the RIA, Section G: Alternatives considered, we discuss a number of different alternatives that we are actively considering. These alternatives examine different type of denominators, different statistical confidence intervals for calculations, and different threshold rates for assessment. We are actively considering these policy alternatives and are seeking comments on them.

III. Collection of Information Requirements

Under the Paperwork Reduction Act (PRA) of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

A. ICRs Regarding Re-Certification and Competition Processes (§ 486.316)

At § 486.316(b), we are proposing to modify language that refers to the current outcome measure requirements that states that an OPO must meet two out of the three outcome measures at § 486.318. They would instead be required to meet both newly proposed outcome measures, or face de-certification which may then be appealed by the OPO. If the OPO does not appeal or the OPO appeals and the reconsideration official and CMS hearing officer uphold the de-certification, the OPO's service area would be opened for competition by other OPOs.

The current information collection request for the OPO CfC (OMB Control Number 0938–0688, Exp. February 2021) estimates that one OPO would face de-certification per year, and under the proposed outcome measures, this number would have potential to increase. We do not know exactly how many would be de-certified under these new measures; however, based on the improvement required to meet the proposed measures it is possible that approximately 7 to 33 OPOs could be de-certified. Assuming some number of these de-certifications are upheld, their respective service areas would be opened for competition.

Under § 486.316(b), an OPO competing for an open service area must submit information and data that describe the barriers in its service area, how they affected organ donation, what steps the OPO took to overcome them, and the results. In addition, § 486.316(c) states that to compete for an open service area, an OPO must meet the performance requirements of the outcome measures at § 486.318 and the requirements for certification at § 486.303, including the conditions for coverage at §§ 486.320 through 486.348. The OPO must also compete for the entire service area.

The burden associated with this requirement is the time it would take to create a document that contains the required information and data related to the OPO's success in identifying and addressing the barriers in its own service area and how they relate to the open service area. We will refer to this documentation as a plan.

Based on historical data and our previous experience with the OPOs, we would expect a total of nine OPOs will want to compete for a new service area and three of those OPOs may want to compete for more than one service area. Thus, we believe there will be a total of 12 plans that will need to be developed for the competition process.

We believe that developing each plan would require the collective efforts of a QAPI director (Registered Nurse, $71/hour), organ procurement coordinator (RN or social worker, $71/hour), medical director ($107/hour), OPO director ($107/hour), and a medical secretary ($35/hour). All wages are adjusted upwards by 100 percent to account for the cost of fringe benefits and overhead. Assuming, consistent with past rulemaking, that it would take these professionals 104 hours to develop such a plan, we estimate each competition would require 1,248 burden hours for all 9 OPOs to complete 12 plans and would cost all 9 OPOs $79,416 (($71 RN × 30 hours × 9 OPOs) + ($71 organ procurement coordinator × 30 hours × 9 OPOs) + ($107 medical director × 12 hours × 9 OPOs) + ($107 OPO director × 30 × 9 OPOs) + ($35 medical secretary × 2 hours × 9 OPOs)). For the annual burden, each of these figures needs to be divided by 4, since competition for open service areas will typically occur every 4 years. Thus, the annual burden hours for all 9 OPOs to prepare 12 plans would be 312 (1,248/4) and the annual cost estimate would be $19,854 ($79,416/4).

B. ICRs Regarding Condition: Reporting of Data (§ 486.328)

We are proposing to revise § 486.318 to eliminate the reporting of the ''Number of eligible deaths'' and modify the reporting of ''Number of eligible donors'' to ''Number of donors.'' Although the current outcome measures include the potentially burdensome OPO self-defined and self-reported ''eligible deaths'' for evaluation purposes, the current information collection request for the OPO requirements (OMB Control Number 0938–0688, Exp. February 2021) does not attribute any burden to this requirement. This is because the type of data and how it is reported to the OPTN is already covered by the information collection requirements associated with the OPTN final rule (42 CFR 121). Thus, we are not attributing any quantifiable burden reduction to this proposed change.

C. ICRs Regarding Quality Assessment and Performance Improvement (§ 486.348)

At § 486.348(d) we are proposing to require that OPOs include a process to evaluate and address their outcome measures in their QAPI program if their rates are statistically significantly lower than the top 25 percent at each assessment. Assessments would occur at least every 12 months with the most recent prior 12 months of available data, meaning there would be 3 assessments in each 4 year re-certification cycle that might require modifications to an OPO's QAPI program.

As stated in the information collection request for the OPO requirements (OMB Control Number 0938–0688, Exp. February 2021), we believe the information collection requirements associated with maintaining a QAPI program are exempt as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with this collection of information would be incurred by persons in the normal course of their activities. Accordingly, we do not believe this proposed change would

impose any additional ongoing quantifiable burden.

If you comment on these information collection, that is, reporting, recordkeeping or third-party disclosure requirements, please submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule.

Comments must be received on/by February 21, 2020.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Analysis

A. Statement of Need

All major government regulations should undergo periodic review to ensure that they do not unduly burden regulated entities or the American people, and that they accomplish their goals effectively and efficiently. It has been apparent for a number of years that the current system for organ donation and the rules under which OPO performance is measured do not create the necessary incentives to optimize organ donation and transplantation as evidenced by performance discrepancies among OPOs, the wide geographic and population diversity among both higher- and lower-performing OPOs, and the significant gap between the number of potential organ donors and the number of actual donors (see the following Tables 3 and 4). Recent article titles tell the story as well: ''Reforms to Organ Donation System Would Save Thousands of Lives, Millions of Taxpayer Dollars Annually,'' ''Lives Lost, Organs Wasted,'' and ''A Simple Bureaucratic Organ Donation Fix Will Save Thousands of Lives.'' [24] All three of these articles include, or reference, in-depth studies of the current organ donation system's problems and discuss reforms that could increase its performance. These problems and the reforms needed to improve organ donation and transplantation have multiple dimensions, including the underperformance of many OPOs to procure and place organs at the levels of the best-performing OPOs and is the basis for President Trump's July 10, 2019 Executive Order on Advancing American Kidney Health, to ''increase access to kidney transplants by modernizing the organ recovery and transplantation systems and updating outmoded and counterproductive regulations.''

We note that the Secretary recently issued a final rule to reduce regulatory burden on several types of health care providers (''Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Fire Safety Requirements for Certain Dialysis Facilities; Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care,'' 84 FR 51732, September 30, 2019) that directly addresses the same policy concern. Under that final rule, performance standards for transplant hospitals were revised to reduce the practice of transplanting only the best organs in the healthiest patients and allowing transplantable organs to be discarded and sicker patients to die without a transplant. Those performance standards rewarded very high one-year organ and patient survival rates by threatening program closure to hospitals that did not achieve such rates. In so doing, those performance standards gave no weight to maximizing treating the many patients on the waiting lists whose lives would be saved, even at a higher risk of failure. As discussed in the regulatory impact analysis (RIA) for CMS–3346–F, there is the potential for regulatory reform to reduce the number of ''transplant quality'' discarded organs, and through transplantation of those organs, save the lives of many patients each year.

Finally, the Executive Order directs the Secretary of HHS as follows: ''Within 90 days of the date of this order, the Secretary shall propose a regulation to enhance the procurement and utilization of organs available through deceased donation by revising Organ Procurement Organization (OPO) rules and evaluation metrics to establish more transparent, reliable, and enforceable objective metrics for evaluating an OPO's performance.'' That directive applies directly to this proposed rule.

B. Scope of Review

We have examined the impacts of this proposed rule as required by E.O. 12866 on Regulatory Planning and Review (September 30, 1993), E.O. 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96 354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), E.O. 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)) and E.O. 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

E.O. 13771 states that it is essential to manage the costs associated with the government imposition of private expenditures required to comply with federal regulations and establishes policies and procedures to reduce the costs of both new and existing federal regulations. Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of E.O. 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the E.O.

An RIA must be prepared for major rules with economically significant effects ($100 million or more in any one year). We estimate that this rulemaking is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared an RIA that to the best of our ability presents the costs and benefits of this rulemaking.

C. Effects on OPO Performance

We are proposing two new outcome measures that would be used to assess an OPO's performance: A measure of an OPO's donation rate and organ

[24] These articles were written by and published in: Goran Klintman, RealClearHealth, March 4, 2019; Kimberly Kindy, Lenny Bernstein, and Dan Keating, Washington Post, December 20, 2018; and Laura and John Arnold, STAT, July 24, 2019.

transplantation rate. Table 3 shows current performance using the donation rate outcome measure that we propose derived from data spanning January 1, 2017 to December 31, 2017. The number of potential donors is similar to the measure used in the current regulatory provisions (on numbers of deceased persons that potentially qualify as organ donors, but the proposed measure would be nationally standardized, using an objective data source); however, the performance variable is the number of actual donors who had at least one organ transplanted, regardless of the number of organs that each provides. This measure focuses on the key task of obtaining family consent, clinically managing the donor, and arranging for the actual surgical and handling procedures involved in getting at least one organ from the deceased donor to placement in a patient on a waiting list. Hearts, lungs, kidneys, intestine, and pancreata (those transplanted or sent for research) count towards this measure of success.

In the tables that follow, the first two digits of the letters in parentheses are, in most cases, the primary state of the OPO. Some OPOs serve more than one state, and some states have more than one OPO. We are also including, in the Appendix, a map for each proposed measure that depicts geographic trends in performance. In a few cases in the tables below, we have abbreviated an OPO name to improve simplicity of presentation. For a complete OPO listing and additional information, see the following link: *https://optn.transplant.hrsa.gov/members/member-directory/?memberType=Organ%20Procurement%20Organizations.*[25] These tables show the performance required of each OPO to reach the proposed performance standard, including an allowance for statistical ''confidence'' (one-tailed test), for the OPOs that fell below the standard. Confidence intervals are calculated based on test statistics derived from the assumed binomial and Poisson distribution for the donation rate and transplant rate, respectively. Specifically, the Wilson score interval with continuity correction (Newcombe 1998) is used to calculate the confidence interval for the donation rate of each OPO. The Wilson and Hilferty formula (Wilson and Hilferty 1931, Breslow and Day 1987, Kulkarni and Hemangi 2012) is used to calculate the confidence interval for the transplant rate of each OPO.

We are committed to using all available data to continue our analysis of OPO performance, including, where possible, historical trends in OPO performance; a range of potential outcomes, including a scenario where high performers remain at steady state; and year over year OPO performance and distribution of scores and improvements within the past two certification cycles, using the proposed metrics.

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[25] Some of these OPOs have changed names in recent years, so some other published lists may be out of date. However, the codes shown in parentheses in our tables have not changed.

Table 3. OPO Donor Rate for Calendar 2017 with Top 25 Percent Cutoff (4.11 incl. Confidence Interval) *(OPOs below Threshold in Bold and Italics)*

OPO Name (Primary State)	Potential Donors (Denominator)	Total Donors	Donation Rate	Upper Bound with Confidence Interval	Additional Donors Needed to Reach 25% Cutoff	Estimated Improvement Required
Organ Procurement Organization at U. of Wisconsin (WIUW)	2,638	149	5.65	6.45	0	0.00%
Lifesharing - A Donate Life Organization (CASD)	1,986	109	5.49	6.42	0	0.00%
DonorConnect (UTOP)	2,048	107	5.22	6.12	0	0.00%
Midwest Transplant Network (MWOB)	4,297	230	5.35	5.96	0	0.00%
Versiti (WIDN)	1,844	92	4.99	5.92	0	0.00%
Nevada Donor Network (NVLV)	2,367	118	4.99	5.80	0	0.00%
Gift of Life Donor Program (PADV)	9,771	509	5.21	5.60	0	0.00%
Donor Network of Arizona (AZOB)	4,991	241	4.83	5.36	0	0.00%
Nebraska Organ Recovery (NEOR)	1,519	66	4.34	5.33	0	0.00%
The Living Legacy Foundation of Maryland (MDPC)	3,171	143	4.51	5.17	0	0.00%
ConnectLife (NYWN)	1,239	50	4.04	5.10	0	0.00%
LifeShare of Oklahoma (OKOP)	3,954	177	4.48	5.06	0	0.00%
Washington Regional Transplant Community (DCTC)	3,158	138	4.37	5.03	0	0.00%
OurLegacy - FL (FLFH)	3,541	153	4.32	4.93	0	0.00%
Southwest Transplant Alliance (TXSB)	8,727	373	4.27	4.65	0	0.00%
Mid-America Transplant Services (MOMA)	5,266	217	4.12	4.61	0	0.00%
Donor Alliance (CORS)	3,469	137	3.95	4.55	0	0.00%
LifeGift (TXGC)	8,579	356	4.15	4.52	0	0.00%
Sierra Donor Services (CAGS)	2,092	78	3.73	4.50	0	0.00%
Lifeshare Carolinas (NCCM)	2,599	98	3.77	4.46	0	0.00%
Gift of Hope Organ & Tissue Donor Network (ILIP)	9,108	372	4.08	4.45	0	0.00%
Tennessee Donor Services (TNDS)	7,189	283	3.94	4.34	0	0.00%

OPO Name (Primary State)	Potential Donors (Denominator)	Total Donors	Donation Rate	Upper Bound with Confidence Interval	Additional Donors Needed to Reach 25% Cutoff	Estimated Improvement Required
Center for Organ Recovery and Education (PATF)	5,500	212	3.85	4.31	0	0.00%
LifeSource - MN (MNOP)	4,707	173	3.68	4.17	0	0.00%
New Mexico Donor Services (NMOP)	1,628	54	3.32	4.16	0	0.00%
Legacy of Life - Hawaii (HIOP)	***1,077***	***33***	***3.06***	***4.11***	***1***	***0.00%***
LifeCenter Organ Donor Network (OHOV)	***2,029***	***68***	***3.35***	***4.10***	***1***	***0.24%***
LifeCenter Northwest (WALC)	***6,408***	***236***	***3.68***	***4.10***	***1***	***0.24%***
New Jersey Sharing Network (NJTO)	***5,093***	***184***	***3.61***	***4.08***	***2***	***0.74%***
LifeBanc (OHLB)	***4,149***	***147***	***3.54***	***4.06***	***2***	***1.23%***
LifeLink of Florida (FLWC)	***5,665***	***205***	***3.62***	***4.06***	***3***	***1.23%***
Louisiana Organ Procurement Agency (LAOP)	***5,072***	***182***	***3.59***	***4.05***	***3***	***1.48%***
Life Alliance Organ Recovery Agency (FLMP)	***4,931***	***175***	***3.55***	***4.02***	***5***	***2.24%***
Lifeline of Ohio (OHLP)	***3,587***	***122***	***3.40***	***3.95***	***6***	***4.05%***
Sharing Hope SC (SCOP)	***4,598***	***156***	***3.39***	***3.87***	***11***	***6.20%***
Donor Network West (CADN)	***8,699***	***298***	***3.43***	***3.77***	***29***	***9.02%***
OneLegacy (CAOP)	***12,725***	***442***	***3.47***	***3.75***	***44***	***9.60%***
Pacific Northwest Transplant Bank (ORUO)	***3,791***	***119***	***3.14***	***3.65***	***17***	***12.60%***
Life Connection of Ohio (OHLC)	***2,072***	***61***	***2.94***	***3.65***	***9***	***12.60%***
Gift of Life Michigan (MIOP)	***8,736***	***289***	***3.31***	***3.64***	***39***	***12.91%***
Texas Organ Sharing Alliance (TXSA)	***5,079***	***162***	***3.19***	***3.63***	***23***	***13.22%***
LifeLink of Georgia (GALL)	***8,573***	***280***	***3.27***	***3.60***	***42***	***14.17%***
LifeQuest Organ Recovery Services (FLUF)	***4,234***	***132***	***3.12***	***3.60***	***21***	***14.17%***
New England Organ Bank (MAOB)	***8,712***	***284***	***3.26***	***3.59***	***43***	***14.48%***
Mid-South Transplant Foundation (TNMS)	***2,305***	***67***	***2.91***	***3.56***	***12***	***15.45%***

OPO Name (Primary State)	Potential Donors (Denominator)	Total Donors	Donation Rate	Upper Bound with Confidence Interval	Additional Donors Needed to Reach 25% Cutoff	Estimated Improvement Required
Carolina Donor Services (NCNC)	***6,781***	***199***	***2.93***	***3.30***	***53***	***24.55%***
LiveOnNY (NYRT)	***9,385***	***278***	***2.96***	***3.27***	***76***	***25.69%***
Indiana Donor Network (INOP)	***5,783***	***161***	***2.78***	***3.17***	***52***	***29.65%***
Iowa Donor Network (IAOP)	***2,136***	***52***	***2.43***	***3.07***	***21***	***33.88%***
Mississippi Organ Recovery Agency (MSOP)	***2,927***	***74***	***2.53***	***3.07***	***29***	***33.88%***
LifeNet Health (VATB)	***5,449***	***144***	***2.64***	***3.03***	***56***	***35.64%***
LifeLink of Puerto Rico (PRLL)	***3,205***	***78***	***2.43***	***2.94***	***35***	***39.80%***
LifeChoice Donor Services (CTOP)	***2,561***	***60***	***2.34***	***2.91***	***29***	***41.24%***
Center for Donation and Transplant (NYAP)	***2,451***	***55***	***2.24***	***2.81***	***30***	***46.26%***
Kentucky Organ Donor Affiliates (KYDA)	***5,389***	***107***	***1.99***	***2.33***	***90***	***76.39%***
Arkansas Regional Organ Recovery Agency (AROR)	***2,604***	***46***	***1.77***	***2.27***	***44***	***81.06%***
Legacy of Hope - Alabama (ALOB)	***8,025***	***159***	***1.98***	***2.26***	***141***	***81.86%***
Finger Lakes Donor Recovery Network (NYFL)	***2,486***	***41***	***1.65***	***2.15***	***45***	***91.16%***
Totals	272,105	9,731			1,015	

Table 4 shows the current range of organ transplantation performance, using the new proposed standard of measuring the total number of organs transplanted from deceased donors (including all transplanted organs from each donor) as a percentage of the same donor potential used for the donation rate.[26] According to the NCHS, there are about 2.8 million deaths each year in the U.S., but the potential donor pool is far lower because it only includes those who die in hospitals, who are age 75 or less, and who have no contraindications to donation (such as metastatic cancers). Table 4 shows that organ transplantation rates range from 19.44 at the highest levels to 4.47 (using data from calendar year 2017), a range of about four to one from highest to lowest. The top one-fourth of OPOs achieve rates above 12 donors/100 inpatient deaths, more than double the rates of many lower performing OPOs. The top-performing OPOs are geographically and demographically diverse, with potential donor pools ranging from about 2,000 deaths a year to almost 10,000 a year. We recognize that some OPOs have fewer transplant programs within their service areas than others, but allocation policies allow OPOs to place organs outside their DSA. The organ match run, which lists all potential recipients for a donated organ, includes eligible patients on the waiting list for that particular organ and organs are often offered to hospitals outside of the DSAs in which the organs were procured.

[26] These results would look similar if we used the current estimates of ''eligible'' deaths but would be an imperfect comparison since that is not a standardized measure.

Table 4. OPO Transplant (TX) Rates for Calendar 2017 with Top 25 Percent Cutoff

(13.73 incl. Confidence Interval) *(OPOs below Threshold in Bold and Italics)*

OPO Name (Primary State)	Potential Donors (Denominator)	Number TX	TX Rate	Upper Bound with Confidence Interval	Additional Organs Needed to Reach 25% Cutoff	Estimated Improvement Required
Lifesharing - A Donate Life Organization (CASD)	1,986	386	19.44	21.14	0	0.00%
Organ Procurement Organization at U. of Wisconsin (WIUW)	2,638	499	18.92	20.37	0	0.00%
Midwest Transplant Network (MWOB)	4,297	821	19.11	20.24	0	0.00%
DonorConnect (UTOP)	2,048	353	17.24	18.82	0	0.00%
Versiti (WIDN)	1,844	314	17.03	18.70	0	0.00%
Donor Network of Arizona (AZOB)	4,991	847	16.97	17.96	0	0.00%
Nebraska Organ Recovery (NEOR)	1,519	245	16.13	17.93	0	0.00%
The Living Legacy Foundation of Maryland (MDPC)	3,171	500	15.77	16.98	0	0.00%
Nevada Donor Network (NVLV)	2,367	367	15.50	16.90	0	0.00%
Gift of Life Donor Program (PADV)	9,771	1,575	16.12	16.80	0	0.00%
Washington Regional Transplant Community (DCTC)	3,158	462	14.63	15.80	0	0.00%
OurLegacy - FL (FLFH)	3,541	506	14.29	15.38	0	0.00%
Southwest Transplant Alliance (TXSB)	8,727	1,275	14.61	15.30	0	0.00%
LifeGift (TXGC)	8,579	1,244	14.50	15.20	0	0.00%
Lifeshare Carolinas (NCCM)	2,599	349	13.43	14.67	0	0.00%
Mid-America Transplant Services (MOMA)	5,266	719	13.65	14.52	0	0.00%
ConnectLife (NYWN)	1,239	156	12.59	14.38	0	0.00%
LifeShare of Oklahoma (OKOP)	3,954	528	13.35	14.35	0	0.00%
Gift of Hope Organ & Tissue Donor Network (ILIP)	9,108	1,243	13.65	14.30	0	0.00%

OPO Name (Primary State)	Potential Donors (Denominator)	Number TX	TX Rate	Upper Bound with Confidence Interval	Additional Organs Needed to Reach 25% Cutoff	Estimated Improvement Required
Louisiana Organ Procurement Agency (LAOP)	5,072	667	13.15	14.02	0	0.00%
Tennessee Donor Services (TNDS)	7,189	944	13.13	13.86	0	0.00%
Sierra Donor Services (CAGS)	2,092	260	12.43	13.77	0	0.00%
LifeSource - MN (MNOP)	***4,707***	***589***	***12.51***	***13.40***	***16***	***2.46%***
Sharing Hope SC (SCOP)	***4,598***	***564***	***12.27***	***13.15***	***26***	***4.41%***
Donor Alliance (CORS)	***3,469***	***410***	***11.82***	***12.83***	***31***	***7.01%***
Donor Network West (CADN)	***8,699***	***1,058***	***12.16***	***12.80***	***80***	***7.27%***
LifeBanc (OHLB)	***4,149***	***479***	***11.54***	***12.45***	***52***	***10.28%***
Lifeline of Ohio (OHLP)	***3,587***	***410***	***11.43***	***12.40***	***46***	***10.73%***
Center for Organ Recovery and Education (PATF)	***5,500***	***637***	***11.58***	***12.37***	***73***	***10.99%***
LifeCenter Northwest (WALC)	***6,408***	***743***	***11.59***	***12.32***	***88***	***11.44%***
Texas Organ Sharing Alliance (TXSA)	***5,079***	***581***	***11.44***	***12.25***	***73***	***12.08%***
LifeLink of Florida (FLWC)	***5,665***	***650***	***11.47***	***12.24***	***82***	***12.17%***
OneLegacy (CAOP)	***12,725***	***1,468***	***11.54***	***12.04***	***210***	***14.04%***
New Mexico Donor Services (NMOP)	***1,628***	***171***	***10.50***	***11.92***	***28***	***15.18%***
New Jersey Sharing Network (NJTO)	***5,093***	***565***	***11.09***	***11.89***	***91***	***15.48%***
LifeCenter Organ Donor Network (OHOV)	***2,029***	***215***	***10.60***	***11.86***	***36***	***15.77%***
Indiana Donor Network (INOP)	***5,783***	***627***	***10.84***	***11.58***	***121***	***18.57%***
Life Alliance Organ Recovery Agency (FLMP)	***4,931***	***515***	***10.44***	***11.23***	***119***	***22.26%***
New England Organ Bank (MAOB)	***8,712***	***920***	***10.56***	***11.15***	***219***	***23.14%***
Carolina Donor Services (NCNC)	***6,781***	***710***	***10.47***	***11.14***	***171***	***23.25%***
LifeQuest Organ Recovery Services (FLUF)	***4,234***	***430***	***10.16***	***11.00***	***112***	***24.82%***
LifeLink of Georgia (GALL)	***8,573***	***883***	***10.30***	***10.89***	***238***	***26.08%***

OPO Name (Primary State)	Potential Donors (Denominator)	Number TX	TX Rate	Upper Bound with Confidence Interval	Additional Organs Needed to Reach 25% Cutoff	Estimated Improvement Required
Pacific Northwest Transplant Bank (ORUO)	*3,791*	*376*	*9.92*	*10.80*	*107*	*27.13%*
Gift of Life Michigan (MIOP)	*8,736*	*888*	*10.16*	*10.74*	*255*	*27.84%*
Mid-South Transplant Foundation (TNMS)	*2,305*	*214*	*9.28*	*10.40*	*73*	*32.02%*
LiveOnNY (NYRT)	*9,385*	*907*	*9.66*	*10.21*	*323*	*34.48%*
Legacy of Life - Hawaii (HIOP)	*1,077*	*90*	*8.36*	*9.96*	*38*	*37.85%*
Life Connection of Ohio (OHLC)	*2,072*	*180*	*8.69*	*9.83*	*77*	*39.67%*
LifeNet Health (VATB)	*5,449*	*493*	*9.05*	*9.75*	*210*	*40.82%*
Mississippi Organ Recovery Agency (MSOP)	*2,927*	*255*	*8.71*	*9.66*	*114*	*42.13%*
Iowa Donor Network (IAOP)	*2,136*	*165*	*7.72*	*8.79*	*100*	*56.20%*
LifeChoice Donor Services (CTOP)	*2,561*	*190*	*7.42*	*8.37*	*131*	*64.04%*
Kentucky Organ Donor Affiliates (KYDA)	*5,389*	*395*	*7.33*	*7.97*	*300*	*72.27%*
LifeLink of Puerto Rico (PRLL)	*3,205*	*217*	*6.77*	*7.58*	*189*	*81.13%*
Center for Donation and Transplant (NYAP)	*2,451*	*162*	*6.61*	*7.53*	*145*	*82.34%*
Legacy of Hope - Alabama (ALOB)	*8,025*	*496*	*6.18*	*6.66*	*551*	*106.16%*
Arkansas Regional Organ Recovery Agency (AROR)	*2,604*	*149*	*5.72*	*6.56*	*178*	*109.30%*
Finger Lakes Donor Recovery Network (NYFL)	*2,486*	*111*	*4.47*	*5.23*	*200*	*162.52%*
Totals	272,105	32,173			4,903	

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Both proposed outcome measures address multiple goals not met by the current requirements: (1) They can be uniformly applied across all OPOs; (2) they capture not only success in obtaining donors but also success in placing as many organs as possible; (3) they capture the entire pool of possible donors (not the pool as determined separately by each OPO); (4) they adjust for the geographic differences in the number and causes of death; and (5) they meet central necessities for a workable performance standard that exhibits uniformity, timeliness, and stability year-to-year. Of particular importance, these measures would replace the non-standardized criteria for ''eligible'' donors as determined by each OPO. The existing denominator standard allows OPOs to exclude from the calculated potential donor pool those cases where the next-of-kin did not authorize donation, a crucial task we believe all OPOs should be effective and continually improving at. For an extensive discussion of these and related issues, see ''Changing Metrics of Organ Procurement Organization Performance in Order to Increase Organ Donation Rates in the United States.'' [27] The proposed measures do not control for every variable that can affect OPO performance for reasons beyond its control. For example, states without motorcycle helmet laws have higher rates of accidents that create potential donors. Some DSAs have greater transplant hospital competition than others, and more competition for transplantable organs is associated with greater use of organs that might otherwise be discarded.[28] Regardless, it is our belief that the untapped donor and organ potential is sufficiently large in every DSA so that every OPO has

[27] Goldberg D, et al, ''Changing Metrics of Organ Procurement Organization Performance in Order to Increase Organ Donation Rates in the United States,'' *AmJTransplant* 2017; 17:3183–3192.

[28] Adler, et al ''Is Donor Service Area Market Competition Associated with Organ Procurement Organization Performance?'' *Transplantation* 2016; 100; 1349–1355.

both potential donors, organs, and transplant recipients to exceed its current performance level.

Tables 3 and 4 also show a very important quantitative result: At present, there are about 10,000 deceased donors a year, which is only about three percent of the 272,000 potential donors in 2017. Importantly, the proposed criteria for potential donors already exclude many deaths, and focus on decedents with greater potential to provide transplantable organs. Hence, all OPOs will have a pool of potential donors many times higher than the number of donors and organs needed to meet the proposed performance standards.

If the number of donors at the lower-performing OPOs were to reach what is now the 75th percentile of achievement, the number of donors would increase by over one thousand by the end of the four-year performance period. Both through this increase, and greater success in maximizing the number of organs actually transplanted from each donor, achieving the 75th percentile for the transplant rate would increase the number of such transplants from about 32,000 by as many as 6,000 by 2024, and by as many as 10,000 by 2026, for a total of about 42,000 in that year (see Table 12). Achieving higher success rates would be unlikely to occur in just the lower performers, and these estimates assume improvements at all current levels of performance as better techniques and methods are identified and widely adopted. For example, there have been major recent improvements in perfusion techniques used to preserve kidneys and extend the time period allowed between donation and transplantation. This technology rewards focusing efforts on extending the placement of organs beyond local areas for appropriate transplant candidates on waiting lists. These techniques are available to all OPOs, but have not been adopted by all OPOs. There may be future improvements as well, but our estimates do not assume any major breakthroughs will be routinely available in the near term. In September 2019, the National Institutes of Health reported that a new method of preserving livers for transplantation would potentially increase the viability of livers from nine to 27 hours, but this is still in a development stage.[29] Our estimates in Tables 5 and 6 assume that all OPOs would achieve either the 75th percentile targets, or increase performance on both measures by 20 percent, whichever is greater.

Nothing guarantees that all OPOs will manage to meet the standards if finalized as proposed. But, the administrative steps we propose to take, the periodic assessments, and the incentives for an OPO to maintain certification at the end of the four-year evaluation period will provide both means and incentives for all OPOs to meet or exceed our proposed standards. Furthermore, there is no need to wait until the end of the four-year period to take action regarding any OPOs that are underperforming. With continuous assessment and public disclosure of the information, OPOs who cannot achieve the outcome measures may decide to voluntarily de-certify and allow a high-performing OPO to take over the DSA, even before the end of the re-certification cycle or form a partnership with a high-performing OPO and allow that OPO to take over the management of the DSA. Our low-end cost and performance calculations assume that this could be avoided through adoption of proven techniques and improved leadership and management by lower-performing OPOs, because careful planning and implementation of de-certification and OPO replacement actions could ease such transitions. The new proposed outcome measures and performance expectations will give each OPO both the opportunity and market incentives to assess its performance and motivate the widespread adoption of best practices.

While we cannot predict future achievement levels, we have developed a hypothetical scenario that we believe is likely to nearly achieve HHS' 2030 target in 2026 (with 4 years remaining to attain that goal) and that we can use in estimating benefits and costs while allowing for either higher or lower results. In Tables 5 and 6, we show the results of all OPOs achieving the minimum performance requirements, or improving by 20 percent, whichever is greater, by 2026. These projections are estimates and are subject to change based on future events and decisions, but fall within the improvement ranges seen in recent years in some OPOs, as well as the consistently high performance levels in many OPOs. Additionally, for these projections we assume CMS monitors OPO performance as frequently as every 12 months, using nationally consistent and timely data in both the numerator and denominator of performance measures, and intervening when the performance lags. Finally, these projections reflect the direct incentives to both OPOs and transplant hospitals to improve donation and transplantation rates from older donors to older patients, which will ultimately facilitate the utilization of the large number of discarded, but transplantable, organs. In assessing this scenario, about 85 percent of all potential donors would still be potential rather than actual donors. These potential donors are concentrated among those in the age range of 55 to 74, but the vast majority of them could provide organs of transplant quality if donated. In this regard, it is important to note that according to OPTN and NCHS mortality data, donation rates are highest among the young and far lower among potential donors in their 50s, 60s, and early 70s.[30] With advances in successful utilization of organs from older donors, we believe the upward potential for both donation and transplantation is higher than shown in tables 5 and 6.

Table 5 shows all OPOs achieving the minimum standard, or a 20 percent increase, whichever is greater. With these parameters, the number of annual donors would rise from about 10,000 in 2017 to over 12,000 by 2026.

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[29] *https://www.nih.gov/news-events/news-releases/scientists-triple-storage-time-human-donor-livers.*

[30] Organ donors <50 make up approximately 67 percent of donors, but make up less than 10 percent of deaths.

Table 5. OPO Donor Rates Assuming All OPOs Attain Donor Rate of 4.11, or an increase of 20 Percent, whichever is greater, by 2026

OPO Name (Primary State)	New Potential Donors (Denominator)	New Total Donors	New Donation Rate
Organ Procurement Organization at U. of Wisconsin (WIUW)	2,638	179	6.78
Lifesharing - A Donate Life Organization (CASD)	1,986	131	6.59
DonorConnect (UTOP)	2,048	128	6.27
Midwest Transplant Network (MWOB)	4,297	276	6.42
Versiti (WIDN)	1,844	110	5.99
Nevada Donor Network (NVLV)	2,367	142	5.98
Gift of Life Donor Program (PADV)	9,771	611	6.25
Donor Network of Arizona (AZOB)	4,991	289	5.79
Nebraska Organ Recovery (NEOR)	1,519	79	5.21
The Living Legacy Foundation of Maryland (MDPC)	3,171	172	5.41
ConnectLife (NYWN)	1,239	60	4.84
LifeShare of Oklahoma (OKOP)	3,954	212	5.37
Washington Regional Transplant Community (DCTC)	3,158	166	5.24
OurLegacy - FL (FLFH)	3,541	184	5.18
Southwest Transplant Alliance (TXSB)	8,727	448	5.13
Mid-America Transplant Services (MOMA)	5,266	260	4.94
Donor Alliance (CORS)	3,469	164	4.74
LifeGift (TXGC)	8,579	427	4.98
Sierra Donor Services (CAGS)	2,092	94	4.47
Lifeshare Carolinas (NCCM)	2,599	118	4.52

OPO Name (Primary State)	New Potential Donors (Denominator)	New Total Donors	New Donation Rate
Gift of Hope Organ & Tissue Donor Network (ILIP)	9,108	446	4.90
Tennessee Donor Services (TNDS)	7,189	340	4.72
Center for Organ Recovery and Education (PATF)	5,500	254	4.63
LifeSource - MN (MNOP)	4,707	208	4.41
New Mexico Donor Services (NMOP)	1,628	67	4.11
Legacy of Life - Hawaii (HIOP)	***1,077***	***44***	***4.11***
LifeCenter Organ Donor Network (OHOV)	***2,029***	***83***	***4.11***
LifeCenter Northwest (WALC)	***6,408***	***283***	***4.42***
New Jersey Sharing Network (NJTO)	***5,093***	***221***	***4.34***
LifeBanc (OHLB)	***4,149***	***176***	***4.25***
LifeLink of Florida (FLWC)	***5,665***	***246***	***4.34***
Louisiana Organ Procurement Agency (LAOP)	***5,072***	***218***	***4.31***
Life Alliance Organ Recovery Agency (FLMP)	***4,931***	***210***	***4.26***
Lifeline of Ohio (OHLP)	***3,587***	***147***	***4.11***
Sharing Hope SC (SCOP)	***4,598***	***189***	***4.11***
Donor Network West (CADN)	***8,699***	***358***	***4.11***
OneLegacy (CAOP)	***12,725***	***530***	***4.17***
Pacific Northwest Transplant Bank (ORUO)	***3,791***	***156***	***4.11***
Life Connection of Ohio (OHLC)	***2,072***	***85***	***4.11***
Gift of Life Michigan (MIOP)	***8,736***	***359***	***4.11***
Texas Organ Sharing Alliance (TXSA)	***5,079***	***209***	***4.11***
LifeLink of Georgia (GALL)	***8,573***	***352***	***4.11***
LifeQuest Organ Recovery Services (FLUF)	***4,234***	***174***	***4.11***
New England Organ Bank (MAOB)	***8,712***	***358***	***4.11***

OPO Name (Primary State)	New Potential Donors (Denominator)	New Total Donors	New Donation Rate
Mid-South Transplant Foundation (TNMS)	*2,305*	*95*	*4.11*
Carolina Donor Services (NCNC)	*6,781*	*279*	*4.11*
LiveOnNY (NYRT)	*9,385*	*386*	*4.11*
Indiana Donor Network (INOP)	*5,783*	*238*	*4.11*
Iowa Donor Network (IAOP)	*2,136*	*88*	*4.11*
Mississippi Organ Recovery Agency (MSOP)	*2,927*	*120*	*4.11*
LifeNet Health (VATB)	*5,449*	*224*	*4.11*
LifeLink of Puerto Rico (PRLL)	*3,205*	*132*	*4.11*
LifeChoice Donor Services (CTOP)	*2,561*	*105*	*4.11*
Center for Donation and Transplant (NYAP)	*2,451*	*101*	*4.11*
Kentucky Organ Donor Affiliates (KYDA)	*5,389*	*221*	*4.11*
Arkansas Regional Organ Recovery Agency (AROR)	*2,604*	*107*	*4.11*
Legacy of Hope - Alabama (ALOB)	*8,025*	*330*	*4.11*
Finger Lakes Donor Recovery Network (NYFL)	*2,486*	*102*	*4.11*
Totals	272,105	12,491	

Table 6 shows a similar magnitude of change for rates of transplantation. It shows an increase in the number of transplants, and a performance of achieving the minimum standard, or a 20 percent increase, whichever is greater. With these parameters, the number of annual transplants would rise from about 32,000 in 2017 to almost 42,000 by 2026. (By contrast, Table 4 shows that, in isolation, achievement of the proposed minimum standard would yield 4,903 additional transplants per year, roughly half the 9,474 [= 41,647 − 32,173] implied by Table 6.)

Table 6. OPO Transplant Rates Assuming All OPOs Attain TX Rate of 13.73, or an increase of 20 Percent, whichever is greater, by 2026

OPO Name (Primary State)	Potential Donors (Denominator)	New Number Transplants	New Transplant Rate
Lifesharing - A Donate Life Organization (CASD)	1,986	463	23.32
Organ Procurement Organization at U. of Wisconsin (WIUW)	2,638	599	22.70
Midwest Transplant Network (MWOB)	4,297	985	22.93
DonorConnect (UTOP)	2,048	424	20.68
Versiti (WIDN)	1,844	377	20.43
Donor Network of Arizona (AZOB)	4,991	1,016	20.36
Nebraska Organ Recovery (NEOR)	1,519	294	19.35
The Living Legacy Foundation of Maryland (MDPC)	3,171	600	18.92
Nevada Donor Network (NVLV)	2,367	440	18.61
Gift of Life Donor Program (PADV)	9,771	1,890	19.34
Washington Regional Transplant Community (DCTC)	3,158	554	17.56
OurLegacy - FL (FLFH)	3,541	607	17.15
Southwest Transplant Alliance (TXSB)	8,727	1,530	17.53
LifeGift (TXGC)	8,579	1,493	17.40
Lifeshare Carolinas (NCCM)	2,599	419	16.11
Mid-America Transplant Services (MOMA)	5,266	863	16.38
ConnectLife (NYWN)	1,239	187	15.11
LifeShare of Oklahoma (OKOP)	3,954	634	16.02
Gift of Hope Organ & Tissue Donor Network (ILIP)	9,108	1,492	16.38

OPO Name (Primary State)	Potential Donors (Denominator)	New Number Transplants	New Transplant Rate
Louisiana Organ Procurement Agency (LAOP)	5,072	800	15.78
Tennessee Donor Services (TNDS)	7,189	1,133	15.76
Sierra Donor Services (CAGS)	2,092	312	14.91
LifeSource - MN (MNOP)	***4,707***	***707***	***15.02***
Sharing Hope SC (SCOP)	***4,598***	***677***	***14.72***
Donor Alliance (CORS)	***3,469***	***492***	***14.18***
Donor Network West (CADN)	***8,699***	***1,270***	***14.59***
LifeBanc (OHLB)	***4,149***	***575***	***13.85***
Lifeline of Ohio (OHLP)	***3,587***	***492***	***13.73***
Center for Organ Recovery and Education (PATF)	***5,500***	***764***	***13.90***
LifeCenter Northwest (WALC)	***6,408***	***892***	***13.91***
Texas Organ Sharing Alliance (TXSA)	***5,079***	***697***	***13.73***
LifeLink of Florida (FLWC)	***5,665***	***780***	***13.77***
OneLegacy (CAOP)	***12,725***	***1,762***	***13.84***
New Mexico Donor Services (NMOP)	***1,628***	***224***	***13.73***
New Jersey Sharing Network (NJTO)	***5,093***	***699***	***13.73***
LifeCenter Organ Donor Network (OHOV)	***2,029***	***279***	***13.73***
Indiana Donor Network (INOP)	***5,783***	***794***	***13.73***
Life Alliance Organ Recovery Agency (FLMP)	***4,931***	***677***	***13.73***
New England Organ Bank (MAOB)	***8,712***	***1,196***	***13.73***
Carolina Donor Services (NCNC)	***6,781***	***931***	***13.73***
LifeQuest Organ Recovery Services (FLUF)	***4,234***	***581***	***13.73***
LifeLink of Georgia (GALL)	***8,573***	***1,177***	***13.73***

OPO Name (Primary State)	Potential Donors (Denominator)	New Number Transplants	New Transplant Rate
Pacific Northwest Transplant Bank (ORUO)	***3,791***	***521***	***13.73***
Gift of Life Michigan (MIOP)	***8,736***	***1,199***	***13.73***
Mid-South Transplant Foundation (TNMS)	***2,305***	***316***	***13.73***
LiveOnNY (NYRT)	***9,385***	***1,289***	***13.73***
Legacy of Life - Hawaii (HIOP)	***1,077***	***148***	***13.73***
Life Connection of Ohio (OHLC)	***2,072***	***284***	***13.73***
LifeNet Health (VATB)	***5,449***	***748***	***13.73***
Mississippi Organ Recovery Agency (MSOP)	***2,927***	***402***	***13.73***
Iowa Donor Network (IAOP)	***2,136***	***293***	***13.73***
LifeChoice Donor Services (CTOP)	***2,561***	***352***	***13.73***
Kentucky Organ Donor Affiliates (KYDA)	***5,389***	***740***	***13.73***
LifeLink of Puerto Rico (PRLL)	***3,205***	***440***	***13.73***
Center for Donation and Transplant (NYAP)	***2,451***	***337***	***13.73***
Legacy of Hope - Alabama (ALOB)	***8,025***	***1,102***	***13.73***
Arkansas Regional Organ Recovery Agency (AROR)	***2,604***	***358***	***13.73***
Finger Lakes Donor Recovery Network (NYFL)	***2,486***	***341***	***13.73***
Totals	272,105	41,647	

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While there is no certainty that these or higher levels of performance will be realized, there is additional evidence beyond the known performance levels of the higher-achieving OPOs. A recent study compared French and American organ utilization in the period from 2004 to 2014.[31] This study showed that the discard rate for kidneys from deceased donors was about nine percent in France and 18 percent in the U.S. The lower discard rate reflected a far greater use in France of kidneys from older donors that had inferior ''kidney donor risk index'' (KDRI) scores. The mean age of donor kidneys in France was 51 years and in the U.S., 37 years. Despite the higher use of seemingly less desirable organs, the study estimates that had the U.S. used French practices, there would have been about 132,000 additional years of graft (and patient) survival in the U.S. While most European countries use mandatory nation-wide ''opt-out'' rather than ''opt-in'' policies and hence more strongly encourage organ donation than in the U.S. (where no states use ''opt-out''), a recent study shows that this policy does not explain European success rates and that many American states have organ donation rates higher than many European countries.[32] One important policy difference that does seem to matter is that in France, as in most other European countries, organs from older donors are systematically matched for use by older patients,

[31] Olivier Aubert et al, ''Disparities in Acceptance of Deceased Donor Kidneys Between the United States and France and Estimated Effects of Increased U.S. Acceptance,'' *JAMA Intern Med.* Doi:10:1001/jamainternmed.2019.2322.

[32] Alexandra Glazier and Thomas Mone, ''Success in Opt-In Organ Donation Policy in the United States,'' August 8, 2019, doi:10.1001/*JAMA*.2019.9187.

without penalizing transplant programs for the lower success rates that inevitably result.[33] These results strongly suggest that with the regulatory penalties removed on transplant centers that do not achieve the highest possible one-year graft and patient survival outcomes (as discussed in the proposed rule, ''Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction'' 83 FR 47686) and with the greater accountability for OPO performance proposed in this rule, performance results such as those achieved in France could be achievable in the U.S.

D. Anticipated Costs and Benefits

There are intrinsic connections between the costs and benefits examined in this section. Consider, for instance, the relatively low costs for OPOs and other entities in the health care industry set forth in the ''Implementation and Continuing Costs'' subsection; such low magnitudes are plausible primarily if OPO decertification is very rare. Without a credible threat of decertification, OPO behavior change may be minimal, in which case low costs would be accompanied by low longevity benefits and medical expenditure impacts (significantly lower than the estimates appearing below in Tables 11R and 12R).

An opposite case is one in which decertification is common, thus motivating OPO behavior change and making non-negligible benefits plausible. OPOs undergoing management change would experience transition costs that are substantial (although difficult to quantify). Broader societal transition costs could include reduced organ recovery while the decertification process unfolds, even if improved practices increase transplant activity in the medium- to long-term.

1. *Effects on Medical Costs.* In the estimates that follow, we rely primarily on recent estimates by staff of the actuarial and consulting firm Milliman. Their study, ''2017 U.S. Organ and Tissue Transplant Cost Estimates and Discussion'' compares charges before, during, and after transplantation for all major and minor categories of transplant.[34] The advantage of these estimates for our purposes is that they cover the pre-, intra-, and post-transplant costs on all organs using a consistent cost-estimating methodology. Unfortunately, accurate medical cost estimates are not publicly available from health insurance firms, since the network discounts received by private firms are generally treated as trade secrets, and Medicare's payments are typically not based directly on costs (with some exceptions, including payments to OPOs). Hence, Milliman uses ''charges'' for its estimates. As with likely excess of charges over costs, there's a netting off of non-transplantation costs—that is, costs associated with organ failure that are not affected by transplantation itself. For estimating purposes, we assume that these divergences between costs and charges largely cancel each other out, but that the net effect is that actual costs are about 20 percent less than the Milliman charge estimates.

In analyzing the medical costs of the proposed rule, we first estimate the costs per transplant of the three most common organ transplants: Kidneys, livers, and hearts. Between them, they account for about 90 percent of all transplants. Kidneys alone are over 60 percent of all organs transplanted. Table 7 shows the data for hearts:

TABLE 7—FIRST YEAR COST PER HEART TRANSPLANT ($)

Heart	Milliman charge estimate	Likely excess of charges over costs	Assumed non-TX costs	Immuno-suppressive drugs (six months)	Net transplant cost
30 days pre-transplant	43,000	9,000	20,000	0	14,000
Procurement	102,000	0	0	0	102,000
Hospital Transplant Admission	887,000	177,000	0	0	710,000
Physician During Admission	92,000	18,000	0	0	74,000
180 Days Medical Post Discharge	223,000	45,000	60,000	0	118,000
180 Days Drugs Post Discharge	34,000	7,000	10,000	15,000	32,000
Total	1,381,000	256,000	90,000	15,000	1,050,000

As shown in Table 7, the one-time cost of a heart transplant is just over one million dollars after adjusting charges to costs and reducing the estimates to account for medical and drug costs, both pre- and post-discharge, that are unlikely to be transplant-related.

TABLE 8—FIRST YEAR COST PER LIVER TRANSPLANT ($)

Liver	Milliman charge estimate	Likely excess of charges over costs	Assumed non-TX costs	Immuno-suppressive drugs (six months)	Net transplant cost
30 days pre-transplant	41,000	8,000	10,000	0	23,000
Procurement	94,000	0	0	0	94,000
Hospital Transplant Admission	463,000	93,000	0	0	370,000
Physician During Admission	56,000	11,000	0	0	45,000
180 Days Medical Post Discharge	127,000	25,000	60,000	0	42,000
180 Days Drugs Post Discharge	31,000	6,000	10,000	15,000	30,000
Total	812,000	143,000	80,000	15,000	604,000

[33] See Olivier Aubert, et al.

[34] T. Scott Bentley and Steven J. Phillips, 2017, available to download at *http://www.milliman.com/insight/2017/2017-U_S_-organ-and-tissue-transplant-cost-estimates-and-discussion/.*

Table 8 shows the estimated average cost for a liver transplant, estimated on the same basis. Table 9 estimates kidney transplant costs, with an additional adjustment. In the case of a kidney transplant, there is an off-setting saving for the elimination of ESRD kidney dialysis costs. This is a substantial saving and in the first year alone, saves about one-third of the estimated transplant cost.

TABLE 9—FIRST YEAR COST PER KIDNEY TRANSPLANT ($)

Kidney	Milliman charge estimate	Likely excess of charges over costs	Assumed non-TX costs	Immuno-suppressive drugs (six months)	Net transplant cost subtotal	Annual dialysis costs avoided	Net first year cost
30 days pre-transplant	30,000	(6,000)	(10,000)	0	14,000	0	14,000
Procurement	97,000	0	0	0	97,000	0	97,000
Hospital Transplant Admission	159,000	(32,000)	0	0	127,000	0	127,000
Physician During Admission	25,000	(5,000)	0	0	20,000	0	20,000
180 Days Medical Post Discharge	75,000	(15,000)	(60,000)	0	0	* (90,000)	(90,000)
180 Days Drugs Post Discharge	29,000	(6,000)	(10,000)	15,000	28,000	0	28,000
Total	415,000	(64,000)	(80,000)	15,000	286,000	(90,000)	196,000

* Estimated annual dialysis costs.

Using these results, it is possible to estimate the extended effects of added and reduced costs over time. In Table 10 we provide a 5-year projection, giving both results for a patient who survives all 5 years with the transplanted organ, and the same estimate adjusted to assume only an 80 to 90 percent patient and organ survival rate for the full 5 years (the higher rate is for kidneys). These estimates do not account for all the varied circumstances that can arise, such as patients whose organs fail and who are then re-transplanted. They include the costs of immunosuppressive drugs. In the case of kidney transplants, the estimates assume a savings of $90,000 for ending dialysis, offset by a $30,000 cost for the immunosuppressive drugs. The weighted results take into account that kidneys account for about 65 percent of transplants for these three organs. As shown in the table, kidney transplants actually save money for the patients who survive the full 5-year period.

TABLE 10—FIVE YEAR COSTS PER WEIGHTED AVERAGE TRANSPLANT ($)

	Heart	Liver	Kidney	All three organs weighted
Annual Percent of Total TX	11%	24%	65%	100%
First Year	1,050,000	604,000	196,000	387,860
Second Year	20,000	20,000	(60,000)	(32,000)
Third Year	20,000	20,000	(60,000)	(32,000)
Fourth Year	20,000	20,000	(60,000)	(32,000)
Fifth Year	20,000	20,000	(60,000)	(32,000)
Total	1,130,000	684,000	(44,000)	259,860
80 to 90% Survival Total *	1,122,000	676,000	(20,000)	272,660

* Rate is higher for kidneys than for other organs. All deaths are assumed to occur prior to Year 2 (that is, before any dialysis-related savings can accrue).

An annually growing performance increase to about 8,000 additional transplants in the last year of the next four-year OPO performance period would be essential in order to have enough growth in the second half of the decade to meet the HHS' 2030 goal of doubling the number of kidneys available for transplants. As Table 11 shows, that will require multi-billion dollar increases over current transplant spending levels by the middle of the next decade (and far more by 2030). As we show in our benefit estimates, these levels are exceeded by the life-saving and life-extending benefits of these additional transplants. As discussed later in this analysis, most of the cost increases we estimate in this proposed rule are reimbursed by private payers, not by Medicare.

HHS has set a quantitative goal of doubling the number of kidneys available for transplant by 2030. While there are multiple pathways to achieve this goal, such as increasing the number of living donors, avoiding penalizing transplant programs for using kidneys with lower likelihood to transplantation success, and improving techniques for maintaining organs during the time before transplantation to reduce discards of organs shared outside the DSA, the main approach for achieving this ambitious goal is to increase the number of deceased donors. This will require continuing improvements over time, and we have estimated the approximate numbers that would have to be achieved in the next four-year OPO performance period to move about half way towards an annual increase of approximately 20,000 more kidneys available and (assuming a reduction in discard rates) approximately 16,000

more kidney transplants by 2030, as shown in Table 11.

In Tables 11 and 12 we show the annual results as each cohort of new transplants arrives over the OPO performance period from 2021 to 2025. These estimates include totals for all organs since one deceased donor normally provides multiple organs. The 10,000 increase shown for 2025 includes about 6,500 kidneys transplanted. These figures assume a 5-year patient and graft survival rate of 90 percent for kidney transplants. As can be seen, the costs grow substantially with each new cohort. These tables include an extra column for 2026 that shows the effects of these same cohorts alone in the sixth year. While total costs grow over time with each new and larger cohort of new transplants, the savings from reduced kidney dialysis costs from previous kidney transplants grow over time, as do the benefits for those patients whose lives were both extended and improved by transplantation.

TABLE 11—COSTS OVER TIME AS ORGAN TRANSPLANTS HYPOTHETICALLY INCREASE

[$ millions]

Year	2021	2022	2023	2024	2025	2026
Increase Over Base Year in Number Transplants.	1,000	3,000	6,000	8,000	10,000	Same Cohorts
Costs for 2021–2 Cohort	$388	($29)	($29)	($29)	($29)	($29)
Costs for 2022–3 Cohort		$1,164	($86)	($86)	($86)	($86)
Costs for 2023–4 Cohort			$2,327	($173)	($173)	($173)
Costs for 2024–5 Cohort				$3,103	($230)	($230)
Costs for 2025–6 Cohort					$3,879	($288)
Total	$388	$1,135	$2,212	$2,815	$3,360	($806)

We note that the expenditure data include procurement costs, which average almost $100,000 per organ transplanted across all three organ types. Accordingly, a cohort of 1,000 patients would involve total procurement costs of about $100 million, and a cohort of 8,000 patients about $800 million. These data do not include all organ types, nor all cost savings (notably end-of-life costs), but are a reasonable approximation to the magnitudes involved. The great bulk of the procurement costs are paid to OPOs and finance not only direct involvement with donor families and donations, but also management and direction of the OPO.

Our estimates also do not include costs of changes in treatment options for both liver and heart patients, including new drug treatments for hepatitis C, one of the main causes of liver failure, and heart assist devices that can serve as a bridge while waiting for a heart transplant.

Table 11R shows estimates using the same per-transplant inputs but with aggregates reflecting the 4,903 new annual transplants shown in Table 4; impacts are assumed to begin in 2023 because existing OPO contracts run through 2022, thus preventing any decertification before then. (We note that a steady new transplant level may be an oversimplification because the proposed policy, setting a threshold at the 75th percentile performance amongst OPOs, could lead to a continual ratcheting of the performance necessary for compliance, and we request comment that would allow for such year-to-year changes to be reflected in our analysis.) These estimates feed into the upper bound estimates that appear in the accounting statement (Table 19), below.

TABLE 11R—COSTS OVER TIME AS ORGAN TRANSPLANTS INCREASE

[$ millions]

Year	2021	2022	2023	2024	2025	2026
Increase Over Base Year in Number Transplants.	0	0	4,903	4,903	4,903	Same Cohorts
Costs for 2023–4 Cohort			$1,902	($142)	($142)	($142)
Costs for 2024–5 Cohort				$1,902	($142)	($142)
Costs for 2025–6 Cohort					$1,902	($142)
Total	$0	$0	$1,902	$1,760	$1,618	($427)

2. *Effects on Patients.* Every organ that is used for transplantation has a very high probability of substantially extending the life of the recipient. There is extensive literature on life expectancy before and after transplant, quality of life, and cost savings for kidney patients. A recent literature synthesis found essentially universal agreement that kidney transplants were not only substantially life extending, but also cost reducing.[35] The authors performed an extensive literature search and found that from 1968 to 2007, seventeen studies assessed the cost-effectiveness of renal transplantation. The authors concluded that ''[r]enal transplantation . . . is the most beneficial treatment option for patients with end-stage renal disease and is highly cost-effective compared to no therapy. In comparison to dialysis, renal transplantation has been found to reduce costs by nontrivial amounts while improving health both in terms of the number of years of life and the quality of those years of life'' (page 31). More recent studies have reached similar conclusions, as have other syntheses. For example, in the article, ''Systematic Review: Kidney Transplantation Compared with Dialysis in Clinically Relevant Outcome,'' the authors reviewed 110 studies and

[35] Huang, E, et al,''The Cost-Effectiveness of Renal Transplantation,'' *When Altruism Isn't Enough,* edited by Sally Satel (AEI Press, 2008).

concluded that the vast majority of kidney transplant recipients showed major improvement in life quality and reductions in mortality compared to those remaining on dialysis.[36] The *Annual Data Report* of the United States Renal Data System utilizes national data on ESRD, and reports that deaths per 1,000 patient years in 2016 were about 134 for dialysis patients and about 29 for transplant recipients (see 2018 report, volume 2, Figure 5.1; accessed at *https://www.usrds.org/adr.aspx* and *https://www.usrds.org/2018/download/v2_c05_Mortality_18_usrds.pdf*). There are similar data on other organs. For example, in 1998, HHS published a final rule with comment period that established governance procedures for the OPTN (63 FR 16296). In the RIA for that rule, HHS estimated that ''the annual benefits of organ transplantation include about eleven thousand lives vastly improved by kidney transplantation, and another eight thousand lives both vastly improved and prolonged by transplantation of other major organs'' (63 FR 16323).

Accordingly, the per-patient potential benefits are substantial. For each new kidney transplant, there would be an average of 10 additional life years per transplant patient compared to those on dialysis.[37] Using the more usual metric of survival rates, the five-year survival rate for kidney transplant patients is 86 percent (Milliman, page 13).

HHS ''Guidelines for Regulatory Impact Analysis'' explain in some detail the concept of QALYs.[38] QALYS, when multiplied by a monetary estimate such as the Value of a Statistical Life Year (VSLY), are estimates of the value that people are willing to pay for life-prolonging and life-improving health care interventions of any kind (see sections 3.2 and 3.3 of the HHS Guidelines for a detailed explanation). The QALY and VSLY amounts used in any estimate of overall benefits, including this one, is not meant to be precise estimates, but instead are rough statistical measures that allow an overall estimate of benefits expressed in dollars.[39]

Table 12 provides estimates of the life-extending and life-improving value of the proposed rule assuming that it succeeds in improving OPO performance in early years at the magnitudes necessary to meet the 2030 HHS goal. For simplicity, we estimate that transplants occur halfway through the year.

TABLE 12—LIFE-EXTENDING AND IMPROVING BENEFITS OVER FIRST 5 YEARS AS TRANSPLANTS HYPOTHETICALLY INCREASE

[$ millions]

Year	2021	2022	2023	2024	2025	2026
Increase Over Base Year in Number Transplants.	1,000	3,000	6,000	8,000	10,000	Same Cohorts.
2021–2 Cohort	$94	$187	$187	$187	$187	$187.
2022–3 Cohort		$281	$562	$562	$562	$562.
2023–4 Cohort			$562	$1,123	$1,123	$1,123.
2024–5 Cohort				$749	$1,497	$1,497.
2025–6 Cohort					$936	$1,872.
Total	$94	$468	$1,310	$2620	$4,305	$5,241.

This table shows only the first 5 years of increasing transplants, with an extra year added with no new cohort to illustrate how the benefits for each group grow over time. Over a ten year period, total life extending benefits from about 18,000 additional kidney transplants would be $23 billion (without discounting) from the 2021 to 2025 cohorts of additional transplants shown in Table 12 (28,000 organs times 65 percent of which are kidneys times ⅔ patient survival rate times $1 million per surviving transplant recipient in life extending benefits = $23 billion). A similar calculation for all additional transplant recipients reaches a total of $35 billion over ten years, with even more years of benefits to most of the same recipients yet to come.[40]

We note that these estimates are averages across patients who vary widely in age, medical condition, and life expectancy, as well as type of organ failure. For example, the sickest patients typically have very low life expectancies without transplant, and hence stand to gain the most years of life from a transplant. Offsetting this, these same patients, on average, have slightly lower survival rates post-transplant. Organ and patient survival issues are complex and dealt with by detailed policies and procedures developed and used by the transplant community. These policies are reviewed and revised frequently based on actual experience and changing technology—over time the success rate from previously marginal organs, and in older and sicker patients, have both increased substantially. There are additional complexities that we have not used in these broad estimates, such as the ability of kidney transplant recipients to return to dialysis if a transplanted kidney fails, leading to both additional costs and additional benefits. For presentation purposes, we have not discounted future costs and benefits to ''present value'' in the preceding tables, but handle discounting in our annualized estimates shown in the Accounting Table that follows. For

[36] Tonelli M, et al, *AmJTransplant* 2011: 2093–2109.

[37] Wolfe RA et al, ''Comparisons of Mortality in All Patients on Dialysis, Patients on Dialysis Awaiting Transplantation, and Recipients of a First Cadaveric Transplant,'' *NEJM,* 1999, 341:1725–30; accessed at *http://www.nejm.org/doi/full/10.1056/NEJM199912023412303#t=article*).

[38] *https://aspe.hhs.gov/pdf-report/guidelines-regulatory-impact-analysis.*

[39] Using such a measure to make coverage or reimbursement determinations is prohibited by Section 1182(e) of the Act. That prohibition does not apply to the situation addressed in this proposed rule, where the purpose is not to determine medical coverage for individual patients, but to measure overall success in raising the number of persons who obtain life-saving treatments.

[40] This method of calculating the value of kidney transplantation is similar to but substantially simplified from the method used in P.J. Held et al, ''A Cost-Benefit Analysis of Government Compensation of Kidney Donors,'' American Journal of Transplantation, 2016, pages 877–885 (plus 65 pages of supplementary details explaining all assumptions, data sources, and calculations). Factors for Hearts and Livers come from Elisa F. Long et al, ''Comparative Survival and Cost-Effectiveness of Advance Therapies for End-Stage Heart Failure,'' *http://circheartfailiure.ahajournals.org,* April 7, 2017; and Fredrik Aberg et al, ''Cost of a Quality-Adjusted Life Year in Liver Transplantation: The Influence of the Indication and the Model for End-Stage Liver Disease Score,'' Liver Transplantation 17:1333–1343, 2011.

purposes of this analysis, the proper measure is the average gain across all patients who would receive transplants in the presence of the proposed rule but not in its absence.

Table 12R shows estimates using the same per-transplant inputs but with aggregates reflecting the 4,903 new annual transplants shown in Table 4; increases are assumed to begin in 2023 because existing OPO contracts run through 2022, thus preventing any decertification before then. (We note that a steady new transplant level may be an oversimplification because the proposed policy, setting a threshold at the 75th percentile performance amongst OPOs, could lead to a continual ratcheting of the performance necessary for compliance, and we request comment that would allow for such year-to-year changes to be reflected in our analysis.) These estimates feed into the upper bound estimates that appear in the accounting statement (Table 19), below.

TABLE 12R—LIFE-EXTENDING AND IMPROVING BENEFITS OVER FIRST 5 YEARS AS TRANSPLANTS INCREASE

[$ millions]

Year	2021	2022	2023	2024	2025	2026
Increase Over Base Year in Number Transplants.	0	0	4,903	4,903	4,903	Same Cohorts.
Costs for 2023–4 Cohort			$461	$917	$917	$917.
Costs for 2024–5 Cohort				$461	$917	$917.
Costs for 2025–6 Cohort					$461	$917.
Total	$0	$0	$461	$1,378	$2,295	$2,751.

3. *Implementation and Continuing Costs.* The requirements of the final rule, if issued, would necessarily have to be read, understood, and implemented by all OPOs. This would create one-time costs even though the proposed requirements would not directly create unreimbursed cost burdens. In many cases, these costs would be very low, and may be as simple as learning where the OPO stands in relationship to other facilities in meeting the new performance standards. In some cases, the OPO would need to significantly adjust its procedures and techniques. In still other cases, time would have to be spent deciding how to change existing policy and procedures. These effects would be felt primarily by the 58 OPOs, but secondarily by the approximately 750 transplant programs in about 250 transplant hospitals. Many of these hospitals would need to respond if OPOs implement new technologies or procedures to optimize their performance. These costs, however, are part of the acquisition costs associated with organ procurement and would be paid by Medicare and other health insurers. Therefore, our estimates assume that ongoing management operations will continue at current levels and focus on costs needed to understand the new rules and plan changes needed for compliance. We welcome comments on our estimates as to skills and occupations involved, and time likely to be spent.

In total, there are about 800 affected entities or programs. We assume that on average there would be one hour of time spent by a lawyer, two hours of time by an administrator or health services manager, and two hours of time by other staff (we assume registered nurses or equivalent in wage costs) of each affected provider to understand the regulatory change(s) and make the appropriate changes in procedures. We further assume that for one-tenth of these providers, two hours of physician time would be needed to consider changes in facility policy. Average hourly costs for these professions, with wage rates doubled to account for fringe benefits and overhead costs, are $139 for lawyers (occupation code 23–1011), $109 for medical and health services managers (occupation code 11–9111), $89 for statisticians (occupation code 15–2041), $73 for registered nurses (occupation code 29–1141), $56 for healthcare social worker (21–1022), and $203 for physicians (occupation code 29–1060). The medical and health services managers would include such occupations as transplant administrator, organ procurement coordinator, and director of nursing. The statistician might instead be a computer analyst or operations research analyst at a similar wage. The underlying wage numbers are from BLS statistics for 2018, at *https://www.bls.gov/oes/current/oes_nat.htm#23-0000.*

We assume that on average, an OPO would involve one person in each occupation and an average of eight hours on an interdisciplinary team tasked with learning the new rules, understanding their implications for that OPO, and initiating plans to address performance levels. Total costs, on average, would be $139 plus $109 plus $89 plus $73 plus $56 plus $203, for a total of $669 per hour and $5,352 (8 × $669) for eight hours. For the 58 OPOs, the first-year cost would therefore be about $310,000 (58 × $5,352). A somewhat different mix of occupations would lead to a similar total cost. For transplant programs, we assume that only half as many hours would be needed, using a similar mix of occupations, for a total of $669 per hour and $2,676 ($669 × 4) for four hours. For 750 transplant programs the total first year cost would therefore be about $2,007,000 ($2,676 × 750).

There would also be continuing and far larger costs over time as OPOs and hospitals manage the substantial increases in numbers of donors and number of organs transplanted. These procurement costs are included in the cost estimates shown in Tables 7 to 9 and summarized in Tables 10 and 11, and average approximately $100,000 per organ. Each additional 1,000 organs would cost about $100 million, with insurance reimbursement and patient cost-sharing covering essentially all of those costs (see the next section of the analysis). As procurement grows, there would be two significant effects. First, there are economies of scale as OPOs and hospitals expand their donor-related and transplant services. Second, and more than offsetting such gains, substantial improvements over time would require additional efforts. Some OPOs would also likely incur additional costs as they consider and in some cases prepare for such actions as mergers or replacements. For both cost savings and cost increases, effects are primarily from staffing changes; we assume there are relatively few fixed investments in plant and equipment. And in both cases, current reimbursement policies and programs pay for all reasonable costs. We welcome comments and if possible, data on these and other workload, cost, and revenue issues and estimates.

We do not expect substantial costs would be incurred by CMS. The data collection required for enforcement of the proposed standards already exists and can readily be used to assess performance. OPOs are already reviewed and assessed on a continuing basis. There would be additional costs for technical assistance and possibly more severe actions regarding any OPOs with major compliance problems, or increased appeals related activities, but our expectation is that these would be managed through any necessary reallocations of staff time from lower priority activities. The number of affected facilities is also small compared to the number of facilities that CMS works with on a regular basis. Regardless, these oversight activities are unlikely to require more than three or four additional person-years of effort, with annual costs of one million dollars or less.

The preceding analysis does not reflect the potentially substantial transition costs associated with the disruptive process of decertification. We request comment that would inform estimates of this category of costs.

E. Effects on Medicare, Medicaid, and Private Payers

The preceding cost estimates include all procurement and transplantation costs, regardless of payer. In practice, however, most of the costs are covered by insurance, and the remainder primarily by patients. Typical insurance shares, both public and private, range from 100 percent (Medicaid) to 80–90 percent in private insurance and Medicare, taking into account hospital, physician, ESRD, and drug costs. While overall cost sharing by category of expense is broadly similar among insurance sources and across organ types, both the transplant cost and the shares paid by public and private insurance vary widely by organ type. Specifically, for heart and liver transplants, the vast majority of patients are enrolled in private insurance or in some cases in Medicaid. Relatively few are Medicare patients. This is because these patients are overwhelmingly below age 65 and ineligible for Medicare unless disabled. The age 65 and older percentage is only 17 percent for hearts, and 18 percent for livers. In sharp contrast, the vast majority of kidney transplants (about 80 percent) are received by patients who have end-stage renal disease and, as ESRD patients, are nearly all entitled to Medicare regardless of age (about half of ESRD patients are also enrolled in Medicaid, but Medicare is ''primary'' and pays most costs). This ESRD/kidney transplant group also differs radically in initial transplant cost (much lower than for hearts and livers, as shown in Tables 7 through 10), and in cost over time. For kidney transplant patients who live 4 years or more after the transplant year, total medical costs over time are lower than for dialysis, resulting in savings to Medicare (see Table 10). For ESRD patients who receive kidney transplants, the public insurance programs would save money over time.

We do not have a definitive estimate of costs to each category of payer because those shares will change considerably over time as new cohorts of patients are served, and will also change depending on whether costs are estimated for 1, 5, or 10 years or more. For kidney patients, who account for almost two-thirds of transplants, Medicare cumulatively saves more money than the transplant cost by the fourth or fifth year after transplant. One simple calculation method is to consider the weighted average of costs billed to Medicare for each 1,000 patients transplanted and surviving 5 years. Taking into account all the preceding factors, the weighted average total cost billed by providers to all payers would be about $270 million (See Table 10). The Medicare share of that would be about $40 million, largely reflecting the lower initial costs of kidney transplants, the continuing dialysis savings, and the relatively small share of heart and liver transplants paid by Medicare. In the first year for these same 1,000 patients (the year of the actual transplant) the Medicare cost would be about $150 million of the $388 million total, reflecting the Medicare coverage of the majority of transplants as well as the lower average cost for those kidney transplants. Across the first 5 years after the final rule takes effect (years in which much of the dialysis savings would not yet be realized), total costs shown in Table 11 over this period are about $10 billion and the average billed to Medicare would be about 25 percent of this, or $2.5 billion. Of this, patients would pay on average almost 20 percent, reducing the Medicare costs to about $2 billion over the five year period.

F. Effects on Small Entities, Effects on Small Rural Hospitals, Unfunded Mandates, and Federalism

1. *Regulatory Flexibility Act.* The Regulatory Flexibility Act (RFA) requires agencies to analyze options for regulatory relief of small entities, if a proposed rule would have a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that almost all health care providers regulated by CMS are small entities as that term is used in the RFA (including small businesses, nonprofit organizations, and small governmental jurisdictions). The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than $7.5 million to $38.5 million in any 1 year, varying by type of provider and highest for hospitals). On average, the 58 OPOs have annual revenues of about $50 million in a market with annual organ acquisition revenues of about $3 billion annually.[41] While few of these would meet SBA revenue size standards for ''small,'' all are by law non-profits. Accordingly, almost all of the direct effects on businesses that this proposed rule would create will affect small entities.

The RFA requires that an Initial Regulatory Flexibility Analysis (IRFA) be prepared if a proposed rule would have a ''significant economic impact'' on a ''substantial number'' of such entities. The HHS standard for ''significant economic impact'' is 3 percent or more of annual revenues. Although the HHS position is that this only applies to negative impacts because the RFA requires agencies to ''minimize'' economic impact, HHS practice in cases involving significant positive effects is to perform the analysis, regardless of the statutory issue. In the case of this rule, we expect some OPOs to prosper as they reform their practices to meet the standards under the proposed rule, but some may lose their certification and be replaced by more effective OPOs. The HHS standard for ''substantial number'' is 5 percent or more of those that will be significantly impacted, but never fewer than 20. There is a possibility that as many as 20 OPOs would lose certification and hence we are unable to certify that an Initial Regulatory Flexibility Analysis is not required under the RFA. Accordingly, we are preparing an IRFA.

The question arises as to whether transplant programs are affected entities. We believe they are not. They are all medical units within hospitals. Only the hospital itself can be a small entity, and many are, as a consequence of their non-profit status. However, nothing in this proposed rule directly

[41] Brigitte Sullivan, Executive Director, NYU Langone Transplant Institute, ''Maximizing Medicare Cost Report Reimbursement,'' 2015, online at *http://organdonationalliance.org/wp-content/uploads/2015/08/ATC_BSullivan_CostReport_062016_S5N0001.pdf.*

regulates either hospitals or their transplant programs. Moreover, nothing in this proposed rule would have any adverse effects on those programs. They would, instead, likely gain revenues from increases in patients transplanted. The pattern of such increases is impossible to predict since organs are increasingly shared across OPO service area boundaries and, in many cases, across hundreds or thousands of miles. Regardless, in the aggregate, hospital revenues nationwide exceed one trillion dollars a year; the estimated costs of this proposed rule over the first 5 years are about $10 billion, averaging $2 billion a year, of which only half falls on transplant programs. This would be a fraction of one percent of hospital costs or revenues in the hospitals that host transplant programs, which are generally larger hospitals. Since organ acquisition costs are reimbursed by patient health insurance, net costs to hospitals with transplant programs are approximately zero and may actually be negative.[42] Indeed, if any hospital determined that its transplant program was no longer a profit center, it could simply cease providing that service. Hence, we conclude that there would be no ''significant economic effect'' on a ''substantial number'' of hospitals, and that increases in transplant volume will be neutral or positive (however, see the further discussion of payment issues in the Alternatives section).

The potential economic effects on OPOs depend on their ability to meet the thresholds established at the beginning of the four-year performance period. OPOs who are at or above this threshold by the end of this period should face relatively small effects (a likely increase in organ donors and organs transplanted that we estimate to be likely to be near 20 percent, with revenues from Medicare that reimburse their incurred reasonable costs) and other health insurers. Those currently below the threshold that can achieve the threshold rate over the four-year period will benefit from the increased revenue associated with procuring more organs. For OPOs that cannot meet the new performance standards, the issue would be making the necessary changes to avert a loss of certification. Our methodology was designed to allow all OPOs the opportunity to achieve the threshold rates; however, based on Tables 3 and 4, we believe that there are a range of potential outcomes, assuming the high performers remain at steady state. These include:

- Eight OPOs who would be subject to de-certification because they would need to increase their donation and/or transplantation rates by more than 50 percent to meet the threshold rates.
- Eighteen OPOs who would be subject to de-certification because they would need to increase their donation and/or transplantation rates by more than 25 percent to meet the threshold rates.
- Thirty-three OPOs who would be subject to de-certification because they would need to increase their donation and/or transplantation rates by more than 10 percent to meet the threshold rates.

In most cases of potential decertification, we would reasonably expect another OPO to take over that service area, retaining the original staff, but changing the leadership and many of the organ procurement practices. Conversely, it is also possible that an OPO taking over a new service area would need to increase its staff or incur costs related to retraining, or implementation of best practices unfamiliar to the de-certified OPO's staff. We solicit comment on the costs associated with an OPO entering a new DSA after a decertification, including retraining, leadership, relationship building, and implementation of other best practices.

Tables 3 and 4 present a list of all affected OPOs and of the gap between their current performance and the proposed standards. These tables use as a base year 2017 data but for most OPOs, the potential donor data from the state death certificates are not likely to change substantially from updates between the proposed and final rule and between the final rule and first performance year. These tables show for each OPO what it would have to achieve over a four-year period to meet the proposed performance standards. Since the threshold rate would be established prior to the assessment period, each OPO would know from its own workload data and the latest potential donor data exactly where it stands at any point in time over the four-year performance period. Since the cost of each OPO's increased effort and performance is covered by Medicare, this is not primarily a cost or revenue issue for the OPOs. Instead, our new performance measures would create an organizational survival issue. The future of an OPO depends largely on its performance in obtaining donors and on utilization of those organs for transplantation.

Since all OPOs are ''small entities,'' all of the alternatives and options presented throughout this preamble meet the RFA requirement that effects on these entities be addressed. We emphasize, however, that we already know that many OPOs already meet or in many cases far exceed our proposed standards without any regulatory relief, and we know that the HHS goal for increasing kidney donation and transplantation can not be met without a substantial increase in performance. We also know that the current performance requirements permit most OPOs to perform far below the levels of their peers in serving the long waiting lists of patients in need of organ donation and transplantation.

Because our proposals are performance standards, they provide flexibility to the OPOs in meeting the standards. For example, in addition to all the possible internal reforms that an OPO could make, OPOs could merge, or service areas could be merged. These flexibilities are not limited to bilateral agreements and could involve multiple OPOs in partnership with each other or with transplant hospitals. OPO boards could replace the executive leadership and the leadership could replace any ineffective coordinators. They could work to improve working relationships with donor hospitals within their service areas through programs such as the Workplace Partnership for Life. Should any case arise where an OPO is unable to make the changes necessary to or constrained by circumstances beyond its control that it cannot reach the performance levels of others, CMS can intervene with technical assistance or to facilitate mergers or other changes. We believe that every OPO can meet the proposed standards through good faith reforms to improve both donation and organ placement.

The RFA contains a number of requirements for the content of an Initial Regulatory Flexibility Analysis, including a description of the reasons why action is being considered, a statement of the objectives and legal basis for the proposed rule, a description of any reporting or record-keeping requirements of the proposed rule, and a description of any other Federal rules that duplicate, overlap, or conflict with the proposed rule (there are none in this case), among others. This RIA and the preamble taken as a whole meet these requirements. We welcome comments about effects on small entities and on alternatives that might improve the rule in meeting its stated objectives. We note that the RFA emphasizes the use of performance

[42] Patients are not ordinarily accepted on transplant waiting lists if they do not have the insurance or other means to ensure that they can pay not only the hospital and surgical fees, but also for the immunosuppressive drugs that are needed for post-transplant survival.

rather than design standards, which is precisely what we propose.

2. *Small Rural Hospitals.* Section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This proposed rule's direct effects do not fall on hospitals and there are no small rural hospitals that operate transplant programs. Accordingly, the Secretary has determined that this proposed rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

3. *Unfunded Mandates Reform Act.* Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any one year of $100 million in 1995 dollars, updated annually for inflation. In 2019, that threshold is approximately $154 million. This proposed rule contains no mandates that directly impose spending costs on State, local, or tribal governments, or by the private sector. Some OPOs would undoubtedly find that meeting the proposed standards would require additional spending, but others may find that better performance can be achieved at little or no cost. In either case, reimbursement by both public and private payers would cover all reasonably estimated costs.

4. *Federalism.* E.O. 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. This proposed rule would impose no such requirements.

G. Alternatives Considered

Throughout the preamble sections, we present our proposals and seek comments on potential alternatives. We seek to implement reform measures that (1) establish empirically-based outcome and process performance measures for OPOs, (2) that can be uniformly applied to all OPOs, (3) that would capture the entire pool of potential deceased-donors, (4) that would use transparent, reliable and objective data that would not require entity-specific judgments, (5) that use data that accounts for geographic differences in the number and causes of death, and (6) that use data that are easily captured and tallied on a continuing annual basis.

In choosing the outcomes measures that we are proposing and setting the threshold donation and organ transplantation rate at the top 25 percent of rates, we sought to strike a balance between the goals set forth by HHS and the potential disruption that could happen if only a few OPOs could comply with our standards. We also analyzed three types of alternatives that could be applied to all the OPOs: Changing the denominator, changing the confidence intervals, and changing the threshold rates. For changes to the denominator, we examined the impact of using the CALC measure as the denominator; using the total unadjusted number of deaths in the DSA as denominator; and using the total population in the DSA as the denominator. For changes to the confidence interval, we examined the impact of changing the confidence interval (CI) to 90 and 99 percent. For changes to the threshold rates, we examined the impact of setting the threshold at an absolute value based on the geometric mean or the median from the year 2016. For the Hawaii OPO, we analyzed one additional alternative to consider: Using the kidney donation and transplantation rates as a measure of success because of the geographical barriers to transporting the other organs for transplantation outside of Hawaii. We are seeking comments to these alternatives in addition to our proposed outcome measures.

Changes to the Denominator

CALC as the Denominator

The following table shows the likely effects of using the CALC to define the donor potential:

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Table 13a. OPO Donation Rates Using CALC Measures
(Threshold donation rates are 4.11 for proposed, and 11.36 for CALC measure. OPOs flagged are in bolded italics.)

	Proposed Measure			CALC Measure		
OPO Name	Donation Rate	Upper Bound of CI	Additional Donors Needed to Reach 25% Cutoff	Donation Rate	Upper Bound of CI	Additional Donors Needed to Reach 25% Cutoff
Organ Procurement Organization at the University of Wisconsin (WIUW)	5.65	6.45	0	14.87	16.87	0
Lifesharing - A Donate Life Organization (CASD)	5.49	6.42	0	12.49	14.50	0
DonorConnect (UTOP)	5.22	6.12	0	13.72	15.94	0
Midwest Transplant Network (MWOB)	5.35	5.96	0	15.31	16.94	0
Versiti (WIDN)	4.99	5.92	0	13.29	15.64	0
Nevada Donor Network (NVLV)	4.99	5.80	0	11.37	13.14	0
Gift of Life Donor Program (PADV)	5.21	5.60	0	14.00	14.99	0
Donor Network of Arizona (AZOB)	4.83	5.36	0	11.42	12.64	0
Nebraska Organ Recovery (NEOR)	4.34	5.33	0	13.15	15.93	0
The Living Legacy Foundation of Maryland (MDPC)	4.51	5.17	0	11.81	13.46	0
ConnectLife (NYWN)	4.04	5.10	0	11.19	14.00	0
LifeShare of Oklahoma (OKOP)	4.48	5.06	0	11.33	12.75	0
Washington Regional Transplant Community (DCTC)	4.37	5.03	0	11.69	13.36	0
OurLegacy - FL (FLFH)	4.32	4.93	0	10.74	12.20	0

	Proposed Measure			CALC Measure		
OPO Name	Donation Rate	Upper Bound of CI	Additional Donors Needed to Reach 25% Cutoff	Donation Rate	Upper Bound of CI	Additional Donors Needed to Reach 25% Cutoff
Southwest Transplant Alliance (TXSB)	4.27	4.65	0	11.70	12.68	0
Mid-America Transplant Services (MOMA)	4.12	4.61	0	12.12	13.48	0
Donor Alliance (CORS)	3.95	4.55	0	10.59	12.12	0
LifeGift (TXGC)	4.15	4.52	0	11.42	12.41	0
Sierra Donor Services (CAGS)	3.73	4.50	0	***8.65***	***10.37***	***9***
Lifeshare Carolinas (NCCM)	3.77	4.46	0	10.47	12.29	0
Gift of Hope Organ & Tissue Donor Network (ILIP)	4.08	4.45	0	11.36	12.32	0
Tennessee Donor Services (TNDS)	3.94	4.34	0	***10.25***	***11.26***	***3***
Center for Organ Recovery and Education (PATF)	3.85	4.31	0	***10.10***	***11.26***	***2***
LifeSource - MN (MNOP)	3.68	4.17	0	***9.89***	***11.16***	***4***
New Mexico Donor Services (NMOP)	3.32	4.16	0	***8.77***	***10.91***	***3***
Legacy of Life - Hawaii (HIOP)	***3.06***	***4.11***	***1***	***7.24***	***9.62***	***8***
LifeCenter Organ Donor Network (OHOV)	***3.35***	***4.10***	***1***	***9.30***	***11.30***	***1***
LifeCenter Northwest (WALC)	***3.68***	***4.10***	***1***	***9.54***	***10.58***	***19***
New Jersey Sharing Network (NJTO)	***3.61***	***4.08***	***2***	***9.37***	***10.53***	***16***
LifeBanc (OHLB)	***3.54***	***4.06***	***2***	***9.91***	***11.29***	***1***
LifeLink of Florida (FLWC)	***3.62***	***4.06***	***3***	***9.47***	***10.58***	***17***

	Proposed Measure			CALC Measure		
OPO Name	Donation Rate	Upper Bound of CI	Additional Donors Needed to Reach 25% Cutoff	Donation Rate	Upper Bound of CI	Additional Donors Needed to Reach 25% Cutoff
Louisiana Organ Procurement Agency (LAOP)	*3.59*	*4.05*	*3*	*9.86*	*11.09*	*5*
Life Alliance Organ Recovery Agency (FLMP)	*3.55*	*4.02*	*5*	*8.25*	*9.31*	*42*
Lifeline of Ohio (OHLP)	*3.40*	*3.95*	*6*	*9.71*	*11.22*	*2*
Sharing Hope SC (SCOP)	*3.39*	*3.87*	*11*	*8.97*	*10.19*	*20*
Donor Network West (CADN)	*3.43*	*3.77*	*29*	*9.17*	*10.06*	*41*
OneLegacy (CAOP)	*3.47*	*3.75*	*44*	*8.11*	*8.75*	*139*
Pacific Northwest Transplant Bank (ORUO)	*3.14*	*3.65*	*17*	*8.65*	*10.02*	*18*
Life Connection of Ohio (OHLC)	*2.94*	*3.65*	*9*	*7.20*	*8.87*	*20*
Gift of Life Michigan (MIOP)	*3.31*	*3.64*	*39*	*9.21*	*10.11*	*38*
Texas Organ Sharing Alliance (TXSA)	*3.19*	*3.63*	*23*	*8.14*	*9.23*	*41*
LifeLink of Georgia (GALL)	*3.27*	*3.60*	*42*	*10.26*	*11.27*	*3*
LifeQuest Organ Recovery Services (FLUF)	*3.12*	*3.60*	*21*	*7.41*	*8.53*	*48*
New England Organ Bank (MAOB)	*3.26*	*3.59*	*43*	*9.52*	*10.46*	*26*
Mid-South Transplant Foundation (TNMS)	*2.91*	*3.56*	*12*	*7.37*	*8.99*	*20*
Carolina Donor Services (NCNC)	*2.93*	*3.30*	*53*	*8.25*	*9.24*	*49*
LiveOnNY (NYRT)	*2.96*	*3.27*	*76*	*8.18*	*9.00*	*78*
Indiana Donor Network (INOP)	*2.78*	*3.17*	*52*	*7.29*	*8.28*	*65*

	Proposed Measure			CALC Measure		
OPO Name	Donation Rate	Upper Bound of CI	Additional Donors Needed to Reach 25% Cutoff	Donation Rate	Upper Bound of CI	Additional Donors Needed to Reach 25% Cutoff
Iowa Donor Network (IAOP)	***2.43***	***3.07***	***21***	***6.27***	***7.86***	***27***
Mississippi Organ Recovery Agency (MSOP)	***2.53***	***3.07***	***29***	***7.13***	***8.61***	***27***
LifeNet Health (VATB)	***2.64***	***3.03***	***56***	***7.38***	***8.44***	***55***
LifeLink of Puerto Rico (PRLL)	***2.43***	***2.94***	***35***	***7.30***	***8.77***	***26***
LifeChoice Donor Services (CTOP)	***2.34***	***2.91***	***29***	***7.07***	***8.72***	***21***
Center for Donation and Transplant (NYAP)	***2.24***	***2.81***	***30***	***6.49***	***8.09***	***26***
Kentucky Organ Donor Affiliates (KYDA)	***1.99***	***2.33***	***90***	***5.50***	***6.44***	***91***
Arkansas Regional Organ Recovery Agency (AROR)	***1.77***	***2.27***	***44***	***4.83***	***6.16***	***46***
Legacy of Hope - Alabama (ALOB)	***1.98***	***2.26***	***141***	***5.76***	***6.55***	***127***
Finger Lakes Donor Recovery Network (NYFL)	***1.65***	***2.15***	***45***	***4.89***	***6.34***	***39***
Totals			1,015			1,223

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As discussed earlier in the preamble, the CALC method proposed by Goldberg et al, has been published in the literature and presented in various forums. This methodology uses the same NCHS database and also uses inpatient deaths to calculate the denominator. The primary difference between the CALC methodology and our proposed methodology is that it uses the ICD–10 codes to identify deaths that are consistent with donation (that is, inclusion criteria) whereas we exclude ICD–10 codes that are an absolute contraindications to organ donation (that is, exclusion criteria). The developers of the CALC methodology believe that the ICD–10 codes used in their inclusion criteria capture 98–99 percent of all donors:

- I20–I25 (ischemic heart disease);
- I60–I69 (cerebrovascular disease)
- V–1–Y89 (external causes of morbidity and mortality): Blunt trauma, gunshot wound, drug overdose, suicide, drowning, and asphyxiation.

We performed a comparative analysis of the CALC methodology and our proposed methodology. There is consistency in the OPOs that were flagged for donation and organ transplantation rates that were below the top 25 percent. Notably, the differences were in the total donor potential (denominator) with CALC method resulting in a donor potential of 101,479 inpatient deaths in 2017, whereas our proposed methodology had 272,105 inpatient deaths. Where there were differences in OPOs being flagged for the donation rates (the CALC method flagged more OPOs), the differences were minor (only a small number of donors per OPO). If all OPOs could increase their donation rates to at the threshold rate, under our proposed methodology, there would be an additional 1,015 donors (approximately 10.43 percent increase), whereas the CALC methodology would yield an additional 1,223 donors (12.57 percent increase).

We also compared the CALC methodology on organs transplanted, as shown in the following table:

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Table 13b. OPO Transplantation Rates Using CALC Measures
(Threshold organ transplantation rates are 13.73 for proposed, and 37.85 for CALC measure. OPOs flagged are in bolded italics.)

	Proposed Measure			CALC Measure		
OPO Name	TX Rate	Upper Bound of CI	Additional Organs Needed to Reach 25% Cutoff	TX Rate	Upper Bound of CI	Additional Organs Needed to Reach 25% Cutoff
Lifesharing - A Donate Life Organization (CASD)	19.44	21.14	0	44.22	48.10	0
Organ Procurement Organization at the University of Wisconsin (WIUW)	18.92	20.37	0	49.80	53.63	0
Midwest Transplant Network (MWOB)	19.11	20.24	0	54.66	57.90	0
DonorConnect (UTOP)	17.24	18.82	0	45.26	49.42	0
Versiti (WIDN)	17.03	18.70	0	45.38	49.82	0
Donor Network of Arizona (AZOB)	16.97	17.96	0	40.14	42.49	0
Nebraska Organ Recovery (NEOR)	16.13	17.93	0	48.80	54.25	0
The Living Legacy Foundation of Maryland (MDPC)	15.77	16.98	0	41.29	44.46	0
Nevada Donor Network (NVLV)	15.50	16.90	0	35.36	38.55	0
Gift of Life Donor Program (PADV)	16.12	16.80	0	43.33	45.17	0
Washington Regional Transplant Community (DCTC)	14.63	15.80	0	39.12	42.25	0
OurLegacy - FL (FLFH)	14.29	15.38	0	35.51	38.22	0
Southwest Transplant Alliance (TXSB)	14.61	15.30	0	39.98	41.87	0
LifeGift (TXGC)	14.50	15.20	0	39.92	41.84	0
Lifeshare Carolinas (NCCM)	13.43	14.67	0	37.29	40.74	0
Mid-America Transplant Services (MOMA)	13.65	14.52	0	40.17	42.72	0

	Proposed Measure			CALC Measure		
OPO Name	TX Rate	Upper Bound of CI	Additional Organs Needed to Reach 25% Cutoff	TX Rate	Upper Bound of CI	Additional Organs Needed to Reach 25% Cutoff
ConnectLife (NYWN)	12.59	14.38	0	34.90	39.86	0
LifeShare of Oklahoma (OKOP)	13.35	14.35	0	***33.80***	***36.32***	***24***
Gift of Hope Organ & Tissue Donor Network (ILIP)	13.65	14.30	0	37.94	39.76	0
Louisiana Organ Procurement Agency (LAOP)	13.15	14.02	0	36.15	38.54	0
Tennessee Donor Services (TNDS)	13.13	13.86	0	***34.20***	***36.09***	***48***
Sierra Donor Services (CAGS)	12.43	13.77	0	***28.82***	***31.94***	***51***
LifeSource - MN (MNOP)	***12.51***	***13.40***	***16***	***33.68***	***36.05***	***31***
Sharing Hope SC (SCOP)	***12.27***	***13.15***	***26***	***32.43***	***34.77***	***52***
Donor Alliance (CORS)	***11.82***	***12.83***	***31***	***31.68***	***34.38***	***44***
Donor Network West (CADN)	***12.16***	***12.80***	***80***	***32.56***	***34.26***	***114***
LifeBanc (OHLB)	***11.54***	***12.45***	***52***	***32.28***	***34.81***	***44***
Lifeline of Ohio (OHLP)	***11.43***	***12.40***	***46***	***32.64***	***35.42***	***30***
Center for Organ Recovery and Education (PATF)	***11.58***	***12.37***	***73***	***30.35***	***32.40***	***111***
LifeCenter Northwest (WALC)	***11.59***	***12.32***	***88***	***30.04***	***31.92***	***143***
Texas Organ Sharing Alliance (TXSA)	***11.44***	***12.25***	***73***	***29.18***	***31.25***	***128***
LifeLink of Florida (FLWC)	***11.47***	***12.24***	***82***	***30.02***	***32.03***	***123***
OneLegacy (CAOP)	***11.54***	***12.04***	***210***	***26.93***	***28.11***	***521***
New Mexico Donor Services (NMOP)	***10.50***	***11.92***	***28***	***27.76***	***31.51***	***37***
New Jersey Sharing Network (NJTO)	***11.09***	***11.89***	***91***	***28.77***	***30.84***	***134***

	Proposed Measure			CALC Measure		
OPO Name	TX Rate	Upper Bound of CI	Additional Organs Needed to Reach 25% Cutoff	TX Rate	Upper Bound of CI	Additional Organs Needed to Reach 25% Cutoff
LifeCenter Organ Donor Network (OHOV)	*10.60*	*11.86*	*36*	*29.41*	*32.93*	*35*
Indiana Donor Network (INOP)	*10.84*	*11.58*	*121*	*28.40*	*30.33*	*162*
Life Alliance Organ Recovery Agency (FLMP)	*10.44*	*11.23*	*119*	*24.27*	*26.10*	*242*
New England Organ Bank (MAOB)	*10.56*	*11.15*	*219*	*30.85*	*32.58*	*154*
Carolina Donor Services (NCNC)	*10.47*	*11.14*	*171*	*29.45*	*31.33*	*153*
LifeQuest Organ Recovery Services (FLUF)	*10.16*	*11.00*	*112*	*24.14*	*26.15*	*202*
LifeLink of Georgia (GALL)	*10.30*	*10.89*	*238*	*32.34*	*34.19*	*98*
Pacific Northwest Transplant Bank (ORUO)	*9.92*	*10.80*	*107*	*27.35*	*29.78*	*107*
Gift of Life Michigan (MIOP)	*10.16*	*10.74*	*255*	*28.30*	*29.91*	*243*
Mid-South Transplant Foundation (TNMS)	*9.28*	*10.40*	*73*	*23.54*	*26.37*	*100*
LiveOnNY (NYRT)	*9.66*	*10.21*	*323*	*26.68*	*28.19*	*321*
Legacy of Life - Hawaii (HIOP)	*8.36*	*9.96*	*38*	*19.74*	*23.52*	*61*
Life Connection of Ohio (OHLC)	*8.69*	*9.83*	*77*	*21.25*	*24.05*	*111*
LifeNet Health (VATB)	*9.05*	*9.75*	*210*	*25.26*	*27.21*	*201*
Mississippi Organ Recovery Agency (MSOP)	*8.71*	*9.66*	*114*	*24.57*	*27.25*	*106*
Iowa Donor Network (IAOP)	*7.72*	*8.79*	*100*	*19.88*	*22.62*	*120*
LifeChoice Donor Services (CTOP)	*7.42*	*8.37*	*131*	*22.38*	*25.24*	*102*

	Proposed Measure			CALC Measure		
OPO Name	TX Rate	Upper Bound of CI	Additional Organs Needed to Reach 25% Cutoff	TX Rate	Upper Bound of CI	Additional Organs Needed to Reach 25% Cutoff
Kentucky Organ Donor Affiliates (KYDA)	***7.33***	***7.97***	***300***	***20.29***	***22.05***	***298***
LifeLink of Puerto Rico (PRLL)	***6.77***	***7.58***	***189***	***20.30***	***22.72***	***155***
Center for Donation and Transplant (NYAP)	***6.61***	***7.53***	***145***	***19.13***	***21.79***	***129***
Legacy of Hope - Alabama (ALOB)	***6.18***	***6.66***	***551***	***17.96***	***19.34***	***497***
Arkansas Regional Organ Recovery Agency (AROR)	***5.72***	***6.56***	***178***	***15.63***	***17.91***	***181***
Finger Lakes Donor Recovery Network (NYFL)	***4.47***	***5.23***	***200***	***13.25***	***15.51***	***177***
Totals			4,903			5,590

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For organs transplanted, if all flagged OPOs were to increase their organs transplanted to the range of the top 25 percent, then using the CMS methodology, there would be an additional 4,903 organs transplanted (15.24 percent increase); using the CALC methodology, there were would be 5,590 more organs transplanted (17.37 percent increase). Other than the approximately 2 percent increase in donations and organ transplantation, another difference in the methodologies is the difference in how much of an increase each particular OPO would need to increase in organs transplanted. We are seeking comments on these differences and whether the CALC method is a more precise and/or accurate assessment of OPO performance.

All Deaths, Age <=75 as the Denominator

In addition to analyzing the CALC method for the denominator, we also considered using the total number of deaths of people 75 years and younger, regardless of location or cause of death to define the donor potential. The following tables show the effects of measure the donor potential based on the total deaths:

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Table 14a: OPO Donation Rates Using Deaths (Age <=75) Measure
(Threshold donation rates are 4.11 for proposed, and 8.11 for Deaths (Age <=75) measure. OPOs flagged are in bolded italics.)

	Proposed Measure			Deaths (Age<=75)		
OPO Name	Donation Rate	Upper Bound of CI	Additional Donors Needed to Reach 25% Cutoff	Rate (per 1,000 deaths)	Upper Bound of CI	Additional Donors Needed to Reach 25% Cutoff
Organ Procurement Organization at the University of Wisconsin (WIUW)	5.65	6.45	0	9.91	11.37	0
Lifesharing - A Donate Life Organization (CASD)	5.49	6.42	0	10.77	12.64	0
DonorConnect (UTOP)	5.22	6.12	0	9.34	10.99	0
Midwest Transplant Network (MWOB)	5.35	5.96	0	9.39	10.48	0
Versiti (WIDN)	4.99	5.92	0	9.31	11.10	0
Nevada Donor Network (NVLV)	4.99	5.80	0	10.81	12.61	0
Gift of Life Donor Program (PADV)	5.21	5.60	0	9.99	10.75	0
Donor Network of Arizona (AZOB)	4.83	5.36	0	8.49	9.45	0
Nebraska Organ Recovery (NEOR)	4.34	5.33	0	8.74	10.76	0
The Living Legacy Foundation of Maryland (MDPC)	4.51	5.17	0	7.77	8.94	0
ConnectLife (NYWN)	4.04	5.10	0	7.35	9.34	0
LifeShare of Oklahoma (OKOP)	4.48	5.06	0	8.68	9.84	0
Washington Regional Transplant Community (DCTC)	4.37	5.03	0	8.98	10.35	0
OurLegacy - FL (FLFH)	4.32	4.93	0	8.15	9.33	0
Southwest Transplant Alliance (TXSB)	4.27	4.65	0	9.12	9.93	0
Mid-America Transplant Services (MOMA)	4.12	4.61	0	8.76	9.81	0
Donor Alliance (CORS)	3.95	4.55	0	***6.57***	***7.58***	***11***

	Proposed Measure			Deaths (Age<=75)		
OPO Name	Donation Rate	Upper Bound of CI	Additional Donors Needed to Reach 25% Cutoff	Rate (per 1,000 deaths)	Upper Bound of CI	Additional Donors Needed to Reach 25% Cutoff
LifeGift (TXGC)	4.15	4.52	0	8.70	9.50	0
Sierra Donor Services (CAGS)	3.73	4.50	0	***6.60***	***7.99***	***2***
Lifeshare Carolinas (NCCM)	3.77	4.46	0	7.69	9.11	0
Gift of Hope Organ & Tissue Donor Network (ILIP)	4.08	4.45	0	8.00	8.72	0
Tennessee Donor Services (TNDS)	3.94	4.34	0	8.28	9.15	0
Center for Organ Recovery and Education (PATF)	3.85	4.31	0	***6.98***	***7.83***	***9***
LifeSource - MN (MNOP)	3.68	4.17	0	***6.92***	***7.86***	***6***
New Mexico Donor Services (NMOP)	3.32	4.16	0	***5.82***	***7.33***	***7***
Legacy of Life - Hawaii (HIOP)	***3.06***	***4.11***	***1***	6.47	8.71	0
LifeCenter Organ Donor Network (OHOV)	***3.35***	***4.10***	***1***	***6.07***	***7.45***	***7***
LifeCenter Northwest (WALC)	***3.68***	***4.10***	***1***	***7.22***	***8.05***	***2***
New Jersey Sharing Network (NJTO)	***3.61***	***4.08***	***2***	7.18	8.12	0
LifeBanc (OHLB)	***3.54***	***4.06***	***2***	***6.61***	***7.59***	***11***
LifeLink of Florida (FLWC)	***3.62***	***4.06***	***3***	***7.15***	***8.03***	***3***
Louisiana Organ Procurement Agency (LAOP)	***3.59***	***4.05***	***3***	7.23	8.18	0
Life Alliance Organ Recovery Agency (FLMP)	***3.55***	***4.02***	***5***	***7.00***	***7.95***	***4***
Lifeline of Ohio (OHLP)	***3.40***	***3.95***	***6***	7.03	8.18	0
Sharing Hope SC (SCOP)	***3.39***	***3.87***	***11***	***6.28***	***7.18***	***22***

	Proposed Measure			Deaths (Age<=75)		
OPO Name	Donation Rate	Upper Bound of CI	Additional Donors Needed to Reach 25% Cutoff	Rate (per 1,000 deaths)	Upper Bound of CI	Additional Donors Needed to Reach 25% Cutoff
Donor Network West (CADN)	*3.43*	*3.77*	*29*	*6.71*	*7.39*	*31*
OneLegacy (CAOP)	*3.47*	*3.75*	*44*	*7.26*	*7.86*	*15*
Pacific Northwest Transplant Bank (ORUO)	*3.14*	*3.65*	*17*	*5.50*	*6.41*	*35*
Life Connection of Ohio (OHLC)	*2.94*	*3.65*	*9*	*4.89*	*6.08*	*24*
Gift of Life Michigan (MIOP)	*3.31*	*3.64*	*39*	*6.42*	*7.09*	*45*
Texas Organ Sharing Alliance (TXSA)	*3.19*	*3.63*	*23*	*6.80*	*7.76*	*8*
LifeLink of Georgia (GALL)	*3.27*	*3.60*	*42*	*6.05*	*6.68*	*64*
LifeQuest Organ Recovery Services (FLUF)	*3.12*	*3.60*	*21*	*5.88*	*6.81*	*28*
New England Organ Bank (MAOB)	*3.26*	*3.59*	*43*	*5.93*	*6.55*	*72*
Mid-South Transplant Foundation (TNMS)	*2.91*	*3.56*	*12*	*6.03*	*7.42*	*8*
Carolina Donor Services (NCNC)	*2.93*	*3.30*	*53*	*5.60*	*6.30*	*61*
LiveOnNY (NYRT)	*2.96*	*3.27*	*76*	*6.87*	*7.59*	*21*
Indiana Donor Network (INOP)	*2.78*	*3.17*	*52*	*5.79*	*6.61*	*40*
Iowa Donor Network (IAOP)	*2.43*	*3.07*	*21*	*4.28*	*5.42*	*30*
Mississippi Organ Recovery Agency (MSOP)	*2.53*	*3.07*	*29*	*5.26*	*6.40*	*23*
LifeNet Health (VATB)	*2.64*	*3.03*	*56*	*5.54*	*6.37*	*43*
LifeLink of Puerto Rico (PRLL)	*2.43*	*2.94*	*35*	*5.30*	*6.42*	*23*
LifeChoice Donor Services (CTOP)	*2.34*	*2.91*	*29*	*4.68*	*5.82*	*27*

	Proposed Measure			Deaths (Age<=75)		
OPO Name	Donation Rate	Upper Bound of CI	Additional Donors Needed to Reach 25% Cutoff	Rate (per 1,000 deaths)	Upper Bound of CI	Additional Donors Needed to Reach 25% Cutoff
Center for Donation and Transplant (NYAP)	***2.24***	***2.81***	***30***	***4.21***	***5.30***	***34***
Kentucky Organ Donor Affiliates (KYDA)	***1.99***	***2.33***	***90***	***3.98***	***4.69***	***87***
Arkansas Regional Organ Recovery Agency (AROR)	***1.77***	***2.27***	***44***	***3.18***	***4.09***	***54***
Legacy of Hope - Alabama (ALOB)	***1.98***	***2.26***	***141***	***5.72***	***6.53***	***42***
Finger Lakes Donor Recovery Network (NYFL)	***1.65***	***2.15***	***45***	***3.69***	***4.81***	***34***
Totals			1,015			933

Table 14b: OPO Transplantation Rate Using Deaths (Age <=75) Measure
(Threshold organ transplantation rates are 13.73, and 27.16 for Deaths (Age <=75 measure. OPOs flagged are in bolded italics.)

	Proposed Measure			Deaths (Age <= 75)		
OPO Name	TX Rate	Upper Bound of CI	Additional Organs Needed to Reach 25% Cutoff	Rate (per 1,000 deaths)	Upper Bound of CI	Additional Organs Needed to Reach 25% Cutoff
Lifesharing - A Donate Life Organization (CASD)	19.44	21.14	0	38.13	41.48	0
Organ Procurement Organization at the University of Wisconsin (WIUW)	18.92	20.37	0	33.20	35.75	0
Midwest Transplant Network (MWOB)	19.11	20.24	0	33.52	35.51	0
DonorConnect (UTOP)	17.24	18.82	0	30.83	33.67	0
Versiti (WIDN)	17.03	18.70	0	31.79	34.90	0
Donor Network of Arizona (AZOB)	16.97	17.96	0	29.84	31.58	0

	Proposed Measure			Deaths (Age <= 75)		
OPO Name	TX Rate	Upper Bound of CI	Additional Organs Needed to Reach 25% Cutoff	Rate (per 1,000 deaths)	Upper Bound of CI	Additional Organs Needed to Reach 25% Cutoff
Nebraska Organ Recovery (NEOR)	16.13	17.93	0	32.45	36.07	0
The Living Legacy Foundation of Maryland (MDPC)	15.77	16.98	0	27.17	29.26	0
Nevada Donor Network (NVLV)	15.50	16.90	0	33.61	36.64	0
Gift of Life Donor Program (PADV)	16.12	16.80	0	30.92	32.24	0
Washington Regional Transplant Community (DCTC)	14.63	15.80	0	30.05	32.45	0
OurLegacy - FL (FLFH)	14.29	15.38	0	26.96	29.01	0
Southwest Transplant Alliance (TXSB)	14.61	15.30	0	31.16	32.63	0
LifeGift (TXGC)	14.50	15.20	0	30.39	31.84	0
Lifeshare Carolinas (NCCM)	13.43	14.67	0	27.38	29.92	0
Mid-America Transplant Services (MOMA)	13.65	14.52	0	29.03	30.88	0
ConnectLife (NYWN)	12.59	14.38	0	***22.93***	***26.19***	***7***
LifeShare of Oklahoma (OKOP)	13.35	14.35	0	25.88	27.81	0
Gift of Hope Organ & Tissue Donor Network (ILIP)	13.65	14.30	0	26.72	28.00	0
Louisiana Organ Procurement Agency (LAOP)	13.15	14.02	0	26.49	28.24	0
Tennessee Donor Services (TNDS)	13.13	13.86	0	27.63	29.16	0
Sierra Donor Services (CAGS)	12.43	13.77	0	***22.01***	***24.39***	***32***
LifeSource - MN (MNOP)	***12.51***	***13.40***	***16***	***23.58***	***25.24***	***47***
Sharing Hope SC (SCOP)	***12.27***	***13.15***	***26***	***22.71***	***24.34***	***68***
Donor Alliance (CORS)	***11.82***	***12.83***	***31***	***19.65***	***21.32***	***118***
Donor Network West (CADN)	***12.16***	***12.80***	***80***	***23.82***	***25.06***	***92***

	Proposed Measure			Deaths (Age <= 75)		
OPO Name	TX Rate	Upper Bound of CI	Additional Organs Needed to Reach 25% Cutoff	Rate (per 1,000 deaths)	Upper Bound of CI	Additional Organs Needed to Reach 25% Cutoff
LifeBanc (OHLB)	*11.54*	*12.45*	*52*	*21.53*	*23.22*	*85*
Lifeline of Ohio (OHLP)	*11.43*	*12.40*	*46*	*23.63*	*25.64*	*26*
Center for Organ Recovery and Education (PATF)	*11.58*	*12.37*	*73*	*20.98*	*22.40*	*141*
LifeCenter Northwest (WALC)	*11.59*	*12.32*	*88*	*22.73*	*24.15*	*96*
Texas Organ Sharing Alliance (TXSA)	*11.44*	*12.25*	*73*	*24.40*	*26.14*	*24*
LifeLink of Florida (FLWC)	*11.47*	*12.24*	*82*	*22.67*	*24.19*	*83*
OneLegacy (CAOP)	*11.54*	*12.04*	*210*	*24.12*	*25.19*	*118*
New Mexico Donor Services (NMOP)	*10.50*	*11.92*	*28*	*18.44*	*20.93*	*55*
New Jersey Sharing Network (NJTO)	*11.09*	*11.89*	*91*	*22.05*	*23.64*	*88*
LifeCenter Organ Donor Network (OHOV)	*10.60*	*11.86*	*36*	*19.20*	*21.49*	*61*
Indiana Donor Network (INOP)	*10.84*	*11.58*	*121*	*22.55*	*24.09*	*83*
Life Alliance Organ Recovery Agency (FLMP)	*10.44*	*11.23*	*119*	*20.61*	*22.17*	*121*
New England Organ Bank (MAOB)	*10.56*	*11.15*	*219*	*19.21*	*20.29*	*322*
Carolina Donor Services (NCNC)	*10.47*	*11.14*	*171*	*19.98*	*21.26*	*205*
LifeQuest Organ Recovery Services (FLUF)	*10.16*	*11.00*	*112*	*19.17*	*20.76*	*139*
LifeLink of Georgia (GALL)	*10.30*	*10.89*	*238*	*19.07*	*20.16*	*317*
Pacific Northwest Transplant Bank (ORUO)	*9.92*	*10.80*	*107*	*17.37*	*18.92*	*172*
Gift of Life Michigan (MIOP)	*10.16*	*10.74*	*255*	*19.74*	*20.86*	*277*
Mid-South Transplant Foundation (TNMS)	*9.28*	*10.40*	*73*	*19.27*	*21.58*	*59*
LiveOnNY (NYRT)	*9.66*	*10.21*	*323*	*22.41*	*23.67*	*138*
Legacy of Life - Hawaii (HIOP)	*8.36*	*9.96*	*38*	*17.65*	*21.04*	*29*

	Proposed Measure			Deaths (Age <= 75)		
OPO Name	TX Rate	Upper Bound of CI	Additional Organs Needed to Reach 25% Cutoff	Rate (per 1,000 deaths)	Upper Bound of CI	Additional Organs Needed to Reach 25% Cutoff
Life Connection of Ohio (OHLC)	***8.69***	***9.83***	***77***	***14.44***	***16.34***	***129***
LifeNet Health (VATB)	***9.05***	***9.75***	***210***	***18.98***	***20.44***	***169***
Mississippi Organ Recovery Agency (MSOP)	***8.71***	***9.66***	***114***	***18.12***	***20.10***	***95***
Iowa Donor Network (IAOP)	***7.72***	***8.79***	***100***	***13.59***	***15.47***	***135***
LifeChoice Donor Services (CTOP)	***7.42***	***8.37***	***131***	***14.82***	***16.71***	***128***
Kentucky Organ Donor Affiliates (KYDA)	***7.33***	***7.97***	***300***	***14.71***	***15.99***	***290***
LifeLink of Puerto Rico (PRLL)	***6.77***	***7.58***	***189***	***14.74***	***16.50***	***150***
Center for Donation and Transplant (NYAP)	***6.61***	***7.53***	***145***	***12.41***	***14.14***	***162***
Legacy of Hope - Alabama (ALOB)	***6.18***	***6.66***	***551***	***17.83***	***19.20***	***215***
Arkansas Regional Organ Recovery Agency (AROR)	***5.72***	***6.56***	***178***	***10.30***	***11.80***	***212***
Finger Lakes Donor Recovery Network (NYFL)	***4.47***	***5.23***	***200***	***9.98***	***11.68***	***163***
Totals			4,903			4,851

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Using total number of deaths as the denominator, the donor potential was 1,376,541 deaths in 2017 of people 75 years and younger (compared with our donor potential of 272,105 inpatient deaths). Despite this large discrepancy in the denominator, we find very similar results for those OPOs being flagged by our methodology versus an approach that uses total deaths. If all OPOs were able to achieve the threshold 25 percent rate using this methodology, we would have 933 additional donors (compared with the 1,105 with our proposed methodology) and 4,851 more organs transplanted, compared with the 4,903 organs from our proposed methodology. Similar to the CALC method, where there were differences in the OPOs being flagged for donation rates, the additional donors needed were mostly in the single digits. For the organ transplantation rates, the greatest differences were not in which OPOs were flagged, but rather, it was the differences by OPO in the number of additional organs that needed to be transplanted in order to reach the top 25 percent threshold rate.

Total Population, Age <75

A third alternative denominator that we analyzed used the U.S. population from the 2010 census of persons less than 75 years old as the denominator.[43] A population-based approach to re-certifying OPOs was used by the Department until the passage of the OPO Certification Act of 2000, which specifically raised concerns about ''[a]n exclusive reliance on population-based measures of performance that do not account for the potential in the population for organ donation and do not permit consideration of other outcome and process standards that would more accurately reflect the relative capability and performance of each organ procurement organization.'' While we considered this approach, for this reason, and others that we discuss in further detail, we chose not to propose it. The following tables show the effects of using an eligible population as the donor potential:

[43] For convenience, we used less than 75 years old rather than 75 and younger because of how the Census data is publicly reported.

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Table 15a: OPO Donation Rates Using Census Population (Age < 75) Measure
(Threshold donation rates are 4.11, and 4.31 for Census Population (Age <75) measure. OPOs flagged are in bolded italics.)

	Proposed Measure			Census Population (Age <75)		
OPO Name	Donation Rate	Upper Bound of CI	Additional Donors Needed to Reach 25% Cutoff	Rate (per 100,000 pop.)	Upper Bound of CI	Additional Donors Needed to Reach 25% Cutoff
Organ Procurement Organization at the University of Wisconsin (WIUW)	5.65	6.45	0	4.73	5.42	0
Lifesharing - A Donate Life Organization (CASD)	5.49	6.42	0	3.76	4.42	0
DonorConnect (UTOP)	5.22	6.12	0	***3.39***	***3.99***	***10***
Midwest Transplant Network (MWOB)	5.35	5.96	0	4.85	5.41	0
Versiti (WIDN)	4.99	5.92	0	4.27	5.10	0
Nevada Donor Network (NVLV)	4.99	5.80	0	6.31	7.37	0
Gift of Life Donor Program (PADV)	5.21	5.60	0	5.27	5.67	0
Donor Network of Arizona (AZOB)	4.83	5.36	0	4.37	4.87	0
Nebraska Organ Recovery (NEOR)	4.34	5.33	0	4.02	4.96	0
The Living Legacy Foundation of Maryland (MDPC)	4.51	5.17	0	4.33	4.99	0
ConnectLife (NYWN)	4.04	5.10	0	3.84	4.88	0
LifeShare of Oklahoma (OKOP)	4.48	5.06	0	5.46	6.19	0
Washington Regional Transplant	4.37	5.03	0	***3.04***	***3.51***	***34***

	Proposed Measure			Census Population (Age <75)		
OPO Name	Donation Rate	Upper Bound of CI	Additional Donors Needed to Reach 25% Cutoff	Rate (per 100,000 pop.)	Upper Bound of CI	Additional Donors Needed to Reach 25% Cutoff
Community (DCTC)						
OurLegacy - FL (FLFH)	4.32	4.93	0	5.18	5.94	0
Southwest Transplant Alliance (TXSB)	4.27	4.65	0	4.51	4.92	0
Mid-America Transplant Services (MOMA)	4.12	4.61	0	5.40	6.06	0
Donor Alliance (CORS)	3.95	4.55	0	***2.80***	***3.23***	***50***
LifeGift (TXGC)	4.15	4.52	0	4.09	4.47	0
Sierra Donor Services (CAGS)	3.73	4.50	0	***2.97***	***3.60***	***17***
Lifeshare Carolinas (NCCM)	3.77	4.46	0	4.43	5.26	0
Gift of Hope Organ & Tissue Donor Network (ILIP)	4.08	4.45	0	***3.48***	***3.79***	***53***
Tennessee Donor Services (TNDS)	3.94	4.34	0	5.95	6.57	0
Center for Organ Recovery and Education (PATF)	3.85	4.31	0	4.55	5.11	0
LifeSource - MN (MNOP)	3.68	4.17	0	***2.87***	***3.26***	***60***
New Mexico Donor Services (NMOP)	3.32	4.16	0	***3.02***	***3.81***	***9***
Legacy of Life - Hawaii (HIOP)	***3.06***	***4.11***	***1***	***2.83***	***3.82***	***6***
LifeCenter Organ Donor Network (OHOV)	***3.35***	***4.10***	***1***	***3.50***	***4.30***	***1***

	Proposed Measure			Census Population (Age <75)		
OPO Name	Donation Rate	Upper Bound of CI	Additional Donors Needed to Reach 25% Cutoff	Rate (per 100,000 pop.)	Upper Bound of CI	Additional Donors Needed to Reach 25% Cutoff
LifeCenter Northwest (WALC)	***3.68***	***4.10***	***1***	***3.31***	***3.69***	***42***
New Jersey Sharing Network (NJTO)	***3.61***	***4.08***	***2***	***2.85***	***3.22***	***67***
LifeBanc (OHLB)	***3.54***	***4.06***	***2***	4.04	4.65	0
LifeLink of Florida (FLWC)	***3.62***	***4.06***	***3***	4.93	5.55	0
Louisiana Organ Procurement Agency (LAOP)	***3.59***	***4.05***	***3***	4.58	5.18	0
Life Alliance Organ Recovery Agency (FLMP)	***3.55***	***4.02***	***5***	***3.37***	***3.82***	***24***
Lifeline of Ohio (OHLP)	***3.40***	***3.95***	***6***	4.13	4.81	0
Sharing Hope SC (SCOP)	***3.39***	***3.87***	***11***	4.07	4.65	0
Donor Network West (CADN)	***3.43***	***3.77***	***29***	***2.64***	***2.90***	***153***
OneLegacy (CAOP)	***3.47***	***3.75***	***44***	***2.59***	***2.80***	***248***
Pacific Northwest Transplant Bank (ORUO)	***3.14***	***3.65***	***17***	***2.71***	***3.16***	***48***
Life Connection of Ohio (OHLC)	***2.94***	***3.65***	***9***	***3.01***	***3.74***	***11***
Gift of Life Michigan (MIOP)	***3.31***	***3.64***	***39***	***3.42***	***3.77***	***44***
Texas Organ Sharing Alliance (TXSA)	***3.19***	***3.63***	***23***	***2.88***	***3.29***	***55***
LifeLink of Georgia (GALL)	***3.27***	***3.60***	***42***	***3.21***	***3.54***	***64***
LifeQuest Organ Recovery Services (FLUF)	***3.12***	***3.60***	***21***	4.08	4.72	0

	Proposed Measure			Census Population (Age <75)		
OPO Name	Donation Rate	Upper Bound of CI	Additional Donors Needed to Reach 25% Cutoff	Rate (per 100,000 pop.)	Upper Bound of CI	Additional Donors Needed to Reach 25% Cutoff
New England Organ Bank (MAOB)	***3.26***	***3.59***	***43***	***2.67***	***2.95***	***139***
Mid-South Transplant Foundation (TNMS)	***2.91***	***3.56***	***12***	3.77	4.64	0
Carolina Donor Services (NCNC)	***2.93***	***3.30***	***53***	***3.23***	***3.64***	***40***
LiveOnNY (NYRT)	***2.96***	***3.27***	***76***	***2.44***	***2.69***	***177***
Indiana Donor Network (INOP)	***2.78***	***3.17***	***52***	***3.25***	***3.71***	***28***
Iowa Donor Network (IAOP)	***2.43***	***3.07***	***21***	***1.99***	***2.52***	***43***
Mississippi Organ Recovery Agency (MSOP)	***2.53***	***3.07***	***29***	3.59	4.37	0
LifeNet Health (VATB)	***2.64***	***3.03***	***56***	***3.10***	***3.56***	***33***
LifeLink of Puerto Rico (PRLL)	***2.43***	***2.94***	***35***	***2.37***	***2.88***	***44***
LifeChoice Donor Services (CTOP)	***2.34***	***2.91***	***29***	***2.09***	***2.60***	***45***
Center for Donation and Transplant (NYAP)	***2.24***	***2.81***	***30***	***2.00***	***2.52***	***45***
Kentucky Organ Donor Affiliates (KYDA)	***1.99***	***2.33***	***90***	***2.83***	***3.34***	***35***
Arkansas Regional Organ Recovery Agency (AROR)	***1.77***	***2.27***	***44***	***2.13***	***2.74***	***31***
Legacy of Hope - Alabama (ALOB)	***1.98***	***2.26***	***141***	3.85	4.40	0

	Proposed Measure			Census Population (Age <75)		
OPO Name	Donation Rate	Upper Bound of CI	Additional Donors Needed to Reach 25% Cutoff	Rate (per 100,000 pop.)	Upper Bound of CI	Additional Donors Needed to Reach 25% Cutoff
Finger Lakes Donor Recovery Network (NYFL)	***1.65***	***2.15***	***45***	***1.76***	***2.30***	***43***
Totals			1,015			1,699

Table 15b: OPO Organ Transplantation Rates Using Census Population (Age < 75) Measure

(Threshold donation rates are 13.73, and 14.26 for Census Population (Age <75) measure. OPOs flagged are in bolded italics.)

	Proposed Measure			Census Population (Age <75)		
OPO Name	TX Rate	Upper Bound of CI	Additional Organs Needed to Reach 25% Cutoff	Rate (per 100,000 pop.)	Upper Bound of CI	Additional Organs Needed to Reach 25% Cutoff
Lifesharing - A Donate Life Organization (CASD)	19.44	21.14	0	13.31	14.48	0
Organ Procurement Organization at the University of Wisconsin (WIUW)	18.92	20.37	0	15.83	17.04	0
Midwest Transplant Network (MWOB)	19.11	20.24	0	17.30	18.32	0
DonorConnect (UTOP)	17.24	18.82	0	***11.19***	***12.22***	***62***
Versiti (WIDN)	17.03	18.70	0	14.58	16.01	0
Donor Network of Arizona (AZOB)	16.97	17.96	0	15.37	16.27	0
Nebraska Organ Recovery (NEOR)	16.13	17.93	0	14.93	16.60	0
The Living Legacy Foundation of Maryland (MDPC)	15.77	16.98	0	15.15	16.32	0
Nevada Donor Network (NVLV)	15.50	16.90	0	19.61	21.38	0

	Proposed Measure			Census Population (Age <75)		
OPO Name	TX Rate	Upper Bound of CI	Additional Organs Needed to Reach 25% Cutoff	Rate (per 100,000 pop.)	Upper Bound of CI	Additional Organs Needed to Reach 25% Cutoff
Gift of Life Donor Program (PADV)	16.12	16.80	0	16.30	16.99	0
Washington Regional Transplant Community (DCTC)	14.63	15.80	0	***10.18***	***11.00***	***144***
OurLegacy - FL (FLFH)	14.29	15.38	0	17.13	18.44	0
Southwest Transplant Alliance (TXSB)	14.61	15.30	0	15.43	16.16	0
LifeGift (TXGC)	14.50	15.20	0	14.31	14.99	0
Lifeshare Carolinas (NCCM)	13.43	14.67	0	15.79	17.26	0
Mid-America Transplant Services (MOMA)	13.65	14.52	0	17.91	19.04	0
ConnectLife (NYWN)	12.59	14.38	0	***11.98***	***13.68***	***8***
LifeShare of Oklahoma (OKOP)	13.35	14.35	0	16.27	17.49	0
Gift of Hope Organ & Tissue Donor Network (ILIP)	13.65	14.30	0	***11.62***	***12.18***	***219***
Louisiana Organ Procurement Agency (LAOP)	13.15	14.02	0	16.78	17.89	0
Tennessee Donor Services (TNDS)	13.13	13.86	0	19.84	20.94	0
Sierra Donor Services (CAGS)	12.43	13.77	0	***9.92***	***10.99***	***82***
LifeSource - MN (MNOP)	***12.51***	***13.40***	***16***	***9.77***	***10.46***	***223***
Sharing Hope SC (SCOP)	***12.27***	***13.15***	***26***	14.71	15.77	0
Donor Alliance (CORS)	***11.82***	***12.83***	***31***	***8.37***	***9.08***	***245***
Donor Network West (CADN)	***12.16***	***12.80***	***80***	***9.36***	***9.85***	***488***
LifeBanc (OHLB)	***11.54***	***12.45***	***52***	***13.18***	***14.21***	***2***

	Proposed Measure			Census Population (Age <75)		
OPO Name	TX Rate	Upper Bound of CI	Additional Organs Needed to Reach 25% Cutoff	Rate (per 100,000 pop.)	Upper Bound of CI	Additional Organs Needed to Reach 25% Cutoff
Lifeline of Ohio (OHLP)	***11.43***	***12.40***	***46***	13.87	15.06	0
Center for Organ Recovery and Education (PATF)	***11.58***	***12.37***	***73***	13.68	14.60	0
LifeCenter Northwest (WALC)	***11.59***	***12.32***	***88***	***10.42***	***11.07***	***222***
Texas Organ Sharing Alliance (TXSA)	***11.44***	***12.25***	***73***	***10.33***	***11.06***	***175***
LifeLink of Florida (FLWC)	***11.47***	***12.24***	***82***	15.64	16.69	0
OneLegacy (CAOP)	***11.54***	***12.04***	***210***	***8.61***	***8.98***	***884***
New Mexico Donor Services (NMOP)	***10.50***	***11.92***	***28***	***9.57***	***10.86***	***58***
New Jersey Sharing Network (NJTO)	***11.09***	***11.89***	***91***	***8.74***	***9.37***	***307***
LifeCenter Organ Donor Network (OHOV)	***10.60***	***11.86***	***36***	***11.08***	***12.41***	***35***
Indiana Donor Network (INOP)	***10.84***	***11.58***	***121***	***12.67***	***13.54***	***35***
Life Alliance Organ Recovery Agency (FLMP)	***10.44***	***11.23***	***119***	***9.91***	***10.66***	***182***
New England Organ Bank (MAOB)	***10.56***	***11.15***	***219***	***8.64***	***9.13***	***534***
Carolina Donor Services (NCNC)	***10.47***	***11.14***	***171***	***11.53***	***12.27***	***120***
LifeQuest Organ Recovery Services (FLUF)	***10.16***	***11.00***	***112***	13.29	14.40	0
LifeLink of Georgia (GALL)	***10.30***	***10.89***	***238***	***10.11***	***10.69***	***304***
Pacific Northwest Transplant Bank (ORUO)	***9.92***	***10.80***	***107***	***8.55***	***9.31***	***210***
Gift of Life Michigan (MIOP)	***10.16***	***10.74***	***255***	***10.50***	***11.10***	***262***

	Proposed Measure			Census Population (Age <75)		
OPO Name	TX Rate	Upper Bound of CI	Additional Organs Needed to Reach 25% Cutoff	Rate (per 100,000 pop.)	Upper Bound of CI	Additional Organs Needed to Reach 25% Cutoff
Mid-South Transplant Foundation (TNMS)	*9.28*	*10.40*	*73*	*12.05*	*13.50*	*13*
LiveOnNY (NYRT)	*9.66*	*10.21*	*323*	*7.95*	*8.40*	*655*
Legacy of Life - Hawaii (HIOP)	*8.36*	*9.96*	*38*	*7.72*	*9.20*	*55*
Life Connection of Ohio (OHLC)	*8.69*	*9.83*	*77*	*8.88*	*10.05*	*81*
LifeNet Health (VATB)	*9.05*	*9.75*	*210*	*10.60*	*11.42*	*128*
Mississippi Organ Recovery Agency (MSOP)	*8.71*	*9.66*	*114*	*12.37*	*13.72*	*11*
Iowa Donor Network (IAOP)	*7.72*	*8.79*	*100*	*6.32*	*7.19*	*176*
LifeChoice Donor Services (CTOP)	*7.42*	*8.37*	*131*	*6.62*	*7.46*	*186*
Kentucky Organ Donor Affiliates (KYDA)	*7.33*	*7.97*	*300*	*10.46*	*11.37*	*106*
LifeLink of Puerto Rico (PRLL)	*6.77*	*7.58*	*189*	*6.61*	*7.39*	*216*
Center for Donation and Transplant (NYAP)	*6.61*	*7.53*	*145*	*5.90*	*6.73*	*197*
Legacy of Hope - Alabama (ALOB)	*6.18*	*6.66*	*551*	*12.00*	*12.93*	*54*
Arkansas Regional Organ Recovery Agency (AROR)	*5.72*	*6.56*	*178*	*6.91*	*7.91*	*130*
Finger Lakes Donor Recovery Network (NYFL)	*4.47*	*5.23*	*200*	*4.77*	*5.58*	*191*
Totals			4,903			7,000

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In the population-based approach, we would have 1,699 more organ donors and 7,000 more organs transplanted if all flagged OPOs were able to increase their performance to that of the top 25 percent. This increase does not seem realistic given how significantly it differs from the increases utilizing the CALC and total death analysis. A fundamental requirement to achieve these increases is a sufficient number of deaths that could lead to organ donation. A population based approach does not account for the death requirement and is problematic given variance in DSA mortality rates from 3.39 to 7.11. We also found a pattern where OPOs in the geographic areas with lower mortality rates, such as the Pacific Northwest, the Rocky Mountain area, New England, Los Angeles area, New York City area, and Hawaii, had depressed performance rates under this method, as compared to the OPOs in the areas of the country with the highest rates of deaths consistent with organ

donation.[44] Although we would not consider a measure which is based solely on population size, we are seeking comments as to whether there are appropriate risk-adjustments that could be used so that a population measure could be reflective of the organ donation potential.

[44] Cannon RM, Jones CM, et al, ''Patterns of geographic variability in mortality and eligible deaths between organ procurement organizations,'' *AmJTransplant.* 2019;00:4 (Fig. 2).

Changing the Confidence Interval

In addition to considering other denominator sources, we considered changing the way in which we measured success. One way in which we measure success is in the confidence that our rate is flagging correctly. Our methodology uses a 95 percent CI, so we analyzed the effects of both the 90 percent and 99 percent CIs; that is, we increased and decreased our confidence that we appropriately flagged OPOs based on our donation and organ transplantation threshold rates. The following tables show the effects of these different CIs:

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Table 16a. OPO Donor Rates Compared at 90 Percent, 95 Percent and 99 Percent Confidence Levels

(Threshold donation rate is 4.11.)

OPO Name	All Organ Donation Rate	Upper Bound of Confidence Interval 90%	Upper Bound of Confidence Interval 95%	Upper Bound of Confidence Interval 99%
Organ Procurement Organization at the University of Wisconsin (WIUW)	5.65	6.27	6.45	6.81
Lifesharing - A Donate Life Organization (CASD)	5.49	6.21	6.42	6.83
DonorConnect (UTOP)	5.22	5.92	6.12	6.52
Midwest Transplant Network (MWOB)	5.35	5.82	5.96	6.22
Versiti (WIDN)	4.99	5.71	5.92	6.34
Nevada Donor Network (NVLV)	4.99	5.61	5.80	6.16
Gift of Life Donor Program (PADV)	5.21	5.51	5.60	5.76
Donor Network of Arizona (AZOB)	4.83	5.24	5.36	5.60
Nebraska Organ Recovery (NEOR)	4.34	5.10	5.33	5.77
The Living Legacy Foundation of Maryland (MDPC)	4.51	5.02	5.17	5.46
ConnectLife (NYWN)	4.04	4.86	5.10	5.59
LifeShare of Oklahoma (OKOP)	4.48	4.93	5.06	5.32
Washington Regional Transplant Community (DCTC)	4.37	4.88	5.03	5.31
OurLegacy - FL (FLFH)	4.32	4.80	4.93	5.20
Southwest Transplant Alliance (TXSB)	4.27	4.57	4.65	4.81
Mid-America Transplant Services (MOMA)	4.12	4.50	4.61	4.82
Donor Alliance (CORS)	3.95	4.41	4.55	4.81
LifeGift (TXGC)	4.15	4.44	4.52	4.69
Sierra Donor Services (CAGS)	3.73	4.32	4.50	4.84
Lifeshare Carolinas (NCCM)	3.77	4.30	4.46	4.76
Gift of Hope Organ & Tissue Donor Network (ILIP)	4.08	4.36	4.45	4.60
Tennessee Donor Services (TNDS)	3.94	4.25	4.34	4.51

OPO Name	All Organ Donation Rate	Upper Bound of Confidence Interval 90%	Upper Bound of Confidence Interval 95%	Upper Bound of Confidence Interval 99%
Center for Organ Recovery and Education (PATF)	3.85	4.21	4.31	4.51
LifeSource - MN (MNOP)	3.68	***4.05***	4.17	4.38
New Mexico Donor Services (NMOP)	3.32	***3.97***	4.16	4.55
Legacy of Life - Hawaii (HIOP)	3.06	***3.86***	***4.11***	4.59
LifeCenter Organ Donor Network (OHOV)	3.35	***3.93***	***4.10***	4.44
LifeCenter Northwest (WALC)	3.68	***4.00***	***4.10***	4.28
New Jersey Sharing Network (NJTO)	3.61	***3.97***	***4.08***	4.28
LifeBanc (OHLB)	3.54	***3.94***	***4.06***	4.29
LifeLink of Florida (FLWC)	3.62	***3.96***	***4.06***	4.25
Louisiana Organ Procurement Agency (LAOP)	3.59	***3.95***	***4.05***	4.26
Life Alliance Organ Recovery Agency (FLMP)	3.55	***3.91***	***4.02***	4.23
Lifeline of Ohio (OHLP)	3.40	***3.83***	***3.95***	4.19
Sharing Hope SC (SCOP)	3.39	***3.76***	***3.87***	***4.08***
Donor Network West (CADN)	3.43	***3.69***	***3.77***	***3.92***
OneLegacy (CAOP)	3.47	***3.69***	***3.75***	***3.88***
Pacific Northwest Transplant Bank (ORUO)	3.14	***3.54***	***3.65***	***3.88***
Life Connection of Ohio (OHLC)	2.94	***3.48***	***3.65***	***3.97***
Gift of Life Michigan (MIOP)	3.31	***3.57***	***3.64***	***3.79***
Texas Organ Sharing Alliance (TXSA)	3.19	***3.53***	***3.63***	***3.83***
LifeLink of Georgia (GALL)	3.27	***3.53***	***3.60***	***3.75***
LifeQuest Organ Recovery Services (FLUF)	3.12	***3.49***	***3.60***	***3.81***
New England Organ Bank (MAOB)	3.26	***3.52***	***3.59***	***3.74***
Mid-South Transplant Foundation (TNMS)	2.91	***3.41***	***3.56***	***3.86***
Carolina Donor Services (NCNC)	2.93	***3.22***	***3.30***	***3.46***
LiveOnNY (NYRT)	2.96	***3.20***	***3.27***	***3.40***

OPO Name	All Organ Donation Rate	Upper Bound of Confidence Interval 90%	Upper Bound of Confidence Interval 95%	Upper Bound of Confidence Interval 99%
Indiana Donor Network (INOP)	2.78	***3.08***	***3.17***	***3.34***
Iowa Donor Network (IAOP)	2.43	***2.93***	***3.07***	***3.37***
Mississippi Organ Recovery Agency (MSOP)	2.53	***2.95***	***3.07***	***3.31***
LifeNet Health (VATB)	2.64	***2.95***	***3.03***	***3.21***
LifeLink of Puerto Rico (PRLL)	2.43	***2.82***	***2.94***	***3.17***
LifeChoice Donor Services (CTOP)	2.34	***2.78***	***2.91***	***3.17***
Center for Donation and Transplant (NYAP)	2.24	***2.68***	***2.81***	***3.08***
Kentucky Organ Donor Affiliates (KYDA)	1.99	***2.25***	***2.33***	***2.49***
Arkansas Regional Organ Recovery Agency (AROR)	1.77	***2.15***	***2.27***	***2.50***
Legacy of Hope - Alabama (ALOB)	1.98	***2.20***	***2.26***	***2.38***
Finger Lakes Donor Recovery Network (NYFL)	1.65	***2.03***	***2.15***	***2.38***

Table 16b. OPO Organ Transplantation Rates Compared at 90 Percent, 95 Percent and 99 Percent Confidence Levels

(Threshold organ transplantation rate is 13.73)

OPO Name	TX Rate	Upper Bound of Confidence Interval 90%	Upper Bound of Confidence Interval 95%	Upper Bound of Confidence Interval 99%
Lifesharing - A Donate Life Organization (CASD)	19.44	20.77	21.14	21.86
Organ Procurement Organization at the University of Wisconsin (WIUW)	18.92	20.05	20.37	20.98
Midwest Transplant Network (MWOB)	19.11	19.99	20.24	20.72
DonorConnect (UTOP)	17.24	18.47	18.82	19.49
Versiti (WIDN)	17.03	18.33	18.70	19.40
Donor Network of Arizona (AZOB)	16.97	17.74	17.96	18.38

OPO Name	TX Rate	Upper Bound of Confidence Interval 90%	Upper Bound of Confidence Interval 95%	Upper Bound of Confidence Interval 99%
Nebraska Organ Recovery (NEOR)	16.13	17.53	17.93	18.69
The Living Legacy Foundation of Maryland (MDPC)	15.77	16.71	16.98	17.49
Nevada Donor Network (NVLV)	15.50	16.59	16.90	17.49
Gift of Life Donor Program (PADV)	16.12	16.65	16.80	17.09
Washington Regional Transplant Community (DCTC)	14.63	15.54	15.80	16.29
OurLegacy - FL (FLFH)	14.29	15.14	15.38	15.84
Southwest Transplant Alliance (TXSB)	14.61	15.15	15.30	15.59
LifeGift (TXGC)	14.50	15.04	15.20	15.49
Lifeshare Carolinas (NCCM)	13.43	14.40	14.67	15.20
Mid-America Transplant Services (MOMA)	13.65	14.33	14.52	14.89
ConnectLife (NYWN)	12.59	13.98	14.38	15.14
LifeShare of Oklahoma (OKOP)	13.35	14.13	14.35	14.77
Gift of Hope Organ & Tissue Donor Network (ILIP)	13.65	14.16	14.30	14.58
Louisiana Organ Procurement Agency (LAOP)	13.15	13.83	14.02	14.38
Tennessee Donor Services (TNDS)	13.13	***13.70***	13.86	14.16
Sierra Donor Services (CAGS)	12.43	***13.48***	13.77	14.34
LifeSource - MN (MNOP)	12.51	***13.20***	***13.40***	13.77
Sharing Hope SC (SCOP)	12.27	***12.96***	***13.15***	***13.52***
Donor Alliance (CORS)	11.82	***12.60***	***12.83***	***13.25***
Donor Network West (CADN)	12.16	***12.66***	***12.80***	***13.06***
LifeBanc (OHLB)	11.54	***12.25***	***12.45***	***12.83***
Lifeline of Ohio (OHLP)	11.43	***12.19***	***12.40***	***12.81***
Center for Organ Recovery and Education (PATF)	11.58	***12.19***	***12.37***	***12.69***
LifeCenter Northwest (WALC)	11.59	***12.16***	***12.32***	***12.62***
Texas Organ Sharing Alliance (TXSA)	11.44	***12.07***	***12.25***	***12.59***
LifeLink of Florida (FLWC)	11.47	***12.07***	***12.24***	***12.57***
OneLegacy (CAOP)	11.54	***11.93***	***12.04***	***12.26***
New Mexico Donor Services (NMOP)	10.50	***11.61***	***11.92***	***12.53***

OPO Name	TX Rate	Upper Bound of Confidence Interval 90%	Upper Bound of Confidence Interval 95%	Upper Bound of Confidence Interval 99%
New Jersey Sharing Network (NJTO)	11.09	***11.72***	***11.89***	***12.23***
LifeCenter Organ Donor Network (OHOV)	10.60	***11.58***	***11.86***	***12.40***
Indiana Donor Network (INOP)	10.84	***11.42***	***11.58***	***11.89***
Life Alliance Organ Recovery Agency (FLMP)	10.44	***11.06***	***11.23***	***11.57***
New England Organ Bank (MAOB)	10.56	***11.02***	***11.15***	***11.40***
Carolina Donor Services (NCNC)	10.47	***10.99***	***11.14***	***11.42***
LifeQuest Organ Recovery Services (FLUF)	10.16	***10.81***	***11.00***	***11.35***
LifeLink of Georgia (GALL)	10.30	***10.76***	***10.89***	***11.14***
Pacific Northwest Transplant Bank (ORUO)	9.92	***10.61***	***10.80***	***11.17***
Gift of Life Michigan (MIOP)	10.16	***10.62***	***10.74***	***10.99***
Mid-South Transplant Foundation (TNMS)	9.28	***10.15***	***10.40***	***10.87***
LiveOnNY (NYRT)	9.66	***10.09***	***10.21***	***10.44***
Legacy of Life - Hawaii (HIOP)	8.36	***9.60***	***9.96***	***10.65***
Life Connection of Ohio (OHLC)	8.69	***9.58***	***9.83***	***10.32***
LifeNet Health (VATB)	9.05	***9.59***	***9.75***	***10.04***
Mississippi Organ Recovery Agency (MSOP)	8.71	***9.45***	***9.66***	***10.07***
Iowa Donor Network (IAOP)	7.72	***8.55***	***8.79***	***9.24***
LifeChoice Donor Services (CTOP)	7.42	***8.16***	***8.37***	***8.77***
Kentucky Organ Donor Affiliates (KYDA)	7.33	***7.83***	***7.97***	***8.23***
LifeLink of Puerto Rico (PRLL)	6.77	***7.40***	***7.58***	***7.92***
Center for Donation and Transplant (NYAP)	6.61	***7.33***	***7.53***	***7.92***
Legacy of Hope - Alabama (ALOB)	6.18	***6.55***	***6.66***	***6.86***
Arkansas Regional Organ Recovery Agency (AROR)	5.72	***6.37***	***6.56***	***6.91***
Finger Lakes Donor Recovery Network (NYFL)	4.47	***5.06***	***5.23***	***5.55***

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By changing to a 99 percent CI, 24 OPOs were flagged for donation rates compared with 33 OPOs (95 percent CI); and, 35 OPOs were flagged for organ transplantation rates compared with 36 OPOs being flagged (95 percent CI). When we examined the effects of the 90 percent CI, the differences were even less noticeable: For donation rates, 35 (90 percent CI) versus 33 (95 percent CI) and for transplantation rates, 38 (90 percent CI) versus 36 (95 percent CI).

Changing the Threshold Rates

An alternative way to measure success would be to change the threshold rate by which OPOs are measured. We examined the impact of using a static, absolute threshold rate based on the geometric mean and the median based on data from 2016 for analyzing data from 2017.

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Table 17a. OPO Donation Rates Using Geometric Mean or Median Measures

(Threshold donation rates are 4.11 for the proposed measure, 3.54 for the median measure, and 3.40 for the geometric mean measure. OPOs flagged are in bolded italics.)

		Upper Bound of CI		
OPO Name	Donation Rate	Proposed	Median	Geometric Mean
Organ Procurement Organization at the University of Wisconsin (WIUW)	5.65	6.45	6.45	6.45
Lifesharing - A Donate Life Organization (CASD)	5.49	6.42	6.42	6.42
DonorConnect (UTOP)	5.22	6.12	6.12	6.12
Midwest Transplant Network (MWOB)	5.35	5.96	5.96	5.96
Versiti (WIDN)	4.99	5.92	5.92	5.92
Nevada Donor Network (NVLV)	4.99	5.80	5.80	5.80
Gift of Life Donor Program (PADV)	5.21	5.60	5.60	5.60
Donor Network of Arizona (AZOB)	4.83	5.36	5.36	5.36
Nebraska Organ Recovery (NEOR)	4.34	5.33	5.33	5.33
The Living Legacy Foundation of Maryland (MDPC)	4.51	5.17	5.17	5.17
ConnectLife (NYWN)	4.04	5.10	5.10	5.10
LifeShare of Oklahoma (OKOP)	4.48	5.06	5.06	5.06
Washington Regional Transplant Community (DCTC)	4.37	5.03	5.03	5.03
OurLegacy - FL (FLFH)	4.32	4.93	4.93	4.93
Southwest Transplant Alliance (TXSB)	4.27	4.65	4.65	4.65
Mid-America Transplant Services (MOMA)	4.12	4.61	4.61	4.61
Donor Alliance (CORS)	3.95	4.55	4.55	4.55
LifeGift (TXGC)	4.15	4.52	4.52	4.52
Sierra Donor Services (CAGS)	3.73	4.50	4.50	4.50
Lifeshare Carolinas (NCCM)	3.77	4.46	4.46	4.46
Gift of Hope Organ & Tissue Donor Network (ILIP)	4.08	4.45	4.45	4.45
Tennessee Donor Services (TNDS)	3.94	4.34	4.34	4.34
Center for Organ Recovery and Education (PATF)	3.85	4.31	4.31	4.31

		Upper Bound of CI		
OPO Name	Donation Rate	Proposed	Median	Geometric Mean
LifeSource - MN (MNOP)	3.68	4.17	4.17	4.17
New Mexico Donor Services (NMOP)	3.32	4.16	4.16	4.16
Legacy of Life - Hawaii (HIOP)	3.06	***4.11***	4.11	4.11
LifeCenter Organ Donor Network (OHOV)	3.35	***4.10***	4.10	4.10
LifeCenter Northwest (WALC)	3.68	***4.10***	4.10	4.10
New Jersey Sharing Network (NJTO)	3.61	***4.08***	4.08	4.08
LifeBanc (OHLB)	3.54	***4.06***	4.06	4.06
LifeLink of Florida (FLWC)	3.62	***4.06***	4.06	4.06
Louisiana Organ Procurement Agency (LAOP)	3.59	***4.05***	4.05	4.05
Life Alliance Organ Recovery Agency (FLMP)	3.55	***4.02***	4.02	4.02
Lifeline of Ohio (OHLP)	3.40	***3.95***	3.95	3.95
Sharing Hope SC (SCOP)	3.39	***3.87***	3.87	3.87
Donor Network West (CADN)	3.43	***3.77***	3.77	3.77
OneLegacy (CAOP)	3.47	***3.75***	3.75	3.75
Pacific Northwest Transplant Bank (ORUO)	3.14	***3.65***	3.65	3.65
Life Connection of Ohio (OHLC)	2.94	***3.65***	3.65	3.65
Gift of Life Michigan (MIOP)	3.31	***3.64***	3.64	3.64
Texas Organ Sharing Alliance (TXSA)	3.19	***3.63***	3.63	3.63
LifeLink of Georgia (GALL)	3.27	***3.60***	3.60	3.60
LifeQuest Organ Recovery Services (FLUF)	3.12	***3.60***	3.60	3.60
New England Organ Bank (MAOB)	3.26	***3.59***	3.59	3.59
Mid-South Transplant Foundation (TNMS)	2.91	***3.56***	3.56	3.56
Carolina Donor Services (NCNC)	2.93	***3.30***	***3.30***	***3.30***
LiveOnNY (NYRT)	2.96	***3.27***	***3.27***	***3.27***
Indiana Donor Network (INOP)	2.78	***3.17***	***3.17***	***3.17***
Iowa Donor Network (IAOP)	2.43	***3.07***	***3.07***	***3.07***
Mississippi Organ Recovery Agency (MSOP)	2.53	***3.07***	***3.07***	***3.07***
LifeNet Health (VATB)	2.64	***3.03***	***3.03***	***3.03***
LifeLink of Puerto Rico (PRLL)	2.43	***2.94***	***2.94***	***2.94***

OPO Name	Donation Rate	Upper Bound of CI		
		Proposed	Median	Geometric Mean
LifeChoice Donor Services (CTOP)	2.34	***2.91***	***2.91***	***2.91***
Center for Donation and Transplant (NYAP)	2.24	***2.81***	***2.81***	***2.81***
Kentucky Organ Donor Affiliates (KYDA)	1.99	***2.33***	***2.33***	***2.33***
Arkansas Regional Organ Recovery Agency (AROR)	1.77	***2.27***	***2.27***	***2.27***
Legacy of Hope - Alabama (ALOB)	1.98	***2.26***	***2.26***	***2.26***
Finger Lakes Donor Recovery Network (NYFL)	1.65	***2.15***	***2.15***	***2.15***

Table 17b. OPO Transplant Rates Using Geometric Mean or Median Measures
(Threshold transplant rates are 13.73 for the proposed measure, 11.61 for the median measure, and 11.25 for the geometric mean measure. OPOs flagged are in bolded italics.)

OPO Name	Transplant Rate	Upper Bound of CI		
		Proposed	Median	Geometric Mean
Lifesharing - A Donate Life Organization (CASD)	19.44	21.14	21.14	21.14
Organ Procurement Organization at the University of Wisconsin (WIUW)	18.92	20.37	20.37	20.37
Midwest Transplant Network (MWOB)	19.11	20.24	20.24	20.24
DonorConnect (UTOP)	17.24	18.82	18.82	18.82
Versiti (WIDN)	17.03	18.70	18.70	18.70
Donor Network of Arizona (AZOB)	16.97	17.96	17.96	17.96
Nebraska Organ Recovery (NEOR)	16.13	17.93	17.93	17.93
The Living Legacy Foundation of Maryland (MDPC)	15.77	16.98	16.98	16.98
Nevada Donor Network (NVLV)	15.50	16.90	16.90	16.90
Gift of Life Donor Program (PADV)	16.12	16.80	16.80	16.80
Washington Regional Transplant Community (DCTC)	14.63	15.80	15.80	15.80
OurLegacy - FL (FLFH)	14.29	15.38	15.38	15.38
Southwest Transplant Alliance (TXSB)	14.61	15.30	15.30	15.30

OPO Name	Transplant Rate	Upper Bound of CI		
		Proposed	Median	Geometric Mean
LifeGift (TXGC)	14.50	15.20	15.20	15.20
Lifeshare Carolinas (NCCM)	13.43	14.67	14.67	14.67
Mid-America Transplant Services (MOMA)	13.65	14.52	14.52	14.52
ConnectLife (NYWN)	12.59	14.38	14.38	14.38
LifeShare of Oklahoma (OKOP)	13.35	14.35	14.35	14.35
Gift of Hope Organ & Tissue Donor Network (ILIP)	13.65	14.30	14.30	14.30
Louisiana Organ Procurement Agency (LAOP)	13.15	14.02	14.02	14.02
Tennessee Donor Services (TNDS)	13.13	13.86	13.86	13.86
Sierra Donor Services (CAGS)	12.43	13.77	13.77	13.77
LifeSource - MN (MNOP)	12.51	***13.40***	13.40	13.40
Sharing Hope SC (SCOP)	12.27	***13.15***	13.15	13.15
Donor Alliance (CORS)	11.82	***12.83***	12.83	12.83
Donor Network West (CADN)	12.16	***12.80***	12.80	12.80
LifeBanc (OHLB)	11.54	***12.45***	12.45	12.45
Lifeline of Ohio (OHLP)	11.43	***12.40***	12.40	12.40
Center for Organ Recovery and Education (PATF)	11.58	***12.37***	12.37	12.37
LifeCenter Northwest (WALC)	11.59	***12.32***	12.32	12.32
Texas Organ Sharing Alliance (TXSA)	11.44	***12.25***	12.25	12.25
LifeLink of Florida (FLWC)	11.47	***12.24***	12.24	12.24
OneLegacy (CAOP)	11.54	***12.04***	12.04	12.04
New Mexico Donor Services (NMOP)	10.50	***11.92***	11.92	11.92
New Jersey Sharing Network (NJTO)	11.09	***11.89***	11.89	11.89
LifeCenter Organ Donor Network (OHOV)	10.60	***11.86***	11.86	11.86
Indiana Donor Network (INOP)	10.84	***11.58***	***11.58***	11.58
Life Alliance Organ Recovery Agency (FLMP)	10.44	***11.23***	***11.23***	***11.23***
New England Organ Bank (MAOB)	10.56	***11.15***	***11.15***	***11.15***
Carolina Donor Services (NCNC)	10.47	***11.14***	***11.14***	***11.14***
LifeQuest Organ Recovery Services (FLUF)	10.16	***11.00***	***11.00***	***11.00***
LifeLink of Georgia (GALL)	10.30	***10.89***	***10.89***	***10.89***

OPO Name	Transplant Rate	Upper Bound of CI		
		Proposed	Median	Geometric Mean
Pacific Northwest Transplant Bank (ORUO)	9.92	***10.80***	***10.80***	***10.80***
Gift of Life Michigan (MIOP)	10.16	***10.74***	***10.74***	***10.74***
Mid-South Transplant Foundation (TNMS)	9.28	***10.40***	***10.40***	***10.40***
LiveOnNY (NYRT)	9.66	***10.21***	***10.21***	***10.21***
Legacy of Life - Hawaii (HIOP)	8.36	***9.96***	***9.96***	***9.96***
Life Connection of Ohio (OHLC)	8.69	***9.83***	***9.83***	***9.83***
LifeNet Health (VATB)	9.05	***9.75***	***9.75***	***9.75***
Mississippi Organ Recovery Agency (MSOP)	8.71	***9.66***	***9.66***	***9.66***
Iowa Donor Network (IAOP)	7.72	***8.79***	***8.79***	***8.79***
LifeChoice Donor Services (CTOP)	7.42	***8.37***	***8.37***	***8.37***
Kentucky Organ Donor Affiliates (KYDA)	7.33	***7.97***	***7.97***	***7.97***
LifeLink of Puerto Rico (PRLL)	6.77	***7.58***	***7.58***	***7.58***
Center for Donation and Transplant (NYAP)	6.61	***7.53***	***7.53***	***7.53***
Legacy of Hope - Alabama (ALOB)	6.18	***6.66***	***6.66***	***6.66***
Arkansas Regional Organ Recovery Agency (AROR)	5.72	***6.56***	***6.56***	***6.56***
Finger Lakes Donor Recovery Network (NYFL)	4.47	***5.23***	***5.23***	***5.23***

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We are actively considering use of a static, absolute threshold as a viable alternative to use of a relative performance metric, but question whether this approach could inadvertently incentivize all OPO performances to move towards a static threshold, thus decreasing total donations and transplantations. We are interested in robust public comments that support or refute these concerns and comments that list the potential impacts, benefits, or consequences of implementing this approach. We specifically request that commenters present data, studies, or other analysis to support their recommendations. We also seek comments on ways to incentivize continual improvement of all OPOs, including high performers and low performers. Additionally, we are interested in ways to ensure that the rates for re-certification continue to be based upon current performance and appropriately reflect potential improvements and changes in technology (such as the development of an implantable, artificial kidney or bioengineered pancreatic islet cells).

There were other alternatives that we chose not to propose. We received comment in response to our RFI that we should consider using the deaths referred from donor hospitals as our donor potential. This approach could rely on the regulatory requirement for hospitals to report imminent deaths to OPOs. We declined to propose this on the basis of concerns regarding its potential for inaccuracy. We believe that this approach incorrectly places the requirement to report an imminent death solely on the donor hospital, rather we believe this is a joint responsibility shared with an OPO.

Another option suggested by some members of the OPO community and commenters in response to the RFI is using donor/ventilated deaths for donor potential. While we appreciate this suggestion, there are no standardized databases that would allow us to determine the ventilator status of deaths, and we are concerned this approach incorrectly assigns ''potential donor'' status solely based on the fact that the patient is on a ventilator in an ICU. This approach does not consider the role of OPOs in educating donor hospital staff about the range of potential donors, such that resuscitation efforts are sufficient and appropriate referrals are made for organ donation, even for older, single-organ donors. Furthermore, asking hospitals to report the ventilator status of inpatient deaths or expecting OPOs to report that status would create an additional burden for all hospitals (not just transplant hospitals or just OPOs) and is inconsistent with our goals in proposing these new performance measures: To reduce the reporting burdens so that resources can go towards increasing organ donation and transplantation.

Also discussed in the preamble, we recognize that the OPO in Hawaii is at a considerable geographic disadvantage for placement of all the organs it could procure. As an alternative, we

considered measuring the performance of the Hawaii OPO based solely on its kidney donation and transplantation rates, excluding other organs, because Hawaii has a kidney transplant program, yet has greater geographic barriers associated with transporting the extra-renal organs outside of the DSA. These tables show the effects of the kidney donation and transplantation rates:

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Table 18a. OPO Donation Rates for All Organs Compared to Kidneys Only with Top 25 Percent Cutoff

(Threshold donation rate for all donors is 4.11 and for kidney donors is 3.45.)

	Donors for Any Organs			Donors of Only Kidneys			
OPO Name	All Organ Donation Rate	Upper Bound of CI	Additional Donors Needed to Reach Cutoff	Kidney Only Donors	Kidney Donation Rate	Upper Bound of CI	Additional Donors Needed to Reach Cutoff
Organ Procurement Organization at the University of Wisconsin (WIUW)	5.65	6.45	0	120	4.55	5.28	0
Lifesharing - A Donate Life Organization (CASD)	5.49	6.42	0	96	4.83	5.72	0
DonorConnect (UTOP)	5.22	6.12	0	94	4.59	5.44	0
Midwest Transplant Network (MWOB)	5.35	5.96	0	200	4.65	5.22	0
Versiti (WIDN)	4.99	5.92	0	70	3.80	4.63	0
Nevada Donor Network (NVLV)	4.99	5.80	0	89	3.76	4.48	0
Gift of Life Donor Program (PADV)	5.21	5.60	0	408	4.18	4.53	0
Donor Network of Arizona (AZOB)	4.83	5.36	0	215	4.31	4.82	0
Nebraska Organ Recovery (NEOR)	4.34	5.33	0	60	3.95	4.89	0
The Living Legacy Foundation of Maryland (MDPC)	4.51	5.17	0	107	3.37	3.96	0
ConnectLife (NYWN)	4.04	5.10	0	44	3.55	4.57	0
LifeShare of Oklahoma (OKOP)	4.48	5.06	0	153	3.87	4.42	0
Washington Regional Transplant Community (DCTC)	4.37	5.03	0	127	3.66	4.24	0
OurLegacy - FL (FLFH)	4.32	4.93	0	137	3.87	4.45	0
Southwest Transplant Alliance (TXSB)	4.27	4.65	0	300	3.44	3.78	0
Mid-America Transplant Services (MOMA)	4.12	4.61	0	165	3.13	3.56	0
Donor Alliance (CORS)	3.95	4.55	0	***50***	***1.95***	***2.48***	***23***
LifeGift (TXGC)	4.15	4.52	0	293	3.42	3.76	0

	Donors for Any Organs			Donors of Only Kidneys			
OPO Name	All Organ Donation Rate	Upper Bound of CI	Additional Donors Needed to Reach Cutoff	Kidney Only Donors	Kidney Donation Rate	Upper Bound of CI	Additional Donors Needed to Reach Cutoff
Sierra Donor Services (CAGS)	3.73	4.50	0	67	3.20	3.92	0
Lifeshare Carolinas (NCCM)	3.77	4.46	0	85	3.27	3.92	0
Gift of Hope Organ & Tissue Donor Network (ILIP)	4.08	4.45	0	287	3.15	3.47	0
Tennessee Donor Services (TNDS)	3.94	4.34	0	227	3.16	3.52	0
Center for Organ Recovery and Education (PATF)	3.85	4.31	0	173	3.15	3.57	0
LifeSource - MN (MNOP)	3.68	4.17	0	149	3.17	3.62	0
New Mexico Donor Services (NMOP)	3.32	4.16	0	48	2.95	3.75	0
Legacy of Life - Hawaii (HIOP)	***3.06***	***4.11***	***1***	31	2.88	3.89	0
LifeCenter Organ Donor Network (OHOV)	***3.35***	***4.10***	***1***	***55***	***2.71***	***3.40***	***1***
LifeCenter Northwest (WALC)	***3.68***	***4.10***	***1***	213	3.32	3.72	0
New Jersey Sharing Network (NJTO)	***3.61***	***4.08***	***2***	***150***	***2.95***	***3.37***	***4***
LifeBanc (OHLB)	***3.54***	***4.06***	***2***	***107***	***2.58***	***3.03***	***17***
LifeLink of Florida (FLWC)	***3.62***	***4.06***	***3***	***167***	***2.95***	***3.35***	***6***
Louisiana Organ Procurement Agency (LAOP)	***3.59***	***4.05***	***3***	***143***	***2.82***	***3.24***	***10***
Life Alliance Organ Recovery Agency (FLMP)	***3.55***	***4.02***	***5***	***142***	***2.88***	***3.31***	***7***
Lifeline of Ohio (OHLP)	***3.40***	***3.95***	***6***	***99***	***2.76***	***3.26***	***7***
Sharing Hope SC (SCOP)	***3.39***	***3.87***	***11***	***131***	***2.85***	***3.29***	***7***
Donor Network West (CADN)	***3.43***	***3.77***	***29***	***256***	***2.94***	***3.26***	***16***
OneLegacy (CAOP)	***3.47***	***3.75***	***44***	***353***	***2.77***	***3.03***	***52***
Pacific Northwest Transplant Bank (ORUO)	***3.14***	***3.65***	***17***	***110***	***2.90***	***3.40***	***2***
Life Connection of Ohio (OHLC)	***2.94***	***3.65***	***9***	***46***	***2.22***	***2.85***	***12***

	Donors for Any Organs			Donors of Only Kidneys			
OPO Name	All Organ Donation Rate	Upper Bound of CI	Additional Donors Needed to Reach Cutoff	Kidney Only Donors	Kidney Donation Rate	Upper Bound of CI	Additional Donors Needed to Reach Cutoff
Gift of Life Michigan (MIOP)	*3.31*	*3.64*	*39*	*232*	*2.66*	*2.96*	*41*
Texas Organ Sharing Alliance (TXSA)	*3.19*	*3.63*	*23*	*153*	*3.01*	*3.44*	*1*
LifeLink of Georgia (GALL)	*3.27*	*3.60*	*42*	*206*	*2.40*	*2.70*	*62*
LifeQuest Organ Recovery Services (FLUF)	*3.12*	*3.60*	*21*	*110*	*2.60*	*3.04*	*16*
New England Organ Bank (MAOB)	*3.26*	*3.59*	*43*	*248*	*2.85*	*3.16*	*24*
Mid-South Transplant Foundation (TNMS)	*2.91*	*3.56*	*12*	*54*	*2.34*	*2.94*	*11*
Carolina Donor Services (NCNC)	*2.93*	*3.30*	*53*	*174*	*2.57*	*2.91*	*35*
LiveOnNY (NYRT)	*2.96*	*3.27*	*76*	*225*	*2.40*	*2.68*	*69*
Indiana Donor Network (INOP)	*2.78*	*3.17*	*52*	*138*	*2.39*	*2.75*	*38*
Iowa Donor Network (IAOP)	*2.43*	*3.07*	*21*	*46*	*2.15*	*2.76*	*14*
Mississippi Organ Recovery Agency (MSOP)	*2.53*	*3.07*	*29*	*62*	*2.12*	*2.62*	*23*
LifeNet Health (VATB)	*2.64*	*3.03*	*56*	*124*	*2.28*	*2.64*	*42*
LifeLink of Puerto Rico (PRLL)	*2.43*	*2.94*	*35*	*56*	*1.75*	*2.19*	*37*
LifeChoice Donor Services (CTOP)	*2.34*	*2.91*	*29*	115	3.64	4.25	0
Center for Donation and Transplant (NYAP)	*2.24*	*2.81*	*30*	*44*	*1.80*	*2.32*	*26*
Kentucky Organ Donor Affiliates (KYDA)	*1.99*	*2.33*	*90*	*87*	*1.61*	*1.93*	*77*
Arkansas Regional Organ Recovery Agency (AROR)	*1.77*	*2.27*	*44*	*39*	*1.50*	*1.96*	*35*
Legacy of Hope - Alabama (ALOB)	*1.98*	*2.26*	*141*	*117*	*1.46*	*1.70*	*133*
Finger Lakes Donor Recovery Network (NYFL)	*1.65*	*2.15*	*45*	*33*	*1.33*	*1.78*	*38*
Totals			1,015	8,030			886

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Table 18b. OPO Organ Transplantation Rates for All Organs Compared to Kidneys Only with Top 25 Percent Cutoff

(Threshold organ transplantation rate for all organs is 13.73 and for kidneys is 6.67)

	Donors for Any Organs			Donors of Only Kidneys			
OPO Name	All Organ Transplant Rate	Upper Bound of CI	Additional Organs Needed to Reach Cutoff	Number of Kidneys Transplanted	Kidney Transplant Rate	Upper Bound of CI	Additional Kidneys Needed to Reach Cutoff
Lifesharing - A Donate Life Organization (CASD)	19.44	21.14	0	186	9.37	10.58	0
Organ Procurement Organization at the University of Wisconsin (WIUW)	18.92	20.37	0	232	8.79	9.81	0
Midwest Transplant Network (MWOB)	19.11	20.24	0	380	8.84	9.63	0
DonorConnect (UTOP)	17.24	18.82	0	181	8.84	10.00	0
Versiti (WIDN)	17.03	18.70	0	134	7.27	8.39	0
Donor Network of Arizona (AZOB)	16.97	17.96	0	411	8.23	8.94	0
Nebraska Organ Recovery (NEOR)	16.13	17.93	0	114	7.50	8.77	0
The Living Legacy Foundation of Maryland (MDPC)	15.77	16.98	0	200	*6.31*	*7.09*	0
Nevada Donor Network (NVLV)	15.50	16.90	0	167	7.06	8.02	0
Gift of Life Donor Program (PADV)	16.12	16.80	0	778	7.96	8.45	0

	Donors for Any Organs			Donors of Only Kidneys			
OPO Name	All Organ Transplant Rate	Upper Bound of CI	Additional Organs Needed to Reach Cutoff	Number of Kidneys Transplanted	Kidney Transplant Rate	Upper Bound of CI	Additional Kidneys Needed to Reach Cutoff
Washington Regional Transplant Community (DCTC)	14.63	15.80	0	223	7.06	7.89	0
OurLegacy - FL (FLFH)	14.29	15.38	0	252	7.12	7.90	0
Southwest Transplant Alliance (TXSB)	14.61	15.30	0	570	*6.53*	*7.00*	0
LifeGift (TXGC)	14.50	15.20	0	548	*6.39*	*6.86*	0
Lifeshare Carolinas (NCCM)	13.43	14.67	0	160	*6.16*	*7.02*	0
Mid-America Transplant Services (MOMA)	13.65	14.52	0	***312***	***5.92***	***6.51***	***9***
ConnectLife (NYWN)	12.59	14.38	0	85	6.86	8.22	0
LifeShare of Oklahoma (OKOP)	13.35	14.35	0	284	7.18	7.92	0
Gift of Hope Organ & Tissue Donor Network (ILIP)	13.65	14.30	0	***535***	***5.87***	***6.31***	***32***
Louisiana Organ Procurement Agency (LAOP)	13.15	14.02	0	***271***	***5.34***	***5.91***	***37***
Tennessee Donor Services (TNDS)	13.13	13.86	0	***426***	***5.93***	***6.42***	***18***

	Donors for Any Organs			Donors of Only Kidneys			
OPO Name	All Organ Transplant Rate	Upper Bound of CI	Additional Organs Needed to Reach Cutoff	Number of Kidneys Transplanted	Kidney Transplant Rate	Upper Bound of CI	Additional Kidneys Needed to Reach Cutoff
Sierra Donor Services (CAGS)	12.43	13.77	0	128	*6.12*	*7.09*	0
LifeSource - MN (MNOP)	***12.51***	***13.40***	***16***	286	*6.08*	*6.70*	0
Sharing Hope SC (SCOP)	***12.27***	***13.15***	***26***	***253***	***5.50***	***6.11***	***25***
Donor Alliance (CORS)	***11.82***	***12.83***	***31***	246	7.09	7.88	0
Donor Network West (CADN)	***12.16***	***12.80***	***80***	***487***	***5.60***	***6.03***	***54***
LifeBanc (OHLB)	***11.54***	***12.45***	***52***	***199***	***4.80***	***5.39***	***51***
Lifeline of Ohio (OHLP)	***11.43***	***12.40***	***46***	***186***	***5.19***	***5.86***	***28***
Center for Organ Recovery and Education (PATF)	***11.58***	***12.37***	***73***	***324***	***5.89***	***6.46***	***12***
LifeCenter Northwest (WALC)	***11.59***	***12.32***	***88***	***393***	***6.13***	***6.67***	***1***
Texas Organ Sharing Alliance (TXSA)	***11.44***	***12.25***	***73***	***287***	***5.65***	***6.23***	***22***
LifeLink of Florida (FLWC)	***11.47***	***12.24***	***82***	***312***	***5.51***	***6.05***	***34***
OneLegacy (CAOP)	***11.54***	***12.04***	***210***	***668***	***5.25***	***5.60***	***133***
New Mexico Donor Services (NMOP)	***10.50***	***11.92***	***28***	***91***	***5.59***	***6.65***	***1***
New Jersey Sharing	***11.09***	***11.89***	***91***	***286***	***5.62***	***6.19***	***24***

	Donors for Any Organs			Donors of Only Kidneys			
OPO Name	All Organ Transplant Rate	Upper Bound of CI	Additional Organs Needed to Reach Cutoff	Number of Kidneys Transplanted	Kidney Transplant Rate	Upper Bound of CI	Additional Kidneys Needed to Reach Cutoff
Network (NJTO)							
LifeCenter Organ Donor Network (OHOV)	*10.60*	*11.86*	*36*	*98*	*4.83*	*5.71*	*18*
Indiana Donor Network (INOP)	*10.84*	*11.58*	*121*	*254*	*4.39*	*4.87*	*100*
Life Alliance Organ Recovery Agency (FLMP)	*10.44*	*11.23*	*119*	*268*	*5.44*	*6.01*	*31*
New England Organ Bank (MAOB)	*10.56*	*11.15*	*219*	*460*	*5.28*	*5.70*	*82*
Carolina Donor Services (NCNC)	*10.47*	*11.14*	*171*	*331*	*4.88*	*5.35*	*86*
LifeQuest Organ Recovery Services (FLUF)	*10.16*	*11.00*	*112*	*205*	*4.84*	*5.44*	*50*
LifeLink of Georgia (GALL)	*10.30*	*10.89*	*238*	*383*	*4.47*	*4.86*	*150*
Pacific Northwest Transplant Bank (ORUO)	*9.92*	*10.80*	*107*	*209*	*5.51*	*6.18*	*18*
Gift of Life Michigan (MIOP)	*10.16*	*10.74*	*255*	*421*	*4.82*	*5.22*	*122*
Mid-South Transplant	*9.28*	*10.40*	*73*	*103*	*4.47*	*5.26*	*31*

	Donors for Any Organs			Donors of Only Kidneys			
OPO Name	All Organ Transplant Rate	Upper Bound of CI	Additional Organs Needed to Reach Cutoff	Number of Kidneys Transplanted	Kidney Transplant Rate	Upper Bound of CI	Additional Kidneys Needed to Reach Cutoff
Foundation (TNMS)							
LiveOnNY (NYRT)	***9.66***	***10.21***	***323***	***431***	***4.59***	***4.97***	***154***
Legacy of Life - Hawaii (HIOP)	***8.36***	***9.96***	***38***	61	*5.66*	*7.01*	0
Life Connection of Ohio (OHLC)	***8.69***	***9.83***	***77***	***84***	***4.05***	***4.86***	***35***
LifeNet Health (VATB)	***9.05***	***9.75***	***210***	***235***	***4.31***	***4.81***	***97***
Mississippi Organ Recovery Agency (MSOP)	***8.71***	***9.66***	***114***	***119***	***4.07***	***4.73***	***53***
Iowa Donor Network (IAOP)	***7.72***	***8.79***	***100***	***87***	***4.07***	***4.87***	***36***
LifeChoice Donor Services (CTOP)	***7.42***	***8.37***	***131***	***90***	***3.51***	***4.19***	***60***
Kentucky Organ Donor Affiliates (KYDA)	***7.33***	***7.97***	***300***	***171***	***3.17***	***3.60***	***157***
LifeLink of Puerto Rico (PRLL)	***6.77***	***7.58***	***189***	***101***	***3.15***	***3.72***	***89***
Center for Donation and Transplant (NYAP)	***6.61***	***7.53***	***145***	***83***	***3.39***	***4.06***	***60***
Legacy of Hope - Alabama (ALOB)	***6.18***	***6.66***	***551***	***221***	***2.75***	***3.08***	***276***

	Donors for Any Organs			Donors of Only Kidneys			
OPO Name	All Organ Transplant Rate	Upper Bound of CI	Additional Organs Needed to Reach Cutoff	Number of Kidneys Transplanted	Kidney Transplant Rate	Upper Bound of CI	Additional Kidneys Needed to Reach Cutoff
Arkansas Regional Organ Recovery Agency (AROR)	***5.72***	***6.56***	***178***	***73***	***2.80***	***3.41***	***79***
Finger Lakes Donor Recovery Network (NYFL)	***4.47***	***5.23***	***200***	***61***	***2.45***	***3.04***	***84***
Totals			4,903	15,144			2,349

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Using just these measures, the Hawaii OPO would be in the top 25 percent for both kidney donation rates and kidney transplantation rates. If we were to use our proposed measure to assess the Hawaii OPO's performance, it would need one additional donor and 38 additional organs transplanted to meet the threshold rate for the top 25 percent of rates. The reason we did not propose this approach for assessing the Hawaii OPO is that we are aware of newer technologies that could significantly reduce the clinical impact of prolonged transport of extra-renal organs and would prefer a policy that encourages the innovation and adoption of these types of technologies for the benefit of all potential recipients. We are seeking comments on this alternative or any other approach that would accurately measure the performance of the Hawaii OPO, such as a phased approach to implementing our new measures.

In analyzing all these different alternatives, we recognize that there were many OPOs whose performance is in the top 25 percent, regardless of which methodology was used. These OPOs are truly high performers and should be the models for the other OPOs. We encourage those OPOs to continue to strive to be top performers and encourage the widespread uptake of best practices. In summary, we welcome comments both on the comparative advantages and disadvantages of alternatives within the scope of this proposed rule, and suggestions for other alternatives that could be addressed in subsequent rule-makings or administrative actions to further improve performance of the organ donation and transplantation system.

H. Accounting Statement and Table

As required by OMB Circular A–4 (available at *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf*), in Table 18, we have prepared an accounting statement showing the classification of the benefits, transfers, and costs that we estimate will arise from the reforms if this proposed rule is adopted.

These reforms will create substantial out-year effects, and the annualized estimates provided in this table display the effects that are expected over the next 5 years, rather than over a longer period of time. The performance uncertainties, technology uncertainties, and future policy uncertainties are so great that we are reluctant to project farther into the future. This means, however, that the Accounting Table estimates do not include very substantial out-year benefits to patients and savings to the ESRD program that will occur outside the five-year estimating window. Also, the effects of this proposed rule on organ recovery and transplantation are of unusual uncertainty even in the short run. The upper bound for benefit and cost reduction estimates are as discussed elsewhere in this regulatory impact analysis. We welcome comments on the estimates made in this proposed rule and on ways to improve their calculation or presentation.

The rule generates a cluster of interrelated effects, so we are treating the increase in health care expenditures as ''negative benefits'' for purposes of the Accounting Table.

TABLE 19—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED BENEFITS, TRANSFERS, AND COSTS

[$ millions]

Category	Primary estimate	Low estimate	High estimate	Units		
				Year dollars	Discount rate (percent)	Period covered
Benefits:						
Health Benefits Annualized Monetized ($million/year)	.....	<0	698	2017	7	2021–2025
	.....	<0	769	2017	3	2021–2025

TABLE 19—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED BENEFITS, TRANSFERS, AND COSTS—Continued

[$ millions]

Category	Primary estimate	Low estimate	High estimate	Units		
				Year dollars	Discount rate (percent)	Period covered
Medical Expenditure Annualized Monetized ($million/year)	.....	>0	−923	2017	7	2021–2025
	.....	>0	−996	2017	3	2021–2025
Benefits Notes: Because increased transplant activity imposes costs upfront but yields savings over time, a longer time horizon would show medical expenditure impacts falling in magnitude, potentially to the point of being exceeded by longevity benefits.						
Costs:						
Annualized Monetized ($million/year)	.....	0.477	.....	2017	7	2021–2025
	.....	0.445	.....	2017	3	2021–2025
Cost Notes: Transition costs in the event of OPO decertification have not been estimated.						
Transfers	None quantified					

I. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771 (January 30, 2017) requires that the costs associated with significant new regulations ''to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.'' This proposed rule has been designated a significant regulatory action as defined by Executive Order 12866, and, if finalized as proposed, is expected to be an E.O. 13771 regulatory action.

J. Conclusion

This proposed rule would substantially reform the incentives facing OPOs and as a result, substantially increase organ procurement and transplants over time for all organs, while reducing continuing costs for dialysis and other treatments for patients with severe kidney disease. Because organ transplants are life-saving and life-extending events, we believe that these benefits to patients will be far more consequential than the effects on medical treatments and costs. Our expectation is that the numbers of lives saved or extended will be many thousands each year, as estimated in the preceding analysis.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 486

Medicare, Organ procurement, and Definitions.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV, part 486, as set forth below:

PART 486—CONDITIONS FOR COVERAGE OF SPECIALIZED SERVICES FURNISHED BY SUPPLIERS

■ 1. The authority citation for part 486 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 2. Section 486.302 is amended by—

■ a. Adding definitions for ''Death that is not an absolute contraindication to organ donation'' and ''Donation rate'';

■ b. Revising the definition of ''Donor'';

■ c. Adding a definition for ''Donor potential'';

■ d. Removing the definitions of ''Eligible death'', ''Eligible donor'', and ''Expected donation rate'';

■ e. Adding a definition for ''Lowest rate among the top 25 percent'';

■ f. Removing the definition of ''Observed donation rate'';

■ g. Revising the definition of ''Organ'';

■ h. Adding a definition for ''Organ transplantation rate''' and

■ i. Removing the definition of ''Standard criteria donor (SCD)''.

The additions and revisions read as follows:

§ 486.302 Definitions.

* * * * *

Death that is not an absolute contraindication to organ donation means all deaths from the state death certificates except those with any cause of death identified by the specific ICD–10 codes that would preclude donation under any circumstance.

Tuberculosis	all.
Other bacterial diseases	A39 Meningococcal infection.
	A40 Streptococcal septicaemia.
	A41 Other septicaemia.
Viral infections of the central nervous system	A82 Rabies.
Viral infections characterized by skin and mucous membrane lesions	B03 Smallpox.
Human immunodeficiency virus [HIV] disease	B20 Human immunodeficiency virus [HIV] disease with infectious and parasitic diseases.
	B21 Human immunodeficiency virus [HIV] disease with malignant neoplasms.
Sequelae of infectious and parasitic diseases	B90 Sequelae of tuberculosis.
Malignant neoplasms of lip, oral cavity and pharynx	all.
Malignant neoplasms of digestive organs	all.
Malignant neoplasms of respiratory and intrathoracic organs	all.
Melanoma and other malignant neoplasms of skin	C43 Malignant melanoma of skin.
Malignant neoplasms of bone and articular cartilage	all.

Melanoma and other malignant neoplasms of skin	all.
Malignant neoplasms of methothelial and soft tissue	all.
Malignant neoplasm of breast	all.
Malignant neoplasms of female genital organs	all.
Malignant neoplasms of male genital organs	all.
Malignant neoplasms of thyroid and other endocrine glands	all.
Malignant neoplasms of ill-defined, secondary and unspecified sites	all.
Malignant neoplasms of lymphoid, haematopoietic and related tissue	all.
Malignant neoplasms of independent (primary) multiple sites	all.
Neoplasms of uncertain or unknown behavior	D44 Neoplasm of uncertain or unknown behaviour of endocrine glands. D46 Meylodysplastic syndromes. D47 Other neoplasms of uncertain or unknown behavior of lymphoid, haematopietic and related tissue. D48 Neoplasms of uncertain or unknown behavior of other and unspecified sites.
Coagulation defects, purpura and other haemorrhagic conditions	D65 Disseminated intravascular coagulation [defibrination syndrome]. D69 Purpura and other haemorrhagic conditions.
Metabolic disorders	E84 Cystic fibrosis.
Infections specific to the perinatal period	P36 Bacterial sepsis of newborn.

* * * * *

Donation rate is the number of donors as a percentage of the donor potential.

* * * * *

Donor means a deceased individual from whom at least one vascularized organ (heart, liver, lung, kidney, pancreas, or intestine) is transplanted. An individual also would be considered a donor if only the pancreas is procured and is used for research or islet cell transplantation.

* * * * *

Donor potential is the number of inpatient deaths within the DSA among patients 75 and younger with any cause of death that is not an absolute contraindication to organ donation.

* * * * *

Lowest rate among the top 25 percent will be calculated by taking the number of total OPOs in the time period identified for establishing the threshold rate. That number will be multiplied by 0.25 and rounded to the closest integer (0.5 will round to the higher integer). The donation rates and organ transplantation rates will be separately ranked and the threshold rate will be the rate that corresponds to the integer when counting down the ranking.

* * * * *

Organ means a human kidney, liver, heart, lung, pancreas, or intestine (or multivisceral organs when transplanted at the same time as an intestine). The pancreas counts as an organ even if it is used for research or islet cell transplantation.

Organ type	Number of organs transplanted
Right or Left Kidney	1
Right and Left Kidney	2
Double/En-Bloc Kidney	2
Heart	1
Intestine	1
Intestine Segment 1 or Segment 2	1
Intestine Segment 1 and Segment 2	2
Liver	1
Liver Segment 1 or Segment 2	1
Liver Segments 1 and Segment 2	2
Right or Left Lung	1
Right and Left Lung	2
Double/En-bloc Lung	2
Pancreas (transplanted whole, research, islet transplant)	1
Pancreas Segment 1 or Segment 2	1
Pancreas Segment 1 and Segment 2	2

Organ transplantation rate is the number of organs transplanted from donors in the DSA as a percentage of the donor potential.

* * * * *

■ 3. Section 486.316 is amended by revising paragraphs (a)(1) and (2), (b), (c), and (d) introductory text to read as follows:

§ 486.316 Re-certification and competition processes.

(a) * * *

(1) Meets the performance requirements of the outcome measures at § 486.318 at the end of the certification cycle; and

(2) Has been shown by survey to be in compliance with the requirements for certification at § 486.303, including the conditions for coverage at §§ 486.320 through 486.360.

(b) *De-certification and competition.* If an OPO does not meet the performance requirements of the outcome measures as described in paragraph (a)(1) of this section at the final assessment prior to the end of the re-certification cycle or the requirements described in paragraph (a)(2) of this section the OPO is de-certified. If the OPO does not appeal or the OPO appeals and the reconsideration official and CMS hearing officer uphold the de-certification, the OPO's service area is opened for competition from other OPOs. The de-certified OPO is not permitted to compete for its open area or any other open area. An OPO competing for an open service area must submit information and data that describe the barriers in its service area, how they affected organ donation, what steps the OPO took to overcome them, and the results.

(c) *Criteria to compete.* To compete for an open service area, an OPO must meet the performance requirements of the outcome measures at § 486.318 and the requirements for certification at § 486.303, including the conditions for coverage at §§ 486.320 through 486.360. The OPO must compete for the entire service area.

(d) *Criteria for selection.* CMS will consider the following criteria in designating an OPO for an open service area:

* * * * *

■ 4. Section 486.318 is revised to read as follows:

§ 486.318 Condition: Outcome measures.

(a) *Outcome measures.* An OPO is evaluated by measuring the donation rate and the organ transplantation rate in their DSA.

(1) The donation rate is calculated as the number of donors in the DSA as a percentage of the donor potential.

(2) The organ transplantation rate is calculated as the number of organs transplanted from organs procured in the DSA as a percentage of the donor potential.

(3) The numerator of donors and organs transplanted is based on the data submitted to the OPTN as required in § 486.328 and/or 42 CFR 121.11.

(4) The denominator is the donor potential and is based on inpatient deaths within the DSA from patients 75

or younger with any cause of death that is an absolute contraindication to organ donation. The data is obtained from the most recent 12 months data from state death certificates.

(5) These outcome measures will be effective beginning with the 2022 re-certification cycle.

(b) *OPO performance on outcome measures.* An OPO must demonstrate a success rate on the outcome measures in accordance with the following parameters and requirements:

(1) For the assessment period, a threshold rate will be established based on the lowest rate among the top 25 percent of donation rates during the 12-month period immediately prior to the period being evaluated.

(2) For the assessment period, a threshold rate will be established based on the lowest rate among the top 25 percent of organ transplantation rates during the 12-month period prior to the period being evaluated.

(3) The 95 percent confidence interval for each OPO will be calculated using a one-sided test.

(4) OPOs whose upper limit of the one-sided 95 percent confidence interval is less than the threshold rate established will be flagged.

(c) *Assessment and data for the outcome measures.* (1) An OPO's performance on the outcome measures is based on an assessment at least every 12 months with the most recent 12 months of data from the OPTN and state death certificates, beginning December 31 of the first year of the re-certification cycle and ending December 31, prior to the end of the re-certification cycle.

(2) If an OPO's performance falls below the outcome measure described in paragraph (b) of this section prior to the last cycle before the end of the certification period, the OPO must meet the requirements of § 486.348(d)(3).

(3) If an OPO takes over another OPO's service area on a date later than January 1 of the first year of the re-certification cycle so that 12 months of data are not available to evaluate the OPO's performance in its new service area, we will not hold the OPO accountable for its performance in the new area until 12 months of data are available.

§ 486.328 [Amended]

■ 5. Section 486.328 is amended—

■ a. In paragraph (a) introductory text by removing the word ''Beneficiaries'' and adding in its place the word ''Recipients'' and by removing the acronym ''DHHS'' and adding in its place the acronym ''HHS''.

■ b. By removing and reserving paragraph (a)(4); and

■ c. In paragraph (a)(7), by removing, the word ''eligible''.

■ 6. Section 486.348 is amended by adding paragraph (d) to read as follows:

§ 486.348 Condition: Quality assessment and performance improvement (QAPI).

* * * * *

(d) *Standard: Review of outcome measures.* (1) An OPO must include a process to review its performance on the outcome measure requirements at § 486.318. The process must be a continuous activity to improve performance.

(2) An OPO must incorporate data on the outcome measures into their QAPI program.

(3) If the outcome measure at each assessment cycle, except the final assessment before re-certification, is statistically significantly lower than the top 25 percent of donation rates or organ transplantation rates, the OPO must identify opportunities for improvement and implement changes that lead to improvement in these measures.

Dated: September 27, 2019.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: November 7, 2019

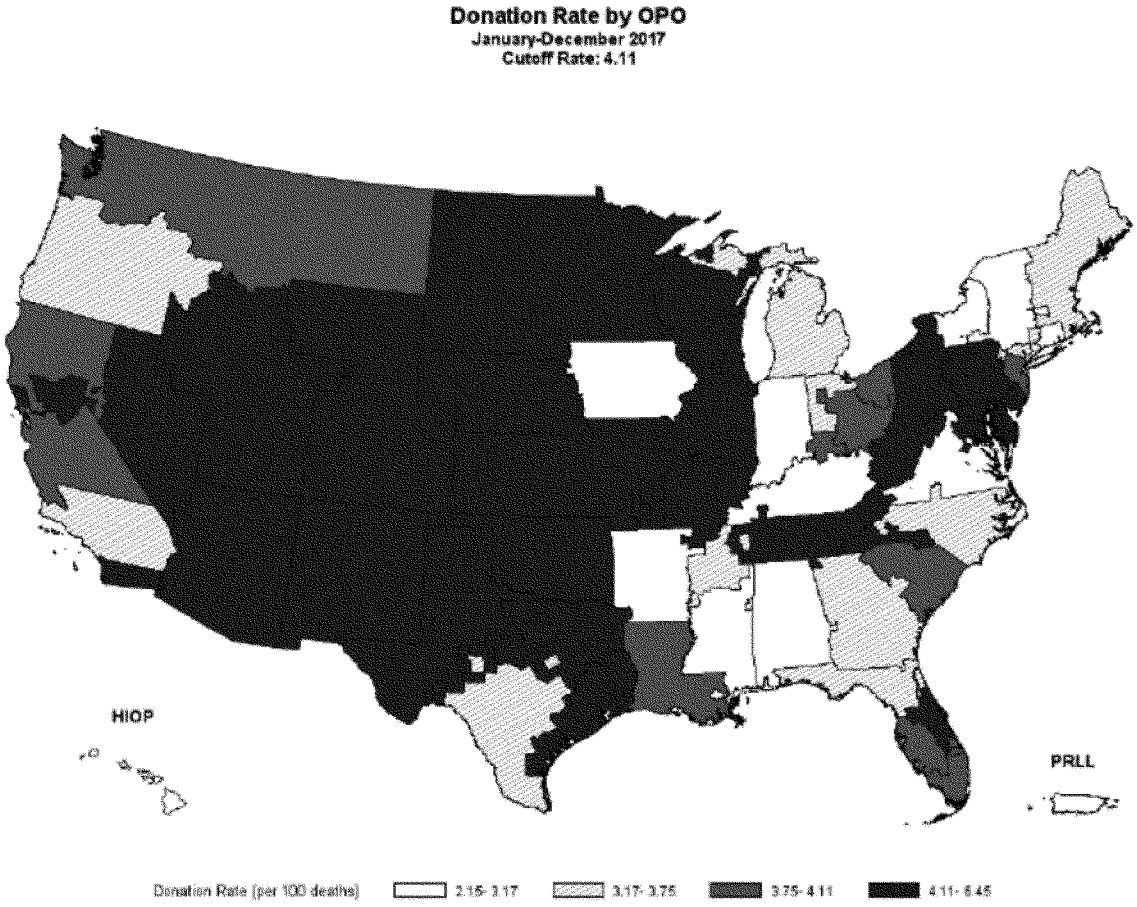
Alex M. Azar II,

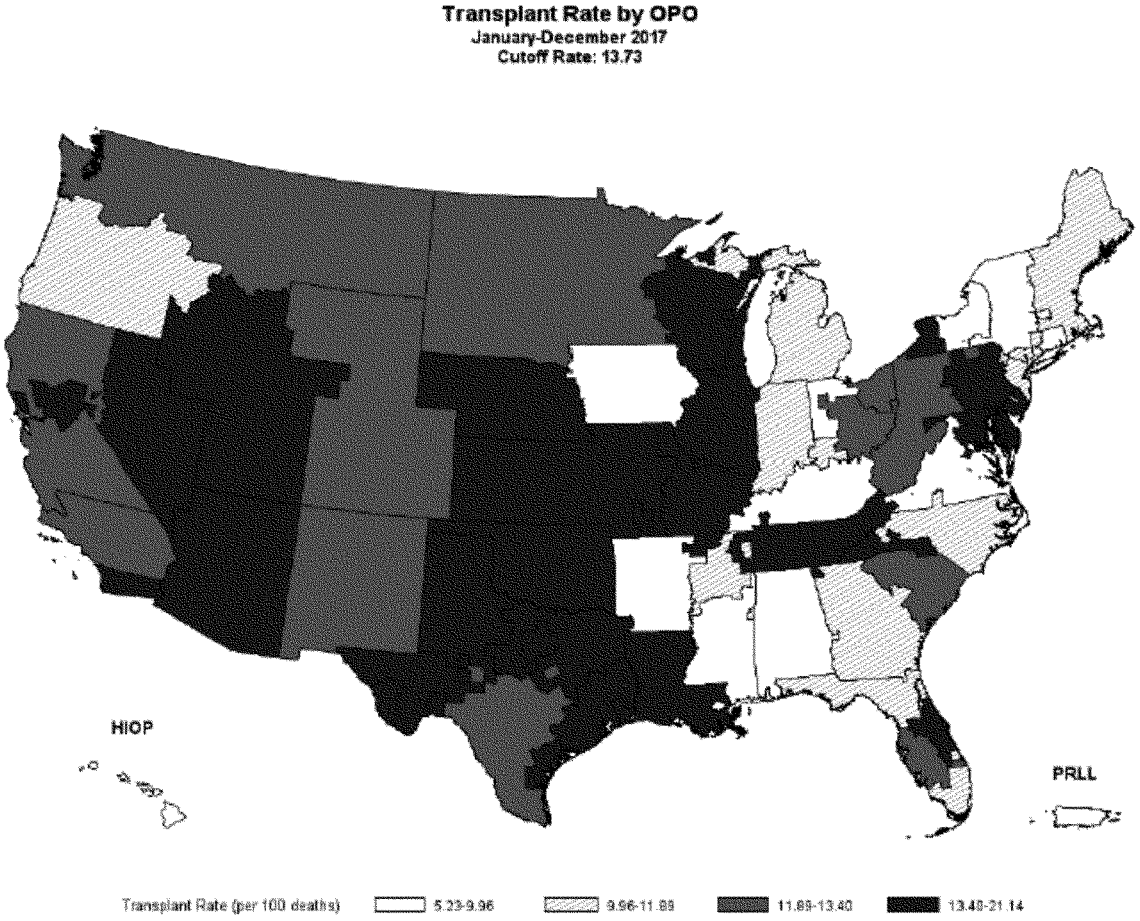
Secretary, Department of Health and Human Services.

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

BILLING CODE 4120–01–P

Appendix


Donation Rate by OPO
January-December 2017
Cutoff Rate: 4.11
HIOP
PRLL
Donation Rate (per 100 deaths)
2.15- 3.17
3.17- 3.75
3.75- 4.11
4.11- 6.45



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Part III

Department of Commerce

National Oceanic and Atmospheric Administration

50 CFR Part 218

Taking and Importing Marine Mammals; Taking Marine Mammals Incidental to the U.S. Navy Training and Testing Activities in the Atlantic Fleet Training and Testing Study Area; Final Rule

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 218

[Docket No. 191211–0106]

RIN 0648–BI85

Taking and Importing Marine Mammals; Taking Marine Mammals Incidental to the U.S. Navy Training and Testing Activities in the Atlantic Fleet Training and Testing Study Area

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

ACTION: Final rule; notification of issuance of Letters of Authorization.

SUMMARY: NMFS, upon request from the U.S. Navy (Navy), issues these regulations pursuant to the Marine Mammal Protection Act (MMPA) to govern the taking of marine mammals incidental to the training and testing activities conducted in the Atlantic Fleet Training and Testing (AFTT) Study Area over the course of seven years, effectively extending the time period from November 13, 2023, to November 13, 2025. In August 2018, the MMPA was amended by the John S. McCain National Defense Authorization Act (NDAA) for Fiscal Year 2019 to allow for seven-year authorizations for military readiness activities, as compared to the previously allowed five years. The Navy's activities qualify as military readiness activities pursuant to the MMPA as amended by the NDAA for Fiscal Year 2004. These regulations, which allow for the issuance of Letters of Authorization (LOAs) for the incidental take of marine mammals during the described activities and timeframes, prescribe the permissible methods of taking and other means of effecting the least practicable adverse impact on marine mammal species or stocks and their habitat, and establish requirements pertaining to the monitoring and reporting of such taking.

DATES: Effective from December 23, 2019 to November 13, 2025.

ADDRESSES: Copies of the Navy's applications, NMFS' proposed rule for these regulations, NMFS' proposed and final rules and subsequent LOAs for the associated five-year AFTT Study Area regulations, other supporting documents cited herein, and a list of the references cited in this document may be obtained online at: *www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-military-readiness-activities.* In case of problems accessing these documents, please use the contact listed here (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Wendy Piniak, Office of Protected Resources, NMFS, (301) 427–8401.

SUPPLEMENTARY INFORMATION:

Purpose of Regulatory Action

These regulations, issued under the authority of the MMPA (16 U.S.C. 1361 *et seq.*), extend the framework for authorizing the take of marine mammals incidental to the Navy's training and testing activities (which qualify as military readiness activities) from the use of sonar and other transducers, in-water detonations, air guns, impact pile driving/vibratory extraction, and the movement of vessels throughout the AFTT Study Area, which includes areas of the western Atlantic Ocean along the East Coast of North America, portions of the Caribbean Sea, and the Gulf of Mexico.

NMFS received an application from the Navy requesting to extend NMFS' existing MMPA regulations (50 CFR part 218, subpart I; hereafter ''2018 AFTT regulations'') that authorize the take of marine mammals incidental to Navy training and testing activities conducted in the AFTT Study Area to cover seven years of the Navy's activities, instead of five. Take is anticipated to occur by Level A harassment and Level B harassment as well as a very small number of serious injuries or mortalities incidental to the Navy's training and testing activities.

Section 101(a)(5)(A) of the MMPA (16 U.S.C. 1371(a)(5)(A)) directs the Secretary of Commerce (as delegated to NMFS) to allow, upon request, the incidental, but not intentional taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if, after notice and public comment, the agency makes certain findings and issues regulations that set forth permissible methods of taking pursuant to that activity, as well as monitoring and reporting requirements. Section 101(a)(5)(A) of the MMPA and the implementing regulations at 50 CFR part 216, subpart I, provide the legal basis for issuing this final rule and the subsequent LOAs. As directed by this legal authority, this final rule contains mitigation, monitoring, and reporting requirements.

Summary of Major Provisions Within the Final Rule

Following is a summary of the major provisions of this final rule regarding the Navy's activities. Major provisions include, but are not limited to:

- The use of defined powerdown and shutdown zones (based on activity);
- Measures to reduce or eliminate the likelihood of ship strikes, especially for North Atlantic right whales (*Eubalaena glacialis*) (NARW);
- Operational limitations in certain areas and times that are biologically important (*i.e.,* for foraging, migration, reproduction) for marine mammals;
- Implementation of a Notification and Reporting Plan (for dead, live stranded, or marine mammals struck by a vessel); and
- Implementation of a robust monitoring plan to improve our understanding of the environmental effects resulting from Navy training and testing activities.

Additionally, the rule includes an adaptive management component that allows for timely modification of mitigation or monitoring measures based on new information, when appropriate.

Background

The MMPA prohibits the ''take'' of marine mammals, with certain exceptions. Sections 101(a)(5)(A) and (D) of the MMPA direct the Secretary of Commerce (as delegated to NMFS) to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, a notice of a proposed authorization is provided to the public for review and the opportunity to submit comments.

An authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stocks and will not have an unmitigable adverse impact on the availability of the species or stocks for taking for subsistence uses (where relevant). Further, NMFS must prescribe the permissible methods of taking and other means of effecting the least practicable adverse impact on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stocks for taking for certain subsistence uses (referred to in this rule as ''mitigation measures''); and requirements pertaining to the monitoring and reporting of such takings. The MMPA defines ''take'' to mean to harass, hunt, capture, or kill, or attempt to harass,

hunt, capture, or kill any marine mammal. The *Analysis and Negligible Impact Determination* section below discusses the definition of ''negligible impact.''

The NDAA for Fiscal Year 2004 (2004 NDAA) (Pub. L. 108–136) amended section 101(a)(5) of the MMPA to remove the ''small numbers'' and ''specified geographical region'' provisions indicated above and amended the definition of ''harassment'' as it applies to a ''military readiness activity'' to read as follows (Section 3(18)(B) of the MMPA): (i) Any act that injures or has the significant potential to injure a marine mammal or marine mammal stock in the wild (Level A Harassment); or (ii) Any act that disturbs or is likely to disturb a marine mammal or marine mammal stock in the wild by causing disruption of natural behavioral patterns, including, but not limited to, migration, surfacing, nursing, breeding, feeding, or sheltering, to a point where such behavioral patterns are abandoned or significantly altered (Level B Harassment). In addition, the 2004 NDAA amended the MMPA as it relates to military readiness activities such that least practicable adverse impact shall include consideration of personnel safety, practicality of implementation, and impact on the effectiveness of the military readiness activity.

More recently, section 316 of the NDAA for Fiscal Year 2019 (2019 NDAA) (Pub. L. 115–232), signed on August 13, 2018, amended the MMPA to allow incidental take rules for military readiness activities under section 101(a)(5)(A) to be issued for up to seven years. Prior to this amendment, all incidental take rules under section 101(a)(5)(A) were limited to five years.

Summary of Request

On November 14, 2018, NMFS issued a five-year final rule governing the taking of marine mammals incidental to Navy training and testing activities conducted in the AFTT Study Area (83 FR 57076; hereafter ''2018 AFTT final rule''). Previously, on August 13, 2018, and towards the end of the time period in which NMFS was processing the Navy's request for the 2018 regulations, the 2019 NDAA amended the MMPA for military readiness activities to allow incidental take regulations to be issued for up to seven years instead of the previous five years. The Navy's training and testing activities conducted in the AFTT Study Area qualify as military readiness activities pursuant to the MMPA, as amended by the 2004 NDAA. On November 16, 2018, the Navy submitted an application requesting that NMFS extend the 2018 AFTT regulations and associated LOAs such that they would cover take incidental to seven years of training and testing activities instead of five, extending the expiration date from November 13, 2023 to November 13, 2025. A revised application correcting the estimated takes due to ship shock trials (Table 5.1–2) was submitted to NMFS by the Navy on January 18, 2019.

In its November 16, 2018, application, as revised on January 18, 2019 (hereafter ''2019 Navy application''), the Navy proposed no changes to the nature of the specified activities covered by the 2018 AFTT final rule, the level of activity within and between years will be consistent with that previously analyzed in the 2018 AFTT final rule, and all activities will be conducted within the same boundaries of the AFTT Study Area identified in the 2018 AFTT final rule. Therefore, the training and testing activities (*e.g.,* equipment and sources used, exercises conducted) and the mitigation, monitoring, and reporting measures are identical to those described and analyzed in the 2018 AFTT final rule. The only changes included in the Navy's request were to conduct those same activities in the same region for an additional two years. In its request, the Navy included all information necessary to identify the type and amount of incidental take that may occur in the two additional years so NMFS could determine whether the analyses and conclusions regarding the impacts of the proposed activities on marine mammal species and stocks previously reached for five years of activities remain applicable for seven years of identical activity.

The purpose of the Navy's training and testing activities is to ensure that the Navy meets its mission mandated by Federal law (10 U.S.C. 8062), which is to maintain, train, and equip combat-ready naval forces capable of winning wars, deterring aggression, and maintaining freedom of the seas. The Navy executes this responsibility by establishing and executing training programs, including at-sea training and exercises, and ensuring naval forces have access to the ranges, operating areas (OPAREAs), and airspace needed to develop and maintain skills for conducting naval activities. The Navy's mission is achieved in part by conducting training and testing within the AFTT Study Area.

The 2019 Navy application reflects the same compilation of training and testing activities presented in the Navy's June 16, 2017, initial rulemaking and LOA application (hereafter ''2017 Navy application'') and the 2018 AFTT regulations that were subsequently promulgated, which can be found at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-military-readiness-activities.* These activities are deemed by the Navy necessary to accomplish military readiness requirements and are anticipated to continue into the reasonably foreseeable future. The 2019 Navy application and this rule cover training and testing activities that will occur over seven years, including the five years already authorized under the 2018 AFTT regulations, with the regulations valid from the publication date of this final rule through November 13, 2025.

Summary of the Regulations

NMFS is extending the incidental take regulations and associated LOAs through November 13, 2025, to cover the same Navy activities covered by the 2018 AFTT regulations. The 2018 AFTT final rule was recently published and its analysis remains current and valid. In its 2019 application, the Navy proposed no changes to the nature (*e.g.,* equipment and sources used, exercises conducted) or level of the specified activities within or between years or to the boundaries of the AFTT Study Area. The mitigation, monitoring, and reporting measures are identical to those described and analyzed in the 2018 AFTT final rule. The regulatory language included at the end of this final rule, which will be published at 50 CFR part 218, subpart I, also is the same as the AFTT 2018 regulations, except for a small number of minor, technical changes. No new information has been received from the Navy, or otherwise become available to NMFS, since publication of the 2018 AFTT final rule that significantly changes the analyses supporting the 2018 findings. Where there is any new information pertinent to the descriptions, analyses, or findings required to authorize incidental take for military readiness activities under MMPA section 101(a)(5)(A), that information is provided in the appropriate sections below.

Because the activities included in the 2019 Navy application have not changed and the analyses and findings included in the documents provided and produced in support of the 2018 AFTT final rule remain current and applicable, this final rule relies heavily on and references to the applicable information and analyses in those documents. Below is a list of the primary documents referenced in this final rule. The list indicates the short name by which the document is referenced in this final rule, as well as

the full titles of the cited documents. All of the documents can be found at: *www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-military-readiness-activities* and *https://www.public.navy.mil/usff/environmental/Pages/aftt.aspx.*

- NMFS March 13, 2018, Atlantic Fleet Training and Testing (AFTT) proposed rule (83 FR 10954; hereafter ''2018 AFTT proposed rule'');
- NMFS November 14, 2018, Atlantic Fleet Training and Testing (AFTT) final rule (83 FR 57076; hereafter ''2018 AFTT final rule'');
- NMFS May 13, 2019, Atlantic Fleet Training and Testing (AFTT) proposed rule (84 FR 21126; hereafter ''2019 AFTT proposed rule'');
- Navy June 16, 2017, MMPA rulemaking and LOA application (hereafter ''2017 Navy application'');
- Navy January 18, 2019, MMPA rulemaking and LOA extension application (hereafter ''2019 Navy application''); and
- September 14, 2018, Atlantic Fleet Training and Testing (AFTT) Final Environmental Impact Statement/Overseas Environmental Impact Statement (FEIS/OEIS) (hereafter ''2018 AFTT FEIS/OEIS'').

Description of the Specified Activity

The Navy requested authorization to take marine mammals incidental to conducting training and testing activities. The Navy has determined that acoustic and explosives stressors are most likely to result in impacts on marine mammals that could rise to the level of harassment. A small number of serious injuries or mortalities are also possible from vessel strikes or exposure to explosive detonations. Detailed descriptions of these activities are provided in Chapter 2 of the 2018 AFTT FEIS/OEIS and in the 2017 and 2019 Navy applications.

Overview of Training and Testing Activities

The Navy routinely trains in the AFTT Study Area in preparation for national defense missions. Training and testing activities and components covered in the 2019 Navy application are described in detail in the *Overview of Training and Testing Activities* sections of the 2018 AFTT proposed rule and the 2018 AFTT final rule and Chapter 2 of the 2018 AFTT FEIS/OEIS. Each military training and testing activity described meets mandated Fleet requirements to deploy ready forces. The Navy proposed no changes to the specified activities described and analyzed in the 2018 AFTT final rule. The boundaries of the AFTT Study Area (see Figure 1.2–1 of the 2019 Navy application); the training and testing activities (*e.g.,* equipment and sources used, exercises conducted); manner of and amount of vessel movement; and standard operating procedures presented in this final rule are identical to those described and analyzed in the 2018 AFTT final rule.

Dates and Duration

The specified activities will occur at any time during the seven-year period of validity of the regulations. The number of training and testing activities are described in the *Detailed Description of the Specified Activities* section (Tables 1 through 4).

Specified Geographical Region

The geographic extent of the AFTT Study Area is identical to that described in the 2018 AFTT final rule. The AFTT Study Area (see Figure 2–1 of the 2019 Navy application) includes areas of the western Atlantic Ocean along the east coast of North America, the Gulf of Mexico, and portions of the Caribbean Sea. The AFTT Study Area begins at the mean high tide line along the U.S. coast and extends east to the 45-degree west longitude line, north to the 65-degree north latitude line, and south to approximately the 20-degree north latitude line. The AFTT Study Area also includes Navy pierside locations, bays, harbors, and inland waterways, and civilian ports where training and testing occurs. The AFTT Study Area generally follows the Commander Task Force 80 area of operations, covering approximately 2.6 million nautical miles squared (nmi^2; approximately 6.7 million kilometers squared) of ocean area, and includes designated Navy range complexes and associated operating areas (OPAREAs) and special use airspace. While the AFTT Study Area itself is very large, the vast majority of Navy training and testing occurs in designated range complexes and testing ranges.

A Navy range complex consists of geographic areas that encompass a water component (above and below the surface) and airspace, and may encompass a land component where training and testing of military platforms, tactics, munitions, explosives, and electronic warfare systems occur. Range complexes include established OPAREAs, which may be further divided to provide better control of the area for safety reasons. Additional detail on range complexes and testing ranges was provided in the *Duration and Location* section of the 2018 AFTT proposed rule; please see the 2018 AFTT proposed rule or the 2017 Navy application for more information.

Description of Acoustic and Explosive Stressors

The Navy uses a variety of sensors, platforms, weapons, and other devices, including ones used to ensure the safety of Sailors and Marines, to meet its mission. Training and testing with these systems may introduce acoustic (sound) energy or shock waves from explosives into the environment. The specific components that could act as stressors by having direct or indirect impacts on the environment are described in detail in the *Description of Acoustic and Explosive Stressors* section of the 2018 AFTT final rule and Chapter 2 of the 2018 AFTT FEIS/OEIS. The Navy proposed no changes to the nature of the specified activities and, therefore, the acoustic and explosive stressors are identical to those described and analyzed in the 2018 AFTT final rule.

Other Stressor—Vessel Strike

Vessel strikes are not specific to any particular training or testing activity, but rather a limited, sporadic, and incidental result of Navy vessel movement within the AFTT Study Area. Navy vessels transit at speeds that are optimal for fuel conservation or to meet training and testing requirements. The average speed of large Navy ships ranges between 10 and 15 knots and submarines generally operate at speeds in the range of 8–13 knots, while a few specialized vessels can travel at faster speeds. By comparison, this is slower than most commercial vessels where full speed for a container ship is typically 24 knots (Bonney and Leach, 2010).

Should a vessel strike occur, it would likely result in incidental take from serious injury and/or mortality and, accordingly, for the purposes of the analysis we assume that any ship strike would result in serious injury or mortality. The Navy proposed no changes to the nature of the specified activities, the training and testing activities, the manner of or amount of vessel movement, and standard operating procedures. Therefore, the description of vessel strikes as a stressor is the same as those presented in the *Other Stressor—Vessel Strike* sections of the 2018 AFTT proposed rule and 2018 AFTT final rule.

Detailed Description of the Specified Activities

The Navy's specified activities are presented and analyzed as a representative year of training to

account for the natural fluctuation of training cycles and deployment schedules in any seven-year period. In the 2018 AFTT final rule, NMFS analyzed activities based on the Navy conducting three years of a representative level of activity and two years of a maximum level of activity. For the purposes of this rulemaking, the Navy presented and NMFS analyzed activities based on the additional two years of training and testing consisting of one additional year of a maximum level of activity and one year of a representative level of activity consistent with the pattern set forth in the 2018 AFTT final rule, the 2018 AFTT FEIS/OEIS, and the 2017 Navy application.

Training Activities

The number of planned training activities that could occur annually and the duration of those activities remains identical to those presented in Table 4 of the 2018 AFTT final rule, and are not repeated here. The number of planned training activities that could occur over the seven-year period are presented in Table 1. The table is organized according to primary mission areas and includes the activity name, associated stressors applicable to these regulations, sound source bin, number of activities, and locations of those activities in the AFTT Study Area. For further information regarding the primary platform used (*e.g.,* ship or aircraft type) see Appendix A (Navy Activity Descriptions) of the 2018 AFTT FEIS/OEIS.

TABLE 1—TRAINING ACTIVITIES ANALYZED FOR SEVEN-YEAR PERIOD IN THE AFTT STUDY AREA

Stressor category	Activity name	Activity description	Source bin	7-Year number of activities [1]	Location [2]
Major Training Exercise—Large Integrated Anti-Submarine Warfare					
Acoustic	Composite Training Unit Exercise.	Aircraft carrier and its associated aircraft integrate with surface and submarine units in a challenging multi-threat operational environment in order to certify them for deployment.	ASW1, ASW2, ASW3, ASW4, ASW5, HF1, LF6, MF1, MF3, MF4, MF5, MF11, MF12.	17	VACAPES RC Navy Cherry Point RC JAX RC.
Major Training Exercises—Medium Integrated Anti-Submarine Warfare					
Acoustic	Fleet Exercises/ Sustainment Exercise.	Aircraft carrier and its associated aircraft integrates with surface and submarine units in a challenging multi-threat operational environment in order to maintain their ability to deploy.	ASW1, ASW2, ASW3, ASW4, HF1, LF6, MF1, MF3, MF4, MF5, MF11, MF12.	28 14	JAX RC. VACAPES RC.
Integrated/Coordinated Training—Small Integrated Anti-Submarine Warfare Training					
Acoustic	Naval Undersea Warfare Training Assessment Course.	Multiple ships, aircraft, and submarines integrate the use of their sensors to search for, detect, classify, localize, and track a threat submarine in order to launch an exercise torpedo.	ASW1, ASW3, ASW4, HF1, LF6, MF1, MF3, MF4, MF5, MF12.	42 21 21	JAX RC. Navy Cherry Point RC. VACAPES RC.
Integrated/Coordinated Training—Medium Coordinated Anti-Submarine Warfare Training					
Acoustic	Anti-Submarine Warfare Tactical Development Exercise.	Surface ships, aircraft, and submarines coordinate to search for, detect, and track submarines.	ASW1, ASW3, ASW4, HF1, LF6, MF1, MF3, MF4, MF5, MF11, MF12.	14 7 7	JAX RC. Navy Cherry Point RC. VACAPES RC.
Integrated/Coordinated Training—Small Coordinated Anti-Submarine Warfare Training					
Acoustic	Group Sail	Surface ships and helicopters search for, detect, and track threat submarines.	ASW2, ASW3, ASW4, HF1, MF1, MF3, MF4, MF5, MF11, MF12.	28 28 35	JAX RC. Navy Cherry Point RC. VACAPES RC.
Amphibious Warfare					
Explosive	Naval Surface Fire Support Exercise—At Sea.	Surface ship crews use large-caliber guns to support forces ashore; however, the land target is simulated at sea. Rounds are scored by passive acoustic buoys located at or near the target area.	E5	28 84 14 266	GOMEX RC. JAX RC. Navy Cherry Point RC. VACAPES RC.
Anti-Submarine Warfare					
Acoustic	Anti-submarine Warfare Torpedo Exercise—Helicopter.	Helicopter aircrews search for, track, and detect submarines. Recoverable air launched torpedoes are employed against submarine targets.	MF4, MF5, TORP1	98 28	JAX RC. VACAPES RC.
Acoustic	Anti-submarine Warfare Torpedo Exercise—Maritime Patrol Aircraft.	Maritime patrol aircraft aircrews search for, track, and detect submarines. Recoverable air launched torpedoes are employed against submarine targets.	MF5, TORP1	98 28	JAX RC. VACAPES RC.
Acoustic	Anti-Submarine Warfare Torpedo Exercise—Ship.	Surface ship crews search for, track, and detect submarines. Exercise torpedoes are used.	ASW3, MF1, TORP1	112 35	JAX RC. VACAPES RC.

TABLE 1—TRAINING ACTIVITIES ANALYZED FOR SEVEN-YEAR PERIOD IN THE AFTT STUDY AREA—Continued

Stressor category	Activity name	Activity description	Source bin	7-Year number of activities [1]	Location [2]
Acoustic	Anti-Submarine Warfare Torpedo Exercise—Submarine.	Submarine crews search for, track, and detect submarines. Exercise torpedoes are used.	ASW4, HF1, MF3, TORP2	84 42 14	JAX RC. Northeast RC. VACAPES RC.
Acoustic	Anti-Submarine Warfare Tracking Exercise—Helicopter.	Helicopter aircrews search for, track, and detect submarines.	MF4, MF5	168 2,590 84 56	Other AFTT Areas. JAX RC. Navy Cherry Point RC. VACAPES RC.
Acoustic	Anti-Submarine Warfare Tracking Exercise—Maritime Patrol Aircraft.	Maritime patrol aircraft aircrews search for, track, and detect submarines.	ASW5, ASW2, MF5	630 1,232 3,675 322	Northeast RC. VACAPES RC. JAX RC. Navy Cherry Point RC.
Acoustic	Anti-Submarine Warfare Tracking Exercise—Ship.	Surface ship crews search for, track, and detect submarines.	ASW1, ASW3, MF1, MF11, MF12.	*35 *770 *35 *3,080 *385 *1,540	Northeast RC. Other AFTT Areas. GOMEX RC. JAX RC. Navy Cherry Point RC. VACAPES RC.
Acoustic	Anti-Submarine Warfare Tracking Exercise—Submarine.	Submarine crews search for, track, and detect submarines.	ASW4, HF1, MF3	308 7 91 126 42	Other AFTT Areas. JAX RC. Navy Cherry Point RC. Northeast RC. VACAPES RC.
Expeditionary Warfare					
Explosive	Maritime Security Operations—Anti-Swimmer Grenades.	Small boat crews engage in force protection activities by using anti-swimmer grenades to defend against hostile divers.	E2	14 14 14 28 35	GOMEX RC. JAX RC. Navy Cherry Point RC. Northeast RC. VACAPES RC.
Mine Warfare					
Acoustic	Airborne Mine Countermeasure—Mine Detection.	Helicopter aircrews detect mines using towed or laser mine detection systems.	HF4	462 2,219 2,597 1,708 10,780	GOMEX RC. JAX RC. Navy Cherry Point RC. NSWC Panama City. VACAPES RC.
Acoustic, Explosive	Civilian Port Defense—Homeland Security Anti-Terrorism/Force Protection Exercise.	Maritime security personnel train to protect civilian ports against enemy efforts to interfere with access to those ports.	HF4, SAS2, E2, E4	4	Beaumont, TX; Boston, MA; Corpus Christi, TX; Delaware Bay, DE; Earle, NJ; GOMEX RC, Hampton Roads, VA; JAX RC, Kings Bay, GA; NS Mayport, Morehead City, NC; Port Canaveral, FL; Savannah, GA; Tampa Bay, FL; VACAPES RC, Wilmington, NC.
Acoustic	Coordinated Unit Level Helicopter Airborne Mine Countermeasure Exercise.	A detachment of helicopter aircrews train as a unit in the use of airborne mine countermeasures, such as towed mine detection and neutralization systems.	HF4	14 14 14 14	GOMEX RC. JAX RC. Navy Cherry Point RC. VACAPES RC.
Acoustic, Explosive	Mine Countermeasures—Mine Neutralization—Remotely Operated Vehicle.	Ship, small boat, and helicopter crews locate and disable mines using remotely operated underwater vehicles.	HF4, E4	924 497 497 4,410	GOMEX RC. JAX RC. Navy Cherry Point RC. VACAPES RC.
Acoustic	Mine Countermeasures—Ship Sonar.	Ship crews detect and avoid mines while navigating restricted areas or channels using active sonar.	HF4	154 371 371	GOMEX RC. JAX RC. VACAPES RC.
Explosive	Mine Neutralization—Explosive Ordnance Disposal.	Personnel disable threat mines using explosive charges.	E4, E5, E6, E7	42 112 140 119 112 3,668	Lower Chesapeake Bay. GOMEX RC. JAX RC. Key West RC. Navy Cherry Point RC. VACAPES RC.
Surface Warfare					
Explosive	Bombing Exercise Air-to-Surface.	Fixed-wing aircrews deliver bombs against surface targets.	E9, E10, E12	469 3,038 756 2,303	GOMEX RC. JAX RC. Navy Cherry Point RC. VACAPES RC.

TABLE 1—TRAINING ACTIVITIES ANALYZED FOR SEVEN-YEAR PERIOD IN THE AFTT STUDY AREA—Continued

Stressor category	Activity name	Activity description	Source bin	7-Year number of activities [1]	Location [2]
Explosive	Gunnery Exercise Surface-to-Surface Boat Medium-Caliber.	Small boat crews fire medium-caliber guns at surface targets.	E1	42	GOMEX RC.
				182	JAX RC.
				896	Navy Cherry Point RC.
				14	Northeast RC.
				1,820	VACAPES RC.
Explosive	Gunnery Exercise Surface-to-Surface Ship Large-Caliber.	Surface ship crews fire large-caliber guns at surface targets.	E3,E5	70	Other AFTT Areas.
				63	GOMEX RC.
				357	JAX RC.
				245	Navy Cherry Point RC.
				525	VACAPES RC.
Explosive	Gunnery Exercise Surface-to-Surface Ship Medium-Caliber.	Surface ship crews fire medium-caliber guns at surface targets.	E1	287	Other AFTT Areas.
				231	GOMEX RC.
				1,127	JAX RC.
				504	Navy Cherry Point RC.
				2,247	VACAPES RC.
Explosive	Integrated Live Fire Exercise.	Naval forces defend against a swarm of surface threats (ships or small boats) with bombs, missiles, rockets, and small-, medium- and large-caliber guns.	E1, E3, E6, E10	14	VACAPES RC.
				14	JAX RC.
Explosive	Missile Exercise Air-to-Surface.	Fixed-wing and helicopter aircrews fire air-to-surface missiles at surface targets.	E6, E8, E10	714	JAX RC.
				364	Navy Cherry Point RC.
				616	VACAPES RC.
Explosive	Missile Exercise Air-to-Surface—Rocket.	Helicopter aircrews fire both precision-guided and unguided rockets at surface targets.	E3	70	GOMEX RC.
				714	JAX RC.
				70	Navy Cherry Point RC.
				644	VACAPES RC.
Explosive	Missile Exercise Surface-to-Surface.	Surface ship crews defend against surface threats (ships or small boats) and engage them with missiles.	E6, E10	112	JAX RC.
				84	VACAPES RC.
Acoustic, Explosive	Sinking Exercise	Aircraft, ship, and submarine crews deliberately sink a seaborne target, usually a decommissioned ship (made environmentally safe for sinking according to U.S. Environmental Protection Agency standards), with a variety of munitions.	TORP2, E5, E8, E9, E10, E11.	7	SINKEX Box.
Acoustic	Elevated Causeway System.	A temporary pier is constructed off the beach. Supporting pilings are driven into the sand and then later removed.	Impact hammer or vibratory extractor.	7	Lower Chesapeake Bay.
				7	Navy Cherry Point RC.
Acoustic	Submarine Navigation	Submarine crews operate sonar for navigation and object detection while transiting into and out of port during reduced visibility.	HF1, MF3	1,183	NSB New London.
				21	NSB Kings Bay.
				21	NS Mayport.
				588	NS Norfolk.
				161	Port Canaveral, FL.
Acoustic	Submarine Sonar Maintenance.	Maintenance of submarine sonar systems is conducted pierside or at sea.	MF3	84	Other AFTT Areas.
				462	NSB New London.
				63	JAX RC.
				14	NSB Kings Bay.
				238	NS Norfolk.
				602	Northeast RC.
				14	Port Canaveral, FL.
				88	Navy Cherry Point RC.
				326	VACAPES RC.
Acoustic	Submarine Under Ice Certification.	Submarine crews train to operate under ice. Ice conditions are simulated during training and certification events.	HF1	21	JAX RC.
				21	Navy Cherry Point RC.
				63	Northeast RC.
				63	VACAPES RC.
Acoustic	Surface Ship Object Detection.	Surface ship crews operate sonar for navigation and object detection while transiting in and out of port during reduced visibility.	HF8, MF1K	532	NS Mayport.
				1,134	NS Norfolk.
Acoustic	Surface Ship sonar Maintenance.	Maintenance of surface ship sonar systems is conducted pierside or at sea.	HF8, MF1	350	JAX RC.
				350	NS Mayport.
				840	Navy Cherry Point RC.
				1,645	NS Norfolk.
				840	VACAPES RC.

[1] The number of training activities that could occur annually and the duration of those activities remains identical to those presented in Table 4 of the 2018 AFTT final rule.

[2] Locations given are areas where activities typically occur. However, activities could be conducted in other locations within the Study Area. Where multiple locations are provided within a single cell, the number of activities could occur in any of the locations, not in each of the locations.

* For Anti-Submarine Warfare Tracking Exercise—Ship, 50 percent of requirements are met through synthetic training or other training exercises.

Notes: GOMEX: Gulf of Mexico; JAX: Jacksonville; NS: Naval Station; NSB: Naval Submarine Base; NSWC: Naval Surface Warfare Center; RC: Range Complex; VACAPES: Virginia Capes.

Testing Activities

The number of planned testing activities that could occur annually and the duration of those activities are identical to those presented in Tables 5 through 7 of the 2018 AFTT final rule, and are not repeated here. Similar to the 2017 Navy application, the Navy's planned testing activities presented here are based on the level of testing activities anticipated to be conducted into the reasonably foreseeable future, with adjustments that account for changes in the types and tempo (increases or decreases) of testing activities to meet current and future military readiness requirements. The number of planned testing activities that could occur for the seven-year period are presented in Tables 2 through 4. The number of ship shock trials for the seven-year period will remain the same as the number covered by the 2018 AFTT final rule.

Naval Air Systems Command

The Naval Air Systems Command testing activities that could occur over the seven-year period within the AFTT Study Area are presented in Table 2.

TABLE 2—NAVAL AIR SYSTEMS COMMAND TESTING ACTIVITIES ANALYZED FOR SEVEN-YEAR PERIOD IN THE AFTT STUDY AREA

Stressor category	Activity name	Activity description	Source bin	7-Year number of activities [1]	Location [2]
Anti-Submarine Warfare					
Acoustic	Anti-Submarine Warfare Torpedo Test.	This event is similar to the training event torpedo exercise. Test evaluates anti-submarine warfare systems onboard rotary-wing (*e.g.,* helicopter) and fixed-wing aircraft and the ability to search for, detect, classify, localize, track, and attack a submarine or similar target.	MF5, TORP1	209 523	JAX RC. VACAPES RC.
Acoustic, Explosive.	Anti-Submarine Warfare Tracking Test—Helicopter.	This event is similar to the training event anti-submarine warfare tracking exercise—helicopter. The test evaluates the sensors and systems used to detect and track submarines and to ensure that helicopter systems used to deploy the tracking system perform to specifications.	MF4, MF5, E3	34 36 64 442 1,368	GOMEX RC. JAX RC. Key West RC. Northeast RC VACAPES RC.
Acoustic, Explosive.	Anti-Submarine Warfare Tracking Test—Maritime Patrol Aircraft.	The test evaluates the sensors and systems used by maritime patrol aircraft to detect and track submarines and to ensure that aircraft systems used to deploy the tracking systems perform to specifications and meet operational requirements.	ASW2, ASW5, E1, E3, MF5, MF6.	85 133 76 101 279 175	GOMEX RC. JAX RC. Key West RC. Navy Cherry Point RC. Northeast RC. VACAPES RC.
Acoustic	Kilo Dip	Functional check of a helicopter deployed dipping sonar system prior to conducting a testing or training event using the dipping sonar system.	MF4	22 12 12 12 200	GOMEX RC. JAX RC. Key West RC. Northeast RC. VACAPES RC.
Acoustic, Explosive.	Sonobuoy Lot Acceptance Test.	Sonobuoys are deployed from surface vessels and aircraft to verify the integrity and performance of a production lot or group of sonobuoys in advance of delivery to the fleet for operational use.	ASW2, ASW5, HF5, HF6, LF4, MF5, MF6, E1, E3, E4.	1,120	Key West RC.
Mine Warfare					
Acoustic	Airborne Dipping Sonar Minehunting Test.	A mine-hunting dipping sonar system that is deployed from a helicopter and uses high-frequency sonar for the detection and classification of bottom and moored mines.	HF4	144 66	NSWC Panama City. VACAPES RC.
Explosive	Airborne Mine Neutralization System Test.	A test of the airborne mine neutralization system evaluates the system's ability to detect and destroy mines from an airborne mine countermeasures capable helicopter. The airborne mine neutralization system uses up to four unmanned underwater vehicles equipped with high-frequency sonar, video cameras, and explosive and non-explosive neutralizers.	E4	154 215	NSWC Panama City. VACAPES RC.
Acoustic	Airborne Sonobuoy Minehunting Test.	A mine-hunting system made up of a field of sonobuoys deployed by a helicopter. A field of sonobuoys, using high-frequency sonar, is used to detect and classify bottom and moored mines.	HF6	364 168	NSWC Panama City. VACAPES RC.

TABLE 2—NAVAL AIR SYSTEMS COMMAND TESTING ACTIVITIES ANALYZED FOR SEVEN-YEAR PERIOD IN THE AFTT STUDY AREA—Continued

Stressor category	Activity name	Activity description	Source bin	7-Year number of activities [1]	Location [2]
Surface Warfare					
Explosive	Air-to-Surface Bombing Test.	This event is similar to the training event bombing exercise air-to-surface. Fixed-wing aircraft test the delivery of bombs against surface maritime targets with the goal of evaluating the bomb, the bomb carry and delivery system, and any associated systems that may have been newly developed or enhanced.	E9	140	VACAPES RC.
Explosive	Air-to-Surface Gunnery Test.	This event is similar to the training event gunnery exercise air-to-surface. Fixed-wing and rotary-wing aircrews evaluate new or enhanced aircraft guns against surface maritime targets to test that the guns, gun ammunition, or associated systems meet required specifications or to train aircrews in the operation of a new or enhanced weapon system.	E1	295 890	JAX RC. VACAPES RC.
Explosive	Air-to-Surface Missile Test	This event is similar to the training event missile exercise air-to-surface. Test may involve both fixed-wing and rotary-wing aircraft launching missiles at surface maritime targets to evaluate the weapon system or as part of another system's integration test.	E6, E9, E10	30 234 234	GOMEX RC. JAX RC. VACAPES RC.
Explosive	Rocket Test	Rocket tests evaluate the integration, accuracy, performance, and safe separation of guided and unguided 2.75-inch rockets fired from a hovering or forward-flying helicopter.	E3	121 233	JAX RC. VACAPES RC.
Other Testing Activities					
Acoustic	Undersea Range System Test.	Following installation of a Navy underwater warfare training and testing range, tests of the nodes (components of the range) will be conducted to include node surveys and testing of node transmission functionality.	MF9, BB4	66	JAX RC.

[1] The number of testing activities that could occur annually and the duration of those activities are identical to those presented in Table 5 of the 2018 AFTT final rule.
[2] Locations given are areas where activities typically occur. However, activities could be conducted in other locations within the Study Area.
Notes: GOMEX: Gulf of Mexico; JAX: Jacksonville; NSWC: Naval Surface Warfare Center; RC: Range Complex; VACAPES: Virginia Capes.

Naval Sea Systems Command

The Naval Sea Systems Command testing activities that could occur over the seven-year period within the AFTT Study Area are presented in Table 3.

TABLE 3—NAVAL SEA SYSTEMS COMMAND TESTING ACTIVITIES ANALYZED FOR SEVEN-YEAR PERIOD IN THE AFTT STUDY AREA

Stressor category	Activity name	Activity description	Source bin	7-year number of activities [1]	Location [2]
Anti-Submarine Warfare					
Acoustic	Anti-Submarine Warfare Mission Package Testing.	Ships and their supporting platforms (*e.g.,* helicopters, unmanned aerial systems) detect, localize, and attack submarines.	ASW1, ASW2, ASW3, ASW5, MF1, MF4, MF5, MF12, TORP1.	294 28 28 182	JAX RC. Newport, RI. NUWC Newport. VACAPES RC.
Acoustic	At-Sea Sonar Testing	At-sea testing to ensure systems are fully functional in an open ocean environment.	ASW3, ASW4, HF1, LF5, M3, MF1, MF1K, MF3, MF5, MF9, MF11, TORP2.	14	JAX RC, Navy Cherry Point RC, Northeast RC, VACAPES RC.
				7	JAX RC, Navy Cherry Point RC, VACAPES RC.

TABLE 3—NAVAL SEA SYSTEMS COMMAND TESTING ACTIVITIES ANALYZED FOR SEVEN-YEAR PERIOD IN THE AFTT STUDY AREA—Continued

Stressor category	Activity name	Activity description	Source bin	7-year number of activities [1]	Location [2]
				14	offshore Fort Pierce, FL, GOMEX RC, JAX RC, SFOMF, Northeast RC, VACAPES RC.
				28	JAX RC.
				14	Navy Cherry Point RC.
				56	NUWC Newport.
				84	VACAPES RC.
Acoustic	Pierside Sonar Testing.	Pierside testing to ensure systems are fully functional in a controlled pierside environment prior to at-sea test activities.	ASW3, HF1, HF3, HF8, M3, MF1, MF1K, MF3, MF9, MF10.	7	NSB New London, NS Norfolk, Port Canaveral, FL.
				77	Bath, ME.
				35	NSB New London.
				28	NSB Kings Bay.
				56	Newport, RI.
				91	NS Norfolk.
				14	Pascagoula, MS.
				21	Port Canaveral, FL.
				14	PNS.
Acoustic	Submarine Sonar Testing/Maintenance.	Pierside testing of submarine systems occurs periodically following major maintenance periods and for routine maintenance.	HF1, HF3, M3, MF3 ..	112	Norfolk, VA.
				168	PNS.
Acoustic	Surface Ship Sonar Testing/Maintenance.	Pierside and at-sea testing of ship systems occur periodically following major maintenance periods and for routine maintenance.	ASW3, MF1, MF1K, MF9, MF10.	7	JAX RC.
				7	NS Mayport.
				21	NS Norfolk.
				21	VACAPES RC.
Acoustic, Explosive.	Torpedo (Explosive) Testing.	Air, surface, or submarine crews employ explosive and non-explosive torpedoes against artificial targets.	ASW3, HF1, HF5, HF6, MF1, MF3, MF4, MF5, MF6, TORP1, TORP2, E8, E11.	28	GOMEX RC, offshore Fort Pierce, FL, Key West RC, Navy Cherry Point RC, Northeast RC, VACAPES RC,.
				14	GOMEX RC, JAX RC, Northeast RC, VACAPES RC.
Acoustic	Torpedo (Non-Explosive) Testing.	Air, surface, or submarine crews employ non-explosive torpedoes against submarines or surface vessels. When performed on a testing range, these torpedoes may be launched from a range craft or fixed structures and may use artificial targets.	ASW3, ASW4, HF1, HF6, MF1, MF3, MF4, MF5, MF6, TORP1, TORP2, TORP 3.	49	GOMEX RC.
				77	offshore Fort Pierce, FL.
				12	JAX RC.
				49	Navy Cherry Point RC.
				54	Northeast RC.
				210	NUWC Newport.
				77	VACAPES RC
Acoustic	Countermeasure Testing.	Countermeasure testing involves the testing of systems that will detect, localize, track, and attack incoming weapons including marine vessel targets. Testing includes surface ship torpedo defense systems and marine vessel stopping payloads.	ASW3, HF5, TORP1, TORP2.	35	GOMEX RC, JAX RC, NUWC Newport, VACAPES RC, Key West RC.
				20	GOMEX RC, JAX RC, Northeast RC, VACAPES RC.
Mine Warfare					
Acoustic, Explosive.	Mine Countermeasure and Neutralization Testing.	Air, surface, and subsurface vessels neutralize threat mines and mine-like objects.	E4, E11	91	NSWC Panama City.
				42	VACAPES RC.

TABLE 3—NAVAL SEA SYSTEMS COMMAND TESTING ACTIVITIES ANALYZED FOR SEVEN-YEAR PERIOD IN THE AFTT STUDY AREA—Continued

Stressor category	Activity name	Activity description	Source bin	7-year number of activities [1]	Location [2]
Acoustic, Explosive.	Mine Countermeasure Mission Package Testing.	Vessels and associated aircraft conduct mine countermeasure operations.	HF4, SAS2, E4	133	GOMEX RC.
				70	JAX RC.
				77	NSWC Panama City.
				14	SFOMF.
				35	VACAPES RC.
Acoustic	Mine Detection and Classification Testing.	Air, surface, and subsurface vessels and systems detect, classify, and avoid mines and mine-like objects. Vessels also assess their potential susceptibility to mines and mine-like objects.	HF1,HF4, HF8, MF1, MF1K, MF9.	42	GOMEX RC.
				70	Navy Cherry Point RC.
				359	NSWC Panama City.
				66	Riviera Beach, FL.
				28	SFOMF.
				21	VACAPES RC.
Surface Warfare					
Explosive	Gun Testing—Large Caliber.	Crews defend against targets with large-caliber guns.	E3, E5	84	GOMEX RC, JAX RC, Key West RC, Navy Cherry Point RC, Northeast RC, VACAPES RC.
				7	GOMEX RC.
				7	JAX RC.
				7	Key West RC.
				7	Navy Cherry Point RC.
				7	Northeast RC.
				231	NSWC Panama City.
				35	VACAPES RC.
Explosive	Gun Testing—Medium-Caliber.	Airborne and surface crews defend against targets with medium-caliber guns.	E1	84	GOMEX RC, JAX RC, Key West RC, Navy Cherry Point RC, Northeast RC, VACAPES RC.
				714	NSWC Panama City.
				34	VACAPES RC.
Explosive	Missile and Rocket Testing.	Missile and rocket testing includes various missiles or rockets fired from submarines and surface combatants. Testing of the launching system and ship defense is performed.	E6, E10	91	GOMEX RC, JAX RC, Key West RC, Navy Cherry Point RC, Northeast RC, VACAPES RC.
				7	GOMEX RC.
				14	JAX RC.
				35	Northeast RC.
				154	VACAPES RC.
Unmanned Systems					
Acoustic, Explosive.	Unmanned Underwater Vehicle Testing.	Testing involves the development or upgrade of unmanned underwater vehicles. This may include testing of mine detection capabilities, evaluating the basic functions of individual platforms, or complex events with multiple vehicles.	ASW4, FLS2, HF1, HF4, HF5, HF6, HF7, LF5, MF9, MF10, SAS1, SA2, SAS3, VHF1, E8.	112	GOMEX RC, JAX RC, NUWC Newport.
				287	GOMEX RC.
				175	JAX RC.
				1,018	NSWC Panama City.
				2,158	NUWC Newport.
				63	Riviera Beach, FL.
				294	SFOMF.
Vessel Evaluation					
Explosive	Large Ship Shock Trial.	Underwater detonations are used to test new ships or major upgrades.	E17	1	GOMEX RC, JAX RC, VACAPES RC.

TABLE 3—NAVAL SEA SYSTEMS COMMAND TESTING ACTIVITIES ANALYZED FOR SEVEN-YEAR PERIOD IN THE AFTT STUDY AREA—Continued

Stressor category	Activity name	Activity description	Source bin	7-year number of activities [1]	Location [2]
Explosive	Surface Warfare Testing.	Tests capability of shipboard sensors to detect, track, and engage surface targets. Testing may include ships defending against surface targets using explosive and non-explosive rounds, gun system structural test firing and demonstration of the response to Call for Fire against land-based targets (simulated by sea-based locations).	E1, E5, E8	14	GOMEX RC.
				91	JAX RC.
				7	Key West RC.
				70	Northeast RC.
				63	VACAPES RC.
Acoustic	Undersea Warfare Testing.	Ships demonstrate capability of countermeasure systems and underwater surveillance, weapons engagement, and communications systems. This tests ships' ability to detect, track, and engage underwater targets.	ASW3, ASW4, HF4, HF8, MF1, MF1K, MF4, MF5, MF9, MF10, TORP1, TORP2.	14	JAX RC, VACAPES RC.
				6	JAX RC, Navy Cherry Point RC, SFOMF, VACAPES RC.
				14	GOMEX RC.
				42	JAX RC.
				14	VACAPES RC.
Explosive	Small Ship Shock Trial.	Underwater detonations are used to test new ships or major upgrades.	E16	3	JAX RC, VACAPES RC.
Acoustic	Submarine Sea Trials—Weapons System Testing.	Submarine weapons and sonar systems are tested at-sea to meet integrated combat system certification requirements.	HF1, M3, MF3, MF9, MF10, TORP2.	14	Offshore Fort Pierce, FL, GOMEX RC, JAX RC, SFOMF, Northeast RC, VACAPES RC.
				28	JAX RC.
				28	Northeast RC.
				28	VACAPES RC.
Other Testing Activities					
Acoustic	Insertion/Extraction	Testing of submersibles capable of inserting and extracting personnel and payloads into denied areas from strategic distances.	MF3, MF9	28	Key West RC.
				1,848	NSWC Panama City.
Acoustic	Acoustic Component Testing.	Various surface vessels, moored equipment, and materials are tested to evaluate performance in the marine environment.	FLS2, HF5, HF7, LF5, MF9, SAS2.	231	SFOMF.
Acoustic	Semi-Stationary Equipment Testing.	Semi-stationary equipment (*e.g.,* hydrophones) is deployed to determine functionality.	AG, ASW3, ASW4, HF5, HF6, LF4, LF5, MF9, MF10, SD1, SD2.	28	Newport, RI.
				77	NSWC Panama City.
				1,330	NUWC Newport.
Acoustic	Towed Equipment Testing.	Surface vessels or unmanned surface vehicles deploy and tow equipment to determine functionality of towed systems.	HF6, LF4, MF9	252	NUWC Newport.
Acoustic	Signature Analysis Operations.	Surface ship and submarine testing of electromagnetic, acoustic, optical, and radar signature measurements.	ASW2, HF1, LF4, LF5, LF6, M3, MF9, MF10.	7	JAX RC.
				413	SFOMF.

[1] The number of testing activities that could occur annually and the duration of those activities are identical to those presented in Table 6 of the 2018 AFTT final rule.

[2] Locations given are areas where activities typically occur. However, activities could be conducted in other locations within the Study Area. Where multiple locations are provided within a single cell, the number of activities could occur in any of the locations, not in each of the locations.

Notes: JEB LC–FS: Joint Expeditionary Base Little Creek-Fort Story; NS: Naval Station; NSB: Naval Submarine Base; NSWC: Naval Surface Warfare Center; NUWC: Naval Undersea Warfare Center; PNS: Portsmouth Naval Shipyard; SFOMF: South Florida Ocean Measurement Facility Testing Range.

Office of Naval Research

The Office of Naval Research testing activities that could occur over the seven-year period within the AFTT Study Area are presented in Table 4.

TABLE 4—OFFICE OF NAVAL RESEARCH TESTING ACTIVITIES ANALYZED FOR SEVEN-YEAR PERIOD IN THE AFTT STUDY AREA

Stressor category	Activity name	Activity description	Source bin	7-Year number of activities [1]	Location
Acoustic and Oceanographic Science and Technology					
Acoustic, Explosive	Acoustic and Oceanographic Research.	Research using active transmissions from sources deployed from ships and unmanned underwater vehicles. Research sources can be used as proxies for current and future Navy systems.	AG, ASW2, BB4, BB5, BB6, BB7, LF3, LF4, LF5, MF8, MF9, MF14, E1.	30 60 16 14	GOMEX RC. Northeast RC. VACAPES RC. Other AFTT Areas.
Acoustic	Emerging Mine Countermeasure Technology Research.	Test involves the use of broadband acoustic sources on unmanned underwater vehicles.	BB1, BB2, SAS4	7 14 7	JAX RC. Northeast RC. VACAPES RC.

[1] The number of testing activities that could occur annually and the duration of those activities are identical to those presented in Table 7 of the 2018 AFTT final rule.

Notes: GOMEX: Gulf of Mexico; JAX: Jacksonville, Florida; RC: Range Complex; VACAPES: Virginia Capes

Summary of Acoustic and Explosive Sources Analyzed for Training and Testing

Tables 5 through 8 show the acoustic source classes and numbers, explosive source bins and numbers, airgun sources, and pile driving and removal activities associated with the Navy's planned training and testing activities over the seven-year period in the AFTT Study Area that were analyzed in the 2019 Navy application and for this final rule. The annual numbers for acoustic source classes, explosive source bins, and airgun sources, as well as the annual pile driving and removal activities associated with Navy training and testing activities in the AFTT Study Area are identical to those presented in Tables 8 through 11 of the 2018 AFTT final rule, and are not repeated here. Consistent with the periodicity in the 2018 AFTT final rule, the Navy included the addition of two pile driving/extraction activities for each of the two additional years.

Table 5 describes the acoustic source classes (*i.e.,* low-frequency (LF), mid-frequency (MF), and high-frequency (HF)) that could occur over seven years under the planned training and testing activities. Acoustic source bin use in the activities would vary annually. The seven-year totals for the planned training and testing activities take into account that annual variability.

TABLE 5—ACOUSTIC SOURCE CLASSES ANALYZED AND NUMBER USED FOR SEVEN-YEAR PERIOD FOR TRAINING AND TESTING ACTIVITIES IN THE AFTT STUDY AREA.

Source class category	Bin	Description	Unit [1]	7-Year total	
				Training	Testing
Low-Frequency (LF): Sources that produce signals less than 1 kHz.	LF3	LF sources greater than 200 dB	H	0	9,156
	LF4	LF sources equal to 180 dB and up to 200 dB.	H C	0 0	6,797 140
	LF5	LF sources less than 180 dB	H	60	12,264
	LF6	LF sources greater than 200 dB with long pulse lengths.	H	1,104	280
Mid-Frequency (MF): Tactical and non-tactical sources that produce signals between 1–10 kHz.	MF1	Hull-mounted surface ship sonars (*e.g.,* AN/SQS–53C and AN/SQS–61).	H	36,833	23,358
	MF1K	Kingfisher mode associated with MF1 sonars.	H	819	1,064
	MF3	Hull-mounted submarine sonars (*e.g.,* AN/BQQ–10).	H	14,604	8,799
	MF4	Helicopter-deployed dipping sonars (*e.g.,* AN/AQS–22 and AN/AQS–13).	H	4,196	3,797
	MF5	Active acoustic sonobuoys (*e.g.,* DICASS).	C	47,340	38,663
	MF6	Active underwater sound signal devices (*e.g.,* MK84).	C	0	8,986
	MF8	Active sources (greater than 200 dB) not otherwise binned.	H	0	2,436
	MF9	Active sources (equal to 180 dB and up to 200 dB) not otherwise binned.	H	0	52,128
	MF10	Active sources (greater than 160 dB, but less than 180 dB) not otherwise binned.	H	6,088	39,830

TABLE 5—ACOUSTIC SOURCE CLASSES ANALYZED AND NUMBER USED FOR SEVEN-YEAR PERIOD FOR TRAINING AND TESTING ACTIVITIES IN THE AFTT STUDY AREA.—Continued

Source class category	Bin	Description	Unit [1]	7-Year total	
				Training	Testing
	MF11	Hull-mounted surface ship sonars with an active duty cycle greater than 80%.	H	6,495	9,968
	MF12	Towed array surface ship sonars with an active duty cycle greater than 80%.	H	2,658	9,716
	MF14	Oceanographic MF sonar	H	0	10,080
High-Frequency (HF): Tactical and non-tactical sources that produce signals between 10—100 kHz.	HF1	Hull-mounted submarine sonars (*e.g.,* AN/BQQ–10).	H	13,504	2,772
	HF3	Other hull-mounted submarine sonars (classified).	H	34,275	215
	HF4	Mine detection, classification, and neutralization sonar (*e.g.,* AN/SQS–20).	H	41,717	179,516
	HF5	Active sources (greater than 200 dB) not otherwise binned.	H	0	13,624
			C	0	280
	HF6	Active sources (equal to 180 dB and up to 200 dB) not otherwise binned.	H	0	15,254
	HF7	Active sources (greater than 160 dB, but less than 180 dB) not otherwise binned.	H	0	8,568
	HF8	Hull-mounted surface ship sonars (*e.g.,* AN/SQS–61).	H	140	14,587
Very High-Frequency Sonars (VHF): Non-tactical sources that produce signals between 100—200 kHz.	VHF1	VHF sources greater than 200 dB	H	0	84
Anti-Submarine Warfare (ASW): Tactical sources (*e.g.,* active sonobuoys and acoustic counter-measures systems) used during ASW training and testing activities.	ASW1	MF systems operating above 200 dB	H	4,251	5,740
	ASW2	MF Multistatic Active Coherent sonobuoy (*e.g.,* AN/SSQ–125).	C	10,572	35,842
	ASW3	MF towed active acoustic countermeasure systems (*e.g.,* AN/SLQ–25).	H	34,275	21,737
	ASW4	MF expendable active acoustic device countermeasures (*e.g.,* MK 3).	C	2,994	24,043
	ASW5	MF sonobuoys with high duty cycles	H	4,244	4,316
Torpedoes (TORP): Source classes associated with the active acoustic signals produced by torpedoes.	TORP1	Lightweight torpedo (*e.g.,* MK 46, MK 54, or Anti-Torpedo Torpedo).	C	399	6,122
	TORP2	Heavyweight torpedo (*e.g.,* MK 48)	C	560	2,600
	TORP 3	Heavyweight torpedo (*e.g.,* MK 48)	C	0	640
Forward Looking Sonar (FLS): Forward or upward looking object avoidance sonars used for ship navigation and safety.	FLS2	HF sources with short pulse lengths, narrow beam widths, and focused beam patterns.	H	0	8,568
Acoustic Modems (M): Systems used to transmit data through the water.	M3	MF acoustic modems (greater than 190 dB).	H	0	4,436
Swimmer Detection Sonars (SD): Systems used to detect divers and submerged swimmers.	SD1—SD2.	HF and VHF sources with short pulse lengths, used for the detection of swimmers and other objects for the purpose of port security.	H	0	1,232
Synthetic Aperture Sonars (SAS): Sonars in which active acoustic signals are post-processed to form high-resolution images of the seafloor.	SAS1	MF SAS systems	H	0	6,720
	SAS2	HF SAS systems	H	33,600	24,584
	SAS3	VHF SAS systems	H	0	6,720
	SAS4	MF to HF broadband mine countermeasure sonar.	H	0	6,720
Broadband Sound Sources (BB): Sonar systems with large frequency spectra, used for various purposes.	BB1	MF to HF mine countermeasure sonar	H	0	6,720
	BB2	HF to VHF mine countermeasure sonar	H	0	6,720

TABLE 5—ACOUSTIC SOURCE CLASSES ANALYZED AND NUMBER USED FOR SEVEN-YEAR PERIOD FOR TRAINING AND TESTING ACTIVITIES IN THE AFTT STUDY AREA.—Continued

Source class category	Bin	Description	Unit [1]	7-Year total	
				Training	Testing
	BB4	LF to MF oceanographic source	H	0	10,884
	BB5	LF to MF oceanographic source	H	0	4,704
	BB6	HF oceanographic source	H	0	4,704
	BB7	LF oceanographic source	C	0	840

[1] H = hours; C = count (*e.g.,* number of individual pings or individual sonobuoys).
Note: dB = decibel

Table 6 describes the number of air gun shots that could occur over seven years under the planned training and testing activities.

TABLE 6—TRAINING AND TESTING AIR GUN SOURCES QUANTITATIVELY ANALYZED IN THE AFTT STUDY AREA

Source class category	Bin	Unit [1]	7-Year total [2]	
			Training	Testing
Air Guns (AG): Small underwater air guns	AG	C	0	4,228

[1] C = count. One count (C) of AG is equivalent to 100 air gun firings.
[2] The annual numbers for airgun sources associated with Navy training and testing activities in the AFTT Study Area are identical to those presented in Table 9 in the 2018 AFTT final rule.

Table 7 summarizes the impact pile driving and vibratory pile removal activities that could occur during a 24-hour period. Annually, for impact pile driving, the Navy will drive 119 piles, two times a year for a total of 238 piles. Over the seven-year period of the rule, the Navy will drive a total of 1,666 piles by impact pile driving. Annually, for vibratory pile removal, the Navy will remove 119 piles, two times a year for a total of 238 piles. Over the seven-year period of the rule, the Navy will remove a total of 1,666 piles by vibratory pile removal.

TABLE 7—SUMMARY OF PILE DRIVING AND REMOVAL ACTIVITIES PER 24-HOUR PERIOD IN THE AFTT STUDY AREA

Method	Piles per 24-hour period	Time per pile (minutes)	Total estimated time of noise per 24-hour period (minutes)
Pile Driving (Impact)	6	15	90
Pile Removal (Vibratory)	12	6	72

Table 8 describes the number of in-water explosives that could be used in any year under the planned training and testing activities. Under the activities, bin use would vary annually, and the seven-year totals for the planned training and testing activities take into account that annual variability.

TABLE 8—EXPLOSIVE SOURCE BINS ANALYZED AND NUMBER USED FOR SEVEN-YEAR PERIOD FOR TRAINING AND TESTING ACTIVITIES WITHIN THE AFTT STUDY AREA

Bin	Net explosive weight [1] (lb.)	Example explosive source	7-Year Total [2]	
			Training	Testing
.				
E1	0.1–0.25	Medium-caliber projectile	53,900	160,880
E2	>0.25–0.5	Medium-caliber projectile	1,486	0
E3	>0.5–2.5	Large-caliber projectile	32,144	20,162
E4	>2.5–5	Mine neutralization charge	913	5,330
E5	>5–10	5-inch projectile	10,052	9,275
E6	>10–20	Hellfire missile	4,214	276
E7	> 20–60	Demo block/shaped charge	28	0
E8	>60–100	Light-weight torpedo	154	231
E9	>100–250	500 lb. bomb	462	28
E10	>250–500	Harpoon missile	630	566
E11	>500–650	650 lb. mine	7	70

TABLE 8—EXPLOSIVE SOURCE BINS ANALYZED AND NUMBER USED FOR SEVEN-YEAR PERIOD FOR TRAINING AND TESTING ACTIVITIES WITHIN THE AFTT STUDY AREA—Continued

Bin	Net explosive weight [1] (lb.)	Example explosive source	7-Year Total [2]	
			Training	Testing
E12	>650–1,000	2,000 lb. bomb	126	0
E16 [2]	>7,250–14,500	Littoral Combat Ship full ship shock trial	0	12
E17 [2]	>14,500–58,000	Aircraft carrier full ship shock trial	0	4

[1] Net Explosive Weight refers to the equivalent amount of Trinitrotoluene (TNT) the actual weight of a munition may be larger due to other components.

[2] The annual numbers for explosive source bins associated with Navy training and testing activities in the AFTT Study Area are identical to those presented in Table 11 in the 2018 AFTT final rule.

Note: Shock trials consist of four explosions each. In any given year there could be 0–3 small ship shock trials (E16) and 0–1 large ship shock trials (E17). Over a 7-year period, there could be three small ship shock trials (E16) and one large ship shock trial (E17) which is the same amount of ship shock trial events that could occur over the original five-year period. Therefore, there is no increase in ship shock trial events under this final rule.

Vessel Movement

Vessel movements associated with the planned activities include both surface and sub-surface operations. Vessels used as part of the activities include ships, submarines, unmanned vessels, and boats ranging in size from small, 22 feet (ft) (7 meters (m)) rigid hull inflatable boats to aircraft carriers with lengths up to 1,092 ft. (333 m). Large Navy ships greater than 60 ft (18 m) generally operate at speeds in the range of 10 to 15 kn for fuel conservation. Submarines generally operate at speeds in the range of 8 to 13 kn in transits and less than those speeds for certain tactical maneuvers. Small craft, less than 60 ft (18 m) in length, have much more variable speeds (dependent on the mission). For small craft types, sizes and speeds vary during training and testing. Speeds generally range from 10 to 14 kn. While these speeds for large and small crafts are representative of most events, some vessels need to temporarily operate outside of these parameters. A full description of Navy vessels that are used during training and testing activities and will be used under the seven-year period of this rule can be found in the 2017 Navy application and Chapter 2 of the 2018 AFTT FEIS/OEIS.

The manner in which Navy vessels will be used during training and testing activities, the speeds at which they operate, the number of vessels that will be used during various activities, and the locations in which Navy vessel movement will be concentrated within the AFTT Study Area are identical to those analyzed in the 2018 AFTT final rule. The only change related to the Navy's request regarding Navy vessel movement is the vessel use associated with the additional two years of Navy activities.

Standard Operating Procedures

For training and testing to be effective, personnel must be able to safely use their sensors and weapon systems as they are intended to be used in a real-world situation and to their optimum capabilities. While standard operating procedures are designed for the safety of personnel and equipment and to ensure the success of training and testing activities, their implementation often yields additional benefits on environmental, socioeconomic, public health and safety, and cultural resources. Because standard operating procedures are essential to safety and mission success, the Navy considers them to be part of the planned activities and has included them in the environmental analysis. Details on standard operating procedures were provided in the 2018 AFTT proposed rule; please see the 2018 AFTT proposed rule, the 2017 Navy application, and Chapter 2 of the 2018 AFTT FEIS/OEIS for more information. The Standard Operating Procedures for the seven-year period will be identical to those in place under the 2018 AFTT final rule.

Comments and Responses

On February 1, 2019, we published a notice of receipt (NOR) of the Navy's application in the **Federal Register** (84 FR 1069), and requested comments and information related to the Navy's request. The review and comment period for the NOR ended on March 4, 2019. We reviewed and considered all comments and information received on the NOR in development of the proposed rule. We published a proposed rule in the **Federal Register** on May 13, 2019 (84 FR 21126), with a 30-day comment period. In that proposed rule, we requested public input on the request for authorization described therein, our analyses, and the proposed authorizations and requested that interested persons submit relevant information, suggestions, and comments. During the 30-day comment period, we received eight comment letters. Of this total, one submission was from the Marine Mammal Commission (hereafter ''Commission''), one letter was from an organization or individual acting in an official capacity (*e.g.,* non-governmental organization (NGO)) and six submissions were from private citizens. NMFS has reviewed and considered all public comments received on the proposed rule and issuance of the LOAs. All relevant comments and our responses are described below. We provide no response to specific comments that addressed species or statutes not relevant to our proposed authorization under section 101(a)(5)(A) of the MMPA (*e.g.,* comments related to sea turtles).

The majority of the six comment letters from private citizens expressed general opposition toward the Navy's proposed training and testing activities and requested that NMFS not issue the LOAs, but without providing information relevant to NMFS' decisions. These comments appear to indicate a lack of understanding of the MMPA's requirement that NMFS ''shall issue'' requested authorizations when certain findings (see the *Background* section) are met; therefore, these comments were not considered further. The remaining comments are addressed below.

Both the Commission and NGO included their comments submitted on the 2018 AFTT proposed rule. The Commission did not reiterate their 2018 AFTT proposed rule recommendations in their comment letter but maintained that the recommendations that NMFS did not incorporate into the 2018 AFTT final rule are still relevant and pertain

to the extension of the five-year rule and asked that they be reviewed again in the course of considering the new seven-year rule. The NGO attached their 2018 AFTT proposed rule comment letter and their comments on the Notice of Receipt of the 2019 Navy application. They stated that ''most of the issues raised [in their 2018 AFTT proposed rule comment letter] were not adequately addressed in the 2018–2023 Final Rule'' and asked that NMFS renew consideration of their prior comments. To the extent they raised concerns with how ''most'' issues were addressed previously, it did not identify which issues those were. NMFS reviewed, considered, and responded to all comments received on the 2018 AFTT proposed rule and issuance of the proposed LOAs. Please see the 2018 AFTT final rule *Comments and Responses* section for a summary of the comments received and NMFS' responses to these comments. As the NGO resubmitted their comments on the Notice of Receipt of the 2019 Navy Application, we respond to those comments below.

Comment 1: Commenters noted that NMFS did not propose to authorize beaked whale mortalities subsequent to MFA sonar use for any of the Navy's Phase III activities and states that that approach is inconsistent with the tack taken for both the Trajectory Analysis Planner (TAP) I and Phase II activities. The Commenters noted that for the previous final rule for AFTT (78 FR 73009; December 4, 2013), NMFS authorized up to 10 beaked whale mortality takes during the five-year period of the final rule (78 FR 73067; December 4, 2013). They noted that NMFS justified authorizing those mortalities by stating that, although NMFS and the Navy do not anticipate any beaked whale strandings to occur and no strandings have ever been reported in the AFTT Study Area, NMFS cannot conclude with certainty the degree to which mitigation measures would eliminate or reduce the potential for serious injury or mortality (78 FR 73043; December 4, 2013). The Commenters stated that this justification is still applicable. The Commenters asserted that NMFS indicated that steep bathymetry, multiple hull-mounted platforms using sonar simultaneously, constricted channels, and strong surface ducts are not all present together in the AFTT Study Area during the specified activities (83 FR 57116; November 14, 2018), and that NMFS specified that it did not authorize beaked whale mortalities in the 2018 AFTT final rule based on the lack of those factors and the lack of any strandings associated with Navy sonar use in the AFTT Study Area (83 FR 57116; November 14, 2018). The Commenters stated that this does not comport with NMFS' acknowledgement in the 2018 AFTT proposed rule that all five of those factors are not necessary for a stranding to occur (83 FR 11012; March 13, 2018). They go on to state that ''NMFS still cannot conclude with certainty the degree to which mitigation measures would eliminate or reduce the potential for serious injury or mortality. This is especially true for a species that is cryptic and difficult for researchers, let alone Navy Lookouts, to observe visually in order to implement mitigation measures, and while passive acoustic monitoring could readily detect beaked whales, it is not used by the Navy as part of its mitigation measures involving MFA sonar.'' Given that the potential for beaked whale mortalities cannot be obviated, the Commenters recommend that NMFS authorize at least 10 mortality takes of beaked whales subsequent to MFA sonar use, consistent with the AFTT Phase II final rule (83 FR 57076).

Response: NMFS does not disregard the fact that it is possible for naval activities using hull-mounted tactical sonar to contribute to the death of marine mammals in certain circumstances (that are not present in the AFTT Study Area) via strandings resulting from behaviorally mediated physiological impacts or other gas-related injuries. NMFS included a discussion in the 2018 AFTT proposed and final rules of these potential causes and outlines the few cases where active naval sonar (in the U.S. or, largely, elsewhere) has either potentially contributed to or (as with the Bahamas example) been more definitively causally linked with marine mammal strandings. As noted, there are a suite of factors that have been associated with these specific cases of strandings directly associated with sonar (steep bathymetry, multiple hull-mounted platforms using sonar simultaneously, constricted channels, strong surface ducts, *etc.*). The Commenters are incorrect, however, in implying that NMFS found all these features must be present together. While not all of these factors must be present for a beaked whale stranding to occur, steep bathymetry and constricted channels specifically are not present in the AFTT Study Area, and surface ducts are not consistently present at any location. Further, in addition to the mitigation and monitoring measures in place (visual monitoring, passive acoustic monitoring when practicable, *etc.,* see the 2018 AFTT final rule *Mitigation* and *Monitoring* sections for a full description of these measures) the Navy minimizes active sonar military readiness activities when these features are present (in other areas outside of the AFTT Study Area) to the maximum extent practicable to meet specific training or testing requirements. Additionally, there have never been any strandings associated with Navy sonar use in the AFTT Study Area, including in the five years of Navy activities since the 2013 authorizations referenced by the Commenters. For these reasons as well as the other reasons discussed more fully in the 2018 AFTT final rule (*e.g.,* mitigation measures, monitoring, *etc.*), NMFS does not anticipate that the Navy's AFTT training and testing activities will result in beaked whale strandings and mortality, and none are authorized.

Comment 2: Commenters stated that NMFS cannot amend the existing five-year rule without undertaking a new negligible impact analysis for the full seven years of AFTT activity. They stated that while the Navy has not proposed any changes in activity parameters for the take that NMFS previously authorized, the addition of two years of explosives, sonar, and other disruptive activities alters the scope of that previous analysis. They go one to state that barring a negligible impact finding predicated on seven years of activity, taking into account the full extent of mortality, injury, and significant behavioral disruption that that entails, NMFS cannot amend the rule as the Navy has requested.

Response: NMFS agrees and conducted a negligible impact analysis for the full seven years of Navy training and testing activity in the AFTT Study Area in both the 2019 AFTT proposed rule and this final rule. Please see the *Analysis and Negligible Impact Determination* section below.

Comment 3: Commenters stated that NMFS must rigorously assess cumulative impacts on the same populations from other authorized and reasonably foreseeable activities, including the five large-scale seismic surveys that NMFS authorized in November, 2018 as well as the additional five years of oil and gas exploration that BOEM included in its 2014 Programmatic Environmental Impact Statement for Atlantic seismic, to which NMFS tiered its November environmental assessments. They note that NMFS has repeatedly recognized the importance of accounting for cumulative effects of human activity on marine mammal populations, including

the cumulative effects of acoustic disturbance and masking, but that despite this NMFS has made its negligible impact findings as though each authorized activity were taking place in a vacuum, resulting in an acoustic environment where the same populations are repeatedly harmed. The Commenters note that at particular risk are range-restricted populations that are resident off Cape Hatteras; as well as species already suffering from poor individual fitness, most notably the North Atlantic right whale.

Response: We recognize the need to address total impacts from the Navy's activities, and that the total impacts of the Navy's training and testing activities could be greater than the impacts of any one particular activity. The total impacts of the Navy's training and testing activities were evaluated for each species and stock in the *Group and Species-Specific Analyses* section of the *Analysis and Negligible Impact Determination* section of this rule and the 2018 AFTT final rule. See also the 2018 AFTT FEIS/OEIS, which evaluated the impacts of a maximum amount of activities, and which NMFS has adopted as the basis for its Record of Decision for the issuance of the final rule and LOAs.

As described in the 2019 AFTT proposed rule and this final rule along with the 2018 AFTT final rule, the preamble for NMFS' implementing regulations under section 101(a)(5) (54 FR 40338; September 29, 1989) explains in responses to comments that the impacts from other past and ongoing anthropogenic activities are incorporated into the negligible impact analysis via their impacts on the environmental baseline. Consistent with that direction, NMFS here has factored into its negligible impact analyses the impacts of other past and ongoing anthropogenic activities via their impacts on the baseline (*e.g.,* as reflected in the density/distribution and status of the species, population size and growth rate, and relevant stressors (such as incidental mortality in commercial fisheries, UMEs, or oil spills)). See the *Analysis and Negligible Impact Determination* section of this rule and the 2018 AFTT final rule.

Our 1989 final rule for the MMPA implementing regulations also addressed how cumulative effects from unrelated activities would be considered. There we stated that such effects are not considered in making findings under section 101(a)(5) concerning negligible impact, but that NMFS would consider cumulative effects that are reasonably foreseeable when preparing a National Environmental Policy Act (NEPA) analysis and also that reasonably foreseeable cumulative effects would be considered under section 7 of the Endangered Species Act (ESA) for ESA-listed species.

The cumulative effects of the incremental impact of the proposed action when added to other past, present, and reasonably foreseeable future actions (as well as the effects of climate change) were evaluated against the appropriate resources and regulatory baselines in the 2018 AFTT FEIS/OIES. The best available science and a comprehensive review of past, present, and reasonably foreseeable actions (including the potential for oil and gas exploration in the Atlantic, as the commenter notes) was used to develop the Cumulative Impacts analysis. This analysis is contained in Chapter 4 of the 2018 AFTT FEIS/OIES. As required under NEPA, the level and scope of the analysis is commensurate with the scope of potential impacts of the action and the extent and character of the potentially-impacted resources (*e.g.,* the geographic boundaries for cumulative impacts analysis for some resources are expanded to include activities outside the AFTT Study Area that might impact migratory or wide-ranging animals), as reflected in the resource-specific discussions in Chapter 3 (Affected Environment and Environmental Consequences) of the 2018 AFTT FEIS/OEIS. The 2018 AFTT FEIS/OEIS considered the proposed training and testing activities alongside other actions in the region whose impacts may be additive to those of the proposed training and testing. Past and present actions are also included in the analytical process as part of the affected environmental baseline conditions presented in Chapter 3 of the 2018 AFTT FEIS/OEIS. The 2018 AFTT FEIS/OEIS did so in accordance with 1997 Council on Environmental Quality (CEQ) guidance. Per the guidance, a qualitative approach and best professional judgment are appropriate where precise measurements are not available. Where precise measurements and/or methodologies were available they were used. Guidance from CEQ states it ''is not practical to analyze cumulative effects of an action on the universe; the list of environmental effects must focus on those that are truly meaningful.'' Further, the U.S. EPA reviewed the 2018 AFTT FEIS/OEIS and rated the document as LO—lack of objections—which means it did not identify any environmental impact requiring substantive changes to the proposal. Information on the NEPA analysis is provided in Section 4.1.1 (Determination of Significance).

Comment 4: Commenters stated that NMFS should rigorously review its adaptive management procedures for military readiness activities for transparency, enforceability, and effectiveness, to strengthen their integrity for a seven-year authorization cycle. They particularly noted the need to ensure that research required, or simply recommended, by NMFS during the rulemaking process is actually completed by the Navy, as adaptive management cannot proceed if the underlying research to resolve uncertainties is not performed.

Response: NMFS has rigorously reviewed its adaptive management procedures for military readiness activities for transparency, enforceability, and effectiveness and continues to do so on an annual basis. In addition to the comprehensive written reports provided by the Navy and reviewed by NMFS, NMFS holds dual-purpose annual Monitoring and Adaptive Management meetings with the Navy that address all of the concerns the commenter raises. First, the Navy annually convenes the researchers conducting the monitoring studies required by the MMPA rules for Navy Training and Testing (along with NMFS and Commission staff) to discuss their work and results, allowing for direct meaningful discourse between the researchers on the ground and regulators, as well as the opportunity for the researchers to highlight challenges and recommendations for future work. Second, NMFS, the Commission, and Navy staff meet to specifically discuss: (1) Exercise Reports detailing the non-classified extent of activities conducted, associated mitigation implemented, and marine mammals detected; (2) the list of monitoring projects and which are finishing, continuing, or newly starting; (3) new science potentially applicable in an adaptive management context, and; (4) whether any changes to monitoring or mitigation are appropriate pursuant to the Adaptive Management provisions.

Comment 5: Commenters stated that NMFS must improve its negligible impact analysis and mitigation in issuing a new rule. They note that the Navy's application proposed no substantial changes in its take estimation, impact assessment, or mitigation measures, notwithstanding the issues raised during the previous rulemaking by Commenters.

Response: NMFS reviewed, considered, and responded to all comments received on the 2018 AFTT proposed rule and issuance of the proposed LOAs. Please see the 2018

AFTT final rule *Comments and Responses* section for a summary of the comments received and NMFS' responses to these comments. The 2019 AFTT proposed rule and this final rule contain thorough and complete analysis of the incidental take that is estimated or has the potential to occur from the Navy's activities, along with analysis of appropriate mitigation measures under the least practicable adverse impact standard. All analysis, including the negligible impact analysis for each species and stock, has been updated from the 2018 AFTT final rule as appropriate based on the Navy's application, any new information, and in consideration of all comments received.

Comment 6: Commenters stated that NMFS presents a flawed updated vessel strike analysis. The Commenters stated that the Navy made its take authorization request based on a Poisson distribution using ship-strike data (from strikes involving Navy vessels only) between 2009 and 2018 in the AFTT Study Area, as well as historical at-sea days in the AFTT Study Area from 2009–2018 and estimated potential at-sea days for the period from 2018–2025 covered by the requested regulations. This distribution predicted the probabilities of a specific number of strikes over the 2018–2025 period. The Commenters go on to state that in its take analysis, NMFS considered two factors in addition to those included in the Navy's request: (1) the relative likelihood of hitting members of one stock versus another, based on available data from all vessel strikes enumerated in the agency's Stock Assessment Reports (SARs); and (2) whether the Navy has ever definitively struck an individual from a particular stock and, if so, how many times. The Commenters stated that, thus in determining vessel strike probability, the agency's analysis only factors in vessel strikes reported by the Navy, rather than more objectively taking into account the total number of Navy ships that will be operating in the AFTT Study Area. The Commenters stated that some conditions the Navy operates in, including darkness and high sea states, would likely make it impossible to detect every vessel strike that occurred. In addition, some of the features of military vessels that NMFS notes as reducing vessel strike probability, such as the use of marine mammal Lookouts, would also only be effective in periods of good visibility. Therefore, the agency should not use the number of vessel strikes reported by the Navy as the basis for its vessel strike analysis. The Commenters stated that NMFS instead should analyze the likelihood of a ship hitting a particular stock in the AFTT Study Area (as based on the SARs) and the total number of Navy vessels, or the total amount of Navy vessel time spent operating within the AFTT Study Area.

Response: The Commenters are correct in stating that the Navy requested incidental takes due to vessel strikes based on probabilities derived from a Poisson distribution using Navy ship strike data between 2009 and 2018 in the AFTT Study Area (the time period from when current vessel strike mitigation measures were instituted until the Navy conducted the analysis for the 2019 Navy application, with no new ship strikes occurring since this analysis), as well as historical at-sea days in the AFTT Study Area from 2009–2018 and estimated potential at-sea days for the period from 2018 to 2025 covered by the requested regulations. NMFS concurs with the Navy that it is appropriate to use Navy ship strike data in this analysis, rather than all known ship strikes (as presented in the SARs), because there are key differences between Navy vessels and commercial vessels, as described in the *Authorized Take from Vessel Strikes* section, which reduce the potential of ship strikes by Navy vessels and provide confidence that any ship strike that did occur would be detected and reported. The Navy also implements mitigation measures (Lookouts, passive sonar when practicable, *etc.*) that are not implemented by commercial vessels. While visibility is decreased in certain situations, such as nighttime as described by the commenters, ships operated by or for the Navy have personnel assigned to stand watch at all times, day and night, when underway for safety of navigation, collision avoidance, range clearance, and man-overboard precautions. After sunset and prior to sunrise, watch personnel employ night visual search techniques, which can include the use of night vision devices. The Navy is able to detect if a whale is struck due to the diligence of standard watch personnel and Lookouts stationed specifically to observe for marine mammals while a vessel is underway, day and night. These measures make it highly unlikely that a Navy vessel would strike a whale, dolphin, porpoise, or pinniped without detecting and reporting it and, accordingly, NMFS is confident that the Navy's reported strikes are accurate and appropriate for use in the analysis.

NMFS uses all available information to determine the likelihood of vessel strike to a particular stock. As the commenter correctly asserts, NMFS considered two factors in addition to those considered in the Navy's request: (1) The relative likelihood of hitting one stock versus another based on available strike data from all vessel types as denoted in the SARs and (2) whether the Navy has ever definitively struck an individual from a particular stock and, if so, how many times. For a detailed description of the methods used to analyze the likelihood of vessel strikes, see the *Authorized Take from Vessel Strikes* section. However, the analysis does take into account the total number of Navy ships that will be operating in the AFTT Study Area. The estimated potential at-sea days for the period from 2018 to 2025 takes into account both the number of vessels and the number of days each vessel will operate in the AFTT Study Area. In other words, the number of vessel at-sea days directly reflects the number of vessels. Indeed this metric does exactly what the commenter suggests, which is that NMFS ''analyze the likelihood of a ship hitting a particular stock in the AFTT Study Area (as based on the SARs) and the total number of Navy vessels, *or the total amount of Navy vessel time spent operating within the AFTT Study Area.*''

Comment 7: Commenters stated that NMFS' adjustment of injury and mortality numbers for ''mitigation effectiveness'' remains arbitrary. The Commenters noted that in the 2018 AFTT final rule, NMFS stated that the Navy quantitatively assessed the effectiveness of its monitoring-based mitigation on a per-scenario basis using four factors: (1) Species sightability; (2) a Lookout's ability to observe the range to permanent threshold shift and range to mortality; (3) the portion of time when mitigation could be observed during periods of poor visibility or at night; and (4) the ability of sound sources to be positively controlled (*i.e.,* powered down) (83 FR 57076, 57115; November 14, 2018). The Commenters noted that NMFS then concluded that the Navy adequately accounted for mitigation effectiveness in its adjustment of take. The Commenters stated that while NMFS explained its support of the Navy's approach, as requested in these Commenters' comments on the 2018 AFTT proposed rule, the adjustments the Navy makes to account for reduced mitigation effectiveness at night or during periods of poor visibility still overestimate the potential level of mitigation effectiveness. The Commenters provided the following example to support this statement: ''If a scenario occurs in a high sea state (Beaufort sea

state of 4 or higher), then the Navy applies a visibility reduction factor of 0.25. However, the probability of sighting a North Atlantic right whale, for example, changed by a factor of 0.628 (95 percent CI: 0.428–0.921) for every unit increase in sea state. From the findings of Baumgartner *et al.* (2003), we would expect a reduction in detection probability of North Atlantic right whales by up to 84.5 percent based on an average Beaufort Sea State of 4, relative to ideal sighting conditions (*i.e.,* Beaufort Sea State = 0). The reduction of the effectiveness of a Navy lookout watching for North Atlantic right whales in Beaufort Sea State 4, would therefore be significantly greater than the 0.25 factored into the Navy's analysis.'' The Commenters reiterated their caution to NMFS against creating an under-supported, nonconservative adjustment for avoidance in the current AFTT final rule.

Response: As described in the technical report titled ''Quantifying Acoustic Impacts on Marine Mammals and Sea Turtles: Methods and Analytical Approach for Phase III Training and Testing'' (U.S. Department of the Navy, 2018), the Navy conservatively factored mitigation effectiveness (*i.e.,* underestimated mitigation effectiveness) into its quantitative analysis process. To calculate a mitigation effectiveness score for each scenario, the Navy multiplied the Species Sightability Factor, g(0), by a Visibility Factor [0.25, 0.5, 0.75, 1], then by an Observation Area Factor [0, 0.5, 1], and lastly by a Positive Control Factor [0, 0.5, 1]. Using a logistic regression model, Baumgartner *et al.* (2003) presented evidence to suggest there is an effect of sea state on the probability of sighting that changes by a factor of 0.628 for every unit increase in sea state. However, the authors did not suggest that the 0.628 factor should be applied to further reduce g(0) values that already consider sea state. The North Atlantic right whale g(0) value used by the Navy already takes into account perception bias (including sea state). Therefore, the Navy's approach to calculating mitigation effectiveness is more conservative than what is being suggested by Baumgartner *et al.* (2003) because the Navy reduced mitigation effectiveness twice based on sea state: once by using g(0) values that already incorporate perception bias, and again by multiplying g(0) by additional visibility factors. Another example of how the Navy's method for calculating mitigation effectiveness is conservative is that the Navy assigns worst-case scores (instead of typical-case scores) to each effectiveness factor. For example, the Navy assigns a visibility reduction factor of 0.25 if a scenario has the ''potential'' to occur in Beaufort sea state 4 or higher, even if it typically occurs in Beaufort sea state 3 or lower. Similarly, the Navy assigns another visibility reduction factor of 0.25 or 0.50 if the scenario ''could'' occur at night, rounding up to the most conservative reduction factor based on percent chance of nighttime occurrence.

Below is a simplified hypothetical calculation for a scenario involving hull-mounted mid-frequency active sonar. The furthest average range to a potential permanent threshold shift (PTS) exposure for the largest source bin used in this scenario, MF1, is 192 m. The hypothetical scenario uses a positive control sound source, would rarely occur in a Beaufort 4 sea state, and has a 10 percent chance of occurring at night. Lookouts are able to observe the entire range to PTS (192 m around the ship) for the duration of the scenario. This hypothetical scenario has 10 model-estimated PTS impacts.

Mitigation Effectiveness = Species Sightability [vessel sightability g(0) of 0.645 (Palka 2006)] × Visibility [1 − (0.25 reduction for sea state + 0.25 reduction for night) = 0.50] × Observation Area [1] × Positive Control [1] = 0.323

Number of animals assumed sighted by Lookouts = Mitigation Effectiveness [0.323] × Model-Estimated Impacts [10 model-estimated PTS impacts] = 3.23 (rounded down to 3)

This hypothetical calculation results in 3 out of 10 marine mammals being sighted by Lookouts within the average range to PTS (192 m from the ship). Mitigation measures would be implemented for these three individuals, and therefore, these animals would not be exposed to PTS-level impacts. The Navy corrects the category of predicted impact for these three animals (*i.e.,* shifts the level of three impacts from PTS to temporary threshold shift (TTS)), but does not modify the total number of impacts predicted from the scenario.

For reasons detailed in the technical report, the small range to PTS and close proximity to the observation platform would in reality result in a much higher likelihood that Lookouts would detect more than three marine mammals within 192 m from the ship hull. For example, the Species Sightability reduction factors, g(0), are based on values obtained during line-transect surveys, where each primary observer looks for marine species in the forward 90-degree quadrant on their side of the survey platform out to the limit of the available optics (*i.e.,* the horizon). In this example, Navy Lookouts would focus their observations directly on the sea space in front of the ship in an area several degrees of magnitude smaller than that used to calculate species sightability. However, as previously described, the Navy's approach to estimating marine mammal impacts integrates a host of conservative assumptions to ensure that potential impacts are overestimated instead of underestimated.

Description of Marine Mammals and Their Habitat in the Area of the Specified Activities

Marine mammal species and their associated stocks that have the potential to occur in the AFTT Study Area are presented in Table 9 along with the best/minimum abundance estimate and associated coefficient of variation value. Some marine mammal species, such as manatees, are not managed by NMFS, but by the U.S. Fish and Wildlife Service and therefore not discussed below. Consistent with the 2018 AFTT final rule, the Navy anticipates the take of individuals of 39 marine mammal species by Level A harassment and Level B harassment incidental to training and testing activities from the use of sonar and other transducers, in-water detonations, air guns, and impact pile driving/vibratory extraction activities. The Navy requested authorization for nine serious injuries or mortalities combined from four marine mammal stocks during ship shock trials, and four takes of large whales by serious injury or mortality from vessel strikes over the seven-year period.

We presented a detailed discussion of marine mammals and their occurrence in the AFTT Study Area, inclusive of important marine mammal habitat (*e.g.,* critical habitat), biologically important areas (BIAs), national marine sanctuaries (NMSs), and unusual mortality events (UMEs) in the 2018 AFTT proposed rule and 2018 AFTT final rule; please see these rules and the 2017 and 2019 Navy applications for additional information. There have been no changes to important marine mammal habitat, BIAs, NMSs, or Endangered Species Act (16 U.S.C. 1531 *et seq.;* ESA) designated critical habitat since the issuance of the 2018 AFTT final rule; therefore the information that supports our determinations here can be found in the 2018 AFTT proposed and final rules. NMFS has reviewed and incorporated into this rule the most recent Stock Assessment Reports (SARs) (Hayes *et al.,* 2019, which can be found

at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessment-reports-region*); updated information on relevant UMEs (see below); and new scientific literature (see the *Potential Effects of Specified Activities on Marine Mammals and their Habitat* section), and determined that none of these nor any other new information changes our determination of which species or stocks have the potential to be affected by the Navy's activities or the pertinent information in the *Description of Marine Mammals and Their Habitat in the Area of the Specified Activities* section in the 2018 AFTT proposed and final rules. Therefore, the information presented in those sections of the 2018 proposed and final rules remains current and valid.

As described in the 2018 AFTT final rule, the species carried forward for analysis are those likely to be found in the AFTT Study Area based on the most recent data available, and do not include stocks or species that may have once inhabited or transited the area but have not been sighted in recent years and therefore are extremely unlikely to occur in the AFTT Study Area (*e.g.,* species which were extirpated because of factors such as nineteenth and twentieth century commercial exploitation).

The species not carried forward for analysis (addressed in more detail in the *Description of Marine Mammals and Their Habitat in the Area of the Specified Activities* section of the 2018 AFTT final rule) include the bowhead whale, beluga whale, and narwhal, as these would be considered extralimital and are not part of the AFTT Study Area seasonal species assemblage. Additionally, for multiple bottlenose dolphin stocks, there was no potential for overlap with any stressors from Navy activities; therefore, there would be no adverse effects (or takes), and those stocks were not considered further. Specifically, with the exception of the Mississippi Sound, Lake Borgne, Bay Boudreau stock of bottlenose dolphins (which is addressed in the *Analysis and Negligible Impact Determination* section below), there is no potential for overlap of any Navy stressor with any other bay, sound, or estuary stocks in the northern Gulf of Mexico. Also, the following bottlenose dolphin stocks for the Atlantic do not have any potential for overlap with Navy activity stressors (or take), and therefore are not considered further: Northern South Carolina Estuarine System, Charleston Estuarine System, Northern Georgia/Southern South Carolina Estuarine System, Central Georgia Estuarine System, Southern Georgia Estuarine System, Biscayne Bay, and Florida Bay stocks. For the same reason, bottlenose dolphins off the coasts of Puerto Rico and the U.S. Virgin Islands were also not considered further.

TABLE 9—MARINE MAMMALS POTENTIALLY PRESENT IN THE AFTT STUDY AREA

Common name	*Scientific name* [1]	*Stock* [2]	*ESA/MMPA Status* [3]	*Stock Abundance* [4]	*Occurrence in AFTT study area* [5]		
				Best/minimum population	*Open ocean*	*Large marine ecosystems*	*Inland waters*
Order Cetacea							
Suborder Mysticeti (baleen whales)							
Family Balaenidae (right whales):							
Bowhead whale.	*Balaena mysticetus*	Eastern Canada-West Greenland.	Endangered, strategic, depleted.	7,660 (4,500–11,100) [6].	Labrador Current	Newfoundland-Labrador Shelf, West Greenland Shelf, Northeast U.S. Continental Shelf.	NA.
North Atlantic right whale.	*Eubalaena glacialis*	Western	Endangered, strategic, depleted.	451 (0)/445	Gulf Stream, Labrador Current, North Atlantic Gyre.	Southeast U.S. Continental Shelf, Northeast U.S. Continental Shelf, Scotian Shelf, Newfoundland-Labrador Shelf, Gulf of Mexico (extralimital).	NA.
Family Balaenopteridae (rorquals):							
Blue whale	*Balaenoptera musculus.*	Western North Atlantic (Gulf of St. Lawrence).	Endangered, strategic, depleted.	Unknown/440 [11] ..	Gulf Stream, North Atlantic Gyre, Labrador Current.	Northeast U.S. Continental Shelf, Scotian Shelf, Newfoundland-Labrador Shelf, Southeast U.S. Continental Shelf, Caribbean Sea, and Gulf of Mexico (strandings only).	NA.
Bryde's whale	*Balaenoptera brydei/edeni.*	Northern Gulf of Mexico and NSD [21].	Endangered, strategic.	33 (1.07)/16	Gulf Stream, North Atlantic Gyre.	Gulf of Mexico	NA.

TABLE 9—MARINE MAMMALS POTENTIALLY PRESENT IN THE AFTT STUDY AREA—Continued

Common name	Scientific name[1]	Stock[2]	ESA/MMPA Status[3]	Stock Abundance[4]	Occurrence in AFTT study area[5]		
				Best/minimum population	Open ocean	Large marine ecosystems	Inland waters
Fin whale	*Balaenoptera physalus.*	Western North Atlantic.	Endangered, strategic, depleted.	1,618 (0. 33)/1,234	Gulf Stream, North Atlantic Gyre, Labrador Current.	Caribbean Sea, Gulf of Mexico, Southeast U.S. Continental Shelf, Northeast U.S. Continental Shelf, Scotian Shelf, Newfoundland-Labrador Shelf.	NA.
		West Greenland	Endangered, strategic, depleted.	4,468 (1,343–14,871)[9].	Labrador Current	West Greenland Shelf.	NA.
		Gulf of St. Lawrence.	Endangered, strategic, depleted.	328 (306–350)[10]	Gulf of St. Lawrence.	Newfoundland-Labrador Shelf, Scotian Shelf.	NA.
Humpback whale	*Megaptera novaeangliae.*	Gulf of Maine	NA	896 (0)/896	Gulf Stream, North Atlantic Gyre, Labrador Current.	Gulf of Mexico, Caribbean Sea, Southeast U.S. Continental Shelf, Northeast U.S. Continental Shelf, Scotian Shelf, Newfoundland-Labrador Shelf.	NA.
Minke whale	*Balaenoptera acutorostrata.*	Canadian Eastern Coastal.	NA	2,591 (0.81)/1,425.	Gulf Stream, North Atlantic Gyre, Labrador Current.	Caribbean Sea, Southeast U.S. Continental Shelf, Northeast U.S. Continental Shelf, Scotian Shelf, Newfoundland-Labrador Shelf.	NA.
		West Greenland[7]	NA	16,609 (range: 7,172–38,461)/NA[7].	Labrador Current	West Greenland Shelf.	NA.
Sei whale	*Balaenoptera borealis.*	Nova Scotia	Endangered, strategic, depleted.	357 (0.52)/236	Gulf Stream, North Atlantic Gyre.	Gulf of Mexico, Caribbean Sea, Southeast Northeast U.S. Continental Shelf, Scotian Shelf, Newfoundland-Labrador Shelf.	NA.
		Labrador Sea	Endangered, strategic, depleted.	Unknown[8]	Labrador Current	Newfoundland-Labrador Shelf, West Greenland Shelf.	NA.
Family Physeteridae (sperm whale)							
Suborder Odontoceti (toothed whales)							
Sperm whale	*Physeter macrocephalus.*	North Atlantic	Endangered, strategic, depleted.	2,288 (0.28)/1,815.	Gulf Stream, North Atlantic Gyre, Labrador Current.	Southeast U.S. Continental Shelf, Northeast U.S. Continental Shelf, Scotian Shelf, Newfoundland-Labrador Shelf, Caribbean Sea.	NA.
		Northern Gulf of Mexico.	Endangered, strategic, depleted.	763 (0.38)/560	NA	Gulf of Mexico	NA.
		Puerto Rico and U.S. Virgin Islands.	Endangered, strategic, depleted.	Unknown	North Atlantic Gyre.	Caribbean Sea	NA.

TABLE 9—MARINE MAMMALS POTENTIALLY PRESENT IN THE AFTT STUDY AREA—Continued

Common name	Scientific name[1]	Stock[2]	ESA/MMPA Status[3]	Stock Abundance[4]	Occurrence in AFTT study area[5]		
				Best/minimum population	Open ocean	Large marine ecosystems	Inland waters
Family Kogiidae (sperm whales)							
Pygmy and dwarf sperm whales.	*Kogia breviceps* and *Kogia sima*.	Western North Atlantic.	NA	3,785 (0.47)/2,598[12].	Gulf Stream, North Atlantic Gyre.	Southeast U.S. Continental Shelf, Northeast U.S. Continental Shelf, Scotian Shelf, Newfoundland-Labrador Shelf, Caribbean Sea.	NA.
		Northern Gulf of Mexico.	NA	186 (1.04)/90[12]	NA	Gulf of Mexico, Caribbean Sea.	NA.
Family Monodontidae (beluga whale and narwhal)							
Beluga whale	*Delphinapterus leucas*.	Eastern High Arctic/Baffin Bay[13].	NA	21,213 (10,985–32,619)[13].	Labrador Current	West Greenland Shelf.	NA.
		West Greenland[14].	NA	10,595 (4.904–24,650)[14].	NA	West Greenland Shelf.	NA.
Narwhal	*Monodon monoceros*.	NA[15]	NA	NA[15]	NA	Newfoundland-Labrador Shelf, West Greenland Shelf.	NA.
Family Ziphiidae (beaked whales)							
Blainville's beaked whale.	*Mesoplodon densirostris*.	Western North Atlantic[16].	NA	7,092 (0.54)/4,632[17].	Gulf Stream, North Atlantic Gyre, Labrador Current.	Southeast U.S. Continental Shelf, Northeast U.S. Continental Shelf, Scotian Shelf, Newfoundland-Labrador Shelf.	NA.
		Northern Gulf of Mexico.	NA	149 (0.91)/77[18]	NA	Gulf of Mexico, Caribbean Sea.	NA.
Cuvier's beaked whale.	*Ziphius cavirostris*	Western North Atlantic[16].	NA	6,532 (0.32)/5,021.	Gulf Stream, North Atlantic Gyre.	Southeast U.S. Continental Shelf, Northeast U.S. Continental Shelf, Scotian Shelf, Newfoundland-Labrador Shelf.	NA.
		Northern Gulf of Mexico[16].	NA	74 (1.04)/36	NA	Gulf of Mexico, Caribbean Sea.	NA.
		Puerto Rico and U.S. Virgin Islands.	Strategic	Unknown	NA	Caribbean Sea	NA.
Gervais' beaked whale.	*Mesoplodon europaeus*.	Western North Atlantic[16].	NA	7,092 (0.54)/4,632[17].	Gulf Stream, North Atlantic Gyre.	Southeast U.S. Continental Shelf, Northeast United States Continental Shelf.	NA.
		Northern Gulf of Mexico[16].	NA	149 (0.91)/77[18]	Gulf Stream, North Atlantic Gyre.	Gulf of Mexico, Caribbean Sea.	NA.
Northern bottlenose whale.	*Hyperoodon ampullatus*.	Western North Atlantic.	NA	Unknown	Gulf Stream, North Atlantic Gyre, Labrador Current.	Northeast U.S. Continental Shelf, Scotian Shelf, Newfoundland-Labrador Shelf.	NA.
Sowerby's beaked whale.	*Mesoplodon bidens*	Western North Atlantic[16].	NA	7,092 (0.54)/4,632[17].	Gulf Stream, North Atlantic Gyre.	Northeast U.S. Continental Shelf, Scotian Shelf, Newfoundland-Labrador Shelf.	NA.

TABLE 9—MARINE MAMMALS POTENTIALLY PRESENT IN THE AFTT STUDY AREA—Continued

Common name	Scientific name[1]	Stock[2]	ESA/MMPA Status[3]	Stock Abundance[4]	Occurrence in AFTT study area[5]		
				Best/minimum population	Open ocean	Large marine ecosystems	Inland waters
True's beaked whale.	*Mesoplodon mirus*	Western North Atlantic[16].	NA	7,092 (0.54)/4,632[17].	Gulf Stream, North Atlantic Gyre.	Southeast U.S. Continental Shelf, Northeast U.S. Continental Shelf, Scotian Shelf, Newfoundland-Labrador Shelf.	NA.
Family Delphinidae (dolphins)							
Atlantic spotted dolphin.	*Stenella frontalis*	Western North Atlantic[16].	NA	44,715 (0.43)/31,610.	Gulf Stream	Southeast U.S. Continental Shelf, Northeast U.S. Continental Shelf.	NA.
		Northern Gulf of Mexico.	NA	Unknown	NA	Gulf of Mexico, Caribbean Sea.	NA.
		Puerto Rico and U.S. Virgin Islands.	Strategic	Unknown	NA	Caribbean Sea	NA.
Atlantic white-sided dolphin.	*Lagenorhynchus acutus.*	Western North Atlantic.	NA	48,819 (0.61)/30,403.	Gulf Stream, Labrador Current.	Northeast U.S. Continental Shelf, Scotian Shelf, Newfoundland-Labrador Shelf.	NA.
Clymene dolphin	*Stenella clymene*	Western North Atlantic[16].	NA	Unknown	Gulf Stream	Southeast U.S. Continental Shelf, Northeast U.S. Continental Shelf.	NA.
		Northern Gulf of Mexico[16].	NA	129 (1.0)/64	NA	Gulf of Mexico, Caribbean Sea.	NA.
Common bottlenose dolphin.	*Tursiops truncatus*	Western North Atlantic Offshore[19].	NA	77,532 (0.40)/56,053.	Gulf Stream, North Atlantic Gyre.	Southeast U.S. Continental Shelf, Northeast U.S. Continental Shelf, Scotian Shelf.	NA.
		Western North Atlantic Northern Migratory Coastal[20].	Strategic, depleted.	6,639 (0.41)/4,759.	NA	Southeast U.S. Continental Shelf, Northeast U.S. Continental Shelf.	Long Island Sound, Sandy Hook Bay, Lower Chesapeake Bay, James River, Elizabeth River.
		Western North Atlantic Southern Migratory Coastal[20].	Strategic, depleted.	3,751 (0.06)/2,353.	NA	Southeast U.S. Continental Shelf.	Lower Chesapeake Bay, James River, Elizabeth River, Beaufort Inlet, Cape Fear River, Kings Bay, St. Johns River.
		Western North Atlantic South Carolina/Georgia Coastal[20].	Strategic, depleted.	6,027 (0.34)/4,569.	NA	Southeast U.S. Continental Shelf.	Kings Bay, St. Johns River.
		Northern North Carolina Estuarine System[20].	Strategic	823 (0.06)/782	NA	Southeast U.S. Continental Shelf, Northeast U.S. Continental Shelf.	Beaufort Inlet, Cape Fear River.
		Southern North Carolina Estuarine System[20].	Strategic	Unknown	NA	Southeast U.S. Continental Shelf.	Beaufort Inlet, Cape Fear River.
		Northern South Carolina Estuarine System[20].	Strategic	Unknown	NA	Southeast U.S. Continental Shelf.	NA.
		Charleston Estuarine System[20].	Strategic	Unknown	NA	Southeast U.S. Continental Shelf.	NA.

TABLE 9—MARINE MAMMALS POTENTIALLY PRESENT IN THE AFTT STUDY AREA—Continued

Common name	Scientific name[1]	Stock[2]	ESA/MMPA Status[3]	Stock Abundance[4]	Occurrence in AFTT study area[5]		
				Best/minimum population	Open ocean	Large marine ecosystems	Inland waters
		Northern Georgia/Southern South Carolina Estuarine System[20].	Strategic	Unknown	NA	Southeast U.S. Continental Shelf.	NA.
		Central Georgia Estuarine System[20].	Strategic	192 (0.04)/185	NA	Southeast U.S. Continental Shelf.	NA.
		Southern Georgia Estuarine System[20].	Strategic	194 (0.05)/185	NA	Southeast U.S. Continental Shelf.	Kings Bay, St. Johns River.
		Western North Atlantic Northern Florida Coastal[20].	Strategic, depleted.	877 (0.49)/595	NA	Southeast U.S. Continental Shelf.	Kings Bay, St. Johns River.
		Jacksonville Estuarine System[20].	Strategic	Unknown	NA	Southeast U.S. Continental Shelf.	Kings Bay, St. Johns River.
		Western North Atlantic Central Florida Coastal[20].	Strategic, depleted.	1,218 (0.35)/913	NA	Southeast U.S. Continental Shelf.	Port Canaveral.
		Indian River Lagoon Estuarine System[20].	Strategic	Unknown	NA	Southeast U.S. Continental Shelf.	Port Canaveral.
		Biscayne Bay[16]	Strategic	Unknown	NA	Southeast U.S. Continental Shelf.	NA.
		Florida Bay[16]	NA	Unknown	NA	Gulf of Mexico	NA.
		Northern Gulf of Mexico Continental Shelf[20].	NA	51,192 (0.10)/46,926.	NA	Gulf of Mexico	NA.
		Gulf of Mexico Eastern Coastal[20].	NA	12,388 (0.13)/11,110.	NA	Gulf of Mexico	NA.
		Gulf of Mexico Northern Coastal[20].	NA	7,185 (0.21)/6,044.	NA	Gulf of Mexico	St. Andrew Bay, Pascagoula River.
		Gulf of Mexico Western Coastal[20].	NA	20,161 (0.17)/17,491.	NA	Gulf of Mexico	Corpus Christi Bay, Galveston Bay.
		Northern Gulf of Mexico Oceanic[20].	NA	5,806 (0.39)/4,230.	NA	Gulf of Mexico	NA.
		Laguna Madre[20]	Strategic	80 (1.57)/Unknown.	NA	Gulf of Mexico	NA.
		Nueces Bay/Corpus Christi Bay[20].	Strategic	58 (0.61)/Unknown.	NA	Gulf of Mexico	NA.
		Copano Bay/Aransas Bay/San Antonio Bay/Redfish Bay/Espiritu Santo Bay[20].	Strategic	55 (0.82)/Unknown.	NA	Gulf of Mexico	NA.
		Matagorda Bay/Tres Palacios Bay/Lavaca Bay[20].	Strategic	61 (0.45)/Unknown.	NA	Gulf of Mexico	NA.
		West Bay[20]	NA	32 (0.015)/Unknown.	NA	Gulf of Mexico	NA.
		Galveston Bay/East Bay/Trinity Bay[20].	Strategic	152 (0.43)/Unknown.	NA	Gulf of Mexico	NA.
		Sabine Lake[20]	Strategic	0	NA	Gulf of Mexico	NA.
		Calcasieu Lake[20]	Strategic	0	NA	Gulf of Mexico	NA.
		Vermilion Bay/West Cote Blanche Bay/Atchafalaya Bay[20].	Strategic	0	NA	Gulf of Mexico	NA.
		Terrebonne Bay/Timbalier Bay[20].	NA	3,870 (0.15)/3,426.	NA	Gulf of Mexico	NA.
		Barataria Bay Estuarine System[20].	Strategic	2,306 (0.09)/2,138.	NA	Gulf of Mexico	NA.
		Mississippi River Delta[20].	Strategic	332 (0.93)/170	NA	Gulf of Mexico	NA.

TABLE 9—MARINE MAMMALS POTENTIALLY PRESENT IN THE AFTT STUDY AREA—Continued

Common name	Scientific name[1]	Stock[2]	ESA/MMPA Status[3]	Stock Abundance[4]	Occurrence in AFTT study area[5]		
				Best/minimum population	Open ocean	Large marine ecosystems	Inland waters
		Mississippi Sound, Lake Borgne, Bay Boudreau[20].	Strategic	3,046 (0.06)/2,896.	NA	Gulf of Mexico	NA.
		Mobile Bay/Bonsecour Bay[20].	Strategic	122 (0.34)/Unknown.	NA	Gulf of Mexico	NA.
		Perdido Bay[20]	Strategic	0	NA	Gulf of Mexico	NA.
		Pensacola Bay/East Bay[20].	Strategic	33 (0.80)/Unknown.	NA	Gulf of Mexico	NA.
		Choctawhatchee Bay[20].	Strategic	179 (0.04)/Unknown.	NA	Gulf of Mexico	NA.
		St. Andrew Bay[20]	Strategic	124 (0.57)/Unknown.	NA	Gulf of Mexico	NA.
		St. Joseph Bay[20]	Strategic	152 (0.08)/Unknown.	NA	Gulf of Mexico	NA.
		St. Vincent Sound/Apalachicola Bay/St. George Sound[20].	Strategic	439 (0.14)/Unknown.	NA	Gulf of Mexico	NA.
		Apalachee Bay[20]	Strategic	491 (0.39)/Unknown.	NA	Gulf of Mexico	NA.
		Waccasassa Bay/Withlacoochee Bay/Crystal Bay[20].	Strategic	Unknown	NA	Gulf of Mexico	NA.
		St. Joseph Sound/Clearwater Harbor[20].	Strategic	Unknown	NA	Gulf of Mexico	NA.
		Tampa Bay[20]	Strategic	Unknown	NA	Gulf of Mexico	NA.
		Sarasota Bay/Little Sarasota Bay[20].	NA	158 (0.27)/126	NA	Gulf of Mexico	NA.
		Pine Island Sound/Charlotte Harbor/Gasparilla Sound/Lemon Bay[20].	Strategic	826 (0.09)/Unknown.	NA	Gulf of Mexico	NA.
		Caloosahatchee River[20].	Strategic	0	NA	Gulf of Mexico	NA.
		Estero Bay[20]	Strategic	Unknown	NA	Gulf of Mexico	NA.
		Chokoloskee Bay/Ten Thousand Islands/Gullivan Bay[20].	Strategic	Unknown	NA	Gulf of Mexico	NA.
		Whitewater Bay[20]	Strategic	Unknown	NA	Gulf of Mexico	NA.
		Florida Keys (Bahia Honda to Key West)[20].	Strategic	Unknown	NA	Gulf of Mexico	NA.
		Puerto Rico and U.S. Virgin Islands.	Strategic	Unknown	NA	Caribbean Sea	NA.
False killer whale	*Pseudorca crassidens.*	Western North Atlantic[22].	Strategic	442 (1.06)/212	NA	Southeast U.S. Continental Shelf, Northeast U.S. Continental Shelf.	NA.
		Northern Gulf of Mexico[16].	NA	Unknown	NA	Gulf of Mexico, Caribbean Sea.	NA.
Fraser's dolphin	*Lagenodelphis hosei.*	Western North Atlantic[23].	NA	Unknown	Gulf Stream	Northeast U.S. Continental Shelf, Southeast U.S. Continental Shelf.	NA.
		Northern Gulf of Mexico[16].	NA	Unknown	NA	Gulf of Mexico, Caribbean Sea.	NA.

TABLE 9—MARINE MAMMALS POTENTIALLY PRESENT IN THE AFTT STUDY AREA—Continued

Common name	Scientific name[1]	Stock[2]	ESA/MMPA Status[3]	Stock Abundance[4]	Occurrence in AFTT study area[5]		
				Best/minimum population	Open ocean	Large marine ecosystems	Inland waters
Killer Whale	*Orcinus orca*	Western North Atlantic[22].	NA	Unknown	Gulf Stream, North Atlantic Gyre, Labrador Current.	Southeast U.S. Continental Shelf, Northeast United States Continental Shelf, Scotian Shelf, Newfoundland-Labrador Shelf.	NA.
		Northern Gulf of Mexico[16].	NA	28 (1.02)/14	NA	Gulf of Mexico, Caribbean Sea.	NA.
Long-finned pilot whale.	*Globicephala melas*	Western North Atlantic.	NA	5,636 (0.63)/3,464.	Gulf Stream	Northeast U.S. Continental Shelf, Scotian Shelf, Newfoundland-Labrador Shelf.	NA.
Melon-headed Whale.	*Peponocephala electra.*	Western North Atlantic[23].	NA	Unknown	Gulf Stream, North Atlantic Gyre.	Southeast U.S. Continental Shelf.	NA.
		Northern Gulf of Mexico[16].	NA	2,235 (0.75)/1,274.	NA	Gulf of Mexico, Caribbean Sea.	NA.
Pantropical spotted-dolphin.	*Stenella attenuate*	Western North Atlantic[16].	NA	3,333 (0.91)/1,733.	Gulf Stream	Southeast U.S. Continental Shelf, Northeast U.S. Continental Shelf.	NA.
		Northern Gulf of Mexico[22].	NA	50,880 (0.27)/40,699.	NA	Gulf of Mexico, Caribbean Sea.	NA.
Pygmy Killer Whales.	*Feresa attenuata*	Western North Atlantic[16].	NA	Unknown	Gulf Stream, North Atlantic Gyre.	Southeast U.S. Continental Shelf.	NA.
		Northern Gulf of Mexico[16].	NA	152 (1.02)/75	NA	Gulf of Mexico, Caribbean Sea.	NA.
Risso's dolphin	*Grampus griseus*	Western North Atlantic.	NA	18,250 (0.46)/12,619.	Gulf Stream, North Atlantic Gyre.	Southeast U.S. Continental Shelf, Northeast United States Continental Shelf, Scotian Shelf, Newfoundland-Labrador Shelf.	NA.
		Northern Gulf of Mexico.	NA	2,442 (0.57)/1,563.	NA	Gulf of Mexico, Caribbean Sea.	NA.
Rough-toothed dolphin.	*Steno bredanensis*	Western North Atlantic[16].	NA	136 (1.00)/67	Gulf Stream, North Atlantic Gyre.	Caribbean Sea Southeast U.S. Continental Shelf, Northeast U.S. Continental Shelf.	NA.
		Northern Gulf of Mexico.	NA	624 (0.99)/311	NA	Gulf of Mexico, Caribbean Sea.	NA.
Short-finned pilot whale.	*Globicephala macrorhynchus.*	Western North Atlantic.	NA	28,924 (0.24)/23,637.	NA	Northeast Continental Shelf, Southeast U.S. Continental Shelf.	NA.
		Northern Gulf of Mexico[22].	NA	2,415 (0.66)/1,456.	NA	Gulf of Mexico, Caribbean Sea.	NA.
		Puerto Rico and U.S. Virgin Islands.	Strategic	Unknown	NA	Caribbean Sea	NA.
Spinner dolphin	*Stenella longirostris*	Western North Atlantic[16].	NA	Unknown	Gulf Stream, North Atlantic Gyre.	Southeast U.S. Continental Shelf, Northeast U.S. Continental Shelf.	NA.
		Northern Gulf of Mexico[16].	NA	11,441 (0.83)/6,221.	NA	Gulf of Mexico, Caribbean Sea.	NA.
		Puerto Rico and U.S. Virgin Islands.	Strategic	Unknown	NA	Caribbean Sea	NA.
Striped dolphin	*Stenella coeruleoalba.*	Western North Atlantic[16].	NA	54,807 (0.30)/42,804.	Gulf Stream	Northeast U.S. Continental Shelf, Scotian Shelf.	NA.

TABLE 9—MARINE MAMMALS POTENTIALLY PRESENT IN THE AFTT STUDY AREA—Continued

Common name	Scientific name[1]	Stock[2]	ESA/MMPA Status[3]	Stock Abundance[4]	Occurrence in AFTT study area[5]		
				Best/minimum population	Open ocean	Large marine ecosystems	Inland waters
		Northern Gulf of Mexico[16].	NA	1,849 (0.77)/ 1,041.	NA	Gulf of Mexico, Caribbean Sea.	NA.
Short-beaked common dolphin.	*Delphinus delphis*	Western North Atlantic.	NA	70,184 (0.28)/ 55,690.	Gulf Stream	Southeast U.S. Continental Shelf, Northeast U.S. Continental Shelf, Scotian Shelf, Newfoundland-Labrador Shelf.	NA.
White-beaked dolphin.	*Lagenorhynchus, albirostris*.	Western North Atlantic[23].	NA	2,003 (0.94)/ 1,023.	Labrador Current	Northeast U.S. Continental Shelf, Scotian Shelf, Newfoundland-Labrador Shelf.	NA.
Family Phocoenidae (porpoises)							
Harbor porpoise	*Phocoena phocoena*.	Gulf of Maine/Bay of Fundy.	NA	79,883 (0.32)/ 61,415.	NA	Northeast U.S. Continental Shelf, Scotian Shelf, Newfoundland-Labrador Shelf.	Narragansett Bay, Rhode Island Sound, Block Island Sound, Buzzards Bay, Vineyard Sound, Long Island Sound, Piscataqua River, Thames River, Kennebec River.
		Gulf of St. Lawrence[24].	NA	Unknown[24]	Labrador Current	Northeast U.S. Continental Shelf, Scotian Shelf, Newfoundland-Labrador Shelf.	NA.
		Newfoundland[25]	NA	Unknown[25]	Labrador Current	Northeast U.S. Continental Shelf, Scotian Shelf, Newfoundland-Labrador Shelf.	NA.
		Greenland[26]	NA	Unknown[26]	Labrador Current	Northeast U.S. Continental Shelf, Scotian Shelf, Newfoundland-Labrador Shelf, West Greenland Shelf.	NA.
Order Carnivora							
Suborder Pinnipedia							
Family Phocidae (true seals):							
Gray seal	*Halichoerus grypus*	Western North Atlantic.	NA	27,131 (0.19)/ 23,158.	NA	Northeast U.S. Continental Shelf, Scotian Shelf, Newfoundland-Labrador Shelf.	Narragansett Bay, Rhode Island Sound, Block Island Sound, Buzzards Bay, Vineyard Sound, Long Island Sound, Piscataqua River, Thames River, Kennebeck River.

TABLE 9—MARINE MAMMALS POTENTIALLY PRESENT IN THE AFTT STUDY AREA—Continued

Common name	Scientific name[1]	Stock[2]	ESA/MMPA Status[3]	Stock Abundance[4]	Occurrence in AFTT study area[5]		
				Best/minimum population	Open ocean	Large marine ecosystems	Inland waters
Harbor seal	*Phoca vitulina*	Western North Atlantic.	NA	75,834 (0.15)/ 66,884.	NA	Southeast U.S. Continental Shelf, Northeast U.S. Continental Shelf, Scotian Shelf, Newfoundland-Labrador Shelf.	Chesapeake Bay, Narragansett Bay, Rhode Island Sound, Block Island Sound, Buzzards Bay, Vineyard Sound, Long Island Sound, Piscataqua River, Thames River, Kennebeck River.
Harp seal	*Pagophilus groenlandicus.*	Western North Atlantic.	NA	Unknown	NA	Northeast U.S. Continental Shelf, Scotian Shelf, Newfoundland-Labrador Shelf.	NA.
Hooded seal	*Cystophora cristata*	Western North Atlantic.	NA	Unknown	NA	Southeast U.S. Continental Shelf, Northeast U.S. Continental Shelf, Scotian Shelf, Newfoundland-Labrador Shelf, West Greenland Shelf.	Narragansett Bay, Rhode Island Sound, Block Island Sound, Buzzards Bay, Vineyard Sound, Long Island Sound, Piscataqua River, Thames River, Kennebec River.

Notes: CV coefficient of variation; ESA: Endangered Species Act; MMPA: Marine Mammal Protection Act; NA: not applicable.

[1] Taxonomy follows (Committee on Taxonomy, 2016).

[2] Stock designations for the U.S. EEZ and abundance estimates are from Atlantic and Gulf of Mexico SARs prepared by NMFS *(Hayes et al.,* 2019) and the final 2018 SARs, unless specifically noted.

[3] Populations or stocks defined by the MMPA as ''strategic'' for one of the following reasons: (1) the level of direct human-caused mortality exceeds the potential biological removal level; (2) based on the best available scientific information, numbers are declining and species are likely to be listed as threatened species under the ESA within the foreseeable future; (3) species are listed as threatened or endangered under the ESA; (4) species are designated as depleted under the MMPA.

[4] Stock abundance, CV, and minimum population are numbers provided by the Stock Assessment Reports *(SARs; Hayes et al.,* 2019). The stock abundance is an estimate of the number of animals within the stock. The CV is a statistical metric used as an indicator of the uncertainty in the abundance estimate. The minimum population estimate is either a direct count (*e.g.,* pinnipeds on land) or the lower 20th percentile of a statistical abundance estimate.

[5] Occurrence in the AFTT Study Area includes open ocean areas—Labrador Current, North Atlantic Gyre, Gulf Stream, and coastal/shelf waters of seven large marine ecosystems—West Greenland Shelf, Newfoundland-Labrador Shelf, Scotian Shelf, and Northeast U.S. Continental Shelf, Southeast U.S. Continental Shelf, Caribbean Sea, Gulf of Mexico, and inland waters of Kennebec River, Piscataqua River, Thames River, Narragansett Bay, Rhode Island Sound, Block Island Sound, Buzzards Bay, Vineyard Sound, Long Island Sound, Sandy Hook Bay, Lower Chesapeake Bay, James River, Elizabeth River, Beaufort Inlet, Cape Fear River, Kings Bay, St. Johns River, Port Canaveral, St. Andrew Bay, Pascagoula River, Sabine Lake, Corpus Christi Bay, and Galveston Bay.

[6] The bowhead whale population off the West Coast of Greenland is not managed by NMFS and, therefore, does not have an associated Stock Assessment Report. Abundance and 95 percent highest density interval were presented in (Frasier *et al.,* 2015).

[7] The West Greenland stock of minke whales is not managed by NMFS and, therefore, does not have an associated Stock Assessment Report. Abundance and 95 percent confidence interval were presented in (Heide-Jørgensen *et al.,* 2010).

[8] The Labrador Sea stock of sei whales is not managed by NMFS and, therefore, does not have an associated Stock Assessment Report. Information was obtained in (Prieto *et al.,* 2014).

[9] The West Greenland stock of fin whales is not managed by NMFS and, therefore, does not have an associated Stock Assessment Report. Abundance and 95 percent confidence interval were presented in (Heide-Jørgensen *et al.,* 2010).

[10] The Gulf of St. Lawrence stock of fin whales is not managed by NMFS and, therefore, does not have an associated Stock Assessment Report. Abundance and 95 percent confidence interval were presented in (Ramp *et al.,* 2014).

[11] Photo identification catalogue count of 440 recognizable blue whale individuals from the Gulf of St. Lawrence is considered a minimum population estimate for the western North Atlantic stock (Waring *et al.,* 2010).

[12] Estimates include both the pygmy and dwarf sperm whales in the western North Atlantic (Waring *et al.,* 2014) and the northern Gulf of Mexico (Waring *et al.,* 2013).

[13] Beluga whales in the Atlantic are not managed by NMFS and have no associated Stock Assessment Report. Abundance and 95 percent confidence interval for the Eastern High Arctic/Baffin Bay stock were presented in (Innes e*t al.,* 2002).

[14] Beluga whales in the Atlantic are not managed by NMFS and have no associated Stock Assessment Report. Abundance and 95 percent confidence interval for the West Greenland stock were presented in (Heide-Jørgensen *et al.,* 2009).

[15] NA = Not applicable. Narwhals in the Atlantic are not managed by NMFS and have no associated Stock Assessment Report.

[16] Estimates for these western North Atlantic stocks are from Waring *et al.* (2014) and the northern Gulf of Mexico stock are from (Waring *et al.,* 2013) as applicable.

[17] Estimate includes undifferentiated *Mesoplodon* species.

[18] Estimate includes Gervais' and Blainville's beaked whales.

[19] Estimate may include sightings of the coastal form.

[20] Estimates for these Gulf of Mexico stocks are from SARs.

[21] These Bryde's whales span the mid- and southern Atlantic and have not been designated as a stock (NSD) under the MMPA and therefore have no associated Stock Assessment Report.

[22] Estimates for these stocks are from Waring *et al.,* (2015).

[23] Estimates for these western North Atlantic stocks are from (Waring *et al.,* 2007).

[24] Harbor porpoise in the Gulf of St. Lawrence are not managed by NMFS and have no associated Stock Assessment Report.

[25] Harbor porpoise in Newfoundland are not managed by NMFS and have no associated Stock Assessment Report.

[26] Harbor porpoise in Greenland are not managed by NMFS and have no associated Stock Assessment Report.

Unusual Mortality Events (UMEs)

An UME is defined under section 410(6) of the MMPA as a stranding that is unexpected; involves a significant die-off of any marine mammal population; and demands immediate response. The six active UMEs with ongoing investigations in the AFTT Study Area that inform our analysis are discussed below. The impacts to Barataria Bay bottlenose dolphins from the closed Northern Gulf of Mexico UME (discussed in the 2018 AFTT proposed rule) associated with the Deep Water Horizon oil spill in the Gulf of Mexico are thought to be persistent and continue to inform population analyses. The other more recent UMEs closed several years ago, and little is known about how the effects of those events might be appropriately applied to an impact assessment several years later.

North Atlantic Right Whale (NARW) UME

NOAA declared an UME for NARWs from January 1, 2017, to the present. The current total number of mortalities included in the event is approximately 30 whales, including potentially 21 NARW carcasses (1 carcass from 2019 is currently unconfirmed) from Canada in 2017 and 2019 and nine carcasses in the United States (5 in 2017; 3 in 2018; 1 in 2019). In 2017, 17 right whale mortalities were documented, in 2018, three right whale mortalities were documented, and in the summer and fall of 2019 (as of October 24, 2019) an additional 10 right whale mortalities have been documented (9 confirmed, 1 unconfirmed). Of the 12 NARW carcasses found in Canadian waters in 2017, six were necropsied and died as a direct result of human activities (either confirmed, probable, or suspect), from either rope entanglements (2) or vessel strikes (4) (Daoust *et al.,* 2017). Of the eight carcasses found in U.S. waters in 2017–2018, the cause of death was determined in six whales, with deaths attributable to either rope entanglement (5) or vessel strikes (1) (Sharp *et al.,* 2019). Eight carcasses were not able to be examined. Of the 10 whales documented in 2019, 8 carcasses were able to be examined at some level. Of the examined whales, three had evidence of vessel strikes and one had evidence of entanglement, the results from the remaining four whales are pending. Daoust *et al.* (2018) also concluded there were no oil and gas seismic surveys authorized in the months prior to or during the period over which these mortalities occurred, as well as no blasting or major marine development projects. Navy was consulted as to sonar use and they confirmed none was used in the vicinity of any of the strandings.

As part of the UME investigation process for NARW, NOAA assembled an independent team of scientists (Investigative Team) that coordinates with the Working Group on Marine Mammal Unusual Mortality Events to review the data collected, sample future whales that strand, and determine the next steps for the investigation. For more information on this UME, please refer to *https://www.fisheries.noaa.gov/national/marine-life-distress/2017-2019-north-atlantic-right-whale-unusual-mortality-event#causes-of-the-north-atlantic-right-whale-ume.*

While data are not yet available to statistically estimate the population's trend beyond 2015, three lines of evidence indicate the population is still in decline. First, calving rates in 2016, 2017, and 2018 were low. Only five new calves were documented in 2017 (Pettis *et al.,* 2017a), well below the number needed to compensate for expected mortalities (Pace *et al.,* 2017), and no new calves were reported for 2018. Long-term photographic identification data indicate new calves rarely go undetected, so these years likely represent a continuation of the low calving rates that began in 2012 (Kraus *et al.,* 2007; Pace *et al.,* 2017). So far in 2019, seven calves have been documented. Second, the abundance estimate for 2016 is 451 individuals, down approximately 1.5 percent from 458 in 2015. Third, since January, 2017, approximately 30 NARWs have died in what has been declared an UME as discussed above (Meyer-Gutbrod *et al.,* 2018; NMFS, 2017).

Humpback Whale UME Along the Atlantic Coast

NOAA declared an UME for humpback whales from January 1, 2016, to the present, along the Atlantic coast from Maine through Florida. As of October 24, 2019, 107 humpback strandings have occurred (26, 34, 25, and 22 whales in 2016, 2017, 2018 and 2019 respectively). As of April 2019, partial or full necropsy examinations have been conducted on 43 cases, or approximately half of the 92 strandings (at that time). Of the 43 whales examined, approximately 20 had evidence of blunt force trauma or pre-mortem propeller wounds indicative of vessel strike and approximately 6 had evidence of entanglements. NOAA, in coordination with our stranding network partners, continues to investigate the recent mortalities and environmental conditions, and conduct population monitoring to better understand the recent humpback whale mortalities. At this time, vessel parameters (including size) are not known for each vessel-whale collision that led to the death of a whale. Therefore, NOAA considers all sizes of vessels to be a potential risk for whale species in highly trafficked areas. The Navy has investigated potential strikes and confirmed that it had none. Please refer to *https://www.fisheries.noaa.gov/national/marine-life-distress/2016-2019-humpback-whale-unusual-mortality-event-along-atlantic-coast* for more information on this UME.

Minke Whale UME Along the Atlantic Coast

NOAA declared an UME for minke whales from January 1, 2017, to the present, along the Atlantic coast from Maine through Florida. As of October 24, 2019, 75 strandings have occurred (27, 30, and 18 whales in 2017, 2018 and 2019, respectively). As of April 1, 2019, full or partial necropsy examinations have been conducted on 33 whales. Preliminary findings on several of the whales have shown evidence of human interactions, primarily fisheries interactions, or infectious disease. These findings are not consistent across all of the whales examined, and final diagnostic results are still pending for many of the cases. Please refer to *https://www.fisheries.noaa.gov/national/marine-life-distress/2017-2019-minke-whale-unusual-mortality-event-along-atlantic-coast* for more information on this UME.

Northeast Pinniped UME Along the Atlantic Coast

NOAA declared an UME on August 30, 2018, due to increased numbers of harbor seal and gray seal strandings along the U.S. coasts of Maine, New Hampshire, and Massachusetts during July and August of 2018. Strandings remained elevated in these three states and expanded south to Virginia primarily in late 2018 to early 2019 with additional cases on-going throughout 2019. In December 2018 and early 2019, harp and hooded seals began stranding as these seals migrated from Canada into U.S. waters and have been included in the investigation. From July 1, 2018, to October 24, 2019, 2,964 seals have stranded with approximately 95 percent of the seals stranding in Maine, New Hampshire, and Massachusetts. Full or partial necropsy examinations have been conducted on many of the seals and samples have been collected for testing. Based on testing conducted so far, the main pathogen found in the seals is phocine distemper virus, with

most positive cases stranded in 2018 and early 2019. Active phocine distemper virus infections have only been detected in harbor and gray seals to date. Please refer to *https://www.fisheries.noaa.gov/new-england-mid-atlantic/marine-life-distress/2018-2019-pinniped-unusual-mortality-event-along* for more information on this UME.

Southwest Florida Bottlenose Dolphin UME Along the Gulf of Mexico

NOAA declared an UME in the summer of 2018 due to elevated bottlenose dolphin mortalities occurring along the Southwest coast of Florida including Collier, Lee, Charlotte, Sarasota, Manatee, Hillsborough, and Pinellas counties. From July 1, 2018, to October 24, 2019, 193 dolphins have been confirmed stranded in this event. Stranding network partners have conducted full or partial necropsy examinations on several dolphins, with positive results for the red tide toxin (brevetoxin) indicating this UME is primarily related to the severe bloom of a red tide that occurred in the area from November, 2017 through February, 2019. Please refer to *https://www.fisheries.noaa.gov/southeast/marine-life-distress/2018-2019-bottlenose-dolphin-unusual-mortality-event-southwest* for more information on this UME.

Bottlenose Dolphin UME Along the Northern Gulf of Mexico

NMFS declared an UME in the spring of 2019 due to elevated bottlenose dolphin strandings occurring in the Northern Gulf of Mexico including Louisiana, Mississippi, Alabama, and the panhandle of Florida (Alabama border through Franklin County). From February 1, 2019 to October 24, 2019, 320 dolphins have stranded, which is approximately three times higher than the average. Testing is underway of tissue samples for morbillivirus, harmful algal bloom toxins and other common causes of stranding. Please refer to *https://www.fisheries.noaa.gov/national/marine-life-distress/2019-bottlenose-dolphin-unusual-mortality-event-along-northern-gulf* for more information on this UME.

Potential Effects of Specified Activities on Marine Mammals and Their Habitat

We provided a full discussion of the potential effects of the specified activities on marine mammals and their habitat in our 2018 AFTT proposed rule and 2018 AFTT final rule. In the *Potential Effects of Specified Activities on Marine Mammals and Their Habitat* sections of the 2018 AFTT proposed and final rules, NMFS provided a description of the ways marine mammals may be affected by the same activities that the Navy will be conducting during the seven-year period analyzed in this rule in the form of serious injury or mortality, physical trauma, sensory impairment (permanent and temporary threshold shifts and acoustic masking), physiological responses (particularly stress responses), behavioral disturbance, or habitat effects. Therefore, we do not repeat the information here, all of which remains current and applicable, but refer the reader to those rules and the 2018 AFTT FEIS/OEIS (Chapter 3, Section 3.7 *Marine Mammals*) which NMFS participated in the development of via our cooperating agency status and adopted to meet our NEPA requirements.

NMFS has reviewed new relevant information from the scientific literature since publication of the 2018 AFTT final rule. Summaries of new scientific literature since publication of the 2018 AFTT final rule are presented below.

Southall *et al.* (2019a) evaluated Southall *et al.* (2007) and used updated scientific information to propose revised noise exposure criteria to predict onset of auditory effects in marine mammals (*i.e.,* PTS and TTS onset). Southall *et al.* (2019a) note that the quantitative processes described and the resulting exposure criteria (*i.e.,* thresholds and auditory weighting functions) are largely identical to those in Finneran (2016) and NOAA (2016 and 2018). However they differ in that the Southall *et al.* (2019a) exposure criteria are more broadly applicable as they include all marine mammal species (rather than those only under NMFS jurisdiction) for all noise exposures (both in air and underwater for amphibious species), and that while the hearing group compositions are identical they renamed the hearing groups.

In continued investigations of pinniped hearing, Kastelein *et al.* (2019a) exposed two female captive harbor seals to 6.5 kHz continuous, sinusoidal tones for 60 minutes (cumulative sound exposure levels (SELs) of 159–195 dB re: 1 μPa²s), then measured TTS using behavioral (psychoacoustic) methods at the center frequency of the fatiguing sound (6.5 kHz) and 0.5 and 1 octave above that frequency (9.2 and 13 kHz). Susceptibility to TTS was similar in both individuals tested. At cumulative SELs below 179 dB re: 1 μPa²s, maximum TTS was induced at the center frequency (6.5 kHz), and at cumulative SELs above 179 dB re: 1 μPa²s, maximum TTS was induced at 0.5 octave above the center frequency (9.2 kHz). The highest TTSs were produced in the one-half octave band above the exposure frequency. Both seals recovered within 1–2 hours for up to 6 dB of TTS. One seal showed 19 dB of TTS after a dB re: 1 μPa²s exposure and recovered within 24 hours. Overall, this study combined with previous work showed that for harbor seals, recovery times are consistent for similar-magnitude TTS, regardless of the type of fatiguing sound exposure (impulsive, continuous noise band, or sinusoidal wave), and that susceptibility to TTS in the fatiguing frequency range tested (2.5–6.5 kHz) varies little with hearing frequency. The two harbor seals in this study (and Kastelein *et al.,* 2012) had similar susceptibility to TTS as the seal in Kastak *et al.* (2005). The authors note that more fatiguing sound frequencies need to be tested in harbor seals to produce equal TTS curves, for generating weighting functions that can be used to develop exposure criteria for broadband sounds in the marine environment (Houser *et al.,* 2017). To determine the distances at which Helicopter Long Range Active Sonar (HELRAS) signals (~1.3–1.4 kHz) can be detected, Kastelein *et al.* (2019b) measured hearing thresholds using behavioral (psychoacoustic) techniques to simulated HELRAS signals in two captive harbor seals. Both seals showed similar thresholds (51 dB re: 1 μPa rms, approximately 4 dB lower than the detection thresholds for the same individuals in Kastelein *et al.,* 2009) to previously obtained data for stimuli having the same center frequencies, which suggests that the harmonics present within HELRAS sources do not impact hearing threshold and that a tonal audiogram can be used to estimate the audibility of more complex narrow-band tonal signals in harbor seals.

Recent studies on the behavioral responses of cetaceans to sonar examine and continue to demonstrate the importance of not only sound source parameters, but exposure context (*e.g.,* behavioral state, presence of other animals and social relationships, prey abundance, distance to source, presence of vessels, environmental parameters, *etc.*) in determining or predicting a behavioral response.

- Kastelein *et al.* (2018) examined the role of sound pressure level (SPL) and duty cycle on the behavior of two captive harbor porpoises when exposed to simulated Navy mid-frequency sonar (53C, 3.5 to 4.1 kHz). Neither harbor porpoise responded to the low duty cycle (2.7 percent) at any of the five SPLs presented, even at the maximum received SPL (143 dB re: 1 μPa). At the

higher duty cycle (96 percent), one porpoise responded by increasing his respiration rate at a received SPL of greater than or equal to 119 dB re: 1 μPa, and moved away from the transducer at a received SPL of 143 dB re: 1 μPa. Kastelein *et al.* (2018) observed that at the same received SPL and duty cycle, harbor porpoises respond less to 53C sonar sounds than 1–2 kHz, 6–7 kHz, and 25 kHz sonar signals observed in previous studies, but noted that when examining behavioral responses it is important to take into account the spectrum and temporal structure of the signal, the duty cycle, and the psychological interpretation by the animal.

• To investigate the effect of signal to noise ratio (SNR) on behavioral responses, Kastelein *et al.* (2019c) observed respiration rates (an indicator of behavioral response) of two captive harbor porpoises when exposed to simulated 30-minute playbacks of Navy mid-frequency sonar (53C, 3.5 to 4.1 kHz, 96 percent duty cycle), in noise simulating sea state 6 conditions. No behavioral responses were observed when the porpoises were exposed to sonar signals at an SPL of 117 dB re: 1 μPa (SNR equal to 49 dB re: 1 Hz). Both porpoises responded when exposed to sonar signals at an SPL of 122 dB re: 1 μPa (SNR equal to 54 dB re: 1 Hz), however in quiet conditions one porpoise responded at similar levels (Kastelein *et al.* 2018), suggesting the behavioral responses of harbor porpoises to sonar signals are not affected in sea state 6 ambient noise conditions.

• Wensveen *et al.* (2019) examined the role of sound source (simulated sonar pulses) distance and received level in northern bottlenose whales in an environment without frequent sonar activity using multi-scaled controlled exposure experiments. They observed behavioral avoidance of the sound source over a wide range of distances (0.8–28 km) and estimated avoidance thresholds ranging from received SPLs of 117–126 dB re: 1 μPa. The behavioral response characteristics and avoidance thresholds were comparable to those previously observed in beaked whale studies; however, they did not observe an effect of distance on behavioral response and found that onset and intensity of behavioral response were better predicted by received SPL.

• Joyce *et al.* (2019) presented movement and dive behavior data from seven Blainville's beaked whales (*Mesoplodon densirostris*) that were satellite tagged prior to naval sonar exercises using mid-frequency active sonar (MFAS, 3–8kHz) at the Atlantic Undersea Test and Evaluation Center (AUTEC) in the Bahamas. Five of the seven tagged were displaced 28–68 km after the onset of sonar exposure and returned to the AUTEC range 2–4 days after exercises ended. Three of the individuals for which modeled received SPLs were available during this movement showed declining received SPLs from initial maxima of 145–172 dB re: 1 μPa to maxima of 70–150 dB re: 1 μPa after displacements. Tagged individuals exhibited a continuation of deep diving activity consistent with foraging during MFAS exposure periods, but data also suggested that time spent on deep dives during initial exposure periods was reduced. These findings provide additional data for ongoing Population Consequences of Acoustic Disturbance assessments of disturbance as authors note that previous studies have suggested foraging dives may be lost in response to MFAS exposure, which could cause a decrease in energy intake and have potential effects on vital parameters. The data presented by Joyce *et al.* (2019) support the initial potential loss of foraging time, however they also suggest that Blainville's beaked whales may have the ability to partially compensate for this loss (assuming they have ample recovery times between dives) by increasing time spent at foraging depths following displacement.

• When conducting controlled exposure experiments on blue whales Southall *et al.* (2019b) observed that after exposure to simulated and operational mid-frequency active sonar, more than 50 percent of blue whales in deep-diving states responded to the sonar, while no behavioral response was observed in shallow-feeding blue whales. The behavioral responses they observed were generally brief, of low to moderate severity, and highly dependent on exposure context (behavioral state, source-to-whale horizontal range, and prey availability). Blue whale response did not follow a simple exposure-response model based on received sound exposure level.

• In a review of the previously published data (included in the 2018 AFTT EIS/OEIS analysis) on the potential impacts of sonar on beaked whales, Bernaldo de Quirós *et al.* (2019) suggested that the effect of mid-frequency active sonar on beaked whales varies among individuals or populations, and that predisposing conditions such as previous exposure to sonar and individual health risk factors may contribute to individual outcomes (such as decompression sickness).

Having considered this information, we have determined that there is no new information that substantively affects our analysis of potential impacts on marine mammals and their habitat that appeared in the 2018 AFTT final rule, all of which remains applicable and valid for our assessment of the effects of the Navy's activities during the seven-year period of this rule.

Estimated Take of Marine Mammals

This section indicates the number of takes that NMFS is authorizing, which are based on the amount of take that NMFS anticipates could occur or is likely to occur, depending on the type of take and the methods used to estimate it, as described below. NMFS coordinated closely with the Navy in the development of their incidental take application, and agrees that the methods the Navy has put forth described herein and in the 2018 AFTT proposed and final rules to estimate take (including the model, thresholds, and density estimates), and the resulting numbers are based on the best available science and appropriate for authorization. The number and type of incidental takes that could occur or are likely to occur annually remain identical to those authorized in the 2018 AFTT regulations.

Takes are predominantly in the form of harassment, but a small number of serious injuries or mortalities are also authorized. For military readiness activities, the MMPA defines ''harassment'' as (i) Any act that injures or has the significant potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) Any act that disturbs or is likely to disturb a marine mammal or marine mammal stock in the wild by causing disruption of natural behavioral patterns, including, but not limited to, migration, surfacing, nursing, breeding, feeding, or sheltering, to a point where such behavioral patterns are abandoned or significantly altered (Level B harassment).

Authorized takes will primarily be in the form of Level B harassment, as use of the acoustic and explosive sources (*i.e.,* sonar, air guns, pile driving, explosives) is more likely to result in behavioral disruption (rising to the level of a take as described above) or temporary threshold shift (TTS) for marine mammals than other forms of take. There is also the potential for Level A harassment, however, in the form of auditory injury and/or tissue damage (the latter from explosives only) to result from exposure to the sound sources utilized in training and testing activities. Lastly, a limited number of serious injuries or mortalities could occur for four species of mid-frequency

cetaceans during ship shock trials and no more than four serious injuries or mortalities total (over the seven-year period) of mysticetes (except for blue whales, Bryde's whales, and North Atlantic right whales) and North Atlantic sperm whales could occur through vessel collisions. Although we analyze the impacts of these potential serious injuries or mortalities that are authorized, the required mitigation and monitoring measures are expected to minimize the likelihood that ship strike or these high-level explosive exposures (and the associated serious injury or mortality) actually occur.

Generally speaking, for acoustic impacts we estimate the amount and type of harassment by considering: (1) Acoustic thresholds above which NMFS believes the best available science indicates marine mammals will be taken by Level B harassment (in this case, as defined in the military readiness definition of Level B harassment included above) or incur some degree of temporary or permanent hearing impairment; (2) the area or volume of water that will be ensonified above these levels in a day or event; (3) the density or occurrence of marine mammals within these ensonified areas; and (4) and the number of days of activities or events.

Acoustic Thresholds

Using the best available science, NMFS, in coordination with the Navy, has established acoustic thresholds that identify the most appropriate received level of underwater sound above which marine mammals exposed to these sound sources could be reasonably expected to experience a disruption in behavior patterns to a point where they are abandoned or significantly altered, or to incur TTS (equated to Level B harassment) or permanent threshold shift (PTS) of some degree (equated to Level A harassment). Thresholds have also been developed to identify the pressure levels above which animals may incur non-auditory injury from exposure to pressure waves from explosive detonation.

Despite the quickly evolving science, there are still challenges in quantifying expected behavioral responses that qualify as Level B harassment, especially where the goal is to use one or two predictable indicators *(e.g.,* received level and distance) to predict responses that are also driven by additional factors that cannot be easily incorporated into the thresholds (*e.g.,* context). So, while the new behavioral Level B harassment thresholds have been refined here to better consider the best available science (*e.g.,* incorporating both received level and distance), they also still, accordingly, have some built-in conservative factors to address the challenge noted. For example, while duration of observed responses in the data are now considered in the thresholds, some of the responses that are informing take thresholds are of a very short duration, such that it is possible some of these responses might not always rise to the level of disrupting behavior patterns to a point where they are abandoned or significantly altered. We describe the application of this Level B harassment threshold as identifying the maximum number of instances in which marine mammals could be reasonably expected to experience a disruption in behavior patterns to a point where they are abandoned or significantly altered. In summary, we believe these behavioral Level B harassment thresholds are the most appropriate method for predicting behavioral Level B harassment given the best available science and the associated uncertainty.

We described these acoustic thresholds, none of which have changed, in detail in the *Acoustic Thresholds* section and Tables 13 through 22 of the 2018 AFTT final rule; please see the 2018 AFTT final rule for detailed information.

Navy's Acoustic Effects Model

The Navy proposed no changes to the Acoustic Effects Model as described in the 2018 AFTT final rule and there is no new information that would affect the applicability or validity of the Model. Please see the 2018 AFTT final rule and Appendix E of the 2018 AFTT FEIS/OEIS for detailed information.

Range to Effects

The Navy proposed no changes from the 2018 AFTT final rule to the type and nature of the specified activities to be conducted during the seven-year period analyzed in this final rule, including equipment and sources used and exercises conducted. There is also no new information that would affect the applicability or validity of the ranges to effects previously analyzed for these activities. Therefore, the ranges to effects in this final rule are identical to those described and analyzed in the 2018 AFTT final rule, including received sound levels that may cause onset of significant behavioral response and TTS and PTS in hearing for each source type or explosives that may cause non-auditory injury. Please see the *Range to Effects* section and Tables 23 through 38 of the 2018 AFTT final rule for detailed information.

Marine Mammal Density

The Navy proposed no changes to the methods used to estimate marine mammal density described in the 2018 AFTT final rule and there is no new information that would affect the applicability or validity of these methods. Please see the 2018 AFTT final rule for detailed information.

Take Requests

As in the 2018 AFTT final rule, in its 2019 application, the Navy determined that the three stressors below could result in the incidental taking of marine mammals. NMFS has reviewed the Navy's data and analysis and determined that it is complete and accurate, and NMFS agrees that the following stressors have the potential to result in takes of marine mammals from the Navy's planned activities:

- Acoustics (sonar and other transducers; air guns; pile driving/extraction);
- Explosives (explosive shock wave and sound, assumed to encompass the risk due to fragmentation); and
- Vessel strike.

NMFS reviewed and agrees with the Navy's conclusion that acoustic and explosive sources have the potential to result in incidental takes of marine mammals by harassment, serious injury, or mortality. NMFS carefully reviewed the Navy's analysis and conducted its own analysis of vessel strikes, determining that the likelihood of any particular species of large whale being struck is quite low. Nonetheless, NMFS agrees that vessel strikes have the potential to result in incidental take from serious injury or mortality for certain species of large whales and the Navy specifically requested coverage for these species. Therefore, the likelihood of vessel strikes, and later the effects of the incidental take that is being authorized, has been fully analyzed and is described below.

Regarding the quantification of expected takes from acoustic and explosive sources (by Level A and Level B harassment, as well as mortality resulting from exposure to explosives), the number of takes are based directly on the level of activities (days, hours, counts, *etc.,* of different activities and events) in a given year. In the 2018 AFTT final rule, take estimates across the five-years were based on the Navy conducting three years of a representative level of activity and two years of maximum level of activity. Consistent with the pattern set forth in the 2017 application, the 2018 AFTT FEIS/OEIS, and the 2018 AFTT final rule, the Navy included one additional

representative year and one additional maximum year to determine the predicted take numbers in this rule. Specifically, as in the 2018 AFTT final rule, here the Navy uses the maximum annual level to calculate annual takes (which would remain identical to what was determined in the 2018 AFTT final rule), and the sum of all years (four representative and three maximum) to calculate the seven-year totals for this rule. The Navy will not conduct any additional ship shock activities, and therefore both the total number and annual number of ship shock takes estimated and authorized for the seven-year period is the same as the number requested in the five-year period under the 2018 AFTT final rule.

The quantitative analysis process used for the 2018 AFTT FEIS/OEIS and the 2017 and 2019 Navy applications to estimate potential exposures to marine mammals resulting from acoustic and explosive stressors is detailed in the technical report titled ''Quantifying Acoustic Impacts on Marine Mammals and Sea Turtles: Methods and Analytical Approach for Phase III Training and Testing'' (U.S. Department of the Navy, 2018). The Navy Acoustic Effects Model estimates acoustic and explosive effects without taking mitigation into account; therefore, the model overestimates predicted impacts on marine mammals within mitigation zones. To account for mitigation for marine species in the take estimates, the Navy conducts a quantitative assessment of mitigation. The Navy conservatively quantifies the manner in which procedural mitigation is expected to reduce model-estimated PTS to TTS for exposures to sonar and other transducers, and reduces model-estimated mortality to injury for exposures to explosives. For a complete explanation of the process for assessing the effects of mitigation, see the 2017 Navy application and the 2018 AFTT final rule. The extent to which the mitigation areas reduce impacts on the affected species and stocks is addressed separately in the *Analysis and Negligible Impact Determination* sections of this rule and the 2018 AFTT final rule.

No changes have been made to the quantitative analysis process to estimate potential exposures to marine mammals resulting from acoustic and explosive stressors and calculate take estimates. In addition, there is no new information that would call into question the validity of the Navy's quantitative analysis process. Please see the documents described in the paragraph above, the 2018 AFTT proposed rule, and the 2018 AFTT final rule for detailed descriptions of these analyses. In summary, we believe the Navy's methods, including the method for incorporating mitigation and avoidance, are the most appropriate methods for predicting PTS, TTS, and behavioral disruption. But even with the consideration of mitigation and avoidance, given some of the more conservative components of the methodology (*e.g.,* the thresholds do not consider ear recovery between pulses), we would describe the application of these methods as identifying the maximum number of instances in which marine mammals would be reasonably expected to be taken through PTS, TTS, or behavioral disruption.

Summary of Authorized Take From Training and Testing Activities

Based on the methods discussed in the previous sections and the Navy's model and quantitative assessment of mitigation, the Navy provided its take estimate and request for authorization of takes incidental to the use of acoustic and explosive sources for training and testing activities both annually (based on the maximum number of activities that could occur per 12-month period) and over the seven-year period covered by the 2019 Navy application. Annual takes (based on the maximum number of activities that could occur per 12-month period) are identical to those presented in Tables 39 through 41 in the *Take Requests* section of the 2018 AFTT final rule. The 2019 Navy application also includes the Navy's take estimate and request for vessel strikes due to vessel movement in the AFTT Study Area and individual small and large ship shock trials over a seven-year period. The Navy will not conduct additional ship shock trials, so the estimated and requested takes from ship shock trials are the same as those authorized in the 2018 AFTT final rule. NMFS has reviewed the Navy's data, methodology, and analysis and determined that it is complete and accurate. NMFS agrees that the estimates for incidental takes by harassment from all sources as well as the incidental takes by serious injury or mortality from explosives requested for authorization are reasonably expected to occur. NMFS also agrees that the takes by serious injury or mortality as a result of vessel strikes could occur. The total amount of estimated incidental take from acoustic and explosive sources over the total seven-year period covered by the 2019 Navy application is less than the annual total multiplied by seven, because although the annual estimates are based on the maximum number of activities per year and therefore the maximum possible estimated takes, the seven-year total take estimates are based on the sum of three maximum years and four representative years. Not all activities occur every year. Some activities would occur multiple times within a year, and some activities would occur only a few times over the course of the seven-year period. Using seven years of the maximum number of activities each year would vastly overestimate the amount of incidental take that would occur over the seven-year period where the Navy knows that it will not conduct the maximum number of activities each and every year for the seven years.

Authorized Harassment Take From Training Activities

For training activities, Table 10 summarizes the Navy's take estimate and request and the maximum amount and type of Level A harassment and Level B harassment for the seven-year period covered by the 2019 Navy application that NMFS concurs is reasonably expected to occur by species or stock, and is therefore authorized. For the authorized amount and type of Level A harassment and Level B harassment annually, see Table 39 in the 2018 AFTT final rule. Note that take by Level B harassment includes both behavioral disruption and TTS. Navy Figures 6.4–10 through 6.5–39 in Section 6 of the 2017 Navy application illustrate the comparative amounts of TTS and behavioral disruption for each species annually, noting that if a modeled marine mammal was ''taken'' through exposure to both TTS and behavioral disruption in the model, it was recorded as a TTS.

TABLE 10—SEVEN-YEAR TOTAL SPECIES- AND STOCK-SPECIFIC TAKE AUTHORIZED FROM ACOUSTIC AND EXPLOSIVE SOUND SOURCE EFFECTS FOR ALL TRAINING ACTIVITIES

Species	Stock	7-Year total [1]	
		Level A	Level B
Suborder Mysticeti (baleen whales)			
Family Balaenidae (right whales):			
North Atlantic right whale *	Western North Atlantic	1,644	0
Family Balaenopteridae (roquals):			
Blue whale *	Western North Atlantic (Gulf of St. Lawrence)	171	0
Bryde's whale	Northern Gulf of Mexico *	5	0
	No Stock Designation	1,351	0
Minke whale	Canadian East Coast	15,824	0
Fin whale *	Western North Atlantic	10,225	19
Humpback whale	Gulf of Maine	1,564	4
Sei whale *	Nova Scotia	1,964	0
Suborder Odontoceti (toothed whales)			
Family Physeteridae (sperm whale):			
Sperm whale *	Gulf of Mexico Oceanic	167	0
	North Atlantic	96,479	0
Family Kogiidae (sperm whales):			
Dwarf sperm whale	Gulf of Mexico Oceanic	103	0
	Western North Atlantic	56,060	68
Pygmy sperm whale	Northern Gulf of Mexico	103	0
	Western North Atlantic	56,060	68
Family Ziphiidae (beaked whales):			
Blainville's beaked whale	Northern Gulf of Mexico	244	0
	Western North Atlantic	85,661	0
Cuvier's beaked whale	Northern Gulf of Mexico	242	0
	Western North Atlantic	317,180	0
Gervais' beaked whale	Northern Gulf of Mexico	244	0
	Western North Atlantic	85,661	0
Northern bottlenose whale	Western North Atlantic	7,504	0
Sowersby's beaked whale	Western North Atlantic	85,661	0
True's beaked whale	Western North Atlantic	85,661	0
Family Delphinidae (dolphins):			
Atlantic spotted dolphin	Northern Gulf of Mexico	6,584	0
	Western North Atlantic	804,058	64
Atlantic white-sided dolphin	Western North Atlantic	99,615	3
Bottlenose dolphin	Choctawhatchee Bay	46	0
	Gulf of Mexico Eastern Coastal	166	0
	Gulf of Mexico Northern Coastal	1,524	0
	Gulf of Mexico Western Coastal	16,778	0
	Indian River Lagoon Estuarine System	1,980	0
	Jacksonville Estuarine System	589	0
	Mississippi Sound, Lake Borgne, Bay Boudreau	0	0
	Northern Gulf of Mexico Continental Shelf	10,918	13
	Northern Gulf of Mexico Oceanic	1,356	0
	Northern North Carolina Estuarine System	16,089	0
	Southern North Carolina Estuarine System	0	0
	Western North Atlantic Northern Florida Coastal	6,060	0
	Western North Atlantic Central Florida Coastal	35,861	0
	Western North Atlantic Northern Migratory Coastal	175,237	30
	Western North Atlantic Offshore	2,062,942	269
	Western North Atlantic South Carolina/Georgia Coastal.	28,814	0
	Western North Atlantic Southern Migratory Coastal	81,155	14
Clymene dolphin	Northern Gulf of Mexico	694	0
	Western North Atlantic	463,220	19
False killer whale	Northern Gulf of Mexico	291	0
	Western North Atlantic	54,818	0
Fraser's dolphin	Northern Gulf of Mexico	418	0
	.		
Western North Atlantic	26,155	0	
Killer whale	Northern Gulf of Mexico	5	0
	Western North Atlantic	522	0
Long-finned pilot whale	Western North Atlantic	116,412	0
Melon-headed whale	Northern Gulf of Mexico	493	0
Western North Atlantic	246,178	4	
Pantropical spotted dolphin	Northern Gulf of Mexico	3,959	0

TABLE 10—SEVEN-YEAR TOTAL SPECIES- AND STOCK-SPECIFIC TAKE AUTHORIZED FROM ACOUSTIC AND EXPLOSIVE SOUND SOURCE EFFECTS FOR ALL TRAINING ACTIVITIES—Continued

Species	Stock	7-Year total [1]	
		Level A	Level B
	Western North Atlantic	964,072	16
Pygmy killer whale	Northern Gulf of Mexico	118	0
	Western North Atlantic	43,009	0
Risso's dolphin	Northern Gulf of Mexico	276	0
	Western North Atlantic	140,368	0
Rough-toothed dolphin	Northern Gulf of Mexico	606	0
	Western North Atlantic	129,594	0
Short-beaked common dolphin	Western North Atlantic	1,467,625	87
Short-finned pilot whale	Northern Gulf of Mexico	251	0
	Western North Atlantic	210,736	0
Spinner dolphin	Northern Gulf of Mexico	1,593	0
	Western North Atlantic	487,644	9
Striped dolphin	Northern Gulf of Mexico	471	0
	Western North Atlantic	631,680	22
White-beaked dolphin	Western North Atlantic	269	0
Family Phocoenidae (porpoises):			
Harbor porpoise	Gulf of Maine/Bay of Fundy	206,071	1,121
Suborder Pinnipedia			
Family Phocidae (true seals):			
Gray seal	Western North Atlantic	10,038	0
Harbor seal	Western North Atlantic	16,277	0
Harp seal	Western North Atlantic	59,063	6
Hooded seal	Western North Atlantic	882	0

[1] The estimated amount and type of Level A harassment and Level B harassment annually are identical to those presented in Table 39 in the 2018 AFTT final rule.
* ESA-listed species or stocks within the AFTT Study Area.
† NSD: No stock designated.

Authorized Harassment Take From Testing Activities

For testing activities (excluding ship shock trials), Table 11 summarizes the Navy's take estimate and request and the maximum amount and type of Level A harassment and Level B harassment for the seven-year period covered by the 2019 Navy application that NMFS concurs is reasonably expected to occur by species or stock, and is therefore authorized. For the authorized amount and type of Level A harassment and Level B harassment annually, see Table 40 in the 2018 AFTT final rule. Note that take by Level B harassment includes both behavioral disruption and TTS. Navy Figures 6.4–10 through 6.5–39 in Section 6 of the 2017 Navy application illustrate the comparative amounts of TTS and behavioral disruption for each species annually, noting that if a modeled marine mammal was ''taken'' through exposure to both TTS and behavioral disruption in the model, it was recorded as a TTS.

TABLE 11—SEVEN-YEAR TOTAL SPECIES AND STOCK-SPECIFIC TAKE AUTHORIZED FROM ACOUSTIC AND EXPLOSIVE SOUND SOURCE EFFECTS FOR ALL TESTING ACTIVITIES

[Excluding Ship Shock Trials]

Species	Stock	7-Year total [1]	
		Level B	Level A
Suborder Mysticeti (baleen whales)			
Family Balaenidae (right whales):			
North Atlantic right whale *	Western North Atlantic	1,528	0
Family Balaenopteridae (roquals):			
Blue whale *	Western North Atlantic (Gulf of St. Lawrence)	127	0
Bryde's whale	Northern Gulf of Mexico *	358	0
	No Stock Designation	856	0
Minke whale	Canadian East Coast	11,155	9
Fin whale *	Western North Atlantic	24,808	22
Humpback whale	Gulf of Maine	3,380	0
Sei whale *	Nova Scotia	3,262	0
Suborder Odontoceti (toothed whales)			
Family Physeteridae (sperm whale):			
Sperm whale *	Gulf of Mexico Oceanic	7,315	0

TABLE 11—SEVEN-YEAR TOTAL SPECIES AND STOCK-SPECIFIC TAKE AUTHORIZED FROM ACOUSTIC AND EXPLOSIVE SOUND SOURCE EFFECTS FOR ALL TESTING ACTIVITIES—Continued

[Excluding Ship Shock Trials]

Species	Stock	7-Year total [1]	
		Level B	Level A
	North Atlantic	71,820	0
Family Kogiidae (sperm whales):			
Dwarf sperm whale	Gulf of Mexico Oceanic	4,787	38
	Western North Atlantic	29,368	91
Pygmy sperm whale	Northern Gulf of Mexico	4,787	38
	Western North Atlantic	29,368	91
Family Ziphiidae (beaked whales):			
Blainville's beaked whale	Northern Gulf of Mexico	9,368	0
	Western North Atlantic	68,738	0
Cuvier's beaked whale	Northern Gulf of Mexico	9,757	0
	Western North Atlantic	252,367	0
Gervais' beaked whale	Northern Gulf of Mexico	9,368	0
	Western North Atlantic	68,738	0
Northern bottlenose whale	Western North Atlantic	6,231	0
Sowersby's beaked whale	Western North Atlantic	68,903	0
True's beaked whale	Western North Atlantic	68,903	0
Family Delphinidae (dolphins):			
Atlantic spotted dolphin	Northern Gulf of Mexico	473,262	18
	Western North Atlantic	708,931	72
Atlantic white-sided dolphin	Western North Atlantic	210,578	8
Bottlenose dolphin	Choctawhatchee Bay	6,297	0
	Gulf of Mexico Eastern Coastal	0	0
	Gulf of Mexico Northern Coastal	108,154	7
	Gulf of Mexico Western Coastal	25,200	0
	Indian River Lagoon Estuarine System	21	0
	Jacksonville Estuarine System	20	0
	Mississippi Sound, Lake Borgne, Bay Boudreau	5	0
	Northern Gulf of Mexico Continental Shelf	841,076	56
	Northern Gulf of Mexico Oceanic	95,044	8
	Northern North Carolina Estuarine System	746	0
	Southern North Carolina Estuarine System	0	0
	Western North Atlantic Northern Florida Coastal	2,263	0
	Western North Atlantic Central Florida Coastal	15,409	0
	Western North Atlantic Northern Migratory Coastal	79,042	20
	Western North Atlantic Offshore	794,581	161
	Western North Atlantic South Carolina/Georgia Coastal.	11,232	0
	Western North Atlantic Southern Migratory Coastal	29,176	0
Clymene dolphin	Northern Gulf of Mexico	27,841	0
	Western North Atlantic	234,001	12
False killer whale	Northern Gulf of Mexico	12,788	0
	Western North Atlantic	24,580	0
Fraser's dolphin	Northern Gulf of Mexico	7,452	0
	Western North Atlantic	8,270	0
Killer whale	Northern Gulf of Mexico	212	0
	Western North Atlantic	264	0
Long-finned pilot whale	Western North Atlantic	131,095	11
Melon-headed whale	Northern Gulf of Mexico	20,324	0
	Western North Atlantic	109,192	6
Pantropical spotted dolphin	Northern Gulf of Mexico	169,678	6
	Western North Atlantic	495,207	26
Pygmy killer whale	Northern Gulf of Mexico	4,771	0
	Western North Atlantic	18,609	0
Risso's dolphin	Northern Gulf of Mexico	10,929	0
	Western North Atlantic	132,141	9
Rough-toothed dolphin	Northern Gulf of Mexico	26,033	0
	Western North Atlantic	58,008	0
Short-beaked common dolphin	Western North Atlantic	2,351,361	101
Short-finned pilot whale	Northern Gulf of Mexico	12,041	0
	Western North Atlantic	111,326	10
Spinner dolphin	Northern Gulf of Mexico	51,039	0
	Western North Atlantic	218,786	10
Striped dolphin	Northern Gulf of Mexico	16,344	0
	Western North Atlantic	652,197	32
White-beaked dolphin	Western North Atlantic	300	0
Family Phocoenidae (porpoises):			
Harbor porpoise	Gulf of Maine/Bay of Fundy	811,201	1,405

TABLE 11—SEVEN-YEAR TOTAL SPECIES AND STOCK-SPECIFIC TAKE AUTHORIZED FROM ACOUSTIC AND EXPLOSIVE SOUND SOURCE EFFECTS FOR ALL TESTING ACTIVITIES—Continued

[Excluding Ship Shock Trials]

Species	Stock	7-Year total [1]	
		Level B	Level A
Suborder Pinnipedia			
Family Phocidae (true seals):			
Gray seal	Western North Atlantic	6,130	14
Harbor seal	Western North Atlantic	9,941	23
Harp seal	Western North Atlantic	53,646	17
Hooded seal	Western North Atlantic	5,335	0

[1] The estimated amount and type of Level A harassment and Level B harassment annually are identical to those presented in Table 40 in the 2018 AFTT final rule.
* ESA-listed species or stocks within the AFTT Study Area.
† NSD: No stock designated.

Authorized Take From Ship Shock

For ship shock trials, Table 12 summarizes the Navy's take estimate and request and the maximum amount and type of Level A and Level B harassment and serious injury/mortality for the seven-year period covered by the Navy application that NMFS concurs is reasonably expected to occur by species or stock per small and large ship shock events, and is therefore authorized. For the authorized amount and type of Level A harassment, Level B harassment, and serious injury/mortality annually, see Table 41 in the 2018 AFTT final rule. The Navy will not conduct additional ship shock trials over the additional two years covered by the 2019 Navy application, so the amount and type of authorized takes are the same as those authorized in the 2018 AFTT final rule.

TABLE 12—SEVEN-YEAR TOTAL SPECIES AND STOCK-SPECIFIC TAKE ESTIMATES AUTHORIZED FROM SHIP SHOCK TRIALS

Species/stock	Small ship shock			Large ship shock			7-Year total		
	Level B harassment	Level A harassment	Mortality	Level B harassment	Level A harassment	Mortality	Level B harassment	Level A harassment	Mortality
Suborder Mysticeti (baleen whales)									
Family Balaenidae (right whales):									
North Atlantic right whale *	1	0	0	2	0	0	5	0	0
Western North Atlantic	1	0	0	2	0	0	5	0	0
Family Balaenopteridae (roquals):									
Blue whale *	0	0	0	1	0	0	1	0	0
Western North Atlantic (Gulf of St. Lawrence)	0	0	0	1	0	0	1	0	0
Bryde's whale	3	0	0	6	1	0	15	1	0
Northern Gulf of Mexico *	0	0	0	3	1	0	3	1	0
NSD †	3	0	0	6	0	0	15	0	0
Minke whale	19	1	0	39	3	0	96	6	0
Canadian East Coast	19	1	0	39	3	0	96	6	0
Fin whale *	131	3	0	234	27	0	627	36	0
Western North Atlantic	131	3	0	234	27	0	627	36	0
Humpback whale	8	0	0	20	2	0	44	2	0
Gulf of Maine	8	0	0	20	2	0	44	2	0
Sei whale *	12	1	0	27	4	0	63	7	0
Nova Scotia	12	1	0	27	4	0	63	7	0
Suborder Odontoceti (toothed whales)									
Family Physeteridae (sperm whale):									
Sperm whale *	1	1	0	3	4	0	6	7	0
Gulf of Mexico Oceanic	0	0	0	2	0	0	2	0	0
North Atlantic	1	1	0	3	4	0	6	7	0
Family Kogiidae (sperm whales):									
Dwarf sperm whale	46	28	0	91	70	0	229	154	0
Gulf of Mexico Oceanic	0	0	0	51	64	0	51	64	0
Western North Atlantic	46	28	0	91	70	0	229	154	0
Pygmy sperm whale	46	28	0	91	70	0	229	154	0
Northern Gulf of Mexico	0	0	0	51	64	0	51	64	0
Western North Atlantic	46	28	0	91	70	0	229	154	0

TABLE 12—SEVEN-YEAR TOTAL SPECIES AND STOCK-SPECIFIC TAKE ESTIMATES AUTHORIZED FROM SHIP SHOCK TRIALS—Continued

Species/stock	Small ship shock			Large ship shock			7-Year total		
	Level B harassment	Level A harassment	Mortality	Level B harassment	Level A harassment	Mortality	Level B harassment	Level A harassment	Mortality
Family Ziphiidae (beaked whales):									
Blainville's beaked whale	1	0	0	1	1	0	4	1	0
Northern Gulf of Mexico	0	0	0	1	0	0	1	0	0
Western North Atlantic	1	0	0	1	1	0	4	1	0
Cuvier's beaked whale	2	1	0	2	3	0	8	6	0
Northern Gulf of Mexico	0	0	0	1	0	0	1	0	0
Western North Atlantic	2	1	0	2	3	0	8	6	0
Gervais' beaked whale	1	0	0	1	1	0	4	1	0
Northern Gulf of Mexico	0	0	0	1	0	0	1	0	0
Western North Atlantic	1	0	0	1	1	0	4	1	0
Northern bottlenose whale	0	0	0	0	0	0	0	0	0
Western North Atlantic	0	0	0	0	0	0	0	0	0
Sowerby's beaked whale	1	0	0	1	1	0	4	1	0
Western North Atlantic	1	0	0	1	1	0	4	1	0
True's beaked whale	1	0	0	1	1	0	4	1	0
Western North Atlantic	1	0	0	1	1	0	4	1	0
Family Delphinidae (dolphins):									
Atlantic spotted dolphin	6	4	0	8	12	0	26	24	0
Northern Gulf of Mexico	0	0	0	2	1	0	2	1	0
Western North Atlantic	6	4	0	8	12	0	26	24	0
Atlantic white-sided dolphin	1	1	0	3	9	1	6	12	1
Western North Atlantic	1	1	0	3	9	1	6	12	1
Bottlenose dolphin	13	10	0	16	24	0	55	54	0
Choctawhatchee Bay	0	0	0	0	0	0	0	0	0
Gulf of Mexico Eastern Coastal	0	0	0	0	0	0	0	0	0
Gulf of Mexico Northern Coastal	0	0	0	1	1	0	1	1	0
Gulf of Mexico Western Coastal	0	0	0	0	0	0	0	0	0
Indian River Lagoon Estuarine System	0	0	0	0	0	0	0	0	0
Jacksonville Estuarine System	0	0	0	0	0	0	0	0	0
Mississippi Sound, Lake Borgne, Bay Boudreau	0	0	0	0	0	0	0	0	0
Northern Gulf of Mexico Continental Shelf	0	0	0	10	6	0	10	6	0
Northern Gulf of Mexico Oceanic	0	0	0	10	9	0	10	9	0
Northern North Carolina Estuarine System	0	0	0	0	0	0	0	0	0
Southern North Carolina Estuarine System	0	0	0	0	0	0	0	0	0
Western North Atlantic Northern Florida Coastal	0	0	0	0	0	0	0	0	0
Western North Atlantic Central Florida Coastal	0	0	0	0	0	0	0	0	0
Western North Atlantic Northern Migratory Coastal	0	0	0	0	0	0	0	0	0
Western North Atlantic Offshore	13	10	0	16	24	0	55	54	0
Western North Atlantic South Carolina/Georgia Coastal	0	0	0	0	0	0	0	0	0
Western North Atlantic Southern Migratory Coastal	0	0	0	0	0	0	0	0	0
Clymene dolphin	2	5	0	9	8	0	15	23	0
Northern Gulf of Mexico	0	0	0	8	6	0	8	6	0
Western North Atlantic	2	5	0	9	8	0	15	23	0
False killer whale	0	0	0	2	1	0	2	1	0
Northern Gulf of Mexico	0	0	0	2	1	0	2	1	0
Western North Atlantic	0	0	0	2	0	0	2	0	0

TABLE 12—SEVEN-YEAR TOTAL SPECIES AND STOCK-SPECIFIC TAKE ESTIMATES AUTHORIZED FROM SHIP SHOCK TRIALS—Continued

Species/stock	Small ship shock			Large ship shock			7-Year total		
	Level B harassment	Level A harassment	Mortality	Level B harassment	Level A harassment	Mortality	Level B harassment	Level A harassment	Mortality
Fraser's dolphin	0	0	0	2	3	0	2	3	0
Northern Gulf of Mexico	0	0	0	2	3	0	2	3	0
Western North Atlantic	0	0	0	0	0	0	0	0	0
Killer whale	0	0	0	0	0	0	0	0	0
Northern Gulf of Mexico	0	0	0	0	0	0	0	0	0
Western North Atlantic	0	0	0	0	0	0	0	0	0
Long-finned pilot whale	2	2	0	5	6	0	11	12	0
Western North Atlantic	2	2	0	5	6	0	11	12	0
Melon-headed whale	1	1	0	5	4	0	8	7	0
Northern Gulf of Mexico	0	0	0	4	4	0	4	4	0
Western North Atlantic	1	1	0	5	1	0	8	4	0
Pantropical spotted dolphin	2	3	0	25	20	1	31	29	1
Northern Gulf of Mexico	0	0	0	25	20	1	25	20	1
Western North Atlantic	2	3	0	7	3	0	13	12	0
Pygmy killer whale	0	0	0	1	1	0	1	1	0
Northern Gulf of Mexico	0	0	0	1	1	0	1	1	0
Western North Atlantic	0	0	0	1	0	0	1	0	0
Risso's dolphin	1	1	0	3	1	0	6	4	0
Northern Gulf of Mexico	0	0	0	2	1	0	2	1	0
Western North Atlantic	1	1	0	3	1	0	6	4	0
Rough-toothed dolphin	1	0	0	3	2	0	6	2	0
Northern Gulf of Mexico	0	0	0	2	2	0	2	2	0
Western North Atlantic	0	0	0	0	0	0	0	0	0
Short-beaked common dolphin	40	51	1	67	107	3	187	260	6
Western North Atlantic	40	51	1	67	107	3	187	260	6
Short-finned pilot whale	2	2	0	4	5	0	10	11	0
Northern Gulf of Mexico	0	0	0	2	3	0	2	3	0
Western North Atlantic	2	2	0	4	5	0	10	11	0
Spinner dolphin	3	1	0	37	45	1	46	48	1
Northern Gulf of Mexico	0	0	0	37	45	1	37	45	1
Western North Atlantic	3	1	0	7	3	0	16	6	0
Striped dolphin	4	8	0	10	12	0	22	36	0
Northern Gulf of Mexico	0	0	0	4	3	0	4	3	0
Western North Atlantic	4	8	0	10	12	0	22	36	0
White-beaked dolphin	0	0	0	0	0	0	0	0	0
Western North Atlantic	0	0	0	0	0	0	0	0	0
Family Phocoenidae (porpoises):									
Harbor porpoisE	43	41	0	120	81	0	249	204	0
Gulf of Maine/Bay of Fundy	43	41	0	120	81	0	249	204	0
Suborder Pinnipedia									
Family Phocidae (true seals):									
Gray seal	0	0	0	0	0	0	0	0	0
Western North Atlantic	0	0	0	0	0	0	0	0	0
Harbor seal	0	0	0	0	0	0	0	0	0
Western North Atlantic	0	0	0	0	0	0	0	0	0
Harp seal	0	0	0	0	0	0	0	0	0
Western North Atlantic	0	0	0	0	0	0	0	0	0
Hooded seal	0	0	0	0	0	0	0	0	0
Western North Atlantic	0	0	0	0	0	0	0	0	0

Note: The table displays maximum ship shock impacts to marine mammals by species (in bold text), as well as maximum impacts on individual stocks.
* ESA-listed species or stocks within the AFTT Study Area.
† NSD: No stock designated.

Authorized Take From Vessel Strikes

Vessel strikes from commercial, recreational, and military vessels are known to affect large whales and have resulted in serious injury and occasional fatalities to cetaceans (Berman-Kowalewski *et al.,* 2010; Calambokidis, 2012; Douglas *et al.,* 2008; Laggner 2009; Lammers *et al.,* 2003). Records of collisions date back to the early 17th century, and the worldwide number of collisions appears to have increased steadily during recent decades (Laist *et al.,* 2001; Ritter, 2012).

Numerous studies of interactions between surface vessels and marine

mammals have demonstrated that free-ranging marine mammals often, but not always (*e.g.,* McKenna *et al.,* 2015), engage in avoidance behavior when surface vessels move toward them. It is not clear whether these responses are caused by the physical presence of a surface vessel, the underwater noise generated by the vessel, or an interaction between the two (Amaral and Carlson, 2005; Au and Green, 2000; Bain *et al.,* 2006; Bauer 1986; Bejder *et al.,* 1999; Bejder and Lusseau, 2008; Bejder *et al.,* 2009; Bryant *et al.,* 1984; Corkeron, 1995; Erbe, 2002; Félix, 2001; Goodwin and Cotton, 2004; Lemon *et al.,* 2006; Lusseau, 2003; Lusseau, 2006; Magalhaes *et al.,* 2002; Nowacek *et al.,* 2001; Richter *et al.,* 2003; Scheidat *et al.,* 2004; Simmonds, 2005; Watkins, 1986; Williams *et al.,* 2002; Wursig *et al.,* 1998). Several authors suggest that the noise generated during motion is probably an important factor (Blane and Jaakson, 1994; Evans *et al.,* 1992; Evans *et al.,* 1994). Water disturbance may also be a factor. These studies suggest that the behavioral responses of marine mammals to surface vessels are similar to their behavioral responses to predators. Avoidance behavior is expected to be even stronger in the subset of instances that the Navy is conducting training or testing activities using active sonar or explosives.

The marine mammals most vulnerable to vessel strikes are those that spend extended periods of time at the surface in order to restore oxygen levels within their tissues after deep dives (*e.g.,* the sperm whale). In addition, some baleen whales, such as the NARW seem generally unresponsive to vessel sound, making them more susceptible to vessel collisions (Nowacek *et al.,* 2004). These species are primarily large, slower moving whales.

Some researchers have suggested the relative risk of a vessel strike can be assessed as a function of animal density and the magnitude of vessel traffic (*e.g.,* Fonnesbeck *et al.,* 2008; Vanderlaan *et al.,* 2008). Differences among vessel types also influence the probability of a vessel strike. The ability of any ship to detect a marine mammal and avoid a collision depends on a variety of factors, including environmental conditions, ship design, size, speed, and personnel, as well as the behavior of the animal. Vessel speed, size, and mass are all important factors in determining if injury or death of a marine mammal is likely due to a vessel strike. For large vessels, speed and angle of approach can influence the severity of a strike. For example, Vanderlaan and Taggart (2007) found that between vessel speeds of 8.6 and 15 knots, the probability that a vessel strike is lethal increases from 0.21 to 0.79. Large whales also do not have to be at the water's surface to be struck. Silber *et al.* (2010) found when a whale is below the surface (about one to two times the vessel draft), there is likely to be a pronounced propeller suction effect. This suction effect may draw the whale into the hull of the ship, increasing the probability of propeller strikes.

There are some key differences between the operation of military and non-military vessels, which make the likelihood of a military vessel striking a whale lower than some other vessels (*e.g.,* commercial merchant vessels). Key differences include:

- Many military ships have their bridges positioned closer to the bow, offering better visibility ahead of the ship (compared to a commercial merchant vessel).
- There are often aircraft associated with the training or testing activity (which can serve as Lookouts), which can more readily detect cetaceans in the vicinity of a vessel or ahead of a vessel's present course before crew on the vessel would be able to detect them.
- Military ships are generally more maneuverable than commercial merchant vessels, and if cetaceans are spotted in the path of the ship, could be capable of changing course more quickly.
- The crew size on military vessels is generally larger than merchant ships, allowing for stationing more trained Lookouts on the bridge. At all times when vessels are underway, trained Lookouts and bridge navigation teams are used to detect objects on the surface of the water ahead of the ship, including cetaceans. Additional Lookouts, beyond those already stationed on the bridge and on navigation teams, are positioned as Lookouts during some activities.
- When submerged, submarines are generally slow moving (to avoid detection) and therefore marine mammals at depth with a submarine are likely able to avoid collision with the submarine. When a submarine is transiting on the surface, there are Lookouts serving the same function as they do on surface ships.

Vessel strike to marine mammals is not associated with any specific training or testing activity but is rather an extremely limited and sporadic, but possible, accidental result of Navy vessel movement within the AFTT Study Area or while in transit.

There have been three recorded Navy vessel strikes (one in 2011 and two in 2012) of large whales in the AFTT Study Area from 2009 through 2018 (ten years), the period in which the Navy began implementing effective mitigation measures to reduce the likelihood of vessel strikes. Two of the vessel strikes occurred in the Virginia Capes Range Complex and one occurred in the lower Chesapeake Bay. One of the whales in 2012 had features suggesting it was most likely a humpback whale. Note that while the Navy was unable to identify the species of whale, it is unlikely the unidentified whales were NARW as the strikes occurred in areas where, or times of year when, NARW are not known to be present. In order to account for the accidental nature of vessel strikes to large whales in general, and the potential risk from any vessel movement within the AFTT Study Area within the seven-year period, the Navy requested incidental takes based on probabilities derived from a Poisson distribution using ship strike data between 2009 and 2018 in the AFTT Study Area (the time period from when current mitigation measures were instituted until the Navy conducted the analysis for the 2019 Navy application, with no new ship strikes occurring since this analysis), as well as historical at-sea days in the AFTT Study Area from 2009–2018 and estimated potential at-sea days for the period from 2018 to 2025 covered by the requested regulations. This distribution predicted the probabilities of a specific number of strikes (n = 0, 1, 2, *etc.*) over the period from 2018 to 2025. The analysis is described in detail in Chapter 6 of the Navy's 2017 and 2019 applications.

For the same reasons listed above describing why a Navy vessel strike is comparatively unlikely, it is highly unlikely that a Navy vessel would strike a whale, dolphin, porpoise, or pinniped without detecting it and, accordingly, NMFS is confident that the Navy's reported strikes are accurate and appropriate for use in the analysis. Specifically, Navy ships have multiple Lookouts, including on the forward part of the ship that can visually detect a hit animal, in the unlikely event ship personnel do not feel the strike. Unlike the situation for non-Navy ships engaged in commercial activities, NMFS and the Navy have no evidence that the Navy has struck a whale and not detected it. Navy's strict internal procedures and mitigation requirements include reporting of any vessel strikes of marine mammals, and the Navy's discipline, extensive training (not only for detecting marine mammals, but for detecting and reporting any potential navigational obstruction), and strict chain of command give NMFS a high level of confidence that all strikes actually get reported.

The Navy used the three whale strikes since 2009 in their calculations to determine the number of strikes likely to result from their activities (although worldwide strike information, from all Navy activities and other strikes, was used to inform the species that may be struck). The Navy evaluated data beginning in 2009, as that was the start of the Navy's Marine Species Awareness Training and adoption of additional mitigation measures to address ship strike, which will remain in place along with additional mitigation measures during the seven years of this rule.

The updated probability analysis in the 2019 Navy application concluded that there was a 12 percent chance that zero whales would be struck by Navy vessels over the next seven years in the AFTT Study Area, indicating an 88 percent chance that at least one whale would be struck over the next seven years. The analysis also concludes that there is a 10 percent chance of striking four whales over the seven-year period. Based on the revised analysis, the Navy requested coverage for one additional large whale mortality not previously included in the 2018 AFTT final rule bringing the total from three vessel strikes over five years to four vessel strikes over seven years. NMFS agrees that there is some probability that the Navy could strike, and take by serious injury or mortality, up to four large whales incidental to training and testing activities within the AFTT Study Area over the course of the seven years covered by this final rule.

Small whales, delphinids, porpoises, and pinnipeds are not expected to be struck by Navy vessels. In addition to the reasons listed above that make it unlikely that the Navy will hit a large whale (more maneuverable ships, larger crew, *etc.*), the following are additional reasons that vessel strike of dolphins, small whales, porpoises, and pinnipeds is very unlikely. Dating back more than 20 years and for as long as it has kept records, the Navy has no records of individuals of these groups being struck by a vessel as a result of Navy activities and, further, their smaller size and maneuverability make a strike unlikely. Also, NMFS has never received any reports from other authorized activities indicating that these species have been struck by vessels. Worldwide ship strike records show little evidence of strikes of these groups from the shipping sector and larger vessels, and the majority of the Navy's activities involving faster-moving vessels (that could be considered more likely to hit a marine mammal) are located in offshore areas where smaller delphinid, porpoise, and pinniped densities are lower. Based on this information, NMFS concurs with the Navy's assessment and recognizes the potential for incidental take by vessel strike of large whales only (*i.e.,* no dolphins, small whales, porpoises, or pinnipeds) over the course of the seven-year period analyzed here from training and testing activities.

Taking into account the available information regarding how many of any given stock could be struck and therefore should be authorized for take NMFS considered two factors in addition to those considered in the Navy's request: (1) The relative likelihood of hitting one stock versus another based on available strike data from all vessel types as denoted in the SARs and (2) whether the Navy has ever definitively struck an individual from a particular stock and, if so, how many times. To address number (1) above, NMFS compiled information from NMFS' SARs on detected annual rates of large whale serious injury and mortality from vessel collisions (Table 13). The annual rates of large whale serious injury and mortality from vessel collisions from the SARs help inform the relative susceptibility of large whale species to vessel strike in the Atlantic Ocean and the Gulf of Mexico. We summed the annual rates of mortality and serious injury from vessel collisions as reported in the SARs, then divided each species' annual rate by this sum to get the relative likelihood. To estimate the percent likelihood of striking a particular species of large whale, we multiplied the relative likelihood of striking each species by the total probability of striking a whale (*i.e.,* 88 percent, as described by the Navy's probability analysis). We also calculated the percent likelihood of striking a particular species of large whale twice by squaring the value estimated for the probability of striking a particular species of whale once (*i.e.,* to calculate the probability of an event occurring twice, multiply the probability of the first event by the second). We note that these probabilities vary from year to year as the average annual mortality for a given five-year window, as analyzed in the SARS, changes (and we include the annual averages from 2017 and 2018 draft SARs in Table 13 to illustrate); however, over the years and through changing SARs, stocks tend to consistently maintain a relatively higher or relatively lower likelihood of being struck. The analysis indicates that there is a very low percent chance of striking any particular species or stock more than once except for humpback whales, as shown in Table 13. The probabilities calculated as described above are then considered in combination with the information indicating the species that the Navy has definitively hit in the AFTT Study Area since 1995 (since they started tracking consistently). Accordingly, stocks that have no record of ever having been struck by any vessel are considered unlikely to be struck by the Navy in the seven-year period of the rule. Stocks that have never been struck by the Navy, have rarely been struck by other vessels, and have a low percentage likelihood based on the SAR calculation and a low relative abundance are also considered unlikely to be struck by the Navy during the seven-year rule.

TABLE 13—ANNUAL RATES OF MORTALITY AND SERIOUS INJURY (M/SI) FROM VESSEL COLLISIONS COMPILED FROM NMFS 2018 FINAL STOCK ASSESSMENT REPORTS (SARS) AND ESTIMATED PERCENT CHANCE OF STRIKING EACH LARGE WHALE SPECIES IN THE AFTT STUDY AREA OVER A SEVEN-YEAR PERIOD

Species (stock) [1]	Annual rate of M/SI from vessel collision (2017 SARs)	Annual rate of M/SI from vessel collision (2018 SARs)	Percent chance of ONE strike	Percent chance of TWO strikes	Annual authorized take	Take authorized over 7 years
Fin whale (Western North Atlantic)	1.6	1.4	19.83	3.93	0.14	1
Sei whale (Nova Scotia)	0.8	0.8	11.33	1.28	0.14	1
Minke whale (Canadian East Coast)	1.4	1	14.16	2.01	0.14	1
Humpback whale (Gulf of Maine)	1.8	2.6	36.82	13.55	0.29	2
Sperm whale (North Atlantic)	0.2	0.2	2.83	0.08	0.14	[2] 1
Bryde's whale (Northern Gulf of Mexico)	0.2	0.2	2.83	0.08	0	[3] 0
Sperm whale (Gulf of Mexico)	0	0	0	0	0	0

TABLE 13—ANNUAL RATES OF MORTALITY AND SERIOUS INJURY (M/SI) FROM VESSEL COLLISIONS COMPILED FROM NMFS 2018 FINAL STOCK ASSESSMENT REPORTS (SARS) AND ESTIMATED PERCENT CHANCE OF STRIKING EACH LARGE WHALE SPECIES IN THE AFTT STUDY AREA OVER A SEVEN-YEAR PERIOD—Continued

Species (stock) [1]	Annual rate of M/SI from vessel collision (2017 SARs)	Annual rate of M/SI from vessel collision (2018 SARs)	Percent chance of ONE strike	Percent chance of TWO strikes	Annual authorized take	Take authorized over 7 years
Blue whale (Western North Atlantic)	0	0	0	0	0	0

[1] North Atlantic right whales are not included in this analysis as NARWs are not anticipated to be struck due to the additional extensive mitigation the Navy implements to minimize the risk of striking this particular species. In addition, the Navy has not struck this species since prior to 2009 when the Navy's current vessel movement mitigation, reporting, and monitoring requirements have been in place.

[2] The analysis indicates only a very small likelihood (less than 3 percent) that a North Atlantic sperm whale would be struck over the seven years, however, the Navy has struck a sperm whale previously in the Atlantic, which may indicate a higher possibility that it could occur and suggests that authorizing one mortality over the seven years would be appropriate.

[3] Due to their low population abundance within the Study Area and lack of previous vessel strikes by the Navy, along with the Navy's enhanced mitigation measures in the Bryde's Whale Mitigation Area, Bryde's whales are not anticipated to be struck, and therefore have zero mortality/serious injury takes. The annual rate of mortality (0.2) is estimated from 1 Bryde's whale in 2009 (no more recent strikes have been documented).

For the reasons discussed in detail in the 2018 AFTT final rule and discussed further below, due to enhanced mitigation measures, NARWs are not anticipated to be struck by Navy vessels and are anticipated to have zero mortality/serious injury takes over the seven years of the rule. In addition, based on the quantitative method described above, blue whales and Gulf of Mexico sperm whales have a zero percent chance of being struck. After considering this result, along with additional factors discussed below, the Navy found that any vessel strike of these two stocks is highly unlikely. After fully considering all relevant information, NMFS agreed with this conclusion. Finally, the quantitative analysis outlined above indicates only a very small likelihood the Navy would strike a Bryde's whale (3 percent). Due to their low population abundance and lack of previous vessel strikes by the Navy, Bryde's whales are also unlikely to be struck and we have not authorized any mortality/serious injury takes. Alternately, the quantitative analysis discussed above also indicates only a very small likelihood that the Navy would strike a North Atlantic sperm whale over the seven years covered by the 2019 Navy application (less than 3 percent), however, the Navy has struck a sperm whale previously in the Atlantic (2005), which points to a higher possibility that it could occur and suggests that authorizing a single mortality/serious injury would be appropriate. Additional discussion relevant to our determinations for North Atlantic blue whales, Gulf of Mexico sperm whale, NARW, and Bryde's whale is included below.

In addition to the zero probability predicted by the quantitative model, there are no recent confirmed records of vessel collision to blue whales in the U.S. Atlantic waters, although there is one older historical record pointing to a ship strike that likely occurred beyond the U.S. Atlantic Exclusive Economic Zone (EEZ; outside of where most Navy activities occur, so less relevant) and one 1998 record of a dead 20 m (66 ft) male blue whale brought into Rhode Island waters on the bow of a tanker. The cause of death was determined to be ship strike; however, some of the injuries were difficult to explain from the necropsy. As noted previously, the Navy has been conducting Marine Species Awareness Training and implementing additional mitigation measures to protect against vessel strikes since 2009. Therefore, given the absence of any strikes in the recent past since the Navy has implemented its current mitigation measures, the very low abundance of North Atlantic blue whales throughout the AFTT Study Area (Nmin = 440 for the Western North Atlantic stock, Waring *et al.,* 2010), and the very low number of blue whales ever known to be struck in the area by any type of vessel (and none known to be struck by Navy vessels), we believe the likelihood of the Navy hitting a blue whale is discountable.

In addition to the zero probability of hitting a sperm whale in the Gulf of Mexico predicted by the quantitative model, there have been no vessel strikes of sperm whales by any entity since 2009 in the Gulf of Mexico per the SAR (2009–2013) and no Navy strikes of any large whales since 1995 (based on our records, which include Navy's records) in the Gulf of Mexico. Further, the Navy has comparatively fewer steaming days in the Gulf of Mexico and there is a fairly low abundance of sperm whales occurring there. As noted previously, the Navy has been conducting Marine Species Awareness Training and implementing additional mitigation measures to protect against vessel strikes since 2009. Therefore, NMFS believes that the likelihood of the Navy hitting a Gulf of Mexico sperm whale is discountable.

Although the quantitative analysis would indicate that NARWs do have a low probability of being struck one time within the seven-year period when vessel strikes across all activity types (including non-Navy) are considered (annual mortality and serious injury, hereafter abbreviated as M/SI, from vessel strikes is calculated as 0.41 in the 2018 SAR), when the enhanced mitigation measures (discussed below) that the Navy has been implementing and will continue to implement for NARWs are considered in combination with this low probability, a vessel strike is highly unlikely. Therefore, lethal take of NARWs was not requested by the Navy and is not authorized by NMFS. We further note that while there have been two strikes of unidentified whales by the Navy since 2009, it is unlikely they were NARW as the strikes occurred in areas where, or times of year when, NARW are not known to be present.

Regarding the Bryde's whale, due to the fact that the Navy has not struck a Bryde's whale (as no Navy strikes have occurred in the Gulf of Mexico), the very low abundance numbers (Nbest = 33 individuals, Hayes *et al.,* 2019), and the limited Navy ship traffic that overlaps with Bryde's whale habitat, neither the Navy nor NMFS anticipate any vessel-strike takes, and none were requested or authorized. The Navy is now also limiting activities (*i.e.,* 200 hr cap on hull-mounted MFAS) and will not use explosives (except during mine warfare activities) in the Bryde's Whale Mitigation Area. For a complete discussion and analysis of these mitigation areas, see the *Mitigation Measures* section in the 2018 AFTT

final rule along with a summary in the *Mitigation Measures* section of this final rule; see also Chapter 5 (Mitigation) of the 2018 AFTT FEIS/OEIS.

In addition to procedural mitigation, the Navy will continue to implement measures in mitigation areas used by NARW for foraging, calving, and migration. For a complete discussion and analysis of these mitigation areas, see the *Mitigation Measures* section in the 2018 AFTT final rule along with a summary in the *Mitigation Measures* section of this final rule; see also Chapter 5 (Mitigation) of the 2018 AFTT FEIS/OEIS. These measures, which go above and beyond those focused on other species (*e.g.,* funding of and communication with sightings systems, implementation of speed reductions during applicable circumstances in certain areas) have succeeded in the Navy avoiding strike of a NARW during training and testing activities in the past and essentially eliminate the potential for vessel strikes to occur during the seven-year period of this rule. In particular, the mitigation pertaining to vessels, including the continued participation in and sponsoring of the Early Warning System, will help Navy vessels avoid NARW during transits and training and testing activities. The Early Warning System is a comprehensive information exchange network dedicated to reducing the risk of vessel strikes to NARW off the southeast United States from all mariners (*i.e.,* Navy and non-Navy vessels). Navy participants include the Fleet Area Control and Surveillance Facility, Jacksonville; Commander, Naval Submarine Forces, Norfolk, Virginia; and Naval Submarine Support Command. The Navy, U.S. Coast Guard, U.S. Army Corps of Engineers, and NMFS collaboratively sponsor daily aerial surveys from December 1 through March 31 (weather permitting) to observe for NARW from the shoreline out to approximately 30–35 nmi offshore. Aerial surveyors relay sightings information to all mariners transiting within the NARW calving habitat (*e.g.,* commercial vessels, recreational boaters, and Navy ships).

In the Northeast NARW Mitigation Area, before all vessel transits, the Navy conducts a web query or email inquiry of NOAA's NARW Sighting Advisory System to obtain the latest NARW sightings information. Navy vessels currently use and will continue to use the obtained sightings information to reduce potential interactions with NARW during transits and prevent ship strikes. In this mitigation area, vessels will continue to implement speed reductions after they observe a NARW; if they are within 5 nmi of the location of a sighting reported to the NARW Sighting Advisory System within the past week; and when operating at night or during periods of reduced visibility. During transits and normal firing involving non-explosive torpedos activities, the Navy ships will continue to maintain a speed of no more than 10 kn. During submarine target firing, ships would maintain speeds of no more than 18 kn. During vessel target firing, vessel speeds would exceed 18 kn for only brief periods of time (*e.g.,* 10–15 min).

In the Southeast NARW Mitigation Area, before transiting or conducting training or testing activities within the mitigation area, the Navy will continue to initiate communication with the Fleet Area Control and Surveillance Facility, Jacksonville to obtain Early Warning System NARW whale sightings data. The Fleet Area Control and Surveillance Facility, Jacksonville will continue to advise vessels of all reported whale sightings in the vicinity to help vessels and aircraft reduce potential interactions with NARWs and prevent ship strikes. Commander Submarine Force U.S. Atlantic Fleet will coordinate any submarine activities that may require approval from the Fleet Area Control and Surveillance Facility, Jacksonville. Vessels will continue to use the sightings information to reduce potential interactions with NARW during transits and prevent ship strikes. Vessels will also implement speed reductions after they observe a NARW, if they are within 5 nmi of a sighting reported within the past 12 hours (hrs), or when operating in the mitigation area at night or during periods of poor visibility. To the maximum extent practicable, vessels will continue to minimize north-south transits in the mitigation area. Finally, the Navy will continue to broadcast awareness notification messages with NARW Dynamic Management Area information (*e.g.,* location and dates) to applicable Navy vessels operating in the vicinity of the Dynamic Management Area. The information will continue to alert assets to the possible presence of a NARW to maintain safety of navigation and further reduce the potential for a vessel strike. Navy platforms would use the information to assist their visual observation of applicable mitigation zones during training and testing activities and to aid in the implementation of procedural mitigation, including but not limited to, mitigation for vessel movement.

Implementation of these measures significantly reduces the possibility of striking NARWs during the seven-year period of the rule. The probability for any particular ship to strike a marine mammal is primarily a product of the ability of the ship to detect a marine mammal and the ability to effectively act to avoid it. Navy combat ships are inherently among the best at both of these because compared to large commercial vessels, they have trained Lookouts which have received specialized Marine Mammal Observer (MMO) training, and they are the most maneuverable ships, which means that they are more likely to sight a marine mammal and more likely to be able to maneuver to avoid it in the available time—both of which decrease the probability of striking a marine mammal below what it would have been in the absence of those abilities. In the case of the NARW, the extensive communication/detection network described above, which is in use in the areas of highest NARW occurrence and where they may be more susceptible to strike, further increases the likelihood of detecting a NARW and thereby avoiding it, which further reduces the probability of NARW strike. Further, detection of NARW in some areas/times is associated with reduced speed requirements, which may reduce the strike probability further by slightly increasing the time within which an operator has to maneuver away from a whale. Because of these additional mitigation measures combined with the already low probability that a NARW will be struck, it is extremely unlikely the Navy would strike a NARW, and mortality/serious injury of a NARW from vessel strike is neither anticipated nor authorized.

In conclusion, although it is generally unlikely that any whales will be struck in a year, based on the information and analysis above, NMFS anticipates that no more than four whales have the potential to be taken by serious injury or mortality over the seven-year period of the rule. Of those four whales over the seven years, no more than two would be humpback whales (Gulf of Maine stock) and no more than one would come from any of the four following stocks: Fin whale (Western North Atlantic stock), minke (Canadian East Coast stock), sperm whale (North Atlantic stock), and sei whale (Nova Scotia stock). Accordingly in the *Analysis and Negligible Impact Determination* section, NMFS has evaluated under the negligible impact standard the serious injury or mortality of 0.14 whales annually from each of these species or stocks (*i.e.,* 1 take over the 7 years divided by 7 to get the annual number), except for the humpback whale (North Atlantic stock) for which we used 0.29 (*i.e.,* 2 takes over

the 7 years divided by 7 to get the annual number) along with other expected harassment incidental take.

Mitigation Measures

Under section 101(a)(5)(A) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to the activity, and other means of effecting the least practicable adverse impact on the species or stock(s) and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of the species or stock(s) for subsistence uses (''least practicable adverse impact''). NMFS does not have a regulatory definition for least practicable adverse impact. The 2004 NDAA amended the MMPA as it relates to military readiness activities and the incidental take authorization process such that a determination of ''least practicable adverse impact'' shall include consideration of personnel safety, practicality of implementation, and impact on the effectiveness of the military readiness activity. For the full discussion of how NMFS interprets least practicable adverse impact, including how it relates to the negligible-impact standard, see the *Mitigation Measures* section in the 2018 AFTT final rule.

Section 101(a)(5)(A)(i)(II) requires NMFS to issue, in conjunction with its authorization, binding—and enforceable—restrictions (in the form of regulations) setting forth how the activity must be conducted, thus ensuring the activity has the ''least practicable adverse impact'' on the affected species or stocks. In situations where mitigation is specifically needed to reach a negligible impact determination, section 101(a)(5)(A)(i)(II) also provides a mechanism for ensuring compliance with the ''negligible impact'' requirement. Finally, we reiterate that the least practicable adverse impact standard also requires consideration of measures for marine mammal habitat, with particular attention to rookeries, mating grounds, and other areas of similar significance, and for subsistence impacts, whereas the negligible impact standard is concerned solely with conclusions about the impact of an activity on annual rates of recruitment and survival.[1] In evaluating what mitigation measures are appropriate, NMFS considers the potential impacts of the Specified Activities, the availability of measures to minimize those potential impacts, and the practicability of implementing those measures, as we describe below.

Implementation of Least Practicable Adverse Impact Standard

Our evaluation of potential mitigation measures includes consideration of two primary factors:

(1) The manner in which, and the degree to which, implementation of the potential measure(s) is expected to reduce adverse impacts to marine mammal species or stocks, their habitat, and their availability for subsistence uses (where relevant). This analysis considers such things as the nature of the potential adverse impact (such as likelihood, scope, and range), the likelihood that the measure will be effective if implemented, and the likelihood of successful implementation; and

(2) The practicability of the measures for applicant implementation. Practicability of implementation may consider such things as cost, impact on activities, and, in the case of a military readiness activity, under section 101(a)(5)(A)(ii) specifically considers personnel safety, practicality of implementation, and impact on the effectiveness of the military readiness activity.

While the language of the least practicable adverse impact standard calls for minimizing impacts to affected species or stocks and their habitats, we recognize that the reduction of impacts to those species or stocks accrues through the application of mitigation measures that limit impacts to individual animals. Accordingly, NMFS' analysis focuses on measures that are designed to avoid or minimize impacts on individual marine mammals when those impacts are likely to increase the probability or severity of population-level effects.

While direct evidence of impacts to species or stocks from a specified activity is rarely available, and additional study is still needed to understand how specific disturbance events affect the fitness of individuals of certain species, there have been improvements in understanding the process by which disturbance effects are translated to the population. With recent scientific advancements (both marine mammal energetic research and the development of energetic frameworks), the relative likelihood or degree of impacts on species or stocks may often be inferred given a detailed understanding of the activity, the environment, and the affected species or stocks—and the best available science has been used here. This same information is used in the development of mitigation measures and helps us understand how mitigation measures contribute to lessening effects (or the risk thereof) to species or stocks and their habitat. We also acknowledge that there is always the potential that new information, or a new recommendation that we had not previously considered becomes available in the future and necessitates reevaluation of mitigation measures (which may be addressed through adaptive management) to see if further reductions of population impacts are possible and practicable.

In the evaluation of specific measures, the details of the specified activity will necessarily inform each of the two primary factors discussed above (expected reduction of impacts and practicability), and are carefully considered to determine the types of mitigation that are appropriate under the least practicable adverse impact standard. Analysis of how a potential mitigation measure may reduce adverse impacts on a marine mammal stock or species, consideration of personnel safety, practicality of implementation, and consideration of the impact on effectiveness of military readiness activities are not issues that can be meaningfully evaluated through a yes/no lens. The manner in which, and the degree to which, implementation of a measure is expected to reduce impacts, as well as its practicability in terms of these considerations, can vary widely. For example, a time/area restriction could be of very high value for decreasing population-level impacts (*e.g.,* avoiding disturbance of feeding females in an area of established biological importance) or it could be of lower value (*e.g.,* decreased disturbance in an area of high productivity but of less firmly established biological importance). Regarding practicability, a measure might involve restrictions in an area or time that impede the Navy's ability to certify a strike group (higher impact on mission effectiveness), or it could mean delaying a small in-port training event by 30 minutes to avoid exposure of a marine mammal to injurious levels of sound (lower impact). A responsible evaluation of ''least practicable adverse impact'' considers the factors along these realistic scales. Accordingly, the greater the likelihood that a measure will contribute to reducing the probability or severity of adverse impacts to the species or stocks or their habitat, the greater the weight that measure is given when considered in combination with practicability to determine the appropriateness of the mitigation measure, and vice versa. In

[1] Outside of the military readiness context, mitigation may also be appropriate to ensure compliance with the ''small numbers'' language in MMPA sections 101(a)(5)(A) and (D).

the evaluation of specific measures, the details of the specified activity necessarily inform each of the two primary factors discussed above (expected reduction of impacts and practicability), and are carefully considered to determine the types of mitigation that are appropriate under the least practicable adverse impact standard. For more detail on how we apply these factors, see the discussion in the *Mitigation Measures* section of the 2018 AFTT final rule.

NMFS fully reviewed the Navy's specified activities and the mitigation measures for the 2018 AFTT rulemaking and determined that the mitigation measures would result in the least practicable adverse impact on marine mammals and their habitat. There is no change in either the activities or the mitigation measures for this seven-year rule. See the 2019 Navy application and the 2018 AFTT final rule for detailed information on the Navy's mitigation measures. NMFS worked with the Navy in the development of the Navy's initially proposed measures, which were informed by years of implementation and monitoring. A complete discussion of the Navy's evaluation process used to develop, assess, and select mitigation measures, which was informed by input from NMFS, can be found in Chapter 5 (Mitigation) of the 2018 AFTT FEIS/OEIS. The process described in Chapter 5 (Mitigation) of the 2018 AFTT FEIS/OEIS robustly supported NMFS' independent evaluation of whether the mitigation measures would meet the least practicable adverse impact standard. The Navy has implemented the mitigation measures under the 2018 AFTT regulations and will continue implementation of the mitigation measures identified in this rule for the full seven years to avoid or reduce potential impacts from acoustic, explosive, and physical disturbance and ship strike stressors.

In its 2019 application, the Navy proposed no changes to the mitigation measures in the 2018 AFTT final rule and there is no new information that affects NMFS' assessment of the applicability or effectiveness of those measures over the new seven-year period. See the 2018 AFTT proposed rule and the 2018 AFTT final rule for our full assessment and description of these measures. In summary, the Navy has agreed to procedural mitigation measures that will reduce the probability and/or severity of impacts expected to result from acute exposure to acoustic sources or explosives, ship strike, and impacts to marine mammal habitat. Specifically, the Navy will use a combination of delayed starts, powerdowns, and shutdowns to minimize or avoid serious injury or mortality, minimize the likelihood or severity of PTS or other injury, and reduce instances of TTS or more severe behavioral disruption caused by acoustic sources or explosives. The Navy also will implement multiple time/area restrictions (several of which were added in the 2018 AFTT final rule since the previous AFTT MMPA incidental take rule) that would reduce take of marine mammals in areas or at times where they are known to engage in important behaviors, such as feeding or calving, where the disruption of those behaviors would have a higher probability of resulting in impacts on reproduction or survival of individuals that could lead to population-level impacts. Summaries of the Navy's procedural mitigation measures and mitigation areas for the AFTT Study Area are provided in Tables 14 and 15.

TABLE 14—SUMMARY OF PROCEDURAL MITIGATION

Stressor or activity	Mitigation zones sizes and other requirements
Environmental Awareness and Education	• Afloat Environmental Compliance Training program for applicable personnel.
Active Sonar	Depending on sonar source: • 1,000 yd power down, 500 yd power down, and 200 yd shut down. • 200 yd shut down.
Air Guns	• 150 yd.
Pile Driving	• 100 yd.
Weapons Firing Noise	• 30 degrees on either side of the firing line out to 70 yd.
Explosive Sonobuoys	• 600 yd.
Explosive Torpedoes	• 2,100 yd.
Explosive Medium-Caliber and Large-Caliber Projectiles	• 1,000 yd (large-caliber projectiles). • 600 yd (medium-caliber projectiles during surface-to-surface activities). • 200 yd (medium-caliber projectiles during air-to-surface activities).
Explosive Missiles and Rockets	• 2,000 yd (21–500 lb net explosive weight). • 900 yd (0.6–20 lb net explosive weight).
Explosive Bombs	• 2,500 yd.
Sinking Exercises	• 2.5 nmi.
Explosive Mine Countermeasure and Neutralization Activities	• 2,100 yd (6–650 lb net explosive weight). • 600 yd (0.1–5 lb net explosive weight).
Explosive Mine Neutralization Activities Involving Navy Divers	• 1,000 yd (21–60 lb net explosive weight for positive control charges and charges using time-delay fuses). • 500 yd (0.1–20 lb net explosive weight for positive control charges).
Maritime Security Operations—Anti-Swimmer Grenades	• 200 yd.
Line Charge Testing	• 900 yd.
Ship Shock Trials	• 3.5 nmi.
Vessel Movement	• 500 yd (whales). • 200 yd (other marine mammals). • North Atlantic right whale Dynamic Management Area notification messages.
Towed In-Water Devices	• 250 yd.
Small-, Medium-, and Large-Caliber Non-Explosive Practice Munitions.	• 200 yd.
Non-Explosive Missiles and Rockets	• 900 yd.
Non-Explosive Bombs and Mine Shapes	• 1,000 yd.

Notes: lb: pounds; nmi: nautical miles; yd: yards.

TABLE 15—SUMMARY OF MITIGATION AREAS FOR MARINE MAMMALS

Summary of mitigation area requirements
Northeast North Atlantic Right Whale Mitigation Area
• The Navy must report the total hrs and counts of active sonar and in-water explosives used in the mitigation area in its annual training and testing activity reports. • The Navy must minimize use of active sonar to the maximum extent practicable and must not use explosives that detonate in the water. • The Navy must conduct non-explosive torpedo testing during daylight hrs in Beaufort sea state 3 or less using three Lookouts (one on a vessel, two in an aircraft during aerial surveys) and an additional Lookout on the submarine when surfaced; during transits, ships must maintain a speed of no more than 10 knots; during firing, ships must maintain a speed of no more than 18 knots except brief periods of time during vessel target firing. • Vessels must obtain the latest North Atlantic right whale sightings data and implement speed reductions after they observe a North Atlantic right whale, if within 5 nmi of a sighting reported within the past week, and when operating at night or during periods of reduced visibility.
Gulf of Maine Planning Awareness Mitigation Area
• The Navy must report the total hrs and counts of active sonar and in-water explosives used in the mitigation area in its annual training and testing activity reports. • The Navy must not conduct major training exercises and must not conduct >200 hrs of hull-mounted mid-frequency active sonar per year.
Northeast Planning Awareness Mitigation Areas and Mid-Atlantic Planning Awareness Mitigation Areas
• The Navy must avoid conducting major training exercises to the maximum extent practicable. • The Navy must not conduct more than four major training exercises per year.
Southeast North Atlantic Right Whale Mitigation Area (November 15–April 15)
• The Navy must report the total hrs and counts of active sonar and in-water explosives used in the mitigation area in its annual training and testing activity reports. • The Navy must not use active sonar except as necessary for navigation training, object detection training, and dipping sonar. • The Navy must not expend explosive or non-explosive ordnance. • Vessels must obtain the latest North Atlantic right whale sightings data; must implement speed reductions after they observe a North Atlantic right whale, if within 5 nmi of a sighting reported within the past 12 hrs, and when operating at night or during periods of reduced visibility; and must minimize north-south transits to the maximum extent practicable.
Jacksonville Operating Area (November 15–April 15)
• Navy units conducting training or testing activities in the Jacksonville Operating Area must obtain and use Early Warning System North Atlantic right whale sightings data as they plan specific details of events to minimize potential interactions with North Atlantic right whales to the maximum extent practicable. The Navy must use the reported sightings information to assist visual observations of applicable mitigation zones and to aid in the implementation of procedural mitigation.
Southeast North Atlantic Right Whale Critical Habitat Special Reporting Area (November 15–April 15)
• The Navy must report the total hrs and counts of active sonar and in-water explosives used in the mitigation area in its annual training and testing activity reports.
Navy Cherry Point Range Complex Nearshore Mitigation Area (March–September)
• The Navy must not conduct explosive mine neutralization activities involving Navy divers in the mitigation area. • To the maximum extent practicable, the Navy must not use explosive sonobuoys, explosive torpedoes, explosive medium-caliber and large-caliber projectiles, explosive missiles and rockets, explosive bombs, explosive mines during mine countermeasure and neutralization activities, and anti-swimmer grenades in the mitigation area.
Bryde's Whale Mitigation Area
• The Navy must report the total hrs and counts of active sonar and in-water explosives used in the mitigation area in its annual training and testing activity reports. • The Navy must not conduct >200 hrs of hull-mounted mid-frequency active sonar per year and must not use explosives (except during explosive mine warfare activities).
Gulf of Mexico Planning Awareness Mitigation Areas
• The Navy must not conduct any major training exercises under the action.

Notes: min.: minutes; nmi: nautical miles.

Mitigation Conclusions

NMFS has carefully evaluated the Navy's proposed mitigation measures—many of which were developed with NMFS' input during the previous phases of Navy training and testing authorizations and none of which have changed since our evaluation during the 2018 AFTT rulemaking—and considered a broad range of other measures (*i.e.,* the measures considered but eliminated in the 2018 AFTT FEIS/OEIS, which reflect many of the comments that have arisen via NMFS or public input in past years) in the context of ensuring that NMFS prescribes the means of effecting the least practicable adverse impact on the

affected marine mammal species and stocks and their habitat. Our evaluation of potential measures included consideration of the following factors in relation to one another: The manner in which, and the degree to which, the successful implementation of the mitigation measures is expected to reduce the likelihood and/or magnitude of adverse impacts to marine mammal species and stocks and their habitat; the proven or likely efficacy of the measures; and the practicability of the measures for applicant implementation, including consideration of personnel safety, practicality of implementation, and impact on the effectiveness of the military readiness activity. There is no new information that affects our analysis from the 2018 AFTT rulemaking, all of which remains applicable and valid for our assessment of the appropriateness of the mitigation measures during the seven-year period of this rule.

Based on our evaluation of the Navy's measures (which are currently being implemented under the 2018 AFTT regulations), as well as other measures considered by the Navy and NMFS, NMFS has determined that the Navy's mitigation measures are appropriate means of effecting the least practicable adverse impacts on marine mammal species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and considering specifically personnel safety, practicality of implementation, and impact on the effectiveness of the military readiness activity. Additionally, as described in more detail below, the 2018 AFTT final rule included an adaptive management provision, which NMFS has extended for the additional two years of this rule, which ensures that mitigation is regularly assessed and provides a mechanism to improve the mitigation, based on the factors above, through modification as appropriate.

Monitoring

Section 101(a)(5)(A) of the MMPA states that in order to authorize incidental take for an activity, NMFS must set forth requirements pertaining to the monitoring and reporting of such taking. The MMPA implementing regulations at 50 CFR 216.104(a)(13) indicate that requests for incidental take authorizations must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present.

In its 2019 application, the Navy proposed no changes to the monitoring described in the 2018 AFTT final rule. They would continue implementation of the robust Integrated Comprehensive Monitoring Program and Strategic Planning Process described in the 2018 AFTT final rule. The Navy's monitoring strategy, currently required by the 2018 AFTT regulations and extended for two years under this final rule, is well-designed to work across Navy ranges to help better understand the impacts of the Navy's activities on marine mammals and their habitat by focusing on learning more about marine mammal occurrence in different areas and exposure to Navy stressors, marine mammal responses to different sound sources, and the consequences of those exposures and responses on marine mammal populations. Similarly, the seven-year regulations include identical adaptive management provisions and reporting requirements as the 2018 AFTT regulations. There is no new information to indicate that the monitoring measures put in place under the 2018 AFTT final rule do not remain applicable and appropriate for the seven-year period of this final rule. See the *Monitoring* section of the 2018 AFTT final rule for more details on the monitoring that is required under this rule.

Adaptive Management

The 2018 AFTT regulations governing the take of marine mammals incidental to Navy training and testing activities in the AFTT Study Area contain an adaptive management component. Our understanding of the effects of Navy training and testing activities (*e.g.,* acoustic and explosive stressors) on marine mammals continues to evolve, which makes the inclusion of an adaptive management component both valuable and necessary within the context of seven-year regulations. The 2019 Navy application proposed no changes to the adaptive management component included in the 2018 AFTT final rule.

The reporting requirements associated with this rule are designed to provide NMFS with monitoring data from the previous year to allow NMFS to consider whether any changes to existing mitigation and monitoring requirements are appropriate. The use of adaptive management allows NMFS to consider new information from different sources to determine (with input from the Navy regarding practicability) on an annual or biennial basis if mitigation or monitoring measures should be modified (including additions or deletions). Mitigation measures could be modified if new data suggests that such modifications would have a reasonable likelihood of more effectively accomplishing the goals of the mitigation and monitoring and if the measures are practicable. If the modifications to the mitigation, monitoring, or reporting measures are substantial, NMFS will publish a notice of the planned LOA in the **Federal Register** and solicit public comment.

The following are some of the possible sources of applicable data to be considered through the adaptive management process: (1) Results from monitoring and exercises reports, as required by MMPA authorizations; (2) compiled results of Navy funded research and development studies; (3) results from specific stranding investigations; (4) results from general marine mammal and sound research; and (5) any information which reveals that marine mammals may have been taken in a manner, extent, or number not authorized by these regulations or subsequent LOAs. The results from monitoring reports and other studies may be viewed at *https://www.navymarinespeciesmonitoring.us/.*

Reporting

In order to issue incidental take authorization for an activity, section 101(a)(5)(A) of the MMPA states that NMFS must set forth requirements pertaining to the monitoring and reporting of such taking. Effective reporting is critical both to compliance as well as ensuring that the most value is obtained from the required monitoring. Reports from individual monitoring events, results of analyses, publications, and periodic progress reports for specific monitoring projects will be posted to the Navy's Marine Species Monitoring web portal: *http://www.navymarinespeciesmonitoring.us.* The 2019 Navy application proposed no changes to the reporting requirements identified in the 2018 AFTT final rule. Reporting requirements under this final rule remain identical to those described in the 2018 AFTT final rule, where there is no new information to indicate that the reporting requirements put in place under the 2018 AFTT final rule do not remain applicable and appropriate for the seven-year period of this final rule. See the *Reporting* section of the 2018 AFTT final rule for more details on the reporting that is required under this rule.

Analysis and Negligible Impact Determination

NMFS has defined negligible impact as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival (50 CFR 216.103). A negligible impact finding is based on the lack of likely adverse effects on annual rates of recruitment or survival (*i.e.,* population-level effects). An estimate of the number of takes alone is not enough information on which to base an impact determination. In addition to considering estimates of the number of marine mammals that might be ''taken'' through mortality, serious injury, and Level A or Level B harassment (as presented in Tables 10–13), NMFS considers other factors, such as the likely nature of any responses (*e.g.,* intensity, duration), the context of any responses (*e.g.,* critical reproductive time or location, migration), as well as effects on habitat, and the likely effectiveness of the mitigation. We also assess the number, intensity, and context of estimated takes by evaluating this information relative to population status. Consistent with the 1989 preamble for NMFS' implementing regulations (54 FR 40338; September 29, 1989), the impacts from other past and ongoing anthropogenic activities are incorporated into this analysis via their impacts on the environmental baseline (*e.g.,* as reflected in the regulatory status of the species, population size and growth rate where known, other ongoing sources of human-caused mortality, and ambient noise levels).

In the *Estimated Take of Marine Mammals* sections of this final rule and the 2018 AFTT final rule (where the activities, species and stocks, potential effects, and mitigation measures are the same as for this rule), we identified the subset of potential effects that would be expected to rise to the level of takes both annually and over the seven-year period covered by this rule, and then identified the number of each of those mortality takes that we believe could occur or the maximum number of harassment takes that are reasonably expected to occur based on the methods described. The impact that any given take will have is dependent on many case-specific factors that need to be considered in the negligible impact analysis (*e.g.,* the context of behavioral exposures such as duration or intensity of a disturbance, the health of impacted animals, the status of a species that incurs fitness-level impacts to individuals, *etc.*). For this final rule we evaluated the likely impacts of the enumerated maximum number of harassment takes proposed to be authorized and reasonably expected to occur, in the context of the specific circumstances surrounding these predicted takes. We also assessed M/SI takes that have the potential to occur, as well as considering the traits and statuses of the affected species and stocks. Last, we collectively evaluated this information, as well as other more taxa-specific information and mitigation measure effectiveness, in group-specific assessments that support our negligible impact conclusions for each stock.

The nature and level of the specified activities and the boundaries of the AFTT Study Area, and therefore the training and testing activities (*e.g.,* equipment and sources used, exercises conducted) are the same as those analyzed in the 2018 AFTT final rule. In addition, the mitigation, monitoring, and reporting measures are identical to those described and analyzed in the 2018 AFTT final rule. As described above, there is no new information available since the publication of the 2018 AFTT final rule regarding the impacts of the specified activities on marine mammals, the status and distribution of any of the affected marine mammal species or stocks, or the effectiveness of the mitigation and monitoring measures that would change our analyses.

Harassment

As described in the *Estimated Takes of Marine Mammals* section, the annual number of takes authorized and reasonably expected to occur by Level A harassment and Level B harassment (based on the maximum number of activities per 12-month period) are identical to those presented in Tables 39 through 41 in the *Take Requests* section of the 2018 AFTT final rule. As such the negligible impact analyses and determinations of the effects of the estimated Level A harassment and Level B harassment takes on annual rates of recruitment or survival for each species and stock are identical to that presented in the 2018 AFTT final rule. The only difference is that the annual levels of take and the associated effects on reproduction or survival will occur for the seven-year period of the rule instead of the five-year period of the 2018 AFTT final rule, which will make no difference in effects on annual rates of recruitment or survival. For detailed discussion of the impacts that affected individuals may experience given the specific characteristics of the specified activities and required mitigation (*e.g.,* from behavioral harassment, masking, and temporary or permanent threshold shift), along with the effects of the expected Level A harassment and Level B harassment take on reproduction and survival, see the applicable subsections in the *Analysis and Negligible Impact Determination* section of the 2018 AFTT final rule (83 FR 57211–57217; November 14, 2018).

Serious Injury or Mortality

No additional ship shock trials will occur during the seven-year period of the rule, so the requested and authorized total takes by M/SI due to explosives used during ship shock trials over seven years are the same as those authorized in the existing 2018 AFTT regulations. There is no new information that affects the methodology or results of the ship-shock analysis presented in the 2018 AFTT final rule. But as these same activities would occur over seven years rather than five years, the estimated annual take is calculated as the number of total takes divided by seven. For each of the dolphin species and stocks listed in Table 16 there would be an annual take of 0.14 dolphins (*i.e.,* for those species and stocks where one take could occur divided by seven years to get the annual number of M/SIs) or 0.86 dolphins in the case of short-beaked common dolphin (*i.e.,* where six takes could occur divided by seven years to get the annual number of M/SIs). This is a decrease from the annual take of 0.2 dolphins (for the three species where one lethal take could occur) and annual take of 1.2 short-beaked common dolphins (where six lethal takes could occur) over the five-year period of the 2018 AFTT regulations, as shown in Table 70 in the 2018 AFTT final rule. As this annual number is less than that analyzed and authorized in the 2018 AFTT final rule and no other relevant information about the status, abundance, or effects of mortality on each species and stock has changed, the analysis of the effects of take from ship shock trials mirrors that presented in the 2018 AFTT final rule.

TABLE 16—SUMMARY INFORMATION RELATED TO AFTT SERIOUS INJURY OR MORTALITY FROM EXPLOSIVES (SHIP SHOCK TRIALS), 2018–2025

Species (stock)	Stock abundance (Nbest)*	Annual estimated take by serious injury or mortality (M/SI) [1]	Total annual M/SI * [2]	Fisheries interactions (Y/N); annual rate of M/SI from fisheries interactions *	Potential biological removal (PBR) * [3]	NEFSC authorized take (annual)	Residual PBR-PBR minus annual M/SI and NEFSC authorized take [4]	Stock trend * [5]	UME (Y/N); number and year
Atlantic white-sided dolphin (Western N. Atlantic).	48,819	0.14	30	30	304	0.6	273.4	?	N
Pantropical spotted dolphin (Northern GOMEX).	50,880	0.14	4.4	4.4	407	0	402.6	?	Y; 3 in 2010–2014
Short-beaked common dolphin (Western N. Atlantic).	70,184	0.86	406	406	557	2	149	?	N
Spinner dolphin (Northern GOMEX)	11,441	0.14	0	0	62	0	62	?	Y; 7 in 2010–2014

* Presented in the 2018 SARS.
[1] This column represents the annual take by M/SI during ship shock trials and was calculated by the number of mortalities planned for authorization divided by seven years (the length of the rule and LOAs).
[2] This column represents the total number of incidents of M/SI that could potentially accrue to the specified species or stock. This number comes from the SAR, but deducts the takes accrued from either Navy or NEFSC takes as noted in the SARs to ensure they are not double-counted against PBR. However, for these species, there were no takes from either Navy or NEFSC as noted in the SARs to deduct that would be considered double-counting.
[3] Potential biological removal (PBR) is defined in section 3 of the MMPA. See the *Analysis and Negligible Impact Determination* section of the 2018 AFTT final rule for a description of PBR.
[4] This value represents the calculated PBR less the average annual estimate of ongoing anthropogenic mortalities (*i.e.,* total annual human-caused M/SI, which is presented in the 2018 SARs) and authorized take for NEFSC.
[5] See relevant SARs for more information regarding stock status and trends.

The other facet of the analysis for which there is a quantitative change from the 2018 AFTT final rule is the number of potential mortalities due to ship strike authorized over the seven-year period. First, based on the information and methods discussed in the *Estimated Take of Marine Mammals* section (which are identical to those used in the 2018 AFTT final rule), NMFS has predicted that mortal takes of four large whales over the course of the seven-year rule could occur (as compared to three large whales over five years in the 2018 AFTT final rule). Second, while no more than one whale over the seven years of any species of fin whale, sei whale, minke whale, or sperm whale (North Atlantic stock) would occur (which is the same as in the five-year 2018 AFTT final rule), as described above in the *Estimated Take of Marine Mammals* section, the number of potential mortality takes of humpback whales has increased from one to two. This means an annual average of 0.29 humpback whales and an annual average of 0.14 whales for each of the other four species or stocks as described in Table 17 (*i.e.,* one, or two, take(s) over seven years divided by seven to get the annual number) are expected to potentially occur and are authorized. As this annual number is less than that analyzed and authorized in the 2018 AFTT final rule for fin whale, sei whale, minke whale, and sperm whale (North Atlantic stock), which was an annual average of 0.2 whales for the same four species and stocks, and no other relevant information about the status, abundance, or effects of mortality on each species or stock has changed, the analysis of the effects of vessel strike mirrors that presented in the 2018 AFTT final rule. For humpback whales, the annual number for potential mortality takes is slightly higher than in the 2018 AFTT final rule, but the number still falls below the insignificance threshold of 10 percent of residual Potential Biological Removal (PBR), which indicates an insignificant incremental increase in ongoing anthropogenic mortality that alone will not adversely affect annual rates of recruitment or survival. The analysis of the effects of this potential mortality on humpback whales' annual rates of recruitment and survival, considered in combination with other estimated harassment takes, appears in the *Group and Species-Specific Analyses* section for Mysticetes below.

See the *Serious Injury and Mortality* subsection in the *Analysis and Negligible Impact Determination* section of the 2018 AFTT final rule (83 FR 57217–57223; November 14, 2018) for detailed discussions of the impacts of M/SI, including a description of how the agency uses the PBR metric and other factors to inform our analysis, and an analysis of the impacts on each species and stock for which mortality is authorized, including the relationship of potential mortality for each species to the insignificance threshold and residual PBR. Because the annual number of potential mortality takes for humpback whales remains below the insignificance threshold, the discussion for humpback whales (83 FR 57221–57222; November 14, 2018) remains fully applicable. For discussion specifically on the role of the calculated PBR in evaluating the effects of M/SI, see both the 2018 AFTT final rule and the 2018 Hawaii-Southern California Training and Testing (HSTT) Study Area final rule (83 FR 66846; December 27, 2018).

TABLE 17—SUMMARY INFORMATION RELATED TO AFTT SHIP STRIKE, 2018–2025.

Species (stock)	Stock abundance (Nbest) *	Annual estimated take by serious injury or mortality (M/SI) [1]	Total annual M/SI * [2]	Fisheries interactions (Y/N); Annual rate of M/SI from fisheries interactions *	Vessel collisions (Y/N); Annual rate of M/SI from vessel collision *	PBR *	NEFSC authorized take (annual)	Residual PBR–PBR minus annual M/SI and NEFSC authorized take [3]	Stock trend * [4]	UME (Y/N); number and year [5]
Fin whale (Western North Atlantic).	1,618	0.14	2.5	Y; 1.1	Y; 1.4	2.5	0	0	?	N.
Sei whale (Nova Scotia).	357	0.14	0.8	N; 0	Y; 0.8 *	0.5	0	-0.3	?	N.
Minke Whale (Canadian East Coast).	2,591	0.14	7.5	Y; 6.5	Y; 1†	14	1	5.5	?	Y; 18 in 2019 as of 10/24/2019 (27 in 2017 and 30 in 2018).

TABLE 17—SUMMARY INFORMATION RELATED TO AFTT SHIP STRIKE, 2018–2025.—Continued

Species (stock)	Stock abundance (Nbest) *	Annual estimated take by serious injury or mortality (M/SI) [1]	Total annual M/SI * [2]	Fisheries interactions (Y/N); Annual rate of M/SI from fisheries interactions *	Vessel collisions (Y/N); Annual rate of M/SI from vessel collision *	PBR *	NEFSC authorized take (annual)	Residual PBR–PBR minus annual M/SI and NEFSC authorized take [3]	Stock trend * [4]	UME (Y/N); number and year [5]
Humpback whale (Gulf of Maine).	896	0.29	9.7	Y; 7.1	Y; 2.6	14.6	0	4.9	↑	Y; 22 in 2019 as of 10/24/2019 (26 in 2016, 34 in 2017 and 25 in 2018).
Sperm whale (North Atlantic).	2,288	0.14	0.8	Y; 0.6	Y; 0.2	3.6	0	2.8	?	N.

* Presented in the 2018 SARS.
† Value presented incorrectly in the 2018 AFTT final rule and corrected here.
[1] This column represents the annual take by M/SI by vessel collision and was calculated by the number of mortalities planned for authorization divided by seven years (the length of the rule and LOAs).
[2] This column represents the total number of incidents of M/SI that could potentially accrue to the specified species or stock. This number comes from the SAR, but deducts the takes accrued from either Navy strikes or NEFSC takes as noted in the SARs to ensure they are not double-counted against PBR. However, for these species, there were no takes from either Navy or NEFSC as noted in the SARs to deduct that would be considered double-counting.
[3] This value represents the calculated PBR less the average annual estimate of ongoing anthropogenic mortalities (*i.e.,* total annual human-caused M/SI, which is presented in the 2018 SARs) and authorized take for NEFSC.
[4] See relevant SARs for more information regarding stock status and trends.
[5] This column presents UME information updated since the 2018 AFTT final rule, as discussed in the earlier section *Potential Effects of Specified Activities on Marine Mammals and their Habitat.*

Group and Species-Specific Analyses

In addition to broader analyses of the impacts of the Navy's activities on mysticetes, odontocetes, and pinnipeds, the 2018 AFTT final rule contained detailed analyses of the effects of the Navy's activities in the AFTT Study Area on each affected species and stock. All of that information and analyses remain applicable and valid for our analyses of the effects of the same Navy activities on the same species and stocks for the seven-year period of this final rule. See the *Group and Species-Specific Analyses* subsection in the *Analysis and Negligible Impact Determination* section of the 2018 AFTT final rule (83 FR 57223–57247; November 14, 2018). In addition, no new information has been received since the publication of the 2018 AFTT final rule that significantly changes the analyses on the effects of the Navy's activities on each species and stock presented in the 2018 AFTT final rule.

In the discussions below, the estimated Level B harassment takes represent instances of take, not the number of individuals taken (the much lower and less frequent Level A harassment takes are far more likely to be associated with separate individuals), and in many cases some individuals are expected to be taken more than one time, while in other cases a portion of individuals will not be taken at all. Below, we compare the total take numbers (including PTS, TTS, and behavioral disruption) for species or stocks to their associated abundance estimates to evaluate the magnitude of impacts across the stock and to individuals. Specifically, when an abundance percentage comparison is below 100, it means that that percentage or less of the individuals in the stock will be affected (*i.e.,* some individuals will not be taken at all), that the average for those taken is one day per year, and that we would not expect any individuals to be taken more than a few times in a year. When it is more than 100 percent, it means there will definitely be some number of repeated takes of individuals. For example, if the percentage is 300, the average would be each individual is taken on three days in a year if all were taken, but it is more likely that some number of individuals will be taken more than three times and some number of individuals fewer or not at all. While it is not possible to know the maximum number of days across which individuals of a stock might be taken, in acknowledgement of the fact that it is more than the average, for the purposes of this analysis, we assume a number approaching twice the average. For example, if the percentage of take compared to the abundance is 800, we estimate that some individuals might be taken as many as 16 times. Those comparisons are included in the sections below. For some stocks these numbers have been adjusted slightly (with these adjustments being in the single digits) so as to more consistently apply this approach, but these minor changes did not change the analysis or findings.

To assist in understanding what this analysis means, we clarify a few issues related to estimated takes and the analysis here. In the annual estimated take tables below, takes within the U.S. EEZ include only those takes within the U.S. EEZ where most Navy activities occur and where we often have the best information on species and stock presence and abundance. Takes inside and outside the EEZ include all takes in the AFTT Study Area. An individual that incurs a PTS or TTS take may sometimes, for example, also be behaviorally disturbed at the same time. As described in the *Harassment* subsection of the *Analysis and Negligible Impact Determination* section of the 2018 AFTT final rule, the degree of PTS, and the degree and duration of TTS, expected to be incurred from the Navy's activities are not expected to impact marine mammals such that their reproduction or survival could be affected. Similarly, data do not suggest that a single instance in which an animal accrues PTS or TTS and is also behaviorally harassed would result in impacts to reproduction or survival. Alternately, we recognize that if an individual is behaviorally harassed repeatedly for a longer duration and on consecutive days, effects could accrue to the point that reproductive success is jeopardized (as discussed below in the stock-specific summaries). Accordingly, in analyzing the number of takes and the likelihood of repeated and sequential takes (which could result in reproductive impacts), we consider the total takes, not just the behavioral Level B harassment takes, so that individuals potentially exposed to both threshold shift and behavioral disruption are appropriately considered. We note that the same reasoning applies with the potential addition of behavioral disruption (harassment) to tissue damage from explosives, the difference

being that we do already consider the likelihood of reproductive impacts whenever tissue damage occurs. Further, the number of Level A harassment takes by either PTS or tissue damage are so low compared to abundance numbers that it is considered highly unlikely that any individual would be taken at those levels more than once.

Having considered all of the information and analyses previously presented in the 2018 AFTT final rule, including the information presented in the *Overview,* the *Deepwater Horizon (DWH) Oil Spill* discussion, and the *Group and Species-Specific Analyses* discussions organized by the different groups and species, below we present tables showing instances of total take as a percentage of stock abundance for each group, updated with the new vessel strike and ship shock calculations for some species. We then summarize the information for each species or stock, considering the analysis from the 2018 AFTT final rule and any new analysis. The analyses below in some cases address species collectively if they occupy the same functional hearing group (*i.e.,* low, mid, and high-frequency cetaceans and pinnipeds in water), share similar life history strategies, and/or are known to behaviorally respond similarly to acoustic stressors. Because some of these groups or species share characteristics that inform the impact analysis similarly, it would be duplicative to repeat the same analysis for each species or stock. In addition, animals belonging to each stock within a species typically have the same hearing capabilities and behaviorally respond in the same manner as animals in other stocks within the species.

Mysticetes

In Table 18 below for mysticetes, we indicate the total annual mortality, Level A and Level B harassment, and a number indicating the instances of total take as a percentage of abundance. Table 18 is unchanged from Table 72 in the 2018 AFTT final rule, except for updated information on mortality, as discussed above. For additional information and analysis supporting the negligible-impact analysis, see the *Mysticetes* discussion in the *Group and Species-Specific Analyses* section of the 2018 AFTT final rule, all of which remains applicable to this final rule unless specifically noted.

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Table 18 -- Annual Estimated Takes by Level B Harassment, Level A Harassment, and Mortality for Mysticetes in the AFTT Study Area and Number Indicating the Instances of Total Take as a Percentage of Stock Abundance.

		Instances of indicated types of incidental take (not all takes represent separate individuals, especially for disturbance)					Total takes		Abundance		Instances of total take as percentage of abundance	
		Level B Harassment		Level A Harassment								
Species	Stock	Behavioral Disturbance	TTS (may also include disturbance)	PTS	Tissue Damage	Mortality	In EEZ	Inside and Outside EEZ	In EEZ	Inside and Outside EEZ	In EEZ	Inside and Outside EEZ
Suborder Mysticeti (baleen whales)												
Family Balaenidae (right whales)												
North Atlantic right whale*	Western North Atlantic	203	268	0	0	0	471	471	343	343	137	137
Family Balaenopteridae (roquals)												
Blue whale*	Western North Atlantic (Gulf of St. Lawrence)	12	35	0	0	0	44	47	9	104	489	45
Bryde's whale	Northern Gulf of Mexico	24	31	1	0	0	56	56	50	50	112	112
	NSD	77	260	0	0	0	313	337	50	563	626	60
Minke whale	Canadian East Coast	796	3,284	5	0	0.14	3,913	4,085	730	7,686	536	53
Fin whale*	Western North Atlantic	1,716	3,671	33	0	0.14	5,368	5,420	1,660	14,769	323	37
Humpback whale	Gulf of Maine	248	498	3	0	0.29	698	749	496	4,580	141	16
Sei whale*	Nova Scotia	245	556	4	0	0.14	779	805	246	11,737	317	7

Note: In the table we compare estimated takes to abundance estimates generated from the same underlying density estimate (as described in the *Estimated Take of Marine Mammals* section of the 2018 AFTT final rule), versus abundance estimates directly from NMFS' SARs, which are not based on the same data and would not be appropriate for this purpose. Note that comparisons are made both within the U.S. EEZ only (where density estimates have lesser uncertainty) and across the whole Study Area (which offers a more comprehensive comparison for many stocks).

Total takes inside and outside U.S. EEZ represent the sum of annual Level A and Level B harassment from training and testing plus harassment take from one large ship shock trial.

The annual mortality of 0.14 is the result of no more than one mortality over the course of seven years from vessel strikes as described above in the *Estimated Take of Marine Mammals* section. The annual mortality of 0.29 is the result of no more than two mortalities over the course of seven years from vessel strikes as described above in the same section.

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Below we compile and summarize the information that supports our determination that the Navy's activities will not adversely affect any species or stocks through effects on annual rates of recruitment or survival for any of the affected mysticete species and stocks.

North Atlantic Right Whale (Western Stock)

As described in the 2018 AFTT final rule, the status of NARW is precarious and they are listed as endangered under the ESA. There is an active UME associated with the recent unusually high number of deaths, some of which have been attributed to entanglement or vessel strike, although no vessel strikes have been attributed to the Navy. The number of births in recent years has been unusually low and recent studies have reported individuals showing poor health or high stress levels. Accordingly, as described above and in the 2018 AFTT final rule, the Navy is implementing and will continue to implement a suite of mitigation measures that not only avoid the likelihood of ship strikes, but also minimize the severity of behavioral disruption by minimizing impacts in areas that are important for feeding and calving, thus ensuring that the relatively small number of Level B harassment takes that do occur are not expected to affect reproductive success or survivorship via detrimental impacts to energy intake or cow/calf interactions. Specifically, no mortality or Level A harassment is anticipated or authorized. Regarding the magnitude of Level B harassment takes (TTS and behavioral disruption), the number of estimated instances compared to the abundance (137 percent) combined with the fact that the AFTT Study Area overlaps most if not all of the range, suggests that many to most of the individuals in the stock will likely be taken, but only on one or two days per year, with no reason to think the days will likely be sequential. Regarding the severity of those individual takes by behavioral Level B harassment, as explained in the 2018 AFTT final rule, the duration of any exposure is expected to be between minutes and hours (*i.e.,* relatively short), the received sound levels are largely below 172 dB with some lesser portion up to 178 dB (*i.e.,* of a moderate or lower level, less likely to evoke a severe response), and because of the mitigation measures the exposures will

not occur in areas or at times where impacts would be likely to affect feeding and energetics or important cow/calf interactions that could lead to reduced reproductive success or survival. Regarding the severity of TTS takes, as explained in the 2018 AFTT final rule, they are expected to be low-level and of short duration and the associated lost opportunities and capabilities are not at a level that would impact reproduction or survival.

Altogether, any individual NARW is likely to be disturbed at a low-moderate level on no more than a couple of likely non-sequential days per year (and not in biologically important areas). Even given the fact that some of the affected individuals may have compromised health, there is nothing to suggest that such a low magnitude and severity of effects would result in impacts on reproduction or survival of any individual, much less annual rates of recruitment or survival for the stock. For these reasons, we have determined, in consideration of all of the effects of the Navy's activities combined, that the authorized take will have a negligible impact on NARW.

Blue Whale (Western North Atlantic Stock)

This is a wide-ranging stock that is best considered as ''an occasional visitor'' to the U.S. EEZ, which may represent the southern limit of its feeding range (Hayes *et al.,* 2018), though no specific feeding areas have been identified. For this reason, the abundances calculated by the Navy based on survey data in the U.S. EEZ are very low (9 and 104, in the U.S. EEZ and throughout the range respectively) and while NMFS' SAR does not predict an abundance, it does report an Nmin (minimum abundance) of 440. There is no currently reported trend for the population and there are no specific issues with the status of the stock that cause particular concern (*e.g.,* no UMEs), although the species is listed as endangered under the ESA. We note, however, that this species was originally listed under the ESA as a result of the impacts from commercial whaling, which is no longer affecting the species. No mortality or Level A harassment is anticipated or authorized for blue whales. Regarding the magnitude of Level B harassment takes (TTS and behavioral disruption), given the number of total takes (47), the large range and wide-ranging nature of blue whales, and the minimum abundance identified in the SAR, there is no reason to think that any single animal will be taken by Level B harassment more than one time (though perhaps a few could be) and less than 10 percent of the population is likely to be impacted. Regarding the severity of those individual Level B harassment behavioral takes, as explained in the 2018 AFTT final rule, the duration of any exposure is expected to be between minutes and hours (*i.e.,* relatively short) and the received sound levels are largely below 172 dB with a portion up to 178 dB (*i.e.,* of a moderate or lower level, less likely to evoke a severe response). Regarding the severity of TTS takes, as explained in the 2018 AFTT final rule, they are expected to be low-level and of short duration and the associated lost opportunities and capabilities not at a level that would impact reproduction or survival.

Altogether, less than 10 percent of the stock is likely to be impacted and any individual blue whale is likely to be disturbed at a low-moderate level on no more than a day or two days per year and not in any known biologically important areas. This low magnitude and severity of effects is unlikely to result in impacts on the reproduction or survival of any individual, much less annual rates of recruitment or survival for the stock. For these reasons, we have determined, in consideration of all of the effects of the Navy's activities combined, that the authorized take will have a negligible impact on blue whales.

Bryde's Whale (Northern Gulf of Mexico Stock)

The Northern Gulf of Mexico Bryde's whale is a small resident population and is listed as endangered under the ESA. Although there is no current UME, the small size of the population and its constricted range, combined with the lingering effects of exposure to oil from the DWH oil spill (which include adverse health effects on individuals, as well as population effects) are cause for considerable caution. Accordingly, as described above, the Navy is implementing and will continue to implement considerable time/area mitigation to minimize impacts within their limited range, including not planning major training exercises (which include the most powerful sound sources operating in a more concentrated area), limiting the hours of other sonar use, and not using explosives, with the exception of mine warfare activities, which has both reduced the amount of take and reduced the likely severity of impacts. No mortality or Level A harassment by tissue damage injury is anticipated or authorized, and only one Level A harassment take by PTS is estimated and authorized.

Regarding the magnitude of Level B harassment takes (TTS and behavioral disruption), the number of estimated instances compared to the abundance (112 percent) combined with the fact that the AFTT Study Area overlaps all of the small range, suggests that most to all of the individuals in the stock will likely be taken, but only on one or two days per year, with no reason to think the days would likely be sequential. Regarding the severity of those individual Level B harassment behavioral takes, as explained in the 2018 AFTT final rule, the duration of any exposure is expected to be between minutes and hours (*i.e.,* relatively short); the received sound levels are largely below 172 dB with a portion up to 178 dB (*i.e.,* of a moderate or lower level, less likely to evoke a severe response); and because of the mitigation the exposures will be of a less impactful nature. Regarding the severity of TTS takes, as explained in the 2018 AFTT final rule, they are expected to be low-level and of short duration and the associated lost opportunities and capabilities not at a level that would impact reproduction or survival. For similar reasons the one estimated Level A harassment take by PTS for this stock is unlikely to have any effect on the reproduction or survival of that individual, even if it were to be experienced by an individual that also experiences one or more Level B harassment takes.

Altogether, any individual Bryde's whale is likely to be disturbed at a low-moderate level on no more than one or two days per year. Even given the fact that some of the affected individuals may have compromised health, there is nothing to suggest that such a low magnitude and severity of effects would result in impacts on the reproduction or survival of any individual, much less annual rates of recruitment or survival for the stock. For these reasons, we have determined, in consideration of all of the effects of the Navy's activities combined, that the authorized take will have a negligible impact on the Gulf of Mexico stock of Bryde's whales.

Bryde's Whale (No Stock Designated—NSD)

These Bryde's whales span the mid- and southern Atlantic and have not been designated as a stock under the MMPA. There is no currently reported trend for the population and there are no specific issues with the status of these whales that cause particular concern (*e.g.,* UMEs). No mortality or Level A harassment is anticipated or authorized. Regarding the magnitude of Level B harassment takes (TTS and

behavioral disruption), the number of estimated instances compared to the abundance within the U.S. EEZ and both in and outside of the U.S. EEZ, respectively, is 626 percent and 60 percent, though the percentages would be far lower if compared against the abundance of the entire range of this species in the Atlantic. This information suggests that only a portion of the stock is likely impacted (significantly less than 60 percent given the large range), but that there is likely some repeat exposure (5 to 12 days within a year) of some subset of individuals within the U.S. EEZ if some animals spend extended time within the U.S. EEZ. Regarding the severity of those individual Level B harassment behavioral takes, as explained in the 2018 AFTT final rule, the duration of any exposure is expected to be between minutes and hours (*i.e.,* relatively short) and the received sound levels are largely below 172 dB with a portion up to 178 dB (*i.e.,* of a moderate or lower level, less likely to evoke a severe response). Regarding the severity of TTS takes, as explained in the 2018 AFTT final rule, they are expected to be low-level and of short duration and the associated lost opportunities and capabilities not at a level that would impact reproduction or survival.

Altogether, only a portion of the population is impacted and any individual Bryde's whale is likely to be disturbed at a low to moderate level, with many animals likely exposed only once or twice and a subset potentially disturbed across 5 to 12 likely non-sequential days not in any known biologically important areas. This low magnitude and severity of effects is not expected to result in impacts on annual rates of recruitment or survival for the stock. For these reasons, we have determined, in consideration of all of the effects of the Navy's activities combined, that the authorized take will have a negligible impact on Bryde's whales.

Minke Whale (Canadian East Coast Stock)

This stock of minke whales spans the East Coast and far into Northern Canada waters. Minke whales in the Atlantic are currently experiencing an UME wherein there have been unexpectedly elevated deaths along the Atlantic Coast, some of which have been preliminarily attributed to human interaction (primarily fisheries interactions) or infectious disease. As of July 26, 2019, six whales have stranded in 2019 (30 whales stranded in 2018 and 27 whales stranded in 2017). Because the most recent population estimate is based only on surveys in U.S. waters and slightly into Canada, and did not cover the habitat of the entire Canadian East Coast stock, the abundance is underestimated in the SAR and is likely significantly greater than what is reflected in the current SAR. NMFS authorizes one mortality in seven years, and the resulting 0.14 annual mortality which falls below 10 percent of residual PBR (0.55), remains under the insignificance threshold, and would be considerably even lower if compared against a more appropriate PBR. As discussed in the 2018 AFTT final rule, there are no known factors, information, or unusual circumstances that indicate that this potential M/SI below the insignificance threshold could have adverse effects on the stock through effects on annual rates of recruitment or survival. Consideration of all applicable information indicates that the authorized mortality of one whale over the seven years will not result in more than a negligible impact on this stock.

Regarding the magnitude of Level B harassment takes (TTS and behavioral disruption), the number of estimated instances compared to the abundance within the U.S. EEZ and both in and outside of the U.S. EEZ, respectively, is 536 percent and 53 percent. This information suggests that approximately less than half of the individuals are likely impacted, but that there is likely some repeat exposure (5 to 10 days within a year) of some subset of individuals within the U.S. EEZ if some animals spend extended time within the U.S. EEZ. Regarding the severity of those individual takes by behavioral Level B harassment, as explained in the 2018 AFTT final rule, the duration of any exposure is expected to be between minutes and hours (*i.e.,* relatively short) and the received sound levels largely below 172 dB, with a portion up to 178 dB (*i.e.,* of a moderate or lower level, less likely to evoke a severe response). Also, the Navy currently implements and will continue to implement time/area mitigation in the Northeast that minimizes major training exercises and total sonar hours in an area that significantly overlaps an important feeding area for minke whales. This mitigation will reduce the severity of impacts to minke whales by reducing interference in feeding that could result in lost feeding opportunities or necessitate additional energy expenditure to find other good foraging opportunities. Regarding the severity of TTS takes, as explained in the 2018 AFTT final rule, they are expected to be low-level and of short duration and the associated lost opportunities and capabilities not at a level that would impact reproduction or survival.

For similar reasons the five estimated Level A harassment takes by PTS for this stock are unlikely to have an effect on the reproduction or survival of any individual, even if PTS were to be experienced by an individual that also experiences one or more Level B harassment takes.

Altogether, only a portion of the stock will be impacted and any individual minke whale is likely to be disturbed at a low to moderate level, with many animals likely exposed only once or twice and a subset potentially disturbed across 5 to 10 likely non-sequential days, minimized in biologically important areas. Even given the potential for compromised health of some individuals, this low magnitude and severity of effects is not expected to result in impacts on the reproduction or survival of individuals, nor are these harassment takes combined with the potential mortality expected to adversely affect this stock through impacts on annual rates of recruitment or survival for the stock. For these reasons, we have determined, in consideration of all of the effects of the Navy's activities combined, that the authorized take will have a negligible impact on minke whales.

Fin Whale (Western North Atlantic Stock)

This stock spans the East Coast north into the Newfoundland waters of Canada. There is no currently reported trend for the population and there are no specific issues with the status of the stock that cause particular concern (*e.g.,* no UMEs), although the species is listed as endangered under the ESA. NMFS authorizes one mortality over the seven years of the rule, or 0.14 annually. With the addition of this 0.14 annual mortality, residual PBR is exceeded, which means the total human-caused mortality would exceed residual PBR by 0.14. However, as explained in the 2018 AFTT final rule, this does not mean that the stock is not at or increasing toward its optimum sustainable population level (OSP) or that one lethal take by the Navy over the seven years covered by this rule would adversely affect the stock through effects on annual rates of reproduction or survival. Consideration of all applicable information indicates that the authorized mortality will not result in more than a negligible impact on this stock.

The abundance of fin whales is likely significantly greater than what is reflected in the current SAR because, as noted in the SAR, the most recent population estimate is based only on

surveys in U.S. waters and slightly into Canada which does not include the habitat of the entire stock as it extends over a very large additional area into Nova Scotian and Newfoundland waters. Accordingly, if the PBR in the SAR reflected the actual abundance across the entire range of the stock, residual PBR would be notably higher. Additionally, the current abundance estimate does not account for availability bias due to submerged animals (*i.e.,* estimates are not corrected to account for the fact that given X number of animals seen at the surface, we can appropriately assume that Y number were submerged and not counted). Without a correction for this bias, the abundance estimate is likely further biased low. Because of these limitations, the current calculated PBR is not a reliable indicator of how removal of animals will affect the stock's ability to reach or maintain OSP. We note that, generally speaking, while the abundance may be underestimated in this manner for some stocks due to the lack of surveys in areas outside of the U.S. EEZ, it is also possible that the human-caused mortality could be underestimated in the un-surveyed area. However, in the case of fin whales, most mortality is caused by entanglement in gear that is deployed relatively close to shore and, therefore, unrecorded mortality offshore would realistically be proportionally less as compared to the unsurveyed abundance and therefore the premise that PBR is likely underestimated still holds. Given the small amount by which residual PBR is exceeded and more significant degree (proportionally) to which abundance is likely underestimated, it is reasonable to conclude that if a more realistic PBR were used, the anticipated total human-caused mortality would be notably under it.

We also note that 0.14 mortalities/serious injuries means one mortality/serious injury in one of the seven years and zero mortalities/serious injuries in six of the seven years. Therefore residual PBR would not be exceeded in 86 percent of the years covered by this rule. In situations where mortality/serious injury is fractional, consideration must be given to the lessened impacts due to the absence of mortality in six of the seven years. Further, as described in the 2018 AFTT final rule, the Atlantic Large Whale Take Reduction Plan directs multiple efforts and requirements towards reducing mortality from commercial fishing (via gear modifications, area closures, and other mechanisms) and NOAA Office of Law Enforcement has reported high compliance rates. Nonetheless, the exceedance of residual PBR calls for close attention to the remainder of impacts on fin whales from this activity to ensure that the total authorized impacts are negligible.

Regarding the magnitude of Level B harassment takes (TTS and behavioral disruption), the number of estimated instances compared to the abundance within the U.S. EEZ and both in and outside of the U.S. EEZ, respectively, is 323 percent and 37 percent. This information suggests that less than a third of the individuals are likely impacted, but that there is likely some repeat exposure (2–6 days within a year) of some subset of individuals within the U.S. EEZ if some animals spend extended time within the U.S. EEZ. Regarding the severity of those individual takes by behavioral Level B harassment, as explained in the 2018 AFTT final rule, the duration of any exposure is expected to be between minutes and hours (*i.e.,* relatively short) and the received sound levels largely below 172 dB (*i.e.,* of a moderate or lower level, less likely to evoke a severe response). Also, the Navy currently implements, and will continue to implement time/area mitigation in the Northeast that minimizes major training exercises and total sonar hours in an area that significantly overlaps an important BIA feeding area for fin whales. This mitigation will reduce the severity of impacts to fin whales by reducing interference in feeding that could result in lost feeding opportunities or necessitate additional energy expenditure to find other good opportunities. Regarding the severity of TTS takes, as explained in the 2018 AFTT final rule, they are expected to be low-level, of short duration, and mostly not in a frequency band that would be expected to interfere with fin whale communication or other important low-frequency cues, and the associated lost opportunities and capabilities are not at a level that would impact reproduction or survival. For these same reasons (low level and frequency band), while a small permanent loss of hearing sensitivity may include some degree of energetic costs for compensating or may mean some small loss of opportunities or detection capabilities, at the expected scale the 33 estimated Level A harassment takes by PTS for fin whales would be unlikely to impact behaviors, opportunities, or detection capabilities to a degree that would interfere with reproductive success or survival of any individuals, even if PTS were experienced by an individual that also experiences one or more Level B harassment takes.

Altogether, only a portion of the stock will be impacted and any individual fin whale is likely to be disturbed at a low to moderate level, with many animals likely exposed only once or twice and a subset potentially disturbed across approximately six likely non-sequential days, minimized in biologically important areas. This low magnitude and severity of effects is not expected to result in impacts on reproduction or survival of individuals, nor are these harassment takes combined with the single potential mortality expected to adversely affect this stock through impacts on annual rates of recruitment or survival for the stock. For these reasons, we have determined, in consideration of all of the effects of the Navy's activities combined, that the authorized take will have a negligible impact on fin whales.

Humpback Whale

The feeding group stock of humpback whales found in the Gulf of Maine is one of several associated with the larger, and increasing, West Indies DPS. The Gulf of Maine stock is reported in the SAR as increasing in abundance. Nonetheless, humpback whales in the Atlantic are currently experiencing an UME in which a portion of the whales have shown evidence of entanglement or vessel strike. There have been 22 strandings so far in 2019 (2018 had 25 total strandings and 2017 had 34 total strandings). NMFS authorizes two mortalities over the seven-year period (versus the one mortality over the five-year period of the 2018 AFTT final rule), as described in the *Estimated Take of Marine Mammals* section above. Though an increase from the 2018 AFTT final rule, this amount of mortality (0.29 per year) still falls below the insignificance threshold of 10 percent of residual PBR (0.49) for the Gulf of Maine stock based on a stock abundance of 896 from the 2018 SAR. As discussed in the 2018 AFTT final rule, there are no known factors, information, or unusual circumstances that indicate that this potential M/SI below the insignificance threshold could have adverse effects on the stock through effects on annual rates of recruitment or survival. Also, importantly, deaths of humpback whales along the Atlantic coast (whether by ship strike or other source) must be considered within the context of the larger West Indies DPS, as animals along the coast could come from the Gulf of Maine stock or any of three or more other associated feeding groups. Specifically, the West Indies DPS, the larger population from which

a humpback whale could potentially be taken, numbers in excess of 10,000 whales and has an increasing growth trend of 3.1 percent (Bettridge *et al.,* 2015), with an associated PBR, if calculated, much larger than that presented for the Gulf of Maine stock. Further, as described in the 2018 AFTT final rule, the Atlantic Large Whale Take Reduction Plan directs multiple efforts and requirements towards reducing mortality from commercial fishing (via gear modifications, area closures, and other mechanisms) and NOAA Office of Law Enforcement has reported high compliance rates. Therefore, even though the potential for M/SI from the Navy's activities has increased since the 2018 AFTT final rule, there is no information to indicate that the loss of two whales over seven years, even if it were to occur, would adversely affect the stock or the overall species through effects on annual rates of recruitment or survival. See the *Humpback Whale* section in the 2018 AFTT final rule for additional supporting information.

Regarding the magnitude of Level B harassment takes (TTS and behavioral disruption), the number of estimated instances (of any humpbacks) compared to the abundance within the U.S. EEZ and both in and outside of the U.S. EEZ, respectively, is 141 percent and 16 percent. This suggests that only a small portion of the humpback whales in the AFTT Study Area would be likely impacted, with perhaps some individuals taken on a few days of the year. It would be impossible to determine exactly what portion of the takes are from the Gulf of Maine stock. However, based on information in the 2018 AFTT final rule, which indicated about one third of the humpback whales traversing the Atlantic Coast likely come from the Gulf of Maine stock, we estimate that approximately 250 of the 749 total humpback whale takes (both by Level A harassment and Level B harassment) might be from the Gulf of Maine stock. Two hundred and fifty represents about 28 percent of the minimum population estimate for the Gulf of Maine humpback whale abundance in NMFS' 2018 SAR, equating to an expectation that few animals would be exposed more than one time. The remaining approximately 499 Level A and Level B harassment takes would affect individuals from the much larger West Indies DPS, with a relatively small percentage of individuals affected as the estimated abundance is greater than 10,000. Regarding the severity of those individual takes by behavioral Level B harassment, as explained in the 2018 AFTT final rule, the duration of any exposure is expected to be between minutes and hours (*i.e.,* relatively short) and the received sound levels largely below 172 dB with a portion above 178 dB (*i.e.,* of a moderate or lower level, less likely to evoke a severe response). Also, the Navy currently implements and will continue to implement time/area mitigation in the Northeast that minimizes major training exercises and total sonar hours in an area that significantly overlaps with an important feeding area for humpbacks. This mitigation will reduce the severity of impacts to humpbacks by reducing interference in feeding that could result in lost feeding opportunities or necessitate additional energy expenditure to find other good opportunities. Regarding the severity of TTS takes, as explained in the 2018 AFTT final rule, they are expected to be low-level and of short duration and the associated lost opportunities and capabilities not at a level that would impact reproduction or survival. For similar reasons the three estimated Level A harassment takes by PTS for this stock are unlikely to have any effect on the reproduction or survival of any individual, even if PTS were to be experienced by an individual that also experiences one or more Level B harassment takes.

Altogether, only a portion of the stock or species is impacted and any individual humpback whale will likely be disturbed at a low-moderate level, with most animals exposed only once or twice, and minimized in biologically important areas. This low magnitude and severity of effects is not expected to result in impacts on the reproduction or survival of any individuals, nor are these harassment takes combined with the potential mortalities of up to two whales expected to adversely affect the stock or species through impacts on annual rates of recruitment or survival. For these reasons, we have determined, in consideration of all of the effects of the Navy's activities combined, that the authorized take will have a negligible impact on humpback whales, including the Gulf of Maine stock, as well as the larger species as a whole.

Sei Whale (Nova Scotia Stock)

This stock spans the northern East Coast and up to southern Newfoundland. There is no currently reported trend for the population and there are no specific issues with the status of the stock that cause particular concern (*e.g.,* no UMEs), although the species is listed as endangered under the ESA. NMFS authorizes one mortality over the seven years of the rule, or 0.14 annually. With the addition of this 0.14 annual mortality, residual PBR is exceeded, which means the total human-caused mortality would exceed residual PBR by 0.44. However, as explained in the 2018 AFTT final rule, this does not mean that the stock is not at or increasing toward its OSP or that one lethal take by the Navy over the seven years covered by this rule would adversely affect the stock through effects on annual rates of reproduction or survival. Consideration of all applicable information indicates that the authorized mortality will not result in more than a negligible impact on this stock.

As noted in the SAR, the abundance of sei whales is likely significantly greater than what is reflected in the current SAR because the population estimate is based only on surveys in U.S. waters and slightly into Canada, which does not cover the habitat of the entire stock, as it extends over a large additional area around to the south of Newfoundland. Accordingly, if a PBR were calculated based on an appropriately enlarged abundance, it would be higher. Additionally, the current abundance estimate does not account for availability bias due to submerged animals (*i.e.,* estimates are not corrected to account for the fact that given X number of animals seen at the surface, we can appropriate assume that Y number were submerged and not counted). Without a correction for this bias, the abundance estimate is likely biased low. Because of these limitations, the current calculated PBR is not a reliable indicator of how removal of animals will affect the stock's ability to reach or maintain OSP. We note that, generally speaking, while the abundance may be underestimated in this manner for some stocks due to the lack of surveys in areas outside of the U.S. EEZ, it is also possible that the human-caused mortality could be underestimated in the un-surveyed area. However, in the case of sei whales, most mortality is caused by ship strike and the density of ship traffic is higher the closer you are to shore (making strikes more likely closer to shore) and, therefore, unrecorded mortality offshore would realistically be proportionally less as compared to the unsurveyed abundance and therefore the premise that PBR is likely underestimated still holds.

Given the small amount by which residual PBR is exceeded and more significant degree (proportionally) to which abundance is likely underestimated, it is reasonable to think that if a more realistic PBR were used,

the anticipated total human-caused mortality would be notably under residual PBR. We also note that 0.14 mortalities/serious injuries means one mortality/serious injury in one of the seven years and zero mortalities/serious injuries in six of the seven years. Further, as described in the 2018 AFTT final rule the Atlantic Large Whale Take Reduction Plan directs multiple efforts and requirements towards reducing mortality from commercial fishing (via gear modifications, area closures, and other mechanisms) and NOAA Office of Law Enforcement has reported high compliance rates.

Regarding the magnitude of Level B harassment takes (TTS and behavioral disruption), the number of estimated instances compared to the abundance within the U.S. EEZ and both in and outside of the U.S. EEZ, respectively, is 317 percent and 7 percent. This information suggests that only a very small portion of individuals in the stock will be likely impacted, but that there will likely be some repeat exposure (several days within a year) of some subset of individuals within the U.S. EEZ if some animals spend extended time within the U.S. EEZ. Regarding the severity of those individual takes by behavioral Level B harassment, as explained in the 2018 AFTT final rule, the duration of any exposure is expected to be between minutes and hours (*i.e.,* relatively short) and the received sound levels largely below 172 dB with a portion up to 178 dB (*i.e.,* of a moderate or lower level, less likely to evoke a severe response). Also, the Navy implements time/area mitigation in the Northeast that minimizes major training exercises and total sonar hours in an area that significantly overlaps an important BIA feeding area for sei whales, which will reduce the severity of impacts to sei whales by reducing interference in feeding that could result in lost feeding opportunities or necessitate additional energy expenditure to find other good opportunities. Regarding the severity of TTS takes, as explained in the 2018 AFTT final rule, they are expected to be low-level and of short duration and the associated lost opportunities and capabilities not at a level that would impact reproduction or survival. For similar reasons the four estimated Level A harassment takes by PTS for this stock are unlikely to have any effect on the reproduction or survival of any individual, even if PTS were to be experienced by an individual that also experiences one or more Level B harassment takes. Altogether, only a small portion of the stock will be impacted and any individual sei whale will likely be disturbed at a low-moderate level, with many animals likely exposed only once or twice and a subset potentially disturbed across a few days, minimized in biologically important areas. This low magnitude and severity of harassment effects is not expected to result in impacts on individual reproduction or survival, nor are these harassment takes combined with the single potential mortality expected to adversely affect this stock through impacts on annual rates of recruitment or survival. For these reasons, we have determined, in consideration of all of the effects of the Navy's activities combined, that the authorized take will have a negligible impact on sei whales.

Odontocetes

Sperm Whales, Dwarf Sperm Whales, and Pygmy Sperm Whales

In Table 19 below for sperm whales, dwarf sperm whales, and pygmy sperm whales, we indicate the total annual mortality, Level A and Level B harassment, and a number indicating the instances of total take as a percentage of abundance. Table 19 is unchanged from Table 73 in the 2018 AFTT final rule, except for updated information on mortality, as discussed above. For additional information and analysis supporting the negligible-impact analysis, see the *Odontocetes* discussion as well as the *Sperm Whales, Dwarf Sperm Whales, and Pygmy Sperm Whales* discussion in the *Group and Species-Specific Analyses* section of the 2018 AFTT final rule, all of which remains applicable to this final rule unless specifically noted.

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Table 19 -- Annual Estimated Takes by Level B Harassment, Level A Harassment, and Mortality for Sperm Whales, Dwarf Sperm Whales, and Pygmy Sperm Whales in the AFTT Study Area and Number Indicating the Instances of Total Take as a Percentage of Stock Abundance.

		Instances of indicated types of incidental take (not all takes represent separate individuals, especially for disturbance)					Total takes		Abundance		Instances of total take as percentage of abundance	
		Level B Harassment		Level A Harassment								
Species	Stock	Behavioral Disturbance	TTS (may also include disturbance)	PTS	Tissue Damage	Mortality	In EEZ	Inside and Outside EEZ	In EEZ	Inside and Outside EEZ	In EEZ	Inside and Outside EEZ
Suborder Odontoceti (toothed whales)												
Family Physeteridae (sperm whale)												
Sperm whale*	Gulf of Mexico Oceanic	1,107	25	0	0	0	1132	1132	2,114	2,114	54	54
	North Atlantic	24,703	662	3	1	0.14	21489	25369	3,950	61,700	544	41
Family Kogiidae (sperm whales)												
Dwarf sperm whale	Gulf of Mexico Oceanic	339	453	70	0	0	862	862	1,107	1,107	78	78
	Western North Atlantic	3,900	9,102	94	0	0	12852	13096	611	3,641	2105	360
Pygmy sperm whale	Northern Gulf of Mexico	339	453	70	0	0	862	862	1,107	1,107	78	78
	Western North Atlantic	3,900	9,102	94	0	0	12852	13096	611	3,641	2105	360

Note: In this table we compare estimated takes to abundance estimates generated from the same underlying density estimate (as described in the *Estimated Take of Marine Mammals* section in the 2018 AFTT final rule), versus abundance estimates directly from NMFS' SARs, which are not based on the same data and would not be appropriate for this purpose. Note that comparisons are made both within the U.S. EEZ only (where density estimates have lesser uncertainty) and across the whole Study Area (which offers a more comprehensive comparison for many stocks).

Total takes inside and outside U.S. EEZ represent the sum of annual Level A and Level B harassment from training and testing plus harassment take from one large ship shock trial.

The annual mortality of 0.14 is the result of no more than one mortality over the course of seven years from vessel strikes as described above in the *Estimated Take of Marine Mammals* section.

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Below we compile and summarize the information that supports our determination that the Navy's activities will not adversely affect any species or stocks through effects on annual rates of recruitment or survival for any of the affected species and stocks addressed in this section.

Sperm Whale (North Atlantic Stock)

This stock spans the East Coast out into oceanic waters well beyond the U.S. EEZ. There is no currently reported trend for the stock and, although the species is listed as endangered under the ESA, there are no specific issues with the status of the stock that cause particular concern (*e.g.,* no UMEs). NMFS authorizes one mortality over the seven years covered by this rule, and the resulting 0.14 annual mortality which falls below 10 percent of residual PBR (0.28), remains below the PBR insignificance threshold. As discussed in the 2018 AFTT final rule, there are no known factors, information, or unusual circumstances that indicate that this potential M/SI below the insignificance threshold could have adverse effects on the stock through effects on annual rates of recruitment or survival. One Level A harassment take by tissue damage is also estimated and authorized which, as discussed in the 2018 AFTT final rule, could range in impact from minor to something just less than M/SI that could seriously impact fitness. However, given the Navy's mitigation and the sperm whale's large size, which improves detection by Lookouts, exposure at the closer to the source and more severe end of the spectrum is less likely, and we cautiously assume some moderate impact for this single take that could lower one individual's fitness within the year such that a female (assuming a 50 percent chance of the one take being a female) might forego reproduction for one year. As discussed in the 2018 AFTT final rule, foregone reproduction has less of an impact on population rates than death (especially for one year) and one instance would not be expected to impact annual rates of recruitment or survival, even if it were a female.

Regarding the magnitude of Level B harassment takes (TTS and behavioral disruption), the number of estimated instances of harassment compared to the abundance within the U.S. EEZ and both in and outside of the U.S. EEZ, respectively, is 544 percent and 41 percent. This information, combined with the known range of the stock, suggests that something less than one half of the individuals in the stock will likely be impacted, but that there will likely be some repeat exposure (2–11 days within a year) of some subset of individuals that remain within the U.S. EEZ for an extended time. Regarding the severity of those individual takes by behavioral Level B harassment, as explained in the 2018 AFTT final rule, the duration of any exposure response is expected to be between minutes and hours (*i.e.,* relatively short) and the received sound levels largely between 160 and 172 dB (*i.e.,* of a lower, to occasionally moderate, level). Regarding the severity of TTS takes, as explained in the 2018 AFTT final rule, they are expected to be low-level and of short duration and the associated lost opportunities and capabilities not at a level that would impact reproduction or survival. For similar reasons three estimated Level A harassment takes by PTS for this stock is unlikely to have any effect on the reproduction or survival of any individual, even if PTS were to be experienced by an individual that also experiences one or more Level B harassment takes.

Altogether, less than one half of the stock will be impacted and any individual sperm whale will likely be disturbed at a low-moderate level, with the majority of animals likely disturbed once or not at all, and a subset potentially disturbed across 2–11 likely non-sequential days. Even for an animal disturbed at the high end of this range (11 days over a year), given the low to moderate impact from each incident, and the fact that few days with take will likely be sequential, no impacts to individual fitness are expected. This low to occasionally moderate magnitude and severity of effects is not expected to result in impacts on reproduction or survival, and nor are these harassment takes combined with the single authorized mortality and one possible instance of foregone reproduction expected to adversely affect the stock through annual rates of recruitment or survival. For these reasons, we have determined, in consideration of all of the effects of the Navy's activities combined, that the authorized take will have a negligible impact on North Atlantic sperm whales.

Sperm Whale, Dwarf Sperm Whale, and Pygmy Sperm Whale (Gulf of Mexico Stocks)

These stocks suffer from lingering health issues from the DWH oil spill (6–7 percent of individuals of these stocks have adverse health effects), which means that some could be more susceptible to exposure to other stressors, and negative population effects (21–42 years until the DWH oil-injured population trajectory is projected to catch up with the baseline population trajectory (*i.e.,* in the absence of DWH, reported as years to recovery)). Neither mortality nor tissue damage from explosives is anticipated or authorized for any of these three stocks, and sperm whales are not expected to incur PTS. Regarding the magnitude of Level B harassment takes (TTS and behavioral disruption), the number of estimated instances of harassment compared to the abundance is 54–78 percent, which suggests that for each of the three species/stocks either this percentage of the individuals in these stocks will all be taken by harassment on a single day each within a year, or a small subset may be taken on a few days and the remainder not taken at all. Regarding the severity of those individual takes by behavioral Level B harassment, as explained in the 2018 AFTT final rule, the duration of any exposure response is expected to be between minutes and hours (*i.e.,* relatively short) and the received sound levels are largely between 160 and 172 dB (*i.e.,* of a lower level, less likely to evoke a severe response). Additionally, the Navy is currently implementing and will continue to implement mitigation areas for sperm whales that are expected to reduce impacts in important feeding areas, further lessening the severity of impacts. In the Gulf of Mexico Planning Awareness Mitigation Areas, the Navy will not conduct any major training exercises. Regarding the severity of TTS takes, as explained in the 2018 AFTT final rule, they are expected to be low-level, of short duration, and mostly not in a frequency band that would be expected to interfere significantly with conspecific communication, echolocation, or other important low-frequency cues. Also, there is no reason to believe that any individual would incur these TTS takes more than a few days in a year, and the associated lost opportunities and capabilities would not be expected to impact reproduction or survival. For these same reasons (low level and frequency band), while a small permanent loss of hearing sensitivity may include some degree of energetic costs for compensating or may mean some small loss of opportunities or detection capabilities, 70 estimated Level A harassment takes by PTS for each of the two Kogia stocks in the Gulf of Mexico would be unlikely to impact behaviors, opportunities, or detection capabilities to a degree that would interfere with reproductive success or survival of any individual, even if PTS were to be experienced by an animal that also experiences one or more Level B harassment takes.

Altogether, only a portion of these stocks will be impacted and any individual sperm, dwarf sperm, or pygmy sperm whale is likely to be disturbed at a low to occasionally moderate level and no more than a few days per year. Even given the fact that some of the affected individuals may have compromised health, there is nothing to suggest that such a low magnitude and severity of effects would result in impacts on the reproduction or survival of individuals, much less annual rates of recruitment or survival for any of the stocks. For these reasons, we have determined, in consideration of all of the effects of the Navy's activities combined, that the authorized take will have a negligible impact on Gulf of Mexico sperm whales, dwarf sperm whales, and pygmy sperm whales.

Pygmy and Dwarf Sperm Whales (Western North Atlantic Stocks)

These stocks span the deeper waters of the East Coast north to Canada and out into oceanic waters beyond the U.S. EEZ. There is no currently reported trend for these populations and there are no specific issues with the status of the stocks that cause particular concern. Neither mortality nor tissue damage from explosives is anticipated or authorized for these stocks. Regarding the magnitude of Level B harassment takes (TTS and behavioral disruption), the number of estimated instances of harassment compared to the abundance within the U.S. EEZ and both in and outside of the U.S. EEZ, respectively, is 2,105 percent and 360 percent. This information, combined with the known range of the stock, suggests that while not all of the individuals in these stocks will most likely be taken (because they span well into oceanic waters) of those that are taken, most would be taken over several repeated days (though likely not sequential) and some subset that spends extended time within the U.S. EEZ will likely be taken over a larger amount of days (likely 15–42 days during a year), some of which could be sequential.

Regarding the severity of the individual takes by behavioral Level B harassment, as explained in the 2018 AFTT final rule, the duration of any exposure response is expected to be between minutes and hours (and likely not more than 24 hours) and the received sound levels are largely between 160 and 172 dB (*i.e.,* of a lower level, less likely to evoke a severe response). Additionally, while interrupted feeding bouts are a known response and concern for odontocetes, we also know that there are often viable alternative habitat options in the relative vicinity. Regarding the severity of TTS takes, as explained in the 2018 AFTT final rule, they are expected to be low-level, of short duration and mostly not in a frequency band that would be expected to interfere significantly with conspecific communication, echolocation, or other important low-frequency cues. Also, there is no reason to believe that any individual would incur these TTS takes more than a few days in a year, and the associated lost opportunities and capabilities would not be expected to impact reproduction or survival. For these same reasons (low level and frequency band), while a small permanent loss of hearing sensitivity may include some degree of energetic costs for compensating or may mean some small loss of opportunities or detection capabilities, at the expected scale the 94 estimated Level A harassment takes by PTS for each of the two Kogia stocks in the North Atlantic would be unlikely to impact behaviors, opportunities, or detection capabilities to a degree that would interfere with reproductive success or survival of any

individual, even if PTS were to be experienced by an individual that also experiences one or more Level B harassment takes.

Altogether, a large portion of each stock will likely be taken (at a low to occasionally moderate level) over several days a year, and some smaller portion of the stock will likely be taken on a relatively moderate to high number of days across the year, some of which could be sequential days. Though the majority of impacts are expected to be of a lower to sometimes moderate severity, the larger number of takes (in total and for certain individuals) makes it more likely (probabilistically) that a small number of individuals could be interrupted during foraging in a manner and amount such that impacts to the energy budgets of females (from either losing feeding opportunities or expending considerable energy to find alternative feeding options) could cause them to forego reproduction for a year (energetic impacts to males generally have little impact on population rates unless they cause death, and it takes extreme energy deficits beyond what would ever be likely to result from these activities to cause the death of an adult pygmy or dwarf sperm whale). As noted previously and discussed more fully in the 2018 AFTT final rule, however, foregone reproduction (especially for one year) has far less of an impact on population rates than mortality, and a small number of instances of foregone reproduction would not be expected to adversely impact annual rates of recruitment or survival, especially given that residual PBR for both of these stocks is 17.5. For these reasons, in consideration of all of the effects of the Navy's activities combined, we have determined that the authorized take will have a negligible impact on Western North Atlantic pygmy and dwarf sperm whales.

Dolphins and Small Whales

In Table 20 below for dolphins and small whales, we indicate the total annual mortality, Level A and Level B harassment, and a number indicating the instances of total take as a percentage of abundance. Table 20 is unchanged from Table 74 in the 2018 AFTT final rule, except for updated information on mortality, as discussed above. For additional information and analysis supporting the negligible-impact analysis, see the *Odontocetes* discussion as well as the *Dolphins and Small Whales* discussion in the *Group and Species-Specific Analyses* section of the 2018 AFTT final rule, all of which remains applicable to this final rule unless specifically noted.

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Table 20 -- Annual Estimated Takes by Level B Harassment, Level A Harassment, and Mortality for Dolphins and Small Whales in the AFTT Study Area and Number Indicating the Instances of Total Take as a Percentage of Stock Abundance.

		Instances of indicated types of incidental take (not all takes represent separate individuals, especially for disturbance)					Total takes		Abundance		Instances of total take as percentage of abundance	
		Level B Harassment		Level A Harassment								
Species	Stock	Behavioral Disturbance	TTS (may also include disturbance)	PTS	Tissue Damage	Mortality	In EEZ	Inside and Outside EEZ	In EEZ	Inside and Outside EEZ	In EEZ	Inside and Outside EEZ
Family Delphinidae (dolphins)												
Atlantic spotted dolphin	Northern Gulf of Mexico	69,225	3,610	3	0	0	72,838	72,838	47,676	47,676	153	153
	Western North Atlantic	208,201	19,383	26	6	0	209,814	227,616	52,118	250,648	403	91
Atlantic white-sided dolphin	Western North Atlantic	44,077	2,207	7	3	0.14	44,210	46,294	14,332	137,305	308	34
Bottlenose dolphin	Choctawhatchee Bay	941	32	0	0	0	973	973	99	99	984	984
	Gulf of Mexico Eastern Coastal	42	0	0	0	0	42	42	9,888	9,888	0	0
	Gulf of Mexico Northern Coastal	15,644	834	2	0	0	16,480	16,480	8,476	8,476	194	194
	Gulf of Mexico Western Coastal	7,191	635	0	0	0	7,826	7,826	33,903	33,903	23	23
	Indian River Lagoon Estuarine System	255	31	0	0	0	286	286	36	36	790	790
	Jacksonville Estuarine System	74	13	0	0	0	87	87	27	27	320	320
	Mississippi Sound, Lake Borgne, Bay Boudreau	1	0	0	0	0	1	1	198	198	1	1
	Northern Gulf of Mexico Continental Shelf	121,223	6,287	15	1	0	127,526	127,526	72,043	72,043	177	177
	Northern Gulf of Mexico Oceanic	13,947	706	8	2	0	14,663	14,663	18,364	18,364	80	80
	Northern North Carolina Estuarine System	2,844	483	0	0	0	3,327	3,327	3,622	3,622	92	92
	Southern North Carolina Estuarine System	0	0	0	0	0	0	0	0	0	0	0
	Western North Atlantic Northern Florida Coastal	1,145	90	0	0	0	1,235	1,235	906	906	136	136
	Western North Atlantic Central Florida Coastal	7,100	513	0	0	0	7,613	7,613	4,528	4,528	168	168
	Western North Atlantic Northern Migratory Coastal	33,993	3,051	7	0	0	37,051	37,051	9,962	9,962	372	372
	Western North Atlantic Offshore	393,416	34,686	77	9	0	421,295	428,188	64,298	186,260	655	230
	Western North Atlantic South Carolina/Georgia Coastal	5,544	416	0	0	0	5,960	5,960	3,622	3,622	165	165
	Western North Atlantic Southern Migratory Coastal	15,411	1,305	2	0	0	16,718	16,718	7,245	7,245	231	231
Clymene dolphin	Northern Gulf of Mexico	4,174	99	4	2	0	4,279	4,279	10,942	10,942	39	39
	Western North Atlantic	97,952	7,816	10	3	0	92,364	105,781	15,370	171,202	601	62
False killer whale	Northern Gulf of Mexico	1,902	72	1	0	0	1,975	1,975	3,136	3,136	63	63
	Western North Atlantic	11,176	863	0	0	0	11,131	12,039	1,254	16,144	888	75
Fraser's dolphin	Northern Gulf of Mexico	1,123	58	2	1	0	1,184	1,184	1,637	1,637	72	72
	Western North Atlantic	4,931	291	0	0	0	3,914	5,222	411	17,588	952	30
Killer whale	Northern Gulf of Mexico	33	0	0	0	0	33	33	176	176	19	19
	Western North Atlantic	113	6	0	0	0	112	119	15	472	747	25
Long-finned pilot whale	Western North Atlantic	35,890	1,656	7	1	0	33,769	37,554	3,863	447,431	874	8
Melon-headed whale	Northern Gulf of Mexico	3,067	66	3	1	0	3,137	3,137	6,725	6,725	47	47
	Western North Atlantic	50,058	3,792	3	0	0	49,707	53,853	5,821	69,526	854	77
Pantropical spotted dolphin	Northern Gulf of Mexico	25,924	596	15	6	0.14	26,541	26,541	82,055	82,055	32	32
	Western North Atlantic	207,279	15,304	8	1	0	196,098	222,592	30,088	275,964	652	81
Pygmy killer whale	Northern Gulf of Mexico	720	16	1	0	0	737	737	2,062	2,062	36	36
	Western North Atlantic	8,702	629	0	0	0	8,507	9,331	1,052	12,296	809	76
Risso's dolphin	Northern Gulf of Mexico	1,647	43	1	0	0	1,691	1,691	3,096	3,096	55	55
	Western North Atlantic	38,887	2,220	2	0	0	40,144	41,109	5,601	39,085	717	105
Rough-toothed dolphin	Northern Gulf of Mexico	3,849	177	1	1	0	4,028	4,028	4,824	4,824	83	83
	Western North Atlantic	25,857	2,476	0	0	0	26,450	28,333	2,793	34,768	947	81
Short-beaked common dolphin	Western North Atlantic	540,662	30,561	101	36	0.86	571,100	571,361	73,481	520,317	777	110
Short-finned pilot whale	Northern Gulf of Mexico	1,835	26	3	0	0	1,864	1,864	2,032	2,032	92	92
	Western North Atlantic	45,724	2,639	5	1	0	34,760	48,369	6,578	450,146	528	11
Spinner dolphin	Northern Gulf of Mexico	7,803	277	31	14	0.14	8,125	8,125	13,653	13,653	60	60
	Western North Atlantic	98,665	8,382	5	1	0	98,817	107,053	11,280	135,573	876	79
Striped dolphin	Northern Gulf of Mexico	2,449	69	2	1	0	2,521	2,521	4,871	4,871	52	52
	Western North Atlantic	181,103	11,992	16	4	0	167,438	193,115	52,222	322,542	321	60
White-beaked dolphin	Western North Atlantic	80	4	0	0	0	84	84	42	42	200	200

Note: In the table we compare estimated takes to abundance estimates generated from the same underlying density estimate (as described in the *Estimated Take of Marine Mammals* section of the 2018 AFFT final rule), versus abundance estimates directly from NMFS' SARs, which are not based on the same data and would not be appropriate for this purpose. Note that comparisons are made both within the U.S. EEZ only (where density estimates have lesser uncertainty) and across the whole Study Area (which offers a more comprehensive comparison for many stocks).

Total takes inside and outside U.S. EEZ represent the sum of annual Level A and Level B harassment from training and testing plus take from one large ship shock trial.

For mortality takes there was an annual average of 0.14 dolphins from each dolphin species/stock listed above (*i.e.*, for those species or stocks where one take could potentially occur divided by seven years to get the annual number of mortalities/serious injuries) or 0.86 dolphins in the case of short-beaked common dolphin (*i.e.*, where six takes could potentially occur divided by seven years to get the annual number of mortalities/serious injuries).

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Below we compile and summarize the information that supports our determination that the Navy's activities will not adversely affect any species or stocks through effects on annual rates of recruitment or survival for any of the affected species or stocks addressed in this section.

Atlantic White-Sided Dolphin and Short-Beaked Common Dolphin (Western North Atlantic Stocks)

There is no currently reported trend for these stocks and there are no specific issues with the status of these stocks that cause particular concern (*e.g.,* no UMEs). We anticipate and therefore authorize one and six mortalities over the course of seven years for these two stocks, which is 0.14 and 0.86 annual mortalities for each stock, respectively. Given the large residual PBR values for these stocks (248 and 148), this number of mortalities falls well under the insignificance threshold. There are no known factors, information, or unusual circumstances that indicate that this estimated M/SI below the insignificance threshold could have adverse effects on these stocks through effects on annual rates of recruitment or survival. Some Level A harassment take by tissue damage from explosives has also been estimated and authorized for these stocks (3 and 36, respectively). As discussed previously and in the 2018 AFTT final rule, tissue damage effects could range in impact from minor to something just less than M/SI that could seriously impact fitness. However, given the Navy's mitigation, which makes exposure at the closer to the source and more severe end of the spectrum less likely, we cautiously assume some moderate impact for this category of take that could lower an individual's fitness within the year such that females (assuming a 50 percent chance that a take is a female) might forego reproduction for one year. As noted previously, foregone reproduction has less of an impact on population rates than death (especially for one year) and the number of takes anticipated for each stock would not be expected to impact annual rates of recruitment or survival, even if all of the takes were females (which would be highly unlikely), especially given the high residual PBRs of these stocks. In other words, if the stocks can absorb the numbers of mortalities indicated through each stock's residual PBR without impacting ability to approach OSP, they could absorb the significantly lesser effects of a small number of one-year delay in calving. Regarding the magnitude of Level B harassment takes (TTS and behavioral disruption), the number of estimated instances of harassment compared to the abundance within the U.S. EEZ and both in and outside of the U.S. EEZ for these two stocks, respectively, is 308 and 777 percent and 34 and 110 percent. This information suggests that some portion of these stocks will likely not be taken at all, but that there will likely be some repeat exposure (2–15 days within a year) of some subset of individuals. Regarding the severity of those individual takes by behavioral Level B harassment, as explained in the 2018 AFTT final rule, the duration of any exposure response is expected to be between minutes and hours (*i.e.,* relatively short) and the received sound levels largely below 172 dB (*i.e.,* of a lower level, less likely to evoke a severe response). Additionally, while we do not have information that indicates that these takes would occur sequentially on more than several days in a row or be more severe in nature, the probability of this occurring increases the higher the total take numbers. While interrupted feeding bouts are a known response and concern for odontocetes, we also know that there are often viable alternative habitat options in the relative vicinity. Given the higher number of takes and the associated abundances (especially for short-beaked common dolphin) we acknowledge the possibility that some smaller subset of individuals could experience behavioral disruption of a degree that impacts energetic budgets such that reproduction could be delayed for a year. However, considering the potential reproductive effects from tissue damage and from these levels of take by behavioral Level B harassment, in combination with the estimated mortality, this degree of effect on the small subset of individuals that could be affected is still not expected to adversely affect the stocks through effects on annual rates of recruitment or survival.

Regarding the severity of TTS takes, as explained in the 2018 AFTT final rule, they are expected to be low-level, of short duration, and not in a frequency band that would be expected to significantly interfere with dolphin communication, or echolocation or other important low-frequency cues. Therefore, the associated lost opportunities and capabilities would not be expected to impact reproduction or survival of any individuals. For these same reasons (low level and the likely frequency band), while a small permanent loss of hearing sensitivity may include some degree of energetic costs for compensating or may mean some small loss of opportunities or detection capabilities, the estimated Level A harassment takes by PTS for the two dolphin stocks (7 and 101, respectively) would be unlikely to impact behaviors, opportunities, or detection capabilities to a degree that would interfere with reproductive success or survival of any individual, even if PTS were to be experienced by an animal that also experiences one or more Level B harassment takes.

Altogether, individual dolphins will likely be taken at a low level, with some animals likely taken once or not at all, many potentially disturbed at low levels across 2–15 predominantly non-sequential days, and a small number potentially experiencing a level of effects that could result in curtailed reproduction for one year. This magnitude and severity of effects,

including consideration of the estimated mortality, is not expected to result in impacts on annual rates of recruitment or survival for either of the stocks, especially given the status of the stocks. For these reasons, we have determined, in consideration of all of the effects of the Navy's activities combined, that the authorized take will have a negligible impact on these two Western North Atlantic dolphins.

Pantropical Spotted Dolphin and Spinner Dolphin (Gulf of Mexico Stocks)

As described in the 2018 AFTT final rule, the Gulf of Mexico dolphin stocks indicated in Table 20 suffer from lingering health issues resulting from the DWH oil spill (7 and 17 percent of individuals of these stocks, respectively, have adverse health effects), which means that some of them could be more susceptible to exposure to other stressors, as well as negative population effects (predicting it will take up to 39 and 105 years, respectively, for stocks to return to population growth rates predicted in the absence of DWH effects). We authorize one mortality over the course of seven years for each of these two stocks, which is 0.14 annual mortalities for each stock. Given the large residual PBR values for these stocks (402 and 62, respectively), this number of mortalities falls well under the insignificance threshold. As discussed in the 2018 AFTT final rule, there are no known factors, information, or unusual circumstances that indicate that this estimated M/SI below the insignificance threshold could have adverse effects on these stocks through effects on annual rates of recruitment or survival. Some Level A harassment take by tissue damage from explosives has also been estimated and authorized for these stocks (6 and 14, respectively). As noted previously, tissue damage effects could range in impact from minor to something just less than M/SI that could seriously impact fitness. However, given the Navy's mitigation, which makes exposure at the closer to the source and more severe end of the spectrum less likely, we cautiously assume some moderate impact for this category of take that could lower an individual's fitness within the year such that females (assuming a 50 percent chance that a take is a female) might forego reproduction for one year. As noted previously, foregone reproduction has less of an impact on population rates than death (especially for one year) and the number of takes anticipated for each stock would not be expected to impact annual rates of recruitment or survival, even if all of the takes were females (which would be highly unlikely), especially given the high residual PBRs of these stocks. In other words, if the stocks can absorb the numbers indicated through each stock's residual PBR without impacting ability to approach OSP, they can absorb the significantly lesser effect of a very small number of one-year delay in calving.

Regarding the magnitude of Level B harassment takes (TTS and behavioral disruption), the number of estimated instances of harassment compared to the abundance is 32 percent and 60 percent, respectively, reflecting that only a subset of each stock will be taken by behavioral Level B harassment within a year. Of that subset, those taken would likely be taken one time, but if taken more than that, the 2 or 3 days would not likely be sequential. Regarding the severity of those individual takes by behavioral Level B harassment, as explained in the 2018 AFTT final rule, the duration of any exposure response is expected to be between minutes and hours (*i.e.,* relatively short) and the received sound levels largely below 172 dB (*i.e.,* of a lower to occasionally moderate severity).

Regarding the severity of TTS takes, as explained in the 2018 AFTT final rule, they are expected to be low-level, of short duration, and not in a frequency band that would be expected to significantly interfere with dolphin communication, or echolocation or other important low-frequency cues. Therefore, the associated lost opportunities and capabilities are not expected to impact reproduction or survival. For these same reasons (low level and the likely frequency band), while a small permanent loss of hearing sensitivity may include some degree of energetic costs for compensating or may mean some small loss of opportunities or detection capabilities, the estimated Level A harassment takes by PTS for the dolphin stocks addressed here (15 and 31, respectively) would be unlikely to impact behaviors, opportunities, or detection capabilities to a degree that would interfere with reproductive success or survival of any individuals.

Altogether, any individual dolphin will likely be taken at a low to occasionally moderate level, with most animals likely not taken at all and with a subset of animals being taken up to a few non-sequential days. Even given the fact that some of the affected individuals may have compromised health, there is nothing to suggest that such a low magnitude and severity of effects, including the potential tissue damage and the estimated mortality of one dolphin from each stock over the seven years, would result in impacts on annual rates of recruitment or survival for either of these two stocks. For these reasons, we have determined, in consideration of all of the effects of the Navy's activities combined, that the authorized take will have a negligible impact on Gulf of Mexico pantropical spotted dolphins and spinner dolphins.

Western North Atlantic Dolphin Stocks (All Stocks in Table 20 Except Atlantic White-Sided Dolphin and Short-Beaked Common Dolphin)

There are no specific issues with the status of these stocks that cause particular concern (*e.g.,* no UMEs). No mortality is expected nor authorized for these stocks. For some of these stocks, some tissue damage has been estimated and authorized (1–9 depending on the stock). As discussed previously, tissue damage effects could range in impact from minor to something just less than M/SI that could seriously impact fitness. However, given the Navy's mitigation, which makes exposure at the closer to the source and more severe end of the spectrum less likely, we cautiously assume some moderate impact for all these takes that could lower an individual's fitness within the year such that a small number of females (assuming a 50 percent chance of being a female) might forego reproduction for one year. As noted previously, foregone reproduction has less of an impact on population rates than death (especially for one year) and one to a few instances would not be expected to impact annual rates of recruitment or survival, even if all of the takes were females (which would be highly unlikely), especially given the higher residual PBRs, which is known for the majority of stocks. For stocks with no calculated residual PBR or where abundance is unknown, the limited information available on population size indicates that the very low number of females who might forego reproduction would have no effect on annual rates of recruitment or survival.

Regarding the magnitude of Level B harassment takes (TTS and behavioral disruption), the number of estimated instances of harassment compared to the abundance ranges up to 984 percent inside the U.S. EEZ (though some are significantly lower) and is generally much lower across the whole range of most stocks, reflecting that for many stocks only a subset of the stock will be impacted—although alternately for a few of the smaller bay stocks all individuals are expected to be taken across multiple days. Generally, individuals of most stocks (especially bottlenose dolphins) might be taken no more than several times each, while the

other species in this group will only accrue takes to a portion of the stock, but individuals might be taken across 2–20 days within a year. Regarding the severity of those individual takes by behavioral Level B harassment, as explained in the 2018 AFTT final rule, the duration of any exposure response is expected to be between minutes and hours (*i.e.,* relatively short) and the received sound levels largely below 172 dB (*i.e.,* of a lower level, less likely to evoke a severe response). While we do not have information to indicate that these takes would occur sequentially on more than several days in a row or be more severe in nature, the probability of this occurring increases the higher the total take numbers. Given higher percentages when compared to abundances, and especially where the absolute number of takes is higher (*e.g.,* spinner dolphin), we acknowledge the possibility that some smaller subset of individuals (especially in the larger stocks with higher total take numbers) could experience behavioral disruption of a degree that impacts energetic budgets such that reproduction could be delayed for a year. However, considering the very small number of potential reproductive effects from Level A harassment by tissue damage (1–9 depending on stock and assuming all individuals are female, which is very unlikely) in addition to the possible reproductive effect on a smaller subset of individuals from the takes by behavioral Level B harassment, this degree of effects on a small subset of individuals is still not expected to adversely affect annual rates of recruitment or survival. For the smaller Estuarine stocks with the potential repeated days of disturbance, we note that as described in the 2018 AFTT final rule, the activities that the Navy conducts in inland areas (not MTEs, *etc.*) are expected to generally result in lower severity responses, further decreasing the likelihood that they would cause effects on reproduction or survival, even if accrued over several sequential days.

Regarding the severity of TTS takes, as explained in the 2018 AFTT final rule, they are expected to be low-level, of short duration, and not in a frequency band that would be expected to significantly interfere with dolphin communication, or echolocation or other important low-frequency cues. Therefore, the associated lost opportunities and capabilities would not be expected to impact reproduction or survival. For these same reasons (low level and the likely frequency band), while a small permanent loss of hearing sensitivity may include some degree of energetic costs for compensating or may mean some small loss of opportunities or detection capabilities, the estimated Level A harassment takes by PTS for the dolphin stocks addressed here (between 1 and 77) would be unlikely to impact behaviors, opportunities, or detection capabilities to a degree that would interfere with reproductive success or survival of any individual, even if PTS were to be experienced by an individual that also experiences one or more Level B harassment takes.

Altogether, any individual dolphin will likely be taken at a low to occasionally moderate level, with some animals likely taken once or not at all, a subset potentially disturbed across 2–20 predominantly non-sequential days, and a small number potentially experiencing a level of effects that could curtail reproduction for one year. The magnitude and severity of effects described is not expected to result in impacts on annual rates of recruitment or survival for any of the stocks. For these reasons, we have determined, in consideration of all of the effects of the Navy's activities combined, that the authorized take will have a negligible impact on these Western North Atlantic dolphins.

Gulf of Mexico Dolphin Stocks (All of the Stocks Indicated in Table 20 Except Pantropical Spotted Dolphin and Spinner Dolphin)

As mentioned above and discussed in the 2018 AFTT final rule, the Gulf of Mexico stocks indicated in Table 20 suffer from lingering health issues resulting from the DWH oil spill (3–30 percent of individuals of these stocks have adverse health effects), which means that some of them could be more susceptible to exposure to other stressors, as well as negative population effects (predicting it will take up to 76 years, with that number varying across stocks, for stocks to return to population growth rates predicted in the absence of DWH effects). Of note, the Northern Coastal bottlenose dolphin adverse effect statistics are about twice as high as the others (*i.e.,* all other stocks are below 17 percent). As described above there is an active UME for bottlenose dolphins in the Northern Gulf of Mexico and in southwest Florida along the Gulf of Mexico. These UMEs could affect bottlenose dolphins from several stocks in the Gulf of Mexico, including those that are anticipated to be impacted by Navy activities and those that are not anticipated to be impacted by Navy activities. No mortality has been estimated or authorized for these stocks, however a few Level A harassment takes by tissue damage from explosives (zero for most, 1–2 for a few, and 6 for the Atlantic spotted dolphin stock) are estimated and authorized. As noted previously, tissue damage effects could range in impact from minor to something just less than M/SI that could seriously impact fitness. However, given the Navy's mitigation, which makes exposure at the closer to the source and more severe end of the spectrum less likely, we cautiously assume some moderate impact for these Level A harassment takes that could lower an individual's fitness within the year such that a female (assuming a 50 percent chance of being a female) might forego reproduction for one year. As noted previously, foregone reproduction has less of an impact on population rates than death (especially for one year) and a few instances, even up to six for the Atlantic spotted dolphin stock, would not be expected to impact annual rates of recruitment or survival, even if all of the takes were of females (which is highly unlikely).

Regarding the magnitude of Level B harassment takes (TTS and behavioral disruption), the number of estimated instances of harassment compared to the abundance ranges up to 177 percent, but is generally much lower for most stocks, reflecting that generally only a subset of each stock will be taken, with those in the subset taken only a few non-sequential days of the year. Regarding the severity of those individual takes by Level B behavioral harassment, as explained in the 2018 AFTT final rule, the duration of any exposure response is expected to be between minutes and hours (*i.e.,* relatively short) and the received sound levels largely below 172 dB (*i.e.,* of a lower to occasionally moderate severity).

Regarding the severity of TTS takes, as explained in the 2018 AFTT final rule, they are expected to be low-level, of short duration, and not in a frequency band that would be expected to significantly interfere with dolphin communication, or echolocation or other important low-frequency cues. Therefore, the associated lost opportunities and capabilities would not be expected to impact reproduction or survival. For these same reasons (low level and the likely frequency band), while a small permanent loss of hearing sensitivity may include some degree of energetic costs for compensating or may mean some small loss of opportunities or detection capabilities, the estimated Level A harassment takes by PTS for the dolphin stocks addressed here (all 3 or below, with the exception of three stocks with much larger abundances with 4, 8, and 15 PTS takes) would be

unlikely to impact behaviors, opportunities, or detection capabilities to a degree that would interfere with reproductive success or survival of any individual, even if PTS were to be experienced by an animal that also experiences one or more Level B harassment takes.

Altogether, any individual dolphin will likely be taken at a low to occasionally moderate level, with many animals likely not taken at all and with a subset of animals being taken up to a few times. A very small number could potentially experience tissue damage that could curtail reproduction for one year. Even given the fact that some of the affected individuals may have compromised health, there is nothing to suggest that such a low magnitude and severity of effects would result in impacts on annual rates of recruitment or survival for any of the Gulf of Mexico stocks indicated in Table 20. For these reasons, we have determined, in consideration of all of the effects of the Navy's activities combined, that the authorized take will have a negligible impact on these Gulf of Mexico dolphins.

Harbor Porpoise

In Table 21 below for porpoises, we indicate the total annual mortality, Level A and Level B harassment, and a number indicating the instances of total take as a percentage of abundance. Table 21 is unchanged from Table 75 in the 2018 AFTT final rule. For additional information and analysis supporting the negligible-impact analysis, see the *Odontocetes* discussion as well as the *Harbor Porpoise* discussion in the *Group and Species-Specific Analyses* section of the 2018 AFTT final rule, all of which remains applicable to this final rule unless specifically noted.

Table 21 -- Annual Estimated Takes by Level B Harassment, Level A Harassment, and Mortality for Porpoises in the AFTT Study Area and Number Indicating the Instances of Total Take as a Percentage of Stock Abundance

		Instances of indicated types of incidental take (not all takes represent separate individuals, especially for disturbance)					Total takes		Abundance		Instances of total take as percentage of abundance	
		Level B Harassment		Level A Harassment								
Species	Stock	Behavioral Disturbance	TTS (may also include disturbance)	PTS	Tissue Damage	Mortality	In EEZ	Inside and Outside EEZ	In EEZ	Inside and Outside EEZ	In EEZ	Inside and Outside EEZ
Family Phocoenidae (porpoises)												
Harbor porpoise	Gulf of Maine/Bay of Fundy	133,396	21,917	454	0	0	155,767	155,767	16,552	195,727	941	80

Note: In the table we compare estimated takes to abundance estimates generated from the same underlying density estimate (as described in the *Estimated Take of Marine Mammals* section of the 2018 AFTT final rule), versus abundance estimates directly from NMFS' SARs, which are not based on the same data and would not be appropriate for this purpose. Note that comparisons are made both within the U.S. EEZ only (where density estimates have lesser uncertainty) and across the whole Study Area (which offers a more comprehensive comparison for many stocks).

Total takes inside and outside U.S. EEZ represent the sum of annual Level A and Level B harassment from training and testing plus harassment take from one large ship shock trial.

Below we compile and summarize the information that supports our determination that the Navy's activities will not adversely affect harbor porpoises through effects on annual rates of recruitment or survival.

The Gulf of Maine/Bay of Fundy stock of harbor porpoise is found predominantly in northern U.S. coastal waters (<150 m depth) and up into Canada's Bay of Fundy. No mortality or tissue damage by explosives are anticipated or authorized for this stock and there are no specific issues with the status of the stock that cause particular concern (*e.g.,* no UMEs). Regarding the magnitude of Level B harassment takes (TTS and behavioral disruption), the number of estimated instances compared to the abundance within the U.S. EEZ and both in and outside of the U.S. EEZ, respectively, is 941 percent and 80 percent. This information, combined with the known range of the stock, suggests that only a portion of the individuals in the stock will likely be impacted (*i.e.,* notably less than 80 percent given the likely repeats; in other words more than 20 percent would be taken zero times), but that there will likely be some amount of repeat exposures across days (perhaps 6–19 days within a year) for some subset of individuals that spend extended times within the U.S. EEZ. Regarding the severity of those individual takes by behavioral Level B harassment, as explained in the 2018 AFTT final rule, the duration of any exposure response is expected to be from minutes to hours and not likely exceeding 24 hrs, and the received sound levels of the MF1 bin are largely between 154 and 166 dB, which, for a harbor porpoise (which have a lower behavioral Level B harassment threshold) would mostly be considered a moderate level.

Regarding the severity of TTS takes, as explained in the 2018 AFTT final rule, they are expected to be low-level, of short duration, and not in a frequency band that would be expected to significantly interfere with harbor porpoise communication, or echolocation or other important low-frequency cues. Therefore, the associated lost opportunities and capabilities would not be expected to impact reproduction or survival. For these same reasons (low level and the likely frequency band), while a small permanent loss of hearing sensitivity may include some degree of energetic costs for compensating or may mean some small loss of opportunities or detection capabilities, the estimated 454 Level A harassment takes by PTS for harbor porpoise would be unlikely to impact behaviors, opportunities, or detection capabilities to a degree that would interfere with reproductive

success or survival for most individuals, even if PTS were to be experienced by an individual that also experiences one or more Level B harassment takes. Because of the high number of PTS takes, we acknowledge that a few animals could potentially incur permanent hearing loss of a higher degree that could potentially interfere with their successful reproduction and growth. However, given the status of the stock (high abundance and residual PBR of 451), even if this occurred, it would not adversely impact rates of recruitment or survival.

Altogether, because harbor porpoises are particularly sensitive, it is likely that a fair number of the responses would be of a moderate nature. Additionally, as noted, some portion of the stock may be taken repeatedly on up to 19 days within a year, with some of those being sequential. Given this and the larger number of total takes (both to the stock and to individuals), it is more likely (probabilistically) that some small number of individuals could be interrupted during foraging in a manner and amount such that impacts to the energy budgets of females (from either losing feeding opportunities or expending considerable energy to find alternative feeding options) could cause them to forego reproduction for a year (energetic impacts to males generally have limited impact on population rates unless they cause death, and it takes extreme energy deficits beyond what would ever be likely to result from these activities to cause the death of an adult harbor porpoise). As noted previously, however, foregone reproduction (especially for one year) has far less of an impact on population rates than mortality and a small number of instances would not be expected to adversely impact annual rates of recruitment or survival, especially given that the residual PBR of harbor porpoises is 451. All indications are that the number of times in which reproduction would be likely to be foregone would not affect the stock's annual rates of recruitment or survival. For these reasons, we have determined, in consideration of all of the effects of the Navy's activities combined, that the authorized take will have a negligible impact on harbor porpoises.

Beaked Whales

In Table 22 below for beaked whales, we indicate the total annual mortality, Level A and Level B harassment, and a number indicating the instances of total take as a percentage of abundance. Table 22 is unchanged from Table 76 in the 2018 AFTT final rule. For additional information and analysis supporting the negligible-impact analysis, see the *Odontocetes* discussion as well as the *Beaked Whales* discussion in the *Group and Species-Specific Analyses* section of the 2018 AFTT final rule, all of which remains applicable to this final rule unless specifically noted.

Table 22 -- Annual Estimated Takes by Level B Harassment, Level A Harassment, and Mortality for Beaked Whales in the AFTT Study Area and Number Indicating the Instances of Total Take as a Percentage of Stock Abundance.

		Instances of indicated types of incidental take (not all takes represent separate individuals, especially for disturbance)					Total takes		Abundance		Instances of total take as percentage of abundance	
		Level B Harassment		Level A Harassment								
Species	Stock	Behavioral Disturbance	TTS (may also include disturbance)	PTS	Tissue Damage	Mortality	In EEZ	Inside and Outside EEZ	In EEZ	Inside and Outside EEZ	In EEZ	Inside and Outside EEZ
Suborder Odontoceti (toothed whales)												
Family Ziphiidae (beaked whales)												
Blainville's beaked whale	Northern Gulf of Mexico	1,420	8	0	0	0	1,428	1,428	966	966	148	148
	Western North Atlantic	22,902	197	1	0	0	19,959	23,100	1,274	14,277	1,567	162
Cuvier's beaked whale	Northern Gulf of Mexico	1,487	8	0	0	0	1,495	1,495	966	966	155	155
	Western North Atlantic	84,460	724	3	0	0	73,799	85,187	4,704	52,716	1,569	162
Gervais' beaked whale	Northern Gulf of Mexico	1,420	8	0	0	0	1,428	1,428	966	966	148	148
	Western North Atlantic	22,902	197	1	0	0	19,959	23,100	1,274	14,277	1,567	162
Northern bottlenose whale	Western North Atlantic	2,040	4	0	0	0	1,836	2,044	100	688	1,836	297
Sowersby's beaked whale	Western North Atlantic	22,930	197	1	0	0	19,987	23,128	1,274	14,277	1,569	162
True's beaked whale	Western North Atlantic	22,930	197	1	0	0	19,987	23,128	1,274	14,277	1,569	162

Note: In the table we compare estimated takes to abundance estimates generated from the same underlying density estimate (as described in the *Estimated Take of Marine Mammals* section of the 2018 AFTT final rule), versus abundance estimates directly from NMFS' SARs, which are not based on the same data and would not be appropriate for this purpose. Note that comparisons are made both within the U.S. EEZ only (where density estimates have lesser uncertainty) and across the whole Study Area (which offers a more comprehensive comparison for many stocks).

Total takes inside and outside U.S. EEZ represent the sum of annual Level A and Level B harassment from training and testing plus harassment take from one large ship shock trial.

Below we compile and summarize the information that supports our determination that the Navy's activities will not adversely affect any species or stocks through effects on annual rates of recruitment or survival for any of the affected species or stocks addressed in this section.

Beaked Whales, Including Northern Bottlenose Whale (Western North Atlantic Stocks)

These stocks span the deeper waters of the East Coast of the U.S. north to Canada and out into oceanic waters beyond the U.S. EEZ. There is no currently reported trend for these populations and there are no specific issues with the status of the stocks that cause particular concern. Neither mortality nor tissue damage from explosives is anticipated or authorized for these stocks. Regarding the magnitude of Level B harassment takes (TTS and behavioral disruption), the number of estimated instances of harassment compared to the abundance within the U.S. EEZ and both in and outside of the U.S. EEZ is 1,567–1,836 percent and 162–297 percent, respectively. This information, combined with the known range of the stocks, suggests that while not all of the individuals in these stocks would most likely be taken (because they span well into oceanic waters, beyond the AFTT Study Area), of those that are, most would be taken over a few days (though likely not sequential) and some subset that spends extended time within the U.S. EEZ will likely be taken over a larger amount of days (maybe 15–37), some of which could be sequential. Regarding the severity of those individual takes by behavioral Level B harassment, as explained in the 2018 AFTT final rule, the duration of any exposure response is expected to generally be between minutes and hours and largely between 148 and 160 dB, though with beaked whales, which are considered somewhat more sensitive, this could mean that some individuals will leave preferred habitat for a day or two. However, while interrupted feeding bouts are a known response and concern for odontocetes, we also know that there are often viable alternative habitat options in the relative vicinity in the Western North Atlantic.

Regarding the severity of TTS takes, as explained in the 2018 AFTT final rule, they are expected to be low-level, of short duration, and not in a frequency band that would adversely affect communication, inhibit echolocation, or otherwise interfere with other low-frequency cues. Therefore any associated lost opportunities and capabilities would not impact reproduction or survival. For the same reasons (low level and frequency band) the one to three estimated Level A harassment takes by PTS for these stocks are unlikely to have any effect on the reproduction or survival of any individual, even if PTS were to be experienced by an individual that also experiences one or more Level B harassment takes.

Altogether, a small portion of the stock will likely be taken (at a relatively moderate level) on a relatively moderate to high number of days across the year, some of which could be sequential. Though the majority of impacts are expected to be of a sometimes low, but more likely, moderate magnitude and severity, the sensitivity of beaked whales and larger number of takes makes it more likely (probabilistically) that a small number of individuals could be interrupted during foraging in a manner and amount such that impacts to the energy budgets of females (from either losing feeding opportunities or expending considerable energy to find alternative feeding options) could cause them to forego reproduction for a year (energetic impacts to males generally have limited impact on population rates unless they cause death, and it takes extreme energy deficits beyond what would ever be likely to result from these activities to cause the death of an adult beaked whale). As noted previously, however, foregone reproduction (especially for one year) has far less of an impact on population rates than mortality and a small number of instances would not be expected to adversely impact annual rates of recruitment or survival. Based on the abundance of these stocks in the area and the evidence of little, if any, known human-caused mortality, all indications are that the small number of times in which reproduction would be likely to be foregone would not affect the stocks' annual rates of recruitment or survival. For these reasons, we have determined, in consideration of all of the effects of the Navy's activities combined, that the authorized take will have a negligible impact on Western North Atlantic beaked whales.

Beaked Whales (Gulf of Mexico Stocks)

The animals in these stocks suffer from lingering health issues resulting from the DWH oil spill (four percent of individuals of these stocks have adverse health effects), which means that some of them could be more susceptible to exposure to other stressors, and negative population effects (10 years for their growth rate to recover to the rate predicted for the stocks if they had not incurred spill impacts). Neither mortality nor tissue damage from explosives is anticipated or authorized for these stocks. Level A harassment take from PTS is also unlikely to occur. Regarding the magnitude of Level B harassment takes (TTS and behavioral disruption), the number of estimated instances of harassment compared to the abundance is 148–155 percent. This information indicates that either the individuals in these stocks would all be taken by harassment one or two days within a year, or that a subset would not be taken at all and a small subset may be taken several times. Regarding the severity of those individual takes, as explained in the 2018 AFTT final rule, the duration of any exposure response is expected to generally be between minutes and hours and largely between 148 and 160 dB, though with beaked whales, which are considered somewhat more sensitive, this could mean that some individuals will leave preferred habitat for a day or two. However, while interrupted feeding bouts are a known response and concern for odontocetes, we also know that there are often viable alternative habitat options in the relative vicinity in the Gulf of Mexico. Regarding the severity of TTS takes, as explained in the 2018 AFTT final rule, they are expected to be low-level, of short duration, and not in a frequency band that would adversely affect communication, inhibit echolocation, or otherwise interfere with other low frequency cues. Therefore any associated lost opportunities and capabilities would not impact reproduction or survival.

Altogether, likely only a portion of these stocks will be impacted and any individual beaked whale likely would be disturbed at a moderate level for no more than a few days per year. Even given the fact that some of the affected individuals may have compromised health, there is nothing to suggest that this magnitude and severity of effects would result in impacts on annual rates of recruitment or survival for any of the stocks. For these reasons, we have determined, in consideration of all of the effects of the Navy's activities combined, that the authorized take will have a negligible impact on Gulf of Mexico beaked whales included in Table 22.

Pinnipeds

In Table 23 below for pinnipeds, we indicate the total annual mortality, Level A and Level B harassment, and a number indicating the instances of total take as a percentage of abundance. Table 23 is unchanged from Table 77 in the 2018 AFTT final rule. For additional

information and analysis supporting the negligible-impact analysis, see the *Pinnipeds* discussion in the *Group and Species-Specific Analyses* section of the 2018 AFTT final rule, all of which remains applicable to this final rule unless specifically noted.

Table 23 -- Annual Estimated Takes by Level B Harassment, Level A Harassment, and Mortality for Pinnipeds in the AFTT Study Area and Number Indicating the Instances of Total Take as a Percentage of Stock Abundance.

		Instances of indicated types of incidental take (not all takes represent separate individuals, especially for disturbance)					Total takes		Abundance		Instances of total take as percentage of abundance	
		Level B Harassment		Level A Harassment								
Species	Stock	Behavioral Disturbance	TTS (may also include disturbance)	PTS	Tissue Damage	Mortality	In EEZ	Inside and Outside EEZ	In EEZ	Inside and Outside EEZ	In EEZ	Inside and Outside EEZ
Suborder Pinnipedia												
Family Phocidae (true seals)												
Gray seal	Western North Atlantic	810	1,528	2	0	0	2,340	2,340	2,472	2,472	95	95
Harbor seal	Western North Atlantic	1,312	2,477	4	0	0	3,793	3,793	11,122	11,122	34	34
Harp seal	Western North Atlantic	6,339	9,955	3	0	0	16,297	16,297	7,242	7,242	225	225
Hooded seal	Western North Atlantic	448	466	0	0	0	914	914	880	880	104	104

Note: In the table we compare estimated takes to abundance estimates generated from the same underlying density estimate (as described in the *Estimated Take of Marine Mammals* section of the 2018 AFTT final rule), versus abundance estimates directly from NMFS' SARs, which are not based on the same data and would not be appropriate for this purpose. Note that comparisons are made both within the U.S. EEZ only (where density estimates have lesser uncertainty) and across the whole Study Area (which offers a more comprehensive comparison for many stocks).

Total takes inside and outside U.S. EEZ represent the sum of annual Level A and Level B harassment from training and testing plus harassment take from one large ship shock trial.

Below we compile and summarize the information that supports our determination that the Navy's activities will not adversely affect any pinnipeds through effects on annual rates of recruitment or survival for any of the affected species or stocks addressed in this section.

The Western North Atlantic pinniped (harp seal, harbor seal, hooded seal, and gray seal) stocks are northern, but highly migratory species. While harp seals are limited to the northern portion of the U.S. EEZ, gray and harbor seals may be found as far south as the Chesapeake Bay in late fall and hooded seals migrate as far south as Puerto Rico. An UME has been designated for seals from Maine to Virginia and the main pathogen found in the seals that have been tested is phocine distemper virus. Neither mortality nor tissue damage from explosives is anticipated or authorized for any of these stocks. Regarding the magnitude of Level B harassment takes (TTS and behavioral disruption), the number of estimated instances of harassment compared to the abundance that is expected within the AFTT Study Area is 34–225 percent, which suggests that only a subset of the animals in the AFTT Study Area would be taken, but that a few might be taken on several days within the year (1–5 days), but not likely on sequential days. When the fact that some of these seals are residing in areas near Navy activities is considered, we can estimate that perhaps some of those individuals might be taken some higher number of days within the year (up to approximately 10 days), but still with no reason to think that these takes would occur on sequential days, which means that we would not expect effects on reproduction or survival. Regarding the severity of those individual behavioral Level B harassment takes, as explained in the 2018 AFTT final rule, the duration of any exposure response is expected to be between minutes and hours (*i.e.,* relatively short) and the received sound levels are largely below 172 dB, with some up to 178 dB (*i.e.,* of a lower to moderate level, less likely to evoke a severe response) and therefore there is no indication that the expected takes by behavioral Level B harassment would have any effect on annual rates of recruitment or survival.

Regarding the severity of TTS takes, as explained in the 2018 AFTT final rule, they are expected to be low-level, of short duration, and not in a frequency band that would adversely affect communication or otherwise interfere with other low-frequency cues. Therefore any associated lost opportunities and capabilities would not impact reproduction or survival. For the same reasons (low level and frequency band) the two to four estimated Level A harassment takes by PTS for these stocks are unlikely to have any effect on the reproduction or survival of any individual, even if PTS were to be experienced by an animal that also experiences one or more Level B harassment takes.

Even given the fact that some of the affected harbor seal individuals may have compromised health due to the UME, there is nothing to suggest that such a low magnitude and severity of effects would result in impacts on annual rates of recruitment or survival, especially given that the stock abundance in the SAR is 75,839 with a residual PBR of 1,651. Similarly, given the low magnitude and severity of effects, there is no indication that these activities would affect reproduction or survival of harp or hooded seals, much less adversely affect rates of recruitment or survival, especially given that harp seal abundance is estimated at 6.9 million and hooded seal residual PBR is

13,950. Gray seals are experiencing an UME as well as an exceedance of more than 4,299 M/SI above PBR, as reported in the SAR. The NMFS SAR notes, however, that the U.S. portion of average annual human-caused M/SI in U.S. waters does not exceed the portion of PBR in U.S. waters, and while the status of the gray seal population relative to OSP in U.S. Atlantic EEZ waters is unknown, despite the exceedance of the reported PBR the stock abundance appears to be increasing in both U.S. and Canadian waters (Hayes *et al.,* 2018). Also, given the low magnitude (take compared to abundance is 95 percent, meaning the subset of individuals taken may be taken a few times on non-sequential days) and low to occasionally moderate severity of impacts, no impacts to individual reproduction or survival are expected and therefore no effects on annual rates of recruitment or survival would occur. For these reasons, in consideration of all of the effects of the Navy's activities combined, we have determined that the authorized take will have a negligible impact on gray seals, harbor seals, hooded seals, and harp seals.

Determination

The 2018 AFTT final rule included a detailed discussion of all of the anticipated impacts on the affected species and stocks from serious injury and mortality, Level A harassment, and Level B harassment; impacts on habitat; and how the Navy's mitigation and monitoring measures reduce the number and/or severity of adverse effects. We evaluated how these impacts and mitigation measures are expected to combine to affect individuals of each stock. Those effects were then evaluated in the context of whether they are reasonably likely to impact reproductive success or survivorship of individuals and then, if so, further analyzed to determine whether there would be effects on annual rates of recruitment or survival that would adversely affect the species or stock.

As described above, the basis for the negligible impact determination is the assessment of effects on annual rates of recruitment and survival. Accordingly, the analysis included in the 2018 AFTT final rule, as updated in this rule to consider new information and include the two additional years of activities, mitigation measures, and monitoring and reporting requirements, uses annual activity levels, the best available science, and approved methods to predict the annual impacts to marine mammals, which were then analyzed in the context of whether each species or stock would incur more than a negligible impact based on anticipated adverse impacts to annual rates of recruitment or survival. As we have described above, none of the factors upon which the annually-based conclusions in the 2018 AFTT final rule were based have changed in a manner that changes our determinations. Therefore, even though this final rule includes two additional years, because our findings are based on annual rates of recruitment and survival, and nothing has changed in a manner that would change our 2018 AFTT rule annual analyses, it is appropriate to rely on those analyses, in addition to the updated information and analysis discussed above, for this final rule.

Based on the applicable information and analysis from the 2018 AFTT final rule as updated with the information and analysis contained herein on the potential and likely effects of the specified activities on the affected marine mammals and their habitat, and taking into consideration the implementation of the monitoring and mitigation measures, NMFS finds that the incidental take from the specified activities will have a negligible impact on all affected marine mammal species and stocks.

Subsistence Harvest of Marine Mammals

There are no subsistence uses or harvest of marine mammals in the geographic area affected by the specified activities. Therefore, NMFS has determined that the total taking affecting species or stocks will not have an unmitigable adverse impact on the availability of such species or stocks for taking for subsistence purposes.

Classifications

Endangered Species Act

There are six marine mammal species under NMFS jurisdiction that are listed as endangered or threatened under the ESA with confirmed or possible occurrence in the AFTT Study Area: Blue whale, fin whale, sei whale, sperm whale, North Atlantic right whale, and Gulf of Mexico subspecies of Bryde's whale. The Navy consulted with NMFS pursuant to section 7 of the ESA for AFTT activities. NMFS also consulted internally on the issuance of the AFTT regulations and LOAs under section 101(a)(5)(A) of the MMPA. NMFS issued a Biological and Conference Opinion on October 22, 2018, concluding that the issuance of the 2018 AFTT final rule and subsequent LOAs are not likely to jeopardize the continued existence of the threatened and endangered species under NMFS' jurisdiction and are not likely to result in the destruction or adverse modification of critical habitat in the AFTT Study Area.

The 2018 Biological and Conference Opinion included specified conditions under which NMFS would be required to reinitiate section 7 consultation. The agency reviewed these specified conditions for this rulemaking and determined that reinitiation of consultation was not warranted. The incidental take statement that accompanied the 2018 Biological and Conference Opinion has been amended to cover the seven-year period of the rule. NMFS also requested that the Conference Opinion for Gulf of Mexico Bryde's whale, which was listed as an endangered species on April 15, 2019, be adopted as a Biological Opinion, which was completed on October 24, 2019. The 2018 Biological and Conference Opinion for this action is available at *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-military-readiness-activities.*

National Marine Sanctuaries Act

Federal agency actions that are likely to injure national marine sanctuary resources are subject to consultation with the Office of National Marine Sanctuaries (ONMS) under section 304(d) of the National Marine Sanctuaries Act (NMSA).

On December 15, 2017, the Navy initiated consultation with ONMS and submitted a Sanctuary Resource Statement (SRS) that discussed the effects of the Navy's AFTT activities in the vicinity of Stellwagen Bank, Gray's Reef, and Florida Keys National Marine Sanctuaries on sanctuary resources. NMFS worked with the Navy in the development of the SRS to ensure that it could serve jointly as an SRS for NMFS' action under the MMPA as well.

On December 20, 2017, NMFS initiated consultation with ONMS on MMPA incidental take regulations for the Navy's AFTT activities. NMFS requested that ONMS consider the description and assessment of the effects of the Navy's activities included in the joint SRS submitted by the Navy, which included an assessment of the effects on marine mammals, as satisfying NMFS' need to provide an SRS.

ONMS reviewed the SRS, as well as an addendum the Navy provided on April 3, 2018. On April 12, 2018, ONMS found the SRS and addendum sufficient for the purposes of making an injury determination and developing recommended alternatives as required

by the NMSA. On May 15, 2018, ONMS recommended two reasonable and prudent measures to the Navy and NMFS (one of which applied to NMFS) to minimize injury and to protect sanctuary resources. ONMS subsequently provided a slight modification of those recommendations to the Navy and NMFS on August 1, 2018. On August 17, 2018, the Navy agreed to implement both ONMS recommendations and on October 30, 2018, NMFS agreed to implement the recommendation that applied to NMFS.

For this rulemaking, NMFS reviewed the conditions for reinitiation of NMSA consultation in ONMS' August 1, 2018, letter. The agency has determined that the current NMSA consultation remains valid for the issuance of the seven-year MMPA incidental take regulations and subsequent LOAs, and that reinitiation of consultation under the NMSA is not warranted. The Navy and NMFS will continue to implement the reasonable and prudent alternatives recommended by ONMS during the 2018 consultation.

National Environmental Policy Act

To comply with the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*) and NOAA Administrative Order (NAO) 216–6A, NMFS must evaluate our proposed actions and alternatives with respect to potential impacts on the human environment. NMFS participated as a cooperating agency on the 2018 AFTT FEIS/OEIS (published on September 14, 2018, *https://www.public.navy.mil/usff/environmental/Pages/aftt.aspx*) which evaluated impacts from Navy training and testing activities in the AFTT Study Area for the reasonably foreseeable future. In accordance with 40 CFR 1506.3, NMFS independently reviewed and evaluated the 2018 AFTT FEIS/OEIS and determined that it was adequate and sufficient to meet our responsibilities under NEPA for the issuance of the 2018 AFTT final rule and associated LOAs. NOAA therefore adopted the 2018 AFTT FEIS/OEIS.

In accordance with 40 CFR 1502.9 and the information and analysis contained in this final rule, NMFS has determined that this final rule and the subsequent LOAs will not result in impacts that were not fully considered in the 2018 AFTT FEIS/OEIS. In addition, as indicated in this final rule, the addition of two years of authorized incidental take associated with the same activities conducted in the same geographic area and having the same potential effects on the same species and stocks is not a substantial change to the action, nor are there significant new circumstances or information relevant to environmental concerns or its impacts. Therefore, NMFS has determined that the 2018 AFTT FEIS/OEIS and 2018 NMFS Record of Decision (ROD) remain valid, and there is no need to supplement either document for this rulemaking.

Regulatory Flexibility Act

The Office of Management and Budget has determined that this rule is not significant for purposes of Executive Order 12866.

Pursuant to the Regulatory Flexibility Act (RFA), the Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration during the proposed rule stage that this action would not have a significant economic impact on a substantial number of small entities. The factual basis for the certification was published in the proposed rule and is not repeated here. No comments were received regarding this certification. As a result, a regulatory flexibility analysis was not required and none was prepared.

Waiver of Delay in Effective Date Under the Administrative Procedure Act

NMFS has determined that there is good cause under the Administrative Procedure Act (5 U.S.C. 553(d)) to waive the 30-day delay in the effective date for this rule. This rule relieves the Navy from the restrictions of the take prohibitions under the MMPA by granting the Navy's request for incidental take authorization under MMPA section 101(a)(5)(A). In addition, there is good cause to waive the 30-day effective date period because the regulations are identical to those that the Navy has been implementing since November 2018 (except for a small number of minor, technical clarifications that do not affect implementation). The only substantive change in the regulations is to extend the mitigation measures and the monitoring and reporting requirements for an additional two years, until November 13, 2025. The Navy is the only entity affected by the regulations, the Navy specifically requested extension of the regulatory requirements for the two years, and the Navy has fully agreed to these requirements for the additional two years through its application for incidental take authorization. The Navy is anticipating finalization of the rule. For all these reasons, there is no need for a period of time following publication of the rule for the Navy to bring its training and testing operations into compliance with the requirements of the rule.

List of Subjects in 50 CFR Part 218

Exports, Fish, Imports, Incidental take, Indians, Labeling, Marine mammals, Navy, Penalties, Reporting and recordkeeping requirements, Seafood, Sonar, Transportation.

Dated: December 11, 2019.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For reasons set forth in the preamble, 50 CFR part 218 is amended as follows:

PART 218—REGULATIONS GOVERNING THE TAKING AND IMPORTING OF MARINE MAMMALS

■ 1. The authority citation for part 218 continues to read as follows:

Authority: 16 U.S.C. 1361 *et seq.,* unless otherwise noted.

■ 2. Revise subpart I to read as follows:

Subpart I—Taking and Importing Marine Mammals; U.S. Navy's Atlantic Fleet Training and Testing (AFTT)

Sec.

218.80 Specified activity and specified geographical region.
218.81 Effective dates.
218.82 Permissible methods of taking.
218.83 Prohibitions.
218.84 Mitigation requirements.
218.85 Requirements for monitoring and reporting.
218.86 Letters of Authorization.
218.87 Renewals and modifications of Letters of Authorization.
218.88–218.89 [Reserved]

Subpart I—Taking and Importing Marine Mammals; U.S. Navy's Atlantic Fleet Training and Testing (AFTT)

§ 218.80 Specified activity and geographical region.

(a) Regulations in this subpart apply only to the U.S. Navy for the taking of marine mammals that occurs in the area described in paragraph (b) of this section and that occurs incidental to the activities listed in paragraph (c) of this section.

(b) The taking of marine mammals by the Navy under this subpart may be authorized in Letters of Authorization (LOAs) only if it occurs within the Atlantic Fleet Training and Testing (AFTT) Study Area, which includes areas of the western Atlantic Ocean along the East Coast of North America, portions of the Caribbean Sea, and the Gulf of Mexico. The AFTT Study Area begins at the mean high tide line along the U.S. East Coast and extends east to

the 45-degree west longitude line, north to the 65-degree north latitude line, and south to approximately the 20-degree north latitude line. The AFTT Study Area also includes Navy pierside locations, bays, harbors, and inland waterways, and civilian ports where training and testing occurs.

(c) The taking of marine mammals by the Navy is only authorized if it occurs incidental to the Navy conducting training and testing activities, including:

(1) *Training.* (i) Amphibious warfare;

(ii) Anti-submarine warfare;

(iii) Electronic warfare;

(iv) Expeditionary warfare;

(v) Mine warfare;

(vi) Surface warfare, and

(vii) Pile driving.

(2) *Testing.* (i) Naval Air Systems Command Testing Activities;

(ii) Naval Sea System Command Testing Activities; and

(iii) Office of Naval Research Testing Activities.

§ 218.81 Effective dates.

Regulations in this subpart are effective from December 23, 2019 through November 13, 2025.

§ 218.82 Permissible methods of taking.

(a) Under LOAs issued pursuant to §§ 216.106 of this chapter and 218.86, the Holder of the LOAs (hereinafter ''Navy'') may incidentally, but not intentionally, take marine mammals within the area described in § 218.80(b) by Level A harassment and Level B harassment associated with the use of active sonar and other acoustic sources and explosives as well as serious injury or mortality associated with ship shock trials and vessel strikes, provided the activity is in compliance with all terms, conditions, and requirements of this subpart and the applicable LOAs.

(b) The incidental take of marine mammals by the activities listed in § 218.80(c) is limited to the following species:

TABLE 1 TO § 218.82

Species	Stock
Suborder Mysticeti (baleen whales)	
Family Balaenidae (right whales):	
North Atlantic right whale	Western.
Family Balaenopteridae (roquals):	
Blue whale	Western North Atlantic (Gulf of St. Lawrence).
Bryde's whale	Northern Gulf of Mexico NSD.
Minke whale	Canadian East Coast.
Fin whale	Western North Atlantic.
Humpback whale	Gulf of Maine.
Sei whale	Nova Scotia.
Suborder Odontoceti (toothed whales)	
Family Physeteridae (sperm whale):	
Sperm whale	Gulf of Mexico Oceanic. North Atlantic.
Family Kogiidae (sperm whales):	
Dwarf sperm whale	Gulf of Mexico Oceanic. Western North Atlantic.
Pygmy sperm whale	Northern Gulf of Mexico. Western North Atlantic.
Family Ziphiidae (beaked whales):	
Blainville's beaked whale	Northern Gulf of Mexico. Western North Atlantic.
Cuvier's beaked whale	Northern Gulf of Mexico. Western North Atlantic.
Gervais' beaked whale	Northern Gulf of Mexico. Western North Atlantic.
Northern bottlenose whale	Western North Atlantic.
Sowersby's beaked whale	Western North Atlantic.
True's beaked whale	Western North Atlantic.
Family Delphinidae (dolphins):	
Atlantic spotted dolphin	Northern Gulf of Mexico. Western North Atlantic.
Atlantic white-sided dolphin	Western North Atlantic.

TABLE 1 TO § 218.82—Continued

Species	Stock
Bottlenose dolphin	Choctawhatchee Bay.
	Gulf of Mexico Eastern Coastal.
	Gulf of Mexico Northern Coastal.
	Gulf of Mexico Western Coastal.
	Indian River Lagoon Estuarine System.
	Jacksonville Estuarine System.
	Mississippi Sound, Lake Borgne, Bay Boudreau.
	Northern Gulf of Mexico Continental Shelf.
	Northern Gulf of Mexico Oceanic.
	Northern North Carolina Estuarine System.
	Southern North Carolina Estuarine System.
	Western North Atlantic Northern Florida Coastal.
	Western North Atlantic Central Florida Coastal.
	Western North Atlantic Northern Migratory Coastal.
	Western North Atlantic Offshore.
	Western North Atlantic South Carolina/Georgia Coastal.
	Western North Atlantic Southern Migratory Coastal.
Clymene dolphin	Northern Gulf of Mexico.
	Western North Atlantic.
False killer whale	Northern Gulf of Mexico.
	Western North Atlantic.
Fraser's dolphin	Northern Gulf of Mexico.
	Western North Atlantic.
Killer whale	Northern Gulf of Mexico.
	Western North Atlantic.
Long-finned pilot whale	Western North Atlantic.
Melon-headed whale	Northern Gulf of Mexico.
	Western North Atlantic.
Pantropical spotted dolphin	Northern Gulf of Mexico.
	Western North Atlantic.
Pygmy killer whale	Northern Gulf of Mexico.
	Western North Atlantic.
Risso's dolphin	Northern Gulf of Mexico.
	Western North Atlantic.
Rough-toothed dolphin	Northern Gulf of Mexico.
	Western North Atlantic.
Short-beaked common dolphin	Western North Atlantic.
Short-finned pilot whale	Northern Gulf of Mexico.
	Western North Atlantic.
Spinner dolphin	Northern Gulf of Mexico.
	Western North Atlantic.
Striped dolphin	Northern Gulf of Mexico.
	Western North Atlantic.
White-beaked dolphin	Western North Atlantic.
Family Phocoenidae (porpoises):	
Harbor porpoise	Gulf of Maine/Bay of Fundy.
Suborder Pinnipedia	
Family Phocidae (true seals):	
Gray seal	Western North Atlantic.
Harbor seal	Western North Atlantic.
Harp seal	Western North Atlantic.
Hooded seal	Western North Atlantic.

§ 218.83 Prohibitions.

Notwithstanding incidental takings contemplated in § 218.82(a) and authorized by LOAs issued under §§ 216.106 of this chapter and 218.86, no person in connection with the activities listed in § 218.80(c) may:

(a) Violate, or fail to comply with the terms, conditions, and requirements of this subpart or an LOA issued under §§ 216.106 of this chapter and 218.86;

(b) Take any marine mammal not specified in § 218.82(b);

(c) Take any marine mammal specified § 218.82(b) in any manner other than as specified in the LOAs; or

(d) Take a marine mammal specified § 218.82(b) if the National Marine Fisheries Service (NMFS) determines such taking results in more than a negligible impact on the species or stocks of such marine mammal.

§ 218.84 Mitigation requirements.

When conducting the activities identified in § 218.80(c), the mitigation measures contained in any LOAs issued under §§ 216.106 of this chapter and 218.86 must be implemented. These mitigation measures include, but are not limited to:

(a) *Procedural mitigation.* Procedural mitigation is mitigation that the Navy must implement whenever and wherever an applicable training or testing activity takes place within the AFTT Study Area for each applicable activity category or stressor category and includes acoustic stressors (*i.e.,* active sonar, air guns, pile driving, weapons

firing noise), explosive stressors (*i.e.,* sonobuoys, torpedoes, medium-caliber and large-caliber projectiles, missiles and rockets, bombs, sinking exercises, mines, anti-swimmer grenades, line charge testing and ship shock trials), and physical disturbance and strike stressors (*i.e.,* vessel movement; towed in-water devices; small-, medium-, and large-caliber non-explosive practice munitions; non-explosive missiles and rockets; non-explosive bombs and mine shapes).

(1) *Environmental awareness and education.* Appropriate personnel (including civilian personnel) involved in mitigation and training or testing activity reporting under the specified activities must complete one or more modules of the U.S. Navy Afloat Environmental Compliance Training Series, as identified in their career path training plan. Modules include: Introduction to the U.S. Navy Afloat Environmental Compliance Training Series, Marine Species Awareness Training, U.S. Navy Protective Measures Assessment Protocol, and U.S. Navy Sonar Positional Reporting System and Marine Mammal Incident Reporting.

(2) *Active sonar.* Active sonar includes low-frequency active sonar, mid-frequency active sonar, and high-frequency active sonar. For vessel-based active sonar activities, mitigation applies only to sources that are positively controlled and deployed from manned surface vessels (*e.g.,* sonar sources towed from manned surface platforms). For aircraft-based active sonar activities, mitigation applies only to sources that are positively controlled and deployed from manned aircraft that do not operate at high altitudes (*e.g.,* rotary-wing aircraft). Mitigation does not apply to active sonar sources deployed from unmanned aircraft or aircraft operating at high altitudes (*e.g.,* maritime patrol aircraft).

(i) *Number of Lookouts and observation platform*—(A) *Hull-mounted sources.* One Lookout for platforms with space or manning restrictions while underway (at the forward part of a small boat or ship) and platforms using active sonar while moored or at anchor (including pierside); two Lookouts for platforms without space or manning restrictions while underway (at the forward part of the ship); and four Lookouts for pierside sonar testing activities at Port Canaveral, Florida and Kings Bay, Georgia.

(B) *Sources that are not hull-mounted sources.* One Lookout on the ship or aircraft conducting the activity.

(ii) *Mitigation zones and requirements.* During the activity, at 1,000 yard (yd) Navy personnel must power down 6 decibels (dB), at 500 yd Navy personnel must power down an additional 4 dB (for a total of 10 dB), and at 200 yd Navy personnel must shut down for low-frequency active sonar ≥200 dB and hull-mounted mid-frequency active sonar; or at 200 yd Navy personnel must shut down for low-frequency active sonar <200 dB, mid-frequency active sonar sources that are not hull-mounted, and high-frequency active sonar.

(A) Prior to the initial start of the activity (*e.g.,* when maneuvering on station), Navy personnel must observe the mitigation zone for floating vegetation; if floating vegetation is observed, Navy personnel must relocate or delay the start until the mitigation zone is clear. Navy personnel also must observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must relocate or delay the start of active sonar transmission.

(B) During low-frequency active sonar at or above 200 dB and hull-mounted mid-frequency active sonar, Navy personnel must observe the mitigation zone for marine mammals and power down active sonar transmission by 6 dB if marine mammals are observed within 1,000 yd of the sonar source; power down by an additional 4 dB (10 dB total) if marine mammals are observed within 500 yd of the sonar source; and cease transmission if marine mammals are observed within 200 yd of the sonar source.

(C) During low-frequency active sonar below 200 dB, mid-frequency active sonar sources that are not hull mounted, and high-frequency active sonar, Navy personnel must observe the mitigation zone for marine mammals and cease active sonar transmission if marine mammals are observed within 200 yd of the sonar source.

(D) Commencement/recommencement conditions after a marine mammal sighting before or during the activity: Navy personnel must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing or powering up active sonar transmission) until one of the following conditions has been met: The animal is observed exiting the mitigation zone; the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the sonar source; the mitigation zone has been clear from any additional sightings for 10 minutes (min) for aircraft-deployed sonar sources or 30 min for vessel-deployed sonar sources; for mobile activities, the active sonar source has transited a distance equal to double that of the mitigation zone size beyond the location of the last sighting; or for activities using hull-mounted sonar where a dolphin(s) is observed in the mitigation zone, the Lookout concludes that the dolphin(s) is deliberately closing in on the ship to ride the ship's bow wave, and is therefore out of the main transmission axis of the sonar (and there are no other marine mammal sightings within the mitigation zone).

(3) *Air guns*—(i) *Number of Lookouts and observation platform.* One Lookout must be positioned on a ship or pierside.

(ii) *Mitigation zone and requirements.* 150 yd around the air gun.

(A) Prior to the initial start of the activity (*e.g.,* when maneuvering on station), Navy personnel must observe the mitigation zone for floating vegetation; if floating vegetation is observed, Navy personnel must relocate or delay the start until the mitigation zone is clear. Navy personnel also must observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must relocate or delay the start of air gun use.

(B) During the activity, Navy personnel must observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must cease use of air guns.

(C) Commencement/recommencement conditions after a marine mammal sighting before or during the activity: Navy personnel must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing air gun use) until one of the following conditions has been met: The animal is observed exiting the mitigation zone; the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the air gun; the mitigation zone has been clear from any additional sightings for 30 min; or for mobile activities, the air gun has transited a distance equal to double that of the mitigation zone size beyond the location of the last sighting.

(4) *Pile driving.* Pile driving and pile extraction sound during Elevated Causeway System training.

(i) *Number of Lookouts and observation platform.* One Lookout must be positioned on the shore, the elevated causeway, or a small boat.

(ii) *Mitigation zone and requirements.* 100 yd around the pile driver.

(A) Prior to the initial start of the activity (for 30 min), Navy personnel must observe the mitigation zone for

floating vegetation; if floating vegetation is observed, Navy personnel must delay the start until the mitigation zone is clear. Navy personnel also must observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must delay the start of pile driving or vibratory pile extraction.

(B) During the activity, Navy personnel must observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must cease impact pile driving or vibratory pile extraction.

(C) Commencement/recommencement conditions after a marine mammal sighting before or during the activity: Navy personnel must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing pile driving or pile extraction) until one of the following conditions has been met: The animal is observed exiting the mitigation zone; the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the pile driving location; or the mitigation zone has been clear from any additional sightings for 30 min.

(5) *Weapons firing noise.* Weapons firing noise associated with large-caliber gunnery activities.

(i) *Number of Lookouts and observation platform.* One Lookout must be positioned on the ship conducting the firing. Depending on the activity, the Lookout could be the same as the one provided for under explosive medium-caliber and large-caliber projectiles or under small-, medium-, and large-caliber non-explosive practice munitions in paragraphs (a)(8)(i) and (a)(19)(i) of this section.

(ii) *Mitigation zone and requirements.* Thirty degrees on either side of the firing line out to 70 yd from the muzzle of the weapon being fired.

(A) Prior to the initial start of the activity, Navy personnel must observe the mitigation zone for floating vegetation; if floating vegetation is observed, Navy personnel must relocate or delay the start until the mitigation zone is clear. Navy personnel also must observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must relocate or delay the start of weapons firing.

(B) During the activity, Navy personnel must observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must cease weapons firing.

(C) Commencement/recommencement conditions after a marine mammal sighting before or during the activity: Navy personnel must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing weapons firing) until one of the following conditions has been met: The animal is observed exiting the mitigation zone; the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the firing ship; the mitigation zone has been clear from any additional sightings for 30 min; or for mobile activities, the firing ship has transited a distance equal to double that of the mitigation zone size beyond the location of the last sighting.

(6) *Explosive sonobuoys*—(i) *Number of Lookouts and observation platform.* One Lookout must be positioned in an aircraft or on small boat. If additional platforms are participating in the activity, personnel positioned in those assets (*e.g.,* safety observers, evaluators) must support observing the mitigation zone for marine mammals and other applicable biological resources while performing their regular duties.

(ii) *Mitigation zone and requirements.* 600 yd around an explosive sonobuoy.

(A) Prior to the initial start of the activity (*e.g.,* during deployment of a sonobuoy field, which typically lasts 20–30 min), Navy personnel must observe the mitigation zone for floating vegetation; if floating vegetation is observed, Navy personnel must relocate or delay the start until the mitigation zone is clear. Navy personnel must conduct passive acoustic monitoring for marine mammals and use information from detections to assist visual observations. Navy personnel also must visually observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must relocate or delay the start of sonobuoy or source/receiver pair detonations.

(B) During the activity, Navy personnel must observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must cease sonobuoy or source/receiver pair detonations.

(C) Commencement/recommencement conditions after a marine mammal sighting before or during the activity: Navy personnel must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing detonations) until one of the following conditions has been met: The animal is observed exiting the mitigation zone; the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the sonobuoy; or the mitigation zone has been clear from any additional sightings for 10 min when the activity involves aircraft that have fuel constraints (*e.g.,* helicopter), or 30 min when the activity involves aircraft that are not typically fuel constrained.

(D) After completion of the activity (*e.g.,* prior to maneuvering off station), when practical (*e.g.,* when platforms are not constrained by fuel restrictions or mission-essential follow-on commitments), Navy personnel must observe for marine mammals in the vicinity of where detonations occurred; if any injured or dead marine mammals are observed, Navy personnel must follow established incident reporting procedures. If additional platforms are supporting this activity (*e.g.,* providing range clearance), these Navy assets must assist in the visual observation of the area where detonations occurred.

(7) *Explosive torpedoes*—(i) *Number of Lookouts and observation platform.* One Lookout positioned in an aircraft. If additional platforms are participating in the activity, Navy personnel positioned in those assets (*e.g.,* safety observers, evaluators) must support observing the mitigation zone for marine mammals and other applicable biological resources while performing their regular duties.

(ii) *Mitigation zone and requirements.* 2,100 yd around the intended impact location.

(A) Prior to the initial start of the activity (*e.g.,* during deployment of the target), Navy personnel must observe the mitigation zone for floating vegetation; if floating vegetation is observed, relocate or delay the start until the mitigation zone is clear. Navy personnel also must conduct passive acoustic monitoring for marine mammals and use the information from detections to assist visual observations. Navy personnel must visually observe the mitigation zone for marine mammals and jellyfish aggregations; if marine mammals or jellyfish aggregations are observed, Navy personnel must relocate or delay the start of firing.

(B) During the activity, Navy personnel must observe for marine mammals and jellyfish aggregations; if marine mammals or jellyfish aggregations are observed, Navy personnel must cease firing.

(C) Commencement/recommencement conditions after a marine mammal sighting before or during the activity: Navy personnel must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during

the activity (by not recommencing firing) until one of the following conditions has been met: The animal is observed exiting the mitigation zone; the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the intended impact location; or the mitigation zone has been clear from any additional sightings for 10 min when the activity involves aircraft that have fuel constraints, or 30 min when the activity involves aircraft that are not typically fuel constrained.

(D) After completion of the activity (*e.g.,* prior to maneuvering off station), when practical (*e.g.,* when platforms are not constrained by fuel restrictions or mission-essential follow-on commitments), Navy personnel must observe for marine mammals in the vicinity of where detonations occurred; if any injured or dead marine mammals are observed, Navy personnel must follow established incident reporting procedures. If additional platforms are supporting this activity (*e.g.,* providing range clearance), these Navy assets must assist in the visual observation of the area where detonations occurred.

(8) *Explosive medium-caliber and large-caliber projectiles.* Gunnery activities using explosive medium-caliber and large-caliber projectiles. Mitigation applies to activities using a surface target.

(i) *Number of Lookouts and observation platform.* One Lookout must be on the vessel or aircraft conducting the activity. For activities using explosive large-caliber projectiles, depending on the activity, the Lookout could be the same as the one described for weapons firing noise in paragraph (a)(5)(i) of this section. If additional platforms are participating in the activity, Navy personnel positioned in those assets (*e.g.,* safety observers, evaluators) must support observing the mitigation zone for marine mammals and other applicable biological resources while performing their regular duties.

(ii) *Mitigation zone and requirements.* (A) 200 yd around the intended impact location for air-to-surface activities using explosive medium-caliber projectiles.

(B) 600 yd around the intended impact location for surface-to-surface activities using explosive medium-caliber projectiles.

(C) 1,000 yd around the intended impact location for surface-to-surface activities using explosive large-caliber projectiles.

(D) Prior to the initial start of the activity (*e.g.,* when maneuvering on station), Navy personnel must observe the mitigation zone for floating vegetation; if floating vegetation is observed, Navy personnel must relocate or delay the start until the mitigation zone is clear. Navy personnel also must observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must relocate or delay the start of firing.

(E) During the activity, Navy personnel must observe for marine mammals; if marine mammals are observed, Navy personnel must cease firing.

(F) Commencement/recommencement conditions after a marine mammal sighting before or during the activity: Navy personnel must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing firing) until one of the following conditions has been met: The animal is observed exiting the mitigation zone; the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the intended impact location; the mitigation zone has been clear from any additional sightings for 10 min for aircraft-based firing or 30 min for vessel-based firing; or for activities using mobile targets, the intended impact location has transited a distance equal to double that of the mitigation zone size beyond the location of the last sighting.

(G) After completion of the activity (*e.g.,* prior to maneuvering off station), when practical (*e.g.,* when platforms are not constrained by fuel restrictions or mission-essential follow-on commitments), Navy personnel must observe for marine mammals in the vicinity of where detonations occurred; if any injured or dead marine mammals are observed, Navy personnel must follow established incident reporting procedures. If additional platforms are supporting this activity (*e.g.,* providing range clearance), these Navy assets must assist in the visual observation of the area where detonations occurred.

(9) *Explosive missiles and rockets.* Aircraft-deployed explosive missiles and rockets. Mitigation applies to activities using a surface target.

(i) *Number of Lookouts and observation platform.* One Lookout must be positioned in an aircraft. If additional platforms are participating in the activity, Navy personnel positioned in those assets (*e.g.,* safety observers, evaluators) must support observing the mitigation zone for marine mammals and other applicable biological resources while performing their regular duties.

(ii) *Mitigation zone and requirements.* (A) 900 yd around the intended impact location for missiles or rockets with 0.6–20 lb net explosive weight.

(B) 2,000 yd around the intended impact location for missiles with 21–500 lb net explosive weight.

(C) Prior to the initial start of the activity (*e.g.,* during a fly-over of the mitigation zone), Navy personnel must observe the mitigation zone for floating vegetation; if floating vegetation is observed, Navy personnel must relocate or delay the start until the mitigation zone is clear. Navy personnel also must observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must relocate or delay the start of firing.

(D) During the activity, Navy personnel must observe for marine mammals; if marine mammals are observed, Navy personnel must cease firing.

(E) Commencement/recommencement conditions after a marine mammal sighting before or during the activity: Navy personnel must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing firing) until one of the following conditions has been met: The animal is observed exiting the mitigation zone; the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the intended impact location; or the mitigation zone has been clear from any additional sightings for 10 min when the activity involves aircraft that have fuel constraints, or 30 min when the activity involves aircraft that are not typically fuel constrained.

(F) After completion of the activity (*e.g.,* prior to maneuvering off station), when practical (*e.g.,* when platforms are not constrained by fuel restrictions or mission-essential follow-on commitments), Navy personnel must observe for marine mammals in the vicinity of where detonations occurred; if any injured or dead marine mammals are observed, Navy personnel must follow established incident reporting procedures. If additional platforms are supporting this activity (*e.g.,* providing range clearance), these Navy assets must assist in the visual observation of the area where detonations occurred.

(10) *Explosive bombs*—(i) *Number of Lookouts and observation platform.* One Lookout must be positioned in an aircraft conducting the activity. If additional platforms are participating in

the activity, Navy personnel positioned in those assets (*e.g.,* safety observers, evaluators) must support observing the mitigation zone for marine mammals and other applicable biological resources while performing their regular duties.

(ii) *Mitigation zone and requirements.* 2,500 yd around the intended target.

(A) Prior to the initial start of the activity (*e.g.,* when arriving on station), Navy personnel must observe the mitigation zone for floating vegetation; if floating vegetation is observed, Navy personnel must relocate or delay the start until the mitigation zone is clear. Navy personnel also must observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must relocate or delay the start of bomb deployment.

(B) During the activity (*e.g.,* during target approach), Navy personnel must observe for marine mammals; if marine mammals are observed, Navy personnel must cease bomb deployment.

(C) Commencement/recommencement conditions after a marine mammal sighting before or during the activity: Navy personnel must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing bomb deployment) until one of the following conditions has been met: The animal is observed exiting the mitigation zone; the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the intended target; the mitigation zone has been clear from any additional sightings for 10 min; or for activities using mobile targets, the intended target has transited a distance equal to double that of the mitigation zone size beyond the location of the last sighting.

(D) After completion of the activity (*e.g.,* prior to maneuvering off station), when practical (*e.g.,* when platforms are not constrained by fuel restrictions or mission-essential follow-on commitments), Navy personnel must observe for marine mammals in the vicinity of where detonations occurred; if any injured or dead marine mammals are observed, Navy personnel must follow established incident reporting procedures. If additional platforms are supporting this activity (*e.g.,* providing range clearance), these Navy assets must assist in the visual observation of the area where detonations occurred.

(11) *Sinking exercises*—(i) *Number of Lookouts and observation platform.* Two Lookouts (one must be positioned in an aircraft and one must be positioned on a vessel). If additional platforms are participating in the activity, Navy personnel positioned in those assets (*e.g.,* safety observers, evaluators) must support observing the mitigation zone for marine mammals and other applicable biological resources while performing their regular duties.

(ii) *Mitigation zone and requirements.* 2.5 nautical miles (nmi) around the target ship hulk.

(A) Prior to the initial start of the activity (90 min prior to the first firing), Navy personnel must conduct aerial observations of the mitigation zone for floating vegetation; if floating vegetation is observed Navy personnel must delay the start until the mitigation zone is clear. Navy personnel also must conduct aerial observations of the mitigation zone for marine mammals and jellyfish aggregations; if marine mammals or jellyfish aggregations are observed, Navy personnel must delay the start of firing.

(B) During the activity, Navy personnel must conduct passive acoustic monitoring for marine mammals and use information from detections to assist visual observations. Navy personnel must visually observe the mitigation zone for marine mammals from the vessel; if marine mammals are observed, Navy personnel must cease firing. Immediately after any planned or unplanned breaks in weapons firing of longer than two hours, Navy personnel must observe the mitigation zone for marine mammals from the aircraft and vessel; if marine mammals are observed, Navy personnel must delay recommencement of firing.

(C) Commencement/recommencement conditions after a marine mammal sighting before or during the activity: Navy personnel must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing firing) until one of the following conditions has been met: The animal is observed exiting the mitigation zone; the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the target ship hulk; or the mitigation zone has been clear from any additional sightings for 30 min.

(D) After completion of the activity (for two hours after sinking the vessel or until sunset, whichever comes first), Navy personnel must observe for marine mammals in the vicinity of where detonations occurred; if any injured or dead marine mammals are observed, Navy personnel must follow established incident reporting procedures. If additional platforms are supporting this activity (*e.g.,* providing range clearance), these Navy assets must assist in the visual observation of the area where detonations occurred.

(12) *Explosive mine countermeasure and neutralization activities*—(i) *Number of Lookouts and observation platform.* (A) One Lookout must be positioned on a vessel or in an aircraft when implementing the smaller mitigation zone defined at paragraph (a)(12)(ii)(A) of this section (using 0.1–5 lb net explosive weight charges).

(B) Two Lookouts (one must be in an aircraft and one must be on a small boat) when implementing the larger mitigation zone defined at paragraph (a)(12)(ii)(B) of this section (using 6–650 lb net explosive weight charges).

(C) If additional platforms are participating in the activity, Navy personnel positioned in those assets (*e.g.,* safety observers, evaluators) must support observing the mitigation zone for marine mammals and other applicable biological resources while performing their regular duties.

(ii) *Mitigation zone and requirements.* (A) 600 yd around the detonation site for activities using 0.1–5 lb net explosive weight.

(B) 2,100 yd around the detonation site for activities using 6–650 lb net explosive weight (including high explosive target mines).

(C) Prior to the initial start of the activity (*e.g.,* when maneuvering on station; typically, 10 min when the activity involves aircraft that have fuel constraints, or 30 min when the activity involves aircraft that are not typically fuel constrained), Navy personnel must observe the mitigation zone for floating vegetation; if floating vegetation is observed, Navy personnel must relocate or delay the start until the mitigation zone is clear. Navy personnel also must observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must relocate or delay the start of detonations.

(D) During the activity, Navy personnel must observe the mitigation zone for marine mammals; if marine mammals are observed, the Navy must cease detonations.

(E) Commencement/recommencement conditions after a marine mammal sighting before or during the activity: Navy personnel must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing detonations) until one of the following conditions has been met: The animal is observed exiting the mitigation zone; the animal is thought to have exited the mitigation zone based on a

determination of its course, speed, and movement relative to detonation site; or the mitigation zone has been clear from any additional sightings for 10 min when the activity involves aircraft that have fuel constraints, or 30 min when the activity involves aircraft that are not typically fuel constrained.

(F) After completion of the activity (typically 10 min when the activity involves aircraft that have fuel constraints, or 30 min when the activity involves aircraft that are not typically fuel constrained), Navy personnel must observe for marine mammals in the vicinity of where detonations occurred; if any injured or dead marine mammals are observed, Navy personnel must follow established incident reporting procedures. If additional platforms are supporting this activity (*e.g.,* providing range clearance), these Navy assets must assist in the visual observation of the area where detonations occurred.

(13) *Explosive mine neutralization activities involving navy divers*—(i) *Number of Lookouts and observation platform.* (A) Two Lookouts must be positioned (two small boats with one Lookout each, or one Lookout must be on a small boat and one must be in a rotary-wing aircraft) when implementing the smaller mitigation zone defined at paragraph (a)(13)(ii)(A) of this section.

(B) Four Lookouts must be positioned (two small boats with two Lookouts each), and a pilot or member of an aircrew must serve as an additional Lookout if aircraft are used during the activity, when implementing the larger mitigation zone defined at paragraph (a)(13)(ii)(B) of this section.

(C) All divers placing the charges on mines must support the Lookouts while performing their regular duties and must report applicable sightings to their supporting small boat or Range Safety Officer.

(D) If additional platforms are participating in the activity, Navy personnel positioned in those assets (*e.g.,* safety observers, evaluators) must support observing the mitigation zone for marine mammals and other applicable biological resources while performing their regular duties.

(ii) *Mitigation zone and requirements.* (A) 500 yd around the detonation site during activities under positive control using 0.1–20 lb net explosive weight.

(B) 1,000 yd around the detonation site during all activities using time-delay fuses (0.1–20 lb net explosive weight) and during activities under positive control using 21–60 lb net explosive weight charges.

(C) Prior to the initial start of the activity (*e.g.,* when maneuvering on station for activities under positive control; 30 min for activities using time-delay firing devices), Navy personnel must observe the mitigation zone for floating vegetation; if floating vegetation is observed, Navy personnel must relocate or delay the start until the mitigation zone is clear. Navy personnel also must observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must relocate or delay the start of detonation or fuse initiation.

(D) During the activity, Navy personnel must observe for marine mammals; if marine mammals are observed, Navy personnel must cease detonation or fuse initiation. To the maximum extent practicable depending on mission requirements, safety, and environmental conditions, boats must position themselves near the mid-point of the mitigation zone radius (but outside of the detonation plume and human safety zone), must position themselves on opposite sides of the detonation location (when two boats are used), and must travel in a circular pattern around the detonation location with one Lookout observing inward toward the detonation site and the other observing outward toward the perimeter of the mitigation zone. If used, aircraft must travel in a circular pattern around the detonation location to the maximum extent practicable. Navy personnel must not set time-delay firing devices (0.1–20 lb. net explosive weight) to exceed 10 min.

(E) Commencement/recommencement conditions after a marine mammal sighting before or during the activity: Navy personnel must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing detonations) until one of the following conditions has been met: The animal is observed exiting the mitigation zone; the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the detonation site; or the mitigation zone has been clear from any additional sightings for 10 min during activities under positive control with aircraft that have fuel constraints, or 30 min during activities under positive control with aircraft that are not typically fuel constrained and during activities using time-delay firing devices.

(F) After completion of an activity (for 30 min), Navy personnel must observe for marine mammals in the vicinity of where any detonations have occurred; if any injured or dead marine mammals are observed, Navy personnel must follow established incident reporting procedures. If additional platforms are supporting this activity (*e.g.,* providing range clearance), these Navy assets must assist in the visual observation of the area where detonations occurred.

(14) *Maritime security operations—anti-swimmer grenades*—(i) *Number of Lookouts and observation platform.* One Lookout must be positioned on the small boat conducting the activity. If additional platforms are participating in the activity, Navy personnel positioned in those assets (*e.g.,* safety observers, evaluators) must support observing the mitigation zone for marine mammals and other applicable biological resources while performing their regular duties.

(ii) *Mitigation zone and requirements.* 200 yd around the intended detonation location.

(A) Prior to the initial start of the activity (*e.g.,* when maneuvering on station), Navy personnel must observe the mitigation zone for floating vegetation; if floating vegetation is observed, Navy personnel must relocate or delay the start until the mitigation zone is clear. Navy personnel also must observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must relocate or delay the start of detonation.

(B) During the activity, Navy personnel must observe for marine mammals; if marine mammals are observed, Navy personnel must cease detonation.

(C) Commencement/recommencement conditions after a marine mammal sighting before or during the activity: Navy personnel must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing detonations) until one of the following conditions has been met: The animal is observed exiting the mitigation zone; the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the intended detonation location; the mitigation zone has been clear from any additional sightings for 30 min; or the intended detonation location has transited a distance equal to double that of the mitigation zone size beyond the location of the last sighting.

(D) After completion of the activity (*e.g.,* prior to maneuvering off station), when practical (*e.g.,* when platforms are not constrained by fuel restrictions or mission-essential follow-on commitments), Navy personnel must observe for marine mammals in the vicinity of where detonations occurred;

if any injured or dead marine mammals are observed, Navy personnel must follow established incident reporting procedures. If additional platforms are supporting this activity (*e.g.,* providing range clearance), these Navy assets must assist in the visual observation of the area where detonations occurred.

(15) *Line charge testing*—(i) *Number of Lookouts and observation platform.* One Lookout must be positioned on a vessel. If additional platforms are participating in the activity, Navy personnel positioned in those assets (*e.g.,* safety observers, evaluators) must support observing the mitigation zone for marine mammals and other applicable biological resources while performing their regular duties.

(ii) *Mitigation zone and requirements.* 900 yd around the intended detonation location.

(A) Prior to the initial start of the activity (*e.g.,* when maneuvering on station), Navy personnel must observe the mitigation zone for floating vegetation; if floating vegetation is observed, Navy personnel must delay the start until the mitigation zone is clear. Navy personnel also must observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must delay the start of detonations.

(B) During the activity, Navy personnel must observe for marine mammals; if marine mammals are observed, Navy personnel must cease detonations.

(C) Commencement/recommencement conditions after a marine mammal sighting before or during the activity: Navy personnel must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing detonations) until one of the following conditions has been met: The animal is observed exiting the mitigation zone; the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the intended detonation location; or the mitigation zone has been clear from any additional sightings for 30 min.

(D) After completion of the activity (*e.g.,* prior to maneuvering off station), when practical (*e.g.,* when platforms are not constrained by fuel restrictions or mission-essential follow-on commitments), Navy personnel must observe for marine mammals in the vicinity of where detonations occurred; if any injured or dead marine mammals are observed, Navy personnel must follow established incident reporting procedures. If additional platforms are supporting this activity (*e.g.,* providing range clearance), these Navy assets must assist in the visual observation of the area where detonations occurred.

(16) *Ship shock trials*—(i) *Number of Lookouts and observation platform.* (A) A minimum of ten Lookouts or trained marine species observers (or a combination thereof) must be positioned either in an aircraft or on multiple vessels (*i.e.,* a Marine Animal Response Team boat and the test ship).

(*1*) If aircraft are used, Lookouts or trained marine species observers must be in an aircraft and on multiple vessels.

(*2*) If aircraft are not used, a sufficient number of additional Lookouts or trained marine species observers must be used to provide vessel-based visual observation comparable to that achieved by aerial surveys.

(B) If additional platforms are participating in the activity, Navy personnel positioned in those assets (*e.g.,* safety observers, evaluators) must support observing the mitigation zone for marine mammals and other applicable biological resources while performing their regular duties.

(ii) *Mitigation zone and requirements.* 3.5 nmi around the ship hull.

(A) The Navy must not conduct ship shock trials in the Jacksonville Operating Area during North Atlantic right whale calving season from November 15 through April 15.

(B) The Navy must develop detailed ship shock trial monitoring and mitigation plans approximately one-year prior to an event and must continue to provide these to NMFS for review and approval.

(C) Pre-activity planning must include selection of one primary and two secondary areas where marine mammal populations are expected to be the lowest during the event, with the primary and secondary locations located more than 2 nmi from the western boundary of the Gulf Stream for events in the Virginia Capes Range Complex or Jacksonville Range Complex.

(D) If it is determined during pre-activity surveys that the primary area is environmentally unsuitable (*e.g.,* observations of marine mammals or presence of concentrations of floating vegetation), the shock trial can be moved to a secondary site in accordance with the detailed mitigation and monitoring plan provided to NMFS.

(E) Prior to the initial start of the activity at the shock trial location (in intervals of 5 hrs, 3 hrs, 40 min, and immediately before the detonation), Navy personnel must observe the mitigation zone for floating vegetation; if floating vegetation is observed, Navy personnel must delay the start until the mitigation zone is clear. Navy personnel also must observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must delay triggering the detonation.

(F) During the activity, Navy personnel must observe for marine mammals, large schools of fish, jellyfish aggregations, and flocks of seabirds; if marine mammals, large schools of fish, jellyfish aggregations, and flocks of seabirds are observed, Navy personnel must cease triggering the detonation. After completion of each detonation, Navy personnel must observe the mitigation zone for marine mammals; if any injured or dead marine mammals are observed, Navy personnel must follow established incident reporting procedures and halt any remaining detonations until Navy personnel can consult with NMFS and review or adapt the mitigation, if necessary.

(G) Commencement/recommencement conditions after a marine mammal sighting before or during the activity: Navy personnel must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing detonations) until one of the following conditions has been met: The animal is observed exiting the mitigation zone; the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the ship hull; or the mitigation zone has been clear from any additional sightings for 30 min.

(H) After completion of the activity (during the following two days at a minimum, and up to seven days at a maximum), Navy personnel must observe for marine mammals in the vicinity of where detonations occurred; if any injured or dead marine mammals are observed, Navy personnel must follow established incident reporting procedures. If additional platforms are supporting this activity (*e.g.,* providing range clearance), these Navy assets must assist in the visual observation of the area where detonations occurred.

(17) *Vessel movement.* The mitigation must not be applied if: The vessel's safety is threatened; the vessel is restricted in its ability to maneuver (*e.g.,* during launching and recovery of aircraft or landing craft, during towing activities, when mooring, *etc.*); or the vessel is operated autonomously.

(i) *Number of Lookouts and observation platform.* One Lookout must be on the vessel that is underway.

(ii) *Mitigation zone and requirements.* (A) 500 yd around whales.

(B) 200 yd around all other marine mammals (except bow-riding dolphins

and pinnipeds hauled out on man-made navigational structures, port structures, and vessels).

(C) During the activity, when underway, Navy personnel must observe the mitigation zone for marine mammals; if any marine mammals are observed, Navy personnel must maneuver to maintain distance.

(D) Additionally, Navy personnel must broadcast awareness notification messages with North Atlantic right whale Dynamic Management Area information (*e.g.,* location and dates) to applicable Navy assets operating in the vicinity of the Dynamic Management Area. The information will alert assets to the possible presence of a North Atlantic right whale to maintain safety of navigation and further reduce the potential for a vessel strike. Platforms must use the information to assist their visual observation of applicable mitigation zones during training and testing activities and to aid in the implementation of procedural mitigation, including but not limited to, mitigation for vessel movement. If a marine mammal vessel strike occurs, Navy personnel must follow the established incident reporting procedures.

(18) *Towed in-water devices.* Mitigation applies to devices that are towed from a manned surface platform or manned aircraft. The mitigation will not be applied if the safety of the towing platform or in-water device is threatened.

(i) *Number of Lookouts and observation platform.* One Lookout must be positioned on a manned towing platform.

(ii) *Mitigation zone and requirements.* 250 yd around marine mammals. During the activity, when towing an in-water device, Navy personnel must observe for marine mammals; if marine mammals are observed, Navy personnel must maneuver to maintain distance.

(19) *Small-, medium-, and large-caliber non-explosive practice munitions.* Mitigation applies to activities using a surface target.

(i) *Number of Lookouts and observation platform.* One Lookout must be positioned on the platform conducting the activity. Depending on the activity, the Lookout could be the same as the one described for weapons firing noise in paragraph (a)(5)(i) of this section.

(ii) *Mitigation zone and requirements.* 200 yd around the intended impact location.

(A) Prior to the initial start of the activity (*e.g.,* when maneuvering on station), Navy personnel must observe the mitigation zone for floating vegetation; if floating vegetation is observed, Navy personnel must relocate or delay the start until the mitigation zone is clear. Navy personnel also must observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must relocate or delay the start of firing.

(B) During the activity, Navy personnel must observe for marine mammals; if marine mammals are observed, Navy personnel must cease firing.

(C) Commencement/recommencement conditions after a marine mammal sighting before or during the activity: Navy personnel must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing firing) until one of the following conditions has been met: The animal is observed exiting the mitigation zone; the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the intended impact location; the mitigation zone has been clear from any additional sightings for 10 min for aircraft-based firing or 30 min for vessel-based firing; or for activities using a mobile target, the intended impact location has transited a distance equal to double that of the mitigation zone size beyond the location of the last sighting.

(20) *Non-explosive missiles and rockets.* Aircraft-deployed non-explosive missiles and rockets. Mitigation applies to activities using a surface target.

(i) *Number of Lookouts and observation platform.* One Lookout must be positioned in an aircraft.

(ii) *Mitigation zone and requirements.* 900 yd around the intended impact location.

(A) Prior to the initial start of the activity (*e.g.,* during a fly-over of the mitigation zone), Navy personnel must observe the mitigation zone for floating vegetation; if floating vegetation is observed, Navy personnel must relocate or delay the start until the mitigation zone is clear. Navy personnel also must observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must relocate or delay the start of firing.

(B) During the activity, Navy personnel must observe for marine mammals; if marine mammals are observed, Navy personnel must cease firing.

(C) Commencement/recommencement conditions after a marine mammal sighting prior to or during the activity: Navy personnel must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing firing) until one of the following conditions has been met: The animal is observed exiting the mitigation zone; the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the intended impact location; or the mitigation zone has been clear from any additional sightings for 10 min when the activity involves aircraft that have fuel constraints, or 30 min when the activity involves aircraft that are not typically fuel constrained.

(21) *Non-explosive bombs and mine shapes.* Non-explosive bombs and non-explosive mine shapes during mine laying activities.

(i) *Number of Lookouts and observation platform.* One Lookout must be positioned in an aircraft.

(ii) *Mitigation zone and requirements.* 1,000 yd around the intended target.

(A) Prior to the initial start of the activity (*e.g.,* when arriving on station), Navy personnel must observe the mitigation zone for floating vegetation; if floating vegetation is observed, Navy personnel must relocate or delay the start until the mitigation zone is clear. Navy personnel also must observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must relocate or delay the start of bomb deployment or mine laying.

(B) During the activity (*e.g.,* during approach of the target or intended minefield location), Navy personnel must observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must cease bomb deployment or mine laying.

(C) Commencement/recommencement conditions after a marine mammal sighting prior to or during the activity: Navy personnel must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing bomb deployment or mine laying) until one of the following conditions has been met: The animal is observed exiting the mitigation zone; the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the intended target or minefield location; the mitigation zone has been clear from any additional sightings for 10 min; or for activities using mobile targets, the intended target has transited a distance equal to double that of the mitigation

zone size beyond the location of the last sighting.

(b) *Mitigation areas.* In addition to procedural mitigation, the Navy must implement mitigation measures within mitigation areas to avoid potential impacts on marine mammals.

(1) *Mitigation areas off the Northeastern United States for sonar, explosives, and physical disturbance and strikes*—(i) *Mitigation area requirements*—(A) *Northeast North Atlantic Right Whale Mitigation Area (year-round).* (*1*) Navy personnel must report the total hours and counts of active sonar and in-water explosives used in the mitigation area (which includes North Atlantic right whale ESA-designated critical habitat) in its annual training and testing activity reports submitted to NMFS.

(*2*) Navy personnel must minimize the use of low-frequency active sonar, mid-frequency active sonar, and high-frequency active sonar to the maximum extent practicable within the mitigation area.

(*3*) Navy personnel must not use Improved Extended Echo Ranging sonobuoys in or within 3 nmi of the mitigation area or use explosive and non-explosive bombs, in-water detonations, and explosive torpedoes within the mitigation area.

(*4*) For activities using non-explosive torpedoes within the mitigation area, Navy personnel must conduct activities during daylight hours in Beaufort sea state 3 or less. The Navy must use three Lookouts (one positioned on a vessel and two positioned in an aircraft during dedicated aerial surveys) to observe the vicinity of the activity. An additional Lookout must be positioned on the submarine, when surfaced. Immediately prior to the start of the activity, Navy personnel must observe for floating vegetation and marine mammals; if floating vegetation or marine mammals are observed, Navy personnel must not commence the activity until the vicinity is clear or the activity is relocated to an area where the vicinity is clear. During the activity, Navy personnel must observe for marine mammals; if observed, Navy personnel must cease the activity. To allow a sighted marine mammal to leave the area, Navy personnel must not recommence the activity until one of the following conditions has been met: The animal is observed exiting the vicinity of the activity; the animal is thought to have exited the vicinity of the activity based on a determination of its course, speed, and movement relative to the activity location; or the area has been clear from any additional sightings for 30 min. During transits and normal firing, ships must maintain a speed of no more than 10 knots (kn). During submarine target firing, ships must maintain speeds of no more than 18 kn. During vessel target firing, vessel speeds may exceed 18 kn for brief periods of time (*e.g.,* 10–15 min).

(*5*) For all activities, before a vessel transits within the mitigation area, Navy personnel must conduct a web query or email inquiry to the National Oceanographic and Atmospheric Administration Northeast Fisheries Science Center's North Atlantic Right Whale Sighting Advisory System to obtain the latest North Atlantic right whale sightings information. Navy personnel on vessels must use the sightings information to reduce potential interactions with North Atlantic right whales during transits. Navy personnel on vessels must implement speed reductions within the mitigation area after observing a North Atlantic right whale, if transiting within 5 nmi of a sighting reported to the North Atlantic Right Whale Sighting Advisory System within the past week, and if transiting at night or during periods of reduced visibility.

(B) *Gulf of Maine Planning Awareness Mitigation Area (year-round).* (*1*) Navy personnel must report the total hours and counts of active sonar and in-water explosives used in the mitigation area in its annual training and testing activity reports submitted to NMFS.

(*2*) Navy personnel must not conduct greater than 200 hrs of hull-mounted mid-frequency active sonar per year within the mitigation area.

(*3*) Navy personnel must not conduct major training exercises (Composite Training Unit Exercises or Fleet Exercises/Sustainment Exercises) within the mitigation area. If the Navy needs to conduct a major training exercise within the mitigation area in support of training requirements driven by national security concerns, Navy personnel must confer with NMFS to verify that potential impacts are adequately addressed.

(C) *Northeast Planning Awareness Mitigation Areas (year-round).* (*1*) Navy personnel will avoid planning major training exercises (Composite Training Unit Exercises or Fleet Exercises/Sustainment Exercises) within the mitigation area to the maximum extent practicable.

(*2*) Navy personnel must not conduct more than four major training exercises per year (all or a portion of the exercise) within the mitigation area.

(*3*) If the Navy needs to conduct additional major training exercises in the mitigation area in support of training requirements driven by national security concerns, Navy personnel must provide NMFS with advance notification and include the information in its annual training and testing activity reports submitted to NMFS.

(ii) [Reserved]

(2) *Mitigation areas off the Mid-Atlantic and Southeastern United States for sonar, explosives, and physical disturbance and strikes*—(i) *Mitigation area requirements*—(A) *Southeast North Atlantic Right Whale Mitigation Area (November 15 through April 15).* (*1*) Navy personnel must report the total hours and counts of active sonar and in-water explosives used in the mitigation area in its annual training and testing activity reports submitted to NMFS.

(*2*) The Navy must not conduct: Low-frequency active sonar (except as noted in paragraph (b)(2)(i)(A)(*3*) of this section), mid-frequency active sonar (except as noted in paragraph (b)(2)(i)(A)(*3*) of this section), high-frequency active sonar, missile and rocket activities (explosive and non-explosive), small-, medium-, and large-caliber gunnery activities, Improved Extended Echo Ranging sonobuoy activities, explosive and non-explosive bombing activities, in-water detonations, and explosive torpedo activities within the mitigation area.

(*3*) To the maximum extent practicable, Navy personnel must minimize the use of: Helicopter dipping sonar, low-frequency active sonar and hull-mounted mid-frequency active sonar used for navigation training, and low-frequency active sonar and hull-mounted mid-frequency active sonar used for object detection exercises within the mitigation area.

(*4*) Before transiting or conducting training or testing activities within the mitigation area, Navy personnel must initiate communication with the Fleet Area Control and Surveillance Facility, Jacksonville to obtain Early Warning System North Atlantic right whale sightings data. The Fleet Area Control and Surveillance Facility, Jacksonville must advise Navy personnel on vessels of all reported whale sightings in the vicinity to help Navy personnel on vessels and aircraft reduce potential interactions with North Atlantic right whales. Commander Submarine Force U.S. Atlantic Fleet must coordinate any submarine activities that may require approval from the Fleet Area Control and Surveillance Facility, Jacksonville. Navy personnel on vessels must use the sightings information to reduce potential interactions with North Atlantic right whales during transits.

(*5*) Navy personnel on vessels must implement speed reductions after they observe a North Atlantic right whale, if

they are within 5 nmi of a sighting reported within the past 12 hrs, or when operating in the mitigation area at night or during periods of poor visibility.

(*6*) To the maximum extent practicable, Navy personnel on vessels must minimize north-south transits in the mitigation area.

(B) *Southeast North Atlantic Right Whale Critical Habitat Special Reporting Area (November 15 through April 15).* (*1*) Navy personnel must report the total hours and counts of active sonar and in-water explosives used in the Special Reporting Area (which includes southeast North Atlantic right whale ESA-designated critical habitat) in its annual training and testing activity reports submitted to NMFS.

(*2*) [Reserved]

(C) *Jacksonville Operating Area (November 15 through April 15).* (*1*) Navy units conducting training or testing activities in the Jacksonville Operating Area must initiate communication with the Fleet Area Control and Surveillance Facility, Jacksonville to obtain Early Warning System North Atlantic right whale sightings data. The Fleet Area Control and Surveillance Facility, Jacksonville must advise Navy personnel on vessels of all reported whale sightings in the vicinity to help Navy personnel on vessels and aircraft reduce potential interactions with North Atlantic right whales. Commander Submarine Force U.S. Atlantic Fleet must coordinate any submarine activities that may require approval from the Fleet Area Control and Surveillance Facility, Jacksonville. Navy personnel must use the reported sightings information as they plan specific details of events (*e.g.,* timing, location, duration) to minimize potential interactions with North Atlantic right whales to the maximum extent practicable. Navy personnel must use the reported sightings information to assist visual observations of applicable mitigation zones and to aid in the implementation of procedural mitigation.

(*2*) [Reserved]

(D) *Navy Cherry Point Range Complex Nearshore Mitigation Area (March through September).* (*1*) Navy personnel must not conduct explosive mine neutralization activities involving Navy divers in the mitigation area.

(*2*) To the maximum extent practicable, Navy personnel must not use explosive sonobuoys, explosive torpedoes, explosive medium-caliber and large-caliber projectiles, explosive missiles and rockets, explosive bombs, explosive mines during mine countermeasure and neutralization activities, and anti-swimmer grenades in the mitigation area.

(E) *Mid-Atlantic Planning Awareness Mitigation Areas (year-round).* (*1*) Navy personnel will avoid planning major training exercises (Composite Training Unit Exercises or Fleet Exercises/ Sustainment Exercises) to the maximum extent practicable.

(*2*) Navy personnel must not conduct more than four major training exercises per year (all or a portion of the exercise) within the mitigation area.

(*3*) If the Navy needs to conduct additional major training exercises in the mitigation area in support of training requirements driven by national security concerns, Navy personnel must provide NMFS with advance notification and include the information in its annual training and testing activity reports submitted to NMFS.

(ii) [Reserved]

(3) *Mitigation areas in the Gulf of Mexico for sonar and explosives*—(i) *Mitigation area requirements*—(A) *Gulf of Mexico Planning Awareness Mitigation Areas (year-round).* (*1*) Navy personnel must not conduct major training exercises within the mitigation area (all or a portion of the exercise).

(*2*) If the Navy needs to conduct a major training exercise within the mitigation areas in support of training requirements driven by national security concerns, Navy personnel must confer with NMFS to verify that potential impacts are adequately addressed.

(B) *Bryde's Whale Mitigation Area (year-round).* (*1*) Navy personnel must report the total hours and counts of active sonar and in-water explosives used in the mitigation area in its annual training and testing activity reports submitted to NMFS.

(*2*) Navy personnel must not conduct greater than 200 hrs of hull-mounted mid-frequency active sonar per year within the mitigation area.

(*3*) Navy personnel must not use explosives (except during mine warfare activities) within the mitigation area.

(ii) [Reserved]

§ 218.85 Requirements for monitoring and reporting.

(a) *Unauthorized take.* The Navy must notify NMFS immediately (or as soon as operational security considerations allow) if the specified activity identified in § 218.80 is thought to have resulted in the mortality or serious injury of any marine mammals, or in any Level A or Level B harassment take of marine mammals not identified in this subpart.

(b) *Monitoring and reporting under the LOAs.* The Navy must conduct all monitoring and required reporting under the LOAs, including abiding by the AFTT Study Area monitoring program. Details on program goals, objectives, project selection process, and current projects are available at *www.navymarinespeciesmonitoring.us.*

(c) *Notification of injured, live stranded, or dead marine mammals.* The Navy must consult the Notification and Reporting Plan, which sets out notification, reporting, and other requirements when dead, injured, or live stranded marine mammals are detected. The Notification and Reporting Plan is available at *www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-military-readiness-activities.*

(d) *Annual AFTT Study Area marine species monitoring report.* The Navy must submit an annual report of the AFTT Study Area monitoring describing the implementation and results from the previous calendar year. Data collection methods must be standardized across range complexes and study areas to allow for comparison in different geographic locations. The report must be submitted to the Director, Office of Protected Resources of NMFS either within 90 days after the calendar year, or within 90 days after the conclusion of the monitoring year to be determined by the Adaptive Management process. This report will describe progress of knowledge made with respect to monitoring plan study questions across all Navy ranges associated with the Integrated Comprehensive Monitoring Program. Similar study questions must be treated together so that progress on each topic can be summarized across all Navy ranges. The report need not include analyses and content that does not provide direct assessment of cumulative progress on the monitoring plan study questions.

(e) *Annual AFTT Study Area training and testing reports.* Each year, the Navy must submit a preliminary report (Quick Look Report) detailing the status of authorized sound sources within 21 days after the anniversary of the date of issuance of each LOA to the Director, Office of Protected Resources, NMFS. Each year, the Navy must submit a detailed report within 3 months after the anniversary of the date of issuance of each LOA to the Director, Office of Protected Resources, NMFS. The annual reports must contain information on major training exercises (MTEs), sinking exercise (SINKEX) events, and a summary of all sound sources used, including within specified mitigation reporting areas, as described in paragraph (e)(3) of this section. The analysis in the detailed report must be

based on the accumulation of data from the current year's report and data collected from the previous report. The detailed reports must contain information identified in paragraphs (e)(1) through (5) of this section.

(1) *Major training exercises (MTEs).* This section of the report must contain the following information for MTEs conducted in the AFTT Study Area:

(i) Exercise information (for each MTE):

(A) Exercise designator;

(B) Date that exercise began and ended;

(C) Location;

(D) Number and types of active sonar sources used in the exercise;

(E) Number and types of passive acoustic sources used in exercise;

(F) Number and types of vessels, aircraft, and other platforms participating in exercise;

(G) Total hours of all active sonar source operation;

(H) Total hours of each active sonar source bin; and

(I) Wave height (high, low, and average) during exercise.

(ii) Individual marine mammal sighting information for each sighting in each exercise where mitigation was implemented:

(A) Date/time/location of sighting;

(B) Species (if not possible, indication of whale/dolphin/pinniped);

(C) Number of individuals;

(D) Initial detection sensor (*e.g.,* sonar, Lookout);

(E) Indication of specific type of platform observation made from (including, for example, what type of surface vessel or testing platform);

(F) Length of time observers maintained visual contact with marine mammal;

(G) Sea state;

(H) Visibility;

(I) Sound source in use at the time of sighting;

(J) Indication of whether animal was less than 200 yd, 200 to 500 yd, 500 to 1,000 yd, 1,000 to 2,000 yd, or greater than 2,000 yd from sonar source;

(K) Mitigation implementation (*e.g.* whether operation of sonar sensor was delayed, or sonar was powered or shut down, and how long the delay was);

(L) If source in use was hull-mounted, true bearing of animal from the vessel, true direction of vessel's travel, and estimation of animal's motion relative to vessel (opening, closing, parallel); and

(M) Lookouts must report, in plain language and without trying to categorize in any way, the observed behavior of the animal(s) (such as animal closing to bow ride, paralleling course/speed, floating on surface and not swimming, *etc.*) and if any calves were present.

(iii) An evaluation (based on data gathered during all of the MTEs) of the effectiveness of mitigation measures designed to minimize the received level to which marine mammals may be exposed. This evaluation must identify the specific observations that support any conclusions the Navy reaches about the effectiveness of the mitigation.

(2) *Sinking exercises (SINKEXs).* This section of the report must include the following information for each SINKEX completed that year:

(i) Exercise information (gathered for each SINKEX):

(A) Location;

(B) Date and time exercise began and ended;

(C) Total hours of observation by Lookouts before, during, and after exercise;

(D) Total number and types of explosive source bins detonated;

(E) Number and types of passive acoustic sources used in exercise;

(F) Total hours of passive acoustic search time;

(G) Number and types of vessels, aircraft, and other platforms participating in exercise;

(H) Wave height in feet (high, low, and average) during exercise; and

(I) Narrative description of sensors and platforms utilized for marine mammal detection and timeline illustrating how marine mammal detection was conducted.

(ii) Individual marine mammal sighting information for each sighting where mitigation was implemented:

(A) Date/time/location of sighting;

(B) Species (if not possible, indicate whale, dolphin, or pinniped);

(C) Number of individuals;

(D) Initial detection sensor (*e.g.,* sonar or Lookout);

(E) Length of time observers maintained visual contact with marine mammal;

(F) Sea state;

(G) Visibility; and

(H) Whether sighting was before, during, or after detonations/exercise, and how many minutes before or after.

(I) Distance of marine mammal from actual detonations (*e.g.* less than 200 yd, 200 to 500 yd, 500 to 1,000 yd, 1,000 to 2,000 yd, or greater than 2,000 yd, or target spot if not yet detonated).

(J) Lookouts must report, in plain language and without trying to categorize in any way, the observed behavior of the animal(s) (such as animal closing to bow ride, paralleling course/speed, floating on surface and not swimming *etc.*), including speed and direction and if any calves were present.

(K) Resulting mitigation implementation: The report must indicate whether explosive detonations were delayed, ceased, modified, or not modified due to marine mammal presence and for how long.

(L) If observation occurred while explosives were detonating in the water, indicate munition type in use at time of marine mammal detection.

(3) *Summary of sources used.* This section must include the following information summarized from the authorized sound sources used in all training and testing events:

(i) Total annual hours or quantity (per the LOA) of each bin of sonar or other acoustic sources (pile driving and air gun activities); and

(ii) Total annual expended/detonated ordnance (missiles, bombs, sonobuoys, *etc.*) for each explosive bin.

(4) *Geographic information presentation.* The reports must present an annual (and seasonal, where practical) depiction of training and testing bin usage (as well as pile driving activities) geographically across the AFTT Study Area.

(5) *Sonar exercise notification.* The Navy must submit to NMFS (contact as specified in the LOA) an electronic report within fifteen calendar days after the completion of any MTE indicating:

(i) Location of the exercise;

(ii) Beginning and end dates of the exercise; and

(iii) Type of exercise.

(f) *Seven-year close-out comprehensive training and testing report.* This report must be included as part of the 2025 annual training and testing report. This report must provide the annual totals for each sound source bin with a comparison to the annual allowance and the seven-year total for each sound source bin with a comparison to the seven-year allowance. Additionally, if there were any changes to the sound source allowance, this report must include a discussion of why the change was made and include the analysis to support how the change did or did not result in a change in the EIS and final rule determinations. The draft report must be submitted within three months after the expiration of this subpart to the Director, Office of Protected Resources, NMFS. NMFS must submit comments on the draft close-out report, if any, within three months of receipt. The report will be considered final after the Navy has addressed NMFS' comments, or 3 months after the submittal of the draft if NMFS does not provide comments.

§ 218.86 Letters of Authorization.

(a) To incidentally take marine mammals pursuant to the regulations in this subpart, the Navy must apply for and obtain Letters of Authorization (LOAs) in accordance with § 216.106 of this chapter.

(b) LOAs, unless suspended or revoked, may be effective for a period of time not to exceed the expiration date of the regulations in this subpart.

(c) If an LOA expires prior to the expiration date of the regulations in this subpart, the Navy may apply for and obtain a renewal of the LOA.

(d) In the event of projected changes to the activity or to mitigation, monitoring, or reporting (excluding changes made pursuant to the adaptive management provision of § 218.87(c)(1) as required by an LOA issued under this subpart, the Navy must apply for and obtain a modification of the LOA as described in § 218.87.

(e) Each LOA will set forth:

(1) Permissible methods of incidental taking;

(2) Specified geographic areas for incidental taking;

(3) Means of effecting the least practicable adverse impact (*i.e.,* mitigation) on the species or stocks of marine mammals and their habitat; and

(4) Requirements for monitoring and reporting.

(f) Issuance of the LOA(s) will be based on a determination that the level of taking must be consistent with the findings made for the total taking allowable under the regulations in this subpart.

(g) Notice of issuance or denial of the LOA(s) will be published in the **Federal Register** within 30 days of a determination.

§ 218.87 Renewals and modifications of Letters of Authorization.

(a) An LOA issued under §§ 216.106 of this subchapter and 218.86 may be renewed or modified upon request by the applicant, provided that:

(1) The planned specified activity and mitigation, monitoring, and reporting measures, as well as the anticipated impacts, are the same as those described and analyzed for the regulations in this subpart (excluding changes made pursuant to the adaptive management provision in paragraph (c)(1) of this section); and

(2) NMFS determines that the mitigation, monitoring, and reporting measures required by the previous LOA(s) under the regulations in this subpart were implemented.

(b) For LOA modification or renewal requests by the applicant that include changes to the activity or to the mitigation, monitoring, or reporting measures (excluding changes made pursuant to the adaptive management provision in paragraph (c)(1) of this section) that do not change the findings made for the regulations in this subpart or result in no more than a minor change in the total estimated number of takes (or distribution by species or stock or years), NMFS may publish a notice of planned LOA in the **Federal Register**, including the associated analysis of the change, and solicit public comment before issuing the LOA.

(c) An LOA issued under §§ 216.106 of this subchapter and 218.86 may be modified by NMFS under the following circumstances:

(1) *Adaptive management.* After consulting with the Navy regarding the practicability of the modifications, NMFS may modify (including adding or removing measures) the existing mitigation, monitoring, or reporting measures if doing so creates a reasonable likelihood of more effectively accomplishing the goals of the mitigation and monitoring.

(i) Possible sources of data that could contribute to the decision to modify the mitigation, monitoring, or reporting measures in an LOA include:

(A) Results from the Navy's monitoring from the previous year(s);

(B) Results from other marine mammal and/or sound research or studies; or

(C) Any information that reveals marine mammals may have been taken in a manner, extent, or number not authorized by the regulations in this subpart or subsequent LOAs.

(ii) If, through adaptive management, the modifications to the mitigation, monitoring, or reporting measures are substantial, NMFS will publish a notice of planned LOA in the **Federal Register** and solicit public comment.

(2) *Emergencies.* If NMFS determines that an emergency exists that poses a significant risk to the well-being of the species or stocks of marine mammals specified in LOAs issued pursuant to §§ 216.106 of this chapter and 218.86, an LOA may be modified without prior notice or opportunity for public comment. Notice would be published in the **Federal Register** within thirty days of the action.

§ § 218.88–218.89 [Reserved]

[FR Doc. 2019–27098 Filed 12–20–19; 8:45 am]

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Part IV

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 1 and 251

Importation of Prescription Drugs; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1 and 251

[Docket No. FDA–2019–N–5711]

RIN 0910–AI45

Importation of Prescription Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is proposing to amend its regulations to implement a provision of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to allow importation of certain prescription drugs from Canada. If the rule is finalized as proposed, States or certain other non-federal governmental entities would be able to submit importation program proposals to FDA for review and authorization. An importation program could be co-sponsored by a pharmacist, a wholesaler, or another State or non-federal governmental entity. The rule, when finalized, would contain all requirements necessary for a State or other non-federal governmental entity and its co-sponsors, if any, to demonstrate that their importation program will pose no additional risk to the public's health and safety. In addition, the proposed rule would require that the State or non-federal governmental entity and its co-sponsors, if any, explain why their program would be expected to result in a significant reduction in the cost of covered products to the American consumer.

DATES: Submit either electronic or written comments on the proposed rule by March 9, 2020. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 (PRA) by January 22, 2020.

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 9, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 9, 2020. 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–2019–N–5711 for ''Importation of Prescription Drugs.'' 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.govinfo.gov/content/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.

Submit comments on information collection issues under the PRA to the Office of Management and Budget (OMB) in the following ways:

• Fax to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or email to *oira_submission@omb.eop.gov.* All comments should be identified with the title, Section 804 Importation Program Proposals—21 CFR part 251.

FOR FURTHER INFORMATION CONTACT: Lyndsay Hennessey, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–7605. With regard to the information collection: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

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I. Executive Summary

A. Purpose of the Proposed Rule

FDA is proposing to amend its regulations to implement section 804(b) through (h) of the FD&C Act (21 U.S.C. 384(b) through (h)) to allow importation of certain prescription drugs shipped from Canada. The purpose of the proposed rule is to lower prices and reduce out of pocket costs for American patients.

B. Summary of the Major Provisions of the Proposed Rule

Under the proposed rule, section 804 of the FD&C Act would be implemented through time-limited Section 804 Importation Programs (SIPs), which would be authorized by FDA and managed by States or certain other non-federal governmental entities and by their co-sponsors, if any (SIP Sponsors). A SIP could be co-sponsored by a pharmacist, a wholesaler, or another State or non-federal governmental entity.

FDA proposes that a SIP Sponsor specify the eligible prescription drugs that would be included in the SIP. To be eligible under the proposed rule, a drug would need to be approved by Health Canada's Health Products and Food Branch (HPFB) and, but for the fact it bears the HPFB-approved labeling when marketed in Canada, it would need to otherwise meet the conditions in an FDA-approved new drug application (NDA) or abbreviated new drug application (ANDA). Essentially, eligible prescription drugs are those that could be sold legally on either the Canadian market or the American market with appropriate labeling.

Under the proposed rule, the SIP Proposal would also need to identify the foreign seller in Canada that will purchase the eligible prescription drug directly from its manufacturer, and the importer in the United States that will buy the drug directly from the foreign seller. While the initial SIP Proposal would identify just one foreign seller and one importer, once the SIP can show that it has consistently imported eligible prescription drug(s) in accordance with section 804 and the rule, the SIP Sponsor would be able to submit a supplemental proposal to add additional foreign sellers or importers. The supply chain for each drug under a SIP would be limited to three entities, *i.e.* one manufacturer, one foreign seller, and one importer.

FDA proposes that the foreign seller be a party that is licensed by Health Canada as a wholesaler and registered with FDA as a foreign seller, and that the importer be a wholesaler or pharmacist licensed to operate in the United States. Both the foreign seller and the importer would be subject to the supply chain security requirements proposed in this rulemaking and under the FD&C Act. Among other things, the foreign seller would have to ensure that a section 804 serial identifier (SSI), which is an alphanumeric serial number unique to each package or homogeneous case, is affixed or imprinted to each package and homogenous case of the drugs, and the importer would have to ensure that a product identifier meeting the requirements of section 582 of the FD&C Act (21 U.S.C. 360eee–1) (*i.e.,* a product identifier that includes a National Drug Code, unique alphanumeric serial number of up to 20 characters, lot number, and expiration date, in both human- and machine-readable format) is affixed or imprinted to each package or homogenous case of the drugs. The importer would also have to maintain records linking the product identifier affixed or imprinted on a package or homogenous case to the SSI that the foreign seller assigned.

After FDA has authorized a SIP Proposal, the importer would submit a Pre-import Request to FDA at least 30 days prior to the scheduled date of arrival or entry for consumption of a shipment containing an eligible prescription drug covered by the SIP, whichever is earlier. Entry and arrival of a shipment containing an eligible prescription drug would be limited under the proposed rule to the U.S. Customs and Border Protection (CBP) port of entry authorized by FDA. The importer, or authorized customs broker, would be required to electronically file an entry for consumption in the Automated Commercial Environment (ACE) or other electronic data interchange system authorized by CBP for each eligible prescription drug imported or offered for import into the United States. These entries would be filed as formal entries. If an eligible prescription drug is imported or offered for import that does not comply with section 804 of the FD&C Act and the provisions of this proposed rule, that drug would be subject to refusal under section 801 of the FD&C Act (21 U.S.C. 381).

The importer would need to arrange for statutorily prescribed testing of the drug for authenticity, degradation, and other statutory testing requirements by a qualifying laboratory in the United States, if the manufacturer does not perform the testing required under section 804, and would also need to ensure that the drug complies with all labeling requirements under the FD&C Act. Section 804 of the FD&C Act requires that the mandatory testing either be performed by the manufacturer of an eligible prescription drug or, if such testing is performed by the importer, that the manufacturer supply the information the importer needs to authenticate the drug and to confirm that its labeling complies with all labeling requirements under the FD&C Act. In the proposed rule, FDA specifies that this information includes, among other things, any relevant testing protocols that the manufacturer has developed.

Under the proposed rule, the importer can choose to admit the drug or drugs specified in the section 804 pre-import request to an authorized Foreign Trade Zone (FTZ) and then conduct the required testing and relabeling, or alternatively, the importer can make an entry for consumption and request to recondition the drug or drug(s), which would entail the required testing and relabeling. Under the proposed rule, the results of this testing would be reviewed and accepted by FDA and subsequently the drug would have to be relabeled with labeling that complies with all labeling requirements under the FD&C Act before the drug can be distributed in the United States.

Pursuant to section 804(c)(3) of the FD&C Act, the proposed rule also sets forth post-importation requirements. Each SIP Sponsor would be required to provide FDA with data and information about its SIP, including the SIP's cost savings to the American consumer. An importer would be required to submit

adverse event, medication error, field alert, and other reports to a drug's manufacturer and to FDA. If FDA or any participant in a SIP determines that a recall is warranted, the SIP Sponsor would be responsible for effectuating the recall. The proposed rule would require that each SIP have a written recall plan that describes the procedures to perform a recall of the product and specifies who will be responsible for performing the procedures.

A SIP is eligible for extension by FDA before the end of its approval period. A SIP may also be terminated by FDA at any time for the reasons outlined in this proposed rule.

C. Legal Authority

Section 804(l)(1) of the FD&C Act provides that section 804 shall become effective only if the Secretary certifies to the Congress that the implementation of this section will pose no additional risk to the public's health and safety, and result in a significant reduction in the cost of covered products to the American consumer. The Secretary of the Department of Health and Human Services (the Secretary or the Secretary of HHS) would make this certification to Congress upon issuance of a final rule based on this proposal. FDA is also issuing this proposed rule under FDA's rulemaking authority regarding importation of prescription drugs under section 804(b) through (h) of the FD&C Act. The proposed rule is also being issued pursuant to FDA's authorities related to adulterated and misbranded drugs under sections 501 and 502 of the FD&C Act (21 U.S.C. 351 and 352); FDA's authorities with regard to wholesale distribution under section 503(e) of the FD&C Act (21 U.S.C. 353(e)); FDA's authority related to new drugs under section 505 of the FD&C Act (21 U.S.C. 355); as well as FDA's rulemaking, inspection, and importation authorities under sections 701(a), 704, and 801(a) of the FD&C Act, respectively (21 U.S.C. 371(a), 374, and 381).

D. Costs and Benefits

The proposed rule, if finalized, would allow commercial importation of certain prescription drugs from Canada through time-limited programs sponsored by at least one non-federal governmental entity with possible co-sponsorship by a wholesaler or pharmacist. As we lack information about the expected scale or scope of such programs, we are unable to estimate how they may affect U.S. markets for prescription drugs. In particular, we are unable to estimate the volume or value of drugs that may be imported under the SIPs or the savings to U.S. consumers who may participate in such programs.

Costs of the proposed rule may accrue to the Federal Government, SIP Sponsors, importers, and manufacturers of imported drugs. The Federal Government would incur one-time fixed costs to implement the rule as well as ongoing costs including those to review program proposals and periodic reports. SIP Sponsors would face costs to prepare SIP Proposals, implement approved SIPs, and produce SIP reports and records. If their drugs are imported into the United States from Canada, drug manufacturers may have to provide importers with certain information. These costs depend on the number and type of participating importation programs. We lack information to estimate these costs.

Finally, U.S. patients, as well as wholesale drug distributors, pharmacies, hospitals, and third-party payers, may all experience savings, but we lack information necessary to estimate such savings. As drug distributors realize savings in acquiring imported drugs and pass some of these savings to consumers and other parties in the drug supply chain, it is possible that U.S. drug manufacturers may experience a transfer in U.S. sales revenues to these parties.

II. Table of Abbreviations/Commonly Used Acronyms in This Document

Abbreviation/acronym	What it means
ACE	Automated Commercial Environment or any Other Electronic Data Interchange System authorized by the U.S. Customs and Border Protection.
ANDA	Abbreviated New Drug Application.
CBP	U.S. Customs and Border Protection.
CGMP	Current Good Manufacturing Practice.
COA	Certificate of Analysis.
DIN	Drug Identification Number.
DSCSA	Drug Supply Chain Security Act.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
FTZ	Foreign Trade Zone.
HPFB	Health Canada Health Products and Food Branch.
NDA	New Drug Application.
OMB	Office of Management and Budget.
SIP	Section 804 Importation Program.
SSI	Section 804 Serial Identifier.

III. Background

Since 1938, the FD&C Act has required the submission of an application to FDA for a new drug before it is marketed in the United States. Under sections 301(d) and 505(a) of the FD&C Act (21 U.S.C. 331(d) and 355(a)), a new drug may not be introduced or delivered for introduction into interstate commerce, which includes importation into the United States, unless an application approved by FDA under section 505 is in effect for the drug. Unapproved new drugs include versions of FDA-approved drugs that are intended for sale outside of the United States, and which have not themselves been approved by FDA for marketing in the United States. (*United States* v. *Genendo Pharmaceutical, N.V.,* 485 F.3d 958 (7th Cir. 2007); *In Re Canadian Imp. Antitrust Litig.,* 470 F.3d 785, 789–90 (8th Cir. 2006).) Under section 801(a)(3) of the FD&C Act, FDA has authority to refuse admission of a drug that is offered for import if, among other things, it appears to be an unapproved new drug and, therefore, in violation of section 505 of the FD&C Act. Under section 801(d)(1)(A) of the FD&C Act, a prescription drug that is manufactured in a State and exported may only be imported into the United States by the manufacturer, except, in addition to another reason not relevant here, as provided in section 804. Under section 801(d)(1)(B) of the FD&C Act,[1] a

[1] Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a draft guidance that describes procedures to obtain an additional National Drug Code for an FDA-approved prescription drug that is imported into the United States in compliance with section 801 of the FD&C Act.

prescription drug manufactured outside the United States may be imported into the United States for commercial use only in situations where the manufacturer has authorized the drug to be marketed in the United States and has caused the drug to be labeled to be marketed in the United States, except, in addition to another reason not relevant here, as provided in section 804.

In 2000, Congress enacted legislation known as the Medicine Equity and Drug Safety (MEDS) Act as part of the Fiscal Year 2001 appropriations bill for the Department of Agriculture and related Agencies (Pub. L. 106–387). The MEDS Act added an earlier version of section 804 to the FD&C Act that, if implemented, would have allowed pharmacists or wholesalers in the United States to import certain prescription drugs without the authorization of the manufacturer. The MEDS Act was intended to ''empower pharmacists and wholesalers to purchase FDA-approved medicines in Canada and pass the discounts along to American patients[.]'' (146 Cong. Rec. S3692, 3693 (daily ed. May 9, 2000)).[2] The law required that, prior to implementation, the Secretary of HHS demonstrate that the importation of these drugs would pose no additional risk to the public's health and safety and would result in a significant reduction in the cost of covered products to the American consumer. HHS was not able to make such demonstration (Ref. 1).

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) was signed into law on December 8, 2003. Section 1121 of the MMA amended section 804 of the FD&C Act to its current version, which, among other things, authorizes the Secretary of HHS, after consultation with the U.S. Trade Representative and the Commissioner of Customs, to issue regulations permitting pharmacists and wholesalers to import certain prescription drugs from Canada under certain conditions and limitations. For section 804 of the FD&C Act to become effective, the Secretary of HHS must certify that its implementation will ''pose no additional risk to the public's health and safety,'' and that it will ''result in a significant reduction in the cost of covered products to the American consumer.''

There has been interest for many years in allowing the importation of less expensive drugs from Canada to help American consumers benefit from these lower prices. However, no prior HHS Secretary has made the certification required under section 804(l) to begin implementing any part of section 804 of the FD&C Act. Past efforts have been unsuccessful in part because of concerns that: (1) FDA could not ensure the safety and effectiveness of drugs imported via such a program, (2) an importation program that opened the ''closed'' U.S. drug distribution system for prescription drugs could increase the opportunity for counterfeit and other substandard drugs to enter the supply chain, and (3) an importation program would not result in a significant reduction in costs to American consumers (Refs. 1 to 4).

In 2003, as part of the MMA, Congress directed HHS to conduct a study on the importation of prescription drugs. The results of this study were presented in a Task Force Report that was submitted to Congress in December 2004 (Ref. 5). The Task Force Report identified concerns about potential risks and challenges associated with implementing section 804, including, but not limited to:

- ''The current system of drug regulation in the U.S. has been very effective in protecting public safety, but is facing new threats. It should be modified only with great care to ensure continued high standards of safety and effectiveness of the U.S. drug supply.''
- ''Overall national savings from legalized commercial importation will likely be a small percentage of total drug spending and developing and implementing such a program would incur significant costs and require significant additional authorities.''
- ''The public expectation that most imported drugs are less expensive than American drugs is not generally true. Generic drugs account for most prescription drugs used in the U.S. and are usually less expensive in the U.S. than abroad.''
- ''The effects of legalized importation on intellectual property rights are uncertain but likely to be significant. . . . These effects could create additional disincentives to develop breakthrough medicines and further limit any potential savings that might have been realized.''
- ''Legalized importation raises liability concerns for consumers, manufacturers, distributors, pharmacies, and other entities. Consumers harmed by imported drugs may not have legal recourse against foreign pharmacies, distributors, or other suppliers. Entities in the pharmaceutical supply chain may take actions to protect themselves from liability that could ultimately raise the cost of drugs'' (Ref. 5).

The continued rise of prescription drug prices since the issuance of the 2004 Task Force Report has raised concerns among policymakers, healthcare professionals, and American consumers. According to a 2017 United States Government Accountability Office (GAO) report, ''[t]he amount of money people spend on prescription drugs has nearly doubled since the 1990s'' (Ref. 6). Additionally, the GAO found that ''[i]n 2015, expenditures for prescription drugs sold through retail pharmacies were estimated to account for nearly 12 percent of total personal health care services spending in the United States, up from approximately 7 percent of such spending through the 1990s.'' The HHS Office of the Assistant Secretary for Planning and Evaluation (ASPE) estimates that the United States spent about $457 billion on prescription drugs in 2015 (Ref. 7). In 2009, by comparison, prescription drug spending in the United States was $354 billion. Prescription drug spending is projected to continue to rise faster than overall health spending (Ref. 7).

FDA is committed to expanding Americans' access to high-quality, safe and effective, affordable medicines. Congress has given FDA, as part of the Agency's mission to promote and protect the public health, responsibility for implementing laws intended to strike a balance between encouraging and rewarding innovation in drug development and facilitating robust and timely market competition. The Agency takes seriously its responsibility to ensure that the medicines Americans use are safe and effective. FDA also recognizes that ''[a]ccess to affordable prescription drugs, many of which are needed to treat life-threatening and serious conditions, is a daily concern and challenge for many Americans.'' (Ref. 5)

Most Americans (79 percent) say the cost of prescription drugs is ''unreasonable'' (Ref. 8). Prohibitive costs can lead to medication nonadherence, which negatively impacts health outcomes and contributes to increased healthcare costs in the United States (Ref. 9). In a recent national poll, almost one-third (29 percent) of U.S. adults have reported ''not taking their medicines as prescribed'' due to the expense, and almost 1 in 10 (8 percent) said this led to a decline in their condition (Ref. 8). National news outlets have reported on the dire consequences of patients rationing immunosuppressive medications needed after organ transplants or delaying cancer

[2] While this statement seems to imply that these amendments were intended to only permit importation from Canada, the actual amendments contained no such restriction.

treatments because of costs (Refs. 10 and 11).

Contributing to public frustration on this issue is the disparity between prices that Americans pay for brand name medications as compared with other developed countries. The reasons for such price disparities are varied. Brand name prescription drugs (as distinct from generic drugs) often are more expensive in the United States than they are in other developed markets (Refs. 12 to 14). For instance, in 2017, Canada's Patented Medicine Prices Review Board (PMPRB) found that patented medicines (*i.e.,* drug products to which patents apply) cost on average three times more in the United States than Canada (Refs. 15 and 16). As a result of these price differentials, some American consumers have sought to import drugs from other countries in an effort to obtain treatments that may be otherwise inaccessible to them because of cost. According to a national poll, millions of Americans have purchased prescription drugs from other countries (Refs. 17 and 18).

FDA has revisited the question of whether section 804 of the FD&C Act could be implemented so that the Secretary could make the required certification under section 804(l)(1). Past analyses regarding the feasibility of implementing section 804 did not consider the possibility of implementing section 804(b) through (h) of the FD&C Act solely through programs proposed by States or certain other non-federal governmental entities and their co-sponsors, if any, and authorized by FDA, as described in this proposed rule. FDA has reviewed these past analyses and proposes that while the concerns about public health and safety and the ability to achieve cost savings remain valid, section 804 of the FD&C Act can be implemented in a manner consistent with the certification criteria through programs, overseen by States or certain other non-federal governmental entities and their co-sponsors, if any, that require authorization by and reporting to FDA. These programs would be required to demonstrate to FDA that they could import drugs from Canada at no additional risk to the public's health and safety consistent with the requirements in section 804 of the FD&C Act and this proposed rule. These include, among other requirements, requirements relating to the types of drugs eligible for importation, the distribution channels and methods used for product traceability, and the testing of eligible prescription drugs for authenticity and degradation. In addition, in accordance with section 804, the proposed rule would require that drugs imported under section 804 meet the specifications of an FDA-approved NDA or ANDA. These programs would also be expected to demonstrate significant cost reductions to the American consumer. Merely because an importation purports to be done pursuant to section 804, that does not mean it has been authorized under section 804 and is compliant with section 804 of the FD&C Act and this rule, if finalized.

FDA is not proposing to implement the personal importation provisions in section 804(j) through this rulemaking. The internet provides consumers with instant access to information and services, including prescription medications. Medications that are purchased online and imported through international mail, express couriers, and other means pose significant challenges for FDA and its ability to adequately safeguard the quality and safety of drugs taken by U.S. consumers. While there are pharmacy websites that operate legally and offer convenience, privacy, and safeguards for purchasing medicines, there are many rogue online pharmacies that sell medicines at deeply discounted prices, often without requiring a prescription or adhering to other safeguards followed by pharmacies licensed by a State in the United States. These rogue online pharmacies are often run by sophisticated criminal networks that knowingly and unlawfully cause the importation of adulterated, counterfeit, misbranded and unapproved drugs into the United States. These criminals frequently use sophisticated technologies and are backed by larger enterprises intent on profiting from illegal drugs at the expense of American patients (Refs. 19 and 20). Consumers go to these websites believing they are buying safe and effective medications, but often they are being deceived and put at risk by individuals who put financial gain above patient safety.

For example, Canada Drugs Ltd. (''Canada Drugs'') was an internet-based pharmacy corporation located in Winnipeg, Manitoba, Canada, which purchased drugs from questionable sources that were outside FDA's closed supply chain (Refs. 21 and 22). Canada Drugs and its subsidiaries put the public health at risk through widespread sales of misbranded and unapproved drugs to U.S. consumers at discounted prices (Ref. 23). Moreover, in two instances, Canada Drugs, through a subsidiary, distributed counterfeit versions of the cancer drugs Avastin and Altuzan (the Turkish version of Avastin) to healthcare providers in the United States. The counterfeits contained no active ingredient. After Canada Drugs became aware that they had shipped counterfeit Avastin and Altuzan to medical clinics in the United States, they tried to conceal the problem. Canada Drugs never notified FDA or other U.S. authorities that it had shipped counterfeit cancer drugs containing no active ingredient to the United States (Ref. 22).

Further, drugs promoted as being from Canada or approved by Health Canada's HPFB that are offered to U.S. citizens in many instances are not actually from Canada and not approved by HPFB. Instead, these drugs are obtained from ever-evolving illicit sources of supply. A 2005 FDA analysis of drugs imported through International Mail Facilities revealed that while nearly half of imported drugs claimed to be Canadian or from Canadian pharmacies, 85 percent of those drugs originated elsewhere and were fraudulently represented as Canadian (Refs. 24 and 25). Typically, these products are smuggled into the United States after being transshipped to third party countries, such as Canada, in an effort to avoid detection and create a more trustworthy appearance (Ref. 25). Given these risks, and other concerns discussed in the Task Force Report (Ref. 5), the proposed rule, if finalized, would not implement personal importation provisions under section 804(j) of the FD&C Act.

In the intervening years since the Task Force Report was issued in 2004, Canada has amended its regulations to strengthen its oversight of both pharmaceutical manufacturing practices (Ref. 26) and pharmaceutical supply chain participants (Ref. 27). Regulatory harmonization between Canada and the United States has also increased bilaterally through the U.S.-Canada Regulatory Cooperation Council and through international organizations such as the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and Pharmaceutical Inspection Co-operation Scheme initiatives, of which both FDA and Health Canada are members. In August 2019, FDA and Health Canada announced a series of joint meetings in advance of each bi-annual ICH face-to-face meeting to seek the public's input on areas where harmonized ICH guidelines would be beneficial (Ref. 28).

Additionally, since the 2004 HHS Task Force report and efforts by Vermont and other States to implement importation programs in the early 2000s, pharmaceutical supply chains have continued to mature and consolidate, and the ability of

companies engaged in the transaction of drugs to conduct business internationally and trace their products has strengthened. This maturation has further grown since 2013, following and due in part to the enactment of the Drug Supply Chain Security Act (DSCSA) (Title II of Pub. L. 113–54). Among other requirements, the DSCSA outlines steps to build an electronic, interoperable system to identify, trace, and verify certain prescription drugs as they are distributed among pharmaceutical supply chain trading partners.

As wholesale drug distributors and pharmacists actively participate, along with manufacturers and other trading partners, in the development of an interoperable electronic system by 2023 in accordance with standards established by FDA, as required under DSCSA, they have developed processes and methods for complying with requirements in place since 2015 for exchanging transaction information and verifying products. Industry stakeholders have steadily marched toward these goals (Ref. 29). With the implementation of the DSCSA, supply chain security is maturing due in part to these technological solutions adopted by manufacturers, wholesale distributors, pharmacists, and other trading partners that serve as important links to help protect U.S. consumers from illegitimate products. In addition, under the DSCSA, FDA, along with the States, exercises oversight over wholesale drug distributors and pharmacists, in addition to manufacturers.

To address the substantial public health risks associated with counterfeits of their prescription drugs, manufacturers around the world now use a number of technologies to detect whether a certain drug is legitimate or fake. These technologies include both overt and covert security technology to enable identification of their authentic drug. Technological advancements that support verification of these overt and covert security features have enhanced the ability to detect counterfeits at the border and prevent their introduction into U.S. commerce.

Finally, FDA believes that at this time it can implement section 804(b) through (h) of the FD&C Act because it proposes to do so through SIPs, which would be authorized by FDA and managed by States or certain other governmental entities and their co-sponsors, if any, and which would last for 2 years from the time a program imports its first eligible prescription drug, with the possibility of extensions for 2-year periods. A State or other governmental entity and its co-sponsors, if any, would need to demonstrate to FDA that, in accordance with the requirements proposed here, the importation would pose no additional risk to the public's health and safety and would be expected to result in a significant reduction in the cost of covered products to the American consumer.

IV. Legal Authority

Section 804(l)(1) of the FD&C Act provides that section 804 shall become effective only if the Secretary certifies to the Congress that the implementation of this section will pose no additional risk to the public's health and safety, and result in a significant reduction in the cost of covered products to the American consumer. The Secretary would make this certification to Congress upon issuance of a final rule based on this proposal. FDA is also issuing this proposed rule under FDA's rulemaking authority regarding importation of prescription drugs under section 804(b) through (h) of the FD&C Act. The proposed rule is also being issued pursuant to FDA's authorities related to adulterated and misbranded drugs under sections 501 and 502 of the FD&C Act; FDA's authorities with regard to wholesale distribution under section 503(e) of the FD&C Act; FDA's authority related to new drugs under section 505 of the FD&C Act; as well as FDA's rulemaking, inspection, and importation authorities under sections 701(a), 704, and 801(a) of the FD&C Act.

V. Description of the Proposed Rule

FDA is proposing to establish new part 251 of Title 21 of the Code of Federal Regulations (CFR) to implement section 804(b) through (h) of the FD&C Act to allow importation of certain prescription drugs from Canada. FDA proposes to implement section 804 through time-limited SIPs, which would be authorized by FDA in 2-year increments and managed by SIP Sponsors, with the possibility of extensions for 2-year periods. If the rule is finalized as proposed, SIP Sponsors that want to facilitate the importation of certain drugs from Canada would be able to submit a SIP Proposal to FDA for review and authorization, in FDA's discretion.

We propose that every SIP be sponsored by a State, tribal, or territorial governmental entity. Under the proposed rule, a SIP could be co-sponsored by a pharmacist, wholesaler, or another State or other non-federal governmental entity. Co-sponsorship could introduce valuable flexibility (for example, multiple States could co-sponsor a plan with a large wholesaler) and allow SIPs to benefit from the experience of pharmacists and wholesalers, while preserving the advantages that accrue from sponsorship by at least one State or other governmental entity. We seek comments on this approach. We are specifically interested in receiving comments on what the division of responsibility between co-sponsors should be and whether there are certain arrangements that should not be permitted. For example, we seek comment on whether a pharmacist or wholesaler should be able to be both a SIP co-sponsor and an Importer within the same SIP. If yes, we seek comment on what safeguards a SIP could include to provide for sufficient oversight of a co-sponsor that is also acting as the Importer of the SIP. We also seek comment on whether non-governmental entities other than pharmacists and wholesalers, such as group purchasing organizations, pharmacy benefit managers, or union health and welfare benefit plans, should be permitted to co-sponsor SIPs.

This notice of proposed rulemaking (NPRM) is not intended to address the applicability of the Medicaid drug rebate program for drugs under a SIP, which may be addressed in further guidance or rulemaking from HHS as appropriate.

We considered whether to allow pharmacists or wholesalers to be SIP Sponsors without a State, tribal, or territorial governmental entity as a co-sponsor. We believe that a State, tribal, or territorial governmental entity should oversee each SIP because only a State, tribal, or territorial government entity would be in a position to demonstrate that it licenses or regulates pharmacists, wholesalers, and others in the prescription drug supply chain. For example, States provide the primary oversight of wholesale distributors' storage, handling, and distribution practices to ensure the quality of drugs is maintained. States also ensure that pharmacies and pharmacists comply with statutes and regulations governing the practice of pharmacy, which includes dispensing of drugs to patients. States have the authority to inspect pharmaceutical supply chain participants and to take disciplinary action against them if warranted. States also have tools that they can use to respond rapidly should activities under their SIP adversely affect the public health. We conclude that a plan that has at least one sponsor that is a State, tribal, or territorial governmental entity under which pharmacists or wholesalers import drugs would offer enhanced accountability and protect the public health.

Although this NPRM proposes to require at least one SIP Sponsor that is a State, tribal, or territorial government for each SIP, we seek comment on whether it could be possible for a pharmacist or wholesaler to be a SIP Sponsor without a State, tribal, or territorial government co-sponsor, while posing no additional risk to the public's health and safety. Although we cannot foresee at this time how this approach could be adopted without posing additional risk to the public's health and safety, if we receive information that demonstrates how a proposal that does not include a State, tribal, or territorial government co-sponsor would provide the same level of assurance of safety as a proposal with such a co-sponsor, we would consider having the final rule account for this possibility. Accordingly, we have provided a proposed alternative codified provision for comment that would also allow pharmacists or wholesalers to sponsor a SIP without a co-sponsor. This alternative codified provision appears under ''Option 2'' in proposed § 251.2. If we do not receive comments containing adequate information for FDA to justify such an allowance, we intend to omit the ''Option 2'' provision when we finalize this rule. In addition, as with any other proposed codified provision, if we decide to provide for additional types of Sponsors, the proposed codified provision under ''Option 2'' may be modified when this rule is finalized. In addition, among other potential revisions that may be necessary, if the final rule were to permit a pharmacist or wholesaler to be a SIP Sponsor without a State, tribal, or territorial government co-sponsor, we would include in the final rule those additional safeguards that would be applicable to most, and perhaps all, proposals without a State, tribal, or territorial government co-sponsor.

A SIP Sponsor could also be defined to include additional or different categories of sponsors and/or to exclude the possibility of co-sponsors where the SIP Sponsor is not a State, tribal, or territorial governmental entity. A co-sponsor could also be defined to include additional or different categories of co-sponsors. Additionally, we seek comment on what safeguards a SIP would need to include to provide for sufficient oversight of a SIP Sponsor who is also acting as the Importer for the SIP.

In its SIP Proposal, the SIP Sponsor would need to show, in accordance with the requirements proposed in this rule, that its proposed importation will pose no additional risk to the public's health and safety. A SIP Proposal would also need to explain why the Sponsor expects the proposal would result in a significant reduction in the cost to the American consumer of the prescription drugs that the Sponsor seeks to import. The explanation regarding the significant reduction in the cost of covered products to the American consumer would need to include any assumptions and uncertainty, and it would need to be sufficiently detailed that it can be evaluated by another component of HHS, as directed by the Secretary, which would make a recommendation to FDA.

Where a SIP Proposal meets the requirements of section 804(b) through (h) of the FD&C Act and this proposed rule, FDA may nonetheless decide, in its discretion, not to authorize the SIP Proposal. Among other reasons, FDA may decide not to authorize a SIP Proposal because of potential safety concerns with the program, because of the relative likelihood the program would not result in significant enough cost savings (based on the recommendation of another HHS component as directed by the Secretary), because FDA needs to limit the number of authorized programs to effectively and efficiently monitor the program, or in light of other resource demands.

In its SIP Proposal, a State or other non-federal governmental entity and its co-sponsors, if any, would specify the eligible prescription drugs it seeks to import. To be eligible, a drug would need to be approved by Canada's HPFB and, but for the fact it bears the HPFB-approved labeling, it would need to meet the conditions in an FDA-approved NDA or ANDA. The SIP Proposal would also need to identify the Foreign Seller in Canada that would purchase the drug directly from its manufacturer, and the Importer in the United States that would buy the drug directly from the Foreign Seller. FDA proposes that the Foreign Seller be registered with FDA as a Foreign Seller and be licensed by Health Canada as a wholesaler, and that the Importer be a wholesaler or pharmacist licensed in the United States.

Due to resource constraints that limit FDA's ability to provide effective safety oversight, we considered placing a limit on the number of SIP Proposals that FDA would authorize and the number of SIPs that FDA would oversee. We considered limiting each State, tribal, or territorial governmental entity and its co-sponsors, if any, to submitting one SIP Proposal for one supply chain. However, there may be State, tribal, or territorial governmental entities and their co-sponsors, if any, that wish to use more than one Foreign Seller or more than one Importer. Other State, tribal, or territorial governmental entities may not wish to submit a SIP Proposal. For this reason, we do not propose to perpetually limit the total number of Foreign Sellers or Importers with which a SIP Sponsor can work, although we do note that each Foreign Seller must buy the drugs to be imported directly from the manufacturer and sell those drugs directly to the Importer. After a State, tribal, or territorial governmental entity and its co-sponsors, if any, has an authorized SIP that has consistently imported eligible prescription drugs in accordance with section 804 of the FD&C Act and this rule, that State, tribal, or territorial governmental entity and its co-sponsors, if any, would be able to submit a supplement to the SIP Proposal to add a Foreign Seller or Importer. We do not expect to be able to find that a SIP Sponsor has consistently imported drugs in accordance with section 804 of the FD&C Act and this rule before it submits its first quarterly report to FDA.

After FDA has authorized a SIP Proposal, the Importer would submit a request to FDA at least 30 days prior to the scheduled date of arrival or entry for consumption of a shipment containing an eligible prescription drug, whichever is earlier. Entry and arrival of a shipment containing an eligible prescription drug would be limited under the proposed rule to the CBP port of entry authorized by FDA. The Importer would be required to electronically file an entry for consumption, including the data elements that FDA requires, in ACE or other electronic data interchange system authorized by CBP for each eligible prescription drug imported or offered for import into the United States. These entries would be filed as formal entries. If an eligible prescription drug is imported or offered for import that does not comply with section 804 or the provisions of this proposed rule, that drug would be subject to refusal under section 801 of the FD&C Act.

In accordance with section 804(e)(1) of the FD&C Act, the proposed rule would require the manufacturer or the Importer to conduct testing of the drugs to be imported for authenticity, degradation, and ''to ensure that the prescription drug is in compliance with established specifications and standards'' (Statutory Testing). Also, in accordance with section 804€(1), the proposed rule would require that the Statutory Testing be done at a qualifying laboratory in the United States. The Importer would also have to ensure that

the drug bears the required U.S. labeling.

Under section 804(e)(2) of the FD&C Act, if the manufacturer of an eligible prescription drug does not test the drug itself, the testing would need to be performed by the Importer using information supplied by the manufacturer, including all the information needed to authenticate the drug and confirm that its labeling complies with labeling requirements under the FD&C Act. In the proposed rule, FDA specifies that this information includes, among other things, any testing methodologies and protocols that the manufacturer has developed that the Importer needs to conduct the Statutory Testing.

Under the proposed rule, the Importer can choose to admit the drug or drugs specified in the section 804 Pre-Import Request to an authorized FTZ and then conduct the required testing and relabeling or, alternatively, the Importer, or an authorized customs broker, can make an entry for consumption and request to recondition the drug or drugs, which would entail the required testing and relabeling. Under the proposed rule, the results of the Statutory Testing would need to be reviewed and found acceptable by FDA, and the drug would have to bear the required U.S. labeling, before the drug is sold in the United States.

Both the Foreign Seller and the Importer would be subject to the supply chain security requirements proposed in this rule. Among other things, the Foreign Seller would have to ensure that the product is serialized at the package level and adhere to applicable DSCSA obligations. The Importer would have to ensure that a product identifier meeting the requirements of section 582 of the FD&C Act is affixed or imprinted to each package and homogenous case of the drugs and adhere to other existing DSCSA obligations, as described below.

The proposed rule also sets forth post-importation requirements. Each SIP Sponsor would be required to provide FDA with data and information about its SIP, including the SIP's cost savings to the American consumer. An Importer would be required to submit adverse event, medication error, field alert, and other reports to a drug's manufacturer and to FDA. If FDA or any participant in a SIP determines that a recall is warranted, the SIP Sponsor would be responsible for effectuating the recall. The proposed rule would require that SIPs have a written recall plan that describes the procedures to perform a recall of the product and specifies who will be responsible for performing the procedures.

Once effective, section 804(b) of the FD&C Act directs the Secretary, after consultation with the U.S. Trade Representative and the Commissioner of Customs, to promulgate regulations permitting pharmacists and wholesalers to import prescription drugs from Canada into the United States. Section 804(c) specifies that the regulations shall require that safeguards be in place to ensure that each prescription drug imported under the regulations complies with section 505 of the FD&C Act (including with respect to being safe and effective for the intended use of the prescription drug), with section 501 of the FD&C Act (relating to adulteration), with section 502 of the FD&C Act (relating to labeling and misbranding) and with other applicable requirements of the FD&C Act. The statute also provides that the regulations require that Importers comply with section 804(d)(1) of the FD&C Act, under which an Importer of a prescription drug under 804(b) must submit certain information and documentation relating to the drug to the Secretary. In addition, the regulations must require compliance with section 804(e), which requires that importers or manufacturers test drugs imported under section 804 at a qualifying laboratory.

Eligible prescription drugs must be in compliance with section 804 of the FD&C Act and with other applicable requirements of the FD&C Act, including sections 505 (including with respect to being safe and effective for the intended use of the prescription drug), 502, and 501 of the FD&C Act, in order to be imported. This proposed regulation would create new exemptions from the statutory requirement of adequate directions for use under section 502(f)(1) of the FD&C Ac and from certain requirements in section 582 of the FD&C Act. Section 804(c)(3) of the FD&C Act provides the Secretary the authority to add regulatory requirements, as appropriate, as a safeguard to protect the public health or to facilitate the importation of prescription drugs. Under the authority of section 804(c) of the FD&C Act, we are proposing additional provisions that we have determined to be appropriate as a safeguard to protect the public health or as a means to facilitate the importation of eligible prescription drugs.

Section 804(l)(1) of the FD&C Act provides that section 804 shall become effective only if the Secretary certifies to the Congress that the implementation of this section will pose no additional risk to the public's health and safety, and result in a significant reduction in the cost of covered products to the American consumer. After consideration of comments received on this NPRM, if warranted, the Secretary will make this certification to Congress concurrent with finalization of this rule. The Secretary's certification will be conditioned on each authorized SIP meeting the relevant requirements of section 804 of the FD&C Act and this rule, including the use of time-limited importation programs as described in this document. If one or more of the provisions in this rule becomes invalid, in addition to the entire rule becoming invalid, the certification would become null and void because the certification is based on a finding that implementation of section 804 will pose no additional risk to the public's health and safety, and that finding would no longer be accurate because it would have been based on a final rule that contains all the requirements that were included when published. We are not implementing section 804(j) of the FD&C Act relating to importation by individuals at this time.

A. Scope/Applicability

These proposed amendments to the regulations at part 251 would apply to eligible prescription drugs that are imported from Canada into the United States pursuant to an importation program authorized by FDA under section 804 of the FD&C Act.

B. Definitions

The proposed rule contains a number of definitions for terms used in the rule. Some of these definitions are provided in section 804 of the FD&C Act or cross-reference definitions elsewhere in part 251. We seek comment on our proposed definitions.

Subject to certain exclusions, section 804(a)(3) defines a ''prescription drug'' as a drug subject to section 503(b) of the FD&C Act, which is the provision requiring a prescription for drugs that are not safe for use except under the supervision of a healthcare practitioner. For purposes of this regulation, we propose to define ''eligible prescription drug'' to mean a drug subject to section 503(b) of the FD&C Act that has a marketing authorization from HPFB and, but for the fact it bears the HPFB-approved labeling, also meets the conditions in an FDA-approved NDA or ANDA, including those relating to the drug substance, drug product, production process, quality controls, equipment, and facilities. Essentially, eligible prescription drugs are those that could be sold legally on either the Canadian market or the American market with appropriate labeling. An eligible prescription drug would need to

be relabeled with the required U.S. labeling, including the carton and container labels, prescribing information, and any patient labeling, before it can be sold in the United States.

In addition, to be eligible for importation under section 804 of the FD&C Act, the proposed rule would require that a prescription drug be marketed in the United States currently. We believe that FDA will be better able to determine if there is a safety issue with an imported HPFB-approved drug if the FDA-approved drug is currently marketed, because that will make it more likely that there will be current adverse event reports, medication error reports, and product quality complaints about the FDA-approved drug. In addition, a comparison between the cost of the HPFB-approved drug sold in Canada and the cost of the FDA-approved drug sold in the United States may be necessary to establish that importation has resulted in a significant reduction in the cost of covered products to the American consumer.

Section 804(a)(3) of the FD&C Act excludes several categories from the definition of prescription drug, including controlled substances, biological products, infused drugs (including a peritoneal dialysis solution), intravenously injected drugs, and drugs that are inhaled during surgery. The proposed regulation excludes these categories from the definition of ''eligible prescription drug.'' In addition, we propose to exclude drugs that are subject to risk evaluation and mitigation strategies (REMS). Section 505–1 of the FD&C Act, which authorizes FDA to require REMS, was passed after section 804 of the FD&C Act. REMS drugs are high-risk products with known safety issues. REMS programs are mandated by FDA but implemented by manufacturers. In order to implement and assess a REMS, a manufacturer needs to have control over the drug that is the subject of the REMS. For example, a REMS could require that a medication's labeling include a Medication Guide for patients. The manufacturer would not be able to ensure that this is done for drugs imported under section 804 of the FD&C Act because these drugs are relabeled by the Importer. Similarly, if it is a requirement of a REMS that a manufacturer provide certain information about a drug to prescribers, this could be complicated by the presence in the supply chain of versions of that drug that are imported by SIPs and so have different NDC numbers. Finally, for REMS that require tight controls on distribution of the drug in order to mitigate risks, use of Foreign Sellers will make it much more difficult to maintain those restrictions and could introduce gaps that have a significant impact on the safety of the drug.

The proposed regulation also excludes drugs that do not meet the definition of a ''product'' for purposes of section 582 of the FD&C Act. The DSCSA, which added section 582, was passed after section 804 of the FD&C Act. As explained earlier, one reason that FDA believes that at this time it can implement section 804(b) through (h) of the FD&C Act is the DSCSA's electronic, interoperable system to identify, trace, and verify certain prescription drugs as they are distributed among pharmaceutical supply chain trading partners. Drugs that are imported under section 804 of the FD&C Act must meet the definition of a DSCSA ''product'' so that they are subject to all DSCSA identification, tracing, and verification requirements.

Under the proposed rule, a SIP Sponsor would need to explain in its SIP Proposal how it will address any concerns arising from the manufacture, storage, and transport of each eligible prescription drug, including concerns related to controlling contamination, preserving sterility, and ensuring stability. We considered excluding other categories of products from eligibility for importation, including: (1) Drug-device combination products that are approved under section 505 of the FD&C Act, whether all such products or certain specific ones, such as dry powder inhalers, metered-dose inhalers, and transdermal patch products; (2) inhaled drugs; (3) modified-release drugs; (4) sterile drugs; (5) ophthalmic drugs; (6) narrow therapeutic index drugs; (7) drugs with boxed warnings; and (8) drugs requiring special storage conditions. While each of these categories of products could pose potentially heightened safety concerns, we did not exclude these categories of products from eligibility in this proposed rule. Instead, we propose that FDA will determine whether a product that falls into one of these categories can be imported safely in the context of a specific SIP Proposal on a product-by-product basis. If the product to be imported is a combination product, this would include whether requirements specific to combination products would be met. We request comments on this approach.

The definition of ''prescription drug'' in section 804(a)(3) of the FD&C Act also excludes ''a drug which is a parenteral drug, the importation of which . . . is determined by the Secretary to pose a threat to the public health.'' We note that several categories of parenteral drugs—infused drugs, intravenously injected drugs, and drugs that are inhaled during surgery—are specifically excluded from importation under section 804 of the FD&C Act. We propose to exclude two other categories of parenteral drugs, intrathecally injected drugs and intraocularly injected drugs, from the definition of eligible prescription drug. Intrathecal and intraocular injection pose potentially significant risks because these routes of administration bypass some of the body's natural defenses. In fact, they pose more risks than intravenous injection, which is excluded by statute from importation under section 804 of the FD&C Act. We propose that other parenteral drugs that are not excluded from importation under section 804 of the FD&C Act or this proposed rule be evaluated in the same way as drugs with other routes of administration. An importation program that seeks to import any eligible prescription drug would have to demonstrate that it can do so without posing additional risk to the public's health and safety.

Consistent with section 804(f) of the FD&C Act, we propose to define ''Foreign Seller'' to mean an establishment within Canada engaged in the distribution of an eligible prescription drug that is imported or offered for importation into the United States. As discussed later in this document, under the proposed rule, Foreign Sellers would be required to be licensed by Health Canada as drug wholesalers and be registered with a provincial pharmacy regulatory authority to distribute HPFB-approved drugs. Under the proposed rule, a Foreign Seller could not be licensed to distribute drugs that are approved by countries other than Canada and that are not HPFB-approved for distribution in Canada. A Foreign Seller also must be registered with FDA as required by section 804 of the FD&C Act.

We propose to define ''Importer'' to mean a U.S. distributor that is a State- or FDA-licensed wholesale drug distributor or a State-licensed pharmacist and that is the U.S. owner of an eligible prescription drug at the time of importation of the drug into the United States.

We propose to define ''manufacturer'' to include an applicant, as defined in 21 CFR 314.3, who owns an approved NDA or ANDA for an eligible prescription drug, or a person who owns or operates an establishment that manufactures an eligible prescription drug. Manufacturer also means a holder of a drug master file containing information necessary to authenticate an eligible prescription

drug. These entities are those that would have the necessary information required of manufacturers in section 804 and the requirements proposed in this rule.

C. Section 804 Importation Program Proposals and Section 804 Pre-Import Requests

Subpart B of the proposed rule provides the procedures for the submission and evaluation of SIP Proposals for time-limited SIPs. Subpart B also covers the submission of Pre-Import Requests by the Importer, which would seek FDA's permission to begin importation of a particular eligible prescription drug(s). In addition, Subpart B outlines the procedures FDA proposes to use to authorize, revise, revoke, and extend SIPs.

Under the proposed rule, once a SIP receives FDA authorization, the SIP's Foreign Seller can purchase eligible prescription drugs with the intent to sell them to the SIP's Importer for importation under section 804 of the FD&C Act, and the SIP's Importer can seek FDA's permission to start importation of the drugs by submitting a section 804 Pre-Import Request, as described later in this document. The Pre-Import Request would include, among other things, a detailed description of the plan for conducting the testing required under section 804 of the FD&C Act and an attestation from the manufacturer that, but for the fact that it bears the HPFB-approved labeling, the HPFB-approved drug meets the conditions in the FDA-approved drug's NDA or ANDA.

Once FDA grants the section 804 Pre-Import Request, the Importer may start the process for the importation of an eligible prescription drug identified in the Pre-Import Request. The Agency's grant of the section 804 Pre-Import Request by itself does not confer any type of right to import. To be imported notwithstanding section 801(d)(1) of the FD&C Act, a particular importation would need to meet the requirements of section 804 and this regulation, including that the prescription drug comply with sections 501, 502, and 505 of the FD&C Act.

The Importer can choose to admit the drug(s) specified in the Section 804 Pre-Import Request to an authorized FTZ and then conduct the required testing and relabeling before offering the drug for entry. Alternatively, the Importer can make an entry and request, under section 801(b) of the FD&C Act and § 1.95 (21 CFR. 1.95), to recondition the drug(s), which would entail the required testing and relabeling. The results of the Statutory Testing would need to be reviewed and found acceptable by FDA before the drugs are relabeled and sold in the United States. We believe this is necessary to prevent having relabeled drugs refused entry and exported back to Canada where they may subsequently be sold illegally back into the United States or elsewhere.

1. The Section 804 Importation Program Proposal

The proposed regulations provide that a SIP Sponsor that seeks to implement a SIP to import prescription drugs from Canada would need to submit a proposal to FDA in electronic form to FDA's Electronic Submissions Gateway (ESG) or to an alternative transmission point identified by the Agency.

The proposal would need to include the following:

- A cover sheet with the name or names of the SIP Sponsor and co-sponsors, if any, and the name and contact information for the point of contact with FDA during its review of the proposal;
- A table of contents;
- An introductory statement that includes an overview of the SIP Sponsor's SIP Proposal; and
- The SIP Sponsor's importation plan.

The overview in the introductory statement would need to identify the State or a tribal or territorial governmental entity that is going to sponsor the SIP, along with any co-sponsors. The overview would also list each of the eligible prescription drugs that the SIP Sponsor seeks to import and provide the name and address of the manufacturer of the finished dosage form for each drug, as well as the name and address of the manufacturer of the active pharmaceutical ingredient (API), if that information is available to the SIP Sponsor. If the API information is not available to the SIP Sponsor at the time their proposal is submitted, the Importer would need to provide it later in the process, when it submits a Pre-Import Request.

The overview in the introductory statement would also need to provide the name and address of the Foreign Seller who will export the drug from Canada to the United States, as well as the name and address of the Importer in the United States. The overview would need to summarize how the SIP Sponsor will ensure (1) that the imported eligible prescription drugs meet the Statutory Testing requirements, (2) that the labeling requirements of the FD&C Act and this rule are met, (3) that the supply chain is secure, and (4) that the post-importation pharmacovigilance and other requirements of the FD&C Act and this rule are met. Finally, the overview would need to summarize the proposer's reasons for expecting that the significant reduction in cost from the importation accrues to the American consumer.

Under the proposed rule, the content of a SIP Proposal would include the following. The SIP Proposal would need to identify the State or tribal or territorial governmental entity that is going to sponsor the SIP, along with its co-sponsors, if any. The SIP Proposal would also need to identify the licensed wholesale drug distributor or licensed pharmacist that will act as the Importer and explain its legal relationship to the SIP Sponsor. Only a pharmacist or wholesaler could import drugs under section 804 of the FD&C Act and this rule. The SIP Proposal would need to identify each of the other entities in the supply chain and explain their legal relationship to the SIP Sponsor, if any, including the finished dosage form manufacturer and the Foreign Seller. The SIP Proposal would need to state and provide supporting evidence to establish that the Importer and the Foreign Seller meet all the requirements in section 804 and this proposed regulation.

FDA proposes to require that a SIP Proposal include the Health Canada inspectional history for the previous 5 years, or if the Foreign Seller has been licensed for less than 5 years, for the duration of its period of licensure, and the State and Federal inspectional history for the Importer for the previous 5 years, or if the Foreign Seller has been licensed for less than 5 years, for the duration of its period of licensure. The SIP Sponsor would also need to provide an attestation containing a complete disclosure of any past or pending civil penalties or violation, or criminal convictions or violations, of applicable State, Federal, or Canadian laws regarding drugs or devices against the Foreign Seller or Importer or an affirmation and attestation that the Foreign Seller or Importer has not been involved in, or convicted of, any such criminal or prohibited acts. Such attestation would need to include principals, any shareholder who owns 10 percent or more of outstanding stock in any non-publicly held corporation, directors, officers, and any facility manager or designated representative of such manager. We also propose that the SIP Proposal include a list of all disciplinary actions, along with the date of and parties to any action, imposed against the Foreign Seller or the Importer by State, Federal, or Canadian regulatory bodies, including any such actions against the principals, owners,

directors, officers, or any facility manager or designated representative of such manager over the previous 7 years. We seek comment on whether the rule should require additional or alternative background information and on whether the background information requirement should cover additional or alternative individuals or entities.

As part of demonstrating that the proposed importation will pose no additional risk to the public's health and safety, the SIP Proposal would need to set forth all the steps the SIP Sponsor would need to take to ensure that the supply chain is secure, including ensuring that the Foreign Seller is able to serialize the drugs to be imported with an SSI. The SIP Proposal would need to include the steps that the SIP Sponsor will take to ensure that the storage, handling, and distribution practices of supply chain participants, including transportation providers, maintain and ensure the quality and security of the drugs. The storage and handling conditions and practices must meet the minimum requirements of 21 CFR part 205. The SIP Proposal would also need to set forth the Importer's responsibility for screening the drug(s) that it imports for issues or problems, including whether they are adulterated, counterfeit, damaged, tampered with, or expired, and the Foreign Seller's and the Importer's responsibilities for adverse event, medication error, field alert reports, or other reporting, in addition to a detailed plan for effectuating any recalls. The SIP Sponsor would have to explain how it will obtain recall or market withdrawal information and how it will ensure that recall or market withdrawal information is shared among the SIP Sponsor, the Foreign Seller, the Importer, and FDA and provided to the manufacturer.

The SIP Proposal would also need to identify the FDA-registered repackager or relabeler in the United States that will relabel the imported drugs with the required U.S. labeling, including the carton and container labels, prescribing information, and any patient labeling, such as medication guides, instruction for use documents, and patient package inserts. The proposed rule would also require that the SIP Proposal describe the ways in which the SIP Sponsor will educate pharmacists, healthcare providers, and patients about its SIP. We seek comment on whether a SIP Proposal should also be required to describe the SIP Sponsor's plan for ensuring that the FDA-approved patient labeling is dispensed to patients with the drug imported under section 804 of the FD&C Act. In its proposal, the SIP would need to provide supporting evidence to establish that the repackager or relabeler is registered with FDA, as required by section 510(b) of the FD&C Act (21 U.S.C. 360(b)) and in accordance with part 207 (21 CFR part 207), and that any objectionable conditions or practices identified during its most recent FDA inspection have been addressed satisfactorily. While an imported drug would need to be relabeled, it would need to remain in the manufacturer's original container-closure system and not be repackaged, except to the limited extent necessary to relabel it, as described in this proposed rule.

Under the proposed rule, the SIP Proposal would be required to identify each HPFB-approved prescription drug that the SIP Sponsor seeks to import. The SIP Proposal would also be required to include the proprietary and established names of the HPFB-approved product and of its FDA-approved counterpart and confirm that the FDA-approved drug is currently marketed. It would need to provide a description of all the information that is available about the HPFB-approved product and its FDA-approved counterpart and would be required to include the name and quantity of the active pharmaceutical ingredient(s) of the two drug products, the inactive ingredients of the two products, and the dosage form of the two drug products. The proposal would also need to include the HPFB-approved product's drug identification number (DIN), and the FDA-approved product's National Drug Code (NDC) and NDA or ANDA numbers. The proposal would also need to include the HPFB-approved drug's labeling. Under the proposed rule, the proposal would be required to include the FDA-approved drug's labeling and the FDA-approved labeling with the revisions necessary for the HPFB-approved drug to meet the requirements of this rule, as well as a side-by-side analysis of the FDA-approved drug's labeling and the proposed labeling to help demonstrate that the applicable FDA labeling requirements and the requirements of this rule are met.

The proposed rule would also require that the proposal identify the establishment where the active ingredient for each drug is manufactured, if this information is available, and the establishment where the finished dosage form for each drug is manufactured, if this information is available. This information is important for FDA to adequately assess whether the eligible prescription drug meets the conditions in an approved NDA or ANDA. If this information is not available to the SIP Sponsor at the time that the proposal is submitted, it would need to be provided later by the Importer in the Pre-Import Request.

The Statutory Testing that would be done under the proposed rule should be described in as much detail as possible in the SIP Proposal. The proposal would also need to explain how the SIP Sponsor will ensure that any information that the manufacturer provides to the Importer to allow the Importer to conduct the Statutory Testing would be kept in strict confidence and used only for purposes of testing or otherwise complying with the FD&C Act, as required by section 804(e)(2)(B). The information that the manufacturer provides must not be disseminated except to the qualified laboratory that will test the drug and to FDA, and the SIP Sponsor would need to explain how it will ensure that the information is not disseminated to any person by the qualified laboratory. If confidential manufacturer information is disclosed beyond the parameters described above, FDA will terminate the SIP. Moreover, a violation of any of these regulations, including this provision, is a prohibited act under section 301(aa) of the FD&C Act. An Importer that fails to comply with the requirement that the manufacturer's information be kept in strict confidence and be used only for testing or otherwise complying with the FD&C Act can be imprisoned for not more than 10 years under section 303(b)(6) of the FD&C Act (21 U.S.C. 333(b)(6)), fined under 18 U.S.C. 3571, or both. We seek comments on this approach.

The proposal would also need to indicate which laboratory in the United States will conduct the testing described in section 804(d)(1)(J) and (L) of the FD&C Act, which is discussed later in this document, and it would need to establish that the laboratory is located in the United States and is qualified to conduct the tests. As discussed later in this document, we propose that when FDA authorizes a SIP Proposal, FDA would thereby approve the laboratory identified in the proposal as a ''qualifying laboratory'' for purposes of section 804, as required by section 804(a)(4) of the FD&C Act. To be approved as a qualifying laboratory, a laboratory would need to have ISO 17025 accreditation and comply with the applicable elements of the pharmaceutical current good manufacturing practice (CGMP) requirements in parts 210 and 211 (21 CFR parts 210 and 211). It would need to have an FDA inspection history and satisfactorily addressed any objectionable conditions or practices

identified during its most recent FDA inspection.

We recognize that not all data and information needed to show that a HPFB-approved drug meets the conditions in an FDA-approved NDA or ANDA may be available to a SIP Sponsor at the time that it submits its SIP Proposal. For example, testing results would not be available until the Importer receives a shipment of an eligible prescription drug and conducts the Statutory Testing. FDA may authorize a SIP based on the available information about a drug. An Importer will not be able to sell a drug imported under section 804 of the FD&C Act in the United States until the testing described in section 804(d) is completed satisfactorily, and the Importer has secured the information from the manufacturer described in section 804(e) that is needed to show that the drug meets the conditions of an approved NDA or ANDA and poses no additional risks to the public's health and safety.

Finally, the SIP Proposal would need to explain how the SIP Sponsor expects that the SIP would result in a significant reduction in the cost to the American consumer of the prescription drugs that the SIP Sponsor seeks to import. The explanation would need to include any assumptions and uncertainty, and it would need to be sufficiently detailed to allow for a meaningful evaluation. We propose that whether a reduction in cost is significant be determined in the context of considering a specific proposal. We seek comment on the factors that should be considered in determining whether a reduction in the cost of covered products is significant.

To demonstrate expected cost savings, a SIP Sponsor could compare anticipated acquisition costs or consumer prices per unit of each drug that the SIP Sponsor is seeking to import. For example, a SIP Sponsor could compare the anticipated acquisition cost per unit of the HPFB-approved drug to the acquisition cost per unit of the FDA-approved drug. A SIP Sponsor could also compare the current retail cash price of the drugs. We seek comment on these and other relevant measures that may be available to SIP Sponsors during proposal development.

We also seek comments on what mechanisms SIPs could use to ensure that there is a significant reduction in the cost of covered products to the American consumer and comments on what, if any, additional showing SIP Sponsors would need to make if the cost savings do not go directly to consumers. If the cost savings do not go directly to consumers directly because, for example, they accrue to a healthcare provider or payor, the SIP Proposal would need to show that there is a significant reduction in the cost of covered products to the American consumer.

We anticipate that some SIP Sponsors may seek to import drugs to be used by patients in State-run programs in which participants do not directly pay the cost of drugs. In such cases, a SIP Sponsor could submit information about whether cost-sharing expenses are reduced for the participants, or whether the program will result in cost savings that are passed on to consumers in other ways, such as increasing the number of people who can be covered by a State program, or increasing the availability of drugs covered by the program. We seek comment on this and on what other cost-related information SIP Sponsors could provide where drugs would be imported for use by patients in State-run programs.

The SIP Sponsor would be responsible for ensuring that the SIP and each entity that participates in the SIP complies with section 804, with other applicable sections of the FD&C Act, and with this and other applicable regulations for the entire length of the approval period. The SIP Sponsor should explain in detail how it will do so in the SIP Proposal.

2. Review and Authorization of Section 804 Importation Program Proposals

FDA will review and approve or deny SIP Proposals. We solicit comments on what the timeline for such review should be, and on what type and frequency of communication between FDA and SIP Sponsors would be helpful and efficient. We also seek comment on whether SIP Proposals should be addressed on a first-come, first-served basis, or whether they should be prioritized. If they should be prioritized, we seek comment on what the basis for prioritization should be.

As noted previously, we recognize that at the time of submission, the SIP Sponsor may not know whether a drug meets the conditions in an FDA-approved NDA or ANDA. FDA will review, among other things, the information that the SIP Sponsor is able to provide about each of the drugs that the SIP Sponsor seeks to import to confirm that each is approved by both HPFB and FDA, that each FDA-approved drug is currently marketed in the United States, and that none of the drugs fall into any of the exclusions from the definition of eligible prescription drug. FDA will also review the proposal to ensure that the requirements of the FD&C Act and this rule are met, and specifically that the proposed supply chain, the proposed plan to relabel the eligible prescription drugs, and the proposed pharmacovigilance measures meet the requirements of the FD&C Act and this rule. FDA intends to call on other divisions of HHS, such as ASPE, to assist with the review and evaluation of the components of the proposal, and to refer questions to such divisions as appropriate, that relate to the price of the drugs to be imported and to the steps that will be taken to ensure that there is a significant reduction in the cost of drugs to consumers. FDA and/or HHS may issue guidance on this topic as appropriate.

Where a SIP Proposal meets the requirements of section 804(b) through (h) of the FD&C Act and the requirements in the proposed rule, FDA may nonetheless decide, in its discretion, not to authorize the SIP Proposal. Among other reasons, FDA may decide not to authorize a SIP Proposal because of potential safety concerns with the SIP, because of the relative likelihood the SIP would not result in significant enough cost savings, or because FDA needs to limit the number of authorized SIPs to effectively and efficiently run the program or in light of other resource demands.

3. The Section 804 Pre-Import Request

After FDA authorizes a SIP, the Foreign Seller can proceed to purchase one or more of the eligible prescription drugs included in the SIP Proposal directly from the manufacturer with the intent to sell them to the Importer. The Importer can then request that the manufacturer agree to conduct the testing set forth in section 804(d)(1)(J) and (L) of the FD&C Act. If the manufacturer declines to do so, the manufacturer must provide the information needed to conduct the testing, as required by section 804(e)(2) of the FD&C Act. The Importer can then submit a section 804 Pre-Import Request to the ESG or other transmission point identified by the Agency.

The Importer would need to submit a section 804 Pre-Import Request at least 30 days prior to the scheduled date of arrival of a shipment containing an eligible prescription drug(s) at the CBP port of entry authorized by FDA, or entry for consumption in ACE of one or more batches of an eligible prescription drug(s) covered by a SIP, whichever occurs first. FDA believes at least 30 days will be needed for FDA to sufficiently review the information provided. Under the proposed process, the Importer would not be permitted to

ship an eligible prescription drug into the United States until a section 804 Pre-Import Request that includes that specific drug was granted by FDA.

Under the proposed rule (§ 251.5), a complete Pre-Import Request would include, at a minimum: Identification of the Importer, including Importer name, business type (wholesale distributor or pharmacist), U.S. license number or numbers and State or States of license, business address, unique facility identifier if required to register with FDA as an establishment under section 510 of the FD&C Act or FDA establishment identification number if not required to register as an establishment, and name of a contact person with their email and phone number; identification of the FDA-authorized SIP Proposal including the name of the SIP, the name or names of the SIP Sponsor and co-sponsors, if any, business address, and name of a contact person, with their email and phone number; identification of the Foreign Seller, including the name of the Foreign Seller, business address, unique facility identifier, any license numbers issued by Health Canada or a provincial pharmacy regulatory body, and the name of a contact person with their email and phone number; and identification and description of the eligible prescription drug or drugs covered by the Pre-Import Request including the following information: Name of the HPFB-approved drug or drugs (established and/or trade), DIN, and complete product description including strength, description of dosage form, and route of administration; API information, including name of API, manufacturer of API and its unique facility identifier, and amount of API and unit measure in each eligible prescription drug; name (established and/or trade) of the FDA-approved counterpart drug or drugs and their NDA or ANDA number or numbers; manufacturer of the eligible prescription drug with the business address and unique facility identifier; copies of the invoice and any other documents related to the manufacturer's sale of the drugs to the Foreign Seller provided by the manufacturer to the Importer and copies of the same documents provided by the Foreign Seller to the Importer; quantity, listed separately by dosage form, strength, batch and lot or control number assigned by the manufacturer to each eligible prescription drug intended to be imported under this Pre-Import Request compared to the quantity of each batch and lot or control number originally received by the Foreign Seller from the manufacturer and the date of such receipt; expiration date of each HPFB-approved drug, listed by lot or control number; expiration date to be assigned to each eligible prescription drug when relabeled by the Importer with a complete description of how that expiration date was calculated to comply with the FDA-approved drug's NDA or ANDA; NDC proposed for assignment by the Importer for each eligible prescription drug to be imported; and FDA product code for each eligible prescription drugs to be imported.

A Statutory Testing plan would also be part of the request, including: A description of how the samples will be selected from a shipment for the Statutory Testing; the name and location of the qualifying laboratory in the United States that will conduct the Statutory Testing; and if the importer will be conducting the Statutory Testing, or a description of the testing method(s) that will be used to conduct the Statutory Testing. If the manufacturer will be conducting the Statutory Testing, the description of the testing methods can be submitted by the manufacturer to FDA directly, as discussed later in this document. An attestation from the manufacturer, which is described in more detail later in this document, that, but for the fact that it bears the HPFB-approved labeling, the eligible prescription drug meets the conditions in the FDA-approved drug's NDA or ANDA, would also be included. If the manufacturer conducts the Statutory Testing, the manufacturer would need to provide the attestation to FDA. If the Importer conducts the Statutory Testing, the manufacturer would need to provide the attestation to the Importer.

Information related to the Importation would be provided, including the location of the eligible prescription drugs in Canada and anticipated date of shipment (date eligible prescription drug or drugs will leave their location in Canada); name, address, email, and telephone number of the foreign shipper; anticipated date of export from Canada and Canadian port of exportation; anticipated date of arrival at port(s) authorized by FDA to import eligible prescription drugs under section 804; the name, address, FDA establishment identification number, and telephone number of the warehouse, location within a specific FTZ, or other secure distribution facility controlled by or under contract with the Importer where the eligible prescription drug(s) will be stored pending testing, relabeling, and FDA determination of admissibility; and information regarding the facility where the relabeling and any limited repackaging activities will occur for all eligible prescription drug(s) covered by this Pre-Import Request, including: (1) The facility's unique facility identifier; (2) the facility's name, address, and FDA establishment identification number; (3) the anticipated date the relabeling and any limited repackaging will be completed; and (4) information about where the relabeled drug will be stored pending distribution, including the FDA establishment identification number of the storage facility, if available.

FDA's grant of a section 804 Pre-Import Request does not constitute an admissibility determination by the Agency of any of the drugs covered by the Request. When a Pre-Import Request is granted by FDA, that Pre-import Request would cover subsequent shipments of the eligible prescription drug(s) identified in the Agency's grant of that Request provided that the rest of the information contained in the Pre-Import Request, with the exception of the anticipated dates of shipment and export, is the same. We seek comment on this approach.

When the Agency grants a section 804 Pre-Import Request, it will specify an FDA field laboratory to which the Importer would need to submit three sets of the samples that the Importer sends to the qualifying laboratory to enable FDA to conduct the Statutory Testing as FDA deems warranted.

4. Importation

When goods are imported into the United States, they must be *entered* at one of the CBP ports of entry (sea, land, rail, and air). The term *entry* generally refers to the information or documentation that an importer of record, or an authorized customs broker, must file with CBP for importing merchandise into the United States. A SIP Importer will be, and must qualify as, the importer of record for eligible prescription drugs imported under section 804.

The proposed rule would require that an entry for consumption of an eligible prescription drug under an authorized SIP be filed electronically in ACE, or any other Electronic Data Interchange (EDI) system authorized by CBP. Currently, ACE is the sole EDI system authorized by CBP for electronic entry of FDA-regulated products. ACE serves as the ''single window'' through which an import filer submits the data elements required for an import entry, including data elements designated by a Partner Government Agency (PGA). As a PGA, FDA has designated a PGA Message Set in ACE for FDA-regulated

products. This message set contains both required and optional data elements to assist us in our admissibility review of FDA-regulated articles. In the **Federal Register** of November 29, 2016 (81 FR 85854), FDA published a final rule, effective December 29, 2016, entitled ''Submission of Food and Drug Administration Import Data in the Automated Commercial Environment,'' which requires certain data elements that are material to our import admissibility review be submitted in ACE or any other EDI system authorized by CBP, at the time of entry. The rule was intended to facilitate automated ''May Proceed'' determinations by the Agency for low-risk FDA-regulated products which, in turn, allows the Agency to focus our limited resources on products that may be associated with a greater public health risk. The final rule is codified in subpart D, 21 CFR part 1.

All shipments containing eligible prescription drugs to be imported under an authorized SIP would need to arrive and be entered at the CBP port of entry that is authorized by FDA. When an entry for consumption containing an FDA-regulated product is processed by CBP, CBP relays the data in the PGA Message Set to FDA using an electronic interface with FDA's import processing system, currently the Operational and Administrative System for Import Support (OASIS). The import filer need only submit this entry information once in the ACE system, provided that the information submitted in ACE is accurate. ACE entries are electronically screened in OASIS against criteria developed by FDA. FDA's Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT) is a risk-based electronic screening tool for OASIS that performs this initial electronic screening to assist FDA entry reviewers by evaluating the potential risks associated with each article and identifying those articles that may present a higher public health risk for further examination by FDA.

As discussed, the drugs covered by a SIP can be imported using two proposed pathways: Admission to an FTZ with later entry for consumption and filing in ACE when compliant, or filing an entry for consumption in ACE with a request to bring the eligible prescription drugs into compliance with the FD&C Act under section 801(b) of the FD&C Act and § 1.95. The plan submitted under §§ 1.95 and 1.96 for the drugs would need to include the testing and relabeling required under this proposed rule.

FDA proposes that the testing and relabeling of a shipment, as described in the Section 804 Pre-Import Request, take place after the shipment has arrived in the United States, but before it can be distributed in the United States. This will enable the Importer to inspect the Canadian labeling and packaging as part of its screening obligations. It will also place the responsibility on the Importer to ensure that the samples submitted for testing are representative of the actual shipment. The Importer will also be responsible for ensuring that the relabeling and the product identifier are compliant with U.S. laws and regulations after FDA has determined that the testing results are acceptable and before an eligible prescription drug is sold in the United States. Placing these responsibilities on Importers will aid FDA in its efforts to monitor compliance with and enforce the requirements of the FD&C Act and this proposed rule when it is finalized.

As discussed earlier, under the proposed rule, an Importer could admit an eligible prescription drug to an FTZ in the United States for the purpose of completing the required testing and relabeling. An FTZ is a secure area under the supervision of CBP. FTZs were established in the United States under the Foreign Trade Zones Act of 1934 (19 U.S.C. 81a-81u) for importers to hold or otherwise manipulate goods without being subject to certain CBP requirements including customs entry (articles are ''admitted'' to an FTZ and not entered), payment of duty, tax, or bond. Since these FTZ Act exclusions only affect the application of certain CBP laws, FDA-regulated articles that are brought into an FTZ remain subject to other U.S. laws and regulations affecting imported goods. Therefore, placement of eligible prescription drugs in an FTZ does not affect FDA's jurisdiction and inspectional authority over them. Samples of the eligible prescription drug or drugs can be removed from the FTZ for the purpose of the required testing by a qualifying laboratory and for providing samples to FDA as proposed in this rule.[3]

If the Importer pursues the second pathway, filing an entry for consumption in ACE and requesting to bring the drugs into compliance, under section 801(b) of the FD&C Act, the Importer would submit Form FDA 766, to the relevant FDA Imports Division Director. After review, the Director would notify the Importer of FDA's approval or disapproval of the plan to bring the drugs into compliance. If approved, the FDA notice of approval will specify the conditions to be fulfilled and the time limit for fulfilling them (see § 1.96). Under the proposed rule, the Importer would need to keep the product at a designated secured warehouse, and under appropriate environmental conditions to maintain the integrity of the products, until FDA issues an admissibility decision. The secured warehouse would need to be within 30 miles of the authorized Port of Entry to facilitate FDA oversight, including the collection and examination of samples.

After the authorized plan has been completed, the Importer will complete the section entitled ''Importer's Certificate'' on Form FDA 766 and provide that certification to the relevant FDA Imports Division Director. At this point, FDA may choose to conduct a followup inspection and/or sampling to determine compliance with the terms of the authorized plan. If FDA determines that the conditions of the authorized plan have been fulfilled, the Agency will notify the Importer through a Notice of Release indicating that the admissible portion of the shipment is no longer subject to detention or refusal of admission. This Notice is usually identified as ''Originally Detained and Now Released.'' A copy of the Notice is sent to the owner or consignee; CBP would then be notified electronically of FDA's ''May Proceed'' determination. If there is a non-admissible portion of the shipment, that portion can be destroyed, or re-exported by the Importer under FDA or CBP supervision (21 U.S.C. 381(a)). A Notice of Refusal of Admission will be issued to the Importer for the rejected portion.

Under the proposed rule, FDA would intend to refuse admission into the United States under section 801(a)(3) of the FD&C Act if: (1) 6 Months have passed since the entry date of the shipment; (2) the conditions of the SIP or the section 804 Pre-Import Request are not met; or (3) the drug otherwise appears to be adulterated, misbranded or unapproved in violation of section 505 of the FD&C Act. If FDA refuses admission into the United States under section 801(a)(3) of the FD&C Act, the drug should be exported or destroyed by the Importer within 90 days of the refusal.

The proposed rule would require that an entry for consumption be made electronically in ACE for any shipment containing an eligible prescription drug. The port of arrival and port of entry would be limited to a CBP port that is authorized by FDA, so that FDA can

[3] Any such samples removed from the FTZ for testing in the customs territory of the United States will have to be entered using normal Customs procedures.

ensure that it has adequate resources at the port to process the arrival and entry of shipments that contain an eligible prescription drug and to perform sampling of any such shipment, if necessary. The following data elements would be required to be submitted in ACE at the time of entry:

a. The unique facility identifier of the Foreign Seller;

b. The Importer's NDC for each eligible prescription drug;

c. The NDA or ANDA number of each eligible prescription drug's FDA-approved counterpart;

d. The lot or control number assigned by the manufacturer for each eligible prescription drug;

e. The FDA Quantity, which is the quantity of the eligible prescription drug or drugs in an import line delineated by packaging level, including the type of package from the largest packaging unit to the smallest packaging unit; the quantity of each packaging unit; and the volume and/or weight of each of the smallest of the packaging units; and

f. The Pre-Import Request number.

FDA would require submission of these data elements in ACE at the time of entry to facilitate the importation of eligible prescription drugs as part of a SIP. The proposed rule would clarify that for eligible prescription drugs the unique facility identifier of the registered Foreign Seller and the NDC proposed for assignment by the Importer be submitted in ACE at the time of entry. The application number of the NDA or ANDA for the FDA-approved drug that is the counterpart of the eligible prescription drug would also be submitted in ACE. This information will help FDA to verify that an entry for consumption contains eligible prescription drugs. The lot or control number of each eligible prescription drug would be required to be submitted by the Importer to FDA under this proposed rule, in accordance with section 804(d)(1)(H) of the FD&C Act.

In accordance with section 804(d)(1)(D) of the FD&C Act, we propose to require the Importer submit information on the quantity of the eligible prescription drug that is shipped in ACE at the time of entry. FDA is proposing to require that quantity include the quantity of each layer/level of packaging of the eligible prescription drug(s); the unit of measure, which is the description of each type of package; and the volume and/or weight of each of the smallest of the packaging units. The quantity would be required to be submitted in decreasing size of packing unit (starting with the outermost/largest package and ending with the innermost/smallest package).

Information on the quantity of each layer or level of packaging will help the Agency identify an article being imported or offered for import as an eligible prescription drug. Although CBP and FDA utilize Harmonized Tariff Schedule codes to generally identify which imports are subject to an FDA admissibility review, these codes are often not sufficient to specifically identify a product for FDA decision making. There may be instances in which a drug's packaging does not meet the conditions of the approved NDA or ANDA. Packaging can affect the safety of an FDA-regulated product, for example, where an article is represented as ''sterile.'' Submission of the quantity, including of each layer or level of packaging, in ACE at the time of entry would assist the Agency should it need to perform field examinations, label examinations, sample collections, detentions, or refusals.

Finally, the Pre-Import Request number, which FDA would provide to the Importer when we grant the Pre-Import Request, would allow FDA's review staff to verify that a Pre-import Request covering the eligible prescription drugs in the shipment has been approved by FDA.

5. Submission and Review of Testing Results

Once the testing described in section 804(d)(1)(J) and (L) of the FD&C Act is complete, the results would be submitted to FDA, along with a Certificate of Analysis (COA), selection method for the samples, the testing methods used, laboratory records required by the proposed rule in accordance with section 804(d)(1)(L), and any other documentation demonstrating that the testing was conducted at a qualifying laboratory and otherwise meets the requirements in section 804(e)(1) of the FD&C Act. If the Importer performs the Statutory Testing after the shipment has been admitted to an FTZ but before filing entry for consumption, the Importer would be required to submit the required testing results and records to FDA in electronic form to the ESG or to an alternative transmission point identified by FDA, prior to relabeling the drugs. If the Importer performs the testing at a qualifying laboratory as part of an FDA-approved plan under §§ 1.95 and 1.96, the Importer would be required to submit the required testing results and records as part of the Importer's plan prior to relabeling of the drugs. If a manufacturer performs the Statutory Testing, the manufacturer would submit the test results and records to FDA directly in electronic form to the ESG or to an alternative transmission point identified by FDA. FDA would review the test results and records and notify the Importer whether the test results are acceptable to the Agency and then the Importer would cause the drugs to be relabeled in accordance with the proposed rule. Under the proposed rule, if the data and information that the manufacturer or Importer submits do not establish that the drug the SIP Sponsor seeks to import is authentic, not degraded, and meets the conditions of an FDA-approved NDA or ANDA, the drug cannot be relabeled, and FDA would refuse admission of the drug. FDA proposes to require that the relabeling only take place after the Agency has accepted the test results to avoid potential diversion that could occur if eligible prescription drugs are relabeled for the U.S. market and then fail the testing requirements, which could happen before or after export of the refused drugs to Canada.

6. Period of Authorization of Section 804 Importation Programs

Under the proposed rule, SIPs would initially be authorized for a 2-year period, with the possibility of extensions for additional 2-year periods. Each 2-year period would begin when the Importer files an electronic import entry for consumption for its first shipment of drugs. If the Importer does not file an electronic import entry for consumption for a shipment of eligible prescription drugs within 1 year of the date the SIP is authorized by FDA, the SIP Sponsor would have to submit, and FDA would have to authorize, a new SIP Proposal before it could begin the importation process.

We believe that SIPs should be given a 2-year period before re-authorization is required to continue in the program because we believe that this will provide sufficient time for SIP Sponsors to demonstrate that they can in fact import drugs from Canada with no additional risk to the public's health and safety and that such importation in fact results in a significant reduction in the cost of covered products to the American consumer. We believe that SIPs should terminate after 2 years unless re-authorized because importation under section 804 is novel. After 2 years, we will have the data necessary to evaluate a SIP's success. We will be able to determine if the safeguards in section 804 of the FD&C Act and in this rule, should it be finalized, are working and, if they are, if there are requirements that could be amended or streamlined. We will be

able to compare and contrast the approaches taken by different SIP Sponsors. FDA will also take the opportunity to assess any changes in the marketplace that result from section 804 importation. For example, we will be able to determine whether section 804 importation resulted in changes in the price or supply of drugs in Canada or the United States, whether there are newly erected or existing barriers to section 804 importation, and whether and how bad actors respond to section 804 importation. FDA seeks comment on this approach, including whether 2 years is the appropriate initial period of time for a SIP, whether 2-year re-authorization periods are appropriate, and whether there should be a limit on the number of re-authorization periods.

7. Modification or Extension of Section 804 Importation Programs

Under the proposed rule, if a SIP Sponsor wishes to make a change to an authorized SIP (for example, to amend the list of eligible drugs it seeks to import or to work with a different Foreign Seller, Importer, or qualifying laboratory), the SIP Sponsor would be required to submit a supplemental proposal for FDA's consideration. As noted earlier, if a SIP Sponsor wishes to work with more than one Foreign Seller or Importer, it must first demonstrate that it has consistently imported eligible prescription drug(s) in accordance with section 804 and this rule. We generally expect that a SIP Sponsor would have submitted its first quarterly report to FDA before it submits a supplement to the SIP Proposal seeking to add an additional Foreign Seller or Importer.

If FDA authorizes the supplemental proposal, a new Pre-Import Request would be required for the next shipment. Under the proposed rule, a SIP Sponsor would not be permitted to make any changes or permit any changes to be made to the SIP without first securing FDA's authorization.

Under the proposed rule, an authorized SIP Sponsor would be able to submit a proposal asking for authorization to extend the SIP for additional 2-year-long periods beyond the initial 2-year long implementation period. To be eligible for extension, a SIP would need to be up to date on all the information and records-related requirements of section 804 and this rule. A request for authorization to extend a SIP should be submitted at least 3 months before the SIP's 2-year-long authorization period expires.

8. Denial, Suspension, or Revocation of Authorization of Section 804 Importation Programs

If at any point in the course of its review of a SIP Proposal, FDA finds minor, correctable deficiencies, the Agency intends to make a reasonable effort to promptly communicate them to the SIP Sponsor so that they can be corrected in a timely way. However, FDA may deny a request for authorization, modification, or extension of a SIP in its discretion, as described elsewhere in this proposed rule, including if a proposed SIP does not meet the standard for authorizing a SIP under this proposed rule.

Under the proposed rule, FDA can revoke the authorization of a SIP in whole or in part, including with respect to one or more drugs in the SIP, at any time for any reason in FDA's discretion, including if, for example: (1) FDA finds that the SIP Proposal contained an untrue statement of material fact or omitted material information required by this part; (2) the SIP no longer meets the requirements of section 804 of the FD&C Act or the standard for authorizing a program under this proposed rule; (3) continued implementation of the SIP will pose additional risk to the public's health and safety; (4) continued implementation of the SIP will not result in a significant reduction in the cost of covered products to the American consumer; or (5) continued monitoring of the SIP imposes too much of a drain on Agency resources or is inconsistent with the Agency's prioritization of resources.

Under the proposed rule, if at any point a SIP Sponsor has reason to suspect that a drug, manufacturer, Foreign Seller, Importer, qualifying laboratory, or other participant in or element of the supply chain that FDA initially authorized does not in fact meet the requirements of section 804 or any other applicable requirements of the FD&C Act, or of any applicable regulation, including this rule, the SIP Sponsor would be required to stop importation immediately, notify FDA, and demonstrate to FDA that importation has in fact been stopped pending an investigation. In addition, FDA may also suspend a SIP under such circumstances, or under other circumstances in FDA's discretion, which would prevent further importation of drugs under it. Under certain circumstances set forth in section 804(g) of the FD&C Act, FDA is required to suspend importation. Section 804(g) provides that the Secretary shall require that importations of a specific prescription drug or importations by a specific importer under subsection (b) be immediately suspended on discovery of a pattern of importation of that specific prescription drug or by that specific importer of drugs that are counterfeit or in violation of any requirement under this section, until an investigation is completed and the Secretary determines that the public is adequately protected from counterfeit and violative prescription drugs being imported under subsection (b).

In addition, under the proposed rule, where a SIP Sponsor fails to timely extend its authorized SIP, the SIP would be considered expired. The sponsor of an expired SIP would need to submit a new SIP Proposal because FDA may be unable to confirm that the SIP Sponsor continues to meet all the necessary requirements. FDA is also proposing to terminate a SIP upon request from the SIP Sponsor when the request includes a notice of the SIP Sponsor's intent to discontinue its activities. The sponsor of an expired SIP would be required to submit a new SIP Proposal should it decide to resume section 804 importation activities.

9. Monitoring and Compliance

SIP Sponsors will be responsible for ensuring that all the participants in a SIP comply with the requirements of section 804 of the FD&C Act and this rule. As noted earlier, a SIP Sponsor would need to develop a compliance plan and describe it in detail in their SIP Proposal for FDA's review and authorization. We ask for comment on what elements should be included in a SIP's compliance plan. Among other things, such a plan could require: (1) A description of the division of responsibilities between co-sponsors, if any, (2) the creation of written compliance policies, procedures, and protocols; (3) the provision of education and training to ensure that Foreign Sellers, Importers, qualifying laboratories, and their employees understand their compliance-related obligations; (4) the creation and maintenance of effective lines of communication, including a process to protect the anonymity of complainants and to protect whistleblowers; and/or (5) the adoption of processes and procedures for uncovering and addressing noncompliance or misconduct. We seek comment on what alternate or additional requirements might be appropriate if a SIP is co-sponsored.

FDA's usual compliance and enforcement tools apply to SIP participants. We will retain our usual rights to conduct pre-authorization,

surveillance, and risk-based inspections under section 704 of the FD&C Act. In addition, the proposed rule would require that SIP Sponsors and other SIP participants agree to submit to audits of their books and records and inspections of their facilities as a condition of participation in a SIP. If a SIP Sponsor, manufacturer, Foreign Seller, Importer, qualifying laboratory, or other participant in or element of the supply chain delays, denies, or limits an inspection, or refuses to permit entry or inspection of their facility or their records, any drug that they have held would be deemed to be adulterated (FDA, 2014. ''Guidance for Industry: Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug Inspection.'' (Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/circumstances-constitute-delaying-denying-limiting-or-refusing-drug-inspection*). FDA could also suspend the SIP, in whole or in part, immediately in that circumstance.

FDA can take action through, *e.g.,* warning letters, seizure, and detention, to address failure to abide by applicable requirements, including requirements in this rule, when finalized, and requirements concerning product quality. FDA would also retain the authority under section 801 of the FD&C Act to refuse admission to a drug that does not comply with the FD&C Act or the rule, including, under section 801(a)(3) of the FD&C Act, the authority to refuse entries of drugs that appear to be adulterated, misbranded, including if it does not comply with the product identifier requirement of section 582 of the FD&C Act, or in violation of section 505 of the FD&C Act.

D. Requirements for Foreign Sellers

A ''Foreign Seller'' under section 804 and this proposed rule is an establishment within Canada engaged in the distribution of an eligible prescription drug that is imported into the United States. Under the proposed rule, the Foreign Seller would buy eligible prescription drugs directly from the manufacturers and then sell them directly to the Importer. The Foreign Seller would also be responsible for relabeling the drug product solely to affix or imprint the SSI on each package and homogenous case of the eligible prescription drug(s).

The SIP Sponsor would be required to ensure that the Foreign Seller meets all the licensing and registration requirements set forth in the statute and this proposed rule. We propose to require that Foreign Sellers have an active drug establishment license as a wholesaler from Health Canada. We also propose to require that they be registered with provincial pharmacy regulatory authority to distribute HPFB-approved drugs. In addition, we propose that a Foreign Seller could not be licensed to distribute drugs that are approved by countries other than Canada and that are not HPFB-approved for distribution in Canada. We believe that this is an important safeguard that will help ensure that only HPFB-approved drugs are imported to the United States under SIPs. We seek comment on what additional standards should be imposed or qualifications required of Foreign Sellers.

The proposed rule would also require Foreign Sellers to register with FDA. Section 804(f) of the FD&C Act requires that any establishment within Canada engaged in the distribution of a prescription drug that is imported or offered for importation into the United States shall register with the Secretary the name and place of business of the establishment and the name of the U.S. agent for the establishment. This proposed rule implements that provision and largely tracks the registration requirements for foreign establishments set forth in 21 CFR 207.21, 207.25, and 207.29.

Facilities that register with FDA as Foreign Sellers should do so using the existing structured product labeling (SPL) format used by establishments required to register under section 510 of the FD&C Act. FDA intends to create a new business operation code for Foreign Sellers, ''Section 804 Foreign Seller.'' After the initial registration, a facility registered with FDA as a Foreign Seller would also be required to register annually for each year thereafter in which it wishes to remain a Foreign Seller, during the registration period between October 1 and December 31. We propose to require in this rule that a Foreign Seller's registration include its name, place of business, unique facility identifier, Health Canada Drug Establishment License number, point of contact email address and telephone number, the name of its U.S. agent, the name of each SIP with which it works, and any other information that FDA may decide is necessary.

U.S. agents of Foreign Sellers would be subject to the same requirements as agents of foreign registrants are under 21 CFR 207.69(b). Their responsibilities would include responding to communications and questions from FDA and helping FDA to schedule inspections. Under the proposed rule, in certain circumstances, FDA may provide information and/or documents to the U.S. agent, which would be considered equivalent to providing the same information and/or documents to the Foreign Seller.

We note that as an entity that holds drugs, the Foreign Seller would be subject to FDA inspection under section 704 of the FD&C Act.

E. Requirements for Importers

Under section 804, an Importer is defined as a pharmacist or a wholesaler. Under the proposed rule, if finalized, to be part of a SIP, an Importer would need to be duly licensed as a pharmacist by the State in which the Importer is located and in which it does business, or duly licensed as a wholesaler. In addition, the Importer's pharmacist or wholesaler licenses would need to be in effect (*i.e.,* not expired), and the Importer must be in good standing with the licensor. Furthermore, the Importer would need to be the U.S. owner of an eligible prescription drug at the time of entry or arrival of the drug into the United States.

We note that the Importer has a number of responsibilities under section 804 and this rule, including screening eligible prescription drugs for evidence regarding whether or not they are adulterated, counterfeit, damaged, tampered with, or expired; arranging for each shipment of eligible prescription drugs to be tested by a qualifying laboratory; and arranging for them to be relabeled with the FDA-approved labeling, including the carton and container labels, prescribing information, and any patient labeling, such as medication guides, instruction for use documents, and patient package inserts. The Importer is also responsible for facilitating the affixation or imprinting of a product identifier at the same time that the eligible prescription drugs are relabeled with the FDA-approved labeling.

We propose that the screening conducted by the Importer would include examination of the Canadian labeling of a sample of each shipment of section 804 drugs to verify that the labeling is consistent with that of an HPFB-approved drug and that the drugs have been serialized as prescribed in the proposed rule, when finalized. The screening could also include a visual comparison of a sample of the section 804 drug to a sample of the HPFB-approved drug. We seek comment on the feasibility and sufficiency of this screening, as well as on what additional or alternative screenings that the Importer could do to ensure that imported eligible prescription drugs are not adulterated, counterfeit, damaged, tampered with, or expired.

If an Importer will be relabeling the drug itself, the Importer must also be registered with FDA under section 510(b) of the FD&C Act and obtain a labeler code from FDA under § 207.33(c) (21 CFR 207.33(c)). If the Importer chooses to contract with a separate entity (*e.g.,* a repackager or relabeler) to relabel the drug on its behalf, the Importer will be a private label distributor, as that term is defined in § 207.1 (21 CFR 207.1), because it will be commercially distributing under its own label drugs that it did not itself manufacture, repackage, or relabel. As noted elsewhere in this proposed rule, a repackager or relabeler acting on an Importer's behalf would only repackage to the extent it is required to label the drug. As a private label distributor, the Importer will not be required to register with FDA, but it must obtain its own labeler code from FDA, under § 207.33(c). Under the proposed rule, the NDCs for the section 804 drugs that are relabeled by an entity other than the Importer would nonetheless incorporate the Importer's labeler code. Among other requirements, before an eligible prescription drug can be released into interstate commerce it will need a new NDC and will need to be listed. We note that a drug imported under section 804 of the FD&C Act will have a different NDC than its FDA-approved counterpart. Under the requirements proposed in this rule, if the Importer is also a repackager or relabeler, it will be the Importer's responsibility to propose an NDC for assignment for each eligible prescription drug under § 207.33. Under these circumstances, the Importer will also be responsible for listing each eligible prescription drug under § 207.53 (21 CFR 207.53). If the Importer is a private label distributor, it would be the Importer's responsibility to ensure that the entity relabeling an eligible prescription drug on its behalf proposes an NDC under § 207.33 and lists each eligible prescription drug under § 207.53.

The Importer, or authorized customs broker, would also be responsible for filing an entry for consumption in ACE for the drugs to be imported through a CBP port of entry designated in a SIP Proposal authorized by FDA. In addition, Importers would be required to collect and submit to FDA the information and documentation about the imported drug that is set forth in section 804(d) of the FD&C Act as discussed later. Importers also would have responsibilities related to adverse event, medication error, field alert reports, and other reports, and related to drug recalls.

We seek comment on whether there are qualifications Importers should be required to have, beyond being licensed as a pharmacist or wholesaler, given their responsibilities.

F. Supply Chain Requirements

When Congress enacted section 804 of the FD&C Act in 2003, FDA's authority with respect to drug supply chain security was more limited than it is today. In 2013, Congress enacted the DSCSA, which strengthened FDA's authority to protect the security and integrity of the drug supply chain. Specifically, section 582 of the FD&C Act, as added by the DSCSA, establishes the product identification, verification, and tracing requirements that manufacturers, wholesale distributors, pharmacists, and other trading partners must adhere to for covered transactions involving certain prescription drugs. Because the DSCSA did not include an exemption for drugs imported under section 804 of the FD&C Act, such drugs are subject to the requirements in section 582 of the FD&C Act. We recognize, however, that certain requirements in section 582 may be difficult or impossible for such drugs to meet. Accordingly, under the authority provided by section 582(a)(3)(A)(iii) of the FD&C Act, FDA proposes to exempt from section 582 certain transactions for drugs imported under section 804 of the FD&C Act.

Under section 804(c)(3), this proposed rule may contain ''any additional provisions determined by the Secretary to be appropriate as a safeguard to protect the public health or as a means to facilitate the importation of prescription drugs.'' To ensure the proposed exemptions from section 582 of the FD&C Act do not compromise the security of the supply chain for drugs imported under section 804 of the FD&C Act, this rule also proposes additional provisions to safeguard the public health. These additional safeguards are necessary for the Secretary to certify that implementation of section 804 of the FD&C Act would pose no additional risk to the public's health and safety.

First, if an eligible prescription drug is manufactured outside of Canada, it would need to be exported commercially into Canada by the manufacturer and labeled for the Canadian market. It could not be transshipped through Canada for sale in another country because this could create opportunities for counterfeiting or other forms of fraud.

Second, an eligible prescription drug would need to be sold by the manufacturer directly to a Foreign Seller in Canada. FDA has determined that this requirement is critical because FDA would generally not possess information needed to trace drug products labeled for the Canadian market back to the original manufacturer. As discussed further in the ''Supply Chain Security Requirements'' section below, for products and transactions that are subject to the DSCSA, supply chain protections are in place to allow for tracing products up to the manufacturer at the package and homogenous case level.

Under FDA's general proposed approach, a Foreign Seller would then ship the drug directly to the Importer in the United States. We considered whether to propose allowing more than one Foreign Seller in the Canadian supply chain but decided against this approach because we do not believe it would be possible for a SIP Sponsor to demonstrate that the same level of safety would be assured. For a SIP to pose no additional risk, it would have to match the protections of the DSCSA through other means. The short supply chain, coupled with this proposed rule's other provisions like serialization and testing, would permit control over and transparency into the supply chain to help ensure comparable safety. Therefore, we propose to require that each Foreign Seller buy the drug directly from the manufacturer and then sell it directly to the Importer in the United States because this would minimize supply chain security risks, including the risks posed by increased opportunities for counterfeiting and other forms of fraud that obscure the origin of drugs imported under section 804 of the FD&C Act. As the number of entities outside the United States that handle the drugs increases, the supply chain becomes progressively less transparent and more vulnerable to risk. The proposed short supply chains would also allow FDA and States to supervise the supply chain participants more closely. This rule proposes additional safeguards on tracing products through the pre-U.S. supply chain, which we believe will result in a level of supply chain security that poses no additional risk to the public's health and safety, but these proposed provisions are premised on the presence of just one Foreign Seller per supply chain. Allowing for additional Foreign Sellers in a supply chain would undermine our ability to ensure that our proposed approach poses no additional risk.

Although we cannot foresee at this time how a longer supply chain would not pose additional risk to the public's health and safety, we seek comment on whether there actually are safeguards

that could be put in place that would enable FDA to authorize a SIP with multiple Foreign Sellers in a single supply chain in Canada. Such comments should provide specific details regarding the additional safeguards and how they would provide the same level of protection to the supply chain. If, in response to comments, we determine that FDA could authorize a SIP with more than one Foreign Seller in a single supply chain because we are able to adopt additional safeguards such that the SIP would pose no additional risk to the public's health and safety, we would consider having the final rule account for this possibility. For example, we could revise §§ 251.3, 251.14(a)(4), 251.19(c), and 251.19(d)(2), as follows.

- Section 251.3 could be revised to state that, in its initial proposal, a SIP Sponsor must only designate one Foreign Seller and one Importer that may engage in the distribution of any drug specified in the proposal, unless the SIP Sponsor demonstrates that the SIP will meet additional safeguards, which would be detailed in the final rule, necessary to ensure that the inclusion of subsequent specified Foreign Sellers would pose no additional risk to the public's health and safety.
- Section 251.14(a)(4) could be revised to state: ''For each drug imported under the SIP, the drug is only shipped by the entities that are specified in the SIP.''
- Section 251.19(c) could be revised to state: ''The Importer must also confirm that the eligible prescription drug was bought directly from the manufacturer by a Foreign Seller, and that all subsequent sales of that eligible prescription drug, up to and including the sale to the Importer, were made only among Foreign Sellers described in the SIP.''
- Section 251.19(d)(2) could be revised to state: ''documentation demonstrating that the eligible prescription drug was only handled by the manufacturer and Foreign Seller(s) described in the SIP before the Importer received the drug;''.

In addition, among other potential revisions that may be necessary, if the final rule were to permit longer supply chains, we would include in the final rule those additional safeguards—submitted in comments justifying an allowance for multiple Foreign Sellers in a single supply chain—that would be applicable to most, and perhaps all, proposals that include multiple Foreign Sellers. We note that other requirements would apply as well that would need to be specified in the final rule, including the testing requirements described in section 804(d)(1)(J)(ii).

Under the proposed rule, following the shipment into the United States, the Importer would be responsible for: (1) Sending FDA information about the drug, including information it receives from the Foreign Seller and the test results from the qualifying laboratory and also for (2) ensuring that the drug is relabeled with the required U.S. labeling and DSCSA product identifier. The Importer would then sell the product to either another entity in the United States (if it is a wholesaler) or dispense the product itself to patients (if it is a pharmacist).

We acknowledge that there are certain assurances regarding authenticity and quality when a manufacturer manufactures drugs intended for sale in the United States. We seek comment on the approach in this proposed rule and whether it contains sufficient safeguards to ensure that the proposed importation poses no additional risk to health or safety.

1. Foreign Seller's Supply Chain Security Obligations

Once the Foreign Seller receives product from a foreign manufacturer, which would be entirely intended and labeled for sale in the Canadian market, the Foreign Seller would need to separate the portion of product it intends to sell to the Importer in the United States under section 804, and maintain that portion in a separate area in its facility from the portion intended for the Canadian market. We anticipate that the volume of drug included in the portion intended for the U.S. market will be agreed upon between the Foreign Seller and the Importer to whom it will sell the drug, and that such volume will be identified in a contract agreement and in records that the Importer is obligated to send to FDA under section 804(d) of the FD&C Act.

Under the proposed rule, for the portion of drug that will be transacted between the Foreign Seller and the Importer under section 804, the Foreign Seller would need to assign an SSI to each package and homogenous case of drug in that portion. The rule proposes that ''package'' means the smallest individual salable unit of product for distribution that is intended by the Foreign Seller for sale to the Importer located in the United States, and that ''individual saleable unit'' means the smallest container of product sold by the Foreign Seller to the Importer. The rule proposes that an ''SSI'' consists of a unique alphanumeric serial number of up to 20 characters. Using a stamp or adhesive sticker, the Foreign Seller would be required to place the SSI on each package and homogenous case, but would not otherwise repackage or relabel the drug. If the product already contained a manufacturer-affixed DSCSA-compliant product identifier at the time the Foreign Seller receives it, the Foreign Seller would not be required to assign an SSI to the product before further engaging in a transaction with the Importer.

Under the proposed rule, the Foreign Seller would need to maintain records identifying its process for serializing and affixing the SSI onto each package and homogenous case, including an explanation of the controls in place to ensure the stamp or adhesive sticker is properly affixed. The Foreign Seller would also be required to adhere to all applicable good manufacturing practice requirements in accordance with section 501(a)(2)(B) of the FD&C Act and part 211. The SSI would need to occupy blank space on the package and homogenous case, and not obscure any other labeling information, including the manufacturer-labeled Canadian DIN that was on the package and homogenous case at the time the Foreign Seller received the product from the manufacturer. Therefore, a drug without a DIN would not be an eligible prescription drug that could be imported into the United States. Finally, the Foreign Seller would need to maintain records associating the SSI with the DIN and all the records it received from the manufacturer upon receipt of the original shipment intended for the Canadian market.

The rule also proposes that various verification requirements on a Foreign Seller, that correspond, where applicable, with those provisions pertaining to a ''manufacturer'' under the DSCSA in section 582(b)(4)(A) through (C) of the FD&C Act. Specifically, the Foreign Seller would need to verify that a drug was not a suspect or illegitimate foreign product and would need to send information to the Importer about the purchase of the drug. ''Suspect foreign product'' and ''illegitimate foreign product'' are proposed in the rule as defined terms relating to the product that the foreign seller purchases from the manufacturer and align with the definitions of ''suspect product'' and ''illegitimate product'' in DSCSA. In addition, the Foreign Seller would need to be able to respond to requests for verification from FDA or others within 24 hours or in other such reasonable time as determined by FDA based on the circumstances of the request. We seek comment on the scope of the foreign seller's proposed verification

responsibilities, and the extent to which Foreign Sellers currently or in the future may have systems or processes in place to meet such requirements.

Under the proposed rule, the Foreign Seller would not be engaged in repackaging, only relabeling, and it would be receiving a product from the original manufacturer that is not DSCSA-compliant, since that product would have been intended and labeled entirely for the Canadian market. To address potential risks, this rule proposes to impose several requirements on Foreign Sellers. For example, as noted above, the Foreign Seller would need to be registered with FDA under section 804 of the FD&C Act. Additionally, the rule proposes that, prior to or at the time of each transaction with the Importer in which the Foreign Seller transfers ownership of the product to the Importer, the Foreign Seller would need to provide the Importer with a statement and information that is comparable with transaction information and transaction statement as defined in section 581(26) and (27) of the FD&C Act, respectively. Specifically, the Foreign Seller would be required to provide to the Importer:

- The proprietary or established name of the product;
- Strength and dosage form of the product;
- The container size;
- The number of containers;
- The lot number of the product;
- The date of the transaction;
- The date of the shipment, if more than 24 hours after the date of the transaction;
- The business name and address of the person associated with the Foreign Seller from whom ownership is being transferred;
- The business name and address of the person associated with the Importer to whom ownership is being transferred;
- The SSI for each package and homogenous case of product; and
- The Canadian DIN for each product transferred.

These requirements would be in addition to the statutory requirement under section 804(d)(1)(G) of the FD&C Act that the Importer obtain from the Foreign Seller, and submit to FDA, documentation specifying the original source of the prescription drug (*i.e.,* identifying the original foreign manufacturer) and the quantity of each lot of the drug the Foreign Seller originally received from the manufacturer. The rule also proposes that the Foreign Seller would be required to send information to FDA and other officials as appropriate and upon request. For example, upon a request by FDA, or other appropriate Federal or State official, in the event of a recall or for purpose of investigating a suspect product or an illegitimate product, the Foreign Seller would need to promptly provide the official with the information about the transaction with the Importer. This is comparable to the requirement for repackagers under section 582(e)(1)(C) of the FD&C Act; other DSCSA trading partners currently have similar obligations.

The required activities of the Foreign Seller proposed in this rule, as described above, presume a single Foreign Seller between the manufacturer and Importer in a particular supply chain. However, as noted above, if in response to comments, we determine that additional safeguards exist such that a SIP with a subsequent Foreign Seller or Foreign Sellers in a supply chain could be proposed to ensure that the longer supply chain would not pose additional risk to the public's health and safety, we would consider having the final rule account for this possibility. Our analysis of comments received will include a consideration of how the requirements described above on the single Foreign Seller (*e.g.,* to place an SSI on products, send transaction information to the Importer, verify products, and maintain records) would be applied to subsequent Foreign Sellers in a supply chain.

In sum, we have determined that a Foreign Seller would need to be capable not only of registering with FDA per section 804(f) of the FD&C Act and sharing relevant information and records with the Importer per section 804(d)(1)(G) of the FD&C Act, but also of preserving supply chain security and sending package-level information about the product they are selling to the Importer in a format that enables interoperability. This is consistent with section 804(c) of the FD&C Act, which permits the Secretary to include any additional requirements determined to be appropriate as a safeguard to protect the public health. Without these requirements, the Secretary would not be able to make the certification required under 804(l) that importation poses ''no additional risk to the public's health and safety.''

2. Importer's Supply Chain Security Obligations

Under the proposed rule, when the Foreign Seller sends a shipment of the product to the Importer, the product would need to include the Foreign Seller-affixed SSI, and, as noted earlier, contain the original Canadian labeling that the manufacturer had applied to the drug. The Importer would be responsible for relabeling the product with the required U.S. labeling.

If the Importer intends to place the product into further transactions in commerce, that relabeling would also need to include placing or affixing a product identifier that is associated with the SSI that the Foreign Seller assigned to the product prior to sending it to the Importer. Therefore, as part of the relabeling, this rule proposes that the Importer is responsible for affixing or placing a product identifier, as that term is defined in section 581(14) of the FD&C Act, on each package and homogenous case of product that it receives from the Foreign Seller. If, however, the Importer intends to directly administer the product to patients, as may be the case if the Importer intends to dispense the drug as a pharmacist, a product identifier would not be required to be affixed or imprinted on each package and homogenous case of the eligible prescription drug.

To avoid unnecessary steps in the supply chain, the product identifier would need to be affixed or imprinted at the same time at which the drug is being relabeled with the required U.S. labeling. As proposed, the Importer may relabel the product itself, or may choose to contract with a separate entity to relabel on its behalf. In either case, the entity that relabels the product must be registered with FDA as a relabeler, or a repackager if limited repackaging will occur as permitted in this proposed rule, under section 510(b) of the FD&C Act, in accordance with part 207, and also list the drug as required. We note that an entity that is a ''repackager'' as defined in the DSCSA under section 581(16) of the FD&C Act is likely to already have facilities and capabilities in place to affix or imprint a product identifier based on existing DSCSA requirements. A relabeler who contracts with the Importer to affix a product identifier on the Importer's behalf must, even if not engaged in a repackaging operation with respect to the eligible prescription drug, have systems and processes in place to meet applicable requirements of a ''repackager'' under section 582(e) of the FD&C Act for any transaction involving the eligible prescription drug.

Per section 581(14) of the FD&C Act, the product identifier must include a standardized numerical identifier (SNI), as that term is defined in section 581(20) of the FD&C Act, the lot number, and expiration date of the product and be in human and machine-readable form encoded in a 2-dimensional barcode. An SNI consists of an alphanumeric serial number and

NDC under section 581(20). For a product imported under section 804 of the FD&C Act, the Importer is responsible for obtaining an NDC for the product (as described elsewhere in this proposed rule). With regard to the serial number component of the SNI, the Importer may elect to use the same serial number (*i.e.,* the SSI) that the Foreign Seller had previously assigned to the product, or it may elect to assign a new serial number. Under the proposed rule, the Importer would need to maintain records, for no less than 6 years, that allow the Importer to associate the product identifier it affixed on each package and homogenous case of product it received from the Foreign Seller, with the SSI that had been assigned by the Foreign Seller, and the Canadian DIN that was on the package when the Foreign Seller received the product from the original manufacturer. This is analogous to the record retention requirement in section 582(e)(2)(A)(iv) of the FD&C Act for a repackager that associates a product identifier with a manufacturer-affixed product identifier.

In addition to the requirements proposed in the rule, the Importer is required to comply with any applicable existing requirement of the DSCSA for subsequent transactions to trading partners in the supply chain once the product has been relabeled with the required U.S. labeling (including the product identifier). For example, any Importer of eligible drugs under a SIP who is a ''pharmacist'' as defined in section 804(a)(2) of the FD&C Act (*i.e.,* a person licensed by a State to practice pharmacy, including the dispensing and selling of prescription drugs), is also considered to be a ''dispenser'' under the DSCSA, as defined in section 581(3) of the FD&C Act. Such dispenser must be ''authorized'' under the DSCSA, *i.e.,* have a valid license under State law (as defined in section 581(2)(D) of the FD&C Act). Such dispenser must also comply with all applicable requirements pertaining to a dispenser under section 582(d) of the FD&C Act. Furthermore, any Importer of eligible drugs under section 804 who is a ''wholesaler'' as defined in section 804(a)(5)(A) of the FD&C Act, is also considered to be a ''wholesale distributor'' under the DSCSA, as defined in section 581(29) of the FD&C Act. Such wholesale distributor must be ''authorized'' under the DSCSA, *i.e.,* have a valid license under State law or section 583, in accordance with section 582(a)(6) of the FD&C Act, and otherwise meet the definition in section 581(2)(C) of the FD&C Act. Such wholesale distributor must also comply with all applicable requirements pertaining to a wholesale distributor under section 582(c) of the FD&C Act.

3. Exemptions From Certain DSCSA Requirements

We propose to exempt certain transactions from DSCSA requirements in section 582 of the FD&C Act, as permitted by section 582(a)(3)(iii), because they would be difficult or impossible for section 804 imported drugs to meet, and the proposed rule includes other safeguards to maintain supply chain security:

- *Section 582(c)(1)(A) and (d)(1)(A):* For an Importer that is a wholesale distributor receiving the product from a Foreign Seller in Canada, the proposed rule would exempt the Importer from the requirement not to accept ownership unless the previous owner provides the transaction history, transaction information, and a transaction statement for the product. Similarly, if the Importer is a pharmacist receiving the product from a Foreign Seller in Canada, the proposed rule would exempt the Importer from the requirement on dispensers to not accept ownership unless the previous owner provides the transaction history, transaction information, and a transaction statement for the product. Instead, as previously described, this rule proposes to require the Foreign Seller to provide certain transaction-related information to the Importer that is adequate to ensure no additional risk to supply chain security.
- *Section 582(c)(2) and (d)(2):* The proposed rule would exempt Importers that are wholesale distributors and dispensers from the prohibition on receiving products that are not encoded with a product identifier. Instead, as previously described, products received from the Foreign Seller would be required to have an SSI. Wholesale distributors and dispensers would otherwise be required to engage only in transactions of products encoded with a product identifier, as defined in DSCSA.
- *Section 582(c)(3) and (d)(3):* Importers that are wholesale distributors and dispensers would be permitted to conduct transactions with Foreign Sellers even though they are not ''authorized trading partners'' under section 581. Wholesale distributors and dispensers would otherwise be required to transact only with authorized trading partners, as defined in the DSCSA.
- *Section 582(c)(4)(A)(i)(II) and (d)(4)(A)(ii)(II):* For section 804 imported products, the proposed rule would exempt an Importer from the requirement to verify that a product in the Importer's possession or control contains a ''standardized numerical identifier.'' Instead, the Importer would be required to verify that the section 804 imported product at the package level includes the SSI that the Foreign Seller had previously assigned to the product.

Note that FDA would not consider a drug imported under section 804 to have been diverted solely as a result of being imported under a SIP. A drug imported under section 804 may meet the definition of suspect or illegitimate product for other reasons, however (*e.g.,* counterfeit or stolen products), and entities that are obligated to identify such products under the DSCSA would be obligated to do so for drugs imported under section 804 in the same manner as they would for any other drugs subject to the same requirement.

We welcome comments on whether FDA should include exemptions from additional DSCSA requirements. We also note that manufacturers, repackagers, wholesale distributors, or dispensers may request waivers or exceptions at any time, under section 582(a)(3)(i) and (ii) of the FD&C Act.

4. Manufacturer's Supply Chain Security Obligations

Pursuant to section 804(d)(1) of the FD&C Act, this regulation, once finalized, would require the Importer to submit to FDA certain information and records about the imported drug. Under section 804(d)(1)(J) of the FD&C Act, such information would include the results of testing for authenticity and degradation, to be done per section 804(e) by either the Importer or the manufacturer. In the case of testing that is done by the Importer, other parts of this regulation specify information that the manufacturer is required to share in confidence with the Importer in order for the testing to occur, but in this section we further propose that the manufacturer would also need to provide to the Importer information it has about the transaction of the drug to the Foreign Seller located in Canada. Such information is necessary, along with other testing and laboratory record information specified elsewhere in this proposed rule, to ensure that the imported drug is authentic, as required in section 804(d)(1)(J) of the FD&C Act. Furthermore, under section 804(d)(1)(N) of the FD&C Act, we consider such information pertaining to drug's transactions in the pre-U.S. supply chain to be necessary to ensure the protection of public health.

Manufacturers would also need to be able to provide sufficient information to the Importer about the imported drug's movements in the pre-U.S. supply chain. To this end, this rule proposes to

require, under section 804(e) of the FD&C Act, that the manufacturer provide to the Importer all relevant documentation about the transaction that it provided to the Foreign Seller, upon its transfer of ownership of the product for the Canadian market. The rule does not propose to require any additional information about this transaction that is otherwise not maintained or submitted in accordance with Canadian law, or in the normal course of business for products the manufacturer intends to introduce to the Canadian market. The Importer would be required to use this information obtained from manufacturers under section 804(e) of the FD&C Act to help determine whether the supply chain was intact, by comparing the information about the transaction between the manufacturer and Foreign Seller to that received by the Importer from the Foreign Seller, as required under this rule.

We seek comments on this approach, including whether different or additional safeguards are necessary to ensure the integrity of the supply chain with respect to drugs imported under section 804 of the FD&C Act.

G. Requirements for Qualifying Laboratories

Section 804 of the FD&C Act requires that imported drugs be tested by a ''qualifying laboratory,'' which is defined as ''a laboratory in the United States that has been approved by the Secretary for the purposes of this section.'' As indicated earlier in this document, a SIP Proposal would need to indicate which laboratory the SIP will use to test the drugs it imports. The SIP Proposal would also need to explain why that laboratory is qualified to do the testing and so should be approved by FDA for use by a SIP.

To be considered qualified, we propose that a laboratory would need to comply with the applicable elements of the CGMP requirements, including provisions regarding laboratory controls in 21 CFR 211.160 and regarding laboratory records in 21 CFR 211.194. In addition, a laboratory would need to have ISO 17025 accreditation. Finally, we propose that it also would need to have an FDA inspection history and it would need to have satisfactorily addressed any objectionable conditions or practices identified during its most recent FDA inspection.

We seek comment on whether there are other requirements that all laboratories should meet before FDA approves them for use by a SIP. For example, we seek comment on whether we should require accreditation different from or in addition to ISO 17025.

If the rule is finalized as proposed, FDA would approve qualifying laboratories for use by a SIP on a case-by-case basis as part of its review and authorization of a SIP Proposal. FDA would also consider publishing a list of approved qualifying laboratories for the benefit of States or other non-federal governmental entities and their co-sponsors, if any, that may be developing a SIP Proposal.

H. Laboratory Testing Requirements

Section 804(d)(1)(J)(i) of the FD&C Act sets forth testing requirements for shipments of imported drugs that are shipped directly to the Importer from the first foreign recipient of the prescription drug from the manufacturer and section 804(d)(1)(J)(ii) sets forth testing requirements for shipments that are not shipped directly to the Importer from the first foreign recipient of the prescription drug from the manufacturer. Because we are proposing to require that all shipments under a SIP be shipped directly from the Foreign Seller, which is the first foreign recipient of the prescription drug from the manufacturer, to the Importer, this rule focuses on the testing requirements in section 804(d)(1)(J)(i) and does not address the requirements in section 804(d)(1)(J)(ii) of the FD&C Act. In addition, section 804(d)(1)(L) of the FD&C Act requires that the Importer provide laboratory records to FDA that include ''complete data derived from all tests necessary to ensure that the prescription drug is in compliance with established specifications and standards.''

Section 804(d)(1)(J)(i) of the FD&C Act provides that, in the case of an initial imported shipment, an Importer must provide documentation to FDA demonstrating that the drug ''was received by the recipient from the manufacturer and subsequently shipped by the first foreign recipient to the importer,'' that ''the quantity being imported into the United States is not more than the quantity that was received by the first foreign recipient,'' and that ''each batch of the prescription drug in the shipment was statistically sampled and tested for authenticity and degradation.'' For any subsequent shipments from the same batch of a drug, section 804(d)(1)(J)(i)(III)(bb) of the FD&C Act allows for more limited testing, of ''a statistically valid sample of the shipment.'' For an initial imported shipment, the testing would have to be done on a statistical sample of ''each batch of the prescription drug in the shipment.'' For example, if a shipment contained drugs from two batches, Batch A and Batch B, the testing would have to be done on a statistical sample of all of the drugs that came from Batch A and on a separate statistical sample of all the drugs that came from Batch B. For a subsequent shipment, the testing could be done on a statistical sample of the shipment as a whole, unless, for example, there are drugs from a third batch, Batch C, in the shipment. In that case, the testing would need to be done on a statistical sample of all the drugs that came from Batch A and Batch B, as a whole, and on a separate statistical sample of all the drugs that came from Batch C.

We propose to require that a statistical sample of a batch or shipment of section 804 drugs be randomly selected from the batch or shipment being tested or, in the alternative, that the sample be representative of the batch or shipment. We seek comment on whether we should specify a sampling method. We also seek comment on whether we should require that sampling be done according to an established standard such as those issued by the American National Standards Institute (ANSI) or by ASTM International.

Regarding the size of the sample, the number of packaged units in the sample would need to be large enough to enable a statistically valid statement to be made regarding the authenticity and stability of the entire batch or entire shipment. We seek comment on whether we should require that the sample size be determined using an established standard such as ASTM International's E122–17 ''Standard Practice for Calculating Sample Size to Estimate, With Specified Precision, the Average for a Characteristic of a Lot or Process'' (Ref. 30).

As noted previously, we propose that the testing done on the sample of the batch or shipment be sufficiently thorough to establish, in conjunction with data and information from the manufacturer, that the batch or shipment is eligible for importation under a SIP. The proposed rule would require the sample of the HPFB-approved drug to be tested to confirm that the HPFB-approved drug meets the FDA-approved drug's specifications, including the analytical procedures and methods and the acceptance criteria. In addition, to meet the statutory requirement that shipments be tested for degradation, a stability-indicating assay provided by the manufacturer would be required to be conducted on the sample of the drug that is proposed for import. Pursuant to section 804, the proposed rule would require all testing to be done

in a qualifying laboratory in the United States.

The testing required under section 804(d)(1)(J) of the FD&C Act can be conducted ''by the importer or by the manufacturer.'' If the Importer conducts the testing, section 804(e)(2)(A) of the FD&C Act requires the manufacturer to provide the Importer with the information needed to authenticate the prescription drug. Under the proposed rule, specifically, the manufacturer would be required to provide the Importer with formulation information about the HPFB-approved drug and the FDA-approved drug and any testing methodologies and protocols that the manufacturer has developed that the Importer needs to conduct the Statutory Testing.

In addition, under the proposed rule, the manufacturer would be required to provide an attestation to the Importer, or alternatively to FDA if the manufacturer conducts the testing itself, to establish that, but for the fact that it bore the HPFB-approved labeling, the drug that the manufacturer sold to the Foreign Seller in fact met the conditions in the FDA-approved NDA or ANDA. This would include any process-related or other requirements for which compliance cannot be established through laboratory testing. If the manufacturer does the testing, the manufacturer would be required to provide the attestation to FDA under the proposed rule. We propose that the attestation would need to include confirmation that the HPFB-approved drug has the active ingredient(s), active ingredient source(s) (including manufacturing facility or facilities), inactive ingredient(s), dosage form, strength(s), route(s) of administration, etc., described in the FDA-approved drug's NDA or ANDA. The attestation would also need to confirm that the HPFB-approved drug conforms to the specifications in the FDA-approved drug's NDA or ANDA regarding the quality of the drug substance(s), drug product, intermediates, raw materials, reagents, components, in-process materials, container closure systems, and other materials used in the production of the drug. In addition, the attestation would need to confirm that the HPFB-approved drug was manufactured in accordance with the specifications described in the FDA-approved drug's NDA or ANDA, including with regard to the facilities and manufacturing lines that are used, and in compliance with CGMP requirements set forth in section 501(a)(2)(B) of the FD&C Act and 21 CFR parts 4 (if a combination product), 210, and 211. The attestation would also need to include the original date of manufacture or whatever date was used in calculating the labeled expiration date based on the HPFB-approved or scientifically validated expiration period, the expiration period set forth in the FDA-approved drug's NDA or ANDA, and any other information needed to label the drug with an expiration date that meets the specifications of the FDA-approved drug's NDA or ANDA.

The attestation would also need to include information needed to confirm that the labeling of the prescription drug complies with labeling requirements of the FD&C Act. Finally, as discussed elsewhere in this proposed rule, the attestation would need to include information about the transaction of the eligible prescription drug to the Foreign Seller.

In addition to the attestation, the manufacturer would need to provide the Importer with the executed batch record, including the executed COA, for at least one recently manufactured, commercial-scale batch of the HPFB-approved drug and for at least one recently manufactured commercial-scale batch of the FDA-approved drug that was produced for and released for distribution to the U.S. market under an NDA or ANDA. The manufacturer would need to provide these analyses for each manufacturing line that the manufacturer used to produce either or both of the drugs.

As discussed earlier in this document, section 804(e)(2)(B) of the FD&C Act states that the information that a manufacturer provides to an Importer under section 804(e)(2)(A) must be kept in strict confidence and used only for purposes of testing or otherwise complying with this Act.'' The statute goes on to state that the regulations implementing section 804 of the FD&C Act can include provisions to provide for the protection of trade secrets and commercial or financial information that is privileged or confidential. We have proposed in § 251.15(g) and (h) additional provisions regarding the protection of information that may be supplied by a manufacturer to an Importer under this rule. We seek comment on whether any other provisions are needed to protect the information that manufacturers would need to provide to Importers under this rule. We note that instead of providing its proprietary test methods to an Importer, a manufacturer can do the testing itself in a qualifying laboratory in the United States.

As discussed above, for subsequent shipments of drugs from a batch, drugs from which have already been imported under a SIP, section 804(d)(1)(J)(i)(III)(bb) of the FD&C Act allows Importers to test a statistically valid sample of each shipment, as opposed to a statistically valid sample of each batch within a shipment. We seek comment on whether a different approach to testing subsequent shipments should be permitted. For example, it may be appropriate to use vibrational spectroscopic tests to test drugs in subsequent shipments. We note, however, that formulation-related physical stability and other quality issues cannot be tested by using spectroscopy. For that reason, a stability-indicating assay developed by USP or the manufacturer would have to be conducted as well. We seek comment on what testing would be appropriate at this stage.

The obligations on manufacturers under section 804(e) of the FD&C Act are enforceable under section 301(aa) of the FD&C Act, which provides that, among other things, a violation of the regulations implementing section 804 is a prohibited act. Furthermore, section 303(b)(6) of the FD&C Act sets forth penalties for manufacturers or Importers that knowingly fail to comply with a requirement of section 804(e) of the FD&C Act. These requirements include that: (1) The manufacturer or Importer conduct the Statutory Testing at a qualifying laboratory; (2) if the Importer conducts the testing, the manufacturer supply the information needed to authenticate the drug being tested and to confirm that the labeling is in compliance with the FD&C Act in a timely fashion, and (3) if the manufacturer supplies information to the Importer, the Importer keep it in strict confidence and only use it for testing and complying with the FD&C Act. A manufacturer or Importer that fails to comply with these requirements can be imprisoned for not more than 10 years under section 303(b)(6) of the FD&C Act, fined under 18 U.S.C.3571, or both.

In the event that a manufacturer fails to provide information required by this proposed rule in a timely fashion, including information necessary for the Importer to conduct the Statutory Testing, authenticate the drug being tested, or confirm that the labeling is in compliance with the FD&C Act, FDA may provide such information to an Importer if the information is contained in the manufacturer's approved NDA or ANDA. We seek comment on what would be considered a timely fashion that would provide the manufacturer adequate time to provide the necessary information and that would not create excessive difficulty for the Importer

who needs that information to import the drugs.

I. Listing and Labeling of Eligible Prescription Drugs

Section 804(d)(1)(K)(ii) of the FD&C Act requires that a drug covered by section 804 meets all labeling requirements of the FD&C Act. Additionally, section 804(c) of the FD&C Act requires that each prescription drug imported under this importation program comply with sections 501, 502, and 505 of the FD&C Act. Under section 804(h) of the FD&C Act, the manufacturer of a prescription drug is required to provide the Importer with written authorization to use the drug's approved labeling at no cost. If the manufacturer fails to do so in a timely fashion, FDA will deem this authorization to have been given. In addition, under the proposed rule, as required by section 804(e)(2)(A)(ii) of the FD&C Act, the manufacturer would need to supply the Importer, in a timely fashion, with information needed to confirm that the labeling of the prescription drug complies with the labeling requirements of the FD&C Act. Furthermore, under the requirements proposed by this rule, before a drug can be introduced into interstate commerce under section 804 of the FD&C Act, it would be required to be listed in accordance with part 207, and it would be relabeled so that it bears certain information that is unique to the eligible prescription drug. Specifically, the labeling will need to display an NDC that is unique to the eligible prescription drug, and it will need to provide information about the Importer. This section describes the proposed requirements for obtaining an NDC, listing, and relabeling an eligible prescription drug.

The rule proposes that before an eligible prescription drug can be sold it would need to bear a new NDC and be listed. We note that drugs imported under section 804 will have the same name but will have a different NDC than do their FDA-approved counterparts. As stated above, the Importer of an eligible prescription drug would need to either: (1) Propose an NDC for the drug, following the procedures in § 207.33, and it would need to list the drug, following the procedures in § 207.53 or (2) if the Importer is a private label distributor, take responsibility to ensure that the entity performing relabeling on its behalf proposes an NDC and lists each eligible prescription drug in accordance with the applicable requirements of part 207.

Additionally, we propose to make the Importer responsible for relabeling the drug, or arranging for it to be relabeled, to meet the requirements of this proposed rule. The relabeling and associated limited repackaging activities must meet applicable requirements, including applicable CGMP requirements under parts 210 and 211. At the time that an eligible prescription drug is sold or dispensed it would need to have been relabeled to be consistent with the FDA-approved the carton and container labels, prescribing information, and any patient labeling, such as medication guides, instruction for use documents, and patient package inserts. In addition, the eligible prescription drug would need to have been assigned a product identifier in compliance with section 582 of the FD&C Act. The relabeled eligible prescription drug will be considered consistent if it varies from the FDA-approved carton and container labels, prescribing information, and patient labeling solely to the extent described in this rule.

Except for repackaging that is necessary to perform the relabeling described in this proposed rule, the proposed rule would not allow further repackaging of drugs imported pursuant to a SIP. ''Repack'' or ''repackage'' is defined in § 207.1 as ''the act of taking a finished drug product or unfinished drug from the container in which it was placed in commercial distribution and placing it into a different container without manipulating, changing, or affecting the composition or formulation of the drug.'' We believe that allowing repackaging that breaches the immediate container closure system introduces unnecessary risk of adulteration, degradation, and fraud for drugs subject to a SIP. We also note that some container closure systems include a tamper-evident seal, which would be disturbed if repackaging were allowed. In addition, if a drug is repackaged from its immediate container closure, the expiration period set forth in the NDA or ANDA may no longer be valid because the expiration period in an approved NDA or ANDA is based on stability studies involving the particular container closure system into which a drug is placed without opening it to expose the contents to the outside environment. Additional stability studies would generally be required to establish a new expiration period.

The proposed rule would require that the prescribing information of an eligible prescription drug would need to include that drug's NDC in the HOW SUPPLIED/STORAGE AND HANDLING section for products with Physician Labeling Rule (PLR) labeling (see § 201.57(c)(17)(iii) (21 CFR 201.57(c)(17)(iii))) or the HOW SUPPLIED section for products with ''old'' (non-PLR) format labeling (see § 201.80(k)(3) (21 CFR 201.80(k)(3))) in place of any NDCs assigned to the FDA-approved U.S. versions of the drug. The proposed rule would also require that the eligible drug's new NDC be added to the container label and the carton labeling. If applicable, the new NDC would replace any NDC otherwise appearing on the label and carton labeling of the FDA-approved version of the drug. We seek comment on whether having multiple otherwise identical drugs in the marketplace with different NDCs will create any issues, such as with pharmacy dispensing or otherwise, and, if so, if there are steps that can be taken to mitigate such issues.

In addition to the names and places of businesses of entities that appear on the FDA-approved labeling, in this rule we propose to require that the label and labeling of an eligible prescription drug also bear conspicuously the name and place of business of the Importer. If the FDA-approved labeling does not include the name and place of business of the manufacturer, the name and place of business of the manufacturer should be added as well.

We also propose to require that the labeling on or within the package from which the drug is dispensed include the following statement: ''This drug was imported from Canada under the [Name of State or Other Governmental Entity and of Its Co-Sponsors, If Any] Section 804 Importation Program to reduce its cost to the American consumer.'' If the SIP maintains a website, the statement could also include the website address. To help avoid potential confusion between products with the same name, we propose that this statement would be included after the PATIENT COUNSELING INFORMATION section for products subject to § 201.56(d) (21 CFR 201.56(d)) and § 201.57, or after the HOW SUPPLIED section (or after the last section of labeling) for products subject to §§ 201.56(e) and 201.80. The statement also would be included on the immediate container and outside package to help pharmacists distinguish a section 804 product when selecting the product on the pharmacy shelf. The statement would be sufficiently prominent to help a pharmacist readily distinguish the eligible prescription drug without obscuring required or recommended information (*e.g.,* information that will reduce the risk of medication errors and ensure safe administration of the drug) (see FDA, 2013, ''Draft Guidance for Industry: Safety Considerations for Container Labels and Carton Labeling Design to

Minimize Medication Errors.'' Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/safety-considerations-container-labels-and-carton-labeling-design-minimize-medication-errors*). The statement may also aid in pharmacovigilance by increasing the likelihood that adverse event, medication error, field alert, and other reports include the fact that the drug was imported under a SIP. We seek comments on the content of the disclosure statement, in particular whether such a statement is necessary, whether it will be understandable and meaningful to prescribers, pharmacists, and patients, and whether more or less information is needed. We seek comment on whether it is necessary to provide the name of the SIP or whether it would be sufficient to state that the drug was imported under a SIP.

If an eligible prescription drug's container is too small to fit the additional information required by this proposed rule, FDA would consider a proposal for supplementary labeling from the SIP Sponsor. The container label would need to include at minimum the product's proprietary and established name (if any); product strength; lot number; and the name of the manufacturer and the Importer (see FDA, 2013, ''Draft Guidance for Industry: Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors.'' Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/safety-considerations-container-labels-and-carton-labeling-design-minimize-medication-errors*).

In addition to the required statement on the labeling, the proposed regulation also would require the SIP Sponsor to describe in the SIP Proposal how it will educate pharmacists, healthcare providers, and patients about its SIP. If pharmacists, healthcare providers, and patients know that a drug was originally intended for sale in Canada, they will have the ability to include this information if they subsequently report any adverse events or quality concerns. It may also help ensure that a recall is effective if healthcare providers and patients have this knowledge.

Among other things, a SIP could create and maintain a website that would set forth the name and NDC number of each drug that it imports. This would allow pharmacists, healthcare providers, and patients to use the NDC number to determine at any time whether a drug was originally intended for sale in Canada. The website could also include any relevant adverse event, medication error, field alert reports, or other reports or recall information. As stated earlier, the website address could be included along with the disclosure statement in the labeling of an eligible prescription drug.

A SIP could also distribute a Dear Healthcare Provider letter to physicians and pharmacists by United States mail, by email, by posting the letter on the Importer's website, or by other effective means, explaining that the drugs will have a different NDC because they were originally intended for sale in Canada. The letter could recommend that patients be counseled that the drugs were originally intended for sale in Canada, that they have different NDCs than their FDA-approved counterparts, and that they can use the NDCs to find out pertinent new information regarding the HPFB-approved drug or its FDA-approved counterpart, including information about recalls. A SIP could also propose to distribute a Dear Consumer letter (similar to a Dear Healthcare Provider letter) that pharmacists could dispense along with eligible prescription drugs and that consumers could access on the SIP's website.

J. Information and Records

Section 804(d) of the FD&C Act lists information and documentation, to be required in the regulations under section 804(b), that Importers of eligible prescription drugs must submit to the Secretary. The rule proposes that section 804(d) information would be submitted to FDA each quarter by SIP Sponsors. SIP Sponsors would be required to submit a report to FDA each quarter containing the information set forth in section 804(d) of the FD&C Act, beginning after the SIP Sponsor files an electronic import entry for consumption for its first shipment of drugs.

Consistent with the statute, the proposed rule would require that Importers collect and submit to FDA the information listed here, but also clarifies that the Importer's submission obligations are met if the SIP sponsor submits a report to FDA as described above: (1) The name, address, telephone number, and professional license number (if any) of the Importer; (2) the name and quantity of the active ingredient of the prescription drug; (3) a description of the dosage form of the prescription drug; (4) the date on which the prescription drug is shipped; (5) the quantity of the prescription drug that is shipped; (6) the lot or control number assigned to the prescription drug by the manufacturer of the prescription drug; (7) the point of origin and destination of the prescription drug; and (8) the per unit price paid by the Importer for the prescription drug in U.S. dollars, as well as any other information that FDA determines is necessary to ensure the protection of the public health. We propose to require that Importers submit to FDA, in addition to the point of origin (*i.e.,* the manufacturer of the finished dosage form) and the destination (*i.e.,* the wholesaler, pharmacy, or patient to whom the Importer sells or dispenses the drug), information regarding the rest of the supply chain, which this rule proposes would consist solely of the Foreign Seller in Canada.

Section 804(d) of the FD&C Act also requires the Importer to collect and submit to FDA certain documentation, including: (1) Documentation from the Foreign Seller specifying the original source of the prescription drug (which under this rule would be the manufacturer of the eligible prescription drug) and the quantity of each lot of the prescription drug originally received by the seller from that source and (2) in the case of a prescription drug that is shipped directly from the first foreign recipient of the prescription drug from the manufacturer (which, under this rule, would be the Foreign Seller), documentation demonstrating that the prescription drug was received by the first foreign recipient from the manufacturer and subsequently shipped by the first foreign recipient to the Importer. The Importer must also collect and submit documentation of the quantity of each lot of the prescription drug received by the first foreign recipient demonstrating that the quantity being imported into the United States is not more than the quantity that was received by the first foreign recipient. While the Importer does not need to submit records associating the eligible prescription drugs' SSIs with their U.S. product identifiers, the Importer would need to maintain such records and make them available to FDA upon request. In the case of an initial imported shipment, Importers would also need to submit documentation demonstrating that each batch of the prescription drug in the shipment was statistically sampled and tested for authenticity and degradation, and in the case of any subsequent shipment, they would need to submit documentation demonstrating that a statistically valid sample of the shipment was tested for authenticity and degradation.

Importers also would need to submit a certification from the Importer or the manufacturer of an imported drug that the drug is approved for marketing in the United States and is not adulterated or misbranded, and meets all labeling

requirements under the FD&C Act. In this rule, we propose to require that the certification include: (1) That there is an approved SIP; (2) that the drug is covered by the SIP; (3) that the drug is an eligible prescription drug as defined in this rule; (4) that the FDA-approved counterpart of the drug is currently commercially marketed in the United States; (5) that the drug is approved for marketing in Canada; and (6) that the drug is not adulterated or misbranded and meets all labeling requirements under the FD&C Act. Importers would need to collect and submit laboratory records, including complete data derived from all tests necessary to ensure that the prescription drug is in compliance with established specifications and standards, and documentation demonstrating that the Statutory Testing was conducted at a qualifying laboratory, unless the manufacturer conducted the Statutory Testing and submitted the relevant information directly to FDA.

In addition, SIP Sponsors would be required to provide FDA with data and information on the SIP's cost savings to the American consumer. We recognize a SIP's scope will influence the appropriate cost savings calculation methodology. SIPs should, therefore, report their total cost savings to consumers as well as the methodology used to calculate this measure. Cost savings calculations should be based on savings to the American consumer. Calculations should therefore rely, to the greatest extent possible, on prices paid by the intended consumer population. Average price measures by drug may be appropriate if drugs are dispensed through multiple channels or if the imported drugs' prices fluctuate throughout the reporting period. Calculation methods should also account for factors that may influence cost savings over time, such as changes in drug utilization, the price of domestic drugs, and exchange rates. As mentioned above, we anticipate that some SIP Sponsors may seek to import drugs to be used by patients in State-run programs. In such cases, a SIP Sponsor could submit information about whether cost-sharing expenses are reduced for the participants, or whether the program will result in cost savings that are passed on to consumers in other ways, such as increasing the number of people who can be covered by a State program, or increasing the availability of drugs covered by the program. We seek comments on these and other factors relevant to the reporting of cost savings.

K. Post-Importation Requirements

Under proposed § 251.18, SIP Sponsors and Importers would be required to take certain actions regarding eligible prescription drugs if they are violative of an applicable requirement. Under the proposed rule, the SIP Sponsor would be required to immediately stop importation of eligible prescription drugs under a SIP if it determines that a drug or entity in the supply chain does not meet all applicable requirements of the FD&C Act, FDA regulations, and the authorized SIP. The Importer must establish and maintain records and submit reports to FDA and to the manufacturer of all domestic adverse events and medication errors associated with the use of their imported eligible prescription drugs about which they obtain or otherwise receive information. These reports would be required to help inform whether there are safety concerns with imported eligible prescription drugs, generally, and also specifically in relation to the handling of these drugs. The Importer must also develop written procedures for the surveillance, receipt, evaluation, and reporting of adverse events and medication errors to FDA and to the relevant manufacturer.

The Importer must submit expedited reports on adverse events that are both serious and unexpected to FDA and the manufacturer as soon as possible but no later than 15 calendar days from initial receipt of the information by the Importer. The Importer must also submit expedited reports on medication errors to FDA and the manufacturer within the same timeframe.

The Importer must promptly investigate all adverse events and medication errors that are the subject of these expedited reports and must submit follow-up reports within 15 calendar days of receipt of new information or as requested by FDA. If additional information is not obtainable, the Importer should maintain records of the unsuccessful steps taken to seek additional information. Furthermore, the Importer must submit reports on adverse events that are both serious and expected or that are nonserious, whether expected or unexpected, to FDA and the manufacturer within a 90-calendar day timeline.

FDA may require the Importer to submit certain adverse events within 15 calendar days, even though the events do not meet the criteria for expedited reporting. FDA will specify these adverse events in advance and will provide the reason for requiring that they be reported to the Agency on an expedited basis.

While § 314.80(c)(1)(iii) (21 CFR 314.80(c)(1)(iii)) gives distributors of approved drugs the choice of submitting reports to either FDA or the applicant, we propose to require that Importers of section 804 drugs be required to submit reports to both FDA and the manufacturer. This will aid the manufacturer in its pharmacovigilance efforts, and it will provide FDA with information that may be relevant to its review of SIP Proposals and Pre-Import Requests as well as to its oversight of drugs imported under section 804 of the FD&C Act and section 804 in general.

FDA proposes to require submission of individual case safety reports (ICSRs) and ICSR attachments in electronic format, as described in § 314.80(g)(1). Importers may request in writing a temporary waiver of the electronic reporting requirements as described in § 314.80(g)(2). Such waivers will be granted on a limited basis and for good cause.

The Importer would also be required to submit to the manufacturer and to FDA field alert reports about the products it distributes. These reports would need to be made when the Importer becomes aware of information concerning any incident that causes the drug product or its labeling to be mistaken for, or applied to, another article, or information concerning any bacteriological contamination, or any significant chemical, physical, or other change or deterioration in the distributed drug product, or any failure of one or more distributed batches of the drug product to meet the specification established for it in the FDA-approved NDA or ANDA. If a SIP imports a drug-device combination product, the Importer would also need to submit to the manufacturer and to FDA the reports described in 21 CFR 4.102(c)(1) for combination products containing a device constituent part, in the manner and by the deadlines provided in part 4. The Importer would also need to maintain the records described in 21 CFR 4.102(c)(1) and 4.105(b).

An Importer should notify the Foreign Seller and the SIP Sponsor any time it makes an adverse event, medication error, field alert report, or other report to FDA and the manufacturer. Notification to Health Canada would be done by the Foreign Seller in accordance with Health Canada requirements. FDA would share adverse event, medication error, field alert report, or other report information it receives with Health Canada as appropriate.

The SIP Sponsor would be required to establish a procedure to track the public announcements of the manufacturer of each of the drugs that they import and they must also monitor FDA's recall website at *https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts,* and Health Canada's recall website at *https://healthycanadians.gc.ca/recall-alert-rappel-avis/index-eng.php?cat=3,* for any recall or market withdrawal information relevant to the drugs that they import under section 804 of the FD&C Act. The SIP Sponsor would have to explain in its SIP Proposal how it will ensure that information about recalls or market withdrawals will be shared among the SIP Sponsor, the Foreign Seller, the Importer, and FDA and provided to the manufacturer.

If FDA or a SIP Sponsor determines that a recall is necessary, the SIP Sponsor must ensure that the recall is carried out effectively based on the classification and depth determined by FDA or the SIP Sponsor. A SIP must have a written recall plan that describes the procedures to perform a recall of the product and specifies who will be responsible for performing the procedures. The recall plan must cover recalls initiated by FDA and recalls initiated by the SIP Sponsor, as well as recalls in Canada or the United States initiated by a drug's manufacturer that implicate a drug imported under a SIP, with which the Foreign Seller and/or Importer must cooperate. The recall plan must include sufficient procedures for the SIP Sponsor, Foreign Seller and/or Importer to:

- Immediately cease distribution of the drugs affected by the recall;
- directly notify consignees of the drug or drugs included in the recall, including how to return or dispose of the recalled drugs;
- specify the depth to which the recall will extend (*e.g.,* wholesale, intermediate wholesale, retail, or consumer level);
- notify the public about any hazard or hazards presented by the recalled drug when appropriate to protect the public health;
- conduct effectiveness checks to verify that all consignees at the specified recall depth have received notification about the recall and have taken appropriate action;
- appropriately dispose of recalled product; and
- notify FDA of the recall.

In addition, in the event of a recall, Importers and Foreign Sellers would be required, upon request by FDA, to provide the transaction history, information, and statement, as those terms are defined in sections 581(25), 581(26), and 581(27) of the FD&C Act, respectively, of the FD&C Act. We seek comment on how a SIP Sponsor and co-sponsor, if any, Foreign Seller, or Importer would effectuate a recall in the United States, given that this will be a new responsibility for these entities.

L. Severability

Proposed § 251.20 contains a severability provision clarifying the Agency's intent regarding whether the provisions of part 251 are severable from the rest of the regulation if one or more of the provisions are stayed or determined to be invalid by a court. The provisions of part 251 contain requirements that are either expressly mandated by section 804 of the FD&C Act, or are otherwise necessary pursuant to section 804(c)(3) because they have been determined by the Secretary to be appropriate as a safeguard to protect the public health or as a means to facilitate the importation of prescriptions drugs under section 804. Each of the requirements that will be included in the final rule will address significant potential safety concerns associated with drugs imported under section 804 and would be necessary to protect public health. If one or more of these provisions becomes invalid, the rule, as a whole, would no longer adequately protect public health and therefore should be invalid in its entirety.

In addition, section 804 of the FD&C Act, and by extension, this regulation, which is promulgated in part pursuant to that authority, only becomes effective if the Secretary certifies to Congress that implementation of section 804 will pose no additional risk to the public's health and safety. This certification is contingent upon this rule becoming effective with all the requirements that are included when finalized. If one or more of the provisions in this rule becomes invalid, in addition to the entire rule becoming invalid, the certification would become null and void because the certification is based on a finding that implementation of section 804 will pose no additional risk to the public's health and safety, and that finding would no longer be accurate because it would have been based on a final rule that contains all the requirements that were included when published.

VI. Proposed Effective and/or Compliance Dates

FDA proposes that any final rule that issues based on this proposal become effective 30 days after the final rule publishes in the **Federal Register**.

VII. Preliminary Economic Analysis of Impacts

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, Executive Order 13771, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 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 a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. We cannot anticipate if sponsors will contract with small entities to implement their authorized SIP proposals and request comment on the impact the proposed rule may have on small entities. We also lack information to quantify the total impacts of the proposed rule. Therefore, 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 $154 million, using the most current (2018) 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.

1. Summary of Costs and Benefits

The proposed rule, if finalized, would allow commercial importation of certain prescription drugs from Canada through time-limited programs, SIPs, sponsored by at least one non-federal governmental entity with possible co-sponsorship by a

wholesaler or pharmacist. If such programs allow Importers to leverage drug price differences between the United States and Canada, they will result in cost savings for U.S. consumers.

Expected costs of the proposed rule accrue to the Federal Government, SIP Sponsors, Importers, and manufacturers of imported drugs. The Federal Government would incur one-time fixed costs as well as ongoing costs to implement the rule, if finalized, and to review SIP Proposals and reports. SIP Sponsors would face costs to prepare proposals, implement approved SIPs, and produce SIP reports and records. SIPs may offer cost savings to consumers, as well as other parties in the drug supply chain including participating wholesale drug distributors, pharmacies, hospitals, and third-party payers. If their drugs are imported into the United States from Canada, drug manufacturers will have to provide importers with certain information. As drug distributors realize savings in acquiring imported drugs and pass some of these savings to consumers, it is possible that U.S. drug manufacturers may experience a transfer in U.S. sales revenues to these parties.

We are unable to estimate the cost savings from this proposed rule, as we lack information about the likely size and scope of SIP programs and about the specific drug products that may become eligible for importation, the degree to which imported drugs would be less expensive than non-imported drugs available in the United States, and which SIP eligible products are produced by U.S. drug manufacturers.

Table 1 summarizes the benefits and costs of the proposed rule.

TABLE 1—SUMMARY OF BENEFITS, COSTS AND DISTRIBUTIONAL EFFECTS OF PROPOSED RULE

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered (years)	
Benefits:							
Annualized Monetized $millions/year	.....	.....	.....	2019	7	10	
				2019	3	10	
Annualized Quantified	.....	.....	.....	2019	7	10	
				2019	3	10	
Qualitative	Potential cost savings to consumers and third-party payers or entities			.....	.....	10	
Costs:							
Annualized Monetized $millions/year	.....	.....	.....	2019	7	10	
				2019	3	10	
Annualized Quantified	.....	.....	.....	2019	7	10	
				2019	3	10	
Qualitative	Potential costs to Federal Government, SIP sponsors, importers, and manufacturers of imported drugs			.....	.....	10	
Transfers:							
Federal Annualized Monetized $millions/year	.....	.....	.....	2019	7	10	
				2019	3	10	
From/To	.....	From:			To:		
Other Annualized Monetized $millions/year	.....	.....	.....	2019	7	10	
				2019	3	10	
From/To	From: U.S. drug manufacturers			To: Importers and U.S. consumers			Not Quantified.

Effects:
State, Local or Tribal Government: Potential costs and cost savings to State, tribal, and territorial government entities from sponsoring SIPs
Small Business:
Wages:
Growth:

We lack information about the likely size and scope of SIP programs, the specific drug products that may become eligible for importation, the degree to which drugs imported under section 804 would be less expensive than drugs not imported under section 804, and which SIP eligible products are produced by U.S. drug manufacturers to estimate the present and annualized values of the costs and cost savings of the proposed rule over an infinite time horizon. The designation under Executive Order 13771 of any final rule resulting from this proposal will be informed by comments received and subsequent analysis at the final rule stage. Thus, we exclude the Executive Order 13771 summary table from this analysis.

We have developed a comprehensive Preliminary Economic Analysis of Impacts that assesses the impacts of the proposed rule. The full preliminary analysis of economic impacts is available in the docket for this proposed rule (Ref. 31) and at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

VIII. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(h) and 25.31(a) 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.

IX. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995

(44 U.S.C. 3501–3521). A description of these provisions is given below under the *Description* heading with an estimate of the annual reporting, recordkeeping, and third-party disclosure burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Section 804 Importation Program Proposals—21 CFR part 251.

Description: The proposed regulations provide that a SIP Sponsor that seeks to implement a SIP to import prescription drugs from Canada must submit a proposal that includes, among other things, information about the SIP Sponsor and the SIP Sponsor's importation plan. In addition, SIP Sponsors must provide FDA with data and information on the drugs the SIP imports and on the SIP's cost savings to the American consumer. Importers would have a number of responsibilities related to submitting a Pre-Import Request, screening eligible prescription drugs and arranging for importation, testing, and relabeling. Manufacturers would provide information needed to authenticate eligible prescription drugs.

Description of Respondents: Respondents would include SIP Sponsors (State, tribal, or territorial governmental entities), Importers (pharmacists or wholesalers), and manufacturers of eligible prescription drugs.

FDA anticipates submissions will be made through the Electronic Submissions Gateway.

FDA estimates that there will be 10 SIP Sponsors requiring 360 hours each to research, prepare, and administer requirements annually; 10 Pre-Import Requests requiring 24 hours each annually; and 20 manufacturers also requiring 24 hours each annually to participate in the program. In addition, FDA estimates that a recordkeeping burden of 52 hours will be imposed annually on the 10 SIP Sponsors; and a recordkeeping burden of 24 hours will be imposed annually on each of the 10 Importers and the 20 manufacturers. The 20 manufacturers anticipated to participate in the program will also incur an estimated burden of 24 hours each for copying and providing records to SIP Sponsors and Importers of foreign transactions.

FDA estimates the burden of this collection of information as follows:

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

Type of information collection activity/respondent	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
SIP Sponsor 251.3; 251.8; 251.14—SIP Proposal Submission Requirements; 251.18—Post-Importation Requirements; 251.19—Reports to FDA	10	1	10	360	3,600
Importer 251.5; 251.12; 251.13; 251.17—Pre-Import Request and Importation Requirements	10	1	10	24	240
Manufacturer 251.16 Lab Testing Requirements	20	1	20	24	480
Total					4,320

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 3—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Type of information collection activity/respondent	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
SIP sponsor 251.8—Modification or Extension of Authorized Importation Programs	10	1	10	52	520
Importer 251.14(d)—Supply Chain Security Requirements; 251.17—Importation Requirements; 251.18 Post-Importation Requirements	10	1	10	24	240
Manufacturer 251.14(b)—Supply Chain Security Requirements	20	1	20	24	480
Total					1,240

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 4—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Type of information collection activity/respondent	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Manufacturer 251.14(b)—Supply Chain Security Requirements	20	1	20	24	480

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

To ensure that comments on information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB (see **ADDRESSES**). All comments should be identified with the title of the information collection.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3407(d)), we have submitted the information collection provisions of this proposed rule to OMB for review. These information collection requirements will not be effective until FDA publishes a final rule, OMB approves the information collection requirements, and the rule goes into effect. FDA will announce OMB approval of these requirements in the **Federal Register**.

X. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that this proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive Order and, consequently, a federalism summary impact statement is not required.

XI. Consultation and Coordination With Indian Tribal Governments

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13175. We have tentatively determined that the rule does not contain policies that would have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. The Agency solicits comments from tribal officials on any potential impact on Indian Tribes from this proposed action.

XII. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. 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.

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* 28. Government of Canada, Health Canada, 2019, ''Health Canada and United States Food and Drug Administration Joint Public Consultation on ICH Guidelines—Update,'' accessed December 10, 2019, *https://www.canada.ca/en/health-canada/services/drugs-health-products/public-involvement-consultations/drug-products/notice-international-council-harmonisation-registration-pharmaceuticals-human-use-consultation-update.html.*

29. Joanne S. Eglovitch, 2019, ''GS1 Standard Would Speed the Sale of Returned Drugs After November Deadline,'' *Pink Sheet,* accessed September 27, 2019, *https://pink.pharmaintelligence.informa.com/PS140811/GS1-Standard-Would-Speed-The-Sale-Of-Returned-Drugs-After-November-Deadline.*

30. ASTM E122–17, 2017, Standard Practice for Calculating Sample Size to Estimate, With Specified Precision, the Average for a Characteristic of a Lot or Process, *www.astm.org.*

* 31. FDA, Preliminary Regulatory Impact Analysis: Importation of Prescription Drugs, *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

List of Subjects

21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 251

Exports, Labeling, Packaging and containers, Prescription drugs, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, the Food and Drug Administration proposes to amend 21 CFR chapter I as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

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

Authority: 15 U.S.C. 1333, 1453, 1454, 1455, 4402; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 342, 343, 350c, 350d, 350e, 350j, 350k, 352, 355, 360b, 360ccc, 360ccc–1, 360ccc–2, 362, 371, 373, 374, 379j–31, 381, 382, 384a, 384b, 384d, 387, 387a, 387c, 393; 42 U.S.C. 216, 241, 243, 262, 264, 271; Pub. L. 107–188, 116 Stat. 594, 668–69; Pub. L. 111–353, 124 Stat. 3885, 3889.

■ 2. Revise § 1.74 to read as follows:

§ 1.74 Human drugs.

In addition to the data required to be submitted in § 1.72, an ACE filer must submit the following information at the time of filing entry in ACE for drugs, including biological products and eligible prescription drugs as defined in § 251.2 of this chapter that are imported or offered for import under section 804 of the Federal Food, Drug, and Cosmetic Act, intended for human use that are regulated by the FDA Center for Drug Evaluation and Research.

(a) For a drug intended for human use that is not an eligible prescription drug covered under paragraph (b) of this section:

(1) *Registration and listing.* The Drug Registration Number and the Drug Listing Number if the foreign establishment where the human drug was manufactured, prepared, propagated, compounded, or processed before being imported or offered for import into the United States is required to register and list the drug under part 207 of this chapter. For the purposes of this section, the Drug Registration Number that must be submitted at the time of entry in ACE is the unique facility identifier of the foreign establishment where the human drug was manufactured, prepared, propagated, compounded, or processed before being imported or offered for import into the United States. The unique facility identifier is the identifier submitted by a registrant in accordance with the system specified under section 510(b) of the Federal Food, Drug, and Cosmetic Act. For the purposes of this section, the Drug Listing Number is the National Drug Code number of the human drug article being imported or offered for import.

(2) *Drug application number.* For a drug intended for human use that is the subject of an approved application under section 505(b) or 505(j) of the Federal Food, Drug, and Cosmetic Act, the number of the new drug application or abbreviated new drug application. For a biological product regulated by the FDA Center for Drug Evaluation and Research that is required to have an approved new drug application or an approved biologics license application, the number of the applicable application.

(3) *Investigational new drug application number.* For a drug intended for human use that is the subject of an investigational new drug application under section 505(i) of the Federal Food, Drug, and Cosmetic Act, the number of the investigational new drug application.

(b) For an eligible prescription drug as defined in § 251.2 of this chapter that is imported or offered for import under section 804 of the Federal Food, Drug, and Cosmetic Act:

(1) *Registration and listing.* The Drug Registration Number and the Drug Listing Number. For the purposes of this section, the Drug Registration Number that must be submitted in ACE is the unique facility identifier of the Foreign

Seller. The unique facility identifier is the identifier submitted by a Foreign Seller registrant under § 251.5 of this chapter. For the purposes of this section, the Drug Listing Number is the National Drug Code that the Importer will use when relabeling the eligible prescription drug as required in § 251.13 of this chapter.

(2) *Drug application number.* The number of the new drug application or abbreviated new drug application for the corresponding FDA-approved drug.

(3) *Lot or control number.* The lot or control number assigned by the manufacturer of the eligible prescription drug.

(4) *FDA Quantity.* FDA Quantity, which is the quantity of each eligible prescription drug in an import line delineated by packaging level, including the type of package from the largest packaging unit to the smallest packaging unit; the quantity of each packaging unit; and the volume and/or weight of each of the smallest of the packaging units.

(5) *Pre-Import Request number.* The Pre-Import Request number assigned by FDA.

■ 3. Add part 251 to read as follows:

PART 251—SECTION 804 IMPORTATION PROGRAM PROPOSAL

Subpart A—General Provisions

Sec.
251.1 Scope of the part.
251.2 Definitions.

Subpart B—Section 804 Importation Program Proposals and Pre-Import Requests

251.3 SIPproposal submission requirements.
251.4 Review and authorization of importation program proposals.
251.5 Pre-Import Request.
251.6 Limitations on authorized importation programs.
251.7 Suspension and revocation of authorized importation programs.
251.8 Modification or extension of authorized importation programs.

Subpart C—Certain Requirements for Section 804 Importation Programs

251.9 Registration of Foreign Sellers.
251.10 Reviewing and updating registration information for Foreign Sellers.
251.11 Official contact and U.S. agent for Foreign Sellers.
251.12 Importer responsibilities.
251.13 Labeling of eligible prescription drugs.
251.14 Supply chain security requirements for eligible prescription drugs.
251.15 Qualifying laboratory requirements.
251.16 Laboratory testing requirements.
251.17 Importation requirements.
251.18 Post-importation requirements.
251.19 Reports to FDA.
251.20 Severability.
251.21 Consequences for violations.

Authority: 21 U.S.C. 351, 352, 353, 355, 371, 374, 381, 384.

Subpart A—General Provisions

§ 251.1 Scope of the part.

(a) This part sets forth the procedures that Section 804 Importation Program sponsors (SIP Sponsors) must follow when submitting plans to implement time-limited programs to begin importation of drugs from Canada under section 804 of the Federal Food, Drug, and Cosmetic Act. This part also sets forth certain requirements that are necessary for such programs to be authorized by FDA. Additionally, this part sets forth requirements for eligible prescription drugs and requirements for entities that engage in importation of eligible prescription drugs.

(b) This part includes provisions that exempt eligible prescription drugs that meet certain requirements from section 502(f)(1) of the Federal Food, Drug, and Cosmetic Act. It also includes provisions that exempt certain transactions involving eligible prescription drugs from certain requirements in section 582 of the Federal Food, Drug, and Cosmetic Act.

§ 251.2 Definitions.

The definitions of terms in section 804 of the Federal Food, Drug, and Cosmetic Act apply to the terms used in this part, if not otherwise defined in this section. The following definitions apply to this part:

Active ingredient means any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect.

Adverse event means any untoward medical occurrence associated with the use of a drug product in humans, whether or not it is considered related to the drug product. An adverse event can occur in the course of the use of a drug product; from overdose of a drug product, whether accidental or intentional; from abuse of a drug product (*e.g.,* physiological withdrawal); and includes any failure of expected pharmacological action.

Combination product has the meaning set forth in § 3.2(e) of this chapter.

Constituent part has the meaning set forth in § 4.2 of this chapter.

Disability means a substantial disruption of a person's ability to conduct normal life functions.

Eligible prescription drug means a drug subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act that has been approved and has received a Notice of Compliance and a Drug Identification Number (DIN) from the Health Products and Food Branch of Health Canada (HPFB) and, but for the fact that it deviates from the required U.S. labeling, also meets the conditions in an FDA-approved new drug application (NDA) or abbreviated new drug application (ANDA) for a drug that is currently marketed in the United States, including those relating to the drug substance, drug product, production process, quality controls, equipment, and facilities.

Exclusion. The term *eligible prescription drug* does not include:

(1) A controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802));

(2) A biological product (as defined in section 351 of the Public Health Service Act (42 U.S.C. 262));

(3) An infused drug (including a peritoneal dialysis solution);

(4) An intravenously injected drug;

(5) A drug that is inhaled during surgery;

(6) An intrathecally or intraocularly injected drug;

(7) A drug that is subject to a risk evaluation and mitigation strategy under section 505–1 of the Federal Food, Drug, and Cosmetic Act;

(8) A drug that is not a ''product'' for purposes of section 582 as defined in section 581(13) of the Federal Food, Drug, and Cosmetic Act;

Entry means the information or data filed electronically to the Automated Commercial Environment (ACE) or any other U.S. Customs and Border Protection (CBP)-authorized electronic data interchange system to secure the release of imported merchandise from CBP, or the act of filing that information or data.

Foreign Seller means an establishment within Canada engaged in the distribution of an eligible prescription drug that is imported or offered for importation into the United States. A Foreign Seller must have an active drug establishment license as a drug wholesaler by Health Canada. A Foreign Seller must be registered with provincial pharmacy regulatory authorities to distribute HPFB-approved drugs. A Foreign Seller must not be licensed by a provincial pharmacy regulatory authority with an international pharmacy license that allows it to distribute drugs that are

approved by countries other than Canada and that are not HPFB-approved for distribution in Canada. A Foreign Seller must also be registered with FDA under section 804 of the Federal Food Drug and Cosmetic Act in accordance with the requirements described in this part.

Illegitimate foreign product means a drug purchased by a Foreign Seller from a manufacturer, and intended for sale to the Importer in the United States, where the Foreign Seller has credible evidence that the product:

(1) Is counterfeit, diverted, or stolen;

(2) Is intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;

(3) Is the subject of a fraudulent transaction; or

(4) Appears otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health consequences or death to humans.

Importer means a pharmacist or wholesaler. An Importer must be a State-licensed pharmacist, or a State or FDA-licensed wholesaler, who is the U.S. owner of an eligible prescription drug at the time of entry into the United States. An Importer's pharmacist or wholesaler license must be in effect (*i.e.,* not expired) and the Importer must be in good standing with the licensor.

Individual case safety report (ICSR) means a description of an adverse event related to an individual patient or subject and/or a description of a medication error.

ICSR attachments means any document related to the adverse event or medication error described in an ICSR, such as medical records, hospital discharge summaries, or other documentation.

Life-threatening adverse event means any adverse event that places the patient, in the view of the initial reporter, at *immediate* risk of death from the adverse event as it occurred, *i.e.,* it does not include an adverse event that, had it occurred in a more severe form, might have caused death.

Manufacturer means an applicant, as defined in § 314.3 of this chapter, or a person who owns or operates an establishment that manufactures an eligible prescription drug. Manufacturer also means a holder of a drug master file containing information necessary to authenticate an eligible prescription drug.

Medication error means any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of a healthcare professional, patient, or consumer. The medication error may or may not result in an adverse event.

Minimum data set for an adverse event means the minimum four elements required for reporting an ICSR of an adverse event: An identifiable patient, an identifiable reporter, a suspect drug product, and an adverse event.

Minimum data set for a medication error means the minimum three elements required for reporting an ICSR of a medication error: An identifiable reporter, a suspect drug product, and a medication error.

Pre-Import Request means a request made to FDA by an Importer that must be granted by FDA before the Importer can start importation under a Section 804 Importation Program.

Qualifying laboratory means a laboratory in the United States that has been approved by FDA for the purposes of section 804 of the Federal Food, Drug, and Cosmetic Act.

Relabel has the meaning set forth in § 207.1 of this chapter.

Relabeler has the meaning set forth in § 207.1 of this chapter.

Repack or repackage has the meaning set forth in § 207.1 of this chapter.

Section 804 Importation Program (''SIP'') means a program under section 804 of the Federal Food, Drug, and Cosmetic Act that has been authorized by FDA for the importation of eligible prescription drugs from Canada.

Section 804 Importation Program Sponsor (''SIP Sponsor''): (Option 1): Means a State, tribal, or territorial governmental entity that regulates wholesale drug distribution and/or the practice of pharmacy, and a co-sponsor or co-sponsors, if any, that submits a proposal to FDA that describes a program to facilitate the importation of prescription drugs from Canada under section 804 of the Federal Food, Drug, and Cosmetic Act. A co-sponsor must be a State, tribal, or territorial governmental entity, a pharmacist, or a wholesaler.

Section 804 Importation Program Sponsor (''SIP Sponsor''): (Option 2): Means a State, tribal, or territorial governmental entity that regulates wholesale drug distribution and/or the practice of pharmacy, a wholesaler, or a pharmacist, and a co-sponsor or co-sponsors, if any, that submits a proposal to FDA that describes a program to facilitate the importation of prescription drugs from Canada under section 804 of the Federal Food, Drug, and Cosmetic Act. A co-sponsor must be a State, tribal, or territorial governmental entity, a wholesaler, or a pharmacist.

Section 804 Serial Identifier (''SSI'') means a unique alphanumeric serial number of up to 20 characters that is assigned and affixed by the Foreign Seller to each package and homogenous case of the product that it intends to sell to the Importer. For purposes of the SSI, ''package'' means the smallest individual saleable unit of product for distribution that is intended by the Foreign Seller for sale to the Importer located in the United States, and ''individual saleable unit'' means the smallest container of product sold by the Foreign Seller to the Importer.

Serious adverse event. (1) An adverse event is considered ''serious'' if it results in any of the following outcomes:

(i) Death;

(ii) A life-threatening adverse event where the patient was at immediate risk of death at the time of the event; it does not include an adverse event that might have caused death had it occurred in a more severe form;

(iii) Inpatient hospitalization or prolongation of existing hospitalization;

(iv) A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions; and/or

(v) A congenital anomaly/birth defect.

(2) Other events that may be considered serious adverse events: Important medical events that may not result in one of the listed outcomes in this definition may be considered serious adverse events when, based upon appropriate medical judgment, they may jeopardize the patient or study subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples include: Allergic bronchospasm requiring intensive treatment in an emergency department or at home, blood dyscrasias, or convulsions that do not result in inpatient hospitalization, or the development of product dependency or product abuse.

Statutory Testing means the testing of an eligible prescription drug for authenticity, degradation, and to ensure that the prescription drug is in compliance with established specifications and standards, as required by section 804(d)(1)(J) and (L) of the Federal Food, Drug, and Cosmetic Act.

Suspect foreign product means a drug purchased by the Foreign Seller from the manufacturer, and intended for sale to the Importer in the United States, that the Foreign Seller has reason to believe is:

(1) Potentially counterfeit, diverted, or stolen;

(2) Potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;

(3) Is potentially the subject of a fraudulent transaction; or

(4) Appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans.

Transaction means the transfer of product between persons in which a change of ownership occurs.

Unexpected adverse event means an adverse event that is not included in the current U.S. labeling for the drug product. Events that may be symptomatically and pathophysiologically related to an adverse event included in the labeling but differ from the labeled event because of greater severity or specificity, would be considered unexpected. ''Unexpected,'' as used in this definition, also refers to adverse events that are mentioned in the product labeling as occurring with a class of products or anticipated from the pharmacological properties of the product but are not specifically mentioned as occurring with the particular product.

(1) *Example of greater severity.* Under this definition, hepatic necrosis would be unexpected if the labeling referred only to elevated hepatic enzymes or hepatitis.

(2) *Example of greater specificity.* Cerebral thromboembolism and cerebral hemorrhage would be unexpected if the labeling included only cerebrovascular accidents.

Unique facility identifier means the identifier required to be submitted by the registrant for drug establishment registration under section 510(b) of the Federal Food, Drug, and Cosmetic Act in accordance with § 207.25 of this chapter.

Wholesaler means a person licensed as a wholesaler or distributor of prescription drugs in the United States under section 503(e)(1) of the Federal Food, Drug, and Cosmetic Act. The term ''wholesaler'' does not include a person authorized to import drugs under section 801(d)(1).

Subpart B—Section 804 Importation Program Proposals and Pre-Import Requests

§ 251.3 SIP proposal submission requirements.

(a) A SIP Sponsor must only designate one Foreign Seller and one Importer per initial proposal. Additional Foreign Sellers and Importers may be added to an authorized SIP through a supplement under § 251.8.

(b) A SIP Sponsor that intends to implement a SIP under this part must submit a proposal to FDA in electronic form to FDA's Electronic Submissions Gateway (ESG) or to an alternative transmission point identified by FDA. The proposal must include:

(1) A cover sheet containing the following:

(i) Name or names of SIP Sponsor and co-sponsors, if any; and

(ii) Name and contact information for a person authorized to serve as the point of contact with FDA during its review of the proposal;

(2) A table of contents;

(3) An introductory statement that includes an overview of the SIP Sponsor's SIP Proposal; and

(4) The SIP Sponsor's importation plan.

(c) The overview of the SIP Proposal must include:

(1) The name or names and address or addresses of the SIP Sponsor and co-sponsors, if any;

(2) The name and DIN of each eligible prescription drug that the SIP Sponsor seeks to include in the SIP;

(3) The name and address of the applicant that owns the approved NDA or ANDA for each eligible prescription drug's FDA-approved counterpart, and the approved NDA or ANDA number;

(4) The name and address of the manufacturer of the finished dosage form of the drug, if available;

(5) The name and address of the manufacturer of the active ingredient or ingredients of the drugs, if available;

(6) The name and address of the Foreign Seller;

(7) The name and address of the Importer;

(8) The name and address of the FDA-registered repackager or relabeler, if different from the Importer, that will relabel the eligible prescription drugs (including any limited repackaging in accordance with the requirements in this part), along with evidence of registration and of satisfactory resolution of any objectionable conditions or practices identified during its most recent FDA inspection, if applicable;

(9) A summary of how the SIP Sponsor will ensure:

(i) That the imported eligible prescription drugs meet the Statutory Testing requirements;

(ii) That the supply chain is secure;

(iii) That the labeling requirements of the Federal Food, Drug, and Cosmetic Act and this part are met;

(iv) That the post-importation pharmacovigilance and other requirements of the Federal Food, Drug, and Cosmetic Act and this part are met; and

(v) That the SIP Proposal would result in a significant reduction in the cost to the American consumer of the prescription drugs that the SIP Sponsor seeks to import.

(d) The SIP Sponsor's importation plan must:

(1) Identify the SIP Sponsor, including any co-sponsors, and identify the finished dosage form manufacturer of each prescription drug that the SIP Sponsor seeks to include in the SIP, the Foreign Seller, and the Importer, and explain the legal relationship of each of these entities to the SIP Sponsor, if any.

(2) Include an attestation containing a complete disclosure of any past criminal convictions or violations of the State, Federal, or Canadian laws regarding drugs or devices against the Foreign Seller or Importer or an attestation that the Foreign Seller or Importer has not been involved in, or convicted of, any such criminal or prohibited acts. Such attestation must include principals, any shareholder who owns 10 percent or more of outstanding stock in any non-publicly held corporation, directors, officers, and any facility manager or designated representative of such manager.

(3) Include a list of all disciplinary actions, to include the date of, and parties to, any action imposed against the Foreign Seller or the Importer by State, Federal, or Canadian regulatory bodies, including any such actions against the principals, owners, directors, officers, or any facility manager or designated representative of such manager for the previous 7 years prior to submission of the SIP Proposal.

(4) Include:

(i) The Health Canada inspectional history for the previous 5 years, or if the Foreign Seller has been licensed for less than 5 years, for the duration of its period of licensure; and

(ii) the State and Federal inspectional history for the Importer for the previous 5 years, or if the Foreign Seller has been licensed for less than 5 years, for the duration of its period of licensure.

(5) Include the proprietary and established names, the approved application numbers, and the DIN and National Drug Code (NDC), for each eligible prescription drug that the SIP Sponsor seeks to import from Canada and for its FDA-approved counterpart. It must also include as much of the information that is required by § 251.5 about the HPFB-approved product and its FDA-approved counterpart as is available, including the name and quantity of the active ingredient, the inactive ingredients, and the dosage form.

(6) Confirm that each HPFB-approved drug's FDA-approved counterpart drug is currently marketed in the United States.

(7) Describe, to the extent possible, the testing that will be done to establish that the HPFB-approved drug meets the conditions in the NDA or ANDA for the HPFB-approved drug's FDA-approved counterpart. It must also identify the qualifying laboratory that will conduct the testing, and it must establish that the laboratory is qualified in accordance with § 251.15 to conduct the tests.

(8) Include a copy of the FDA-approved labeling for the FDA-approved version of the eligible prescription drug, a copy of the proposed labeling that will be used for the eligible prescription drug, and a side-by-side comparison of the FDA-approved labeling and the proposed labeling including, if applicable, any patient labeling, with all differences annotated and explained. The SIP Proposal must also include a copy of the HPFB-approved labeling.

(9) Explain how the SIP Sponsor expects that the SIP will result in a significant reduction in the cost to the American consumer of the prescription drugs that the SIP Sponsor seeks to import. The explanation must include any assumptions and uncertainty, and it must be sufficiently detailed to allow for a meaningful evaluation.

(10) Explain how the SIP Sponsor will ensure that all of the participants in the SIP comply with the requirements of section 804 of the Federal Food, Drug, and Cosmetic Act and this part.

(11) Describe the procedures the SIP Sponsor will use to ensure that the requirements of this part are met, including the steps that will be taken to ensure that the:

(i) Storage, handling, and distribution practices of supply chain participants, including transportation providers, meet the minimum requirements of part 205 of this chapter and do not affect the quality or impinge on the security of the eligible prescription drugs;

(ii) Supply chain is secure;

(iii) Importer screens the eligible prescription drugs it imports for evidence that they are adulterated, counterfeit, damaged, tampered with, or expired; and

(iv) Importer fulfills its responsibilities to submit adverse event, medication error, field alert, and other reports.

(12) Explain how the SIP Sponsor will educate pharmacists, healthcare providers, and patients about the drugs imported under its SIP.

(13) Include the SIP's recall plan, including an explanation of how the SIP Sponsor will obtain recall or market withdrawal information and how it will ensure that recall or market withdrawal information is shared among the SIP Sponsor, the Foreign Seller, the Importer, and FDA and provided to the manufacturer; and

(14) Explain how the SIP Sponsor will ensure that any information that the manufacturer provides to the Importer to allow the Importer to conduct the Statutory Testing, or information otherwise obtained by the Importer for such purposes, would be kept in strict confidence and used only for purposes of testing or otherwise complying with the Federal Food, Drug, and Cosmetic Act, as required by section 804(e)(2)(B).

§ 251.4 Review and authorization of importation program proposals.

Based on a review of a SIP Proposal submitted under this part, FDA may authorize, modify, or extend the authorization period of a SIP that meets the requirements of this part. FDA may deny a request for authorization, modification, or extension of a SIP in its discretion, including if a proposed SIP does not meet the standard for authorizing a SIP under this part. Where a SIP Proposal meets the requirements of this part, FDA may nonetheless decide, in its discretion, not to authorize the SIP Proposal.

(a) Among other reasons, FDA may decide not to authorize a SIP Proposal because of potential safety concerns with the SIP, because of the degree of uncertainty that the SIP Proposal would adequately ensure the protection of public health, because, based on the recommendation of another Health and Human Services (HHS) component as directed by the Secretary, the relative likelihood that the SIP Proposal would not result in significant cost savings, or in order to limit the number of authorized SIP programs so FDA can effectively and efficiently carry out its responsibilities under section 804 of the Federal Food, Drug, and Cosmetic Act in light of the amount of resources allocated to carrying out such responsibilities.

(b) FDA will notify a SIP Sponsor in writing, including through electronic means, when FDA receives the SIP Sponsor's SIP Proposal.

(c) FDA will make a reasonable effort to promptly communicate to a SIP Sponsor about any information required by § 251.3 that was not submitted in a SIP Proposal.

(1) FDA may notify a SIP Sponsor if FDA believes additional information would help FDA's review of a SIP Proposal.

(2) FDA will notify a SIP Sponsor in writing, including through electronic means, whether FDA has decided to authorize or not to authorize the SIP Sponsor's SIP Proposal.

§ 251.5 Pre-Import Request.

(a) A prescription drug may not be imported or offered for import under this part unless the Importer has filed a Pre-Import Request for that drug, which has been granted by FDA.

(b) The Importer must submit a complete Pre-Import Request at least 30 days prior to scheduled date of arrival or entry for consumption, whichever occurs first, of an eligible prescription drug covered under an authorized SIP.

(c) A complete Pre-Import Request must include, at a minimum:

(1) Identification of the Importer including Importer name, business type (wholesale distributor or pharmacist), U.S. license number(s) and State(s) of license, business address, unique facility identifier if required to register with FDA as an establishment under section 510 of the Federal Food, Drug, and Cosmetic Act or FDA establishment identification number if not required to register under section 510 of the Federal Food, Drug, and Cosmetic Act, and name of a contact person with their email and phone number.

(2) Identification of the FDA-authorized SIP including the name of the SIP; the name or names of the SIP Sponsor and co-sponsors, if any; business address; and the name, email address, and phone number of a contact person.

(3) Identification of the Foreign Seller, including the name of the Foreign Seller, business address, unique facility identifier, any license numbers issued by Health Canada or a provincial pharmacy regulatory body, and the name, email address, and phone number of a contact person.

(4) Identification and description of the drug(s) covered by the Pre-Import Request, including the following information:

(i) Established and trade name of the HPFB-approved drug(s), as applicable, DIN, and complete product description including strength, description of dosage form, and route of administration.

(ii) Active pharmaceutical ingredient (API) information, including:

(A) Name of API;

(B) Manufacturer of API and its unique facility identifier; and

(C) Amount of API and unit measure in each eligible prescription drug;

(iii) Established name and trade name, as applicable, of FDA-approved counterpart drug(s) and NDA or ANDA number.

(iv) Manufacturer of the eligible prescription drug with the business address and unique facility identifier.

(v) Copies of the invoice and any other documents related to the manufacturer's sale of the drugs to the Foreign Seller provided by the manufacturer to the Importer, and copies of the same documents provided by the Foreign Seller to the Importer.

(vi) Quantity, listed separately by dosage form, strength, batch and lot or control number assigned by the manufacturer to each eligible prescription drug intended to be imported under this Pre-Import Request compared to the quantity of each batch and lot or control number originally received by the Foreign Seller from the manufacturer, and the date of such receipt.

(vii) Expiration date of each HFPB-approved drug, listed by lot or control number.

(viii) Expiration date to be assigned to the eligible prescription drug when relabeled by the Importer with a complete description of how that expiration date was calculated to comply with the FDA-approved NDA or ANDA.

(ix) NDC proposed for assignment by the Importer.

(x) FDA product code for the eligible prescription drug(s) to be imported.

(xi) A Statutory Testing plan that includes:

(A) A description of how the samples will be selected from a shipment for the Statutory Testing;

(B) The name and location of the qualifying laboratory in the United States that will conduct the Statutory Testing; and

(C) A description of the testing method(s) that will be used to conduct the Statutory Testing, if the Importer will be conducting the Statutory Testing, or the description of the testing methods must be submitted by the manufacturer to FDA directly under § 251.17 if the manufacturer will be conducting the Statutory Testing.

(xii) Attestation from the manufacturer that must establish that the drug proposed for import, but for the fact that it bears the HPFB-approved labeling, meets the conditions in the FDA-approved NDA or ANDA, including any process-related or other requirements for which compliance cannot be established through laboratory testing. Accordingly, the attestation must include:

(A) Confirmation that the HPFB-approved drug has the active ingredient(s), active ingredient source(s) (including manufacturing facility or facilities), inactive ingredient(s), dosage form, strength(s), and route(s) of administration, described in the FDA-approved drug's NDA or ANDA.

(B) Confirmation that the HPFB-approved drug conforms to the specifications in the FDA-approved drug's NDA or ANDA regarding the quality of the drug substance(s), drug product, intermediates, raw materials, reagents, components, in-process materials, container closure systems, and other materials used in the production of the drug.

(C) Confirmation that the HPFB-approved drug was manufactured in accordance with the specifications described in the FDA-approved drug's NDA or ANDA, including with regard to the facilities and manufacturing lines that are used, and in compliance with current good manufacturing practice requirements set forth in section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act and parts 4 (if a combination product), 210, and 211 of this chapter.

(D) Original date of manufacture or the date used to calculate the labeled expiration date based on the HPFB-approved or scientifically validated expiration period, the expiration period set forth in the FDA-approved drug's NDA or ANDA, and any other information needed to label the drug with an expiration date that meets the specifications of the FDA-approved drug's NDA or ANDA.

(E) Information needed to confirm that the labeling of the prescription drug complies with labeling requirements of the Federal Food, Drug, and Cosmetic Act.

(xiii) Information related to the Importation, including:

(A) Location of the eligible prescription drugs in Canada and anticipated date of shipment (date eligible prescription drug(s) will leave their location in Canada);

(B) Name, address, email, and telephone number of the Foreign Shipper;

(C) Anticipated date of export from Canada and Canadian port of exportation;

(D) Anticipated date and approximate time of arrival at a port authorized by FDA to import eligible prescription drugs under section 804 of the Federal Food, Drug, and Cosmetic Act;

(E) The name, address, unique facility identifier or FDA establishment identification number, and telephone number of the warehouse, location within a specific foreign trade zone, or other secure distribution facility controlled by or under contract with the Importer where the eligible prescription drug(s) will be stored pending testing, relabeling, and FDA determination of admissibility;

(F) Information regarding the facility where the relabeling and any limited repackaging activities will occur for all eligible prescription drugs covered by this Pre-Import Request, including:

(*1*) The facility's unique facility identifier;

(*2*) The facility's name, address, and FDA establishment identifier number;

(*3*) The anticipated date the relabeling and any limited repackaging will be completed; and

(*4*) Information about where the relabeled drug will be stored pending distribution, including the FDA establishment identification number of the storage facility, if available.

(d) If the manufacturer conducts the Statutory Testing, the manufacturer must provide the attestation to FDA. If the Importer conducts the Statutory Testing, the manufacturer must provide the attestation to the Importer.

(e)(1) The Importer must provide the executed batch record, including the executed certificate of analysis for at least one recently manufactured, commercial-scale batch of the HPFB-approved drug; and at least one recently manufactured, commercial-scale batch of the FDA-approved drug that was produced for and released for distribution to the U.S. market under an NDA or ANDA.

(2) The manufacturer must provide these analyses for each manufacturing line that the manufacturer used to produce either or both of the drugs.

§ 251.6 Limitations on authorized importation programs.

(a) Unless an extension is granted under this section, authorization for a SIP automatically terminates after 2 years, or a shorter period of time if a shorter period of time is specified in the authorization for the SIP.

(b) The 2-year authorization period for a SIP begins when the Importer files an electronic import entry for consumption for its first shipment of drugs under the SIP.

(c) Notwithstanding paragraph (a) of this section, authorization for a SIP terminates if the Importer does not file an electronic import entry for consumption for a shipment of eligible prescription drugs under the SIP within 1 year of the date that the SIP was authorized.

(d) FDA will terminate authorization of a SIP upon request from the SIP Sponsor that includes a notice of the SIP Sponsor's intent to discontinue its activities.

§ 251.7 Suspension and revocation of authorized importation programs.

(a) FDA may suspend a SIP under the circumstances set forth in § 251.18, or under other circumstances in FDA's discretion. Importation of drugs under a SIP that has been suspended is prohibited.

(b) SIP Sponsors and other SIP participants must agree to submit to audits of their books and records and inspections of their facilities as a condition of participation in a SIP. If a SIP Sponsor, manufacturer, Foreign Seller, Importer, qualifying laboratory, or other participant in the supply chain delays, denies, or limits an inspection, or refuses to permit entry or inspection of their facility or their records, any drug that has been held by such entity will be deemed to be adulterated and the SIP may be suspended, in whole or in part, immediately.

(c) FDA may revoke authorization of a SIP, in whole or in part, including with respect to one or more drugs in the SIP, at any time for any reason if FDA determines, in its discretion, or on the recommendation of another HHS component as directed by the Secretary, that:

(1) The SIP Proposal contained an untrue statement of material fact;

(2) The SIP Proposal omitted material information;

(3) The SIP no longer meets the requirements of section 804 of the Federal Food, Drug, and Cosmetic Act, this part, or the SIP, including, among other things, if the manufacturer, the Foreign Seller, the Importer, or any other SIP entity is found to be not compliant with section 501(a)(2)(A) or (B) of the FD&C Act;

(4) Continued implementation of the SIP is likely to pose additional risk to the public's health and safety;

(5) Confidential manufacturer information was disclosed in violation of § 251.16;

(6) Continued implementation of the SIP will not result in a significant reduction in the cost of the drugs covered by the SIP to the American consumer;

(7) Continued monitoring of the SIP imposes too much of a drain on FDA or HHS resources or is inconsistent with FDA or HHS prioritization of resources; or

(8) Continued implementation of the SIP is otherwise inappropriate.

§ 251.8 Modification or extension of authorized importation programs.

(a) A supplement to modify or extend an authorized SIP must be submitted via the ESG for FDA's consideration.

(b) A SIP Sponsor can propose to add additional Foreign Sellers or additional Importers to an authorized SIP once it has consistently imported eligible prescription drugs in accordance with section 804 of the Federal Food, Drug, and Cosmetic Act and this part.

(c) If FDA authorizes changes to the SIP, the Importer must submit a new Pre-Import Request in accordance with § 251.5.

(d) A SIP Sponsor must not make any changes or permit any changes to be made to a SIP without first securing FDA's authorization. If FDA authorizes changes to a SIP under this section, such authorization does not change the authorization of the original SIP.

(e) A SIP Sponsor may request that FDA extend the authorization period of an authorized SIP. Such a request must be submitted via the ESG for FDA's consideration at least 3 months before the SIP's authorization period will expire. To be eligible for an extension of the authorized SIP, a SIP must be up to date on all of the information and records-related requirements of section 804 of the Federal Food, Drug, and Cosmetic Act and this part. FDA may, in its sole discretion, extend the authorization period for up to 2 years at a time.

Subpart C—Certain Requirements for Section 804 Importation Programs

§ 251.9 Registration of Foreign Sellers.

(a) Foreign Sellers must be registered with FDA before FDA will authorize a SIP Proposal.

(b) To register, a Foreign Seller must provide the following information:

(1) Name of the owner or operator; if a partnership, the name of each partner; if a corporation, the name of each corporate officer and director, and the place of incorporation;

(2) All names of the Foreign Seller, including names under which the Foreign Seller conducts business or names by which the Foreign Seller is known;

(3) Physical address, telephone number(s), and email address of the Foreign Seller;

(4) Registration number, if previously assigned by FDA;

(5) A copy of the Foreign Seller's Health-Canada Drug Establishment License;

(6) All types of operations performed by the Foreign Seller;

(7) Name, mailing address, telephone number, and email address of the official contact for the establishment; and

(8) Name, mailing address, telephone number, and email address of:

(i) The U.S. agent;

(ii) The Importer to which the Foreign Seller plans to sell eligible prescription drugs; and

(iii) Each SIP Sponsor with which the Foreign Seller works.

§ 251.10 Reviewing and updating registration information for Foreign Sellers.

(a) *Expedited updates.* A Foreign Seller must update its registration information no later than 30 calendar days after:

(1) Closing or being sold;

(2) Changing their name or physical address; or

(3) Changing the name, mailing address, telephone number, or email address of the official contact or the U.S. agent. A Foreign Seller, official contact, or U.S. agent may notify FDA about a change of information for the designated official contact or U.S. agent, but only a Foreign Seller is permitted to designate a new official contact or U.S. agent.

(b) *Annual review and update of registration information.* A Foreign Seller must review and update all registration information required under § 251.9.

(1) The first review and update must occur during the period beginning on October 1 and ending December 31 of the year of initial registration, if the initial registration occurs prior to October 1. Subsequent reviews and updates must occur annually, during the period beginning on October 1 and ending December 31 of each calendar year.

(2) The updates must reflect new changes not previously required to be reported along with a summary of the registration updates that were provided to FDA as required during the calendar year.

(3) If no changes have occurred since the last registration, a Foreign Seller must certify that no changes have occurred.

§ 251.11 Official contact and U.S. agent for Foreign Sellers.

(a) *Official contact.* A Foreign Seller subject to the registration requirements of this part must designate an official contact. The official contact is responsible for:

(1) Ensuring the accuracy of registration information as required by § 251.9; and

(2) Reviewing, disseminating, routing, and responding to all communications from FDA, including emergency communications.

(b) *U.S. agent.* (1) A Foreign Seller must designate a single U.S. agent. The U.S. agent must reside or maintain a place of business in the United States

and may not be a mailbox, answering machine or service, or other place where a person acting as the U.S. agent is not physically present. The U.S. agent is responsible for:

(i) Reviewing, disseminating, routing, and responding to all communications from FDA, including emergency communications;

(ii) Responding to questions concerning those drugs that are imported or offered for import to the United States; and

(iii) Assisting FDA in scheduling inspections.

(2) FDA may provide certain information and/or documents to the U.S. agent. The provision of information and/or documents by FDA to the U.S. agent is equivalent to providing the same information and/or documents to the Foreign Seller.

§ 251.12 Importer responsibilities.

(a) The Importer is responsible for:

(1) In accordance with the procedures set forth in § 207.33 of this chapter, proposing an NDC for assignment for each eligible prescription drug imported pursuant to this part;

(2) Examining the Canadian labeling of a sample of each shipment of eligible prescription drugs to verify that the labeling is consistent with that of an HPFB-approved drug, and attesting that such examination has been conducted through reports to FDA required under this part;

(3) Screening eligible prescription drugs for evidence that they are adulterated, counterfeit, damaged, tampered with, or expired;

(4) Ensuring the eligible prescription drug is relabeled with the required U.S. labeling, including the container and carton labels; prescribing information; and patient labeling, such as medication guides, instruction for use documents, and patient package inserts, in accordance with §§ 251.13 and 251.14(d);

(5) Arranging for an entry to be submitted in accordance with § 251.17;

(6) Collecting and submitting the information and documentation to FDA about the imported drug(s) pursuant to section 804(d) of the Federal Food, Drug, and Cosmetic Act, in addition to information about the Foreign Seller, as set forth in § 251.19; and

(7) Submitting the adverse event, medication error, field alert, and other reports, and complying with drug recalls, in accordance with § 251.18.

(b) If the Importer is also relabeling the eligible prescription drug, the Importer must also:

(1) Register with FDA as a repackager or relabeler under section 510(b) of the Federal Food, Drug, and Cosmetic Act, in accordance with § 207.25 of this chapter;

(2) Obtain a labeler code from FDA and propose an NDC for each eligible prescription drug pursuant to § 207.33 of this chapter; and

(3) List each eligible prescription drug pursuant to § 207.53 of this chapter.

(c) If the Importer is not itself relabeling the eligible prescription drug, the Importer must:

(1) Obtain its own labeler code from FDA under § 207.33(c) of this chapter;

(2) Ensure that the eligible prescription drug incorporates the NDC the Importer proposed for assignment, which must include the Importer's labeler code; and

(3) Ensure that the entity relabeling an eligible prescription drug on its behalf proposes an NDC pursuant to § 207.33 of this chapter and lists each eligible prescription drug pursuant to § 207.53 of this chapter.

§ 251.13 Labeling of eligible prescription drugs.

(a) Upon the request of a SIP Sponsor or Importer, the manufacturer of a prescription drug must provide an Importer written authorization for the Importer to use, at no cost, the FDA-approved labeling for the prescription drug. If the manufacturer fails to do so within a timely fashion, FDA may deem this authorization to have been given.

(b) In addition to the exemption provided in subpart D of part 201 of this chapter, an eligible prescription drug imported for purposes of this part is exempt from section 502(f)(1) of the Federal Food, Drug, and Cosmetic Act if all the following conditions are met:

(1) The Importer or the manufacturer certifies that the drug meets all labeling requirements under the Federal Food, Drug, and Cosmetic Act, including the requirements of this part. The Importer of an eligible prescription drug must either:

(i) Propose an NDC for the drug following the procedures in § 207.33 of this chapter and list the drug following the procedures in § 207.53 of this chapter, or

(ii) If the Importer is a private label distributor, take responsibility to ensure that the entity performing relabeling on its behalf proposes an NDC and lists each eligible prescription drug in accordance with the applicable requirements of part 207 of this chapter.

(2) The drug must be:

(i) In the possession of a person (or his agents or employees), including Foreign Sellers and Importers, regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale distribution of prescription drugs;

(ii) In the possession of a retail, hospital, or clinic pharmacy, or a public health agency, regularly and lawfully engaged in dispensing prescription drugs; or

(iii) In the possession of a practitioner licensed by law to administer or prescribe such drugs.

(3) The drug is to be dispensed in accordance with section 503(b) of the Federal Food, Drug, and Cosmetic Act.

(4) The label of the drug must be the same as the label authorized by the approved NDA or ANDA of the FDA-approved drug, except that the label must bear conspicuously:

(i) The Importer's NDC for the eligible prescription drug, and such NDC must replace any other NDC otherwise appearing on the label of the FDA-approved drug; and

(ii) The name and place of business of the manufacturer and the Importer.

(5) The container label must include at a minimum the product's proprietary and established name (if any); product strength; lot number; and the name of the manufacturer and the Importer.

(6) Labeling on or within the package from which the eligible prescription drug is to be dispensed is the same as the labeling authorized by the NDA or the ANDA of the FDA-approved drug, except that:

(i) The labeling must bear the statement: ''This drug was imported from Canada under the [Name of State or Other Governmental Entity and of Its Co-Sponsors, If Any] Section 804 Importation Program to reduce its cost to the American consumer.'' If the SIP maintains a website, the statement could also include the website address. This statement must be included after the PATIENT COUNSELING INFORMATION section for products subject to §§ 201.56(d) and 201.57 of this chapter, or after the HOW SUPPLIED section (or after the last section of labeling) for products subject to §§ 201.56(e) and 201.80 of this chapter. The statement also must be included on the immediate container and outside package;

(ii) For products subject to §§ 201.56(d) and 201.57(c)(17)(iii) of this chapter, the NDC(s) assigned to the eligible prescription drug in accordance with the procedures in § 207.33 of this chapter must be included in the HOW SUPPLIED/STORAGE AND HANDLING section in place of the NDC(s) assigned to the FDA-approved U.S. versions of the drug; and

(iii) For products subject to §§ 201.56(e) and 201.80(k)(3) of this chapter, the NDC(s) assigned to the

eligible prescription drug in accordance with the procedures in § 207.33 of this chapter must be included in the HOW SUPPLIED section in place of the NDC(s) assigned to the FDA-approved U.S. versions of the drug.

(c) The Importer is responsible for relabeling the drug, or arranging for it to be relabeled, to meet the requirements of this part. The relabeling and associated limited repackaging activities must meet applicable requirements, including applicable current good manufacturing practice requirements under parts 210 and 211 of this chapter. Except for repackaging that is necessary to perform the relabeling described in this part, further repackaging of drugs imported pursuant to a SIP is prohibited.

§ 251.14 Supply chain security requirements for eligible prescription drugs.

(a) *SIP Sponsors.* A sponsor of an authorized SIP must ensure that:

(1) Each drug imported under the SIP is HPFB-approved and labeled for sale in Canada from the point of manufacture until it reaches the Foreign Seller;

(2) For each drug that is imported under the SIP and that is manufactured outside Canada, the drug was authorized for import into Canada by the manufacturer and labeled by the manufacturer for the Canadian market before importation under the SIP (*i.e.* the drug was not transshipped through Canada for sale in another country);

(3) For each drug imported under the SIP, the drug was sold by the manufacturer directly to a Foreign Seller;

(4) For each drug imported under the SIP, the Foreign Seller ships the drug directly to the Importer in the United States; and

(5) The Importer(s) and Foreign Seller(s) identified in the SIP meet the applicable requirements of this part and in section 582(c) and (d) of the Federal Food, Drug, and Cosmetic Act.

(b) *Manufacturer.* The manufacturer must provide to the Importer a copy of any transaction documents that were provided from the manufacturer to the Foreign Seller.

(c) *Foreign Seller.*

(1) A Foreign Seller must have systems in place to:

(i) Determine whether a drug in its possession or control that it intends to sell to the Importer under a SIP is a suspect foreign product. Upon making a determination that a drug in its possession or control is a suspect foreign product, or upon receiving a request for verification from FDA that the Foreign Seller has determined that a product within its possession or control is a suspect foreign product, a Foreign Seller must:

(A) Quarantine such product within its possession or control until such product is cleared or dispositioned;

(B) Promptly conduct an investigation, in coordination with the Importer and the manufacturer, as applicable, to determine whether the product is an illegitimate foreign product, and verify the product at the package level, including the SSI; and

(C) If the Foreign Seller makes the determination that a suspect foreign product is not an illegitimate foreign product, promptly notify FDA of such determination (such product may be further distributed).

(ii) Determine whether a drug in its possession or control that it intends to sell to the Importer under a SIP is an illegitimate foreign product. Upon making a determination that a drug in its possession or control is an illegitimate foreign product, the Foreign Seller must:

(A) Quarantine such product within the possession or control of the Foreign Seller from product intended for distribution until such product is dispositioned;

(B) Disposition the illegitimate foreign product within the possession or control of the Foreign Seller;

(C) Take reasonable and appropriate steps to assist a manufacturer or Importer to disposition an illegitimate product not in the possession or control of the Foreign Seller; and

(D) Retain a sample of the product for further physical examination or laboratory analysis of the product by the manufacturer or the Secretary (or other appropriate Federal or State official) upon request by the Secretary (or other appropriate Federal or State official), as necessary and appropriate.

(2)(i) Upon determining that a product in the possession or control of the Foreign Seller is an illegitimate foreign product, the Foreign Seller must notify FDA and the Importer that the Foreign Seller received such illegitimate product not later than 24 hours after making such determination.

(ii) Upon the receipt of a notification from FDA, the Importer, or other authorized repackager, wholesale distributor, or dispenser that a determination has been made that a product that had been sold by the Foreign Seller is an illegitimate foreign product, a Foreign Seller must identify all illegitimate foreign product subject to such notification that is in the possession or control of the Foreign Seller, including any product that is subsequently received, and perform the activities to investigate the product described in paragraph (c)(1) of this section.

(iii) Upon making a determination, in consultation with FDA, that a notification is no longer necessary, a Foreign Seller must promptly notify the Importer and person who sent the notification that the notification is terminated.

(iv) A Foreign Seller must keep records of the disposition of an illegitimate foreign product for not less than 6 years after the conclusion of the disposition.

(3) Upon request by FDA, or other appropriate Federal or State official, in the event of a recall or for purposes of investigating a suspect foreign product or an illegitimate foreign product, a Foreign Seller must promptly provide the official with information about its transactions with the manufacturer and the Importer.

(4) A Foreign Seller, upon receiving a shipment of eligible prescription drugs from the manufacturer, must:

(i) Separate the portion of drugs intended for sale to the Importer located in the United States, and store such portion separately from that portion of product intended for sale in the Canadian market;

(ii) Assign a SSI to each package and homogenous case intended for sale to the Importer in the United States, unless each such package and homogenous case contains a manufacturer-affixed or imprinted product identifier, as such term is defined in section 581(14) of the Federal Food, Drug, and Cosmetic Act, at the time of receipt by the Foreign Seller; and

(iii) Affix or imprint the SSI on each package and homogenous case intended for sale to the Importer in the United States. Such SSI must be located on blank space on the package or homogenous case and must not obscure any labeling for the Canadian market, including the DIN.

(5) Upon receiving a request for verification from the Importer or other authorized repackager, wholesale distributor, or dispenser that is in possession or control of a product such person believes to be distributed by such Foreign Seller, a Foreign Seller must, not later than 24 hours after receiving the request for verification or in other such reasonable time as determined by the Secretary, based on the circumstances of the request, notify the person making the request whether the product identifier, including the standardized numerical identifier, that is the subject of the request corresponds to the SSI affixed or imprinted by the

Foreign Seller. If a Foreign Seller responding to a request for verification identifies a product identifier that does not correspond to that SSI affixed or imprinted by the Foreign Seller, the Foreign Seller must treat such product as suspect foreign product and conduct an investigation as described in paragraph (c)(1) of this section. If the Foreign Seller has reason to believe the product is an illegitimate foreign product, the Foreign Seller must advise the person making the request of such belief at the time such Foreign Seller responds to the request for verification.

(6) For each transaction between the Foreign Seller and the Importer for an eligible prescription drug, the Foreign Seller must provide:

(i) A statement that the Foreign Seller received the product from an FDA-registered manufacturer;

(ii) The proprietary or established name of the product;

(iii) The strength and dosage form of the product;

(iv) The container size;

(v) The number of containers;

(vi) The lot number of the product;

(vii) The date of the transaction;

(viii) The date of the shipment, if more than 24 hours after the date of the transaction;

(ix) The business name and address of the person associated with the Foreign Seller from whom ownership is being transferred;

(x) The business name and address of the person associated with the Importer to whom ownership is being transferred;

(xi) The SSI for each package and homogenous case of product; and

(xii) The Canadian DIN for each product transferred.

(7) Upon a request by FDA, or other appropriate Federal or State official, in the event of a recall or for purposes of investigating a suspect foreign product or an illegitimate foreign product, the Foreign Seller must promptly provide the official with information about its transactions with the manufacturer and the Importer.

(d) Importers. (1) An Importer of an eligible prescription drug must purchase the drug directly from a Foreign Seller in Canada.

(2) Upon receipt of a product from the Foreign Seller, an Importer must facilitate the affixation or imprinting of a product identifier, as defined in section 581(14) of the Federal Food, Drug, and Cosmetic Act. The Importer must ensure that such affixation or imprinting occurs at the same time the product is relabeled with the required U.S.-approved labeling for the drug product and, except for repackaging necessary to perform the relabeling described in this part, cannot otherwise relabel or repackage the product. The Importer may contract with an entity registered with FDA under part 207 of this chapter to accomplish such relabeling, provided that the entity does not otherwise relabel or repackage the product, except for repackaging that is necessary to perform the relabeling described in this part.

(3) The repackager or relabeler that affixes or imprints the product identifier to each package and homogenous case of an eligible prescription drug in accordance with section 582 of the Federal Food, Drug, and Cosmetic Act—

(i) May affix or imprint a product identifier only on a package of an eligible prescription drug that has a serial number that was assigned and affixed by the Foreign Seller;

(ii) Must maintain the product identifier information for such drug for not less than 6 years; and

(iii) Must maintain records for not less than 6 years that associate the product identifier the repackager affixes or imprints with the serial number assigned by the Foreign Seller and the Canadian DIN.

(4) An Importer must retain records, for no less than 6 years, that allow the Importer to associate the product identifier affixed or imprinted on each package or homogenous case of product it received from the Foreign Seller, with the SSI that had been assigned by the Foreign Seller, and the Canadian DIN that was on the package when the Foreign Seller received the product from the original manufacturer. An Importer must also have processes in place to, upon receipt of a drug and records from a Foreign Seller, compare such information with information the Importer received from the manufacturer, including relevant documentation about the transaction that the manufacturer provided to the Foreign Seller upon its transfer of ownership of the product for the Canadian market.

(5) An Importer must comply with all applicable requirements of section 582 of the Federal Food, Drug, and Cosmetic Act, including requirements that apply to subsequent transactions with trading partners, unless a waiver, exception, or exemption applies.

(6) For transactions of eligible prescription drugs between Importers and Foreign Sellers, an Importer is exempt from the following supply chain security requirements that are otherwise applicable:

(i) An Importer is exempt from the prohibition on receiving a product for which the previous owner did not provide the transaction history, transaction information, and transaction statement, under section 582(c)(1)(A) or (d)(1)(A) of the Federal Food, Drug, and Cosmetic Act as applicable; provided that the Importer receives from the Foreign Seller the information required under paragraph (c) of this section.

(ii) An Importer is exempt from the prohibition on receiving a product that is not encoded with a product identifier, under section 582(c)(2) or (d)(2) of the Federal Food, Drug, and Cosmetic Act as applicable, provided that the product the Importer received from the Foreign Seller has an SSI.

(iii) An Importer is exempt from the prohibition on conducting a transaction with an entity that is not an ''authorized trading partner,'' under section 582(c)(3) or (d)(3) of the Federal Food, Drug, and Cosmetic Act as applicable.

(iv) An Importer is exempt from the requirement to verify that a product in the Importer's possession or control contains a ''standardized numerical identifier'' at the package level, under section 582(c)(4)(A)(i)(II) or (d)(4)(A)(ii)(II) of the Federal Food, Drug, and Cosmetic Act as applicable, provided that the Importer verifies that each package and homogenous case of the product includes the SSI affixed or imprinted by the Foreign Seller.

§ 251.15 Qualifying laboratory requirements.

(a) To be considered a qualifying laboratory for purposes of section 804 of the Federal Food, Drug, and Cosmetic Act and this part, a laboratory must have ISO 17025 accreditation.

(b) To be considered a qualifying laboratory for purposes of section 804 of the Federal Food, Drug, and Cosmetic Act and this part, a laboratory must have an FDA inspection history and it must have satisfactorily addressed any objectionable conditions or practices identified during its most recent FDA inspection, if applicable.

(c) To be considered a qualifying laboratory for purposes of section 804 of the Federal Food, Drug, and Cosmetic Act and this part, a laboratory must comply with the applicable elements of current good manufacturing practice requirements, including but not limited to provisions regarding laboratory controls in § 211.160 of this chapter and laboratory records in § 211.194 of this chapter.

§ 251.16 Laboratory testing requirements.

(a) The manufacturer or the Importer must arrange for eligible prescription drugs to be tested by a qualifying laboratory.

(b) If the tests are conducted by the Importer, the manufacturer of the

prescription drug must supply to the Importer all information needed to authenticate the prescription drug being tested, including any necessary testing methodologies and protocols that the manufacturer has developed. The manufacturer must also provide the Importer with formulation information about the HPFB-approved drug and the FDA-approved drug to facilitate authentication.

(c) Testing done on a statistically valid sample of the batch or shipment, as applicable, must be sufficiently thorough to establish, in conjunction with data and information from the manufacturer, that the batch or shipment is eligible for importation under a SIP. The size of the sample must be large enough to enable a statistically valid statement to be made regarding the authenticity and stability of the quantity of the batch in the shipment or the entire shipment, as applicable.

(d) The statistically valid sample of the HPFB-approved drug must be subjected to testing to confirm that the HPFB-approved drug meets the FDA-approved drug's specifications, including the analytical procedures and methods and the acceptance criteria. In addition, to testing for degradation, a stability-indicating assay provided by the manufacturer must be conducted on the sample of the drug that is proposed for import.

(e) If the manufacturer performs the testing required under section 804(e)(1) of the Federal Food, Drug, and Cosmetic Act at a qualifying laboratory, the testing results, a complete set of laboratory records, a detailed description of the selection method for the samples, the testing methods used, complete data derived from all tests necessary to ensure that the eligible prescription drug meets the specifications of the FDA-approved drug that are established in the NDA or ANDA, a Certificate of Analysis, and any other documentation demonstrating that the testing meets the requirements under section 804(e)(1) of the Federal Food, Drug, and Cosmetic Act must be submitted in electronic form directly to FDA via the ESG or to an alternative transmission point identified by FDA.

(f) Regardless of whether testing under this section is performed by the manufacturer or Importer, the sample of a batch or shipment of drugs must be randomly selected for testing or, in the alternative, the sample must be selected to be representative of the quantity of the batch in a shipment or of a shipment, as applicable.

(g) Information supplied under this part must be kept in strict confidence by the recipient and only for the purpose of testing or otherwise complying with this part.

(h) To ensure that trade secret and commercial or financial information is protected:

(1) The information that the manufacturer provides must not be disseminated except to the qualifying laboratory and to FDA; and

(2) The SIP Sponsor must explain how it will ensure that the information is not disseminated beyond the qualifying laboratory.

(i) FDA may transmit information that the manufacturer is required to provide to an Importer under this section on the manufacturer's behalf if the manufacturer has not transmitted such information to the Importer in a timely fashion and if such information is available to FDA in the NDA or ANDA.

§ 251.17 Importation requirements.

(a) Importers must ensure that each shipment of eligible prescription drugs imported or offered for import pursuant to this part is accompanied by an import entry for consumption filed electronically as a formal entry in ACE, or another CBP-authorized electronic data interchange system, and designated in such a system as a drug imported pursuant to this part.

(b) The Importer may make entry for consumption and arrival of shipments containing eligible prescription drugs only at the CBP port of entry authorized by FDA to import eligible prescription drugs under section 804 of the Federal Food, Drug, and Cosmetic Act. The Importer must keep the product at a designated secured warehouse, and under appropriate environmental conditions to maintain the integrity of the products, until FDA issues an admissibility decision. The secured warehouse must be within 30 miles of the authorized Port of Entry for examination.

(c) If the entry for consumption is filed in ACE before the testing and relabeling of the eligible prescription drug, the Importer must submit an application to bring the drug into compliance and must relabel and test the drug in accordance with the plan approved by FDA pursuant to §§ 1.95 and 1.96 of this chapter.

(d) Upon arrival in the United States of an initial shipment that contains a batch of an eligible prescription drug identified in a Pre-Import Request that has been granted by FDA, the Importer must select a statistically valid sample of that batch to send to a qualifying laboratory for Statutory Testing, unless the manufacturer conducts the Statutory Testing at a qualifying laboratory.

(1) In the case of any subsequent shipment composed entirely of a batch of an eligible prescription drug that has already been tested in accordance with this part, the Importer must select a statistically valid sample of the shipment to send to a qualifying laboratory for Statutory Testing.

(2) The Importer must send three sets of the samples sent to the qualifying laboratory in accordance with § 251.16 to the FDA field lab identified by FDA when the Agency granted the Pre-Import Request.

(3) The Importer must submit to FDA a complete set of laboratory records, a detailed description of the selection method for the sample of the eligible prescription drug sent to the qualifying laboratory, the testing methods used, complete data derived from all tests necessary to ensure that the eligible prescription drug meets the specifications of the FDA-approved drug that are established in the NDA or ANDA, a complete Certificate of Analysis, and all relevant documentation demonstrating that the testing meets the requirements under section 804(e)(1) of the Federal Food, Drug, and Cosmetic Act, as well as any additional information FDA deems necessary to evaluate whether the drug meets manufacturing, quality, and safety standards.

(e) If the manufacturer conducts the Statutory Testing, upon arrival in the United States of an initial shipment that contains a batch of an eligible prescription drug identified in a Pre-Import Request that has been granted by FDA, the manufacturer must select a statistically valid sample of that batch to send to a qualifying laboratory for the Statutory Testing.

(1) In the case of any subsequent shipment composed entirely of a batch or batches of an eligible prescription drug that has already been tested in accordance with this part, the manufacturer must select a statistically valid sample of that shipment to send to a qualifying laboratory for that Statutory Testing.

(2) The manufacturer must send three sets of the samples the manufacturer sent to the qualifying laboratory in accordance with § 251.16 to the FDA field lab identified by FDA when the Agency granted the Pre-Import Request.

(3) The manufacturer must submit to FDA, directly in electronic form to the ESG or to an alternative transmission point identified by FDA, a complete set of laboratory records, a detailed description of the selection method for the sample of the eligible prescription drug sent to the qualifying laboratory, the testing methods used, complete data

derived from all tests necessary to ensure that the eligible prescription drug meets the conditions in the FDA-approved drug's NDA or ANDA, a complete Certificate of Analysis, and all relevant documentation demonstrating that the testing meets the requirements under section 804(e)(1) of the Federal Food, Drug, and Cosmetic Act, as well as any additional information FDA deems necessary to evaluate whether the drug meets manufacturing, quality, and safety standards.

(f) After FDA has reviewed the testing results provided by the Importer or manufacturer and determined that they are acceptable, FDA will notify the Importer and then the Importer must cause the eligible prescription drug to be relabeled with the required U.S. labeling.

(g) After the eligible prescription drug has been shown by testing and relabeling to meet the requirements of section 804 of the Federal Food, Drug, and Cosmetic Act and this part, the Importer or the manufacturer must provide the written certification described in section 804(d)(1)(K) of the Federal Food, Drug, and Cosmetic Act to FDA.

§ 251.18 Post-importation requirements.

(a) *Stopping importation.* If at any point a SIP Sponsor determines that a drug, manufacturer, Foreign Seller, Importer, qualifying laboratory, or other participant in or element of the supply chain in the authorized SIP does not in fact meet all applicable requirements of the Federal Food, Drug, and Cosmetic Act, FDA regulations, and the authorized SIP, the SIP Sponsor immediately must stop importation of all drugs under the SIP, notify FDA, and demonstrate to FDA that importation has in fact been stopped.

(b) *Field alert reports.* Importers must submit NDA and ANDA field alert reports, as described in §§ 314.81(b)(1) and 314.98 of this chapter, to the manufacturer and to FDA.

(c) *Additional reporting requirements for combination products.* For combination products containing a device constituent part, Importers must submit the reports to the manufacturer and to FDA described in § 4.102(c)(1) of this chapter and maintain the records described in §§ 4.102(c)(1) and 4.105(b) of this chapter.

(d) *Adverse event and medication error reports.* (1) *Scope.* An Importer must establish and maintain records and submit reports to FDA and the manufacturer of all adverse events and medication errors associated with the use of their drug products imported under this part.

(2) *Review of safety information.* The Importer must promptly review all domestic safety information for the eligible prescription drugs obtained or otherwise received by the Importer.

(3) *Expedited ICSRs.* The Importer must submit expedited ICSRs for each domestic adverse event or medication error to FDA and the manufacturer as soon as possible but no later than 15 calendar days from the date when the Importer has both met the reporting criteria described in this paragraph (d) and acquired a minimum data set for that adverse event or medication error.

(i) *Serious, unexpected adverse events.* The Importer must submit expedited ICSRs for domestic adverse events reported to the Importer spontaneously (such as reports initiated by a patient, consumer, or healthcare professional) that are both serious and unexpected, whether or not the Importer believes the events are related to the product.

(ii) *Other adverse event reports to be expedited upon notification by FDA.* Upon notification by FDA, the Importer must submit as expedited ICSRs any adverse event reports that do not qualify for expedited reporting under paragraph (d)(3)(i) of this section. The notice will specify the adverse events to be reported and the reason for requiring the expedited reports.

(iii) *ICSRs for medication errors.* The Importer must submit an expedited ICSR for each domestic medication error. If the report also involves one or more adverse events, the Importer must comply with all adverse event reporting requirements in this section and submit one ICSR describing both the medication error and the adverse event(s).

(4) *Followup reports for expedited ICSRs.* The Importer must actively seek any missing data elements under paragraph (d)(7) of this section or updated information for any previously submitted expedited ICSR under paragraph (d)(3) of this section. The Importer must also investigate any new information it obtains or otherwise receives about previously submitted expedited ICSRs. The Importer must submit followup reports for expedited ICSRs to FDA and the manufacturer, as soon as possible, but no later than 15 calendar days after obtaining the new information. The Importer must document and maintain records of their efforts to obtain missing or incomplete information.

(5) *Nonexpedited ICSRs.* The Importer must submit an ICSR for each domestic adverse event not reported under paragraph (d)(3)(i) of this section (all serious, expected and nonserious adverse drug experiences) to FDA and the manufacturer within 90 days from the date when the Importer has both met the reporting criteria described in this paragraph (d) and acquired a minimum data set for that adverse event.

(6) *Completing and submitting safety reports.* This paragraph (d)(6) describes how to complete and submit expedited ICSRs required under this section. Additionally, upon written notice, FDA may require the Importer to submit any of this section's adverse event and medication error safety reports at a different time period than identified in other paragraphs.

(i) *Electronic format for submissions.* (A) ICSR and ICSR attachments must be submitted in an electronic format that FDA can process, review, and archive, as described in § 314.80(g)(1) of this chapter.

(B) The Importer may request, in writing, a temporary waiver of the requirements in paragraph (d)(6)(i)(A) of this section, as described in § 314.80(g)(2) of this chapter. These waivers will be granted on a limited basis for good cause shown.

(ii) *Completing and submitting ICSRs.*

(A) *Single submission.* Submit each ICSR only once.

(B) *Labeling.* Each ICSR must be accompanied by a copy of the current U.S. labeling as an ICSR attachment unless it is already on file at FDA as part of the SIP.

(C) *Separate ICSR.* The Importer must submit a separate ICSR for:

(*1*) Each patient who experiences an adverse event reportable under paragraphs (d)(3)(i) or (ii), (d)(4), or (d)(5) of this section.

(*2*) Each medication error reportable under paragraph (d)(3)(iii) of this section. For reports that include both a medication error and an adverse event, the Importer need only submit one ICSR describing both the medication error and the adverse event.

(D) *Coding terms.* The adverse event and medication error terms described in the ICSR must be coded using standardized medical terminology.

(E) *Minimum data set.* All ICSRs submitted under this section must contain at least the minimum data set appropriate to the type of report (adverse event or medication error). The Importer must actively seek the minimum data set in a manner consistent with its written procedures under paragraph (d)(9) of this section. The Importer must document and maintain records of their efforts to obtain the minimum data set.

(F) *ICSR elements.* The Importer must complete all available elements of an

ICSR as specified in paragraph (d)(7) of this section.

(*1*) The Importer must actively seek any information needed to complete all applicable elements, consistent with their written procedures under paragraph (d)(9) of this section.

(*2*) The Importer must document and maintain records of their efforts to obtain the missing information.

(G) *Supporting documentation.* When submitting supporting documentation for expedited ICSRs of adverse events, the Importer must:

(1) Submit for each ICSR for a domestic adverse event, if available, a copy of the autopsy report if the patient died, or a copy of the hospital discharge summary if the patient was hospitalized. The Importer must submit each document as an ICSR attachment. The ICSR attachment must be submitted either with the initial ICSR or no later than 15 calendar days after obtaining the document.

(2) Include in the ICSR a list of available, relevant documents (such as medical records, laboratory results, death certificates) that are held in their drug product safety files. Upon written notice from FDA, the Importer must submit a copy of these documents within 5 calendar days of the FDA notice.

(7) *Information reported on ICSRs.* ICSRs must include the following information:

(i) Patient information, which includes:

(A) Patient identification code;

(B) Patient age at the time of adverse event or medication error, or date of birth;

(C) Patient gender; and

(D) Patient weight.

(ii) Adverse event or medication error.

(A) Outcome attributed to adverse event or medication error;

(B) Date of adverse event or medication error;

(C) Date of ICSR submission;

(D) Description of adverse event or medication error (including a concise medical narrative);

(E) Adverse drug event or medication error terms(s);

(F) Description of relevant tests, including dates and laboratory data; and

(G) Other relevant patient history, including preexisting medical conditions.

(iii) Suspect medical product(s), which includes:

(A) Name;

(B) Dose, frequency, and route of administration used;

(C) Therapy dates;

(D) Diagnosis for use (indication);

(E) Whether the product is a combination product;

(F) Whether adverse event abated after drug use stopped or dose reduced;

(G) Whether adverse event reappeared after reintroduction of drug;

(H) Lot number;

(I) Expiration date;

(J) NDC; and

(K) Concomitant medical products and therapy dates.

(iv) Initial reporter information.

(A) Name, address, and telephone number;

(B) Whether the initial reporter is a healthcare professional; and

(C) Occupation, if a healthcare professional.

(v) Importer information, which includes:

(A) Importer name and contact office address;

(B) Importer telephone number;

(C) Date the report was received by the Importer;

(D) Whether the ICSR is an expedited report;

(E) Whether the ICSR is an initial report or followup report; and

(F) Unique case identification number, which must be the same in the initial report and any subsequent followup report(s).

(8) *Recordkeeping.*

(i) For a period of 10 years from the initial receipt of information, the Importer must maintain records of information relating to adverse events and medication error safety reports under this section, whether or not submitted to FDA.

(ii) These records must include raw data, correspondence, and any other information relating to the evaluation and reporting of adverse events and medication error safety information that is obtained by the Importer.

(iii) Upon written notice by FDA, the Importer must submit any or all of these records to FDA within 5 calendar days after receipt of the notice. The Importer must permit any authorized FDA employee, at reasonable times, to access, copy, and verify its established and maintained records described in this section.

(9) *Written procedures.* The Importer must develop, maintain, and follow written procedures needed to fulfill the requirements in this section for the surveillance, receipt, evaluation, and reporting to FDA and the manufacturer of adverse events and medication error safety information, including procedures for employee training, and for obtaining and processing safety information from the Foreign Seller.

(10) *Patient privacy.* The Importer must not include in reports under this section the names and addresses of individual patients; instead, the Importer must assign a unique code for identification of the patient. The Importer must include the name of the reporter from whom the information was received as part of the initial reporter information, even when the reporter is the patient. The names of patients, individual reporters, healthcare professionals, hospitals, and geographical identifiers in reports are not releasable to the public under FDA's public information regulations in part 20 of this chapter.

(11) *Safety reporting disclaimer.* (i) A report or information submitted by the Importer under this section (and any release by FDA of that report or information) does not necessarily reflect a conclusion by the Importer or by FDA that the report or information constitutes an admission that the eligible prescription drug imported under section 804 of the Federal Food, Drug, and Cosmetic Act caused or contributed to an adverse event or a medication error.

(ii) The Importer need not admit, and may deny, that the report or information submitted as described in this section constitutes an admission that the drug product caused or contributed to an adverse event or a medication error.

(e) *Drug recalls.* (1) The SIP Sponsor must establish a procedure to track the public announcements of the manufacturer of each drug they import under section 804 of the Federal Food, Drug, and Cosmetic Act and they must also monitor FDA's recall website for recall or market withdrawal information relevant to the drugs that they import under section 804.

(2) If FDA or any participant in a SIP determines that a recall is warranted, the SIP Sponsor must effectuate the recall in accordance with its written recall plan under paragraph (e)(3) of this section.

(3) A SIP must have a written recall plan that describes the procedures to perform a recall of the product and specifies who will be responsible for performing the procedures. The recall plan must cover recalls initiated by FDA, recalls initiated by the Foreign Seller or by the Importer, and recalls initiated by a drug's manufacturer, with which the Foreign Seller and/or Importer must cooperate. The recall plan must include sufficient procedures for the SIP to:

(i) Immediately cease distribution of the drugs affected by the recall;

(ii) Directly notify consignees of the drug(s) included in the recall, including how to return or dispose of the recalled drugs;

(iii) Specify the depth to which the recall will extend (*e.g.,* wholesale,

intermediate wholesale, retail or consumer level);

(iv) Notify the public about any hazard(s) presented by the recalled drug when appropriate to protect the public health;

(v) Conduct effectiveness checks to verify that all consignees at the specified recall depth have received notification about the recall and have taken appropriate action;

(vi) Appropriately dispose of recalled product; and

(vii) Notify FDA of the recall.

(4) In the event of a recall, Importers and Foreign sellers must, upon request by FDA, provide transaction history, information, and statement (as these terms are defined in sections 581(25), 581(26), and 581(27) of the Federal Food, Drug, and Cosmetic Act).

§ 251.19 Reports to FDA.

(a) A SIP Sponsor must submit a report to FDA each quarter containing the information set forth in this section, beginning after the SIP Sponsor files an electronic import entry for consumption for its first shipment of drugs under the SIP. If the SIP Sponsor specifies in such report that the information contained in the report is being transmitted on behalf of the Importer and in order to fulfill the Importer's obligation under § 251.12, the Importer need not separately submit such information to FDA.

(b) The report must contain the following information:

(1) The name, address, telephone number, and professional license number (if any) of the Importer;

(2) The name and quantity of the active ingredient of the imported eligible prescription drug(s);

(3) A description of the dosage form of the eligible prescription drugs;

(4) The date(s) on which the eligible prescription drug(s) were shipped;

(5) The quantity of the eligible prescription drug(s) that was shipped;

(6) The lot or control number assigned to the eligible prescription drug(s) by the manufacturer of the eligible prescription drug(s);

(7) The point of origin (*i.e.,* the manufacturer) and the destination (*i.e.,* the wholesaler, pharmacy, or patient to whom the Importer sells the drug) of the eligible prescription drug(s);

(8) The per unit price paid by the Importer for the prescription drug(s) in U.S. dollars; and

(9) Any other information that FDA determines is necessary for the protection of the public health.

(c) The Importer must also confirm that the eligible prescription drugs was bought directly from the manufacturer by the Foreign Seller and that the Foreign Seller sold the eligible prescription drug(s) directly to the Importer.

(d) The report must include the following documentation:

(1) Documentation from the Foreign Seller specifying the manufacturer of each eligible prescription drug and the quantity of each lot of the eligible prescription drug(s) received by the Foreign Seller from that manufacturer;

(2) Documentation demonstrating that the eligible prescription drug was received by the Foreign Seller from the manufacturer and subsequently shipped by the Foreign Seller to the Importer;

(3) Documentation of the quantity of each lot of the eligible prescription drug(s) received by the Foreign Seller demonstrating that the quantity being imported into the United States is not more than the quantity that was received by the Foreign Seller;

(4) Documentation demonstrating that the sampling and testing requirements described in section 804(d)(1)(J)(i)(III) of the Federal Food, Drug, and Cosmetic Act were met for each shipment of each eligible prescription drug.

(e) The report must include certifications from the Importer for each shipment of each eligible prescription drug that the drug is approved for marketing in the United States and is not adulterated or misbranded and meets all labeling requirements under the Federal Food, Drug, and Cosmetic Act. This certification must include:

(1) That there is an authorized SIP.

(2) That the imported drug is covered by the authorized SIP.

(3) That the drug is an eligible prescription drug as defined in this part.

(4) That the FDA-approved counterpart of the drug is currently commercially marketed in the United States.

(5) That the drug is approved for marketing in Canada.

(6) That the drug is not adulterated or misbranded and meets all labeling requirements under the Federal Food, Drug, and Cosmetic Act.

(f) The report must include laboratory records, including complete data derived from all tests necessary to ensure that each eligible prescription drug is in compliance with established specifications and standards, and documentation demonstrating that the Statutory Testing was conducted at a qualifying laboratory, unless the manufacturer conducted the testing and submitted this information directly to FDA.

(g) The report must include data, information, and analysis on the SIP's cost savings to the American consumer for the drugs imported under the SIP.

§ 251.20 Severability.

The provisions of this part are not separate and are not severable from one another. If any provision is stayed or determined to be invalid, the remaining provisions shall not continue in effect.

§ 251.21 Consequences for violations.

(a) An article that is imported or offered for import into the United States in violation of section 804 of the Federal Food, Drug, and Cosmetic Act or this part is subject to refusal under section 801 of the Federal Food, Drug, and Cosmetic Act.

(b) The importation of a prescription drug in violation of section 804 of the Federal Food, Drug, and Cosmetic Act, the falsification of any record required to be maintained or provided to FDA under such section, or any other violation of this part is a prohibited act under section 301(aa) of the Federal Food, Drug, and Cosmetic Act.

Dated: December 11, 2019.

Brett P. Giroir,

Acting Commissioner of Food and Drugs.

[FR Doc. 2019–27474 Filed 12–18–19; 8:45 am]

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Part V

Department of Energy

10 CFR Part 430

Energy Conservation Program: Test Procedures for Consumer Refrigeration Products; Proposed Rule

DEPARTMENT OF ENERGY

10 CFR Part 430

[EERE–2017–BT–TP–0004]

RIN 1904–AD84

Energy Conservation Program: Test Procedures for Consumer Refrigeration Products

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Notice of proposed rulemaking and request for comment.

SUMMARY: The U.S. Department of Energy (''DOE'') proposes to amend the test procedures for consumer refrigerators, refrigerator-freezers, and freezers, and miscellaneous refrigeration products (collectively ''consumer refrigeration products''). The proposed test procedure amendments would, among other things, define the term ''compartment,'' and revise the method for including the energy use of automatic icemakers and certain other energy-using functions. DOE is also proposing to adjust the standards for these products to ensure that this change in test methodology does not require manufacturers to increase the efficiency of already compliant products or allow previously non-compliant products to meet the current energy conservation standard. DOE is announcing a public meeting and comment period to collect comments and data on its proposal, and methods to reduce regulatory burden while ensuring the test procedures' representativeness of energy use during an average use cycle or period of use.

DATES: *Meeting:* DOE will hold a public meeting on January 9, 2020 from 9 a.m. to 4 p.m., in Washington, DC. The meeting will also be broadcast as a webinar. See section V, ''Public Participation,'' of this document for webinar registration information, participant instructions, and information about the capabilities available to webinar participants.

DOE will accept comments, data, and information regarding this proposal no later than February 21, 2020. See section V, ''Public Participation,'' for details.

ADDRESSES: The public meeting will be held at the U.S. Department of Energy, Forrestal Building, Room 8E–089, 1000 Independence Avenue SW, Washington, DC 20585.

Interested persons are encouraged to submit comments using the Federal eRulemaking Portal at *http://www.regulations.gov.* Follow the instructions for submitting comments. Alternatively, interested persons may submit comments, identified by docket number EERE–2017–BT–TP–0004, by any of the following methods:

(1) *Federal eRulemaking Portal: http://regulations.gov.* Follow the instructions for submitting comments.

(2) *Email: ConsumerRefrigFreezer 2017TP0004@ee.doe.gov.* Include the docket number EERE–2017–BT–TP–0004 or regulatory information number (RIN) 1904–AD84 in the subject line of the message.

(3) *Postal Mail:* Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Office, Mailstop EE–5B, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 287–1445. If possible, please submit all items on a compact disc (''CD''), in which case it is not necessary to include printed copies.

(4) *Hand Delivery/Courier:* Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Office, 950 L'Enfant Plaza SW, Suite 600, Washington, DC 20024. Telephone: (202) 287–1445. If possible, please submit all items on a CD, in which case it is not necessary to include printed copies.

No telefacsimilies (faxes) will be accepted. For detailed instructions on submitting comments and additional information on the rulemaking process, see section V, ''Public Participation,'' of this document.

Docket: The docket, which includes **Federal Register** notices, public meeting attendee lists and transcripts, comments, and other supporting documents/materials, is available for review at *http://www.regulations.gov.* All documents in the docket are listed in the *http://www.regulations.gov* index. However, some documents listed in the index, such as those containing information that is exempt from public disclosure, may not be publicly available.

The docket web page can be found at *http://www.regulations.gov/#!docketDetail;D=EERE-2017-BT-TP-0004.* The docket web page contains instructions on how to access all documents, including public comments, in the docket. See section V for information on how to submit comments through *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT:

Dr. Stephanie Johnson, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, EE–5B, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 287–1943. Email: *ApplianceStandardsQuestions@ee.doe.gov.*

Mr. Peter Cochran, U.S. Department of Energy, Office of the General Counsel, GC–33, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 586–9496. Email: *Peter.Cochran@hq.doe.gov.*

For further information on how to submit a comment, review other public comments and the docket, or regarding a public meeting, contact the Appliance and Equipment Standards Program staff at (202) 287–1445 or by email: *ApplianceStandardsQuestions@ee.doe.gov.*

SUPPLEMENTARY INFORMATION: DOE proposes to maintain a previously approved incorporation by reference and to incorporate by reference the following industry standard into 10 CFR part 430:

AHAM HRF–1–2016, (''HRF–1–2016''), Energy and Internal Volume of Refrigerating Appliances (January 1, 2016), including Errata to Energy and Internal Volume of Refrigerating Appliances, Correction Sheet.

Copies of HRF–1–2016 can be obtained from the Association of Home Appliance Manufacturers, 1111 19th Street NW, Suite 402, Washington, DC 20036, (202) 872–5955, or go to *http://www.AHAM.org.*

See section IV.N of this document for a more detailed discussion of this industry standard.

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I. Authority and Background

Consumer refrigerators, refrigerator-freezers, and freezers are included in the list of ''covered products'' for which DOE is authorized to establish and amend energy conservation standards and test procedures. (42 U.S.C. 6292(a)(1)) DOE's energy conservation standards for consumer refrigerators, refrigerator-freezers, and freezers are currently prescribed at title 10 of the Code of Federal Regulations (''CFR'') 430.32(a). DOE's test procedures are currently prescribed at 10 CFR 430.23(a) and part 430, subpart B, appendix A (''Appendix A'') for refrigerators and refrigerator-freezers, and 10 CFR 430.23(b) and 10 CFR part 430, subpart B, appendix B (''Appendix B'') for freezers.

Additionally, under 42 U.S.C. 6292(a)(20), DOE may extend coverage over a particular type of consumer product provided that DOE determines that classifying products of such type as covered products is necessary or appropriate to carry out the purposes of EPCA, and specified requirements are met. See 42 U.S.C. 6292(b)(1) and 6295(l)(1). Consistent with its statutory obligations, DOE established regulatory coverage over miscellaneous refrigeration products (''MREFs'').[1] 81 FR 46768 (July 18, 2016). The current test procedures for MREFs are prescribed at 10 CFR 430.23(ff) and Appendix A.

The following sections discuss DOE's authority to establish and amend test procedures for consumer refrigerators, refrigerator-freezers, freezers, and MREFs, as well as relevant background information regarding DOE's proposed amendments to the test procedures for these products.

A. Authority

The Energy Policy and Conservation Act of 1975, as amended, (EPCA)[2] among other things, authorizes DOE to regulate the energy efficiency of a number of consumer products and certain industrial equipment (42 U.S.C. 6291–6317). Title III, Part B[3] of EPCA established the Energy Conservation Program for Consumer Products Other Than Automobiles, which sets forth a variety of provisions designed to improve energy efficiency. These products include consumer refrigerators, refrigerator-freezers, and freezers, the subject of this document. (42 U.S.C. 6292(a)(1))

Under EPCA, DOE's energy conservation program consists essentially of four parts: (1) Testing, (2) labeling, (3) Federal energy conservation standards, and (4) certification and enforcement procedures. Relevant provisions of EPCA specifically include definitions (42 U.S.C. 6291), energy conservation standards (42 U.S.C. 6295), test procedures (42 U.S.C. 6293), labeling provisions (42 U.S.C. 6294), and the authority to require information and reports from manufacturers (42 U.S.C. 6296).

The Federal testing requirements consist of test procedures that manufacturers of covered products must use as the basis for: (1) Certifying to DOE that their products comply with the applicable energy conservation standards adopted pursuant to EPCA (42 U.S.C. 6295(s)), and (2) making representations about the efficiency of those consumer products (42 U.S.C. 6293(c)). Similarly, DOE must use these test procedures to determine whether the products comply with relevant standards promulgated under EPCA. (42 U.S.C. 6295(s))

Federal energy efficiency requirements for covered products established under EPCA generally supersede State laws and regulations concerning energy conservation testing, labeling, and standards. (See 42 U.S.C. 6297) DOE may, however, grant waivers of Federal preemption for particular State laws or regulations, in accordance with the procedures and other provisions of EPCA. (42 U.S.C. 6297(d))

Under 42 U.S.C. 6293, EPCA sets forth the criteria and procedures DOE must follow when prescribing or amending test procedures for covered products. EPCA requires that any test procedures prescribed or amended under this section be reasonably designed to produce test results which measure energy efficiency, energy use or estimated annual operating cost of a covered product during a representative average use cycle or period of use and not be unduly burdensome to conduct. (42 U.S.C. 6293(b)(3))

Further, when amending a test procedure, DOE must determine the extent to which, if any, the proposal would alter the measured energy use of a given product as determined under the existing test procedure. (42 U.S.C. 6293(e)(1)) If DOE determines that the amended test procedure would alter the measured energy use of a covered product, DOE must also amend the applicable energy conservation standard during the rulemaking carried out with respect to such test procedure. (42 U.S.C. 6293(e)(2)) In determining the amended energy conservation standard, the Secretary shall measure, pursuant to the amended test procedure, the energy efficiency, energy use, or water use of a representative sample of covered products that minimally comply with the existing standard. The average of such energy efficiency, energy use, or water use levels determined under the amended test procedure shall constitute the amended energy conservation standard for the applicable covered products. *Id.*

In addition, EPCA requires that DOE amend its test procedures for all covered products to integrate measures of standby mode and off mode energy consumption. (42 U.S.C. 6295(gg)(2)(A)) Standby mode and off mode energy consumption must be incorporated into the overall energy efficiency, energy consumption, or other energy descriptor

[1] An MREF is defined as a consumer refrigeration product other than a refrigerator, refrigerator-freezer, or freezer, which includes coolers and combination cooler refrigeration products. 10 CFR 430.2.

[2] All references to EPCA in this document refer to the statute as amended through America's Water Infrastructure Act of 2018, Public Law 115–270 (October 23, 2018).

[3] For editorial reasons, upon codification in the U.S. Code, Part B was redesignated Part A.

for each covered product unless the current test procedures already account for and incorporate standby and off mode energy consumption or such integration is technically infeasible. If an integrated test procedure is technically infeasible, DOE must prescribe a separate standby mode and off mode energy use test procedure for the covered product, if technically feasible. (42 U.S.C. 6295(gg)(2)(A)(ii)) Any such amendment must consider the most current versions of the International Electrotechnical Commission (IEC) Standard 62301 [4] and IEC Standard 62087 [5] as applicable. (42 U.S.C. 6295(gg)(2)(A))

If DOE determines that a test procedure amendment is warranted, it must publish proposed test procedures and offer the public an opportunity to present oral and written comments on them. (42 U.S.C. 6293(b)(2)) EPCA also requires that, at least once every 7 years, DOE evaluate test procedures for each type of covered product, including consumer refrigeration products, to determine whether amended test procedures would more accurately or fully comply with the requirements for the test procedures to not be unduly burdensome to conduct and be reasonably designed to produce test results that measure energy efficiency, energy use, and estimated operating costs during a representative average use cycle or period of use. (42 U.S.C. 6293(b)(1)(A)) If the Secretary determines, on his own behalf or in response to a petition by any interested person, that a test procedure should be prescribed or amended, the Secretary shall promptly publish in the **Federal Register** proposed test procedures and afford interested persons an opportunity to present oral and written data, views, and arguments with respect to such procedures. The comment period on a proposed rule to amend a test procedure shall be at least 60 days and may not exceed 270 days. In prescribing or amending a test procedure, the Secretary shall take into account such information as the Secretary determines relevant to such procedure, including technological developments relating to energy use or energy efficiency of the type (or class) of covered products involved. (42 U.S.C. 6293(b)(2)) If DOE determines that test procedure revisions are not appropriate, DOE must publish its determination not to amend the test procedures. DOE is publishing this NOPR in satisfaction of the 7-year review requirement specified in EPCA. (42 U.S.C. 6293(b)(1)(A))

B. Background

As described, DOE's existing test procedure for consumer refrigerators, refrigerator-freezers, and MREFs appears at Appendix A (''Uniform Test Method for Measuring the Energy Consumption of Refrigerators, Refrigerator-Freezers, and Miscellaneous Refrigeration Products''). DOE's existing test procedure for freezers appears at Appendix B (''Uniform Test Method for Measuring the Energy Consumption of Freezers'').

These test procedures are the result of numerous evaluations and updates that have occurred since DOE initially established its test procedures for these products in a final rule published in the **Federal Register** on September 14, 1977. 42 FR 46140. The original test procedures were generally viewed as too complex, and industry stakeholders developed alternative test procedures in conjunction with the Association of Home Appliance Manufacturers (''AHAM'') that were incorporated into the 1979 version of AHAM Standard HRF–1, ''Household Refrigerators, Combination Refrigerator-Freezers, and Household Freezers'' (''HRF–1–1979''). Using this industry-created test procedure, DOE revised its test procedures on August 10, 1982, which were codified as a new Appendix A1 for refrigerators and refrigerator-freezers and a new Appendix B1 for freezers. 47 FR 34517.

On August 31, 1989, DOE amended the Appendix A1 and Appendix B1 test procedures further when it published a final rule establishing test procedures for variable-defrost control refrigeration products, dual-compressor refrigerator-freezers, and freezers equipped with ''quick-freeze.'' 54 FR 36238.

DOE amended the Appendix A1 test procedure again on March 7, 2003, by modifying the test period used for products equipped with long-time automatic defrost or variable defrost. 68 FR 10957.

On December 16, 2010, DOE published a final and interim final rule (the ''December 2010 Final Rule and Interim Final Rule'') that amended the test procedures in Appendix A1 and Appendix B1 and established new test procedures in Appendix A and Appendix B. 75 FR 78810. The December 2010 Final Rule and Interim Final Rule established a number of comprehensive changes to improve the measurement of energy consumption of refrigerators, refrigerator-freezers, and freezers. These changes included, among other things: (1) Adjusting the standardized compartment temperatures and volume-adjustment factors, (2) adding new methods for measuring compartment volumes, (3) modifying the long-time automatic defrost test procedure to measure all energy use associated with the defrost function, (4) adding test procedures for products with a single compressor and multiple evaporators with separate active defrost cycles, and (5) updating the industry standard reference to the 2008 version of HRF–1, ''Energy and Internal Volume of Refrigerating Appliances'' (''HRF–1–2008''). Lastly, the December 2010 Final Rule and Interim Final Rule addressed icemaking energy use by including a fixed energy use adder for those products equipped with an automatic icemaker. Using available data submitted by stakeholders, this value was set at 84 kilowatt-hours (''kWh'') per year. *Id.* On January 25, 2012, DOE finalized the test procedures established in the December 2010 Final Rule and Interim Final Rule and required use of the new test procedures at Appendix A and Appendix B for certifying basic models as compliant with the energy conservation standards starting on September 15, 2014. 77 FR 3559.

On July 10, 2013, DOE proposed further amending the consumer refrigerator and refrigerator-freezer test procedure to address products with multiple compressors and to allow an alternative method for measuring and calculating energy consumption for refrigerator-freezers and refrigerators with freezer compartments. 78 FR 41610 (the ''July 2013 NOPR''). DOE also proposed to amend certain aspects of the consumer refrigerator, refrigerator-freezer, and freezer test procedures to ensure better accuracy and repeatability. Additionally, DOE solicited comment on a proposed automatic icemaker test procedure and on whether built-in products should be tested in a built-in configuration. *Id.* In response to the July 2013 NOPR, interested parties requested that DOE grant more time to respond to the proposal for measuring energy use associated with icemaking and to DOE's request for comment regarding testing of built-in products in a built-in configuration. DOE granted the comment period extension request for these two topics. 78 FR 53374 (Aug. 29, 2013).

On April 21, 2014, DOE published a final rule for the refrigerator, refrigerator-freezer, and freezer test procedures (the ''April 2014 Final Rule''). 79 FR 22320. The amendments enacted by the April 2014 Final Rule addressed products with multiple compressors and established an

[4] IEC 62301, *Household electrical appliances—Measurement of standby power* (Edition 2.0, 2011–01).

[5] IEC 62087, *Methods of measurement for the power consumption of audio, video, and related equipment* (Edition 3.0, 2011–04).

alternative method for measuring and calculating energy consumption for refrigerator-freezers and refrigerators with freezer compartments. The April 2014 Final Rule also amended certain aspects of the test procedures to improve test accuracy and repeatability. To allow additional time to review comments and data received during the comment period extension, DOE did not address automatic icemaking energy use or built-in testing configuration in the April 2014 Final Rule. *Id.*

On July 18, 2016, DOE published a final rule (the ''July 2016 Final Rule'') that established coverage and test procedures for MREFs.[6] 81 FR 46768. Included within this category are refrigeration products that include one or more compartments that maintain higher temperatures than typical refrigerator compartments, such as wine chillers and beverage coolers. Additionally, the July 2016 Final Rule amended Appendix A and Appendix B to include provisions for testing MREFs and to improve the clarity of certain existing test requirements. *Id.*

On June 30, 2017, DOE published a request for information (the ''June 2017 RFI'') to initiate a data collection process to inform DOE's decision on whether to amend its test procedures in Appendix A and Appendix B. 82 FR 29780. DOE received seven comments in response to the June 2017 RFI from the interested parties listed in Table I–I.

TABLE I–I—JUNE 2017 RFI WRITTEN COMMENTS

Organization(s)	Reference in this NOPR	Organization type
Appliance Standards Awareness Project, American Council for an Energy-Efficient Economy, Northeast Energy Efficiency Partnerships, Alliance to Save Energy, Natural Resources Defense Council, Northwest Energy Efficiency Alliance.	Joint Commenters	Efficiency Organizations
Association of Home Appliance Manufacturers	AHAM	Trade Association
BSH Home Appliances Corporation	BSH	Manufacturer
Felix Storch, Inc.	FSI	Manufacturer
Samsung Electronics America	Samsung	Manufacturer
Sub Zero Group, Inc.	Sub Zero	Manufacturer
Whirlpool Corporation	Whirlpool	Manufacturer

DOE has considered the comments and information submitted by these interested parties in determining the proposals included in this NOPR. Summaries of the comments related to the proposals included in this NOPR submitted by interested parties and DOE's responses are included in the relevant sections of this proposed rule.[7]

II. Synopsis of the Notice of Proposed Rulemaking

In this NOPR, DOE proposes a number of changes to the current test procedures for consumer refrigeration products. DOE has tentatively determined that two of the proposed amendments would alter the measured efficiency of certain consumer refrigeration products.

The proposal to amend the energy adder for products with automatic icemakers would alter the energy use of certain consumer refrigeration products as determined under the test procedure and would provide more representative energy use measurements for those products with automatic icemakers. As a result, in accordance with 42 U.S.C. 6293(e)(2), DOE proposes to amend the energy conservation standards for these products. Manufacturers would be required to comply with these amended standards one year after publication of a final rule incorporating these amendments. Correspondingly, use of the test procedure provisions that incorporate the updated icemaker energy adder would be required one year after publication of any final rule incorporating these amendments. During the one-year compliance lead-time period, manufacturers would be required to use the test procedure provisions that incorporate the current icemaker adder. DOE is proposing to provide separate sections within Appendix A and Appendix B to include both the current icemaker energy adder and the updated value.

Additionally, the proposal to test demand-response capable products[8] with the communication module off may reduce the measured energy consumption for certain products. However, DOE is not proposing to amend the energy conservation standards for these products based on this proposed test procedure change as discussed in section III.H.2 of this document.

DOE has also tentatively determined that the proposed test procedure would not be unduly burdensome to conduct.

Specifically, as discussed in this document, DOE is proposing to:

- Establish a compartment definition that is consistent with the industry term;
- Update references to the relevant industry standard (HRF–1) to the sections of the current version;
- Update the fixed value used to represent the energy use of automatic icemakers;
- Amend the energy conservation standards for consumer refrigeration products with automatic ice makers in accordance with 42 U.S.C. 6293(e)(2);
- Provide additional detail on the test set-up regarding thermocouple placement, vented test chamber floors, and units with external controls;
- Provide additional detail on test conditions regarding maintenance and measurement of the vertical ambient temperature gradient, the use of data during the stabilization period, and the stabilization of units with multiple compressors;
- Require testing demand-response capable units with the communication module off; and
- Reinsert an inadvertently omitted method for calculating the average per-cycle energy consumption of refrigerators and refrigerator-freezers, and other corrections.

[6] As part of the rulemaking process to establish the scope of coverage, definitions, test procedures, and corresponding energy conservation standards for MREFs, DOE established an Appliance Standards and Rulemaking Federal Advisory Committee negotiated rulemaking working group (the ''MREF Working Group''). See, 80 FR 17355 (April 1, 2015).

[7] Comments received not related to the proposals in this NOPR will be considered and addressed as appropriate should DOE undertake additional rulemakings.

[8] ''Demand response'' capability refers to product functionality that can be controlled, via signals from the electrical distribution grid, to improve the overall operation of the electrical grid; for example, by reducing energy consumption during peak periods and/or shifting power consumption to off-peak periods.

DOE's proposed actions are summarized in Table II–I and addressed in detail in section III of this proposed rule.

TABLE II–I—SUMMARY OF CHANGES IN PROPOSED TEST PROCEDURE RELATIVE TO CURRENT TEST PROCEDURE

Current DOE test procedure	Proposed test procedure	Attribution
No definition for term ''compartment''	Defines ''compartment'' consistent with AS/NZS 4474.1:2007.	Adopt industry standard.
Incorporates by reference (IBR) AHAM HRF–1–2008	Updates IBR to AHAM HRF–1–2016	Harmonize with industry standard update.
Energy use adder for automatic icemakers of 84 kWh/year.	Updates energy use adder for automatic icemakers to 28 kWh/year.	Provide more representative measure of average use cycle.
Does not explicitly specify the setup for test chamber floors that have vents for airflow.	Provides consistent specifications for test platform and floor requirements.	Improves representativeness, repeatability, and reproducibility.
Does not specify test setup for products with controls external to the cabinet.	Specifies test setup for products with controls external to the cabinet.	Address current waiver
Does not explicitly specify timing of required temperature range conditions and thermocouple placement in certain product configurations.	Provides additional timing and thermocouple placement specifications.	Improves repeatability and reproducibility.
Specified time and temperature conditions may not apply to certain products with irregular compressor cycling or multiple compressors.	Allows measuring average temperatures over multiple compressor cycles or for a given time period to determine stable operation.	Address current waiver.
Requires a separate stabilization and test period when conducting all energy tests.	Allows test period to serve as stabilization period when conducting certain energy tests.	Reduce test burden while maintaining representative results.
Requires testing demand-response function communication modules in the as-shipped configuration.	Requires testing demand-response function communication modules in the off configuration.	Address representative average use.
Inadvertently omits optional method for calculating average per-cycle energy consumption of refrigerators and refrigerator-freezers.	Reinstates method and makes other non-substantive corrections.	Correction.

In this NOPR, DOE also requests feedback on additional topics for which it is not proposing test procedure amendments at this time, including: Built-in product test configuration, door-in-door features, display screens, and connected functions (other than for demand-response capable products). Additionally, DOE requests feedback on any topics not specifically addressed in this NOPR.

III. Discussion

A. Scope of Applicability

The proposed amendments in this document apply to products that meet the definition for ''consumer refrigeration product,'' as codified in 10 CFR 430.2. Consumer refrigeration products generally refer to cabinets used with one or more doors that are capable of maintaining temperatures colder than the ambient temperature. While these products are typically used for the storage and freezing of food or beverages, the definitions do not require that the products be designed or marketed for that purpose. The definitions only require that the product be capable of maintaining compartment temperatures within certain ranges, regardless of use. 10 CFR 430.2.

Consumer refrigeration products include consumer refrigerators, refrigerator-freezers, freezers, and MREFs. Because of the similarities between consumer refrigerators, refrigerator-freezers, and MREFs, the test procedures for these products are all included in Appendix A. As a result, any amendments to Appendix A would be applicable to testing for each of these product categories. Section III.K of this document discusses the extent to which the proposed amendments, if finalized, would alter the measured energy consumption of consumer refrigeration products as compared to the existing Federal test procedures.

The amendments proposed in this NOPR would not change the scope of applicability of the test procedure.

B. Compartment Definitions

Although the term ''compartment'' is used throughout the DOE test procedures in Appendix A and Appendix B, it is not defined. The DOE test procedures use the term to refer to both individual enclosed spaces within a product (*e.g.,* referring to a specific freezer compartment), as well as all enclosed spaces within a product that meet the same temperature criteria (*e.g.,* referring to the freezer compartment temperature—a volume-weighted average temperature for all individual freezer compartments within a product).

The MREF Working Group [9] considered the issue of a compartment definition in its discussions. Working Group members indicated that the term ''compartment,'' as included in the existing test procedures, was well-understood by industry and test laboratories, and that a definition intended to cover the multiple uses in the test procedure would potentially

[9] After reviewing the comments received in response to the NOPR published ahead of the July 2016 Final Rule, and in response to the preliminary analysis conducted for potential MREF energy conservation standards, DOE determined that its efforts would benefit from the direct and comprehensive input provided through the negotiated rulemaking process. On April 1, 2015, DOE published a notice of intent to establish a Working Group under the Appliance Standards and Rulemaking Federal Advisory Committee (''ASRAC'') that would use the negotiated rulemaking process to discuss and, if possible, reach consensus recommendations on the scope of coverage, definitions, test procedures, and energy conservation standards for MREFs. 80 FR 17355. Subsequently, DOE formed a Miscellaneous Refrigeration Products Working Group (''MREF Working Group'' or, in context, ''the Working Group'') to address these issues. The Working Group consisted of 15 members, including two members from ASRAC and one DOE representative. The MREF Working Group met in-person during six sets of meetings held in 2015 on May 4–5, June 11–12, July 15–16, August 11–12, September 16–17, and October 20. On August 11, 2015, the MREF Working Group reached consensus on a term sheet (Term Sheet #1) that recommended the relevant scope of coverage, definitions, and test procedures for MREFs. See public docket EERE–2011–BT–STD–0043–0113.

introduce confusion. Accordingly, the MREF Working Group recommendation did not include a ''compartment'' definition and suggested that DOE address this issue in a future rulemaking for refrigerator, refrigerator-freezer, and freezer test procedures.[10]

In the July 2016 Final Rule, consistent with the MREF Working Group recommendation, DOE did not amend Appendix A or Appendix B to include a definition for the term ''compartment.'' 81 FR 46768, 46779 (July 18, 2016).

In the June 2017 RFI, DOE requested comment on the issue of defining the term ''compartment'' in Appendix A and Appendix B. 82 FR 29784.

AHAM commented that it has previously suggested that DOE define the term ''compartment' consistent with Australian/New Zealand Standard 4474.1:2007, ''Performance of household electrical appliances—Refrigerating appliances, Part 1: Energy consumption and performance'' (AS/NZS 4474.1:2007) [11] and use the term consistently throughout the test procedures, but that this undertaking is a complex one and requires a review of the entire test procedure. In addition, AHAM noted that the definition could reclassify certain compartments and would likely impact measured energy use. AHAM stated that this is one of the items it will review as part of its HRF–1 task force; accordingly, there is no need for DOE to duplicate those efforts. AHAM requested that DOE review the completed HRF–1 update as a reference for the ''compartment'' definition. (AHAM, No. 5 at pp. 9–10) Sub Zero also commented that the ''compartment'' definition should be addressed in the HRF–1 update to avoid DOE and industry duplicating efforts. (Sub Zero, No. 4 at pp. 2–3)

As recommended by the MREF Working Group, and as previously supported by AHAM, DOE is proposing to include a definition for ''compartment'' consistent with AS/NZS 4474.1:2007, but adapted to use the appropriate DOE terminology for certain terms within the definition. AS/NZS 4474.1:2007 defines compartment as ''an enclosed space within a refrigerating appliance, which is directly accessible through one or more external doors. A compartment may contain one or more sub-compartments and one or more convenience features.'' DOE is proposing to define compartment as ''an enclosed space within a consumer refrigeration product that is directly accessible through one or more external doors and may be divided into sub-compartments.'' Based on this proposal, compartments would be treated in the same way as under the current test procedure. Accordingly, DOE does not expect that any compartments would be reclassified and the proposed definition would not impact measured energy consumption.

Additionally, to provide further understanding of the proposed definition for ''compartment,'' DOE is proposing to define ''sub-compartment'' as an enclosed space within a compartment that may have a different operating temperature from the compartment within which it is located. This definition, coupled with the new definition for ''compartment,'' would remove the need to separately define ''separate auxiliary compartment'' and ''special compartment'' because these terms are redundant with the proposed compartment definitions. Use of the proposed terms ''compartment'' and ''sub-compartment'' would not change how compartments currently defined as ''separate auxiliary compartment'' and ''special compartment'' would be treated under the existing test procedure instructions. Therefore, DOE is proposing to remove the terms ''separate auxiliary compartment'' and ''special compartment'' from Appendix A and Appendix B and replace them with compartment or sub-compartment as appropriate.

DOE requests comment on its proposal to establish definitions for ''compartment'' and ''sub-compartment'' in Appendix A and Appendix B.

C. AHAM HRF–1 Standard

As discussed in section I.B of this document, Appendix A and Appendix B incorporate by reference the AHAM industry standard HRF–1–2008. DOE references HRF–1–2008 for definitions, installation and operating conditions, temperature measurements, and volume measurements. In August 2016, AHAM released an updated version of the HRF–1 standard, HRF–1–2016.

In the June 2017 RFI, DOE stated that based on review of HRF–1–2016, the majority of the updates from the 2008 standard were clarifications or other revisions to harmonize with DOE's test procedures. DOE requested comment on whether Appendix A and Appendix B should incorporate by reference the newer version of HRF–1 and whether the revisions between the two versions of HRF–1 would substantively affect any of the test requirements in Appendix A and Appendix B. 82 FR 29785.

AHAM, BSH, and Sub Zero commented in support of DOE incorporating HRF–1–2016 by reference because the 2016 version is intended to harmonize with the current DOE test procedure, and therefore would not change the DOE test procedure. (AHAM, No. 5 at p. 11; BSH, No. 2 at p. 2; Sub Zero, No. 4 at p. 3) AHAM also stated that it is currently revising AHAM HRF–1–2016, and DOE should not duplicate those efforts. AHAM recommended that DOE instead participate in the HRF–1 task force to discuss potential changes to the test procedure. (AHAM, No. 5 at p. 2)

As noted in comments from interested parties, the updates included in HRF–1–2016 harmonize with the current DOE test procedure. This includes updates to definitions, test requirements, formatting, and organization that are consistent with DOE's requirements. Therefore, DOE is proposing to incorporate by reference HRF–1–2016 in Appendix A and Appendix B. As indicated in the comments from interested parties, DOE does not expect that updating its references to HRF–1–2016 would substantively affect the existing test procedures in Appendix A and Appendix B. DOE is not proposing to require the use of HRF–1–2016 in its entirety. Certain of the updates made in HRF–1–2016 to harmonize with DOE are now out of date; for example, the product definitions included in HRF–1–2016 are harmonized with the DOE definitions included in 10 CFR 430.2 at the time HRF–1–2016 was published, but do not reflect the recent amendments made in the July 2016 Final Rule (*e.g.,* those related to MREFs). Furthermore, HRF–1–2016 covers only compressor-driven products, whereas the DOE test procedure applies to all consumer refrigeration products, including those with non-compressor refrigeration systems.

As stated in the AHAM comment, the AHAM task force is working to revise HRF–1–2016. (AHAM, No. 5 at p. 2) AHAM has recently released a draft of an updated HRF–1–2019 for public review.[12] Based on a review of the draft for public review, the in-progress updates to HRF–1 are generally consistent with the proposals included in this NOPR. However, because the current version available from AHAM is a draft for public review and not available for distribution, DOE is not

[10] See Term Sheet #1, which recommended the relevant scope of coverage, definitions, and test procedures for MREFs, available in public docket EERE–2011–BT–STD–0043–0113.

[11] Available online at *https://infostore.saiglobal.com/en-us/Standards/AS-NZS-44741-2007-383878/.*

[12] The draft revision for review is available at *http://www.aham.org/AHAM/Standard_Chart_Page.aspx* (accessed June 5, 2019).

proposing to incorporate by reference this initial draft version of the standard. DOE would consider incorporating by reference the updated HRF–1 standard in its entirety when it is available for public distribution.

DOE requests feedback on its proposal to incorporate by reference the most current version of HRF–1, HRF–1–2016, rather than HRF–1–2008. DOE also requests feedback on a potential updated reference to HRF–1–2019 based on the public draft currently available for review. DOE also requests feedback on whether any of the differences between HRF–1–2008 and HRF–1–2016 (or HRF–1–2019) would substantively affect the requirements currently incorporated by reference in Appendix A and Appendix B—and if so, how.

D. Icemaking Energy Consumption

In 2010, DOE initiated a test procedure rulemaking to address a variety of test procedure-related issues, including energy use associated with automatic icemaking. On May 27, 2010, DOE published a NOPR (the ''May 2010 NOPR'') proposing to use a fixed value of 84 kWh per year to represent the energy use associated with automatic icemaking. 75 FR 29824. The May 2010 NOPR also indicated that DOE would consider adopting an approach based on testing to determine icemaking energy use if a suitable test procedure could be developed. *Id.* at 29846–29847. A broad group of interested parties submitted a consensus recommendation comment supporting DOE's proposal to use a fixed value to represent the energy use of automatic icemakers, and requesting that DOE subsequently initiate a rulemaking to amend the test procedures to incorporate a laboratory-based measurement of icemaking energy use. (Test Procedure for Refrigerators, Refrigerator-Freezers, and Freezers, Docket Number EERE–2009–BT–TP–0003; Consensus Recommendation,[13] No. 20 at pp. 5–6) As noted, DOE adopted a fixed energy use adder for those products equipped with an automatic icemaker. 75 FR 78810.

In January 2012, AHAM provided DOE with a draft test procedure for measuring automatic icemaker energy usage. (AHAM Refrigerator, Refrigerator-Freezer and Freezer Ice Making Energy Test Procedure, Revision 1.0—12/14/11, No. 4) [14] AHAM then submitted a revised automatic icemaker test procedure on July 18, 2012. (AHAM Refrigerator, Refrigerator-Freezer and Freezer Ice Making Energy Test Procedure, Revision 2.0—7/10/12, No. 5) [15] In the subsequent July 2013 NOPR, as mentioned in section I.B of this document, DOE proposed a method for measuring the energy usage associated with automatic icemaking based on the revised approach submitted by AHAM. 78 FR 41610, 41618–41629. In response to the July 2013 NOPR, AHAM submitted comments to DOE requesting that DOE grant its members more time to respond to the automatic icemaker testing proposal, which DOE granted. 78 FR 53374 (Aug. 29, 2013). In the April 2014 Final Rule, DOE maintained the fixed adder approach and stated that it would review comments received during the comment period extension to address the icemaking test procedure issue in a future notice. See 79 FR 22320, 22341–22342.

Multiple interested parties supported the development and adoption of a test procedure that measures the energy use of automatic icemakers. These commenters presented a number of reasons that they stated justified a laboratory-based icemaker energy test procedure, including: (1) A direct laboratory test would be more accurate and representative of actual icemaking energy use, and (2) the fixed adder approach would not reward improvements in icemaking efficiency or provide incentives to reduce icemaker energy consumption. (BSH, 2012 TP Rulemaking No. 21 at p. 1; [16] Joint Commenters,[17] 2012 TP Rulemaking No. 42 at pp. 1–5; Samsung, 2012 TP Rulemaking No. 39 at p. 2)

Other interested parties supported the existing fixed adder approach, stating that the proposed icemaking test procedure would create a significant test burden and that there are limited opportunities to reduce icemaking energy consumption. (AHAM, 2012 TP Rulemaking No. 37 at p. 2–5; GE Appliances (''GE''), 2012 TP Rulemaking No. 40 at p. 5; Sub Zero, 2012 TP Rulemaking No. 36 at p. 2)

Further, DOE received data indicating that consumers likely use less ice than assumed in calculating the 84 kWh per year adder. The Northwest Energy Efficiency Alliance (''NEEA'') and Northwest Power & Conservation Council (''NPCC'') conducted field research to assess the existing icemaking adder of 84 kWh per year. Their results showed average daily ice consumption of 0.83 pounds per day (''lbs/day'') for through-the-door service models and 0.61 lbs/day for in-freezer models. NEEA and NPCC stated that this field research shows that the earlier estimate of 1.8 lbs/day (the basis for the 84 kWh per year adder) is significantly overestimated. NEEA and NPCC also stated that the distribution of annual icemaking cycles is skewed toward the lower end of the range, with the average being impacted by a relatively small number of frequent ice users; accordingly, NEEA and NPCC commented that median usage values of 0.63 lbs/day and 0.49 lbs/day for through-the-door and in-freezer models, respectively, would be more representative of typical use. (NEEA and NPCC, 2012 TP Rulemaking No. 41 at p. 2)

Similarly, a GE study on approximately 4,900 units found average ice consumption of 0.83 lbs/day, with a median consumption of 0.59 lbs/day. GE and AHAM both supported a revised fixed icemaking energy consumption adder of 28 kWh per year, based on the median usage rate of 0.59 lbs/day. (AHAM, 2012 TP Rulemaking No. 37 at p. 6; GE, 2012 TP Rulemaking No. 40 at pp. 3–4) AHAM further commented that it would oppose any adder greater than 36 kWh per year, corresponding to the average daily ice use of 0.76 lbs/day from the NEEA and NPCC studies. (AHAM, 2012 TP Rulemaking No. 37 at p. 6)

In the June 2017 RFI, DOE again requested comment on how its test procedures should account for automatic icemaking energy consumption and on the availability of any additional consumer use data. 82 FR 29782–29783.

[13] The ''Consensus Recommendation'' was submitted by AHAM and the American Council for an Energy-Efficient Economy, on behalf of: Whirlpool, General Electric, Electrolux, LG Electronics, BSH, Alliance Laundry, Viking Range, Sub-Zero Wolf, Friedrich A/C, U-Line, Samsung, Sharp Electronics, Miele, Heat Controller, AGA Marvel, Brown Stove, Haier, Fagor America, Airwell Group, Arcelik, Fisher & Paykel, Scotsman Ice, Indesit, Kuppersbusch, Kelon, DeLonghi, Appliance Standards Awareness Project, Natural Resources Defense Council, Alliance to Save Energy, Alliance for Water Efficiency, Northwest Power and Conservation Council, Northeast Energy Efficiency Partnerships, Consumer Federation of America, and the National Consumer Law Center.

[14] Document No. 4 in Docket No. EERE–2012–BT–TP–0016, available for review at *https://www.regulations.gov.*

[15] Document No. 5 in Docket No. EERE–2012–BT–TP–0016, available for review at *https://www.regulations.gov.*

[16] A notation in the form ''BSH, 2012 TP Rulemaking No. 21 at p. 1'' identifies a written comment: (1) Made by BSH Home Appliances Corporation; (2) recorded in document number 21 that is filed in the docket of the test procedure rulemaking (Docket No. EERE–2012–BT–TP–0016) and available for review at *https://www.regulations.gov;* and (3) which appears on page 1 of document number 21.

[17] ''Joint Commenters'' refers to the Appliance Standards Awareness Project, American Council for an Energy-Efficient Economy, Consumer Federation of America, National Consumer Law Center, and Natural Resources Defense Council.

AHAM recommended that DOE adopt a permanent adder of 28 kWh per year for icemaker energy use. AHAM reiterated its 2014 comments, which indicated that the current understanding of consumer ice consumption rates supports a lower ice consumption than previously estimated. (AHAM, No. 5 at pp. 2–3) AHAM also noted that 28 kWh per year may even be an overestimate because it accounts for converting 90 °F water into ice. (AHAM, No. 5 at p. 3) Samsung noted that it had previously commented in support of measuring automatic icemaker energy consumption, but that was based on the fixed adder of 84 kWh per year. With more current ice usage data corresponding to a fixed adder of 28 kWh per year, the Samsung stated that the potential for energy savings is only around 2 percent and measuring icemaker energy use would not be appropriate, and instead supported a revised fixed adder of 28 kWh per year. (Samsung, No. 8 at p. 2) BSH also commented that more recent consumer use data indicates lower rates of ice consumption than assumed to develop the current 84 kWh per year adder. BSH stated that the lower ice consumption rate corresponds to 28 kWh per year, over half of which is the latent energy required for the phase change to make ice, so less than half of the energy use is the result of the automatic icemaker, and does not warrant any testing. Therefore, BSH supported revising the adder from 84 kWh per year to 28 kWh per year. (BSH, No. 2 at pp. 1–2)

AHAM also commented that an icemaker energy test would significantly increase burden without a corresponding benefit to the representativeness or accuracy of the test procedure. (AHAM, No. 5 at p. 2) AHAM stated that an icemaker energy test would increase burden by 50 percent to account for only 2.5 to 4.5 percent of a product's energy use. (AHAM, No. 5 at p. 4) BSH commented that an icemaker test is very burdensome and would more than double the amount of time required to test the appliance, and therefore opposed an energy test for icemaking. (BSH, No. 2 at p. 2) FSI strongly supports the use of, or option to use, a placeholder value for icemaker installation because it stated that a test for automatic icemaking would be beyond the capabilities of smaller laboratories (meeting supply water conditions) and would significantly increase the costs for outside test laboratories. (FSI, No. 6 at pp. 1–2) Samsung also stated that because of the additional test burden and uncertainty in an icemaking measurement, it no longer believes that a measurement is appropriate and supports a revised fixed adder of 28 kWh per year. (Samsung, No. 8 at p. 2) Sub Zero referred to AHAM's estimate that half of icemaker energy use is the thermodynamic energy needed to freeze water, and therefore only 14 kWh per year is attributed to the automatic icemaker. Sub Zero commented that any feasible improvements to the icemaker would save a homeowner well less than a dollar per year, which is not worth the burden and cost of icemaker testing. (Sub Zero, No. 4 at p. 2)

The Joint Commenters commented that a test to measure actual icemaker energy use is the most appropriate approach to account for icemaker energy use. They stated that measured energy use is superior to the fixed adder approach currently in use not only because it provides consumers with more accurate information on the energy use associated with icemaking, but it provides manufacturers with an incentive to improve icemaker energy efficiency and drive reductions in total refrigerator energy consumption. (Joint Commenters, No. 7 at p. 3) The Joint Commenters noted that testing of 10 icemakers conducted by DOE and the National Institute of Standards and Technology (''NIST'') found that some icemakers use up to twice as much energy per pound of ice produced as others and that differences in energy use were significant even among similar refrigerator models. They continued to urge DOE to investigate a method to measure icemaker energy use without adding undue additional test burden. (Joint Commenters, No. 7 at p. 3) The Joint Commenters further commented that if the fixed adder approach is retained for icemaker energy use, DOE should evaluate available data to determine a more appropriate value for the adder. They referred to field data from NEEA and one manufacturer suggesting that average ice production is closer to 0.8 lbs/day rather than 1.8 lbs/day, and to testing by DOE and NIST that found icemaker energy use ranging from 0.092 to 0.192 kWh per pound, or 27 to 56 kWh per year assuming an ice production rate of 0.8 lbs/day. The Joint Commenters stated that, given the small number of products tested, the range of energy use could be much larger and demonstrates the difficulty in establishing a single fixed adder value. (Joint Commenters, No. 7 at p. 4)

DOE agrees that the more recent consumer use data suggest that typical daily ice consumption is lower than previously estimated. Consistent with the recommendations from interested parties during the previous test procedure rulemaking and in response to the June 2017 RFI, DOE has initially determined that the median ice consumption value of 0.59 lbs/day is representative of typical consumer use.

DOE initially considered a test procedure for icemaking energy consumption to better represent the energy consumption of units in the field and to incentivize manufacturers to improve efficiencies of automatic icemakers. However, based on a lower value of daily ice consumption as identified through data submitted by commenters, the overall energy consumption associated with icemaking in actual operation appears much lower than estimated for the current fixed adder. As a result, icemaker efficiency would have a much lower impact on a unit's overall energy consumption, and DOE expects that manufacturers would have even less incentive to pursue efficiency improvements through icemaker performance.

A laboratory-based icemaker test may allow for a more representative estimate of icemaking energy consumption for a given model, which could in some instances provide incentives for manufacturers to improve icemaking efficiency. However, DOE agrees with the comments from interested parties estimating that incorporation of an icemaking energy test procedure would increase testing time by 50 percent. Based on testing cost estimates provided in response to the June 2017 RFI, this would equate to a cost increase of $2,500 per test as compared to the current test procedure.[18] At ice consumption levels reported by NEEA and NPCC and GE, the benefits of a laboratory-based test procedure would likely not outweigh the burdens associated with this testing. Therefore, DOE is proposing to continue using the fixed adder approach, rather than a laboratory-based test method, to account for automatic icemaker energy consumption, with a revised value of 28 kWh per year (through an adder of 0.0767 kW in the per-day energy use calculations). DOE continues to request comment on whether the proposed fixed adder of 28 kWh per year is appropriate and on any additional consumer use data regarding automatic icemakers.

DOE is aware of products available on the market with two automatic icemakers. Typically, these products are certified as product class 5A (automatic defrost refrigerator-freezers with bottom-

[18] The total cost per test is based on FSI's comment stating between $4,500 and $5,000 per refrigerator test conducted at outside laboratories. (FSI, No. 6 at p. 1)

mounted freezers and through-the-door ice service) with an icemaker in the freezer compartment and another contained in the through-the-door ice service in the fresh food compartment. The refrigerator-based icemaker provides access for frequent through-the-door ice service, while the freezer-based icemaker provides an in-freezer storage container for infrequent bulk ice use. In the June 2017 RFI, DOE requested comment on how its test procedures should address products with multiple automatic icemakers. 82 FR 29783.

AHAM commented that consumer ice consumption rates likely do not change based on the number of automatic icemakers their product has because the second icemaker is typically used on occasions such as a party or to fill a cooler, which would likely be true for a consumer with one icemaker on those occasions. AHAM stated that the second icemaker is a matter of convenience rather than increased production, and therefore proposed applying the same fixed adder of 28 kWh per year for these products. (AHAM, No. 5 at p. 5)

Upon further consideration, including AHAM's comment, DOE understands that consumers with dual-icemaker products are not likely to use more ice than consumers with single-icemaker products. DOE is proposing that the same fixed adder would apply for any products with automatic icemaking, regardless of the number of icemakers in the product. DOE requests comment on this proposal and feedback regarding any available consumer use data for products with multiple automatic icemakers.

In response to the June 2017 RFI, AHAM also commented that DOE should not immediately require manufacturers to use the revised fixed adder. Instead, AHAM stated that DOE should wait until the compliance date of the next potentially amended standards, otherwise, manufacturers would have to re-certify and re-label their products. (AHAM, No. 5 at pp. 4–5)

DOE acknowledges AHAM's comment regarding the burden of re-certifying and re-labeling their products. However, as DOE has tentatively determined that the revised energy adder would more accurately measure energy use during a representative average use cycle, DOE is required to include the revised energy adder in the amended test procedure. (42 U.S.C. 6293(b)(1)(A)) Additionally, having tentatively determined that the revised energy adder will alter the measured energy use of consumer refrigeration products with automatic icemakers as determined under the existing test procedure, DOE is required to amend the energy conservation standards for these products during this test procedure rulemaking. (42 U.S.C. 6293(e)(2)) In determining the amended energy conservation standard, DOE must measure, pursuant to the amended test procedure, the energy use of a representative sample of these consumer refrigeration products with automatic icemakers that minimally comply with the existing standard. The average of such energy use under the amended test procedure then must constitute the amended energy conservation standard for the applicable covered products. *Id.* In this case, as DOE is proposing to reduce the energy adder for automatic icemakers by 56 kWh per year (the difference between the current value of 84 kWh per year and the proposed value of 28 kWh per year), the measured energy use of minimally-compliant products will also decrease by 56 kWh per year. As such, DOE is proposing to amend the energy conservation standards for consumer refrigeration products with automatic icemakers to reflect a reduction of 56 kWh per year in the equation for maximum energy use. Further, in order to reduce the burden on manufacturers of re-certifying and re-labeling their products, DOE is proposing a one-year lead-time period before any amended standards would go into effect. Table III–I and Table III–II include the current and proposed amended energy conservation standards for the product classes with automatic icemakers.

TABLE III–I—PROPOSED AMENDED ENERGY CONSERVATION STANDARDS FOR CONSUMER REFRIGERATOR, REFRIGERATOR-FREEZER, AND FREEZER PRODUCT CLASSES WITH AUTOMATIC ICEMAKERS

Product class	Current equations for maximum energy use (kWh/yr)		Proposed equations for maximum energy use (kWh/yr)	
	Based on AV (ft^3)	Based on av (L)	Based on AV (ft^3)	Based on av (L)
3I. Refrigerator-freezers—automatic defrost with top-mounted freezer with an automatic icemaker without through-the-door ice service	8.07AV + 317.7	0.285av + 317.7	8.07AV + 261.7	0.285av + 261.7
3I–BI. Built-in refrigerator-freezers—automatic defrost with top-mounted freezer with an automatic icemaker without through-the-door ice service	9.15AV + 348.9	0.323av + 348.9	9.15AV + 292.9	0.323av + 292.9
4I. Refrigerator-freezers—automatic defrost with side-mounted freezer with an automatic icemaker without through-the-door ice service	8.51AV + 381.8	0.301av + 381.8	8.51AV + 325.8	0.301av + 325.8
4I–BI. Built-In Refrigerator-freezers—automatic defrost with side-mounted freezer with an automatic icemaker without through-the-door ice service	10.22AV + 441.4	0.361av + 441.4	10.22AV + 385.4	0.361av + 385.4
5I. Refrigerator-freezers—automatic defrost with bottom-mounted freezer with an automatic icemaker without through-the-door ice service	8.85AV + 401.0	0.312av + 401.0	8.85AV + 345.0	0.312av + 345.0
5I–BI. Built-In Refrigerator-freezers—automatic defrost with bottom-mounted freezer with an automatic icemaker without through-the-door ice service	9.40AV + 420.9	0.332av + 420.9	9.40AV + 364.9	0.332av + 364.9
5A. Refrigerator-freezer—automatic defrost with bottom-mounted freezer with through-the-door ice service	9.25AV + 475.4	0.327av + 475.4	9.25AV + 419.4	0.327av + 419.4
5A–BI. Built-in refrigerator-freezer—automatic defrost with bottom-mounted freezer with through-the-door ice service	9.83AV + 499.9	0.347av + 499.9	9.83AV + 443.9	0.347av + 443.9
6. Refrigerator-freezers—automatic defrost with top-mounted freezer with through-the-door ice service	8.40AV + 385.4	0.297av + 385.4	8.40AV + 329.4	0.297av + 329.4

TABLE III–I—PROPOSED AMENDED ENERGY CONSERVATION STANDARDS FOR CONSUMER REFRIGERATOR, REFRIGERATOR-FREEZER, AND FREEZER PRODUCT CLASSES WITH AUTOMATIC ICEMAKERS—Continued

Product class	Current equations for maximum energy use (kWh/yr)		Proposed equations for maximum energy use (kWh/yr)	
	Based on AV (ft^3)	Based on av (L)	Based on AV (ft^3)	Based on av (L)
7. Refrigerator-freezers—automatic defrost with side-mounted freezer with through-the-door ice service	8.54AV + 432.8	0.302av + 432.8	8.54AV + 376.8	0.302av + 376.8
7–BI. Built-In Refrigerator-freezers—automatic defrost with side-mounted freezer with through-the-door ice service	10.25AV + 502.6	0.362av + 502.6	10.25AV + 446.6	0.362av + 446.6
9I. Upright freezers with automatic defrost with an automatic icemaker	8.62AV + 312.3	0.305av + 312.3	8.62AV + 256.3	0.305av + 256.3
9I–BI. Built-in upright freezers with automatic defrost with an automatic icemaker	9.86AV + 344.9	0.348av + 344.9	9.86AV + 288.9	0.348av + 288.9
13I. Compact refrigerator-freezers—automatic defrost with top-mounted freezer with an automatic icemaker	11.80AV + 423.2	0.417av + 423.2	11.80AV + 376.2	0.417av + 376.2
14I. Compact refrigerator-freezers—automatic defrost with side-mounted freezer with an automatic icemaker	6.82AV + 540.9	0.241av + 540.9	6.82AV + 484.9	0.241av + 484.9
15I. Compact refrigerator-freezers—automatic defrost with bottom-mounted freezer with an automatic icemaker	11.80AV + 423.2	0.417av + 423.2	11.80AV + 367.2	0.417av + 367.2

TABLE III–II—PROPOSED AMENDED ENERGY CONSERVATION STANDARDS FOR PRODUCT CLASSES OF MISCELLANEOUS REFRIGERATION PRODUCTS WITH AUTOMATIC ICEMAKERS

Product class	Current maximum AEU (kWh/yr)	Proposed maximum AEU (kWh/yr)
C–9I. Cooler with upright freezer with automatic defrost with an automatic icemaker	5.58AV + 231.7	5.58AV + 175.7
C–9I–BI. Built-in cooler with upright freezer with automatic defrost with an automatic icemaker	6.38AV + 252.8	6.38AV + 196.8

E. Built-In Test Configuration

Built-in consumer refrigeration products generally are products that (1) have unfinished sides that are not intended to be viewable after installation; (2) are designed exclusively to be installed totally encased by cabinetry, fastened to the adjoining cabinetry, walls, or floor; and (3) are either equipped with a factory-finished face or accept a custom front panel. 10 CFR 430.2. In the July 2013 NOPR, DOE presented data indicating that testing in a built-in enclosure may affect measured energy consumption for certain configurations of built-in products. 79 FR 41610, 41649–41650. Specifically, those products that reject condenser heat at the back of the unit showed a potential increase in energy use when tested in an enclosure. DOE observed no significant change in energy use associated with the test configuration for those products that reject heat from the front of the unit. DOE did not propose any changes to the test requirements for built-in products at that time, but requested comment on the appropriate test configuration for built-in refrigerators, refrigerator-freezers, and freezers. *Id.* DOE provided additional time to comment on the built-in testing issue prior to the April 2014 Final Rule, but did not address the issue in that rule.

In the rulemaking leading to the April 2014 Final Rule, DOE received multiple comments on testing for built-in products. Some commenters supported testing built-in products in an enclosure, stating that this would represent how the products are used in the field. (Joint Commenters, 2012 TP Rulemaking No. 42 at pp. 5–6; NEEA and NPCC, 2012 TP Rulemaking No. 41 at p. 4)

Other interested parties opposed the enclosure test setup, stating that it would result in a significant increase in test burden with little or no corresponding change in measured energy consumption. These interested parties also stated that, for the products with different measured energy use between the freestanding and enclosure test setups (*i.e.,* those products with heat rejection at the rear of the unit), the enclosure configuration that DOE used (based on Underwriters Laboratories (''UL'') Standard 250, ''Household Refrigerators and Freezers'' (''UL 250'')) was not necessarily consistent with manufacturer installation instructions. (AHAM, 2012 TP Rulemaking No. 37 at pp. 16–17; BSH, 2012 TP Rulemaking No. 21 at p. 1; Liebherr-Canada, Ltd. (''Liebherr''), 2012 TP Rulemaking No. 34 at pp. 1–4; Sub-Zero, 2012 TP Rulemaking No. 36 at p. 2) Liebherr provided additional test data indicating that units with rear condensers do not have significantly different measured energy consumption when tested without an enclosure compared to that when testing in an enclosure consistent with the manufacturer installation instructions. (Liebherr, 2012 TP Rulemaking No. 34 at pp. 1–4)

In the June 2017 RFI, DOE requested further information on appropriate testing for built-in products, including energy impacts of testing in an enclosure, representativeness of test results compared to actual consumer use, test burden, and any potential alternative test approaches. 82 FR 29783–29784.

AHAM stated that there is no value in requiring built-in testing for products that reject heat out the front of the unit because doing so would not increase the representativeness of the test. (AHAM, No. 5 at p. 5) FSI stated that it strongly supports the current procedure of testing built-in appliances in a freestanding configuration. (FSI, No. 6 at p. 2)

AHAM commented that the UL 250 enclosure is not the most representative test for built-in products that reject heat from the back of the unit because it would not include proper venting according to the manufacturer

installation instructions. AHAM noted that, when installed according to manufacturer instructions, these units would consume little or no additional energy when compared to the freestanding test. Therefore, AHAM opposed any revisions to the test procedure that would require testing built-in models in the built-in condition. (AHAM, No. 5 at pp. 5–6) BSH stated that its products discharge condenser air out the front of the product, and while there is some residual heat gain from an enclosure, it is minimal. BSH stated that the potential variation from misinterpretation of installation instructions is not worth the small amount of energy captured through an enclosure test procedure. (BSH, No. 2 at p. 2) Sub Zero commented that, based on decades of testing, it sees no need to test built-in products in enclosures. Sub Zero stated that it has more experience with built-in products than any other manufacturers, and for its products that exhaust air through the front of the product, there is no technical reason to expect a difference when testing with or without an enclosure. (Sub Zero, No. 4 at p. 2)

BSH further commented that an enclosure for built-in products can lead to different interpretations and variations in the test because products can be installed in many different ways (*e.g.,* side-by-side, with cabinets between the refrigerator and freezer, *etc.*), so installation instructions differ for the various applications. (BSH, No. 2 at p. 2) FSI stated that, unless instructions were followed precisely, reproducible results would be impossible because many units have specific installation instructions for ventilation. Additionally, FSI commented that if manufacturers must submit installation instructions to DOE, it would impose another reporting burden, and that preparing proper installation instructions may also be costly and difficult to reproduce for verification. (FSI, No. 6 at p. 2)

AHAM commented that requiring enclosures for built-in testing would significantly increase burden without a corresponding benefit to the representativeness or accuracy of the test procedure. AHAM commented that the built-in test would make the test procedure unduly burdensome to conduct because there are so many different sizes of built-in units and so many customizable configurations that would require an excessive number enclosures. According to data AHAM collected from its members, it is possible that manufacturers could be required to have from three to 12 different size enclosures in order to test built-in units. AHAM noted that manufacturers would need more than one of each of those sizes, for example, up to four, which means that manufacturers could be required to build and house 12 to 48 enclosures. AHAM stated that number would increase even further were the enclosure to be built according to the manufacturer's installation instructions (as it would need to be for a representative measurement). Additionally, AHAM commented that third-party test laboratories would potentially need to have all of the possible enclosures available as well. AHAM noted that not only would there be an expense to create all of those enclosures, but neither manufacturer nor third-party laboratories have the capacity to store them, and the enclosure would increase test time to install units in a built-in configuration. (AHAM, No. 5 at p. 2, 6)

BSH, FSI, and Sub Zero echoed AHAM's comments, stating that an enclosure would make the test longer and more burdensome due to the different sizes of enclosures needed for the range of different size products available. (BSH, No. 2 at p. 2; FSI, No. 6 at p. 2; Sub Zero, No. 4 at p. 2) FSI further stated that the labor for a custom enclosure could add $1,000 or more to each energy test. (FSI, No. 6 at p. 2)

The Joint Commenters stated that built-in products should be tested in an enclosure, regardless of their configuration or heat-rejection approach. They commented that testing of built-in products in a built-in condition, as they are installed in the field, will be more representative of field energy consumption than testing in a free-standing condition. They also stated that DOE should establish guidelines for the test enclosure that are consistent with general installation instructions for these products. (Joint Commenters, No. 7 at p. 4)

DOE acknowledges that the test enclosures based on UL 250 are not consistent with all manufacturer instructions, which may provide for additional spacing and airflow pathways around the test unit to ensure adequate airflow across the condenser and heat transfer from the condenser to the ambient air. Accordingly, the test results presented in the July 2013 NOPR for the unit with a rear condenser when tested with an enclosure may not represent energy use when installed according to manufacturer instructions for all such units.

Test results from the July 2013 NOPR indicate that the test configuration does not have a significant impact on measured energy consumption when testing units that exhaust heat from the front of the unit. For units with rear condensers, test configuration appears to have no significant impact on measured energy consumption when tested in an enclosure consistent with manufacturer recommendations (according to additional data supplied by Liebherr in response to the July 2013 NOPR). Additionally, because of the variety of manufacturer installation instructions, a standardized test enclosure may not produce measurements of energy use representative of actual installations for all units with rear condensers. As such, DOE believes that testing with an enclosure would impose an unnecessary test burden on manufacturers and third-party test laboratories that would outweigh any corresponding improvement to measured energy consumption. DOE has tentatively determined that testing built-in units in enclosures consistent with the manufacturer installation instructions would have no significant difference compared to testing in a freestanding configuration. Therefore, DOE is not proposing to amend the current requirement that all units be tested in the freestanding configuration.

However, because any test procedure that DOE adopts must be reasonable designed to produce results that measure energy use of the relevant product during a representative average use cycle or period of use, and must not be unduly burdensome to conduct, DOE welcomes further comment and additional data on this issue. Specifically, DOE requests any information on how built-in products are installed in the field (*i.e.,* whether they are installed in accordance with manufacturers' instructions) and on whether the built-in installation, as installed in the field, has any impact on energy consumption.

F. Test Setup

1. Thermocouple Configuration for Freezer Drawers

As discussed in section III.C of this document, Appendix A and Appendix B incorporate by reference portions of HRF–1–2008 for testing requirements. Section 5.5.5.5 of HRF–1–2008 includes figures specifying thermocouple placement for several example fresh food and freezer compartment configurations. HRF–1–2008 also notes that in situations where the interior of a cabinet does not conform to the configurations shown in the example figures, measurements must be taken at

locations chosen to represent approximately the entire cabinet.

In the June 2017 RFI, DOE discussed that HRF–1–2008 and HRF–1–2016 provide a specific thermocouple location diagram for freezer compartments in refrigerator-freezers (type 6 in Figure 5–2). However, the diagram for this configuration is based on an upright, front-opening freezer compartment, and does not explicitly address drawer-type freezer compartments. Based on its experience testing these products at third-party test laboratories, DOE noted that additional specification may be required regarding which thermocouple layout is appropriate for drawer-type freezer compartments in refrigerator-freezers. DOE stated in the June 2017 RFI that sensor layout type 6 is likely appropriate for testing drawer-type freezer compartments in refrigerator-freezers and requested feedback on this clarification. 82 FR 29784.

AHAM commented that it had issued errata to HRF–1–2008 and HRF–1–2016 adding a note to Figure 5–2 indicating that if the compartment volume is less than 2 cubic feet, then a single thermocouple shall be located at the geometric center of the compartment. AHAM noted that this statement was previously included in HRF–1–2008 Section 5.8.1, but AHAM issued the errata because it believed placement of the sentence was causing confusion regarding thermocouple placement in freezer drawers (*i.e.,* freezers with compartment volume less than 2 cubic feet). AHAM stated that this change should resolve DOE's concern and urged DOE to acknowledge the errata as part of its incorporation by reference of Figure 5–2, and there would be no need for DOE to change the test procedure. AHAM commented that DOE could, perhaps, issue guidance acknowledging that the errata are included in DOE's incorporation by reference of Figure 5–2; alternatively, AHAM stated that DOE could incorporate by reference HRF–1–2016, for which AHAM has also issued the same errata. (AHAM, No. 5 at p. 9)

As stated in section III.C of this proposed rule, DOE is proposing to incorporate by reference HRF–1–2016 for both Appendix A and Appendix B. This incorporation by reference would also include any relevant errata to HRF–1–2016, including the clarification to Figure 5–2. DOE is also proposing to amend Appendix A and Appendix B to explicitly specify that for freezer drawers, the thermocouple setup for drawer-type freezer compartments shall follow sensor layout type 6 specified in HRF–1–2016. DOE expects that all drawer-type freezer compartments are already tested using sensor layout type 6, and therefore, this proposed amendment would likely not affect how any units are currently tested. DOE requests feedback on whether this sensor layout or any other thermocouple configurations set forth in HRF–1–2016 require any additional detail.

2. Test Platform Requirements

Section 2.1.3 in both Appendix A and Appendix B requires that a test platform be used if the test chamber floor temperature is not within 3 °F of the measured ambient temperature. If a platform is used, it must have a solid top with all sides open for air circulation underneath, and its top shall extend at least 1 foot beyond each side and front of the unit under test and extend to the wall in the rear. DOE included this requirement to limit the variability of airflow near the unit during testing. Airflow directly at the base of the unit may increase heat transfer from the condenser and compressor compartment, resulting in better measured energy performance compared to a unit with no airflow at the base of the unit.

The text of section 2.1.3 in Appendix A and Appendix B does not explicitly address the setup for a test chamber floor that has vents for airflow. Such a test chamber floor is analogous to a ''platform'' because the floor is elevated above an airflow pathway. Therefore, testing should follow the same procedure required for a test platform. To limit potential confusion regarding appropriate test setup and corresponding variability in airflow at the base of a unit under test, DOE is proposing that a floor with holes or vents for airflow at the base of a test unit would need to meet the same requirements as a platform. Therefore, DOE is proposing to specify that for a test chamber floor that allows for airflow (*e.g.,* through a vent or holes), any airflow pathways through the floor must be located at least 1 foot away from all sides of the unit. DOE requests comment on this proposed amendment, including information on any associated testing burden and whether additional instructions regarding airflow around the test unit may be necessary to limit test variability. Based on DOE's experience with third party laboratories, DOE believes that this proposal is consistent with current industry practice, and therefore DOE expects that this proposal would not impact measured energy use.

3. Separate External Temperature Controls

Certain refrigerators do not include integrated temperature controls within the cabinet assembly. Rather, the refrigerator is intended to be connected to a separate freezer that houses the controls for both the refrigerator and freezer cabinets. DOE granted a waiver to Liebherr Canada, Ltd. (Liebherr) to allow for testing such a product. 79 FR 19886 (April 10, 2014). Under the waiver approach, Liebherr must test the refrigerator according to Appendix A with the additional requirement that the freezer cabinet (with controls for both the refrigerator and freezer) be close enough to allow for the electrical connection to the refrigerator, but far enough away to avoid interfering with ambient airflow or other test conditions. The freezer must be set to the ''off'' position for testing. *Id.* at 79 FR 19887–19888.

DOE is not aware of any other products for which the cabinet controls are housed in a separate product; however, DOE is proposing to amend Appendix A and Appendix B to address such cases to eliminate the potential need for additional test procedure waivers. DOE is proposing to follow the approach specified in the Liebherr waiver, but with revisions to be applicable to different cabinet configurations. The proposed test procedure specifies that if a product's controls are external to the cabinet, the product shall be connected to the controls as needed for normal operation, but any additional equipment needed for testing shall not interfere with ambient airflow or other test conditions, and the controls for any other cabinets shall be set to the ''off'' position during testing. DOE is proposing to include these requirements in new sections 2.10 and 2.9 in Appendix A and Appendix B, respectively.

DOE requests comment on its proposed approach and on whether any further instructions would be needed to address products with temperature controls separate from the product cabinet.

G. Test Conditions

1. Vertical Gradient

Section 2.1.2 of both Appendix A and Appendix B requires that a test room vertical ambient temperature gradient of no more than 0.5 °F per foot (0.9 °C per meter) must be maintained during testing. To demonstrate that this requirement has been met, test data must include measurements taken using temperature sensors at locations 10 inches from the center of the two sides

of the unit under test at heights of 2 inches and 36 inches above the floor or supporting platform and at a height of 1 foot above the unit under test.

Section 2.1.2 does not, however, specify when the vertical ambient temperature gradient must be maintained. Section 2.1.1 of both appendices specifies that the ambient temperature shall be maintained during both the stabilization period and test period. DOE believes that the vertical ambient temperature gradient should also be maintained during both the stabilization period and test period to ensure consistent ambient conditions throughout both periods. Thus, DOE is proposing that the vertical ambient temperature gradient be maintained during both the stabilization period and test period. DOE expects that this proposal would reduce the potential for testing variability, but does not believe that this proposal would impact measured energy use.

Additionally, the requirement to measure temperature 1 foot above the unit under test does not explicitly address products with components that extend above the top of the refrigerated storage cabinet (*e.g.,* beer dispensers or ''keg refrigerators'' with taps on top of the cabinet). The test procedure does not specify whether the temperature measurement should be made 1 foot above the main storage cabinet or 1 foot above the highest point of the unit under test. DOE is proposing that when measuring the vertical gradient from 1 foot above the unit, the top of the unit should be determined by the refrigerated cabinet height, excluding any accessories or protruding components on the top of the unit (*e.g.,* taps/dispensers). DOE expects that this proposal would reduce the potential for testing variability and does not expect it to impact measured energy use, should it be adopted.

2. Stabilization

Section 2.9 in Appendix A and section 2.7 in Appendix B each provide two options for determining whether steady-state conditions exist, based on a maximum rate of change of average compartment temperatures, for a unit under test. The first option specifies determining the rate of change of compartment temperatures by comparing temperature measurements recorded during a period of at least 2 hours to the measurements recorded over an equivalent time period, with 3 hours elapsing between the two measurement periods.

For test units with cycling compressors, it may not be possible to measure temperatures over complete compressor cycles while allowing exactly 3 hours to elapse between the measurement periods. However, as DOE stated in the July 2013 NOPR discussion of this topic, DOE considers the 3-hour period to represent a minimum elapsed time between temperature checkpoint periods. 78 FR 41610, 41651. Accordingly, DOE is proposing that for the stability check, the time elapsed between measurement periods must be at least 3 hours. This proposed amendment is consistent with the steady-state condition requirements included in section 3.28 of HRF–1–2008 and section 3.32 of HRF–1–2016. Additionally, DOE is proposing to amend the Appendix B stabilization criteria to match the wording and formatting of Appendix A for consistency.

Additionally, in response to the June 2017 RFI, multiple interested parties commented regarding the use of the same data for the stabilization period and the test period when testing certain products. AHAM commented to reiterate its proposal that DOE include the stabilization period as part of the test period. Specifically, AHAM proposed that, in cases where part A stability (as stated in Appendix A, section 2.9) data can be used, the full stability data be used for the first part of the test instead of requiring a separate part one of the test. AHAM noted that this approach would shorten test time and allow testers to use data established over a long period of time (*e.g.,* 54 hours), instead of requiring that data to be essentially ignored. AHAM stated that with electronic data acquisition systems, there is no need to require separate data acquisition periods for stabilization and part one of the test. AHAM commented that this proposed change would not only reduce burden, but it would increase the accuracy of the test because part one of the test would be based on known stability, not on however the product behaves on a separate part one of the test. AHAM noted that for part B stability (as stated in Appendix A, section 2.9), the procedure should remain as currently written. AHAM included a graphical representation of its proposal attached at Exhibit B in the submitted comment. (AHAM, No. 5 at p. 8) BSH and Sub Zero both commented in support of AHAM's comment. (BSH, No. 2 at p. 2; Sub Zero, No. 4 at p. 2)

DOE tentatively agrees that the stabilization period and part one of a two-part energy test capture essentially the same unit operation. As AHAM stated, using the stabilization period as the test period would also ensure that the product is stable. The current requirements establish stability prior to the test period. It could be possible, although unlikely, that a unit under test achieves stability during the stabilization period and reverts to unstable operation for the test period. Accordingly, DOE is proposing to amend the test period requirements in Appendix A and Appendix B to require that, if the part A stabilization criteria is used, that same period shall be used for test period data, where appropriate (*i.e.,* for the test periods that do not capture defrosts).

Additionally, DOE is aware that stabilization determinations may be difficult for products with multiple compressors or irregular compressor cycling. For these products, the average compartment temperatures over one complete compressor cycle may not be representative of the average compartment temperatures over a longer period of operation with multiple compressor cycles. For example, a product with a combination of long and short compressor on cycles during normal operation would likely have either higher or lower average compartment temperatures over an individual compressor on/off cycle, when compared to the average compartment temperatures over a longer period of operation with multiple compressor cycles.

Products with this type of operation may not be able to meet the requirements for determining the start and end points for the defrost portion of the test when using the two-part test as provided in section 4.2.1.1 in Appendix A and Appendix B (and 4.2.3.4.2 in Appendix A for multiple-compressor products) because the average temperature of an individual compressor cycle may never match the average temperature over a longer period of operation including many compressor cycles. For these products using the two-part test method, DOE is proposing to include an alternate determination of when to start and end the defrost test period. To begin the period, DOE is proposing that average compartment temperatures be determined over one or more complete compressor cycles before a defrost. The average temperatures over the multiple complete compressor cycles must be within 0.5 °F of the average determined over the first part of the test, and all cycles included in the averaging period would be included within the defrost test period. Similarly, the test period would end with a period of complete compressor cycles after a defrost with the average compartment temperatures over that period within 0.5 °F of the average determined over the first part of

the test. All compressor cycles included in the averaging period would be included in the defrost test period.

For products with multiple compressors, the asynchronous cycling of the different compressors may make it even more difficult to determine whether average compartment temperatures are within 0.5 °F of the average temperatures for the first part of the test. To address this issue, DOE is proposing that if a multiple compressor product cannot meet the 0.5 °F criteria, the test period shall include precool, defrost, and recovery time for the defrosted compartment, as well as sufficient dual compressor cycles to allow the length of the test period to be at least 24 hours, unless a second defrost occurs prior to completion of 24 hours, in which case the second part of the test shall include a whole number of complete primary compressor cycles comprising at least 18 hours. The test period would start at the end of a regular freezer compressor on-cycle after the previous defrost occurrence (refrigerator or freezer). The test period would also include the target defrost and following freezer compressor cycles, ending at the end of a freezer compressor on-cycle before the next defrost occurrence (refrigerator or freezer). This proposed approach is consistent with an existing waiver test method for a multiple compressor product, as described further in Section III.J.2.a of this document.[19]

DOE requests feedback on these proposed amendments and whether they would result in any unexpected testing issues. Additionally, DOE seeks comment on the proposed amendments for testing conditions, including the vertical ambient temperature gradient and stabilization provisions. DOE welcomes information on the testing burden and impacts on test repeatability and reproducibility associated with these proposed test conditions.

H. Features Not Directly Addressed in Appendix A or Appendix B

1. Door-In-Door Designs

DOE's test procedures for consumer refrigeration products represent operation in typical room conditions with door openings by testing at an elevated ambient temperature with no door openings. 10 CFR 430.23(a)(7). The increased thermal load from the elevated ambient temperature represents the thermal load associated with both door openings, as warmer ambient air mixes with the refrigerated air inside the cabinet, and the loading of warmer items in the cabinet.

As discussed in the June 2017 RFI, DOE is aware of certain products available on the market that incorporate a door-in-door design. This feature allows the consumer to access items loaded in the door shelves without opening an interior door that encloses the inner cabinet. This feature potentially prevents much of the cool cabinet air from escaping to the room and being replaced by warmer ambient air, as would be the case during a typical total door opening. 82 FR 29782.

In response to the June 2017 RFI, AHAM and BSH commented that they do not have consumer use data regarding door-in-door designs, and that DOE should not amend the test procedure to address these features without having consumer use data. (AHAM, No. 5 at pp. 6–7; BSH, No. 2 at p. 2) AHAM further stated that it would oppose any proposed change that would alter the closed door test, which is representative of consumer use because it is based on reliable data regarding ambient conditions and door openings. AHAM commented that door openings introduce significant variation into the test and dramatically increase test burden because of the need to control the door openings with precision; thus, the test should not be revised to include door openings even for only certain types of products. AHAM suggested that once statistically significant consumer data from field studies are available, DOE should evaluate possible calculation or other approaches that do not add test burden or change the representativeness, repeatability, or reproducibility of the test to account for door-in-door designs. (AHAM, No. 5 at p. 7) Sub Zero further commented that the benefits of a 90 °F ambient closed-door test have been fully demonstrated and no other test method provides the same accuracy, repeatability, comparability among models and configurations, and reasonable burden and cost for testing. Sub Zero stated that it appreciates the need for this type of test as a smaller manufacturer striving to remain competitive with large multi-national producers. (Sub Zero, No. 4 at pp. 1–2)

The Joint Commenters stated that DOE's test procedures should be designed to capture the benefits of features that can provide energy savings in the field; therefore, additional investigation may be warranted to evaluate whether door-in-door designs have the potential to save a significant amount of energy, and if so, how these savings could be captured in the test procedure. The Joint Commenters provided the following example data regarding door-opening energy consumption: A Trinity University study estimated that door openings and container replacement account for about 17 to 23 percent of the overall cabinet load; and a study by the Florida Solar Energy Center similarly found that for a refrigerator with a rated annual energy consumption of 760 kWh per year, door openings were responsible for about 19 percent of the total energy consumption. The Joint Commenters noted that reducing the energy consumption associated with door openings may therefore represent an opportunity for energy savings. (Joint Commenters, No. 7 at pp. 1–2)

Samsung commented in support of accounting for door-in-door designs using a field use factor to be established by testing various product configurations to establish energy-saving potential, and provided an example of how such a factor may be determined. Samsung stated that the door-in-door design on its products allows quick access to main door bins without opening the main refrigerator door, which reduces energy loss due to door openings. Limited Samsung testing indicated that the door-in-door feature reduces energy consumption by 7.4 percent assuming 12 door openings per day; assuming 40 door openings per day and 50 percent use of the outer door only, Samsung estimated that the door-in-door feature would save around 9.8 percent energy consumption. Samsung also commented that it has developed a camera and display system that shows food items inside the refrigerator without opening the door, which similarly reduces door openings and saves energy. (Samsung, No. 8 at pp. 1–2, 4–5)

DOE agrees with the Joint Commenters and Samsung that the door-in-door feature and camera/display systems have the potential to reduce energy consumption associated with door openings for these products. However, DOE does not believe that there is sufficient data regarding consumer usage patterns of this feature to warrant revisions to the test procedure at this time.

Additionally, DOE notes that the storage volume associated with door shelves is typically much smaller than the main cabinet storage volume. Accordingly, DOE expects that most door openings are intended to provide access to the main storage cabinet, and that consumers are unlikely to frequently use only the outer door of products with a door-in-door feature.

For these reasons, DOE is not proposing to amend its test procedures

[19] See case number RF–042.

to address door-in-door designs (or other features that potentially reduce door openings, *e.g.,* internal cameras) in this NOPR.

To ensure that DOE's test procedures measure energy use of a product during a representative average use cycle or period of use, DOE continues to request comment on whether the existing test procedures should be amended to account for door-in-door designs or any other features that may reduce door openings. DOE also seeks information regarding what steps, if any, manufacturers are taking to estimate the energy use characteristics of products that use door-in-door designs. Further, DOE requests data, if any, on consumer use of the door-in-door feature or internal cameras (or any available consumer use information regarding door openings), including how often the outer door or camera is used in comparison to a full door opening, and the corresponding energy impacts of each type of door opening.

2. Display Screens and Connected Functions

DOE observes that consumer refrigeration products that include user control panels or displays located on the front of the product are being introduced into the market. Many products incorporating these more advanced user interfaces also include internet connections to allow for additional functions. These features, which can control the product's function and provide additional user features, such as television or internet access, operate with many different control schemes, including activation by proximity sensors.

The current DOE test procedures require that consumer refrigeration products that have a communication module for demand-response functions be tested with the communication module in the ''as shipped'' configuration. Section 2.10 of Appendix A and section 2.8 of Appendix B. Additionally, the current DOE test procedures, by referencing HRF–1–2008, require testing with customer-accessible features not required for normal operation and which are electrically powered, manually initiated, and manually terminated, set at their lowest energy usage positions when adjustment is provided.

In the June 2017 RFI, DOE requested feedback on how consumers typically use these product features. Specifically, DOE sought information on typical settings, and the manner and frequency in which consumers use the features to inform appropriate test procedures. 82 FR 29782.

AHAM strongly objected to DOE amending the test procedure to address these features absent consumer use data. (AHAM, No. 5 at p. 6) AHAM, Samsung, and Sub Zero commented that connected products are in the early stages of development and meaningful data on consumer use for connected features or display screens are currently unavailable, as there has been limited market penetration. (AHAM, No. 5 at p. 7; Samsung, No. 8 at p. 3; Sub Zero, No. 4 at p. 2) AHAM and Samsung stated that DOE should continue to require testing with these features in their lowest energy-use positions to avoid limiting innovation. (AHAM, No. 5 at p. 7; Samsung, No. 8 at p. 3)

BSH commented that display screens consume energy in normal use and that energy is not captured during the existing test procedure. BSH supported a reasonable proposal to include some portion of the energy consumed by these features in the energy test, if they do not add burden to the test procedure. BSH noted that Appendix A refers to products with demand-response capability, and recommends that the test procedure instead refer to all connected products. BSH stated that connected communication modules consume a small amount of energy and can be easily captured during the energy test. BSH recommended testing with the communication module in the on position but not connected, consistent with the European energy test. (BSH, No. 2 at p. 2)

The Joint Commenters encouraged DOE to amend the test procedure to capture energy consumption associated with display screens and connected functions. They noted that approximately 4 percent of ENERGY STAR-qualified products have connected capabilities. The Joint Commenters stated that there are at least two general types of display screens that are currently present in some consumer refrigeration products: One is a more advanced option screen for refrigerator functionality; the other, which is sometimes referred to as a ''Smart Screen,'' is essentially a tablet embedded into the refrigerator and offers users a view into the refrigerator as well as access to other features (*e.g.,* to stream music, access the weather, *etc.*). The Joint Commenters recommended that DOE consider specifying that display screens be tested at their highest energy use position to provide both a consistent method for capturing the energy consumption associated with display screens and an incentive for manufacturers to provide display screen functionality with low power consumption. The Joint Commenters noted that the test procedure already uses the ''highest energy use'' approach for testing convertible compartments. The Joint Commenters also encouraged DOE to ensure that any network mode power consumption is captured in the test procedure, and referred to IEC Standard 62301 ''Household electrical appliances—Measurement of standby power'' (IEC Standard 62301) as a possible reference. (Joint Commenters, No. 7 at pp. 2–3)

DOE acknowledges that the current version of IEC Standard 62301 includes specifications for a ''network mode''; however, that standard defines network mode as a mode in which at least one network function is activated (such as reactivation via network command or network integrity communication), but where the primary function is not active. DOE notes that for consumer refrigeration products, the primary function of refrigerating the cabinet requires continuous operation, and therefore would always be active. Accordingly, consumer refrigeration products would never operate in network mode as defined in IEC Standard 62301.

DOE expects that some consumers will use connected features if offered on a product. However, as noted by AHAM, Samsung, and Sub-Zero, connected products are in the early stages of development and meaningful data on consumer use for connected features or display screens are currently unavailable (AHAM, No. 5 at p. 7; Samsung, No. 8 at p. 3; Sub Zero, No. 4 at p. 2). While the Joint Commenters referred to a ''network mode,'' DOE notes that Wi-Fi connectivity and associated display screens are relatively new features in consumer refrigeration products. DOE does not want to limit innovation or hinder manufacturers from offering these functions to consumers or impede the ability to provide potential utility that these features may offer. DOE understands that the connected features vary by model, and that further specifying a test to reflect the energy consumption of the various connected features would likely introduce test variability and increase test burden. Absent additional consumer use data, DOE is not proposing any amendments to the current test procedure approach.

DOE also proposes to remove sections 2.10 of Appendix A and 2.8 of Appendix B, which state that products ''that have a communication module for demand response functions that is located within the cabinet shall be tested with the communication module in the configuration set at the factory

just before shipping.'' DOE recently published an RFI on the emerging smart technology appliance and equipment market. 83 FR 46886 (Sept. 17, 2018). In that RFI, DOE sought information to better understand market trends and issues in the emerging market for appliances and commercial equipment that incorporate smart technology. DOE's intent in issuing the RFI was to ensure that DOE did not inadvertently impede such innovation in fulfilling its statutory obligations in setting efficiency standards for covered products and equipment. Additionally, as discussed in the RFI, DOE lacks data regarding consumer use of network features, including demand response. In this NOPR, consistent with the RFI, DOE proposes to remove the sections addressing products with demand-response capability from Appendix A and Appendix B. Under the proposed approach, the HRF–1–2016 requirement that customer accessible features not required for maintaining temperature be set at their lowest energy usage positions would apply to communication modules in demand-response capable products (with the ''off'' position as the lowest energy usage position). DOE seeks comment on this proposal and on the same issues presented in the RFI as they may be applicable to consumer refrigeration products.

As discussed, under the current regulations, demand-response capable products are only tested with the communication module in the on position if a manufacturer ships the product in that configuration. A manufacturer may ship the demand-response capable product with the communication module in the off position, in which case, the communication module remains off for testing. Whether the energy use associated with the communication module is measured during testing is dependent upon the manufacturer. While the proposed change regarding demand-response capable products would affect the measured energy use for any demand-response capable products with the communication module shipped in the on position, DOE is not proposing to amend the energy conservation standards for these products in accordance with 42 U.S.C. 6293(e)(2). DOE is only aware of demand-response capable products available on the market that are also ENERGY STAR qualified. Because manufacturers have the option of setting the as-shipped position, if a manufacturer were to sell a minimally-compliant demand-response capable product, the manufacturer would likely set the as-shipped position of the communication module to the off position. Accordingly, DOE estimates that this proposed test procedure change would have no impact on the measured energy use of minimally-compliant products and no amendment to the energy conservation standards is required.

For other consumer-accessible features, such as display screens, DOE is proposing to maintain the existing approach, by referencing HRF–1–2016, that these features be tested in their lowest energy use position. For displays screens, the lowest energy use position is with the screen off. Accordingly, the existing approach does not limit innovation or features available for use in display screens or similar consumer-accessible features, and is consistent with the discussion included in the September 2018 RFI.

Although the Joint Commenters referred to the ''highest energy use'' approach for convertible compartments in supporting similar requirements for testing display screens and connected functions, DOE notes that the convertible compartment requirements are for testing associated with the primary function of the unit—refrigerating the internal storage cabinets. Display screens and connected functions are secondary features available on consumer refrigeration products.

DOE requests information on the prevalence of models with display screens and connected functions, so that DOE can determine whether measurement of the energy use of these connected features would contribute to a test procedure that is reasonably designed to measure energy use or energy efficiency during a representative average use cycle or period of use, as required by EPCA (42 U.S.C. 6293(b)(3).

DOE again requests information on how consumers typically use exterior display screens and control panels, when available. While any information would be welcome, because DOE is interested in information on energy use ratings that are representative of products in the field, DOE is particularly interested in any data that may yield insight into the manner and frequency with which consumers use these features. Additionally, DOE requests detailed feedback on the appropriate energy-related settings to use for these types of features during testing.

DOE also requests information on whether and how consumers typically use an internet connection, when available, for consumer refrigeration products. DOE also requests information on the potential energy impacts, if any, these available features would have on consumer refrigeration products.

I. Corrections

The July 2016 Final Rule inadvertently omitted from Appendix A an optional method for calculating the average per-cycle energy consumption of refrigerators and refrigerator-freezers, which had been previously included as section 6.2.2.3 in the version of Appendix A established by the July 2014 Final Rule. See, section 6.2.2.3 of Appendix A to subpart B of 10 CFR part 430 (2015); see also, 79 FR 22320, 22330–22332, 22354. That missing provision comprised a method for calculating average per-cycle energy consumption for models with two compartments and user-operable controls when using the optional test control settings and methodology specified for such models in section 3.3 of Appendix A. Specifically, it calculated the average per-cycle energy consumption as the sum of: (1) The energy consumption defined and calculated as described in appendix M, section M4(a) of AS/NZS 4474.1:2007, and (2) ''IET'', defined as 0.23 kWh per cycle for products with an automatic icemaker and 0 kWh per cycle for products without an automatic icemaker. DOE proposes to reinstate the missing section of Appendix A as established in the July 2014 Final Rule as section 6.2.3.3 to correspond to the revised section numbering established by the July 2016 Final Rule.

DOE is proposing to revise the order of definitions in Appendix A to alphabetize the defined terms.

DOE is also aware that section 6.1 in Appendix B inconsistently refers to adjusted volume using the terms ''AV'' and ''VA.'' DOE is proposing to amend section 6.1 so that only ''AV'' is used to refer to adjusted volume, consistent with the usage in Appendix A. DOE is also proposing to revise section 2.2 of Appendix B to include language consistent with Appendix A regarding exceptions and clarifications to cited sections of HRF–1–2016.

In sections 3.2.1.1 of Appendix A and 3.2.1 of Appendix B, DOE is also proposing to modify the instructions to specify that the instructions regarding electronic control settings refer to the appropriate settings for the median test. In addition, DOE proposes to modify the formatting of Table 1 in both Appendix A and Appendix B, which summarizes the appropriate temperature settings, to better show how test settings and results match for each row in the table.

Additionally, DOE proposes to amend Table 1 in Appendix A and Appendix B to provide instructions regarding coverage and test procedure waivers rather than the current ''No energy use rating'' entry.

DOE understands these proposed corrections as improving the readability of the test procedures and expects that, if adopted, these corrections would not impact how refrigeration products are currently tested, or impact the test results as compared to the current test procedures.

J. Compliance Date and Waivers

1. Compliance Date

EPCA prescribes that all representations of energy efficiency and energy use, including those made on marketing materials and product labels, must be made in accordance with an amended test procedure, beginning 180 days after publication of such a test procedure final rule in the **Federal Register**. (42 U.S.C. 6293(c)(2)) As noted, should the amendments proposed in this document be made final, the updated test procedure provisions related to the icemaker fixed adder, and the associated amended energy conservation standards, would be required for use one year after publication of such a test procedure final rule in the **Federal Register**.

If DOE were to publish an amended test procedure for consumer refrigeration products, EPCA provides an allowance for individual manufacturers to petition DOE for an extension of the 180-day period if the manufacturer may experience undue hardship in meeting the deadline. (42 U.S.C. 6293(c)(3)) To receive such an extension, petitions must be filed with DOE no later than 60 days before the end of the 180-day period and must detail how the manufacturer will experience undue hardship. *Id.*

2. Waivers

Upon the compliance date of an amended test procedure, should DOE issue such an amendment, any waivers that had been previously issued and are in effect that pertain to issues addressed by the amended test procedure are terminated. 10 CFR 430.27(h)(2). Recipients of any such waivers would be required to test the products subject to the waiver according to the amended test procedure as of the effective date of the amended test procedure.

a. Waivers Relevant to the Proposed Amendments

DOE has granted a test procedure waiver to address testing multiple-compressor products that may not be able to meet all requirements included in Appendix A.[20] That waiver addressed models with non-uniform cycling that makes direct use of the Appendix A requirements for evaluating temperature stability problematic. In its April 2014 final rule, DOE incorporated provisions to address the testing of products with multiple compressors, which were intended to obviate the need for waivers for multiple-compressor products. 79 FR 22320, 22330 (April 21, 2014). However, in its petition for waiver, GE contended that due to certain characteristics of the basic models listed in the petition, the Appendix A test procedure does not allow for accurately measuring the energy consumption of these basic models. 80 FR 7851, 7852 (Feb. 12, 2015). In the notice granting the waiver, DOE determined that the specified models would not be able to reach the temperature stability conditions specified in Appendix A. *Id.* at 80 FR 7853. DOE has not received additional petitions for waiver on this issue. As discussed in section III.G.2 of this document, DOE is proposing amendments to Appendix A and Appendix B to address the issue in the GE waiver to limit the potential need for waivers for similar models that are unable to meet the current stability requirements in the test procedures. Should the proposed test procedure in this document be made final, GE's waiver would terminate on the compliance date of such a final rule and GE would be required to test the product that was the subject of its waiver according to the amended test procedure. DOE continues to request comment on potential amendments to Appendix A and Appendix B to address the issue of determining temperature stability for multiple-compressor products or other products with irregular compressor cycles.

DOE has also granted a waiver to allow for testing an all-refrigerator while connected to an upright freezer model that houses the controls for both cabinets.[21] As discussed in section III.F.3 of this document, Liebherr offers a product which relies on a companion upright freezer model for control. DOE granted a waiver for this model that requires the manufacturer to test and rate the all-refrigerator while connected to the upright freezer controls, but with the freezer located away from the refrigerator to avoid interfering with ambient airflow or other test conditions. 79 FR 19886 (April 10, 2014). As discussed in section III.F.3 of this document, DOE is proposing amendments to Appendix A and Appendix B that would eliminate the need for waivers to test products with separate external controls. Should the proposed test procedure in this document be made final, Liebherr's waiver would terminate on the compliance date of such a final rule and Liebherr would be required to test the product that was the subject of its waiver according to the amended test procedure. DOE continues to request comment on whether such amendments to Appendix A and Appendix B are appropriate.

b. MREF Waivers

At present, DOE has granted multiple waivers from the test procedures for consumer refrigeration products to address testing of products that currently are defined as refrigerators and combination cooler refrigeration products to determine compliance with the current consumer refrigerator, refrigerator-freezer, and freezer energy conservation standards.[22] As explained in the July 2016 Final Rule, prior to the compliance date of the MREF energy conservation standards, combination cooler refrigeration products are subject to the energy conservation standards for refrigerators, refrigerators, and freezers based on testing according to relevant test procedure waivers. *Id.* at 46771. As noted in the waivers,[23] upon the compliance date of the MREF energy conservation standards (October 28, 2019) those waivers will terminate. The issues addressed in these waivers, specifically the alternate correction factor used for testing to determine compliance with existing refrigerator, refrigerator-freezer, and freezer energy conservation standards, would not be affected by the amendments proposed in this NOPR.

K. Test Procedure Impacts and Other Topics

1. Test Procedure Costs and Impacts

EPCA requires that test procedures proposed by DOE not be unduly burdensome to conduct. In this NOPR, DOE proposes to amend the existing test procedures for consumer refrigeration products in Appendix A and Appendix B. In general, the proposed changes would update the referenced industry test procedure; define the term ''compartment;'' amend the fixed adder

[20] See case number RF–042.

[21] See case number RF–035.

[22] See case numbers RF–040, RF–041, RF–044, RF–045, and RF–047.

[23] See, 79 FR 55769 (Sep. 17, 2014); 82 FR 21209 (May 5, 2017); 82 FR 36386 (Aug. 4, 2017); 80 FR 7854 (Feb. 12, 2015); 82 FR 21211 (May 5, 2017); and 83 FR 11743 (March 16, 2018).

that accounts for automatic icemakers to better reflect consumer use; provide additional specificity for a number of test setup and test procedure requirements; combine the stabilization period with the test period for certain products; and add regulatory text inadvertently omitted in the previous test procedure rulemaking. DOE has tentatively determined that these proposed amendments would not be unduly burdensome for manufacturers to conduct and would reduce test burden for manufacturers.

DOE's analysis of this proposal indicates that, if finalized, it would result in net cost savings to manufacturers.

TABLE III.1—SUMMARY OF COST IMPACTS FOR CONSUMER REFRIGERATION PRODUCTS

Category	Present value (million 2016$)	Discount rate (percent)
Costs		
One-time re-testing and re-labeling costs	0.7 0.6	3 7
Cost Savings		
Reduction in future testing costs	35.6 24.3	3 7
Total Net Cost Impacts		
Total net cost impacts	(34.8) (23.6)	3 7

TABLE III.2—SUMMARY OF ANNUALIZED COST IMPACTS FOR CONSUMER REFRIGERATION PRODUCTS

Category	Annualized value (thousand 2016$)	Discount rate (percent)
Annualized Costs		
One-time re-testing and re-labeling costs	22 44	3 7
Annualized Cost Savings		
Reduction in Future Testing Costs	1,067 952	3 7
Total Net Annualized Cost Impact		
Total Net Cost Impact	(1,045) (907)	3 7

Further discussion of the cost impacts of the proposed test procedure amendments are presented in the following paragraphs.

a. Proposed Amendment Regarding the Stabilization and Test Periods

DOE proposes to combine the stabilization period with the test period for certain models of consumer refrigeration products. This proposal would decrease test burden by shortening the test duration for any model with stabilization determined according to sections 2.9(a) of Appendix A or 2.7(A) of Appendix B and with non-automatic defrost, or that would be tested to using the two-part test period. This amendment would apply to consumer refrigerators, refrigerator-freezers, freezers, and MREFs.

Based on review of the Compliance Certification Database in DOE's Compliance Certification Management System (CCMS), DOE has identified 3,641 models of consumer refrigerators, refrigerator-freezers, and freezers, representing 49 manufacturers, and 439 models of MREFs, representing 32 manufacturers, that would be impacted by this proposed amendment.

DOE expects that this proposal would decrease test duration by at least 6 hours for these models (reflecting the 3-hour minimum test period duration at two temperature settings) and up to 48 hours (reflecting 24-hour test periods at each setting). Based on an estimated decreased test duration of at least 6 hours (*i.e.,* a decrease in test time of greater than ten percent), DOE assumed a cost savings of approximately ten percent (*i.e.,* $500 per test).[24]

Additionally, based on data from DOE's Compliance Certification Database, DOE anticipates that manufacturers would replace or modify existing models every 3.5 years. Therefore, on average, consumer refrigerator, refrigerator-freezer, and freezer manufacturers would introduce approximately 1,040 new or modified consumer refrigerator, refrigerator-freezer, or freezer models each year that would use these shorter overall testing periods. While, on average, MREF manufacturers would introduce 125 new or modified consumer MREF models each year that would use these shorter overall testing periods. Because DOE requires manufacturers to test at least two units per model, manufacturers would on average conduct 2,330 tests annually

[24] DOE expects that costs would decrease by a smaller percentage than the total reduction in test time due to fixed overhead and labor requirements for testing (*i.e.,* test set up and data analysis would be unchanged). The total cost per test is based on FSI's comment stating between $4,500 and $5,000 per refrigerator test conducted at outside laboratories. (FSI, No. 6 at p. 1)

using these shorter overall testing periods. Using these estimates, DOE anticipates industry cost savings of approximately $1,040,000 per year for consumer refrigerator, refrigerator-freezer, or freezer manufacturers and approximately $125,000 per year for MREF manufacturers.

DOE has initially determined that this proposed amendment to the test procedures for consumer refrigeration products would not require changes to the designs of these products, and that the proposed amendments would not impact the utility or the availability of consumer refrigeration product options. DOE expects that the proposed amendments would not impact the representations of energy efficiency or energy use for consumer refrigeration products currently on the market. Manufacturers would be able to rely on data generated under the current test procedure, should the proposed amendments regarding stabilization and test period be finalized. As such, manufacturers would not be required to retest consumer refrigeration products as a result of DOE's adoption of the proposed amendment to the test procedure stabilization period.

DOE requests comment on its understanding of the impact and associated costs of this proposed stabilization and test period amendment.

b. Proposed Amendment Regarding Products With Demand-Response Capability

DOE proposes to remove the sections addressing products with demand-response capability from Appendix A and Appendix B. Under the proposed approach, the HRF–1–2016 requirement that customer accessible features not required for maintaining temperature be set at their lowest energy usage positions would apply to communication modules in demand-response capable products (with the ''off'' position as the lowest energy usage position). This proposal could increase test burden by requiring some models to be re-tested with communication modules in the off position and potentially re-labeled if the re-tested energy consumption value changes. This would be a one-time re-testing and re-labeling cost for manufacturers, as models introduced into the market after the test procedure proposal is required would not incur any additional costs.

Based on review of the ENERGY STAR Database, DOE has identified 83 models of refrigerators or refrigerator-freezers, representing 12 manufacturers, and 8 models of freezers, representing two manufacturers that would be impacted by this proposed amendment.

DOE conservatively estimates that all 91 models would be required to be re-tested with the communications models in the off position. Because DOE requires manufacturers to test at least two units per model, manufacturers would have to re-test 182 units to comply with this proposed test procedure amendment. DOE estimates a re-testing cost to manufacturers of $4,500 for a single unit.[25] Using these estimates, DOE anticipates industry could incur costs up to $819,000 re-testing products in the 180 days after this test procedure is finalized.

Additionally, manufacturers would have to re-label models if the re-tested energy consumption value changes. DOE estimates the average wage rate plus employer provided benefits for an employee to re-label models is $39.35 per hour.[26] DOE estimates that it would take an employee approximately one hour to re-label a single model. Given the conservative estimate of 91 models that could have their measured energy consumption changed after being re-tested with the communications in the off position, DOE estimates industry would incur costs of approximately $3,580 to re-label models in the 180 days after this test procedure is finalized.

DOE requests comment on its understanding of the impact and associated costs of the proposed amendment regarding products with demand-response capability.

c. Proposed Amendment Regarding Energy Use Associated With Automatic Icemaking

DOE is proposing to amend the automatic icemaker energy use adder in Appendix A and Appendix B and to amend the corresponding energy conservation standards for consumer refrigeration products with automatic icemakers (both amendments would reflect an energy use reduction of 56 kWh per year). This proposal would increase burden on manufacturers by requiring some models to be re-labeled with the updated annual energy consumption values.

Based on review of the Compliance Certification Database in DOE's Compliance Certification Management System (CCMS), DOE has identified 1,334 models with automatic icemakers, representing 28 manufacturers that could be impacted by this proposed amendment.

As discussed in the previous section, DOE estimates approximately one hour for an employee to re-label a consumer freezer with automatic icemakers based on the proposed updated energy consumption values. Using the average wage rate plus employer provided benefits for an employee to re-label models of $39.35 per hour, calculated in the previous section, DOE anticipates industry would incur costs of approximately $52,500 one year after this test procedure is finalized.

DOE requests comment on its understanding of the impact and associated costs of the proposed amendment regarding energy use associated with automatic icemaking.

d. Impact of the Other Proposed Amendments

DOE anticipates that the remainder of the amendments proposed in this NOPR would not impact manufacturers' test or certification costs. Most of the proposed amendments would provide additional specificity to the applicability and conduct of the test procedures.

DOE has initially determined that these other proposed amendments would not require changes to the designs of consumer refrigeration products, and that the proposed amendments would not impact the utility or availability of these products. The other proposed amendments would not impact the representations of energy efficiency or energy use of consumer refrigeration products. As a result, manufacturers would be able to rely on data generated under the current test procedure, should the proposed amendments be finalized. Manufacturers would not be required to retest consumer refrigeration products as a result of DOE's adoption of the other proposed amendments to the test procedure.

DOE requests comment on its understanding of the impact and associated potential costs of these proposed amendments.

2. Harmonization With Industry Standards

The test procedures for consumer refrigeration products at Appendix A and Appendix B incorporate by

[25] Based on the initial $5,000 testing cost estimate and the $500 savings due to the stabilization criteria proposed in this amended test procedure proposal. DOE estimates that the stabilization period time savings would apply to all demand-response capable products.

[26] The Bureau of Labor Statistics mean hourly wage rate for ''Mechanical Engineering Technicians'' is $28.00. (May 2018; *https://www.bls.gov/oes/current/oes173027.htm*).

Additionally, according to the 2016 Annual Survey of Manufacturers for NAICS code 33522, major appliance manufacturing, wages represent approximately 71 percent of the total cost of employment for an employer.

(AMS 2016, NAICS code 33522; *https://www.census.gov/programs-surveys/asm.html*.)

reference the AHAM industry standard HRF–1–2008. DOE references HRF–1–2008 for definitions, installation and operating conditions, temperature measurements, and volume measurements. In August 2016, AHAM released an updated version of the HRF–1 standard, HRF–1–2016, which DOE is evaluating as part of this rulemaking. As noted in comments from interested parties, the updates included in HRF–1–2016 harmonize with the current DOE test procedure. This includes updates to definitions, test requirements, formatting, and organization that are consistent with DOE's requirements.

DOE requests comments on the benefits and burdens of the proposed updates and additions to industry standards referenced in the test procedure for consumer refrigeration products.

DOE also requests comment on the benefits and burdens of adopting any industry/voluntary consensus-based or other appropriate test procedure, without modification.

DOE notes that it is also aware of other international standards for testing consumer refrigeration products. AS/NZS 4474.1:2007 and Standard 62552:2007 (as well as a newer 2015 version) are used as test standards for international efficiency programs. These tests follow a similar methodology to the DOE and AHAM HRF–1 procedures—a closed door test in elevated ambient temperatures. However, the international standards vary from the DOE test by specifying different standardized compartment temperatures, ambient temperatures, and test periods. DOE has carefully considered these requirements when developing its existing test procedures and expects that its procedures, with HRF–1 incorporated by reference, result in energy use ratings that are the most representative of consumer use in the United States, while limiting test burden.

3. Other Test Procedure Topics

In addition to the issues identified earlier in this document, DOE welcomes comment on any other aspect of the existing test procedures for consumer refrigeration products not already addressed by the specific areas identified in this document. DOE particularly seeks information that would ensure that the test procedure measures energy efficiency during a representative average use cycle or period of use, as well as information that would help DOE create a procedure that would limit manufacturer test burden. Comments regarding repeatability and reproducibility are also welcome.

In particular, DOE notes that under Executive Order 13771, ''Reducing Regulation and Controlling Regulatory Costs,'' Executive Branch agencies such as DOE must manage the costs associated with the imposition of expenditures required to comply with Federal regulations. See 82 FR 9339 (Feb. 3, 2017). Consistent with that Executive Order, DOE encourages the public to provide input on measures DOE could take to lower the cost of its regulations applicable to consumer refrigeration products consistent with the requirements of EPCA.

IV. Procedural Issues and Regulatory Review

A. Review Under Executive Order 12866

The Administrator of the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB) has determined that the proposed regulatory action is a significant regulatory action under section (3)(f) of Executive Order 12866. Accordingly, this action was reviewed by OIRA in the Office of Management and Budget (OMB).

B. Review Under Executive Orders 13771 and 13777

On January 30, 2017, the President issued Executive Order (E.O.) 13771, ''Reducing Regulation and Controlling Regulatory Costs.'' E.O. 13771 stated the policy of the executive branch is to be prudent and financially responsible in the expenditure of funds, from both public and private sources. E.O. 13771 stated it is essential to manage the costs associated with the governmental imposition of private expenditures required to comply with Federal regulations.

Additionally, on February 24, 2017, the President issued E.O. 13777, ''Enforcing the Regulatory Reform Agenda.'' E.O. 13777 required the head of each agency designate an agency official as its Regulatory Reform Officer (RRO). Each RRO oversees the implementation of regulatory reform initiatives and policies to ensure that agencies effectively carry out regulatory reforms, consistent with applicable law. Further, E.O. 13777 requires the establishment of a regulatory task force at each agency. The regulatory task force is required to make recommendations to the agency head regarding the repeal, replacement, or modification of existing regulations, consistent with applicable law. At a minimum, each regulatory reform task force must attempt to identify regulations that:

(i) Eliminate jobs, or inhibit job creation;

(ii) Are outdated, unnecessary, or ineffective;

(iii) Impose costs that exceed benefits;

(iv) Create a serious inconsistency or otherwise interfere with regulatory reform initiatives and policies;

(v) Are inconsistent with the requirements of Information Quality Act, or the guidance issued pursuant to that Act, in particular those regulations that rely in whole or in part on data, information, or methods that are not publicly available or that are insufficiently transparent to meet the standard for reproducibility; or

(vi) Derive from or implement Executive Orders or other Presidential directives that have been subsequently rescinded or substantially modified.

DOE initially concludes that this rulemaking is consistent with the directives set forth in these executive orders. This proposed rule is estimated to result in a cost savings. The proposed rule would yield an annualized cost savings of approximately $907,000 (2016$) using a perpetual time horizon discounted to 2016 at a 7 percent discount rate. Therefore, if finalized as proposed, this rule is expected to be an E.O. 13771 deregulatory action.

C. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires preparation of an initial regulatory flexibility analysis (IRFA) for any rule that by law must be proposed for public comment, unless the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. As required by Executive Order 13272, ''Proper Consideration of Small Entities in Agency Rulemaking,'' 67 FR 53461 (Aug. 16, 2002), DOE published procedures and policies on February 19, 2003, to ensure that the potential impacts of its rules on small entities are properly considered during the DOE rulemaking process. 68 FR 7990. DOE has made its procedures and policies available on the Office of the General Counsel's website: *http://energy.gov/gc/office-general-counsel.*

DOE reviewed this proposed rule to amend the test procedures for consumer refrigeration products under the provisions of the Regulatory Flexibility Act and the procedures and policies published on February 19, 2003. This NOPR proposes to amend DOE's consumer refrigeration products test procedure to include a compartment definition; incorporate by reference AHAM HRF–1–2016; revise the energy-

use adder for automatic icemakers; provide further specification on test setup, conduct, and calculations; require that the stabilization period be used as the test period for certain products; and correct minor issues in Appendix A and Appendix B.

DOE uses the Small Business Administration's (''SBA'') small business size standards to determine whether manufacturers qualify as small businesses, which are listed by the North American Industry Classification System (''NAICS'').[27] The SBA considers a business entity to be a small business, if, together with its affiliates, it employs less than a threshold number of workers specified in 13 CFR part 121. The 2017 NAICS code for consumer refrigeration products is 335220, major household appliance manufacturing.[28] The threshold number for NAICS code 335220 is 1,500 employees. This employee threshold includes all employees in a business's parent company and any other subsidiaries.

Most of the manufacturers supplying consumer refrigeration products are large multinational corporations. DOE conducted a focused inquiry into small business manufacturers of products covered by this rulemaking. DOE primarily used DOE's Compliance Certification Database [29] for consumer refrigerators, refrigerator-freezers, and freezers to create a list of companies that sell consumer refrigeration products covered by this rulemaking in the United States. DOE identified a total of 67 distinct companies that sell consumer refrigeration products in the United States.

DOE then reviewed these companies to determine whether the entities met the SBA's definition of ''small business'' and screened out any companies that do not offer products covered by this rulemaking, do not meet the definition of a ''small business,'' or are foreign-owned and operated. Based on this review, DOE has identified eight domestic manufacturers of consumer refrigeration products that are potential small businesses. Through this analysis, DOE has determined the expected effects of this rulemaking on these covered small businesses and whether an IRFA was needed (*i.e.,* whether DOE could certify that this rulemaking would not have a significant impact).

DOE is proposing to combine the stabilization period with the test period for certain products. DOE expects that this proposal would decrease test duration by at least 6 hours for these models (reflecting the 3-hour minimum test period duration at two temperature settings) and up to 48 hours (reflecting 24-hour test periods at each setting). DOE estimates that this would translate to a cost savings of $500 per test for these models (an estimated 10 percent of total testing costs). Based on review of the Compliance Certification Database in DOE's CCMS, DOE has identified 312 models affected by the proposed amendment of the stabilization period, representing seven small domestic manufacturers. Additionally, based on data from DOE's Compliance Certification Database, DOE anticipates that small domestic manufacturers would replace or modify existing models every 3.5 years; therefore, on average, small domestic manufacturers would introduce approximately 89 new or modified models each year that would use these shorter overall testing periods. Because DOE requires manufacturers to test at least two units per model, small manufacturers would on average conduct 178 tests annually using these shorter overall testing periods. Using these estimates, DOE anticipates the proposed stabilization amendment would save small domestic manufacturers approximately $89,000 per year. Therefore, DOE determined that this proposed amendment to the test procedure would lead to cost savings for small domestic manufacturers.

FSI commented in response to the June 2017 RFI that, on average, they pay between $4,500 and $5,000 per refrigerator test conducted at outside laboratories. FSI further stated that test costs can be reduced and procedures simplified by allowing the use of manufacturers' stated volumes (from computer-aided design (''CAD'') or other accurate drawings and calculations) instead of requiring a measurement for each test. FSI noted that this approach is likely to be more accurate than manual measurements, referencing a NIST study identifying as high as a 40-percent discrepancy between laboratories measuring volume in compact refrigerators. To minimize test cost and burden, FSI recommended: Accepting manufacturer volume calculations, accepting a wider range of temperatures (*e.g.,* 40 or 41 °F in the fresh food compartment for dual zone units), and allowing more simplified and flexible probe locations. (FSI, No. 6 at pp. 1, 3)

DOE is not proposing any amendments to the test procedures for consumer refrigeration products that would increase the cost of these tests at third-party or manufacturer test laboratories. DOE understands that relying on CAD to calculate volumes decreases test burden compared to physically measuring volume on each test unit. Accordingly, DOE already allows manufacturers to use such designs in certifying product volumes. In 10 CFR 429.72, DOE states that total refrigerated volume of a basic model may be determined by performing a calculation of the volume based upon CAD models of the basic model in lieu of physical measurements of a production unit of the basic model, according to the applicable provisions in the test procedures for measuring volume. DOE is not proposing amendments to allow different ranges for standardized compartment temperatures nor to allow for multiple thermocouple locations during testing (except for when the standardized locations cannot be followed). These test requirements ensure that test results are comparable between models and between test facilities. The requirements also limit variability by ensuring that the test is conducted consistently for a given model. Therefore, DOE is proposing to maintain the existing standardized compartment temperatures and thermocouple locations.

FSI further commented that DOE's test procedures impose a significant burden on businesses. For small businesses, FSI stated that staff time for testing is not available for innovating, designing, or researching, and that the complexity of the test procedure makes it unlikely that anyone with less than an engineering degree or equivalent would be able to read, interpret, and implement the testing and reporting. FSI commented that testing to understand uncertainty regarding repeatability and reproducibility is worthwhile to better understand the limitations of the test procedure, but it is unaware of results of any such testing. FSI noted that the NIST study for volume measurements showed significant differences between laboratories and would argue that the test procedures are too complex. For a small business, FSI commented that the burden is magnified by smaller available resources and a smaller base of sales. (FSI, No. 6 at pp. 2–3)

As stated earlier in this section, DOE is not proposing any amendments to the test procedures for consumer refrigeration products that would increase the cost of these tests at third-

[27] Available online at: *https://www.sba.gov/document/support-table-size-standards.*

[28] The NAICS Association updated its industry classification codes in early 2017. The previous 2012 NAICS code for consumer refrigerators, refrigerator-freezers, and freezers was 335222, household refrigerator and home freezer manufacturing.

[29] *www.regulations.doe.gov/certification-data.* Accessed October 5, 2018.

party or manufacturer test laboratories. Similarly, none of the proposed amendments would increase the test procedure complexity beyond the current level. DOE requests feedback on how the test procedure may be simplified to further reduce the burden associated with manufacturer testing.

The proposed test procedure amendments could increase burden on small businesses either due to potential re-testing of products with demand response capabilities and/or re-labeling of products with automatic icemakers. DOE was not able to identify any small businesses that manufacture products with demand response capabilities.[30] Based on review of the Compliance Certification Database in DOE's CCMS, DOE has identified 109 models of consumer refrigerators, refrigerator-freezers, and freezers, representing four small businesses, that manufacture products with automatic icemakers. Using these estimates, DOE estimates that the four small businesses manufacturing products with automatic icemakers would incur a one-time re-labeling cost of approximately $4,290, or approximately $1,072 per small business.

As previously discussed, DOE expects that the proposed merging of the stabilization and test periods for certain models would decrease manufacturer test burden for small businesses, by approximately $89,000 per year. Overall, DOE estimates that the proposed amendments for small businesses would translate to a cost savings of approximately $84,700 in the year small businesses must re-label products with automatic icemakers and then cost savings of approximately $89,000 each year after.

Therefore, DOE concludes that the impacts of the proposed test procedure amendments in this NOPR would not have a ''significant economic impact on a substantial number of small entities,'' and that the preparation of an IRFA is not warranted. DOE will transmit the certification and supporting statement of factual basis to the Chief Counsel for Advocacy of the Small Business Administration for review under 5 U.S.C. 605(b).

DOE seeks comment on its initial finding that eight small businesses manufacture consumer refrigeration products in the United States with fewer than 1,500 total employees. Additionally, DOE requests comment on its determination that the proposed amendments would not have a significant economic impact on these small businesses.

D. Review Under the Paperwork Reduction Act of 1995

Manufacturers of consumer refrigeration products must certify to DOE that their products comply with any applicable energy conservation standards. To certify compliance, manufacturers must first obtain test data for their products according to the DOE test procedures, including any amendments adopted for those test procedures. DOE has established regulations for the certification and recordkeeping requirements for all covered consumer products and commercial equipment, including consumer refrigeration products. (See generally 10 CFR part 429.) The collection-of-information requirement for the certification and recordkeeping is subject to review and approval by OMB under the Paperwork Reduction Act (''PRA''). This requirement has been approved by OMB under OMB control number 1910–1400. Public reporting burden for the certification is estimated to average 35 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB Control Number.

E. Review Under the National Environmental Policy Act of 1969

DOE is analyzing this proposed regulation in accordance with the National Environmental Policy Act of 1969 (NEPA) and DOE's NEPA implementing regulations (10 CFR part 1021). DOE's regulations include a categorical exclusion for rulemakings interpreting or amending an existing rule or regulation that does not change the environmental effect of the rule or regulation being amended. 10 CFR part 1021, subpart D, Appendix A5. DOE anticipates that this rulemaking qualifies for categorical exclusion A5 because it is an interpretive rulemaking that does not change the environmental effect of the rule and otherwise meets the requirements for application of a categorical exclusion. See 10 CFR 1021.410. DOE will complete its NEPA review before issuing the final rule.

F. Review Under Executive Order 13132

Executive Order 13132, ''Federalism,'' 64 FR 43255 (Aug. 4, 1999) imposes certain requirements on agencies formulating and implementing policies or regulations that preempt State law or that have Federalism implications. The Executive Order requires agencies to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and to carefully assess the necessity for such actions. The Executive Order also requires agencies to have an accountable process to ensure meaningful and timely input by State and local officials in the development of regulatory policies that have Federalism implications. On March 14, 2000, DOE published a statement of policy describing the intergovernmental consultation process it will follow in the development of such regulations. 65 FR 13735. DOE has examined this proposed rule and has determined that it 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. EPCA governs and prescribes Federal preemption of State regulations as to energy conservation for the products that are the subject of this proposed rule. States can petition DOE for exemption from such preemption to the extent, and based on criteria, set forth in EPCA. (42 U.S.C. 6297(d)) No further action is required by Executive Order 13132.

G. Review Under Executive Order 12988

Regarding the review of existing regulations and the promulgation of new regulations, section 3(a) of Executive Order 12988, ''Civil Justice Reform,'' 61 FR 4729 (Feb. 7, 1996), imposes on Federal agencies the general duty to adhere to the following requirements: (1) Eliminate drafting errors and ambiguity, (2) write regulations to minimize litigation, (3) provide a clear legal standard for affected conduct rather than a general standard, and (4) promote simplification and burden reduction. Section 3(b) of Executive Order 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) Clearly specifies the preemptive effect, if any, (2) clearly specifies any effect on existing Federal law or regulation, (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction, (4) specifies the retroactive effect, if any, (5) adequately

[30] Based on DOE's search of the ENERGY STAR database.

defines key terms, and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires Executive agencies to review regulations in light of applicable standards in sections 3(a) and 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. DOE has completed the required review and determined that, to the extent permitted by law, the proposed rule meets the relevant standards of Executive Order 12988.

H. Review Under the Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (''UMRA'') requires each Federal agency to assess the effects of Federal regulatory actions on State, local, and Tribal governments and the private sector. Public Law 104–4, sec. 201 (codified at 2 U.S.C. 1531). For a proposed regulatory action likely to result in a rule that may cause the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector of $100 million or more in any one year (adjusted annually for inflation), section 202 of UMRA requires a Federal agency to publish a written statement that estimates the resulting costs, benefits, and other effects on the national economy. (2 U.S.C. 1532(a), (b)) The UMRA also requires a Federal agency to develop an effective process to permit timely input by elected officers of State, local, and Tribal governments on a proposed ''significant intergovernmental mandate,'' and requires an agency plan for giving notice and opportunity for timely input to potentially affected small governments before establishing any requirements that might significantly or uniquely affect small governments. On March 18, 1997, DOE published a statement of policy on its process for intergovernmental consultation under UMRA. 62 FR 12820; also available at *http://energy.gov/gc/office-general-counsel.* DOE examined this proposed rule according to UMRA and its statement of policy and determined that the rule contains neither an intergovernmental mandate, nor a mandate that may result in the expenditure of $100 million or more in any year, so these requirements do not apply.

I. Review Under the Treasury and General Government Appropriations Act, 1999

Section 654 of the Treasury and General Government Appropriations Act, 1999 (Public Law 105–277) requires Federal agencies to issue a Family Policymaking Assessment for any rule that may affect family well-being. This rule would not have any impact on the autonomy or integrity of the family as an institution. Accordingly, DOE has concluded that it is not necessary to prepare a Family Policymaking Assessment.

J. Review Under Executive Order 12630

DOE has determined, under Executive Order 12630, ''Governmental Actions and Interference with Constitutionally Protected Property Rights'' 53 FR 8859 (March 18, 1988), that this regulation would not result in any takings that might require compensation under the Fifth Amendment to the U.S. Constitution.

K. Review Under Treasury and General Government Appropriations Act, 2001

Section 515 of the Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516 note) provides for agencies to review most disseminations of information to the public under guidelines established by each agency pursuant to general guidelines issued by OMB. OMB's guidelines were published at 67 FR 8452 (Feb. 22, 2002), and DOE's guidelines were published at 67 FR 62446 (Oct. 7, 2002). DOE has reviewed this proposed rule under the OMB and DOE guidelines and has concluded that it is consistent with applicable policies in those guidelines.

L. Review Under Executive Order 13211

Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use,'' 66 FR 28355 (May 22, 2001), requires Federal agencies to prepare and submit to OMB, a Statement of Energy Effects for any proposed significant energy action. A ''significant energy action'' is defined as any action by an agency that promulgated or is expected to lead to promulgation of a final rule, and that (1) is a significant regulatory action under Executive Order 12866, or any successor order; and (2) is likely to have a significant adverse effect on the supply, distribution, or use of energy; or (3) is designated by the Administrator of OIRA as a significant energy action. For any proposed significant energy action, the agency must give a detailed statement of any adverse effects on energy supply, distribution, or use should the proposal be implemented, and of reasonable alternatives to the action and their expected benefits on energy supply, distribution, and use.

The proposed regulatory action would not have a significant adverse effect on the supply, distribution, or use of energy, nor has it been designated as a significant energy action by the Administrator of OIRA. Therefore, it is not a significant energy action, and, accordingly, DOE has not prepared a Statement of Energy Effects.

M. Review Under Section 32 of the Federal Energy Administration Act of 1974

Under section 301 of the Department of Energy Organization Act (Pub. L. 95–91; 42 U.S.C. 7101), DOE must comply with section 32 of the Federal Energy Administration Act of 1974, as amended by the Federal Energy Administration Authorization Act of 1977. (15 U.S.C. 788; FEAA) Section 32 essentially provides in relevant part that, where a proposed rule authorizes or requires use of commercial standards, the notice of proposed rulemaking must inform the public of the use and background of such standards. In addition, section 32(c) requires DOE to consult with the Attorney General and the Chairman of the Federal Trade Commission (''FTC'') concerning the impact of the commercial or industry standards on competition.

The proposed amendments to the test procedures for consumer refrigeration products incorporate testing methods contained in certain sections of the following commercial standard: AHAM Standard HRF–1–2016, ''Energy and Internal Volume of Refrigerating Appliances,'' including Errata to Energy and Internal Volume of Refrigerating Appliances, Correction Sheet issued August 3, 2016. DOE has evaluated this standard and is unable to conclude whether it fully complies with the requirements of section 32(b) of the FEAA, (*i.e.,* that they were developed in a manner that fully provides for public participation, comment, and review). DOE will consult with the Attorney General and the Chairman of the FTC concerning the impact of this test procedure on competition, prior to prescribing a final rule.

N. Description of Materials Incorporated by Reference

In this NOPR, DOE proposes to incorporate by reference the test standard published by AHAM, titled ''Energy and Internal Volume of Refrigerating Appliances,'' HRF–1–2016, including Errata to Energy and Internal Volume of Refrigerating Appliances, Correction Sheet issued August 3, 2016. HRF–1–2016 is an industry standard used to evaluate energy use and refrigerated volume for

consumer refrigeration products. Specifically, the test procedures proposed in this NOPR would reference: (i) Section 3–Definitions; (ii) Section 4–Method for Computing Refrigerated Volume of Refrigerators, Refrigerator-Freezers, Wine Chillers, and Freezers; Section 4.2–Total volume; Section 4.3–Legend for Figures 4–1 through 4–3; Figure 4–2; and Figure 4–3; and (iii) Section 5–Method for Determining the Energy Consumption of Refrigerators, Refrigerator-Freezers, Wine Chillers, and Freezers; Section 5.3.2–Ambient Relative Humidity through Section 5.5.6.4–Freezer Compartment Temperature (Automatic Defrost Freezer); Figure 5–1; and Figure 5–2.

Copies of HRF–1–2016 may be purchased from the Association of Home Appliance Manufacturers at 1111 19th Street NW, Suite 402, Washington, DC 20036, (202) 872–5955, or by going to *http://www.aham.org/.*

The incorporation by reference of AS/NZS 4474.1:2007 in appendix A to subpart B of part 430 has already been approved by the Director of the **Federal Register** and there are no proposed changes in this NOPR.

V. Public Participation

A. Attendance at Public Meeting

The time, date and location of the public meeting are listed in the **DATES** and **ADDRESSES** sections at the beginning of this document. If you plan to attend the public meeting, please notify the Appliance and Equipment Standards Program staff at (202) 287–1445 or by email: *Appliance_Standards_Public_Meetings@ee.doe.gov.*

Please note that foreign nationals visiting DOE Headquarters are subject to advance security screening procedures which require advance notice prior to attendance at the public meeting. If a foreign national wishes to participate in the public meeting, please inform DOE of this fact as soon as possible by contacting Ms. Regina Washington at (202) 586–1214 or by email: *Regina.Washington@ee.doe.gov* so that the necessary procedures can be completed.

DOE requires visitors to have laptops and other devices, such as tablets, checked upon entry into the building. Any person wishing to bring these devices into the Forrestal Building will be required to obtain a property pass. Visitors should avoid bringing these devices, or allow an extra 45 minutes to check in. Please report to the visitor's desk to have devices checked before proceeding through security.

Due to the REAL ID Act implemented by the Department of Homeland Security (DHS), there have been recent changes regarding ID requirements for individuals wishing to enter Federal buildings from specific states and U.S. territories. DHS maintains an updated website identifying the State and territory driver's licenses that currently are acceptable for entry into DOE facilities at *https://www.dhs.gov/real-id-enforcement-brief.* Acceptable alternate forms of Photo-ID include a U.S. Passport or Passport Card; an Enhanced Driver's License or Enhanced ID-Card issued by States and territories identified on the DHS website (Enhanced licenses issued by these states are clearly marked Enhanced or Enhanced Driver's License); a military ID; or other Federal government issued Photo-ID card.

In addition, you can attend the public meeting via webinar. Webinar registration information, participant instructions, and information about the capabilities available to webinar participants will be published on DOE's website: *https://www1.eere.energy.gov/buildings/appliance_standards/standards.aspx?productid=37&action=viewlive.* Participants are responsible for ensuring their systems are compatible with the webinar software.

B. Procedure for Submitting Prepared General Statements for Distribution

Any person who has plans to present a prepared general statement may request that copies of his or her statement be made available at the public meeting. Such persons may submit requests, along with an advance electronic copy of their statement in PDF (preferred), Microsoft Word or Excel, WordPerfect, or text (ASCII) file format, to the appropriate address shown in the **ADDRESSES** section at the beginning of this document. The request and advance copy of statements must be received at least one week before the public meeting and may be emailed, hand-delivered, or sent by mail. DOE prefers to receive requests and advance copies via email. Please include a telephone number to enable DOE staff to make a follow-up contact, if needed.

C. Conduct of Public Meeting

DOE will designate a DOE official to preside at the public meeting and may also use a professional facilitator to aid discussion. The meeting will not be a judicial or evidentiary-type public hearing, but DOE will conduct it in accordance with section 336 of EPCA (42 U.S.C. 6306). A court reporter will be present to record the proceedings and prepare a transcript. DOE reserves the right to schedule the order of presentations and to establish the procedures governing the conduct of the public meeting. After the public meeting and until the end of the comment period, interested parties may submit further comments on the proceedings and any aspect of the rulemaking.

The public meeting will be conducted in an informal, conference style. DOE will present summaries of comments received before the public meeting, allow time for prepared general statements by participants, and encourage all interested parties to share their views on issues affecting this rulemaking. Each participant will be allowed to make a general statement (within time limits determined by DOE), before the discussion of specific topics. DOE will permit, as time permits, other participants to comment briefly on any general statements.

At the end of all prepared statements on a topic, DOE will permit participants to clarify their statements briefly and comment on statements made by others. Participants should be prepared to answer questions by DOE and by other participants concerning these issues. DOE representatives may also ask questions of participants concerning other matters relevant to this rulemaking. The official conducting the public meeting will accept additional comments or questions from those attending, as time permits. The presiding official will announce any further procedural rules or modification of the above procedures that may be needed for the proper conduct of the public meeting.

A transcript of the public meeting will be included in the docket, which can be viewed as described in the *Docket* section at the beginning of this document. In addition, any person may buy a copy of the transcript from the transcribing reporter.

D. Submission of Comments

DOE will accept comments, data, and information regarding this proposed rule no later than the date provided in the **DATES** section at the beginning of this proposed rule. Interested parties may submit comments using any of the methods described in the **ADDRESSES** section at the beginning of this proposed rule.

Submitting comments via *http://www.regulations.gov.* The *http://www.regulations.gov* web page will require you to provide your name and contact information. Your contact information will be viewable to DOE Building Technologies staff only. Your contact information will not be publicly viewable except for your first and last names, organization name (if any), and submitter representative name (if any).

If your comment is not processed properly because of technical difficulties, DOE will use this information to contact you. If DOE cannot read your comment due to technical difficulties and cannot contact you for clarification, DOE may not be able to consider your comment.

However, your contact information will be publicly viewable if you include it in the comment or in any documents attached to your comment. Any information that you do not want to be publicly viewable should not be included in your comment, nor in any document attached to your comment. Persons viewing comments will see only first and last names, organization names, correspondence containing comments, and any documents submitted with the comments.

Do not submit to *http://www.regulations.gov* information for which disclosure is restricted by statute, such as trade secrets and commercial or financial information (hereinafter referred to as Confidential Business Information (CBI)). Comments submitted through *http://www.regulations.gov* cannot be claimed as CBI. Comments received through the website will waive any CBI claims for the information submitted. For information on submitting CBI, see the Confidential Business Information section.

DOE processes submissions made through *http://www.regulations.gov* before posting. Normally, comments will be posted within a few days of being submitted. However, if large volumes of comments are being processed simultaneously, your comment may not be viewable for up to several weeks. Please keep the comment tracking number that *http://www.regulations.gov* provides after you have successfully uploaded your comment.

Submitting comments via email, hand delivery, or postal mail. Comments and documents submitted via email, hand delivery, or mail also will be posted to *http://www.regulations.gov.* If you do not want your personal contact information to be publicly viewable, do not include it in your comment or any accompanying documents. Instead, provide your contact information on a cover letter. Include your first and last names, email address, telephone number, and optional mailing address. The cover letter will not be publicly viewable as long as it does not include any comments.

Include contact information each time you submit comments, data, documents, and other information to DOE. If you submit via mail or hand delivery, please provide all items on a CD, if feasible. It is not necessary to submit printed copies. No facsimiles (faxes) will be accepted.

Comments, data, and other information submitted to DOE electronically should be provided in PDF (preferred), Microsoft Word or Excel, WordPerfect, or text (ASCII) file format. Provide documents that are not secured, written in English and free of any defects or viruses. Documents should not contain special characters or any form of encryption and, if possible, they should carry the electronic signature of the author.

Campaign form letters. Please submit campaign form letters by the originating organization in batches of between 50 to 500 form letters per PDF or as one form letter with a list of supporters' names compiled into one or more PDFs. This reduces comment processing and posting time.

Confidential Business Information. According to 10 CFR 1004.11, any person submitting information that he or she believes to be confidential and exempt by law from public disclosure should submit via email, postal mail, or hand delivery two well-marked copies: one copy of the document marked confidential including all the information believed to be confidential, and one copy of the document marked ''non-confidential'' with the information believed to be confidential deleted. Submit these documents via email or on a CD, if feasible. DOE will make its own determination about the confidential status of the information and treat it according to its determination.

Factors of interest to DOE when evaluating requests to treat submitted information as confidential include (1) a description of the items, (2) whether and why such items are customarily treated as confidential within the industry, (3) whether the information is generally known by or available from other sources, (4) whether the information has previously been made available to others without obligation concerning its confidentiality, (5) an explanation of the competitive injury to the submitting person which would result from public disclosure, (6) when such information might lose its confidential character due to the passage of time, and (7) why disclosure of the information would be contrary to the public interest.

It is DOE's policy that all comments may be included in the public docket, without change and as received, including any personal information provided in the comments (except information deemed to be exempt from public disclosure).

E. Issues on Which DOE Seeks Comment

Although DOE welcomes comments on any aspect of this proposal, DOE is particularly interested in receiving comments and views of interested parties concerning the following issues:

1. The proposed definition for ''compartment'' and whether any further clarifying amendments are needed for the use of the term ''compartment.'' (See section III.B.2 of this document.)

2. The proposal to update the industry standard reference to HRF–1–2016, and whether the updated reference would substantively impact any test requirements. (See section III.C of this document.)

3. The proposal to change the current icemaker fixed adder from 84 kWh per year to 28 kWh per year to better reflect typical residential ice making and consumption, and whether this adder is appropriate for products incorporating multiple icemakers. (See section III.D of this document.)

4. The proposal to amend the energy conservation standards for consumer refrigeration products with automatic icemakers in accordance with 42 U.S.C. 6293(e), including the proposed one-year lead-time period. (See section III.D of this document.)

5. The proposal to maintain the freestanding test approach for built-in products. (See section III.E of this document.)

6. The proposed clarification to the thermocouple configuration for drawer freezer compartments. (See section III.F.1 of this document.)

7. The proposal to clarify that floors with holes or vents for airflow be subject to the existing platform requirements. (See section III.F.2 of this document.)

8. The proposed instructions for testing products with separate external temperature controls. (See section III.F.3 of this document.)

9. The proposed revisions to the vertical gradient and stabilization test conditions, including the proposed requirement that, in certain test situations, the stabilization period serve as the test period. (See section III.G of this document.)

10. Whether additional test procedures amendments are necessary to accurately reflect energy use of products with door-in-door designs, products that incorporate display screens, or products with connected functions. (See section III.H of this document.)

11. Whether additional test procedure amendments may be appropriate to address issues identified in existing test procedure waivers. (See section III.J.2 of this document.)

12. The testing cost impacts and manufacturer burden associated with the test procedure amendments described in this document, including, but not limited to, the proposed stabilization and test period amendment, the proposed amendment regarding products with demand-response capabilities, and the proposed amendment regarding the automatic icemaker energy adder. (See section III.K.1 of this document.)

13. The benefits and burdens of adopting any industry/voluntary consensus-based or other appropriate test procedure, without modification. (See section III.K.2 of this document.)

14. Any other aspect of the existing test procedure for consumer refrigeration products not already addressed by the specific areas identified in this document. DOE particularly seeks information that would improve the representativeness of the test procedure, as well as information that would help DOE create a procedure that would limit manufacturer test burden. Comments regarding repeatability and reproducibility are also welcome. (See section III.K.3 of this document.)

15. Information that would help DOE create procedures that would limit manufacturer test burden through streamlining or simplifying testing requirements. Consistent with Executive Order 13771 ''Reducing Regulation and Controlling Regulatory Costs,'' DOE encourages the public to provide input on measures DOE could take to lower the cost of its regulations applicable to consumer refrigeration products consistent with the requirements of EPCA. (See section III.K.3 of this document.)

16. The initial finding that there are eight small businesses manufacturing consumer refrigeration products in the United States with fewer than 1,500 total employees and that the proposed amendments would not have a significant economic impact on these small businesses. (See section IV.C of this document.)

VI. Approval of the Office of the Secretary

The Secretary of Energy has approved publication of this proposed rule.

List of Subjects in 10 CFR Part 430

Administrative practice and procedure, Confidential business information, Energy conservation, Household appliances, Imports, Incorporation by reference, Intergovernmental relations, Small businesses.

Signed in Washington, DC, on November 18, 2019.

Alexander Fitzsimmons,

Acting Deputy Assistant Secretary for Energy Efficiency, Energy Efficiency and Renewable Energy.

For the reasons stated in the preamble, DOE is proposing to amend part 430 of Chapter II of Title 10, Code of Federal Regulations as set forth below:

PART 430—ENERGY CONSERVATION PROGRAM FOR CONSUMER PRODUCTS

■ 1. The authority citation for part 430 continues to read as follows:

Authority: 42 U.S.C. 6291–6309; 28 U.S.C. 2461 note.

■ 2. In § 430.3 revise paragraph (i)(4) to read as follows:

§ 430.3 Materials incorporated by reference.

* * * * *

(i) * * *

(4) AHAM HRF–1–2016, (''HRF–1–2016''), *Energy and Internal Volume of Refrigerating Appliances* (January 1, 2016), including *Errata to Energy and Internal Volume of Refrigerating Appliances, Correction Sheet* (August 3, 2016), IBR approved for appendices A and B to subpart B of this part.

* * * * *

■ 3. Appendix A to subpart B of part 430 is amended by:

■ a. Revising the introductory note and sections 1, 2.1.2, 2.1.3, 2.2, 2.6, 2.7, 2.9, 3.2.1.1, 3.2.1.2, 3.2.1.3, 3.2.3, 4.1, 4.2.1, 4.2.1.1, 4.2.3.4.2, 5.1, 5.1.3, 5.1.4, 5.1.5, 5.3, and 6.2.3.1;

■ b. Removing section 2.10; and

■ c. Adding new sections 0, 2.10, and 6.2.3.3.

The additions and revisions read as follows:

Appendix A to Subpart B of Part 430—Uniform Test Method for Measuring the Energy Consumption of Refrigerators, Refrigerator-Freezers, and Miscellaneous Refrigeration Products

Note: Prior to [DATE 180 DAYS AFTER DATE OF PUBLICATION OF THE FINAL RULE], any representations of energy use of consumer refrigeration products must be based on the results of testing pursuant to either this appendix or the procedures in Appendix A as it appeared at 10 CFR part 430, subpart B, Appendix A, in the 10 CFR parts 200 to 499 edition revised as of January 1, 2019. Any representations of energy use must be in accordance with whichever version is selected. On or after [DATE 180 DAYS AFTER DATE OF PUBLICATION OF THE FINAL RULE], any representations of energy use must be based on the results of testing pursuant to this appendix.

For refrigerators and refrigerator-freezers, manufacturers must use the rounding requirements specified in sections 5.3.e and 6.1 of this appendix for all representations of energy use on or after the compliance date of any amendment of energy conservation standards for these products published after [DATE OF PUBLICATION OF THE FINAL RULE]. For combination cooler refrigeration products, manufacturers must use the test procedures in this appendix for all representations of energy use on or after October 28, 2019.

Section 0. Incorporation by Reference

DOE incorporated by reference HRF–1–2016 in its entirety in § 430.3; however, only enumerated provisions of this document are applicable to this appendix, as follows:

(a) AHAM HRF–1–2016, (''HRF–1–2016''), Energy and Internal Volume of Refrigerating Appliances (January 1, 2016), including Errata to Energy and Internal Volume of Refrigerating Appliances, Correction Sheet, as follows:

(i) Section 3—Definitions, as specified in section 1 of this appendix; and Section 3.34, as specified in section 5.3 of this appendix;

(ii) Section 4—Method for Computing Refrigerated Volume of Refrigerators, Refrigerator-Freezers, Wine Chillers, and Freezers; Section 4.2—Total volume; Section 4.3—Legend for Figures 4–1 through 4–3; Figure 4–2; and Figure 4–3, as specified in section 5.3 of this appendix; and

(iii) Section 5—Method for Determining the Energy Consumption of Refrigerators, Refrigerator-Freezers, Wine Chillers, and Freezers; Section 5.5.1, as specified in section 2.6 of this appendix; Section 5.3.2—Ambient Relative Humidity through Section 5.5.6.4—Freezer Compartment Temperature (Automatic Defrost Freezer), as specified in sections 2.2, and 2.6 of this appendix; and Figure 5–1; and Figure 5–2, as specified in section 5.1 of this appendix.

1. Definitions

Section 3, *Definitions,* of HRF–1–2016 applies to this test procedure, except that the term ''wine chiller'' means ''cooler'' as defined in § 430.2.

Anti-sweat heater means a device incorporated into the design of a product to prevent the accumulation of moisture on the exterior or interior surfaces of the cabinet.

Anti-sweat heater switch means a user-controllable switch or user interface which modifies the activation or control of anti-sweat heaters.

AS/NZS 4474.1:2007 means Australian/New Zealand Standard 4474.1:2007, Performance of household electrical appliances—Refrigerating appliances, Part 1: Energy consumption and performance. Only sections of AS/NZS 4474.1:2007 (incorporated by reference; see § 430.3) specifically referenced in this test procedure are part of this test procedure. In cases where there is a conflict, the language of the test procedure in this appendix takes precedence over AS/NZS 4474.1:2007.

Automatic defrost means a system in which the defrost cycle is automatically initiated and terminated, with resumption of normal refrigeration at the conclusion of the

defrost operation. The system automatically prevents the permanent formation of frost on all refrigerated surfaces.

Automatic icemaker means a device that can be supplied with water without user intervention, either from a pressurized water supply system or by transfer from a water reservoir located inside the cabinet, that automatically produces, harvests, and stores ice in a storage bin, with means to automatically interrupt the harvesting operation when the ice storage bin is filled to a pre-determined level.

Compartment means an enclosed space within a consumer refrigeration product that is directly accessible through one or more external doors and may be divided into sub-compartments.

Complete temperature cycle means a time period defined based upon the cycling of compartment temperature that starts when the compartment temperature is at a maximum and ends when the compartment temperature returns to an equivalent maximum (within 0.5 °F of the starting temperature), having in the interim fallen to a minimum and subsequently risen again to reach the second maximum. Alternatively, a complete temperature cycle can be defined to start when the compartment temperature is at a minimum and ends when the compartment temperature returns to an equivalent minimum (within 0.5 °F of the starting temperature), having in the interim risen to a maximum and subsequently fallen again to reach the second minimum.

Cooler compartment means a refrigerated compartment designed exclusively for wine or other beverages within a consumer refrigeration product that is capable of maintaining compartment temperatures either (a) no lower than 39 °F (3.9 °C), or (b) in a range that extends no lower than 37 °F (2.8 °C) but at least as high as 60 °F (15.6 °C) as determined according to § 429.14(d)(2) or § 429.61(d)(2) of this chapter.

Cycle means a 24-hour period for which the energy use of a product is calculated based on the consumer-activated compartment temperature controls being set to maintain the standardized temperatures (see section 3.2 of this appendix).

Cycle type means the set of test conditions having the calculated effect of operating a product for a period of 24 hours, with the consumer-activated controls, other than those that control compartment temperatures, set to establish various operating characteristics.

Defrost cycle type means a distinct sequence of control whose function is to remove frost and/or ice from a refrigerated surface. There may be variations in the defrost control sequence, such as the number of defrost heaters energized. Each such variation establishes a separate, distinct defrost cycle type. However, defrost achieved regularly during the compressor off-cycles by warming of the evaporator without active heat addition, although a form of automatic defrost, does not constitute a unique defrost cycle type for the purposes of identifying the test period in accordance with section 4 of this appendix.

HRF–1–2016 means AHAM Standard HRF–1–2016, Association of Home Appliance Manufacturers, Energy and Internal Volume of Refrigerating Appliances (2016), including Errata to Energy and Internal Volume of Refrigerating Appliances, Correction Sheet issued August 3, 2016. Only sections of HRF–1–2016 specifically referenced in this test procedure are part of this test procedure. In cases where there is a conflict, the language of the test procedure in this appendix takes precedence over HRF–1–2016.

Ice storage bin means a container in which ice can be stored.

Long-time automatic defrost means an automatic defrost system whose successive defrost cycles are separated by 14 hours or more of compressor operating time.

Multiple-compressor product means a consumer refrigeration product with more than one compressor.

Multiple refrigeration system product means a multiple-compressor product or a miscellaneous refrigeration product with more than one refrigeration system for which the operation of the systems is not coordinated. For non-compressor multiple refrigeration system products, ''multiple-compressor product'' as used in this appendix shall be interpreted to mean ''multiple refrigeration system product.''

Precooling means operating a refrigeration system before initiation of a defrost cycle to reduce one or more compartment temperatures significantly (more than 0.5 °F) below its minimum during stable operation between defrosts.

Recovery means operating a refrigeration system after the conclusion of a defrost cycle to reduce the temperature of one or more compartments to the temperature range that the compartment(s) exhibited during stable operation between defrosts.

Stable operation means operation after steady-state conditions have been achieved but excluding any events associated with defrost cycles. During stable operation the rate of change of compartment temperatures must not exceed 0.042 °F (0.023 °C) per hour for all compartment temperatures. Such a calculation performed for compartment temperatures at any two times, or for any two periods of time comprising complete cycles, during stable operation must meet this requirement.

(a) If compartment temperatures do not cycle, the relevant calculation shall be the difference between the temperatures at two points in time divided by the difference, in hours, between those points in time.

(b) If compartment temperatures cycle as a result of compressor cycling or other cycling operation of any system component (*e.g.,* a damper, fan, heater, etc.), the relevant calculation shall be the difference between compartment temperature averages evaluated for the whole compressor cycles or complete temperature cycles divided by the difference, in hours, between either the starts, ends, or mid-times of the two cycles.

Stabilization period means the total period of time during which steady-state conditions are being attained or evaluated.

Standard cycle means the cycle type in which the anti-sweat heater control, when provided, is set in the highest energy-consuming position.

Sub-compartment means an enclosed space within a compartment that may have a different operating temperature from the compartment within which it is located.

Through-the-door ice/water dispenser means a device incorporated within the cabinet, but outside the boundary of the refrigerated space, that delivers to the user on demand ice and may also deliver water from within the refrigerated space without opening an exterior door. This definition includes dispensers that are capable of dispensing ice and water or ice only.

Variable anti-sweat heater control means an anti-sweat heater control that varies the average power input of the anti-sweat heater(s) based on operating condition variable(s) and/or ambient condition variable(s).

Variable defrost control means an automatic defrost system in which successive defrost cycles are determined by an operating condition variable (or variables) other than solely compressor operating time. This includes any electrical or mechanical device performing this function. A control scheme that changes the defrost interval from a fixed length to an extended length (without any intermediate steps) is not considered a variable defrost control. A variable defrost control feature predicts the accumulation of frost on the evaporator and reacts accordingly. Therefore, the times between defrost must vary with different usage patterns and include a continuum of periods between defrosts as inputs vary.

2. Test Conditions

* * * * *

2.1.2 Ambient Temperature Gradient. The test room vertical ambient temperature gradient in any foot of vertical distance from 2 inches (5.1 cm) above the floor or supporting platform to a height of 1 foot (30.5 cm) above the top of the unit under test is not to exceed 0.5 °F per foot (0.9 °C per meter) during the stabilization period and the test period. The vertical ambient temperature gradient at locations 10 inches (25.4 cm) out from the centers of the two sides of the unit being tested is to be maintained during the test. To demonstrate that this requirement has been met, test data must include measurements taken using temperature sensors at locations 10 inches (25.4 cm) from the center of the two sides of the unit under test at heights of 2 inches (5.1 cm) and 36 inches (91.4 cm) above the floor or supporting platform and at a height of 1 foot (30.5 cm) above the unit under test. The top of the unit under test shall be determined by the refrigerated cabinet height, excluding any special or protruding components on the top of the unit.

2.1.3 Platform. A platform must be used if the floor temperature is not within 3 °F (1.7 °C) of the measured ambient temperature. If a platform is used, it is to have a solid top with all sides open for air circulation underneath, and its top shall extend at least 1 foot (30.5 cm) beyond each side and the front of the unit under test and extend to the wall in the rear. For a test chamber floor that allows for airflow through the floor (*e.g.,* through a vent or holes), any airflow pathways through the floor must be located at least 1 foot away from all sides of the unit.

2.2 Operational Conditions. The unit under test shall be installed and its operating

conditions maintained in accordance with sections 5.3.2 through 5.5.6.4 of HRF–1–2016. Exceptions and clarifications to the cited sections of HRF–1–2016 are noted in sections 2.3 through 2.8, 2.10, and 5.1 of this appendix.

* * * * *

2.6 The cabinet and its refrigerating mechanism shall be assembled and set up in accordance with the printed consumer instructions supplied with the cabinet. Set-up of the test unit shall not deviate from these instructions, unless explicitly required or allowed by this test procedure. Specific required or allowed deviations from such set-up include the following:

(a) Connection of water lines and installation of water filters are not required;

(b) Clearance requirements from surfaces of the product shall be as described in section 2.8 of this appendix;

(c) The electric power supply shall be as described in section 5.5.1 of HRF–1–2016;

(d) Temperature control settings for testing shall be as described in section 3 of this appendix. Settings for temperature-controllable sub-compartments shall be as described in section 2.7 of this appendix;

(e) The product does not need to be anchored or otherwise secured to prevent tipping during energy testing;

(f) All the product's chutes and throats required for the delivery of ice shall be free of packing, covers, or other blockages that may be fitted for shipping or when the icemaker is not in use; and

(g) Ice storage bins shall be emptied of ice.

For cases in which set-up is not clearly defined by this test procedure, manufacturers must submit a petition for a waiver (see section 7 of this appendix).

2.7 Compartments that are convertible (*e.g.,* from fresh food to freezer or cooler) shall be operated in the highest energy use position. A compartment may be considered to be convertible to a cooler compartment if it is capable of maintaining compartment temperatures at least as high as 55 °F (12.8 °C) and also capable of operating at storage temperatures less than 37 °F. Sub-compartments with a temperature control shall be tested with controls set to provide the coldest temperature. However, for sub-compartments in which temperature control is achieved using the addition of heat (including resistive electric heating, refrigeration system waste heat, or heat from any other source, but excluding the transfer of air from another part of the interior of the product) for any part of the controllable temperature range of that compartment, the product energy use shall be determined by averaging two sets of tests. The first set of tests shall be conducted with such sub-compartments at their coldest settings, and the second set of tests shall be conducted with such sub-compartments at their warmest settings. The requirements for the warmest or coldest temperature settings of this section do not apply to features or functions associated with temperature controls (such as fast chill compartments) that are initiated manually and terminated automatically within 168 hours. Movable subdividing barriers that separate compartments shall be placed in the median position. If such a subdividing barrier has an even number of positions, the near-median position representing the smallest volume of the warmer compartment(s) shall be used.

* * * * *

2.9 Steady-State Condition. Steady-state conditions exist if the temperature measurements in all measured compartments taken at 4-minute intervals or less during a stabilization period are not changing at a rate greater than 0.042 °F (0.023 °C) per hour as determined by the applicable condition of paragraph (a) or (b) of this section.

(a) The average temperature of the measurements during a 2-hour period if no cycling occurs or during a number of complete repetitive compressor cycles occurring through a period of no less than 2 hours is compared to the average over an equivalent time period with at least 3 hours elapsing between the two measurement periods.

(b) If paragraph (a) of this section cannot be used, the average of the measurements during a number of complete repetitive compressor cycles occurring through a period of no less than 2 hours and including the last complete cycle before a defrost period (or if no cycling occurs, the average of the measurements during the last 2 hours before a defrost period) are compared to the same averaging period before the following defrost period.

2.10 Products with External Temperature Controls. If a product's controls are external to the cabinet assembly, the product shall be connected to the controls as needed for normal operation. Any additional equipment needed to ensure that the controls function properly shall not interfere with ambient airflow around the product or any other test conditions. If the controls provide temperature settings for additional separate products, the controls for those products shall be set to the ''off'' position during testing.

3. Test Control Settings

* * * * *

3.2.1.1 Setting Temperature Controls. For mechanical control systems, knob detents shall be mechanically defeated if necessary to attain a median setting, and the warmest and coldest settings shall correspond to the positions in which the indicator is aligned with control symbols indicating the warmest and coldest settings. For electronic control systems, the median setting test shall be performed with all compartment temperature controls set at the average of the coldest and warmest settings; if there is no setting equal to this average, the setting closest to the average shall be used. If there are two such settings equally close to the average, the higher of these temperature control settings shall be used.

3.2.1.2 Test Sequence. A first test shall be performed with all compartment temperature controls set at their median position midway between their warmest and coldest settings. A second test shall be performed with all controls set at their warmest setting or all controls set at their coldest setting (not electrically or mechanically bypassed). For units with a single standardized temperature (*e.g.,* all-refrigerator or cooler), this setting shall be the appropriate setting that attempts to achieve compartment temperatures measured during the two tests that bound (*i.e.,* one is above and one is below) the standardized temperature. For other units, the second test shall be conducted with all controls at their coldest setting, unless all compartment temperatures measured during the first test are lower than the standardized temperatures, in which case the second test shall be conducted with all controls at their warmest setting.

3.2.1.3 Temperature Setting Table. See Table 1 of this section for a general description of which settings to use and which test results to use in the energy consumption calculation for products with one, two, or three standardized temperatures.

TABLE 1—TEMPERATURE SETTINGS: GENERAL CHART FOR ALL PRODUCTS

First test		Second test		Energy calculation based on:
Setting	Results	Setting	Results	
Mid for all compartments.	All compartments low	Warm for all compartments.	All compartments low	Second Test Only.
			One or more compartments high.	First and Second Test.
.....	One or more compartments high.	Cold for all compartments.	All compartments low	First and Second Test.
			One or more compartments high.	Model may not be certified as compliant with energy conservation standards based on testing of this unit. Confirm that unit meets product definition. If so, see section 7 of this appendix.

* * * * *

3.2.3 Temperature Settings for Convertible Compartments. For convertible compartments tested as freezer compartments, the median setting shall be within 2 °F (1.1 °C) of the standardized freezer compartment temperature, and the warmest setting shall be at least 5 °F (2.8 °C) warmer than the standardized temperature. For convertible compartments tested as fresh food compartments, the median setting shall be within 2 °F (1.1 °C) of 39 °F (3.9 °C), the coldest setting shall be below 34 °F (1.1 °C), and the warmest setting shall be above 43 °F (6.1 °C). For convertible compartments tested as cooler compartments, the median setting shall be within 2 °F (1.1 °C) of 55 °F (12.8 °C), and the coldest setting shall be below 50 °F (10.0 °C). For compartments where control settings are not expressed as particular temperatures, the measured temperature of the convertible compartment rather than the settings shall meet the specified criteria.

* * * * *

4. Test Period

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4.1 Non-automatic Defrost. If the model being tested has no automatic defrost system, the test period shall be the stabilization period specified in section 2.9(a) of this appendix.

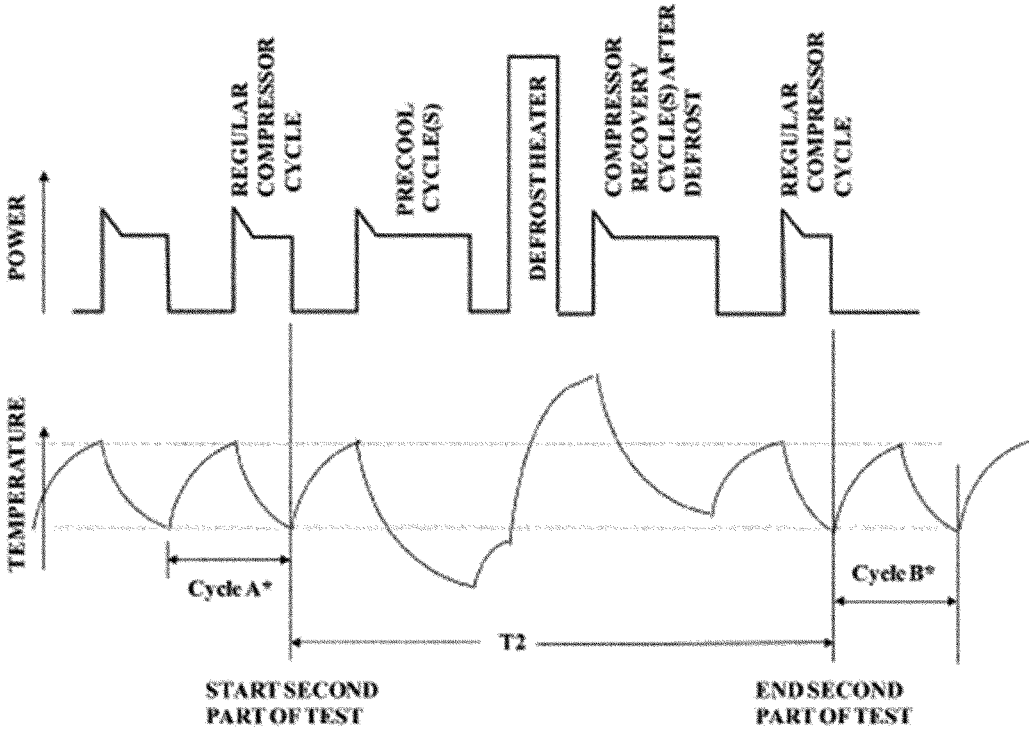
* * * * *

4.2.1 Long-time Automatic Defrost. If the model being tested has a long-time automatic defrost system, the two-part test described in this section may be used. If steady-state conditions are determined according to section 2.9(a) of this appendix, the first part is a stable period of compressor operation that includes no portions of the defrost cycle, such as precooling or recovery, that is otherwise the same as the test for a unit having no defrost provisions (section 4.1 of this appendix). If steady-state conditions are determined according to section 2.9(b) of this appendix, the first part of the test shall start after steady-state conditions have been achieved and be no less than three hours in duration. During the test period, the compressor motor shall complete two or more whole compressor cycles. (A compressor cycle is a complete ''on'' and a complete ''off'' period of the motor.) If no ''off'' cycling occurs, the test period shall be three hours. If fewer than two compressor cycles occur during a 24-hour period, then a single complete compressor cycle may be used. The second part is designed to capture the energy consumed during all of the events occurring with the defrost control sequence that are outside of stable operation.

4.2.1.1 Cycling Compressor System. For a system with a cycling compressor, the second part of the test starts at the termination of the last regular compressor ''on'' cycle. The average compartment temperatures measured from the termination of the previous compressor ''on'' cycle to the termination of the last regular compressor ''on'' cycle must be within 0.5 °F (0.3 °C) of their average temperatures measured for the first part of the test. If any compressor cycles occur prior to the defrost heater being energized that cause the average temperature in any compartment to deviate from its average temperature for the first part of the test by more than 0.5 °F (0.3 °C), these compressor cycles are not considered regular compressor cycles and must be included in the second part of the test. As an example, a ''precooling'' cycle, which is an extended compressor cycle that lowers the temperature(s) of one or more compartments prior to energizing the defrost heater, must be included in the second part of the test. The test period for the second part of the test ends at the termination of the first regular compressor ''on'' cycle after compartment temperatures have fully recovered to their stable conditions. The average temperatures of the compartments measured from this termination of the first regular compressor ''on'' cycle until the termination of the next regular compressor ''on'' cycle must be within 0.5 °F (0.3 °C) of the average temperatures measured for the first part of the test. See Figure 1 of this section. Note that Figure 1 illustrates the concepts of precooling and recovery but does not represent all possible defrost cycles. If average compartment temperatures measured over individual compressor cycles are never within 0.5 °F (0.3 °C) of the average temperatures measured for the first part of the test (for example, in products with irregular compressor cycling), the start of the second part of the test shall be at the beginning of a period of multiple complete compressor cycles prior to the defrost over which average temperatures are within 0.5 °F (0.3 °C) of the average temperatures measured for the first part of the test. Similarly, the end of the second part of the test shall be at the end of a period of multiple complete compressor cycles after the defrost over which average compartment temperatures are within 0.5 °F (0.3 °C) of the average measured for the first part of the test.

Figure 1

Long-time Automatic Defrost Diagram for Cycling Compressors



*Average compartment temperature during cycles A & B must be within 0.5°F of the average temperature for the first part of the test.

* * * * *

4.2.3.4.2 Second Part of Test. (a) If at least one compressor cycles, the test period for the second part of the test starts during stable operation before all portions of the defrost cycle, at the beginning of a complete primary compressor cycle. The test period for the second part of the test ends during stable operation after all portions of the defrost cycle, including recovery, at the termination of a complete primary compressor cycle. The start and stop for the test period shall both occur either when the primary compressor starts or when the primary compressor stops. For each compressor system, the compartment temperature averages for the first and last complete compressor cycles that lie completely within the second part of the test must be within 0.5 °F (0.3 °C) of the average compartment temperature measured for the first part of the test. If any one of the compressor systems is non-cycling, its compartment temperature averages during the first and last complete primary compressor cycles of the second part of the test must be within 0.5 °F (0.3 °C) of the average compartment temperature measured for the first part of the test.

(1) If average compartment temperatures measured over individual compressor cycles are never within 0.5 °F (0.3 °C) of the average temperatures measured for the first part of the test (for example, in products with irregular compressor cycling), the start of the second part of the test shall be at the beginning of a period of multiple complete compressor cycles prior to the defrost over which average temperatures are within 0.5 °F (0.3 °C) of the average temperatures measured for the first part of the test. Similarly, the end of the second part of the test shall be at the end of a period of multiple complete compressor cycles after the defrost over which average temperatures are within 0.5 °F (0.3 °C) of the average temperatures measured for the first part of the test.

(2) If these criteria cannot be met, the test period shall comprise at least 24 hours, unless a second defrost occurs prior to completion of 24 hours, in which case the test shall comprise at least 18 hours. The test period shall start at the end of a regular freezer compressor on-cycle after the previous defrost occurrence (refrigerator or freezer). The test period also includes the target defrost and following freezer compressor cycles, ending at the end of a freezer compressor on-cycle before the next defrost occurrence (refrigerator or freezer).

(b) If no compressor cycles, the test period for the second part of the test starts during stable operation before all portions of the defrost cycle, when the compartment temperatures of all compressor systems are within 0.5 °F (0.3 °C) of their average temperatures measured for the first part of the test. The test period for the second part ends during stable operation after all portions of the defrost cycle, including recovery, when the compartment temperatures of all compressor systems are within 0.5 °F (0.3 °C) of their average temperatures measured for the first part of the test.

* * * * *

5. Test Measurements

5.1 Temperature Measurements. (a) Temperature measurements shall be made at the locations prescribed in HRF–1–2016 Figure 5–1 for cooler and fresh food compartments and Figure 5–2 for freezer compartments and shall be accurate to within ±0.5 °F (0.3 °C). No freezer temperature measurements need be taken in an all-refrigerator or cooler-all-refrigerator.

(b) If the interior arrangements of the unit under test do not conform with those shown in Figure 5–1 or Figure 5–2 of HRF–1–2016, as appropriate, the unit must be tested by relocating the temperature sensors from the locations specified in the figures to avoid interference with hardware or components within the unit, in which case the specific locations used for the temperature sensors shall be noted in the test data records maintained by the manufacturer in accordance with 10 CFR 429.71, and the certification report shall indicate that non-standard sensor locations were used. If any temperature sensor is relocated by any amount from the location prescribed in Figure 5–1 or Figure 5–2 of HRF–1- 2016 in order to maintain a minimum 1-inch air space from adjustable shelves or other components that could be relocated by the consumer, except in cases in which the

Figures prescribe a temperature sensor location within 1 inch of a shelf or similar feature (*e.g.,* sensor T3 in Figure 5–1), this constitutes a relocation of temperature sensors that must be recorded in the test data and reported in the certification report as described in this paragraph (b).

(c) Freezer compartments that are accessed via a drawer shall be tested according to the Type 6 thermocouple configuration in Figure 5–2 of HRF–1–2016.

* * * * *

5.1.3 Fresh Food Compartment Temperature. The fresh food compartment temperature shall be calculated as:

$$TR = \frac{\sum_{i=1}^{R}(TR_i) \times (VR_i)}{\sum_{i=1}^{R}(VR_i)}$$

Where:

R is the total number of applicable fresh food compartments;

TR_i is the compartment temperature of fresh food compartment ''i'' determined in accordance with section 5.1.2 of this appendix; and

VR_i is the volume of fresh food compartment ''i.''

5.1.4 Freezer Compartment Temperature. The freezer compartment temperature shall be calculated as:

$$TF = \frac{\sum_{i=1}^{F}(TF_i) \times (VF_i)}{\sum_{i=1}^{F}(VF_i)}$$

Where:

F is the total number of applicable freezer compartments;

TF_i is the compartment temperature of freezer compartment ''i'' determined in accordance with section 5.1.2 of this appendix; and

VF_i is the volume of freezer compartment ''i''.

5.1.5 Cooler Compartment Temperature. The cooler compartment temperature shall be calculated as:

$$TC = \frac{\sum_{i=1}^{C}(TC_i) \times (VC_i)}{\sum_{i=1}^{C}(VC_i)}$$

Where:

C is the total number of applicable cooler compartments;

TC_i is the compartment temperature of cooler compartment ''i'' determined in accordance with section 5.1.2 of this appendix; and

VC_i is the volume of cooler compartment ''i.''

* * * * *

5.3 Volume Measurements. (a) The unit's total refrigerated volume, VT, shall be measured in accordance with sections 3.34, 4.2 through 4.3 of HRF–1–2016. The measured volume shall include all spaces within the insulated volume of each compartment except for the volumes that must be deducted in accordance with section 4.2.2 of HRF–1–2016, as provided in paragraph (b) of this section, and be calculated equivalent to:

VT = VF + VFF + VC

Where:

VT = total refrigerated volume in cubic feet,

VF = freezer compartment volume in cubic feet,

VFF = fresh food compartment volume in cubic feet, and

VC = cooler compartment volume in cubic feet.

(b) The following component volumes shall not be included in the compartment volume measurements: Icemaker compartment insulation (*e.g.,* insulation isolating the icemaker compartment from the fresh food compartment of a product with a bottom-mounted freezer with through-the-door ice service), fountain recess, dispenser insulation, and ice chute (if there is a plug, cover, or cap over the chute per Figure 4–2 of HRF–1–2016). The following component volumes shall be included in the compartment volume measurements: Icemaker auger motor (if housed inside the insulated space of the cabinet), icemaker kit, ice storage bin, and ice chute (up to the dispenser flap, if there is no plug, cover, or cap over the ice chute per Figure 4–3 of HRF–1–2016).

(c) Total refrigerated volume is determined by physical measurement of the test unit. Measurements and calculations used to determine the total refrigerated volume shall be retained as part of the test records underlying the certification of the basic model in accordance with 10 CFR 429.71.

(d) Compartment classification shall be based on subdivision of the refrigerated volume into zones separated from each other by subdividing barriers: No evaluated compartment shall be a zone of a larger compartment unless the zone is separated from the remainder of the larger compartment by subdividing barriers; if there are no such subdividing barriers within the larger compartment, the larger compartment must be evaluated as a single compartment rather than as multiple compartments. If the cabinet contains a movable subdividing barrier, it must be placed as described in section 2.7 of this appendix.

(e) Freezer, fresh food, and cooler compartment volumes shall be calculated and recorded to the nearest 0.01 cubic foot. Total refrigerated volume shall be calculated and recorded to the nearest 0.1 cubic foot.

* * * * *

6. Calculation of Derived Results From Test Measurements

* * * * *

6.2.3.1 If the fresh food compartment temperature is always below 39 °F (3.9 °C) and the freezer compartment temperature is always below 15 °F (−9.4 °C) in both tests of a refrigerator or always below 0 °F (−17.8 °C) in both tests of a refrigerator-freezer, the average per-cycle energy consumption shall be:

E = ET1 + IET

Where:

ET is defined in section 5.2.1 of this appendix;

For representations of energy use before [DATE ONE YEAR AFTER DATE OF PUBLICATION OF THE FINAL RULE], IET, expressed in kilowatt-hours per cycle, equals 0.23 for a product with one or more automatic icemakers and otherwise equals 0 (zero);

For representations of energy use on or after [DATE ONE YEAR AFTER DATE OF PUBLICATION OF THE FINAL RULE], IET, expressed in kilowatt-hours per cycle, equals 0.0767 for a product with one or more automatic icemakers and otherwise equals 0 (zero); and

The number 1 indicates the test during which the highest freezer compartment temperature was measured.

* * * * *

6.2.3.3 Optional Test for Models with Two Compartments and User-Operable Controls. If the procedure of section 3.3 of this appendix is used for setting temperature controls, the average per-cycle energy consumption shall be defined as follows:

$E = E_x + IET$

Where:

E is defined in 6.2.1.1 of this appendix;

IET is defined in 6.2.3.1 of this appendix; and

E_x is defined and calculated as described in appendix M, section M4(a) of AS/NZS 4474.1:2007 (incorporated by reference; see § 430.3). The target temperatures t_{xA} and t_{xB} defined in section M4(a)(i) of AS/NZS 4474.1:2007 shall be the standardized temperatures defined in section 3.2 of this appendix.

* * * * *

■ 4. Appendix B to subpart B of part 430 is amended by:

■ a. Revising the introductory note and sections 1, 2.1.2, 2.1.3, 2.2, 2.4, 2.5, 2.7, 2.8, 3.1, 3.2, 3.2.1, 4.1, 4.2.1, 4.2.1.1, 5.1, 5.1.3, 5.3, 6.1, and 6.2.1;

■ b. Removing section 2.8;

■ c. Redesignating section 2.9 as 2.8; and

■ d. Adding new sections 0 and 2.9.

The additions and revisions read as follows:

Appendix B to Subpart B of Part 430—Uniform Test Method for Measuring the Energy Consumption of Freezers

Note: Prior to [DATE 180 DAYS AFTER DATE OF PUBLICATION OF THE FINAL RULE], any representations of energy use of freezers must be based on the results of testing pursuant to either this appendix or the procedures in Appendix B as it appeared at 10 CFR part 430, subpart B, Appendix B, in the 10 CFR parts 200 to 499 edition revised as of January 1, 2019. Any representations of energy use must be in accordance with whichever version is selected. On or after [DATE 180 DAYS AFTER DATE OF PUBLICATION OF THE FINAL RULE], any representations of energy use must be based on the results of testing pursuant to this appendix.

For freezers, manufacturers must use the rounding requirements specified in sections 5.3.e and 6.1 of this appendix for all representations of energy use on or after the compliance date of any amendment of energy conservation standards for these products published after [DATE OF PUBLICATION OF THE FINAL RULE].

0. Incorporation by Reference

DOE incorporated by reference HRF–1–2016 in its entirety in § 430.3; however, only

enumerated provisions of this document are applicable to this appendix, as follows:

(a) AHAM HRF–1–2016, (''HRF–1–2016''), Energy and Internal Volume of Refrigerating Appliances (January 1, 2016), including Errata to Energy and Internal Volume of Refrigerating Appliances, Correction Sheet, as follows:

(i) Section 3—Definitions, as specified in section 1 of this appendix; and Section 3.34, as specified in section 5.3 of this appendix;

(ii) Section 4—Method for Computing Refrigerated Volume of Refrigerators, Refrigerator-Freezers, Wine Chillers, and Freezers; Section 4.2—Total volume; Section 4.3—Legend for Figures 4–1 through 4–3; Figure 4–2; and Figure 4–3, as specified in section 5.3 of this appendix; and

(iii) Section 5—Method for Determining the Energy Consumption of Refrigerators, Refrigerator-Freezers, Wine Chillers, and Freezers; Section 5.3.2–Ambient Relative Humidity through Section 5.5.6.4–Freezer Compartment Temperature (Automatic Defrost Freezer), as specified in sections 2.2, 2.4, and 2.8 of this appendix; and Figure 5–2, as specified in section 5.1 of this appendix.

1. Definitions

Section 3, *Definitions,* of HRF–1–2016 applies to this test procedure.

Adjusted total volume means the product of the freezer volume as defined in HRF–1–2016 in cubic feet multiplied by an adjustment factor.

Anti-sweat heater means a device incorporated into the design of a freezer to prevent the accumulation of moisture on exterior or interior surfaces of the cabinet.

Anti-sweat heater switch means a user-controllable switch or user interface which modifies the activation or control of anti-sweat heaters.

Automatic defrost means a system in which the defrost cycle is automatically initiated and terminated, with resumption of normal refrigeration at the conclusion of defrost operation. The system automatically prevents the permanent formation of frost on all refrigerated surfaces. Nominal refrigerated food temperatures are maintained during the operation of the automatic defrost system.

Automatic icemaker means a device that can be supplied with water without user intervention, either from a pressurized water supply system or by transfer from a water reservoir that automatically produces, harvests, and stores ice in a storage bin, with means to automatically interrupt the harvesting operation when the ice storage bin is filled to a pre-determined level.

Compartment means an enclosed space within a consumer refrigeration product that is directly accessible through one or more external doors and may be divided into sub-compartments.

Complete temperature cycle means a time period defined based upon the cycling of compartment temperature that starts when the compartment temperature is at a maximum and ends when the compartment temperature returns to an equivalent maximum (within 0.5 °F of the starting temperature), having in the interim fallen to a minimum and subsequently risen again to reach the second maximum. Alternatively, a complete temperature cycle can be defined to start when the compartment temperature is at a minimum and end when the compartment temperature returns to an equivalent minimum (within 0.5 °F of the starting temperature), having in the interim risen to a maximum and subsequently fallen again to reach the second minimum.

Cycle means the period of 24 hours for which the energy use of a freezer is calculated as though the consumer-activated compartment temperature controls were set to maintain the standardized temperature (see section 3.2 of this appendix).

Cycle type means the set of test conditions having the calculated effect of operating a freezer for a period of 24 hours with the consumer-activated controls other than the compartment temperature control set to establish various operating characteristics.

HRF–1–2016 means AHAM Standard HRF–1–2016, Association of Home Appliance Manufacturers, Energy and Internal Volume of Refrigerating Appliances (2016), including Errata to Energy and Internal Volume of Refrigerating Appliances, Correction Sheet issued August 3, 2016. Only sections of HRF–1–2016 specifically referenced in this test procedure are part of this test procedure. In cases where there is a conflict, the language of the test procedure in this appendix takes precedence over HRF–1–2016.

Ice storage bin means a container in which ice can be stored.

Long-time automatic defrost means an automatic defrost system where successive defrost cycles are separated by 14 hours or more of compressor operating time.

Precooling means operating a refrigeration system before initiation of a defrost cycle to reduce one or more compartment temperatures significantly (more than 0.5 °F) below its minimum during stable operation between defrosts.

Quick freeze means an optional feature on freezers that is initiated manually. It bypasses the thermostat control and operates continually until the feature is terminated either manually or automatically.

Recovery means operating a refrigeration system after the conclusion of a defrost cycle to reduce the temperature of one or more compartments to the temperature range that the compartment(s) exhibited during stable operation between defrosts.

Stabilization period means the total period of time during which steady-state conditions are being attained or evaluated.

Stable operation means operation after steady-state conditions have been achieved but excluding any events associated with defrost cycles. During stable operation the rate of change of compartment temperatures must not exceed 0.042 °F (0.023 °C) per hour. Such a calculation performed for compartment temperatures at any two times, or for any two periods of time comprising complete cycles, during stable operation must meet this requirement.

(a) If compartment temperatures do not cycle, the relevant calculation shall be the difference between the temperatures at two points in time divided by the difference, in hours, between those points in time.

(b) If compartment temperatures cycle as a result of compressor cycling or other cycling operation of any system component (*e.g.,* a damper, fan, or heater), the relevant calculation shall be the difference between compartment temperature averages evaluated for whole compressor cycles or complete temperature cycles divided by the difference, in hours, between either the starts, ends, or mid-times of the two cycles.

Standard cycle means the cycle type in which the anti-sweat heater switch, when provided, is set in the highest energy-consuming position.

Sub-compartment means an enclosed space within a compartment that may have a different operating temperature from the compartment within which it is located.

Through-the-door ice/water dispenser means a device incorporated within the cabinet, but outside the boundary of the refrigerated space, that delivers to the user on demand ice and may also deliver water from within the refrigerated space without opening an exterior door. This definition includes dispensers that are capable of dispensing ice and water or ice only.

Variable defrost control means an automatic defrost system in which successive defrost cycles are determined by an operating condition variable (or variables) other than solely compressor operating time. This includes any electrical or mechanical device performing this function. A control scheme that changes the defrost interval from a fixed length to an extended length (without any intermediate steps) is not considered a variable defrost control. A variable defrost control feature should predict the accumulation of frost on the evaporator and react accordingly. Therefore, the times between defrost must vary with different usage patterns and include a continuum of lengths of time between defrosts as inputs vary.

2. Test Conditions

* * * * *

2.1.2 Ambient Temperature Gradient. The test room vertical ambient temperature gradient in any foot of vertical distance from 2 inches (5.1 cm) above the floor or supporting platform to a height of 1 foot (30.5 cm) above the top of the unit under test is not to exceed 0.5 °F per foot (0.9 °C per meter) during the stabilization period and the test period. The vertical ambient temperature gradient at locations 10 inches (25.4 cm) out from the centers of the two sides of the unit being tested is to be maintained during the test. To demonstrate that this requirement has been met, test data must include measurements taken using temperature sensors at locations 10 inches (25.4 cm) from the center of the two sides of the unit under test at heights of 2 inches (5.1 cm) and 36 inches (91.4 cm) above the floor or supporting platform and at a height of 1 foot (30.5 cm) above the unit under test. The top of the unit under test shall be determined by the refrigerated cabinet height, excluding any special or protruding components on the top of the unit.

2.1.3 Platform. A platform must be used if the floor temperature is not within 3 °F (1.7 °C) of the measured ambient temperature. If a platform is used, it is to have a solid top with all sides open for air circulation

underneath, and its top shall extend at least 1 foot (30.5 cm) beyond each side and front of the unit under test and extend to the wall in the rear. For a test chamber floor that allows for airflow through the floor (*e.g.,* through a vent or holes), any airflow pathways through the floor must be located at least 1 foot away from all sides of the unit.

2.2 Operational Conditions. The freezer shall be installed and its operating conditions maintained in accordance with sections 5.3.2 through 5.5.6.4 of HRF–1–2016. The quick freeze option shall be switched off except as specified in section 3.1 of this appendix. Exceptions and clarifications to the cited sections of HRF–1–2016 are noted in sections 2.3 through 2.9 and 5.1 of this appendix.

* * * * *

2.4 The cabinet and its refrigerating mechanism shall be assembled and set up in accordance with the printed consumer instructions supplied with the cabinet. Set-up of the freezer shall not deviate from these instructions, unless explicitly required or allowed by this test procedure. Specific required or allowed deviations from such set-up include the following:

(a) Connection of water lines and installation of water filters are not required;

(b) Clearance requirements from surfaces of the product shall be as described in section 2.6;

(c) The electric power supply shall be as described in section 5.5.1 of HRF–1–2016;

(d) Temperature control settings for testing shall be as described in section 3 of this appendix. Settings for sub-compartments shall be as described in section 2.5 of this appendix;

(e) The product does not need to be anchored or otherwise secured to prevent tipping during energy testing;

(f) All the product's chutes and throats required for the delivery of ice shall be free of packing, covers, or other blockages that may be fitted for shipping or when the icemaker is not in use; and

(g) Ice storage bins shall be emptied of ice.

For cases in which set-up is not clearly defined by this test procedure, manufacturers must submit a petition for a waiver (see section 7 of this appendix).

2.5 Sub-compartments with a temperature control shall be tested with controls set to provide the coldest temperature. However, for sub-compartments in which temperature control is achieved using the addition of heat (including resistive electric heating, refrigeration system waste heat, or heat from any other source, but excluding the transfer of air from another part of the interior of the product) for any part of the controllable temperature range of that compartment, the product energy use shall be determined by averaging two sets of tests. The first set of tests shall be conducted with such compartments at their coldest settings, and the second set of tests shall be conducted with such compartments at their warmest settings. The requirements for the warmest or coldest temperature settings of this section do not apply to features or functions associated with temperature control (such as quick freeze) that are initiated manually and terminated automatically within 168 hours. Movable subdividing barriers that separate compartments shall be placed in the median position. If such a subdividing barrier has an even number of positions, the near-median position representing the smallest volume of the warmer compartment(s) shall be used.

* * * * *

2.7 Steady State Condition. Steady-state conditions exist if the temperature measurements in all measured compartments taken at 4-minute intervals or less during a stabilization period are not changing at a rate greater than 0.042 °F (0.023 °C) per hour as determined by the applicable condition of paragraph (a) or (b) of this section.

(a) The average temperature of the measurements during a 2-hour period if no cycling occurs or during a number of complete repetitive compressor cycles occurring through a period of no less than 2 hours is compared to the average over an equivalent time period with at least 3 hours elapsing between the two measurement periods.

(b) If paragraph (a) of this section cannot be used, the average of the measurements during a number of complete repetitive compressor cycles occurring through a period of no less than 2 hours and including the last complete cycle before a defrost period (or if no cycling occurs, the average of the measurements during the last 2 hours before a defrost period) are compared to the same averaging period before the following defrost period.

2.8 For products that require the freezer compartment to be loaded with packages in accordance with section 5.5.6.2 of HRF–1–2016, the number of packages comprising the 75% load shall be determined by filling the compartment completely with the packages that are to be used for the test, such that the packages fill as much of the usable refrigerated space within the compartment as is physically possible, and then removing from the compartment a number of packages so that the compartment contains 75% of the packages that were placed in the compartment to completely fill it. If multiplying the total number of packages by 0.75 results in a fraction, the number of packages used shall be rounded to the nearest whole number, rounding up if the result ends in 0.5. For multi-shelf units, this method shall be applied to each shelf. For both single- and multi-shelf units, the remaining packages shall be arranged as necessary to provide the required air gap and thermocouple placement. The number of packages comprising the 100% and 75% loading conditions shall be recorded in the test data maintained in accordance with 10 CFR 429.71.

2.9 Products with External Temperature Controls. If a product's controls are external to the cabinet assembly, the product shall be connected to the controls as needed for normal operation. Any additional equipment needed to ensure that the controls function properly shall not interfere with ambient airflow around the product or any other test conditions. If the controls provide temperature settings for additional separate products, the controls for those products shall be set to the ''off'' position during testing.

3. Test Control Settings

3.1 Model with No User-Operable Temperature Control. A test shall be performed during which the compartment temperature and energy use shall be measured. A second test shall be performed with the temperature control electrically short circuited to cause the compressor to run continuously. If the model has the quick freeze option, this option must be used to bypass the temperature control.

3.2 Model with User-Operable Temperature Control. Testing shall be performed in accordance with one of the following sections using the standardized temperature of 0.0 °F (−17.8 °C). For the purposes of comparing compartment temperatures with standardized temperatures, as described in sections 3.2.1 and 3.2.2 of this appendix, the freezer compartment temperature shall be as specified in section 5.1.3 of this appendix.

3.2.1 A first test shall be performed with all temperature controls set at their median position midway between their warmest and coldest settings. For mechanical control systems, knob detents shall be mechanically defeated if necessary to attain a median setting, and the warmest and coldest settings shall correspond to the positions in which the indicator is aligned with control symbols indicating the warmest and coldest settings. For electronic control systems, the median setting test shall be performed with all compartment temperature controls set at the average of the coldest and warmest settings; if there is no setting equal to this average, the setting closest to the average shall be used. If there are two such settings equally close to the average, the higher of these temperature control settings shall be used. A second test shall be performed with all controls set at either their warmest or their coldest setting (not electrically or mechanically bypassed), whichever is appropriate, to attempt to achieve compartment temperatures measured during the two tests that bound (*i.e.,* one is above and one is below) the standardized temperature. If the compartment temperatures measured during these two tests bound the standardized temperature, then these test results shall be used to determine energy consumption. If the compartment temperature measured with all controls set at their warmest setting is below the standardized temperature, then the result of this test alone will be used to determine energy consumption. Also see Table 1 of this appendix, which summarizes these requirements.

TABLE 1—TEMPERATURE SETTINGS FOR FREEZERS

First test		Second test		Energy calculation based on:
Settings	Results	Settings	Results	
Mid	Low	Warm	Low	Second Test Only.
			High	First and Second Tests.
	High	Cold	Low	First and Second Tests.
			High	Model may not be certified as compliant with energy conservation standards based on testing of this unit. Confirm that unit meets product definition. If so, see section 7 of this appendix.

* * * * *

4. Test Period

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4.1 Non-automatic Defrost. If the model being tested has no automatic defrost system, the test period shall be the same as the stabilization period specified in section 2.7(a) of this appendix.

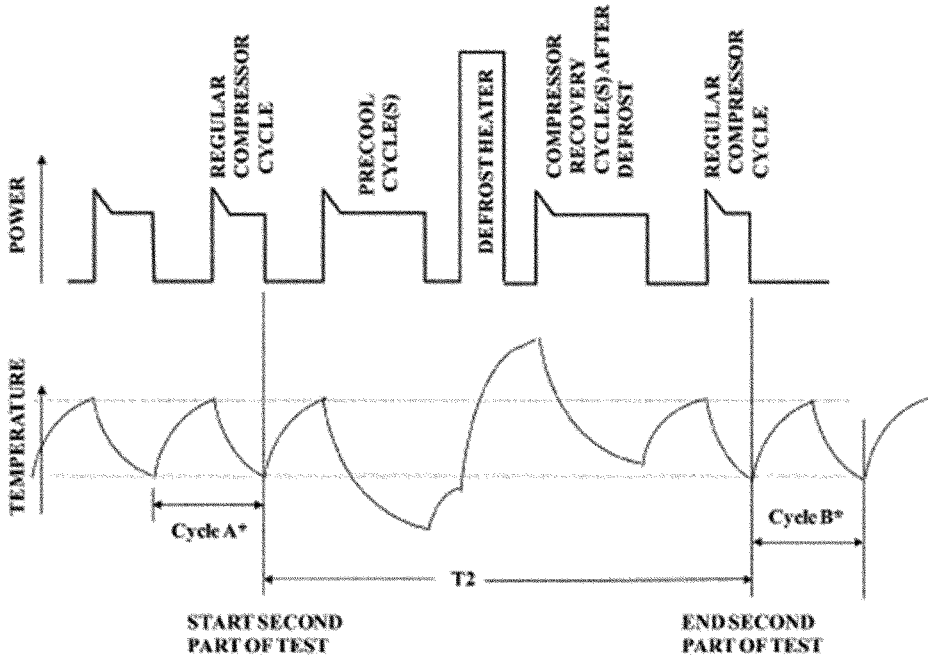
* * * * *

4.2.1 Long-time Automatic Defrost. If the model being tested has a long-time automatic defrost system, the two-part test described in this section may be used. If steady-state conditions are determined according to section 2.7(a) of this appendix, the first part is a stable period of compressor operation that includes no portions of the defrost cycle, such as precooling or recovery, that is otherwise the same as the test for a unit having no defrost provisions (section 4.1 of this appendix). If steady-state conditions are determined according to section 2.7(b) of this appendix, the first part of the test shall start after steady-state conditions have been achieved and be no less than three hours in duration. During the test period, the compressor motor shall complete two or more whole compressor cycles. (A compressor cycle is a complete ''on'' and a complete ''off'' period of the motor.) If no ''off'' cycling occurs, the test period shall be three hours. If fewer than two compressor cycles occur during a 24-hour period, then a single complete compressor cycle may be used. The second part is designed to capture the energy consumed during all of the events occurring with the defrost control sequence that are outside of stable operation.

4.2.1.1 Cycling Compressor System. For a system with a cycling compressor, the second part of the test starts at the termination of the last regular compressor ''on'' cycle. The average temperature of the compartment measured from the termination of the previous compressor ''on'' cycle to the termination of the last regular compressor ''on'' cycle must be within 0.5 °F (0.3 °C) of the average temperature of the compartment measured for the first part of the test. If any compressor cycles occur prior to the defrost heater being energized that cause the average temperature in the compartment to deviate from the average temperature for the first part of the test by more than 0.5 °F (0.3 °C), these compressor cycles are not considered regular compressor cycles and must be included in the second part of the test. As an example, a ''precooling'' cycle, which is an extended compressor cycle that lowers the compartment temperature prior to energizing the defrost heater, must be included in the second part of the test. The test period for the second part of the test ends at the termination of the first regular compressor ''on'' cycle after the compartment temperatures have fully recovered to their stable conditions. The average temperature of the compartment measured from this termination of the first regular compressor ''on'' cycle until the termination of the next regular compressor ''on'' cycle must be within 0.5 °F (0.3 °C) of the average temperature of the compartment measured for the first part of the test. See Figure 1. Note that Figure 1 illustrates the concepts of precooling and recovery but does not represent all possible defrost cycles. If average compartment temperatures measured over individual compressor cycles are never within 0.5 °F (0.3 °C) of the average temperature of the compartment measured for the first part of the test (for example, in products with irregular compressor cycling), the start of the second part of the test shall be at the beginning of a period of multiple complete compressor cycles prior to the defrost over which average temperatures are within 0.5 °F (0.3 °C) of the average temperature of the compartment measured for the first part of the test. Similarly, the end of the second part of the test shall be at the end of a period of multiple complete compressor cycles after the defrost over which average compartment temperatures are within 0.5 °F (0.3 °C) of the average measured for the first part of the test.

Figure 1

Long-time Automatic Defrost Diagram for Cycling Compressors



*Average compartment temperature during cycles A & B must be within 0.5°F of the average temperature for the first part of the test.

* * * * *

5. Test Measurements

5.1 Temperature Measurements. (a) Temperature measurements shall be made at the locations prescribed in Figure 5–2 of HRF–1–2016 and shall be accurate to within ± 0.5 °F (0.3 °C).

(b) If the interior arrangements of the unit under test do not conform with those shown in Figure 5–2 of HRF–1–2016, the unit must be tested by relocating the temperature sensors from the locations specified in the figures to avoid interference with hardware or components within the unit, in which case the specific locations used for the temperature sensors shall be noted in the test data records maintained by the manufacturer in accordance with 10 CFR 429.71, and the certification report shall indicate that non-standard sensor locations were used. If any temperature sensor is relocated by any amount from the location prescribed in Figure 5–2 of HRF–1–2016 in order to maintain a minimum 1-inch air space from adjustable shelves or other components that could be relocated by the consumer, except in cases in which the Figure prescribe a temperature sensor location within 1 inch of a shelf or similar feature, this constitutes a relocation of temperature sensors that must be recorded in the test data and reported in the certification report as described above.

(c) Freezer compartments that are accessed via a drawer shall be tested according to the Type 6 thermocouple configuration in Figure 5–2 of HRF–1–2016.

* * * * *

5.1.3 Freezer Compartment Temperature. The freezer compartment temperature shall be calculated as:

$$TF = \frac{\sum_{i=1}^{F}(TF_i) \times (VF_i)}{\sum_{i=1}^{F}(VF_i)}$$

Where:

F is the total number of applicable freezer compartments;

TF_i is the compartment temperature of freezer compartment ''i'' determined in accordance with section 5.1.2 of this appendix; and

VF_i is the volume of freezer compartment ''i''.

* * * * *

5.3 Volume Measurements. (a) The unit's total refrigerated volume, VT, shall be measured in accordance with sections 3.34, 4.2 through 4.3 of HRF–1–2016. The measured volume shall include all spaces within the insulated volume of each compartment except for the volumes that must be deducted in accordance with section 4.2.2 of HRF–1–2016, as provided in paragraph (b) of this section.

(b) The following component volumes shall not be included in the compartment volume measurements: Icemaker compartment insulation, fountain recess, dispenser insulation, and ice chute (if there is a plug, cover, or cap over the chute per Figure 4–2 of HRF–1–2016). The following component volumes shall be included in the compartment volume measurements: Icemaker auger motor (if housed inside the insulated space of the cabinet), icemaker kit, ice storage bin, and ice chute (up to the dispenser flap, if there is no plug, cover, or cap over the ice chute per Figure 4–3 of HRF–1–2016).

(c) Total refrigerated volume is determined by physical measurement of the test unit. Measurements and calculations used to determine the total refrigerated volume shall be retained as part of the test records underlying the certification of the basic model in accordance with 10 CFR 429.71.

(d) Compartment classification shall be based on subdivision of the refrigerated volume into zones separated from each other by subdividing barriers: No evaluated compartment shall be a zone of a larger compartment unless the zone is separated from the remainder of the larger compartment by subdividing barriers; if there are no such subdividing barriers within the larger compartment, the larger compartment must be evaluated as a single compartment rather than as multiple compartments. If the cabinet contains a movable subdividing barrier, it must be placed as described in section 2.5 of this appendix.

(e) Freezer compartment volumes shall be calculated and recorded to the nearest 0.01 cubic feet. Total refrigerated volume shall be calculated and recorded to the nearest 0.1 cubic feet.

6. Calculation of Derived Results From Test Measurements

6.1 Adjusted Total Volume. The adjusted total volume of each tested unit must be determined based upon the volume measured in section 5.3 of this appendix using the following calculations. Where volume measurements for the freezer are recorded in liters, the measured volume must be converted to cubic feet and rounded to the

nearest 0.01 cubic foot prior to calculating the adjusted volume. Adjusted total volume shall be calculated and recorded to the nearest 0.1 cubic foot. The adjusted total volume, AV, for freezers under test shall be defined as:

$AV = VT \times CF$

Where:

AV = adjusted total volume in cubic feet;
VT = total refrigerated volume in cubic feet; and
CF = dimensionless correction factor of 1.76.

* * * * *

6.2.1 If the compartment temperature is always below 0.0 °F (−17.8 °C), the average per-cycle energy consumption shall be equivalent to:

$E = ET1 + IET$

Where:

E = total per-cycle energy consumption in kilowatt-hours per day;

ET is defined in section 5.2.1 of this appendix;

The number 1 indicates the test during which the highest compartment temperature is measured; and

For representations of energy use before [DATE ONE YEAR AFTER DATE OF PUBLICATION OF THE FINAL RULE], IET, expressed in kilowatt-hours per cycle, equals 0.23 for a product with one or more automatic icemakers and otherwise equals 0 (zero);

For representations of energy use on or after [DATE ONE YEAR AFTER DATE OF PUBLICATION OF THE FINAL RULE], IET, expressed in kilowatt-hours per cycle, equals 0.0767 for a product with one or more automatic icemakers and otherwise equals 0 (zero).

* * * * *

■ 5. In § 430.32 revise paragraphs (a) and (aa)(2) to read as follows:

§ 430.32 Energy and water conservation standards and their compliance dates.

* * * * *

(a) *Refrigerators/refrigerator-freezers/freezers.* These standards do not apply to refrigerators and refrigerator-freezers with total refrigerated volume exceeding 39 cubic feet (1,104 liters) or freezers with total refrigerated volume exceeding 30 cubic feet (850 liters). The energy standards as determined by the equations of the following table(s) shall be rounded off to the nearest kWh per year. If the equation calculation is halfway between the nearest two kWh per year values, the standard shall be rounded up to the higher of these values.

The following standards remain in effect from July 1, 2001 until September 15, 2014:

Product class	Energy standard equations for maximum energy use (kWh/yr)
1. Refrigerators and refrigerator-freezers with manual defrost	8.82AV + 248.4, 0.31av + 248.4.
2. Refrigerator-freezers—partial automatic defrost	8.82AV + 248.4, 0.31av + 248.4.
3. Refrigerator-freezers—automatic defrost with top-mounted freezer without through-the-door ice service and all-refrigerator—automatic defrost.	9.80AV + 276.0, 0.35av + 276.0.
4. Refrigerator-freezers—automatic defrost with side-mounted freezer without through-the-door ice service.	4.91AV + 507.5, 0.17av + 507.5.
5. Refrigerator-freezers—automatic defrost with bottom-mounted freezer without through-the-door ice service.	4.60AV + 459.0, 0.16av + 459.0.
6. Refrigerator-freezers—automatic defrost with top-mounted freezer with through-the-door ice service	10.20AV + 356.0, 0.36av + 356.0.
7. Refrigerator-freezers—automatic defrost with side-mounted freezer with through-the-door ice service	10.10AV + 406.0, 0.36av + 406.0.
8. Upright freezers with manual defrost	7.55AV + 258.3, 0.27av + 258.3.
9. Upright freezers with automatic defrost	12.43AV + 326.1, 0.44av + 326.1.
10. Chest freezers and all other freezers except compact freezers	9.88AV + 143.7, 0.35av + 143.7.
11. Compact refrigerators and refrigerator-freezers with manual defrost	10.70AV + 299.0, 0.38av + 299.0.
12. Compact refrigerator-freezer—partial automatic defrost	7.00AV + 398.0, 0.25av + 398.0.
13. Compact refrigerator-freezers—automatic defrost with top-mounted freezer and compact all-refrigerator—automatic defrost.	12.70AV + 355.0, 0.45av + 355.0.
14. Compact refrigerator-freezers—automatic defrost with side-mounted freezer	7.60AV + 501.0, 0.27av + 501.0.
15. Compact refrigerator-freezers—automatic defrost with bottom-mounted freezer	13.10AV + 367.0, 0.46av + 367.0.
16. Compact upright freezers with manual defrost	9.78AV + 250.8, 0.35av + 250.8.
17. Compact upright freezers with automatic defrost	11.40AV + 391.0, 0.40av + 391.0.
18. Compact chest freezers	10.45AV + 152.0, 0.37av + 152.0.

AV: Adjusted Volume in ft^3; av: Adjusted Volume in liters (L).

The following standards apply to products manufactured starting on September 15, 2014 until [DATE ONE YEAR AFTER PUBLICATION OF A FINAL RULE]:

Product class	Equations for maximum energy use (kWh/yr)	
	Based on AV (ft^3)	Based on av (L)
1. Refrigerator-freezers and refrigerators other than all-refrigerators with manual defrost	7.99AV + 225.0	0.282av + 225.0.
1A. All-refrigerators—manual defrost	6.79AV + 193.6	0.240av + 193.6.
2. Refrigerator-freezers—partial automatic defrost	7.99AV + 225.0	0.282av + 225.0.
3. Refrigerator-freezers—automatic defrost with top-mounted freezer without an automatic icemaker	8.07AV + 233.7	0.285av + 233.7.
3–BI. Built-in refrigerator-freezer—automatic defrost with top-mounted freezer without an automatic icemaker.	9.15AV + 264.9	0.323av + 264.9.
3I. Refrigerator-freezers—automatic defrost with top-mounted freezer with an automatic icemaker without through-the-door ice service.	8.07AV + 317.7	0.285av + 317.7.
3I–BI. Built-in refrigerator-freezers—automatic defrost with top-mounted freezer with an automatic icemaker without through-the-door ice service.	9.15AV + 348.9	0.323av + 348.9.
3A. All-refrigerators—automatic defrost	7.07AV + 201.6	0.250av + 201.6.

Product class	Equations for maximum energy use (kWh/yr)	
	Based on AV (ft^3)	Based on av (L)
3A–BI. Built-in All-refrigerators—automatic defrost	8.02AV + 228.5	0.283av + 228.5.
4. Refrigerator-freezers—automatic defrost with side-mounted freezer without an automatic icemaker.	8.51AV + 297.8	0.301av + 297.8.
4–BI. Built-In Refrigerator-freezers—automatic defrost with side-mounted freezer without an automatic icemaker.	10.22AV + 357.4	0.361av + 357.4.
4I. Refrigerator-freezers—automatic defrost with side-mounted freezer with an automatic icemaker without through-the-door ice service.	8.51AV + 381.8	0.301av + 381.8.
4I–BI. Built-In Refrigerator-freezers—automatic defrost with side-mounted freezer with an automatic icemaker without through-the-door ice service.	10.22AV + 441.4	0.361av + 441.4.
5. Refrigerator-freezers—automatic defrost with bottom-mounted freezer without an automatic icemaker.	8.85AV + 317.0	0.312av + 317.0.
5–BI. Built-In Refrigerator-freezers—automatic defrost with bottom-mounted freezer without an automatic icemaker.	9.40AV + 336.9	0.332av + 336.9.
5I. Refrigerator-freezers—automatic defrost with bottom-mounted freezer with an automatic icemaker without through-the-door ice service.	8.85AV + 401.0	0.312av + 401.0.
5I–BI. Built-In Refrigerator-freezers—automatic defrost with bottom-mounted freezer with an automatic icemaker without through-the-door ice service.	9.40AV + 420.9	0.332av + 420.9.
5A. Refrigerator-freezer—automatic defrost with bottom-mounted freezer with through-the-door ice service.	9.25AV + 475.4	0.327av + 475.4.
5A–BI. Built-in refrigerator-freezer—automatic defrost with bottom-mounted freezer with through-the-door ice service.	9.83AV + 499.9	0.347av + 499.9.
6. Refrigerator-freezers—automatic defrost with top-mounted freezer with through-the-door ice service.	8.40AV + 385.4	0.297av + 385.4.
7. Refrigerator-freezers—automatic defrost with side-mounted freezer with through-the-door ice service.	8.54AV + 432.8	0.302av + 432.8.
7–BI. Built-In Refrigerator-freezers—automatic defrost with side-mounted freezer with through-the-door ice service.	10.25AV + 502.6	0.362av + 502.6.
8. Upright freezers with manual defrost	5.57AV + 193.7	0.197av + 193.7.
9. Upright freezers with automatic defrost without an automatic icemaker	8.62AV + 228.3	0.305av + 228.3.
9I. Upright freezers with automatic defrost with an automatic icemaker	8.62AV + 312.3	0.305av + 312.3.
9–BI. Built-In Upright freezers with automatic defrost without an automatic icemaker	9.86AV + 260.9	0.348av + 260.9.
9I–BI. Built-in upright freezers with automatic defrost with an automatic icemaker	9.86AV + 344.9	0.348av + 344.9.
10. Chest freezers and all other freezers except compact freezers	7.29AV + 107.8	0.257av + 107.8.
10A. Chest freezers with automatic defrost	10.24AV + 148.1	0.362av + 148.1.
11. Compact refrigerator-freezers and refrigerators other than all-refrigerators with manual defrost	9.03AV + 252.3	0.319av + 252.3.
11A. Compact all-refrigerators—manual defrost	7.84AV + 219.1	0.277av + 219.1.
12. Compact refrigerator-freezers—partial automatic defrost	5.91AV + 335.8	0.209av + 335.8.
13. Compact refrigerator-freezers—automatic defrost with top-mounted freezer	11.80AV + 339.2	0.417av + 339.2.
13I. Compact refrigerator-freezers—automatic defrost with top-mounted freezer with an automatic icemaker.	11.80AV + 423.2	0.417av + 423.2.
13A. Compact all-refrigerators—automatic defrost	9.17AV + 259.3	0.324av + 259.3.
14. Compact refrigerator-freezers—automatic defrost with side-mounted freezer	6.82AV + 456.9	0.241av + 456.9.
14I. Compact refrigerator-freezers—automatic defrost with side-mounted freezer with an automatic icemaker.	6.82AV + 540.9	0.241av + 540.9.
15. Compact refrigerator-freezers—automatic defrost with bottom-mounted freezer	11.80AV + 339.2	0.417av + 339.2.
15I. Compact refrigerator-freezers—automatic defrost with bottom-mounted freezer with an automatic icemaker.	11.80AV + 423.2	0.417av + 423.2.
16. Compact upright freezers with manual defrost	8.65AV + 225.7	0.306av + 225.7.
17. Compact upright freezers with automatic defrost	10.17AV + 351.9	0.359av + 351.9.
18. Compact chest freezers	9.25AV + 136.8	0.327av + 136.8.

AV = Total adjusted volume, expressed in ft^3, as determined in appendices A and B of subpart B of this part.
av = Total adjusted volume, expressed in Liters.

The following standards apply to products manufactured starting on [DATE ONE YEAR AFTER PUBLICATION OF A FINAL RULE]:

Product class	Equations for maximum energy use (kWh/yr)	
	Based on AV (ft^3)	Based on av (L)
1. Refrigerator-freezers and refrigerators other than all-refrigerators with manual defrost	7.99AV + 225.0	0.282av + 225.0.
1A. All-refrigerators—manual defrost	6.79AV + 193.6	0.240av + 193.6.
2. Refrigerator-freezers—partial automatic defrost	7.99AV + 225.0	0.282av + 225.0.
3. Refrigerator-freezers—automatic defrost with top-mounted freezer without an automatic icemaker	8.07AV + 233.7	0.285av + 233.7.
3–BI. Built-in refrigerator-freezer—automatic defrost with top-mounted freezer without an automatic icemaker.	9.15AV + 208.9	0.323av + 208.9.

Product class	Equations for maximum energy use (kWh/yr)	
	Based on AV (ft^3)	Based on av (L)
3I. Refrigerator-freezers—automatic defrost with top-mounted freezer with an automatic icemaker without through-the-door ice service.	8.07AV + 261.7	0.285av + 261.7.
3I–BI. Built-in refrigerator-freezers—automatic defrost with top-mounted freezer with an automatic icemaker without through-the-door ice service.	9.15AV + 292.9	0.323av + 292.9.
3A. All-refrigerators—automatic defrost	7.07AV + 201.6	0.250av + 201.6.
3A–BI. Built-in All-refrigerators—automatic defrost	8.02AV + 228.5	0.283av + 228.5.
4. Refrigerator-freezers—automatic defrost with side-mounted freezer without an automatic icemaker.	8.51AV + 297.8	0.301av + 297.8.
4–BI. Built-In Refrigerator-freezers—automatic defrost with side-mounted freezer without an automatic icemaker.	10.22AV + 357.4	0.361av + 357.4.
4I. Refrigerator-freezers—automatic defrost with side-mounted freezer with an automatic icemaker without through-the-door ice service.	8.51AV + 325.8	0.301av + 325.8.
4I–BI. Built-In Refrigerator-freezers—automatic defrost with side-mounted freezer with an automatic icemaker without through-the-door ice service.	10.22AV + 385.4	0.361av + 385.4.
5. Refrigerator-freezers—automatic defrost with bottom-mounted freezer without an automatic icemaker.	8.85AV + 317.0	0.312av + 317.0.
5–BI. Built-In Refrigerator-freezers—automatic defrost with bottom-mounted freezer without an automatic icemaker.	9.40AV + 336.9	0.332av + 336.9.
5I. Refrigerator-freezers—automatic defrost with bottom-mounted freezer with an automatic icemaker without through-the-door ice service.	8.85AV + 345.0	0.312av + 345.0.
5I–BI. Built-In Refrigerator-freezers—automatic defrost with bottom-mounted freezer with an automatic icemaker without through-the-door ice service.	9.40AV + 364.9	0.332av + 364.9.
5A. Refrigerator-freezer—automatic defrost with bottom-mounted freezer with through-the-door ice service.	9.25AV + 419.4	0.327av + 419.4.
5A–BI. Built-in refrigerator-freezer—automatic defrost with bottom-mounted freezer with through-the-door ice service.	9.83AV + 443.9	0.347av + 443.9.
6. Refrigerator-freezers—automatic defrost with top-mounted freezer with through-the-door ice service.	8.40AV + 329.4	0.297av + 329.4.
7. Refrigerator-freezers—automatic defrost with side-mounted freezer with through-the-door ice service.	8.54AV + 376.8	0.302av + 376.8.
7–BI. Built-In Refrigerator-freezers—automatic defrost with side-mounted freezer with through-the-door ice service.	10.25AV + 446.6	0.362av + 446.6.
8. Upright freezers with manual defrost	5.57AV + 193.7	0.197av + 193.7.
9. Upright freezers with automatic defrost without an automatic icemaker	8.62AV + 228.3	0.305av + 228.3.
9I. Upright freezers with automatic defrost with an automatic icemaker	8.62AV + 256.3	0.305av + 256.3.
9–BI. Built-In Upright freezers with automatic defrost without an automatic icemaker	9.86AV + 260.9	0.348av + 260.9.
9I–BI. Built-in upright freezers with automatic defrost with an automatic icemaker	9.86AV + 288.9	0.348av + 288.9.
10. Chest freezers and all other freezers except compact freezers	7.29AV + 107.8	0.257av + 107.8.
10A. Chest freezers with automatic defrost	10.24AV + 148.1	0.362av + 148.1.
11. Compact refrigerator-freezers and refrigerators other than all-refrigerators with manual defrost	9.03AV + 252.3	0.319av + 252.3.
11A. Compact all-refrigerators—manual defrost	7.84AV + 219.1	0.277av + 219.1.
12. Compact refrigerator-freezers—partial automatic defrost	5.91AV + 335.8	0.209av + 335.8.
13. Compact refrigerator-freezers—automatic defrost with top-mounted freezer	11.80AV + 339.2	0.417av + 339.2.
13I. Compact refrigerator-freezers—automatic defrost with top-mounted freezer with an automatic icemaker.	11.80AV + 376.2	0.417av + 376.2.
13A. Compact all-refrigerators—automatic defrost	9.17AV + 259.3	0.324av + 259.3.
14. Compact refrigerator-freezers—automatic defrost with side-mounted freezer	6.82AV + 456.9	0.241av + 456.9.
14I. Compact refrigerator-freezers—automatic defrost with side-mounted freezer with an automatic icemaker.	6.82AV + 484.9	0.241av + 484.9.
15. Compact refrigerator-freezers—automatic defrost with bottom-mounted freezer	11.80AV + 339.2	0.417av + 339.2.
15I. Compact refrigerator-freezers—automatic defrost with bottom-mounted freezer with an automatic icemaker.	11.80AV + 367.2	0.417av + 367.2.
16. Compact upright freezers with manual defrost	8.65AV + 225.7	0.306av + 225.7.
17. Compact upright freezers with automatic defrost	10.17AV + 351.9	0.359av + 351.9.
18. Compact chest freezers	9.25AV + 136.8	0.327av + 136.8.

AV = Total adjusted volume, expressed in ft^3, as determined in appendices A and B of subpart B of this part.
av = Total adjusted volume, expressed in Liters.

* * * * *

(aa) * * *

(2) Combination cooler refrigeration products manufactured starting on October 28, 2019 until [DATE ONE YEAR AFTER PUBLICATION OF A FINAL RULE] shall have Annual Energy Use (AEU) no more than:

Product class	AEU (kWh/yr)
C–3A. Cooler with all-refrigerator—automatic defrost	4.57AV + 130.4.
C–3A–BI. Built-in cooler with all-refrigerator—automatic defrost	5.19AV + 147.8.
C–9. Cooler with upright freezers with automatic defrost without an automatic icemaker	5.58AV + 147.7.

Product class	AEU (kWh/yr)
C–9–BI. Built-in cooler with upright freezer with automatic defrost without an automatic icemaker	6.38AV + 168.8.
C–9I. Cooler with upright freezer with automatic defrost with an automatic icemaker	5.58AV + 231.7.
C–9I–BI. Built-in cooler with upright freezer with automatic defrost with an automatic icemaker	6.38AV + 252.8.
C–13A. Compact cooler with all-refrigerator—automatic defrost	5.93AV + 193.7.
C–13A–BI. Built-in compact cooler with all-refrigerator—automatic defrost	6.52AV + 213.1.

AV = Total adjusted volume, expressed in ft^3, as calculated according to appendix A of subpart B of this part.

(3) Combination cooler refrigeration products manufactured starting on [DATE ONE YEAR AFTER PUBLICATION OF A FINAL RULE] shall have Annual Energy Use (AEU) no more than:

Product class	AEU (kWh/yr)
C–3A. Cooler with all-refrigerator—automatic defrost	4.57AV + 130.4.
C–3A–BI. Built-in cooler with all-refrigerator—automatic defrost	5.19AV + 147.8.
C–9. Cooler with upright freezers with automatic defrost without an automatic icemaker	5.58AV + 147.7.
C–9–BI. Built-in cooler with upright freezer with automatic defrost without an automatic icemaker	6.38AV + 168.8.
C–9I. Cooler with upright freezer with automatic defrost with an automatic icemaker	5.58AV + 175.7.
C–9I–BI. Built-in cooler with upright freezer with automatic defrost with an automatic icemaker	6.38AV + 196.8.
C–13A. Compact cooler with all-refrigerator—automatic defrost	5.93AV + 193.7.
C–13A–BI. Built-in compact cooler with all-refrigerator—automatic defrost	6.52AV + 213.1.

AV = Total adjusted volume, expressed in ft^3, as calculated according to appendix A of subpart B of this part.

* * * * *

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